CLINICAL REPORT

Lumbar Radiofrequency Ablation Interfering With S1 Dorsal Root Ganglion Stimulation Systems: Experience From Two Cases

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■ **Abstract**

Background: Dorsal root ganglion stimulation (DRG-S) has emerged as a treatment for complex regional pain syndrome (CRPS) of the lower extremities, and recent small studies are demonstrating its potential efficacy in pain syndromes that are traditionally considered nociceptive in nature, such as axial low back pain. While improvements in neuromodulation technology have been substantial over the past decade, patients with DRG-S systems occasionally require additional interventional pain treatments for treatment of pain from other sources. Radiofrequency ablation (RFA) of medial branch nerves innervating the facet joints is an accepted therapy for pain arising from the facet joints.

Methods: We describe 2 cases from the same practice where we observed similar phenomena while performing a 2-needle monopolar lumbar RFA in patients with a DRG-S system implanted with leads positioned bilaterally at the S1 DRGs.

Results: Initiation of RFA resulted in motor activation and discomfort in an S1 distribution in the legs in both individual cases.

Conclusions: RFA can interfere with implanted DRG-S systems, resulting in overstimulation with motor recruitment. Specific anatomical considerations and device settings that may prevent interference are discussed. ■

Key Words: dorsal root ganglion stimulation, radiofrequency ablation, interference

INTRODUCTION

Neuromodulation for chronic pain uses electrically active implantable devices to change neural activity and transmission to reduce the perception of neuropathic pain. Spinal cord stimulation (SCS) is one common form of neuromodulation. Dorsal root ganglion stimulation (DRG-S) has recently emerged as another. DRG-S has proven to be beneficial in patients with complex regional pain syndrome (CRPS) of the lower extremities,[1] and recent small studies are demonstrating its potential efficacy in pain syndromes that are traditionally considered nociceptive in nature, such as axial low back pain.[2–4] While improvements in neuromodulation technology have been substantial over the past decade, patients occasionally require additional

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interventional pain treatments after implantation of SCS or DRG-S systems for treatment of pain.

Radiofrequency ablation (RFA) of medial branch nerves innervating the facet joints is an accepted therapy for pain arising from the facet joints.[5–7] Conventional monopolar RFA uses a generator, electrodes, and a grounding pad on the skin to deliver an alternating electromagnetic field at 500 kHz, causing well-defined local heating via oscillation of charged molecules to induce neurolysis in the target tissue.[8,9]

In the context of cardiac implantable devices, such as pacemakers and automatic implantable cardioverter-defibrillators, a concern of RFA interfering with these devices has been described.[10,11] In the pain neuromodulation literature, only a single case of RFA interfering with an SCS system has been reported, and this case occurred with the SCS device turned off.[9] No reports of RFA interfering with DRG-S devices have been published. The aim of this report was to describe 2 cases from the same practice where we observed similar phenomena while performing a 2-needle monopolar lumbar RFA in patients with a DRG-S system implanted with leads positioned bilaterally at the S1 DRGs.

Both patients described in this report provided written informed consent for the publication of their cases.

CASE DESCRIPTION 1

Patient 1 was a 58-year-old man with nonsurgical bilateral lower extremity radicular pain who had received multiple epidural injections and who had undergone explantation of an SCS system in 2012 due to loss of efficacy. At our institution, he underwent implantation with a DRG-S system (Proclaim, Abbott, Chicago, IL, U.S.A.) with bilateral S1 leads. The implantable pulse generator (IPG) was implanted in the right buttock, below the iliac crest. Programming for S1 leads was paresthesia based with ultimately subthreshold settings for use (Table 1). He experienced 100% relief of his leg pain over the months following implantation. However, 7 months after implantation he developed worsening right-sided axial low back pain, and he was scheduled for an RFA of the right L2–5 lumbar medial branch nerves after experiencing pain relief from local anesthetic block.

On the day of the procedure, the patient was positioned, monitors were placed, the skin was prepared, and 2 mg midazolam IV was given for sedation. The grounding pad was positioned on the left side of the patient's low back, approximately 8 cm rostral to the iliac crest and 10 cm left of the midline. Four 10-cm, 10-mm curved active-tip, 20-gauge RFA needles were used with probes, in combination with a 4-lesion generator (NeuroTherm, Abbott).

Table 1. Settings for Dorsal Root Ganglion Stimulation in Both Patients Described in This Report

	Patient 1		Patient 2	
	Left	Right	Left	Right
Frequency (Hz)	6	4	10	8
Pulse width (microseconds)	220	290	240	260
Amplitude (mA)	0.350	0.525	0.425	0.550

A 2-needle technique was used as described by Chapman et al.,[12] with 2 RFA probes placed per medial branch level: one probe placed 2 to 3 mm below the base of the junction of the superior articular process (SAP) and the transverse process and a second probe placed 6 mm rostral to that needle, with the active needle tip contacting the SAP, posterior to the anterior border of the SAP (Figure 1). Motor testing was performed on each needle individually at 2 Hz and 1.5 mA with no evidence of muscle activation. 0.5 mL of 2% lidocaine was then injected at the L4 medial branch and L5 medial branch levels. Upon initiation of the RFA, contractions of muscles in the S1 distribution were observed, and the ablation was immediately halted. Muscle activation and discomfort in the legs dissipated once the ablation was halted. Needle positioning was confirmed once again. Motor testing was repeated, again with no evidence of muscle activation. Ablation commenced a second time, and twitching was noted in an S1 distribution and the patient complained of spasms and discomfort in the legs. It was noted that the muscle activity occurred in the bilateral lower extremities. Again, the procedure was halted, and symptoms resolved.

At this point, we identified that the RFA was interfering with the S1 DRG-S system, and we realized the DRG-S system was in the "on" mode. We noted the grounding pad to be 13.5 cm from the closest point to the RF needles, and the IPG was noted to be 12.2 cm from the lower L5 RFA needle (Figure 2).

Options were discussed with the patient, and it was decided that we would turn off his DRG-S system and attempt the ablation once again. We then used our Abbott DRG-S clinician programmer and turned the patient's DRG-S system to "off." Needle position was once again confirmed, and motor stimulation testing

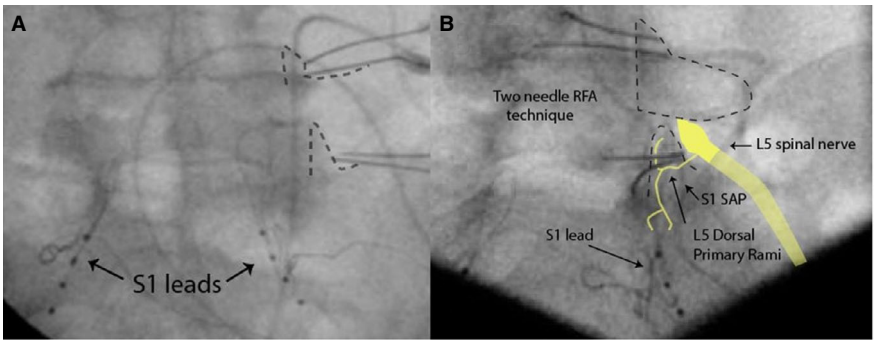

Figure 1. A, Anteroposterior view of the L5–S1 junction. Two radiofrequency ablation (RFA) cannulae are visible at the L5 and S1 superior articular process (SAP) (represented by dashed line). Distance of the S1 leads from the L5 cannula is 5 cm. B, Right oblique view. Two RFA cannulae lie on the S1 SAP (represented by dashed line). The L5 nerve root and medial branch are depicted in yellow.

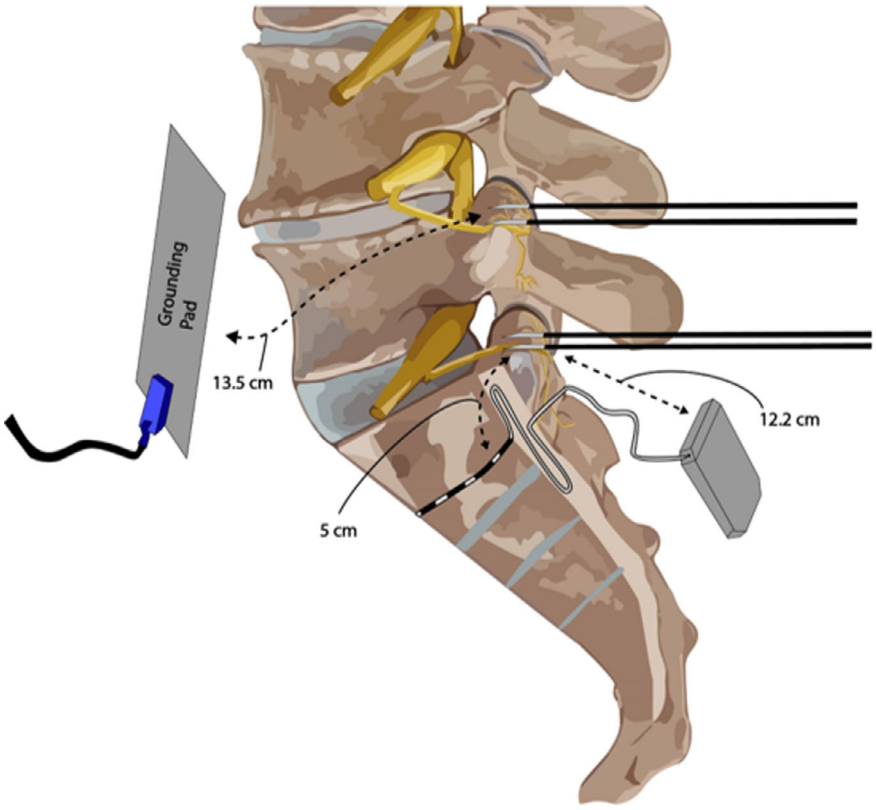

Figure 2. S1 dorsal root ganglion stimulation (DRG-S) system in place with 2-needle radiofrequency ablation (RFA) technique being performed. In our case, the RFA needles were closer to the S1 DRG-S leads (5 cm) and implantable pulse generator (12.2 cm) than to the grounding pad (13.5 cm).

was negative. The ablation procedure proceeded at 80°C for 90 seconds without incident.

The patient was taken to the recovery room and remained neurologically intact with no deficits. The IPG was then turned back to the "on" mode and the system was evaluated and found to be functioning satisfactory. At 5 months' follow-up, the patient was still experiencing maximal pain relief in the bilateral lower extremities as well as 80% relief of lower back pain on the right side.

CASE DESCRIPTION 2

The second case involves a 50-year old female with a history of persistent bilateral leg pain after an L5–S1 laminectomy and discectomy. She had undergone implantation of a DRG-S system at the bilateral S1 DRGs and was being treated by another physician within the same practice. She had good coverage of her leg pain, which was in the L5–S1 distribution, with the S1 DRG-S leads. Her IPG was implanted on the right

buttock below the iliac crest, and the settings are displayed in Table 1. Eight months after implantation she complained of new pain in the low back. After a positive response to 2 lumbar medial branch blocks, an RFA procedure followed using the same approach as in case 1, with a 2-needle technique using monopolar RF with the grounding pad on the contralateral side of the patient's low back. After needle placement and negative motor testing, RFA was initiated. The patient experienced motor activation and discomfort in her legs, and the ablation procedure was then stopped immediately. Needle positioning was confirmed again using fluoroscopy. At that time, the physician performing the RFA realized the stimulator was in the "on" mode, and neither he nor the patient had a programmer available to deactivate the device. After discussing with the patient, the physician performing the procedure turned the IPG to the "off" mode with a magnet. The needle position was confirmed once more, results of motor testing were negative, and the RFA was initiated again. There was no motor stimulation observed, and the patient reported no pain or discomfort. The rest of the procedure was performed without incident. The distances of the RF cannulas to the grounding pad and the grounding pad to the IPG were not measured in this case.

In the recovery room, the patient did not complain of symptoms in the legs, and her DRG-S stimulator remained off. We advised her to turn her stimulator on when she got home. She returned to the office 3 days later for an evaluation of the DRG-S system with a company representative and the system was found to be functioning correctly. The DRG-S system has maintained its efficacy and has been without any error readings at 5 months post-incident.

DISCUSSION

In our aging population, RFA procedures have been increasing in utilization for the treatment of a number of pain conditions,[13] as has the proportion of the population requiring neuromodulatory devices such as pacemakers, defibrillators, and stimulators for pain. There are several published case reports involving interference of RFA with cardiac implantable devices; general precautions and recommendations in these patients have been detailed.[14–16] Our 2 cases are the first reports of patients with a DRG-S system (Proclaim, Abbott), demonstrating interference of RFA with the DRG-S systems resulting in overstimulation with motor recruitment at the S1 level. Upon literature review, we identified only 1 previous case report of RFA interfering with an implanted neuromodulation device. Jeon et al. described performing RFA of cervical medial branch nerves in a patient with an implanted cervical SCS device.[9] Despite turning off the IPG prior to the procedure, the patient exhibited symptoms of pain and paresthesias in both upper extremities when ablation was initiated, and the procedure was rapidly aborted. The SCS system was found to malfunction after the procedure, and at 1-month follow-up the patient reported that his pain relief from the SCS therapy had decreased from 50% to 20%.[9]

We also accessed adverse events reports from the Manufacturer and User Facility Device Experience (MAUDE) database[17] for reported cases involving electrosurgery using the search terms "Dorsal root ganglion stimulator for pain relief" and event type "malfunction". The MAUDE database is supported by the U.S. Food & Drug Administration (FDA) for reporting medical device-related adverse events. We queried the MAUDE database on October 16, 2019, for reports between May 1, 2016, and February 27, 2020. There are no entries in the database for DRG-S from before May 1, 2016, because the device only received approval for the U.S. market in February 2016. Each entry in the MAUDE database contains a report number, event date, event type, manufacturer, date received, product code, brand name, and event text. Five cases were reported in which monopolar electrosurgery was used and led to malfunction of the IPG over this period. In 3 of the 5 cases, the IPG was reprogrammed and maintained functionality; however, in 1 case, the IPG could not be salvaged. It is important to note that these cases described malfunction of DRG-S systems after surgical cases using monopolar electrosurgery rather than eliciting physical symptoms during the procedure.

The underlying mechanism for the interference phenomenon we observed in our patients with DRG-S systems is not certain. While conventional SCS has been used as a treatment for chronic pain over the past 30 years, there is little indication of RFA inducing problems in patients with SCS. DRG-S differs from SCS on several particular anatomic aspects that may make it more susceptible to more subtle changes in either frequency, pulse width, or amplitude of neurostimulation. When compared to SCS, these differences include:

1. The DRG is surrounded with a thin layer of cerebrospinal fluid (CSF) and the stimulation lead is closer to the neural tissue.

2. In the lumbar foramen, the DRG and the motor nerve root lie in a bundle and are surrounded by dura, making it easier to directly activate the motor root with smaller charges.
3. At the S1 level, 40% to 45% of time the DRG is within the sacral canal rather than within the foramen itself,[18] and direct stimulation of the motor and sensory roots may occur.
4. SCS typically runs at 2 to 4 times the frequency (Hz) and 5 to 10 times the amplitude (mA) of DRG-S; therefore, the amount of electrical energy required to cause a substantial difference in delivery would have to be significantly more than the minimum amount required for interference with DRG-S. In addition, DRG-S leads may more directly stimulate the motor nerve, whereas SCS leads are only in proximity to the Aβ fibers of the dorsal columns.

These anatomical factors (Figure 3) allow DRG-S to use a lower electrical dose for effective pain treatment when compared to SCS; however, it may also make it more susceptible to symptoms of overstimulation when a small additional electrical dose is given.

The activation of motor nerve fibers that we observed is the result of the current from the monopolar RFA using the electrodes or the IPG as a ground rather than the grounding pad itself. This may have led to the direct activation of the ventral root motor fibers adjacent to the DRG, or potentially caused the IPG to discharge electrical impulses at higher settings than programmed. In Figure 2 we depict the anatomical distances between the RFA probes, grounding pad, DRG-S leads, and IPG. The IPG was 1.3 cm closer than the grounding pad to the nearest RF cannula; the right S1 lead was 6 cm closer to the RF cannula than the grounding pad. DRG-S lead location and grounding pad placement must be taken into account since our DRG-S leads were closer to the RFA probes than the grounding pad. This likely represented one factor that contributed to the observed interference.

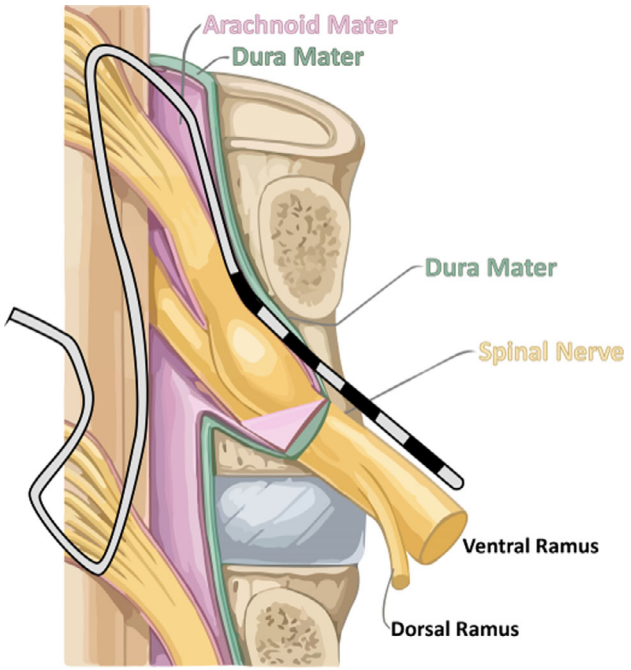

Figure 3. Anatomical relationship between dorsal root ganglion stimulation (DRG-S) lead, DRG, and meninges. Note that the DRG and the ventral root are adjacent to each other within the dura.

A second potential mechanism would be an alteration in the frequency and/or amplitude of electrical current within the DRG, initiating a looped reflex arc causing a continual stimulation of the same motor nerves. These are working theories that warrant further investigation.

Future Preventative Measures

Bautista et al.[19] proposed the use of bipolar RF in patients with cardiac implantable devices and facetogenic pain since the current flow remains between the active tips of the needles. This contrasts with monopolar RF, which allows the current to travel from the active electrode, through the patient, and back to the generator using a grounding pad. The possibility that lumbar medial branch procedures can be performed safely using bipolar RF without having to shut off the DRG-S could be explored.[8] Indeed, Abbott recommendations for their Proclaim DRG IPG include avoiding monopolar devices in order to keep the current paths from electrosurgery devices as far from the neurostimulation system as possible, to set electrosurgery devices to the lowest possible energy setting, and to confirm that the neurostimulation system is functioning correctly post-procedure. We utilized a 2-needle monopolar RF technique to maximize lesion size when performing lumbar RFA,[12] and given the presence of a DRG-S system, switching to bipolar RF could have easily been performed.

As illustrated by the previous case report involving SCS and RFA, turning off the IPG may not be an adequate precaution since the electrodes on the lead may be used as a ground for the electrosurgical unit. In order to mitigate the risk of the electrode and IPG functioning as a ground for the electrical current with potential to the IPG, the Proclaim line of IPG implemented a "surgery mode" setting. In this setting,

the IPG releases a small amount of electrical current to offset/block the lead from becoming a ground for the electrical current from RFA. Prior versions of the Proclaim IPG demonstrated cases of loss of efficacy after monopolar electrosurgery. Surgery mode was designed to provide greater protection against the potential effects of monopolar electrosurgery and should reduce the number of IPGs entering a state where therapy is not delivered. However, surgery mode does not eliminate the risk for an IPG becoming nonresponsive and requiring replacement surgery.[20] This mode can be activated with either the clinician programmer or the patient programmer.

Given that in both of our cases the stimulators were turned off and not placed into surgery mode, both practitioners were fortunate that the devices did not malfunction and were able to function properly post-procedure. The short duration of overstimulation secondary to interference may have protected us from IPG malfunction and potential injury to the patient.

CONCLUSION

These 2 cases are the first published reports of monopolar RFA interfering with implanted DRG-S systems. We surmise that the electrodes on the DRG-S lead likely served as a ground for the electrical current and caused motor activation of the S1 nerves bilaterally. Given the specific anatomical properties of the DRG and its spatial relationship with the implanted DRG-S system, the DRG-S IPG needs to be placed in surgery mode, and a bipolar technique should be used for RFA procedures. Distance from the RF cannulae to the grounding pad should be less than from the RF needles to the IPG or the leads. Having an awake and conscious patient able to confirm the presence of pain or muscle activation provides an additional safeguard. The functionality of the DRG-S device should be assessed post-RFA in the recovery room and appropriate follow-up should occur. The presented cases also underscore the importance of communication between practitioners, since our physicians were in the same practice. Education of physicians and patients about the potential risk for using RFA with a DRG-S in place may minimize the potential for interference and malfunction.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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