PERMANENT NEUROLOGICAL DEFICIT RELATED TO MAGNETIC RESONANCE IMAGING IN A PATIENT WITH IMPLANTED DEEP BRAIN STIMULATION ELECTRODES FOR PARKINSON'S DISEASE: CASE REPORT

Jaimie M. Henderson, M.D.

Department of Neurosurgery,
Stanford University,
Stanford, California

Jean Tkach, Ph.D.

Department of Radiology,
The Cleveland Clinic Foundation,
Cleveland, Ohio

Michael Phillips, M.D.

Department of Radiology,
The Cleveland Clinic Foundation,
Cleveland, Ohio

Kenneth Baker, Ph.D.

Center for Neurological Restoration,
The Cleveland Clinic Foundation,
Cleveland, Ohio

Frank G. Shellock, Ph.D.

Keck School of Medicine,
University of Southern California,
Los Angeles, California

Ali R. Rezai, M.D.

Center for Neurological Restoration,
The Cleveland Clinic Foundation,
Cleveland, Ohio

Reprint requests:
Frank G. Shellock, Ph.D.,
Institute for Magnetic Resonance
Safety, Education, and Research,
7511 McConnell Avenue,
Los Angeles, CA 90045.
Email: frank.shellock@gte.net

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OBJECTIVE AND IMPORTANCE: Deep brain stimulation (DBS) is an accepted treatment for patients with Parkinson's disease refractory to medication. The efficacy of this therapy has led to increasing numbers of patients receiving DBS implants. Importantly, physicians caring for patients with implantable neurostimulators must be aware of treatment guidelines for these patients, including the use of therapeutic ultrasound, diathermy, and imaging studies such as magnetic resonance imaging (MRI).

CLINICAL PRESENTATION: We describe a case of serious, permanent neurological injury secondary to a radiofrequency lesion produced by heating of a DBS electrode associated with MRI of the lumbar spine in a patient with Parkinson's disease.

INTERVENTION: MRI may be performed safely in patients with DBS devices only by following the specific guidelines of the manufacturer. The generalization of these conditions to other neurostimulation system positioning schemes, other scanners, and other imaging scenarios can lead to significant patient injuries.

CONCLUSION: To prevent catastrophic incidents, the manufacturer's guidelines should be followed carefully because they are known to result in the safe performance of MRI examinations of patients with neurostimulation systems used for DBS.

KEY WORDS: Deep brain stimulation, Magnetic resonance imaging, Neurostimulation, Parkinson's disease

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Deep brain stimulation (DBS) is an accepted treatment for patients with Parkinson's disease refractory to medication. The efficacy of this therapy has led to increasing numbers of patients receiving DBS implants. Importantly, physicians caring for patients with implantable neurostimulators must be aware of treatment guidelines for these patients, including the use of therapeutic ultrasound, diathermy, and imaging studies such as magnetic resonance imaging (MRI) (1–3, 5, 6, 8). The potential risks of performing MRI examinations in patients with neurostimulation systems include those associated with heating, magnetic field interactions, induced electrical currents, and the disruption of the operational aspects of these devices (1–3, 5, 6, 8). In vitro studies have demonstrated the potential for excessive heating of neurostimulation systems during MRI (2, 3).

Recently, Spiegel et al. (7) reported that a 73-year-old patient with bilateral implanted DBS electrodes for Parkinson's disease exhibited dystonic and partially ballistic movements of the left leg immediately after undergoing an MRI procedure of the head. This scan was performed with a transmit/receive head coil on a 1.0-T MRI system (Expert; Siemens, Erlangen, Germany) with the leads externalized and not connected to pulse generators. As such, these conditions deviated substantially from the manufacturer's highly specific MRI safety guidelines (*Table 1*), which have recommendations for MRI performed at 1.5-T using a transmit/receive head coil only (1, 6). The authors speculated that this adverse side effect was a result of induced current in the implanted leads that caused heating and subsequent thermal tissue damage (7). In the present report, we describe a case of serious, permanent neurological injury secondary to a

TABLE 1. Manufacturer's recommendations and guidelines for neurostimulation system used for deep brain stimulation[a]

These recommendations were developed on the basis of experimental and clinical findings obtained for this particular implant (includes Model 7426 Soletra and Model 7424 Itrel II neurostimulators; Model 7482 and Model 7495 extensions; Model 3387 and Model 3389 DBS leads; Product Information, Medtronic, Minneapolis, MN). It is important to follow all safety warnings, precautions, and recommendations as stated in the Product Insert information for this specific neurostimulation system used for DBS. Failure to follow all warnings and guidelines could result in serious and permanent injury.[b,c]

- On the basis of tests to date, some MRI procedures can be performed safely with an implanted Activa system. MRI systems used to safely perform MRI include MRI systems operating at 1.5 T. The safety of other MRI machines used with implanted Activa systems is not known.
- Patients should be informed about potential problems; interrogate the system before and after MRI scanning
- All scans should be supervised carefully by an MRI-trained radiologist or physicist
- Program the system to off and at 0-V setting
- Use only a transmit-and-receive-type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields.
- Do not use a whole-body RF coil, a receive-only head coil, or a head transmit coil that extends over the chest area
- Select imaging parameters to perform MRI at an SAR that does not exceed 0.4 W/kg in the head[d]
- After performing the prescan for the MRI examination, the MRI parameters and conditions should not be changed, because this could alter the RF power deposition (i.e., the SAR level)
- The limit for the gradient magnetic fields used for MRI is dB/dt to 20 T/s or less

[a] DBS, deep brain stimulation; MRI, magnetic resonance imaging; RF, radio frequency; SAR, specific absorption rate.
[b] Because of the number and variability of parameters that affect MRI compatibility, the safety of patients cannot be fully ensured.
[c] MRI systems tested include 1.5-T Siemens Magnetom 1.5-T Vision, Picker International 1.5-T Edge, GE Signa 1.5-T Echospeed. The exact safety of other MRI systems is not known.
[d] Note that the implant manufacturer's recommendation for selecting "imaging parameters to perform MRI at an SAR that does not exceed 0.4 W/kg in the head" may need to be refined to specify the particular MRI system platform (i.e., model and software version used) that this applies to, given the previously stated issues related to using calculated SAR values. Accordingly, it may not be acceptable to use "generic" SAR recommendations for this neurostimulation system used for DBS.

radiofrequency lesion produced by heating of the electrode of a DBS system during MRI of the lumbar spine in a patient with Parkinson's disease.

CASE REPORT

The patient was a 56-year-old, right-handed Caucasian man with a 10- to 12-year history of Parkinson's disease. The earliest symptoms he could recall involved stumbling when walking, left-sided clumsiness, and mild tremor. He initially responded well to antiparkinsonian medications, but over time, his symptoms continued to progress. Dose increases were associated with hallucinations and dyskinesia. At the time of evaluation for surgery, he had difficulties in several areas, including gait freezing, bradykinesia, tremor, and dyskinesia. He was experiencing falls from festination and gait freezing. Although his balance was reasonably good, he still frequently used a walker outside of his home.

His medical regimen at this time consisted of Sinemet CR 50/200 (DuPont Pharmaceuticals, Wilmington, DE), one tablet four times per day; Sinemet 25/100, two tablets four times per day; and Mirapex (Boehringer Ingelheim Pharmaceuticals, Inc., Ingelheim, Germany), 1.5 mg three times per day. He developed a brittle and unpredictable response to his medications, including wide "on-off" fluctuations with dyskinesia when "on" and severe bradykinesia and freezing when "off." He had episodes of sudden and unexpected "off" times. Despite multiple manipulations of his medication regimen, he was unable to obtain sustained good response, although there were some increasingly rare periods during which his symptoms were minimal or altogether absent.

On preoperative neurological examination in the "on" state, he exhibited moderate dyskinesia, no rigidity, and mild to moderate bradykinesia, without gait freezing or shuffling. Evaluation performed off medications for 12 hours and 45 minutes after his usual medication dose revealed severe gait difficulties and bradykinesia in the "off" state, which improved remarkably in the "on" state, with some peak-dose dyskinesia. He was deemed to be a very good candidate for implantation of a neurostimulation system used for DBS.

The patient subsequently underwent bilateral microelectrode-guided placement of DBS electrodes (Model 3387; Medtronic, Inc., Minneapolis, MN) into the subthalamic nucleus without incident. He was discharged from the hospital on postoperative Day 2 in stable condition. Two weeks later, he underwent placement of bilateral Soletra pulse generators (Model 7426; Medtronic, Inc.). Because he was an avid hunter, the pulse generator on his shooting side (the left) was placed in the abdomen rather than the infraclavicular region to avoid interference with the butt of his rifle (lead length: left side, 66 cm; right side, 51 cm). The pulse generators were activated 19 days after electrode placement. After a total of four programming sessions over a period of 2 months, the patient experienced marked improvement in his motor function, with motor Unified Parkinson's Disease Rating Scale scores in the on medication/on stimulation state decreased

from 2 to 3/4 to 0/4 in all categories except dyskinesia, which was still present but mild at 1/4. His medication dose was gradually tapered at the time of his transfer to a neurology program closer to his home with experience in the implantation and programming of DBS systems.

Seven months after pulse generator placement and 5 months after his last office visit at the Cleveland Clinic, the patient underwent an MRI scan of the lumbar spine for the evaluation of back pain and left leg pain. (The operation mode of the neurostimulation system during the MRI examination was unknown.) Multiple scan sequences were performed with a 1.0-T MRI system (Expert; Siemens Medical Solutions) with a transmit/receive body radiofrequency coil. After the MRI procedure, the patient was reported to have sustained a neurological deficit. According to the written MRI report, "Upon removal of the patient from the MR scanner he had developed a new right hemiparesis."

The patient was subsequently evaluated by his neurologist, who stated in an office note that he exhibited "obtunded aphasia with right hemiplegia, bilateral extensor plantar responses, and skew deviation, right eye below left." A computed tomographic scan performed immediately after the lumbar spine MRI scan revealed hemorrhage surrounding the left electrode (*Fig. 1A*). An MRI scan of the brain with magnetic resonance angiography was performed 2 days after the lumbar MRI scan on a 1.5-T MRI system (Signa; General Electric Medical Systems, Milwaukee, WI). The MRI report described "subacute hemorrhage with methemoglobin in the left thalamus, posterior limb of the left internal capsule, and left cerebral peduncle. This hemorrhage is just adjacent to the tip of a deep brain stimulator electrode. There is surrounding edema on T2-weighted sequences" (*Fig. 1B*).

Seven months after the lumbar MRI scan, the patient was reevaluated at the Cleveland Clinic. On examination, he was found to have severe dysarthria that made his speech nearly impossible to understand at times. He had persistent right hemiparesis with falling toward the right and clumsiness of his right hand. He continued to have some mild dysconjugate gaze. Tremor and bradykinesia remained improved on the left side, similar to previous postoperative evaluations.

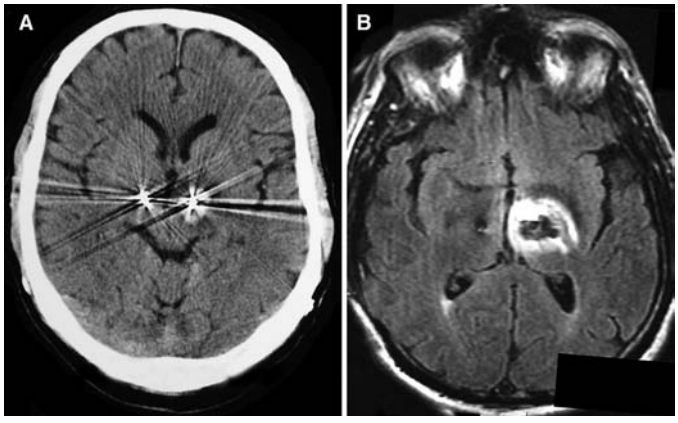

FIGURE 1. A, *computed tomographic scan performed immediately after the lumbar spine MRI scan revealed evidence of a hemorrhage surrounding the left DBS electrode.* B, *T2-weighted MRI scan of the brain showing edema around the left DBS electrode.*

The lumbar MRI films were reviewed. A total of 186 images were obtained during this study, with various pulse sequences used in both the axial and sagittal planes. Although specific scan parameters were not present for many of the sequences, approximate settings could be deduced, and estimates of whole-body-averaged and local specific absorption rates (SARs) could be calculated. On the basis of the imaging parameters used for the MRI examination and the weight of the patient, the whole-body-averaged SAR values ranged from 0.57 to 1.26 W/kg, with local SAR values of up to 3.92 W/kg.

DISCUSSION

This patient's neurological deficits were noted immediately upon his removal from the MRI system, implying a direct relationship between the MRI procedure and the subsequent brain lesion. In addition, the hemorrhage and edema demonstrated on subsequent brain imaging surrounded the DBS electrode circumferentially, as would be expected of a lesion generated by radiofrequency heating. MRI-related heating of DBS systems has been studied in vitro (2, 3). Depending on the MRI conditions, temperature alterations can range from small, physiologically insignificant changes to relatively large temperature elevations that might be expected to result in permanent brain lesions. Heating of up to 25.3°C has been reported with the use of a transmit/receive radiofrequency body coil in a 1.5-T MRI system, with the pulse generators and leads in standard positions (3). Notably, the patient described here sustained a lesion on the left side of the brain, corresponding with the left-sided lead and abdominal implantable pulse generator (i.e., which resulted in a longer length for the lead on the left side). No lesion was produced on the right side, where the lead and implantable pulse generator were in the standard infraclavicular position.

This serious accident, as well as the case described by Spiegel et al. (7), emphasizes the fact that, although MRI may be performed safely in patients with DBS devices by following specific guidelines (1–3, 5, 6, 8), the generalization of these conditions to other neurostimulation system positioning schemes, other scanners, and other imaging scenarios can lead to significant injuries. In both incidents, the performance of the MRI scan deviated substantially from the manufacturer's recommendations (1, 6). To prevent similar catastrophic incidents, the manufacturer's guidelines should be followed carefully, because they are known to result in the safe performance of MRI examinations.

MRI-related heat generated in a neurostimulation system used for DBS has a complicated dependence on multiple factors related to the specific type of implanted device and various aspects of the MRI procedure (2–4, 8). These factors include the electronic characteristics of the neurostimulation system; the static magnetic field strength of the MRI system;

the orientation of the implantable pulse generator (which affects the length of the lead), extension, and lead relative to the source of radiofrequency coil used for MRI; the amount of radiofrequency energy delivered (i.e., the SAR); and how the SAR is calculated by a given MRI system (2–5, 8).

The calculation or estimation of the SAR values can vary on the basis of the model type and software of the MRI system. This issue is of special concern because safety information identified to prevent heating for an implant that is determined for a given scanner may not be applicable to another scanner, even if it is from the same manufacturer (4). As such, safety recommendations developed for a given neurostimulation system to prevent excessive heating may not be implemented across MRI systems, especially when one considers that the SAR calculations used on older scanners may have changed for present-day scanners and with regard to the software version that is in use (4).

In addition, as indicated by Rezai et al. (4), it is often presumed that if an implant is safe for a patient undergoing an MRI examination at 1.5 T, the use of an MRI system operating at a lower field strength will likewise be safe. However, this is not the case for implants made from conducting materials, because MRI-related heating issues are highly dependent on the field strength and the radiofrequency wavelength of the MRI system because of resonant effects and other factors (5). As such, it is inappropriate to extrapolate safety information defined for a particular static magnetic field to a lower-field-strength scanner.

In conclusion, specific safety information for a particular neurostimulation system with regard to the implantable pulse generator, leads, extensions, and the positioning of these components, as well as the MRI system conditions (including static magnetic field strength, software version, type of radiofrequency coil, amount of radiofrequency energy used, and other factors), must be considered carefully when subjecting a patient to MRI (2–5, 8). Safe SAR levels determined for one scanner platform may not necessarily apply to another (4). It is crucial to ensure that the specific MRI system and software used for imaging are identical to those used to derive the safety recommendations or to perform in vitro safety testing before imaging patients with implanted neurostimulation systems (2–4, 8). Finally, careful adherence to the manufacturer's guidelines will ensure safe MRI examinations (1, 6).

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COMMENTS

This is a very important case report for neurosurgeons and other physicians who work with patients who have been implanted with the Medtronic Activa Deep Brain Stimulation (DBS) system (Medtronic, Inc., Minneapolis, MN). Since we learned of this case, we have been much more cautious about magnetic resonance imaging (MRI) scanning in DBS patients. We no longer perform body MRI in patients with a DBS system, and perform brain MRI in patients with complete DBS systems only at 1.5 T with careful attention to the specific absorption rate and the use of a transmit/receive headcoil. We advise our patients that a major disadvantage of having a DBS system implanted is the inability to have an MRI exam of most body areas. Clearly it will be important for DBS manufacturers to introduced new systems with improved MR compatibility.

Philip A. Starr
San Francisco, California

There have been approximately 30,000 patients implanted with DBS systems. Many of these patients will require ongoing examinations, including MRI scanning and other diagnostic and therapeutic interventions. Indeed, reports of complications related to the application diathermy has already been documented and there are an increasing number of reports of complications related to MRI scanning in patients with implanted stimulators. This type of report emphasizes first the need for caution and safety guidelines to obtain the imaging that it necessary for these patients. Secondly, they ask the manufacturers of DBS systems, as well as manufacturers of imaging and diagnostic technology, to come up with practical solutions to avoid these serious adverse effects.

Andres M. Lozano
Toronto, Ontario, Canada