

Do we need to establish guidelines for patients with neuromodulation implantable devices, including spinal cord stimulators undergoing nonspinal surgeries?

[Ramsis F. Ghaly](#),^{1,2,3,4,*} [Tatiana Tverdohle](#),¹ [Kenneth D. Candido](#),^{1,4} and [Nebojsa Nick Knezevic](#)^{1,4}

¹Department of Anesthesiology, Advocate Illinois Masonic Medical Center, Chicago, IL, USA

²Department of Anesthesiology, JHS Hospital of Cook County, Chicago, IL, USA

³Ghaly Neurosurgical Associates, Aurora, IL, USA

⁴Department of Anesthesiology, University of Illinois, Chicago, IL, USA

Ramsis F. Ghaly: rfghaly@aol.com; Tatiana Tverdohle: tverdohlebtatiana777@gmail.com; Kenneth D. Candido: kdcandido1@gmail.com;

Nebojsa Nick Knezevic: nick.knezevic@gmail.com

* Corresponding author

Received 2015 Dec 22; Accepted 2016 Jan 5.

[Copyright](#) : © 2016 Surgical Neurology International

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

Abstract

Background:

Spinal cord stimulation is currently approved to treat chronic intractable pain of the trunk and limbs. However, such implantable electronic devices are vulnerable to external electrical currents and magnetic fields. Within the hospitals and modern operating rooms (ORs), there is an abundance of electrical devices and other types of equipment that could interfere with such devices. Despite the increasing number of patients with neuromodulation implantable devices, there are no written guidelines available or consensus of cautions for such patients undergoing unrelated surgery.

Case Descriptions:

A 60-year-old female with a permanent St. Jude's spinal cord stimulator (SCS) presented for open total abdominal hysterectomy. Both the anesthesia and gynecology staffs were aware of the device presence, but were unaware of any precautions regarding intraoperative management. The device was found to be nonmagnetic resonance imaging compatible, and bipolar cautery was used instead of monopolar cautery. A 59-year-old female with a 9-year-old permanent Medtronic SCS, presented for right total hip arthroplasty. The device was switched off prior to entering the OR, bipolar cautery was used, and grounding pads were placed away from her battery site. In each case, the manufacturer's representative was contacted

preoperative. Both surgeries proceeded uneventfully.

Conclusions:

The Food and Drug Administration safety information manual warns about the use of diathermy, concomitant implanted stimulation devices, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, and high-output ultrasound, all of which can lead to permanent implant damage if not turned off prior to undertaking procedures. Lack of uniform guidelines makes intraoperative management, as well as remote anesthesia care of patients with previously implanted SCSs unsafe.

Key Words: Guidelines, neuromodulation, safety, spinal cord stimulator

INTRODUCTION

Spinal cord stimulation is currently approved for the treatment of chronic intractable pain of the trunk and limbs.[34] The spinal cord stimulator (SCS) device consists of spinal epidural electrode arrays (leads) and an implantable pulse generator (IPG) with a rechargeable battery.[20] The newer IPG is a complex and computerized device that is able to carry out programs with highly specific characteristics unique to the generated electrical pulses to the spinal leads. Newer technical advances allow a precise delivery of independent electrical pulses with specific amplitude (V or mA), width (μ s), and frequency (Hz) to cover one or more painful areas.[10]

The procedure of SCS placement of the IPG is accomplished by making a small incision in approved locations (upper buttock, lower back, abdomen, midline, or flank), followed by insertion of the IPG under the subcutaneous tissue.[21] The leads with electrodes are placed in the epidural space of the spinal cord. The electrodes have longitudinal contact arrays that can be programed as cathodes and anodes. Cathodic stimulation is preferred because the cathodic threshold for nerve fiber stimulation is 3–7 times lower compared to the anode threshold, which translates as the exact location of the axons stimulation is determined by the position of the cathode.[33] In monopolar stimulation, the cathode is placed in close proximity to the axons meant for stimulation while the anode is at a greater distance, whereas in bipolar stimulation, the anode is close to the cathode. In bipolar stimulation, the threshold for nerve fiber stimulation parallel to the cathode–anode axis will be decreased.[33]

The proposed theory of SCS mechanism of action is not completely elucidated or understood, partially because not all types of pain (nociceptive vs. nonnociceptive) are modulated uniformly.[2]

The spinal cord stimulation device stimulates several structures: the dorsal column, the lateral funicular, and dorsal root fibers.[29] It creates an electrical field that can be placed along The dorsal column fibers with subsequent inhibition in pain transmission in the ascending nociceptive pathway and activation of descending anti-nociceptive pathways.[29]

However, such implantable electronic devices are vulnerable to external electrical currents and magnetic fields.[26] It is known that magnetic resonance imaging (MRI) and electrocautery are not recommended to use in patients having SCS device implanted, with rare exceptions.[19,26] External, electrical and magnetic devices may interfere with the function of the device or result in current induction with local excessive heat transmission to the neural tissue, or lead to migration due to interfering magnetic fields.[19,24,26] Within the hospitals and modern operating rooms (ORs), there is an abundance of electrical devices and many types of equipment that could influence the implantable neuromodulation devices.

Spinal cord stimulation is a part of a fascinating, growing field of neuromodulation and includes implantation of various electronic devices. It is estimated that approximately 14,000 patients undergo SCS implantation each year and this accounts for 70% of all the neuromodulation devices treatment.[34] However, indication for such devices has expanded not only to the pain management field (chronic low back pain and headache), but also to neurology (epilepsy, Parkinson disease), psychiatry (depression, obsessive-compulsive disorder, and addiction), sleep medicine (sleep apnea), with potentials on the rise for cardiology (arrhythmia, hypertension, and ischemia), gastroenterology (obesity and gastroparesis), and urology (urinary incontinence and painful bladder syndrome), substantially increasing the patient population with such devices in the recent years.[9]

Despite the increasing number of patients with implantable devices and broader use of the neuromodulation implanted devices, there are no written guidelines or instructions from device companies or consensus on cautions and concerns of such patients undergoing unrelated surgery. In fact, medical care providers and patients are unaware of certain precautions that should be taken to prevent untoward events or injury during the surgery.[14,37]

In this era of evidence-based medicine, it is well known that guidelines improve patient care and safety as well as decrease medical liability, and to be renewed rigorously to comply with the best existing evidence as we move forward into the future.[7,12] There is a dire need for guidelines and standardized protocols to improve safety of patient with implanted neuromodulation devices. In addition, there is a requirement for educational programs for specialists such as interventional pain management physicians, neurologists and neurosurgeons, cardiologists and cardiothoracic surgeons, psychiatrists, gastroenterologists, urologists, gynecologists, and physiatrists where finding a common language and raising awareness of implantable neuromodulation devices will provide a more realistic expectation of device reliability for patients and physicians and will lead to enhanced prevention of serious adverse events and medical liability.[14] The Food and Drug Administration (FDA), Medtronic and St. Jude Medical have issued some warnings and precautions for SCS device. Furthermore, an MRI guideline for SCS systems was provided by Medtronic Corporation.[19,26,35] However, our literature search has not identified any guidelines or standardized practices or protocols for the routine perioperative assessment of patients with implanted neuromodulation devices. Given the noted profitability of the SCS manufacturing industry, a neutral and a well-balanced representation using a multidisciplinary approach is required (interventional pain management physicians, neuromodulation device (NMD) interventionists, surgeons, anesthesiologists, and neurologists) to implement such guidelines.[28]

We herein present two cases which demonstrate a lack of guidelines in today's literature regarding patients having SCSs undergoing nonspinal procedures, in the hope of raising awareness for potential and preventable patient harm.

CASE DESCRIPTION

Case 1

A 60-year-old female with failed back surgery syndrome required SCS placement in 2012 for long-term pain relief, and subsequently presented for open total abdominal hysterectomy.

Existing pain clinic documentation from 2012 showed that the St. Jude Medical SCS leads were located with the most proximal contacts situated at the intervertebral disc level of T8–T9, with her IPG placed over

the right buttock. Both anesthesia and gynecology specialists were aware of device presence, but were unaware of any precautions needed regarding intraoperative management. The manufacturer's representative was contacted and the device was found to be non-MRI compatible, which triggered the use of bipolar cautery instead of monopolar cautery. The device was turned off prior to entering the OR, and grounding pads were placed at least 10 cm away from the IPG site. Surgery proceeded uneventfully, and the patient was sent to the pain clinic for a device function's re-evaluation.

Case 2

A 59-year-old female with a history of chronic debilitating back pain and a Medtronic SCS placement in April, 2012 by the interventional pain management team, presented for right total hip arthroplasty surgery.

Precautions were taken, and the device was switched off prior to entering the OR, bipolar cautery was used, and grounding pads were placed >10 cm away from her IPG site.

The surgeon was made aware of the preexisting SCS, but was uncertain of whether hammering and manipulation of her hip could be safely done without dislodging the leads. A last minute literature search did not reveal any additional information or guidelines regarding the management of the SCS system under such circumstances.

Surgery proceeded uneventfully and the patient was sent for immediate pain clinic follow-up to re-evaluate device function.

DISCUSSION

The two cases presented raise serious real-world concerns of the stark lack of awareness not only for the patients with implantable devices but also for the entire perioperative medical and surgical care provider teams. In fact, both patients indicated that the pain interventionists had never discussed the limitations and steps to be taken in the case of future unrelated surgeries. Moreover, the existing peer-referred literature is devoid of articles describing the importance of future constraints that are engendered by implanted neuromodulation devices. We have found no well-established guidelines, protocols, or consensus statements for the management of patients with neuromodulation implants undergoing unrelated surgery.

Currently, the perioperative patient safety concerns are restricted to the FDA website (www.fda.gov) and to brief statements contained in the manufacturer's device brochures.[19,26,35] In both of those, concerns for patients with implants and steps required to improve awareness for physicians, surgeons, or nursing staff are absent. Walsh *et al.*, provided a review of safety literature in SCS and found no consensus in the appropriate management of patients with SCS implants.[37]

The major safety concern with stimulation implants is that both the spinal cord and brain electrode arrays are seated into vulnerable, but highly functioning neural tissues and could be influenced by external environmental devices. Concerns in regard to the potential dangers for subjects with implantable neuromodulation devices within the hospital environment, including the OR may include permanent neural thermal injury, lead dislodgement, lead migration and tissue trauma, electrical shock, lead failure and device/IPG damage, device output program change of the electrical pulses, and even death [Table 1]. [5,19,20,23,24,30,35]

Compared to neurological implantable devices, cardiac implants have well-established guidelines and

protocols for perioperative management.[27] The most recent of these, introduced worldwide is a comprehensive presurgical and preprocedural checklist.[38]

Implantable cardiac devices

It is believed that patients with concomitant implanted cardiac and neurostimulation (NS) devices are at a high risk of interference between these two systems.[26] Ooi *et al.* retrospectively reviewed the charts for safety assessment of simultaneous use of neurostimulator and cardiovascular implanted device in six patients.[25] There was no interaction found between the two systems following implantation of the SCS. Both devices were on bipolar sensing mode and were implanted on the opposite sides of the body away from each other. Continuous electrocardiographic (ECG) monitoring was performed throughout the implantation period and no changes in the waveform pattern were observed.[25] Even though the study findings suggest that taking adequate precautions makes the implantation of the device safe, some authors point to an under-estimation of these findings.

NS systems are known to cause ECG artifacts.[11] One of the recommendations for such patients is to undergo baseline ECG after the implantation of a neurostimulator. In addition, analysis of interactions between the two devices should be performed after the procedure and for the follow-up visit. This consists of setting the ICD to a maximum sensitivity and the stimulator to the highest tolerated settings, while observing for any device interference or dysfunction. After this test, both devices should be reset to the initial values and patient should be advised to keep those settings to the level of adequate pain control.[22]

Electrocautery

Monopolar electrocautery generates current that travels from the electrode instrument to the surgical site through the patient's body into a grounding pad and back to the electrocautery unit, completing a circuit. Without a grounding pad, the current disperses throughout the body with potential harm to the implanted electrical device (reprogramming, change in neurostimulator output) and to the patient. The grounding pad should be placed as far away from the IPG as feasible, and if possible on the opposite side of the body.[36]

Shortwave, microwave, and therapeutic ultrasound diathermy should not be used in patients with implanted SCSs. The energy generated by the diathermy can be transferred through the stimulator system with subsequent severe tissue damage and even death ensuing.[26] Whether the SCS is turned on or off, still a high risk for damage exists.[13,36,40] Instead of the mentioned methods of assuring hemostasis, we recommend that bipolar electrocautery can be used or heat electrocautery with the latter converting electrical energy into thermal energy that heats the metal tip of the device; the heated metal tip produces hemostasis when in contact with the tissue.[17,36]

Imaging

The heating mechanism of the NS implanted device following exposure to MRI is explained by the use of radiofrequency (RF) coils to transmit and receive pulsed RF magnetic fields to alert the spin axis of hydrogen nuclei.[3] However, the pulsed RF magnetic fields spread the electric fields to body tissues and implanted metallic devices with further current dissipation at the electrode-tissue interface and tissue damage may result.[3] Specialists involved in the treatment of a patient that has an implanted metallic device or a neuromodulation device may be unaware of the serious consequences electromagnetic fields pose on the patient's life. Even with the newer MRI compatible cardiac or NS implantable devices, there is still a chance of tissue damage from heated electrodes. As long as metallic wires are conducting electricity

between the IPG and the electrode leads, there will be an increase in temperature in the MRI environment.
[3]

Computerized tomography (CT) scanning is preferred for patients with implanted neuromodulation devices to avoid serious consequences of the MRI. The CT-scan can provide sufficient anatomic information in a majority of cases. However, CT-scan use is not completely benign, as there are some reported concerns with the CT use in patients with an implanted pacemaker or NS device; these concerns are explained by the fact that high levels of radiation from the CT-scan can shock the patient or damage the stimulator device.

[4,6,18,37,39]

Environmental interference

The electronic anti-theft system (EAS) has evolved to prevent unauthorized appropriation of valuable items. It is known that patients with implanted electrical stimulators following a prolonged exposure to anti-theft devices are at a risk of developing serious adverse reactions in patients or with device malfunction.[32] A case report described a patient with an implanted cardiac defibrillator for complete atrioventricular block following cardiac arrest; while standing in a bookstore, he received a shock from his defibrillator followed by three more shocks. A bystander who happened to be a registered nurse noticed that the patient was standing next to the bookstore anti-theft system. He was pulled away and no shocks followed thereafter.[31] Mugica *et al.* conducted a study on patients with implanted pacemakers to assess the interaction with an electronic anti-theft surveillance system. The results showed a range of 0–30% interference; however, the variability of various program and various device models was not compared for susceptibility.[23] Undersensing (atrial, ventricular), atrial oversensing, and mode disruptions were the interferences observed. Patients with unipolar leads and pacemakers with low programmed sensitivity were more likely to show interference.[23] The authors of this study concluded that the interference had not reached any statistical significance and the period the patient was exposed to the EAS was typical of that expected from a normal passage through the beams of the EAS, contrary to the time exposed to the EAS of the patient from the clinical case described above.[23,31] Seventeen reports have been made to the FDA because of interference between the EAS and the SCS. Patients reported pain, jolts, and shocks. Precautions should be taken when a prolonged time of exposure to the EAS occurs and patients should be notified of such possibility where patients should notify the security personnel of the presence of the SCS.[8]

Work environment and occupation

Patients who need to undergo implantation of a NS device should be asked about their occupation to avoid serious potential consequences. Electric arc welding machines, degaussing coils, high-voltage generators, and magnetized stereo speakers are sources of electromagnetic radiation. Patients have to be informed that exposure to such machines can lead to adverse reactions related to both an implanted device output and to the patients themselves.[26,32] To avoid such hazards, it is recommended to perform a formal electromagnetic radiation testing at the workplace while the neurostimulator implanted device is operating.
[32]

Another consideration for patients and health care providers is to be aware of repetitive spine movements during the performance of several sports or as part of a professional occupation (weightlifting and construction workers). This can lead to lead fracture or lead displacement.[1,32]

Congress approved the Safe Medical Devices Act in 1990 and the Medical Device Amendments in 1992.
[15] Health care facilities and manufacturers are required to report any device-related serious injuries,

deaths, and device malfunction to the FDA.[15] The decision of the manufacturer to report to the implanting physicians, patients, or to the general public is not very clear. Most of the time, the reporting has been done on a case-by-case basis, in the form of news bulletins, depending on the likelihood of producing any patient injury and related device malfunction. It is required to directly notify the patients having implants about the safety issues, but some physicians think that the medical information is too complex for the patient to understand and possibly withhold it from them. This appears to not be as true nowadays because more and more patients are becoming proactive and are very well-informed about their conditions and treatments.[16] Another important aspect is that the National Physician and Medical Device Organizations must provide guidance and educational programs to physicians, patients, regulators, and industry. The lack of uniform standards for reporting and the management of patients with implanted cardiac and neuromodulatory devices raises high concerns [Table 2].[16]

CONCLUSION

The FDA safety information manual warns about the use of diathermy, concomitant implanted stimulation devices, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, and high-output ultrasound, all of which can lead to permanent implant damage if not turned off prior medical and surgical procedures. Lack of uniform guidelines, protocols, and consensus statements, and an absence of evidence-based literature makes intraoperative management, as well as remote anesthesia care of patients with previously implanted SCSs, potentially hazardous. A lack of clinical case reports documenting injuries sustained from health care providers unfamiliar with SCSs makes a strong case to advocate for the creation of essential guidelines of management. Companies manufacturing SCSs are aware of MRI compatibility issues, prompting the rise of MRI compatible stimulators, but without clear guidelines for the management and care of patients with such devices implicating that significant risk for injuries still exist.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Footnotes

<http://surgicalneurologyint.com/Do-we-need-to-establish-guidelines-for-patients-with-neuromodulation-implantable-devices,-including-spinal-cord-stimulators-undergoing-nonspinal-surgeries?/>

REFERENCES

1. Akmal S, Eljamel MS. Spinal cord stimulation for chronic pain: Causes of long-term paddle-lead failure. *Neuromodulation*. 2008;11:282–5. [PubMed: 22151142]
2. Atkinson L, Sundaraj SR, Brooker C, O’Callaghan J, Teddy P, Salmon J, et al. Recommendations for patient selection in spinal cord stimulation. *J Clin Neurosci*. 2011;18:1295–302. [PubMed: 21719293]
3. Coffey RJ, Kalin R, Olsen JM. Magnetic resonance imaging conditionally safe neurostimulation leads: Investigation of the maximum safe lead tip temperature. *Neurosurgery*. 2014;74:215–24.

[PubMed: 24176957]

4. ECRI Institute Problem Reporting System. Hazard report – CT scans can affect the operation of implanted electronic devices. *Health Devices*. 2007;36:136–8. [PubMed: 17555167]
5. Ector H, Rickards AF, Kappenberger L, Linde C, Vardas P, Oto A, et al. The world survey of cardiac pacing and implantable cardioverter defibrillators: Calendar year 1997 - Europe. *Pacing Clin Electrophysiol*. 2001;24:863–8. [PubMed: 11388106]
6. FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) [Last updated on 2015 Aug 06; Last cited on 2015 Dec 03]. Available from: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061994.htm> .
7. Grol R. Between evidence-based practice and total quality management: The implementation of cost-effective care. *Int J Qual Health Care*. 2000;12:297–304. [PubMed: 10985267]
8. Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICDs, and Spinal Cord Stimulators. [Last updated on 2015 Oct 20; Last cited on 2015 Dec 04]. Available from: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062288.htm> .
9. International Neuromodulation Society. [Last updated on 2015 May 13; Last cited on 2015 Nov 25]. Available from: <http://www.neuromodulation.com/about-neuromodulation> .
10. Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, et al. Novel 10-kHz high-frequency therapy (HF10 Therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: The SENZA-RCT randomized controlled trial. *Anesthesiology*. 2015;123:851–60. [PubMed: 26218762]
11. Khan IA. Differential electrocardiographic artifact from implanted thalamic stimulator. *Int J Cardiol*. 2004;96:285–6. [PubMed: 15262047]
12. Kirkpatrick DH, Burkman RT. Does standardization of care through clinical guidelines improve outcomes and reduce medical liability? *Obstet Gynecol*. 2010;116:1022–6. [PubMed: 20966684]
13. LeVasseur JG, Kennard CD, Finley EM, Muse RK. Dermatologic electrosurgery in patients with implantable cardioverter-defibrillators and pacemakers. *Dermatol Surg*. 1998;24:233–40. [PubMed: 9491118]
14. Levy RM. The evolving definition of neuromodulation. *Neuromodulation*. 2014;17:207–10. [PubMed: 24773384]
15. Maisel WH. Medical device regulation: An introduction for the practicing physician. *Ann Intern Med*. 2004;140:296–302. [PubMed: 14970153]
16. Maisel WH. Safety issues involving medical devices: Implications of recent implantable cardioverter-defibrillator malfunctions. *JAMA*. 2005;294:955–8. [PubMed: 16118386]
17. Martinelli PT, Schulze KE, Nelson BR. Mohs micrographic surgery in a patient with a deep brain stimulator: A review of the literature on implantable electrical devices. *Dermatol Surg*. 2004;30:1021–30. [PubMed: 15209793]

18. McCollough CH, Zhang J, Primak AN, Clement WJ, Buysman JR. Effects of CT irradiation on implantable cardiac rhythm management devices. *Radiology*. 2007;243:766–74. [PubMed: 17463138]
19. Medtronic for Health Care Professionals. Magnetic Resonance Imaging. [Last updated on 2015; Last cited on 2015 Dec 01]. Available from: <http://www.professional.medtronic.com/mri/index.htm#.VI3FAH4zZQK> .
20. Medtronic for Health Care Professionals. Spinal Cord Stimulation. About Spinal Cord Stimulation. [Last updated on 2015; Last cited on 2015 Dec 02]. Available from: <http://www.professional.medtronic.com/pt/neuro/scs/edu/about/index.htm#.VI8ViX4zZQI> .
21. Medtronic for Health Care Professionals. Spinal Cord Stimulation. Products and Procedures. Spinal Cord Stimulation System Procedure Overview. [Last updated on 2015; Last cited on 2015 Dec 02]. Available from: <http://www.professional.medtronic.com/pt/neuro/scs/prod/index.htm#section1> .
22. Monahan K, Casavant D, Rasmussen C, Hallet N. Combined use of a true-bipolar sensing implantable cardioverter defibrillator in a patient having a prior implantable spinal cord stimulator for intractable pain. *Pacing Clin Electrophysiol*. 1998;21:2669–72. [PubMed: 9894659]
23. Mugica J, Henry L, Podeur H. Study of interactions between permanent pacemakers and electronic antitheft surveillance systems. *Pacing Clin Electrophysiol*. 2000;23:333–7. [PubMed: 10750133]
24. Oluigbo CO, Rezai AR. Magnetic resonance imaging safety of deep brain stimulator devices. *Handb Clin Neurol*. 2013;116:73–6. [PubMed: 24112886]
25. Ooi YC, Falowski S, Wang D, Jallo J, Ho RT, Sharan A. Simultaneous use of neurostimulators in patients with a preexisting cardiovascular implantable electronic device. *Neuromodulation*. 2011;14:20–5. [PubMed: 21992157]
26. Physician Implant Manual, Advanced Bionics Corporation. 2004. [Last cited on 2015 Dec 01]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017c.pdf .
27. Pinski SL, Trohman RG. Interference in implanted cardiac devices, part II. *Pacing Clin Electrophysiol*. 2002;25:1496–509. [PubMed: 12418748]
28. Priori SG, Werner K, Bassand JP. Medical practice guidelines. Separating science from economics. *Eur Heart J*. 2003;24:1962–4. [PubMed: 14585255]
29. Raphael JH, Muntagi H, Kapur S. Spinal cord stimulation and its anesthetic implications. *Contin Educ Anaesth Crit care Pain*. 2009;9:78–81.
30. Rezai AR, Phillips M, Baker KB, Sharan AD, Nyenhuis J, Tkach J, et al. Neurostimulation system used for deep brain stimulation (DBS): MR safety issues and implications of failing to follow safety recommendations. *Invest Radiol*. 2004;39:300–3. [PubMed: 15087724]
31. Santucci PA, Haw J, Trohman RG, Pinski SL. Interference with an implantable defibrillator by an electronic antitheft-surveillance device. *N Engl J Med*. 1998;339:1371–4. [PubMed: 9801398]
32. Shan PM, Ellenbogen KA. Life after pacemaker implantation: Management of common problems and environmental interactions. *Cardiol Rev*. 2001;9:193–201. [PubMed: 11405899]
33. Smits H, van Kleef M, Holsheimer J, Joosten EA. Experimental spinal cord stimulation and neuropathic

pain: Mechanism of action, technical aspects, and effectiveness. *Pain Pract.* 2013;13:154–68. [PubMed: 22780956]

34. Spinal Cord Simulation. Spinal Cord Stimulation's Role in Managing Chronic Disease Symptoms. [Last updated on 2014 Mar 20; Last cited on 2015 Dec 14]. Available from: <http://www.neuromodulation.com/spinal-cord-stimulation> .

35. St. Jude Medical. Protégé MRI. SCS System for Chronic Pain. [Last updated on 2015 Apr 29; Last cited on 2015 Dec 01]. Available from: <http://www.professional.sjm.com/therapies/protege-mri/safety-info> .

36. Voutsalath MA, Bichakjian CK, Pelosi F, Blum D, Johnson TM, Farrehi PM. Electrosurgery and implantable electronic devices: Review and implications for office-based procedures. *Dermatol Surg.* 2011;37:889–99. [PubMed: 21585593]

37. Walsh KM, Machado AG, Krishnaney AA. Spinal cord stimulation: A review of the safety literature and proposal for perioperative evaluation and management. *Spine J.* 2015;15:1864–9. [PubMed: 25957536]

38. World Alliance for Patient Safety. WHO Surgical Safety Checklist and Implementation Manual. [Last updated on 2015; Last cited on 2015 Dec 15]. Available from: http://www.who.int/patientsafety/safesurgery/ss_checklist/en/

39. Yamaji S, Imai S, Saito F, Yagi H, Kushiro T, Uchiyama T. Does high-power computed tomography scanning equipment affect the operation of pacemakers? *Circ J.* 2006;70:190–7. [PubMed: 16434814]

40. Yu SS, Tope WD, Grekin RC. Cardiac devices and electromagnetic interference revisited: New radiofrequency technologies and implications for dermatologic surgery. *Dermatol Surg.* 2005;31(8 Pt 1):932–40. [PubMed: 16042939]

Figures and Tables

Table 1

Interference and as a result employment/job restriction such as jobs involving electricity, magnetic field, high machinery/motorized demand, and critical switch on/off

Interaction of NS device on cardiac implants (inhibition, inappropriate or spurious tachyarrhythmia)

Interference and as a result procedure limitation such as in lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, and high-output ultrasound

Radiation-induced current induction/shock/damage

Dislodgement of NS system

NS system breakage

NS system exposure

Migration of leads

Lead failure

Device/IPG damage

Overlying skin erosion, pressure sore

Electrical shock

Neural tissue trauma

Neural permanent thermal injury

Device output program change of the electrical pulses

Interference of image resolution as a result of metal artifact

Inaccurate information for intraoperative image guidance navigation system

Infection and system contamination

Hemorrhage

Death

NS: Neurostimulation, IPG: Implantable pulse generator

Unrelated procedural reported complications in patients with neuromodulation devices

Table 2

General

- Review patient's wrist band with the pertinent device and contact information
- Team communication and information sharing to the perioperative surgical team regarding the neuromodulation device and develop contingency plan
- Restrict use in lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, and high-output ultrasound
- Awareness of concomitant implanted cardiac devices and possible interaction with NS devices
- Restrict use in jobs involving working with electricity/magnetic equipment or motorized machinery with stimulation switched on

Preoperative device evaluation

- Device interrogation and it ensures normal impedances and voltages and no current leakage

Imaging

- Weigh the potential risks of MRI against the benefits
- Weigh potential radiation effect of CT-scan/X-rays

SCS interventionalist technique evaluation

- Tunneling the lead and lead extender at a horizontal plane in relation to the vertical axis of the spine to prevent lead failure/displacement in patients subjected to increased demand of spinal movement (e.g., construction)

Specific (including surgical planning)

- Presurgical check list "time out" should include spinal and brain implants
- Turn off the device
- Outline the location of the entire NS device components and ensure it is sufficiently away from the surgical field
- Patient's positioning to avoid potential skin erosion/pressure sore or direct trauma/stretching loose connection over the lead-IPG system
- Awareness of imaging artifact produced by the implants on the intraoperative navigation system

Intraoperative diathermy and hemostasis

- Use alternative hemostatic agents (such as Surgiflo™ by Ethicon®) and techniques (such as bipolar RF, ultrasonic)
- Use "blunt" dissection when close to any part of the NS system
- Use the lowest electrical setting in electrocautery
- Ensure normal impedance in the system
- Use bipolar for electrocautery rather than monopolar mode
- Place the grounding pad as far as possible from the NS system (≥ 10 cm)

Immediate postoperative evaluation

- Postoperative, confirm continuity of the NS system such as no system breakage, violation, or exposure of any of its components
- Device interrogation and ensure normal impedances and voltages and no current leakage
- Postoperative, ensure proper functioning of spinal/brain implant
- Address infection risk/device repair

NS: Neurostimulation, IPG: Implantable pulse generator, MRI: Magnetic resonance imaging, CI: Computed tomography, RF: Radiofrequency, SCS: Spinal cord stimulator

Perioperative guidelines for neuromodulation devices undergoing surgery

Articles from Surgical Neurology International are provided here courtesy of **Medknow Publications**