Safety assessment of spine MRI in deep brain stimulation patients

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OBJECTIVE Many centers are hesitant to perform clinically indicated MRI in patients who have undergone deep brain stimulation (DBS). Highly restrictive guidelines prohibit the use of most routine clinical MRI protocols in these patients. The authors' goals were to assess the safety of spine MRI in patients with implanted DBS devices, first through phantom model testing and subsequently through validation in a DBS patient cohort.

METHODS A phantom was used to assess DBS device heating during 1.5-T spine MRI. To establish a safe spine protocol, routinely used clinical sequences deemed unsafe (a rise in temperature $> 2^{\circ}\text{C}$) were modified to decrease the rise in temperature. This safe phantom-based protocol was then used to prospectively run 67 spine MRI sequences in 9 DBS participants requiring clinical imaging. The primary outcome was acute adverse effects; secondary outcomes included long-term adverse clinical effects, acute findings on brain MRI, and device impedance stability.

RESULTS The increases in temperature were highest when scanning the cervical spine and lowest when scanning the lumbar spine. A temperature rise $< 2^{\circ}\text{C}$ was achieved when 3D sequences were modified to 2D and when the number of slices was decreased by the minimum amount compared to routine spine MRI protocols (but there were still more slices than allowed by vendor guidelines). Following spine MRI, no acute or long-term adverse effects or acute findings on brain MR images were detected. Device impedances remained stable.

CONCLUSIONS Patients with DBS devices may safely undergo spine MRI with a fewer number of slices compared to those used in routine clinical protocols. Safety data acquisition may allow protocols outside vendor guidelines with a maximized number of slices, reducing the need for radiologist supervision.

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KEYWORDS magnetic resonance imaging; spine; safety; implants; deep brain stimulation; neurostimulator; functional neurosurgery; diagnostic technique

To date, more than 150,000 patients have received deep brain stimulation (DBS) neuromodulation devices worldwide.¹⁴ DBS is best established as a therapy for movement disorders, including Parkinson's disease (PD), essential tremor, and dystonia. In recent

years, it has also become of interest as a treatment strategy for psychiatric and cognitive disorders, such as major depressive disorder, obsessive-compulsive disorder, and, possibly, Alzheimer's disease.²¹ DBS surgery entails the insertion of electrodes into deep brain structures and mod-

ABBREVIATIONS B1+rms = root-mean-square value of the MRI effective component of the radiofrequency magnetic (B_1) field; C-spine = cervical spine; DBS = deep brain stimulation; IPG = implantable pulse generator; L-spine = lumbar spine; PD = Parkinson's disease; RF = radiofrequency; SAR = specific absorption rate; T-spine = thoracic spine; T1W = T1-weighted; T2W = T2-weighted.

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ulation of desired brain targets using electric current. DBS electrodes are connected to an implantable pulse generator (IPG) via extension wires that are tunneled under the skin. The IPG is typically placed subcutaneously in the upper chest wall. Because of safety concerns and stringent vendor guidelines, MRI of patients following DBS implantation is highly restricted.^{7,12,20,33} Prior studies have investigated the safety of brain MRI in these patients,^{6,7,13,26} but safety data for MRI of other body parts, such as the spine, are lacking.

Due to 3 previous cases of DBS patient injuries presumed to be related to MRI, MRI guidelines for DBS systems have become restrictive, as well as vendor and hardware specific.^{15,31,35} In particular, one case of perielectrode hemorrhage and permanent neurological changes occurred during a 1.0-T lumbar spine (L-spine) MRI session.¹⁵ At present, FDA-approved MRI conditional DBS devices are available from Medtronic, Boston Scientific, and Abbott.^{5,23,32} Depending on the models of the DBS leads, extension wires, and IPG, patients may be eligible for head or full-body MRI. For MRI safety purposes, the spine is considered within the category of “full body.” DBS devices are approved for MRI at specific magnetic field strengths (i.e., 1.5 T) and with specific heating-related thresholds. These thresholds are based on a specific absorption rate (SAR) and root-mean-square (rms) value of the MRI effective component of the radiofrequency (RF) magnetic (B_1) field (B_1 +rms). The SAR should remain ≤ 0.1 W/kg during the MRI session.^{5,23} These MRI restrictions are in place mainly to prevent heating of the DBS system (particularly the electrode tips) and potential brain injury.^{6,13} However, these guidelines prohibit the use of most routine clinical MRI protocols, unless they are modified. SAR or B_1 +rms requirements can be met by reducing the number of slices/echoes or increasing the repetition time, which usually lengthens the acquisition time. In addition, reducing the number of slices typically warrants radiologist supervision to ensure that adequate anatomy is imaged.¹

With the exception of acute intracranial indications, MRI is the diagnostic imaging modality of choice for most cranial and spinal clinical queries. CT of the spine is insufficient for visualizing nonbony structures, while CT myelography is generally inferior to MRI and can be associated with complications such as bleeding, infection, seizures, and contrast-induced nephrotoxicity.^{24,27} Under-scoring the clinical demand for MRI in this unique patient population, one study estimated that 66%–75% of patients diagnosed with PD, essential tremor, or dystonia need to undergo MRI within 10 years of DBS surgery.¹⁰ With most of these indications (62%) calling for body and/or spine MRI, there is evident value in establishing a safe MRI protocol for these patients.¹⁰ Except for a single study in the early 2000s comparing brain and chest MRI safety,¹⁹ to our knowledge, no studies have investigated the safety profile of body MRI, particularly spine MRI, in DBS patients.

Similar to our previous safety studies for brain MRI,^{6,13,26} the goals of this study were to: 1) investigate the safety of spine MRI outside the prescribed vendor guidelines using a phantom model, 2) thereby establish safe

protocols for spine MR image acquisition with optimized acquisition parameters (e.g., the number of slices), and 3) validate these protocols clinically by prospectively imaging a cohort of DBS patients who required spine MRI.

Methods

Phantom Safety Data

To evaluate heating of the DBS system during MRI, a phantom study was conducted. The experimental setup has recently been described by our group.^{6,13} Briefly, a Lucite phantom was equipped with a full-body, eligible DBS device consisting of two DBS leads (model 3387; Medtronic), two extension wires (model 37086, 60 cm; Medtronic), and an IPG (Activa PC model 37601; Medtronic). In this phantom experiment, we did not test IPG output stability; the IPG was turned off during scanning. This was done because patients would undergo spine MRI either without stimulation (if tolerated) or with bipolar stimulation, which is approved by Medtronic guidelines.²³

The phantom was placed head first and in supine position in the MRI scanner isocenter and was landmarked at the typical location for cervical (C-), thoracic (T-), or L-spine imaging to simulate conventional patient positioning. All experiments were performed with a 1.5-T MRI (GE Signa Excite MRI, software level HD 12x; GE Healthcare). A transmit-body spine-receive coil (8-channel coil, GE model 5268673) was used on the phantom, corresponding to the C-spine, T-spine, and L-spine. In contrast to head MRI, where a single RF coil is usually used to transmit the RF and receive the signal, spine MRI utilizes a transmit coil that is integrated into the bore of the scanner. This transmit-body coil exposes the DBS system to higher RF and can generate more device heating. The pulse sequences tested are listed in Table 1.

Similar to recent investigations by our group,^{6,13} temperature changes were measured at the most distal contacts of each lead using two fiber-optic temperature probes connected to a fiber-optic thermometer (model 790; Luxtron; 0.1°C temperature resolution). Additionally, a third thermometer (model FTI-10; FISO; 0.01°C temperature resolution) was placed adjacent to the posterior aspect of the IPG. Temperature change was defined as the difference between the baseline temperature, as measured prior to sequence initiation, and the so-called during-sequence temperature (including pre-scans). Once the recorded temperature had remained stable for a duration of at least 1 minute, during-sequence temperature rises were computed by averaging the temperature of the last 5 seconds recorded. This was done because the highest temperature would be expected with longer scanning time (logarithmic increase in temperature over time^{3,4}) and because the fiber-optic probes' high sensitivity creates slight variations across data points.

We first investigated the temperature rises associated with cervical, thoracic, and lumbar protocols that are routinely employed for spine imaging at our institution. Once a pulse sequence triggered a temperature rise $> 2^\circ\text{C}$, it was deemed unsafe, and scanning was aborted. In such cases, protocols were adjusted in a stepwise manner to decrease heating: first, if the employed protocol entailed

TABLE 1. Summary of pulse sequences and associated parameters used for the various experiments

Spine Image	Pulse Sequence	TR (msec)	TE (msec)	TI (msec)	BW (kHz)	FOV (mm)	FA (°)	No. of Slices	ST (mm)	Gap (mm)	ETL	Matrix	Frequency-Encoding Direction	NEX
C/T	3-plane Loc	5.2	1.6	—	31.25	48	80	—	5.0	10.0	—	256 × 128	Rt/lt	1.00
T/L	3-plane Loc	5.2	1.6	—	31.25	48	80	—	5.0	10.0	—	256 × 128	Rt/lt	1.00
C	Cal scan	150	1.4	—	31.2	48	70	—	9.0	0	—	32 × 32	Rt/lt	1.00
C	3D Ax FRFSE T2W*	2200	102.0	—	41.67	18.0	XL/90	—	2.5	0	39	320 × 224	Rt/lt	1.00
C	Ax T2W 2D #1	2500	85.0	—	25.00	20	XL/90	8	4.0	0.5	15	256 × 224	A/P	2.00
C	Ax T2W 2D #2	3000	85	—	25.00	20	XL/90	8	4.0	0.5	8	256 × 224	A/P	2.00
C	Sag T1W*	450	Min	—	25.0	22.0	SE	13	3.0	0.5	—	384 × 256	A/P	3.00
C	Sag T1W #1	500	Min	—	25.00	22	SE	3	3.0	0.5	—	384 × 256	A/P	3.00
C	Sag FRFSE T2W*	5800	114.0	—	41.67	22.0	XL/90	13	3.0	0.5	33	384 × 256	A/P	4.00
C	Sag FRFSE T2W #1	3000	114.0	—	41.67	22.0	XL/90	6	3.0	0.5	33	384 × 256	A/P	4.00
C	Sag FRFSE T2W #2	3000	114.0	—	41.67	22.0	XL/90	3	3.0	0.5	33	384 × 256	A/P	4.00
T/L	Cal scan	150	1.4	—	31.2	48	70	—	9.0	0	—	32 × 32	Rt/lt	1.00
T	Ax 3D FRFSE*	2200	102	—	41.67	18.0	XL/90	—	2.5	0	39	320 × 224	Rt/lt	1.00
T	Ax FRFSE 2D #1	3000	85.0	—	25.00	20.0	XL/90	20	4.0	0.5	15	256 × 224	A/P	2.00
T	Ax T2W 2D #2	4000	85.0	—	25.00	20	XL/90	20	4.0	0.5	15	256 × 124	A/P	2.00
T	Sag T1W*	500	Min	—	15.63	32.0	SE	15	3.0	0.5	—	320 × 256	A/P	3.00
T	Sag T1W #1	400	Min	—	15.63	32.0	SE	6	3.0	0.5	—	256 × 256	A/P	3.00
T	Sag FRFSE T2W*	4350	116.0	—	41.67	32.0	XL/90	17	3.0	0.5	27	320 × 256	A/P	4.00
T	Sag FRFSE T2W #1	4350	116	—	41.67	32.0	XL/90	8	3.0	0.5	27	320 × 256	A/P	4.00
T/L	Cal scan	150	1.4	—	31.2	48	70	—	9.0	0	—	32 × 32	Rt/lt	1.00
L	Ax T2W 2D*	4800	85.0	—	25.00	20.0	XL/90	23	4.0	0.5	15	256 × 224	A/P	2.00
L	Sag T1W*	350	Min	—	31.25	32	SE	9	3.0	0.5	—	384 × 256	Rt/lt	2.00
L	Sag FRFSE T2W*	4000	107.0	—	25.00	32	XL/90	14	3.0	0.5	19	384 × 256	Rt/lt	4.00

A = anterior; Ax = axial; BW = bandwidth; Cal = calibration; ETL = echo train length; FA = flip angle; FOV = field of view; FRFSE = fast relaxation fast spin echo sequence; Loc = localizer; Min = minimum; NEX = number of excitations; P = posterior; Sag = sagittal; SE = spin echo; ST = slice thickness; TE = echo time; TI = inversion time; TR = repetition time; XL = accelerated; — = not applicable.

Sequences routinely used at our institution are identified with an asterisk (*), and modified sequences deemed to be safe (< 2°C) during the phantom study are shown in boldface. To ensure patient safety during imaging, 3 additional safety measures were taken: 1) routinely performed calibration scans were omitted, 2) the overall number of slices in each sequence was reduced by 33% (e.g., T-spine sagittal T1W #1 [i.e., T-spine Sag T1W #1] would become 4 slices when scanning patients), and 3) T-spine sequences were used for imaging of both the T- and L-spine, since the lack of a detectable temperature rise during L-spine sequences precluded the establishment of a safety threshold for these sequences (refer to Table 3).

a 3D scan, the sequence was changed from 3D to 2D; second, the number of slices was gradually reduced until temperature changes were within acceptable limits (< 2°C); and third, repetition-time lengthening was similarly performed but to a lesser extent. Probes were inspected immediately after scanning to ensure that no movement had occurred.

In addition to absolute temperature differences, the SAR—a parameter associated with implant heating—was also measured. Whole-body SAR values, assuming a patient weight of 70 kg, were recorded from the scanner console during imaging. The SAR is the dosimetric standard to characterize the thermogenic aspects of an electromagnetic field. To determine the relationship between temperature rise and the SAR, each temperature rise was divided by the associated SAR, yielding a $\Delta T/\text{SAR}$ value.

Study Participants

Following ethics approval (University Health Network Research Ethics Board), and for the prospective component

of this study (clinical trial registration no.: NCT03753945, clinicaltrials.gov), we recruited participants who required a spine MRI study as per assessment by their treating physicians (Fig. 1). All patients provided written informed consent. Inclusion criteria were as follows: 1) participants receiving active DBS system at any therapeutic targets, 2) ability to provide written informed consent, and 3) implantation of specific models of Medtronic DBS hardware (leads: 3387 or 3389; extension wire: 37086, 60 cm; IPG: Activa PC 37601, Activa RC 37612, or Activa SC 37603) with a configuration similar to that tested in the phantom experiments. DBS device models with comparable MRI safety guidelines to those used in the phantoms were deemed acceptable. Participants who were unable to give written informed consent (e.g., owing to cognitive or psychological impairment) or who required nonroutine spine protocols (e.g., using a contrast agent) were excluded. Patients with electrode impedances outside vendor guidelines (monopolar > 2000 Ω and bipolar < 250 Ω)²³ and clinical indication of a short or open circuit (e.g., recent

FIG. 1. Study flowchart showing participant recruitment and referrals from treating physicians and inclusion/exclusion criteria.

change in clinical efficacy or sudden impedance changes at the previous DBS clinic visit) were also excluded. Study protocols and data generated during the study are available from the corresponding author upon request.

From March 2019 to early July 2019, we performed 1.5-T MRI (GE Signa Excite MRI, software level HD 12x; GE Healthcare) with a transmit-body spine-receive coil (8-channel coil, GE model 5268673) in 9 participants with fully internalized DBS systems (Table 2). If tolerated by participants, MR images were acquired with the DBS device turned off; otherwise, the DBS was left on in a bipolar stimulation configuration for the duration of the MRI session in accordance with current vendor guidelines.²³ Patients in whom monopolar stimulation settings were used were temporarily put on bipolar settings of approximate clinical equivalency according to a specific algorithm (i.e., the cathode remained unchanged, an adjacent contact was set to be the anode, and the voltage was increased by 20%–30%).^{9,25} To ensure safety during imaging, only pulse sequences that yielded temperature increases < 2°C in the phantom experiment (listed in bold in Table 1) were employed in participants. Furthermore, routinely performed calibration scans were omitted, and the overall number of slices in each sequence was reduced by 33%. Finally, T-spine sequences were used for imaging of both the T- and the L-spine, since the lack of detectable temperature rise during L-spine sequences precluded the establishment of a safety threshold for these sequences (Table 3). In the event that the number of slices in a given sequence provided insufficient anatomical coverage, the

TABLE 2. Summary of DBS participants' demographic and clinical data (n = 9)

Demographic & Clinical Data	Value
Age (yrs), mean	62.4 ± 12.3
Sex	
Female	2 (22)
Male	7 (78)
Time btwn MRI & DBS surgery (mos), mean	39.9 ± 23.2
No. of patients w/ DBS-on during MRI	5 (56)
Primary DBS indication/target	
PD/subthalamic nucleus	7
PD/globus pallidus interna	1
Dystonia/globus pallidus interna	1

Unless otherwise specified, values are presented as the number of participants (%). Mean values are presented ± SD.

sequence was repeated, visualizing the contiguous anatomy. Between each sequence, scanning was held for 45 seconds to allow for heat dissipation (Fig. 2). Finally, a T2-weighted (T2W) brain MRI sequence (3-plane localizer and axial T2W image: TR 4000 msec, TE 85 msec, 0.5 × 0.5 × 3-mm voxels) covering the contact portion of the DBS leads was performed before and after the spine MRI to assess for acute intracranial findings such as edema. This T2W brain MRI study was obtained using a transmit-receive head coil (GE model 2341973), consistent with vendor guidelines.

The primary outcome measure of this prospective trial was short-term adverse events as detected during a complete neurological examination immediately after MRI. Motor, sensory (upper and lower limbs), and cranial nerve functions were evaluated, as were alertness and orientation. Any clinical changes from baseline were considered an adverse event. Secondary outcomes included the following: 1) long-term adverse effects assessed at latest routine DBS visits after MRI (any clinical change from baseline was considered an adverse event); 2) acute intracranial findings on immediate post-imaging brain MRI (defined as signal changes adjacent to the neurostimulator other than the typical metallic artifact); and 3) change in electrical circuit integrity of the DBS system as evaluated by comparison of pre- and post-MRI DBS impedances (Activa Patient Programmer; 37642; Medtronic).

For each patient, whole-body SAR values were recorded from the scanner console.

Statistical Analysis

For the phantom, analysis of temperature rises and SARs was conducted using R (version 3.4.3, <https://www.r-project.org/>).

For the study participants, a paired t-test was used to assess the difference in impedances before and after spine MRI. Any p value < 0.05 was considered statistically significant. Statistical analyses were performed using R (version 3.4.3, <https://www.r-project.org/>). Mean values are presented ± SD.

TABLE 3. Pulse sequences and associated parameters used in patients

Spine Region	Pulse Sequence	TR (msec)	TE (msec)	TI (msec)	BW (kHz)	FOV (mm)	FA (°)	No. of Slices	ST (mm)	Gap (mm)	ETL	Matrix	Frequency-Encoding Direction	NEX
C & T	3-plane Loc	5.2	1.6	600	31.25	48	80	—	5.0	10.0	—	256 × 128	Rt/lt	1.00
T & L	3-plane Loc	5.2	1.6	600	31.25	48	80	—	5.0	10.0	—	256 × 128	Rt/lt	1.00
C	Ax T2W 2D #2	3000	85	—	25.00	20	XL/90	5	4.0	0.5	8	256 × 224	A/P	2.00
C	Sag T1W #1	500	Min	—	25.00	22	SE	2	3.0	0.5	—	384 × 256	A/P	3.00
C	Sag FRFSE T2W #2	3000	114.0	—	41.67	22.0	XL/90	2	3.0	0.5	33	384 × 256	A/P	4.00
T & L	Ax T2W 2D #2	4000	85.0	—	25.00	20	XL/90	13	4.0	0.5	15	256 × 124	A/P	2.00
T & L	Sag T1W #1	400	Min	—	15.63	32.0	SE	4	3.0	0.5	—	256 × 256	A/P	3.00
T & L	Sag FRFSE T2W #1	4350	116	—	41.67	32.0	XL/90	5	3.0	0.5	27	320 × 256	A/P	4.00

The parameters are based on modified sequences deemed to be safe (< 2°C) during the phantom study.

Results

Phantom Data Suggest Safe Imaging Outside of Prescribed Vendor Guidelines

Table 4 summarizes the observed temperature increases at the electrode tips. Except for the localizer of the upper spine, temperature rises were higher at the right electrode tip compared to the left electrode tip. The thermometer probe adjacent to the posterior surface of the IPG detected no changes in temperature across all employed sequences.

A craniocaudal temperature gradient was observed along the different levels of the spine during imaging (Table 4). The routine L-spine protocol sequences triggered a maximum temperature rise of 0.2°C, whereas all routine sequences used for the C- and T-spine were associated with at least a 1.7°C temperature increase (Fig. 3). By changing 3D to 2D acquisition and reducing the number of slices—up to 77% and 60% for the C-spine and T-spine, respectively—we were able to decrease heating

at the electrode tips to < 2°C for all sequences, thereby establishing a safe protocol to use for participants. The dynamics of scanning-related temperature rises are shown in an exemplar sequence (i.e., routine axial T2W C-spine sequence) as well as the modified and safe version of the sequence in Fig. 2.

Notably, all estimated whole-body SAR values were outside prescribed vendor guidelines (> 0.1 W/kg), including the sequences deemed safe. SARs varied from 0.3 W/kg (C-spine sagittal T1-weighted [T1W] image) to 1.8 W/kg (localizer upper spine). The calculated $\Delta T/\text{SAR}$ was highest for the C-spine (2.3°C/[W/kg]), followed by the T-spine (1.1°C/[W/kg]), and reached negligible values during L-spine sequences (0.1°C/[W/kg]). Figure 4 features a linear model displaying the relationship between temperature increase and the SAR. Based on this relationship, SAR thresholds associated with a temperature rise of 2°C were estimated for each spine segment. The maximum employable SAR within safe limits was lowest for the C-spine (0.9 W/kg) and T-spine (1.8 W/kg) and

FIG. 2. Dynamics of temperature rise in a phantom model. **A:** Representation of temperature rises over time in an unsafe spine sequence (routinely used C-spine axial T2W image). Within 20 seconds of scanning initiation, the temperature increased rapidly above 2°C. As scanning was discontinued, the temperature exhibited an exponential decline, returning to baseline after approximately 45 seconds. **B:** Modified axial C-spine T2W imaging with a temperature of < 2°C is deemed safe. The routine axial C-spine T2W image was transformed into a 2D sequence with slightly longer repetition time. The red line indicates a safe threshold of 2°C. Figure is available in color online only.

TABLE 4. Temperature rises measured at the electrode tips

Region/Pulse Sequence	Temperature Measurements (°C)			SAR (W/kg)
	Right	Left	IPG	
Cervical spine				
Localizer top	1.0	1.4	0	1.8
Localizer bottom	0.2	0.1	0	1.8
Calibration	>2	0	0	1.6
Ax T2W*	>2	0	0	1
Ax T2W #1	1.9	0	0	0.5
Ax T2W #2	1.2	0.2	0	0.4
Sag T1W*	>2	0	0	1.7
Sag T1W #1	1.1	0.1	0	0.3
Sag T2W*	>2	0	0	0.9
Sag T2W #1	1.7	0.1	0	0.8
Sag T2W #2	1.2	0.2	0	0.4
Thoracic spine				
Calibration	0.9	0	0	1.6
Ax T2W*	>2	0.4	0	1.3
Ax T2W #1	1.8	0.3	0	1
Ax T2W #2	0.8	0.2	0	0.6
Sag T1W*	1.9	0.8	0	1.7
Sag T1W #1	1	0	0	0.9
Sag T2W*	1.7	0.5	0	1.3
Sag T2W #1	0.7	0	0	0.6
Lumbar spine				
Calibration	0.1	0.1	0	1.4
Ax T2W*	0	0	0	1
Sag T1W*	0.1	0.1	0	1.5
Sag T2W*	0.2	0	0	0.9

The rises in temperature measured during various experimental configurations using MRI pulse sequences are shown in the "Right" and "Left" columns, measuring the rises in temperature at the right and left electrodes, respectively. The estimated whole-body SAR is also shown. Sequences routinely used at our institution are identified with an asterisk (*), and modified sequences deemed to be safe (< 2°C) during the phantom study are shown in boldface.

reached very high values during imaging of the L-spine (25.6 W/kg).

Validation of Phantom Safety Data in Participants With DBS Devices

Safety protocols derived from the phantom study (Table 3) were clinically validated in a cohort of 9 patients (67 individual spine sequences overall; Table 5) whose mean age was 62.4 ± 12.3 years (Table 2); 7 participants were male and 2 were female. Exemplar spine images are shown in Fig. 5. There were no acute MRI-related short- or long-term adverse events (mean follow-up period 91 ± 57 days). Limited T2W brain MRI demonstrated no acute brain changes following spine MRI.

To cover the entire anatomy needed to answer the clinical question, sequences may have been repeated in a spatially contiguous manner. The mean number of spatially

contiguous acquisitions per patient was 2 (range 1–3) for axial T2W images (C-, T-, and L-spine), 2 (range 1–3) for sagittal T1W images (C-, T-, and L-spine), and 3 (range 1–5) for sagittal T2W images (C-, T-, and L-spine) (Table 5). Similar to routine spine protocols, sagittal T2W images typically included full anatomical spine coverage, whereas other sequences, such as axial T2W images, were limited to the abnormal spine levels and may thus have had variable acquisition times. To compare acquisition time of our phantom-based safe protocol to routine clinical protocols, we therefore only compared sagittal T2W sequences, which had full spine anatomical coverage in both cases (Table 6). For the phantom-based protocol, the mean sagittal C- and L-spine sagittal T2W acquisition times were 8.5 minutes (single patient) and 10.8 ± 2.7 minutes (multiple patients), respectively. For routine protocols, the mean sagittal C- and L-spine sagittal T2W acquisition times were 3.2 and 4.6 minutes, respectively.

Prior to MRI, the mean DBS system impedance was $1602.9 \pm 817.6 \Omega$. After MRI, the mean DBS system impedance was $1608.6 \pm 819.7 \Omega$ (mean of changes 5.7 ± 117.0 ; > 0.1 , paired t-test). No significant differences were found between pre- and post-MRI impedances.

SAR Estimations in Participants With DBS

Mean SARs were 0.29 W/kg (range 0.26–0.32 W/kg) for the C-spine, 0.46 W/kg (range 0.44–0.47 W/kg) for the T-spine, and 0.64 W/kg (range 0.32–1.06 W/kg) for the L-spine. Similar to the phantom data, these values were all outside the vendor recommended guidelines (> 0.1 W/kg).

Discussion

The present study established safe spine MRI protocols in a DBS phantom model and successfully validated these protocols in a cohort of 9 DBS patients (67 spine imaging sequences) with fully internalized DBS systems who clinically required MRI of the C-, T-, or L-spine. A suboptimal alternative would have been a spine CT scan. To achieve safe spine imaging, the number of slices acquired per sequence was reduced, and sequences were repeated in a spatially contiguous fashion to provide the necessary anatomical coverage. Notably, this established protocol used a higher SAR than recommended, which allowed maximization of the number of slices acquired per sequence compared to the number of slices that would have been acquired with protocols respecting guidelines. The lack of both short- and long-term adverse effects and the absence of acute intracranial findings on T2W brain imaging following spine imaging indicate the safety of the protocols employed. Finally, we demonstrated a steep safety gradient along the length of the spine: L-spine scanning triggered no appreciable rise in temperature, whereas routinely used C-spine MRI protocols produced unacceptable heating. To our knowledge, this is the first MRI safety study to investigate body MRI in patients with DBS.

Recently, specific models have been deemed full-body MRI eligible. This change in guidelines will dramatically impact the care for patients with DBS, given that nearly 75% of patients are expected to require MRI within 10 years of DBS surgery, with more than half of the indica-

FIG. 3. Rises in temperature at the right electrode tips for localizer, C-, T-, and L-spine sequences are shown. When above (or approaching) a 2°C temperature rise, sequences were modified to reduce heating. The red line indicates a safe threshold of 2°C. Sequences routinely used at our institution are identified by an asterisk (*) and bolded sequences represent those deemed to be safe for participants with DBS devices. Ax = axial; Sag = sagittal. Figure is available in color online only.

tions being for body MRI.¹⁰ Because the vast majority of MRI scans performed in patients with DBS currently constitute brain sequences (e.g., electrode localization)^{10,33} and because there is paucity of literature outlining safety and best practices for body MRI in DBS patients,^{6,17} work such as this is crucial to facilitate improved overall clinical care of DBS patients. Of note, as recently as 2009, nearly half of imaging centers were not performing brain MRI in DBS patients.³³ It is not unreasonable to infer that these imaging centers would be even more uncomfortable performing body MRI. Expanding safety-related knowledge of MRI in patients with DBS devices, in particular body MRI, will minimize the chances that clinically necessary MRI studies are not performed based on what may be an extreme interpretation of the associated risks.^{7,22}

Currently proposed MRI guidelines for DBS patients are highly restrictive, commonly imposing modifications on routine MRI protocols. These restrictions are in place to prevent additional MRI-related injuries. Modifications of routine MRI protocols typically require a specialized knowledge base (i.e., radiologists and physicists) and may result in increased acquisition time and compromised image quality.^{1,28} To decrease the SAR and B1+rms, and thus conform to guidelines, several options are available: reduced number of slices, echoes, and/or flip angles, as well as increased repetition time.¹ Reducing the number of slices requires radiologist supervision to ensure the suspected problematic area is included in the field of view. This is

FIG. 4. The relationship between temperature increases and the SAR. Temperature rises and the associated SAR were plotted. The $\Delta T/SAR$ is represented with a linear relationship. The $\Delta T/SAR$ was greatest for the C-spine (2.3°C/[W/kg]), followed by the T-spine (1.1°C/[W/kg]). It was near 0 for the L-spine (0.1°C/[W/kg]). Using this linear relationship, the SAR for a temperature increase of 2°C can be calculated: 0.9 W/kg for the C-spine, 1.8 W/kg for the T-spine, and 25.6 W/kg for the L-spine (25.6 W/kg). The red line indicates a safe threshold of 2°C. Note that the linear model assumed an intercept at 0 and excluded sequences for which a maximal temperature rise could not be defined because they were stopped once 2°C was reached. Figure is available in color online only.

TABLE 5. The number of times sequences were acquired

Case No. (n = 9)	Cervical Spine			Thoracic Spine			Lumbar Spine		
	Axial T2W	Sagittal T2W	Sagittal T1W	Axial T2W	Sagittal T2W	Sagittal T1W	Axial T2W	Sagittal T2W	Sagittal T1W
1	—	—	—	—	—	—	2	2	2
2	2	5	2	—	—	—	—	1	—
3	—	—	—	—	—	—	2	4	3
4	—	—	—	—	—	—	3	3	1
5	—	—	—	—	—	—	2	4	2
6	—	1	—	—	1	—	2	5	—
7	—	—	—	—	1	—	1	4	1
8	—	—	—	—	—	—	2	3	—
9	—	—	—	—	—	—	2	4	—
Total	2	6	2	0	2	0	16	30	9

A total of 67 sequences were obtained.

particularly problematic for spine imaging to ensure appropriate levels are imaged. Autonomous technologist-driven MRI as is commonly employed in the clinical setting is consequently not possible. Alternatively, repetition time and flip angle may be modified to conform to vendor guidelines. However, they may affect image contrast, and the adjustment of these parameters is generally less practical and may be associated with technical difficulties.^{1,28} In summary, while DBS devices may be full-body eligible, performing body MRI in these patients according to vendor guidelines will usually prevent autonomous technologist-driven scanning.

The SARs of our spine protocols largely exceeded the recommended values.²³ To decrease unacceptable tem-

perature increases, in addition to changing a 3D into a 2D sequence, we most commonly decreased the number of slices because insufficient anatomical coverage can be solved by repeated acquisition of spatially contiguous sequences. Changing the number of slices does not compromise image quality itself and may only add a few minutes of acquisition time to cover the required anatomical area. Importantly, although the number of slices had to be decreased compared to the routine spine protocols, this number was still higher than the number of slices that would have been included in protocols within the vendor guidelines. Having established spine MRI protocols with the highest slice numbers (i.e., body coverage) while maintaining safety will lead to greater technologist autonomy and will minimize the need for radiologist’s supervision. Our safety data show, however, that the use of 3D sequences should generally not be entertained for DBS patients undergoing spine MRI.

Apart from the type of MRI hardware and parameters, and neuromodulation systems, DBS device configuration (i.e., geometry) is known to play a central role in device heating.^{6,17} Positioning the DBS system off the isocenter¹⁷ or with a rotational angle has each been shown to increase the overall measured temperatures in phantom studies.^{11,29,30} Similarly, investigators have commonly found larger temperature increases at the left compared to the right electrode tip; this may be owing to the different configuration of leads as the extension wire is most commonly tunneled under the right lateral side. Interestingly, we recorded larger temperature rises at the right electrode tips. Because heating at the right electrode tip was recorded during localizers and because the temperature probe location accuracy was ensured before and after the experiment, we think this finding is likely related to the interplay between the MRI and DBS devices. Our data highlighted the importance of the spatial relationship between the DBS device and the emitted RF pulses (and thus the coils): there was a clear difference in heating between the C- and L-spine, presumably related to the relationship between RF pulses and the device components included in the images. This finding is in line with the literature pertaining to other implants such as pacemakers.⁸

FIG. 5. Exemplar spine images. Sagittal (A and C) and axial (B and D) T2W cervical (A and B) and lumbar (C and D) MR images.

TABLE 6. Mean acquisition time per patient for C- and L-spine sagittal T2W MRI

Pulse Sequence	No. of Patients	Mean Acquisition Time Needed/ Patient (mins)*	
		Phantom-Based Safety Protocol	Routine Clinical Protocol
C-spine sagittal T2W	1	8.5	3.2
L-spine sagittal T2W	8	10.8 ± 2.7	4.6

For the phantom-based safety protocol, acquisition times for C- and L-spine sagittal T2W MRI were 1.7 and 3 minutes, respectively. The mean acquisition time per patient was determined by summing the acquisition time of each repeat image acquisition. For example, case 1 (see Table 5) required two L-spine sagittal T2W images to cover the full anatomy ($2 \times 3 = 6$ minutes). Eight patients underwent full coverage of L-spine on sagittal T2W images (cases 1 and 3–9 [Table 5]), and 1 patient underwent full coverage of C-spine sagittal T2W (case 2 [Table 5]). The patient in case 2 (Table 5) also underwent one L-spine sagittal T2W imaging sequence to acquire screening images (rather than full anatomical coverage) and was not included in the L-spine sagittal T2W group. Clinical protocols on patients without DBS devices require one sequence acquisition to cover the required spine anatomy.

* Values are presented as the mean acquisition time or as the mean acquisition time ± SD.

Alternatively, different body landmarks used for the spine segments changes the proximity to coil rung elements and capacitors, which may induce high local SARs.³⁴ Previous studies have also found a linear relationship between the SAR and temperature rise; however, the $\Delta T/\text{SAR}$ was inconsistent across different MRI hardware combinations.^{3,4} Similarly, although we showed linear $\Delta T/\text{SAR}$ s, they were different across the spine segments being scanned. As suggested in previous studies,^{3,4,6,18} these general indicators of heating are unreliable for predicting heating for specific MRI hardware and DBS device models/configurations.

Study Limitations

Our study has a number of limitations. Although a large number of spine sequences ($n = 67$) were acquired overall, 9 different patients were scanned. Also, acute intracranial findings immediately adjacent to the DBS leads may have been masked by the metallic artifact. As stated previously in similar reports, phantom studies have a number of limitations.⁶ Most importantly, our safety data are not generalizable to other MRI hardware or institutions. However, with careful planning and the appropriate expertise, other institutions may replicate our experiment without substantial costs. Similarly, findings in this study are not generalizable to other magnetic field strengths (e.g., 3 T) and other implants (e.g., spinal cord stimulators). Furthermore, since our MRI software did not compute $B_1\text{-rms}$, our phantom safety data were based on SARs only. As $B_1\text{-rms}$ was recently incorporated into the vendor guidelines, it would have been preferable to also compute this measure of heating. Finally, given the adoption of one manufacturer only (i.e., Medtronic), our results are difficult to generalize to the other DBS companies.

Guidelines have been developed to assess the MRI-related safety of medical implants.^{2,16} These guidelines may

allow increased safety data generalizability across MRI systems and institutions. As patients with DBS systems are increasing in number, clinicians are often faced with clinical queries in this patient population that are best assessed using MRI. While waiting for updated vendor guidelines is the optimal option for patient safety, it also has negative impact on patient care as it limits the use of an important diagnostic imaging modality. As with most aspects of medicine, clinicians should always weigh the advantages and disadvantages of a diagnostic test. If MRI is likely to provide significant benefits for the patient with DBS, then assumption of some degree of risk may be acceptable.²²

Conclusions

We safely acquired spine MR images in patients with fully internalized DBS systems using a protocol outside the prescribed vendor safety guidelines. This MRI protocol was predicated on local phantom safety data, which maximized the number of acquired slices compared to guideline-consistent MRI protocols, thus minimizing the need for radiologists to continually monitor acquired images. Our phantom safety data also clearly demonstrated a safety gradient among the different spine segments. As a large proportion of patients with DBS are likely to be denied clinically indicated MRI, this study is intended to share our experience performing spine MRI that is required for the management of spine disorders in a large proportion of these patients. We hope this study will prompt other groups to confirm and build on our findings, such that MRI use in DBS patients might be expanded.

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