VIEWPOINT

The Current State of Postoperative Imaging in the Presence of Deep Brain Stimulation Electrodes

Greydon Gilmore, MSc [1,2*] Donald H. Lee, MD, FRCPC,[3] Andrew Parrent, MD, FRCPC,[2,4] and Mandar Jog, MD[1,2]

[1]Department of Biomedical Engineering, Western University, London, Canada
[2]Department of Clinical Neurological Sciences, University Hospital, London, Canada
[3]Department of Medical Imaging, University Hospital, London, Canada
[4]Department of Neurosurgery, University Hospital, London, Canada

For more than a decade, medically refractory movement disorders have been treated with deep brain stimulation (DBS) devices. Bilateral DBS of the subthalamic nucleus (STN), globus pallidus, and thalamus have been effective in reducing the complications of medications in later-stage movement disorder patients. However, the effectiveness of the DBS device is highly dependent on the proper radiologic and electrophysiological identification of DBS target structures and the accurate placement of the DBS electrodes. The reasons for suboptimal results from DBS surgery could be related to several factors such as patient selection (preoperative), precision of DBS electrode placement (intraoperative), and inadequate device programming and follow-up (postoperative).[1] It should be mentioned from the outset that, regardless of the target, the issues of postoperative MRI in the presence of electrodes hold true.

Limited clinical improvement from DBS therapy may result from misplaced electrodes during the intraoperative procedure. Magnetic resonance imaging (MRI) of DBS electrodes is the preferred method for confirming the anatomical location of electrodes given the amount of detail obtained. Recently, computerized topography (CT) has been used for electrode localization by fusing the postoperative CT with the preoperative MRI. This method could introduce more error given the fusion process required (eg, brain shift, CT air pockets). There is an implicit need for the localization of DBS electrodes with a postoperative MRI, and no amount of experienced DBS programming can compensate for a poorly placed electrode.[1] Furthermore, a CT scan cannot replace invaluable MRI scan sequences that are used for diagnostic purposes (outside electrode localization).

However, the current restrictions on the postoperative MRI of electrodes has resulted in many centers opting out of the procedure. Importantly, although the potential danger imposed by MRI scanning in the presence of electrodes should not be disregarded, the fear of such procedures should not impact patient care. The current viewpoint will assume that MRI scanning is being performed with both the leads and implantable pulse generator in place. Regardless of the patient, treating neurologist, or the implantation technique, postoperative MRI scanning is invaluable for proper electrode placement verification and diagnostic applications.

Specific Absorption Rate

In 1979, the concept of specific absorption rate (SAR) was introduced by the National Council on Radiation Protection and Measurements for measuring the rate of radiofrequency (RF) energy absorbed by the body. SAR is defined as the mass normalized rate at which RF power is coupled to biological tissue.[2] SAR is measured in units of watts per kilogram (W/kg).[2] The objective of calculating SAR is to limit the rise in body temperature as a result of RF deposition during the MRI procedure. During the MRI procedure, the patient's body temperature is not easy to detect, so SAR is used to control the potential temperature increases.[2] The MRI software calculates the SAR value before the scan sequence and the technician can manipulate scan parameters to reduce the SAR. In general, the SAR value is calculated as follows:

*Corresponding author: Greydon Gilmore, Department of Biomedial Engineering, University Hospital, 339 Windermere Road, Room BLL-250, London, Canada; ggilmore@uwo.ca

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$$SAR_{avg} = \frac{N_{RF} * {J_{RF}}^2}{T_R * M_{pat}}$$

where N_{RF} is the number of radiofrequency pulses in the sequence, J_{RF} is the energy deposited by the standard radiofrequency pulse, T_R is the repetition time, and M_{pat} is the weight of the patient.[2]

The SAR value is strictly an estimate produced by the MRI software based on numerous variables such as frequency, type of RF pulse sequence, repetition time, type of RF coil used, and patient weight.[3] Gorny and colleagues[4] performed calorimetric measurements to determine the SAR generated from MRI head scans. It was found that the amount of RF required to reach the 90^0 flip angle, in a fast spin echo (FSE) sequence, increases as the patient weight also increases.[4] However, the SAR values may differ between 2 individuals weighing the same as a result of variables such as patient body habitus,[4] precise positioning within the scanner,[2] and even oral surgery history.[5] The fluctuations of SAR values between patients are of concern, especially when the value is used to estimate RF deposition.

Current Industry-Approved MRI Scan Parameters

Currently, the U.S. Food and Drug Administration permits a whole-body SAR limit of 4.0 W/kg and a local head SAR limit of 3.2 W/kg in individuals without DBS devices.[6] Prior to 2005, Medtronic had approved a local head SAR limit of 0.4W/kg for individuals with DBS devices. However, 2 injury cases[7,8] led Medtronic (Minneapolis, MN, USA) to update their safety guidelines for postoperative MRI scans with DBS devices (see ensuing section). The reduction of the maximum allowed SAR value went from 0.4 W/kg to 0.1 W/kg in 2005,[9] which is well below the U.S. Food and Drug Administration permitted whole-body and local head SAR limits. Recent reports have provided evidence that the strict restriction on SAR is unreasonable and provides poor quality MRI images that may hinder clinical outcomes.[9-11]

Electrode Heating During MRI

The most important safety concern with postoperative MRI of DBS electrodes is the potential risk of heating during the scanning procedure. The electrical field accompanying the RF magnetic field induces current within the electrode wires, which essentially act as antennas. The induced current passes through the electrode contacts into the surrounding tissue, resulting in heating and potential lesions.[12] The amount of RF charge deposited into tissue depends predominantly on the specific MRI scan sequence selected. Scan sequences produce higher SAR values as a result of the specific scan parameter settings required for their acquisition (eg, FSE, Fluid attenuation inversion recovery. (FLAIR)). Finelli and colleagues[13] studied the effect of T2-weighted FSE sequences on local thermal temperature elevations with DBS electrodes. It was found that FSE sequences produced a local head SAR of <0.5 W/kg and temperature elevations $<0.5^{\circ}$C. This relationship was consistent with other clinically relevant sequences such as gradient echo (GRE) and echo-planer.[13] Finelli and colleagues[13] concluded that MRI scanning of DBS electrodes with a transmit/receive head coil poses no significant risk with local SAR values less than 1.2 W/kg.[13] Minor, physiologically tolerable, safe temperature elevations in the 1 to 2°C range are expected with a local SAR value of 2.4 W/kg.[13]

Imaging Modalities for DBS Localization

Postoperative imaging in DBS is crucial to determine final electrode position and assess surgical complications.[14-16] Imaging with an MRI or CT scan can assess various surgical complications such as hemorrhage,[17] edema,[18] infarction,[19] and brain shift.[20] However, there is still an ongoing debate about which imaging modality provides the most precise information about electrode position.[10,21,22] Proper electrode placement is important for effective therapeutic effect; if an electrode lead is misplaced it may be the cause of poor therapeutic results. Anheim and colleagues[23] reimplanted misplaced DBS electrodes in 7 individuals who had undergone surgery more than 1 year prior. It was found that reimplantation of misplaced electrode leads, confirmed with MRI, improved response to the DBS therapy.[23]

The risk of electrode heating is nonexistent with CT scanning, and the scans provide geometric accuracy. However, CT images lack the soft tissue contrast needed to identify deep brain structures,[16] and they contain significant electrode induced artifacts.[16] Typically, postoperative CT images need to be fused with preoperative MRI images.[24] However, because the anatomical target cannot be viewed on the CT image, the fusion relies on the assumption that anatomical structures have not moved.[11] Fusion errors can arise from the brain shift effect commonly occurring during the surgical procedure.[20] To avoid fusion errors and obtain precise anatomical electrode placement, a postoperative MRI is performed.

The advantages of using MRI examinations in the postoperative management of DBS is implicit.[11,25-28] MRI imaging of DBS electrodes has been performed at many centers with few adverse events despite the concern of DBS electrode heating.[11] A postoperative MRI can provide important information about surgical consequences that may impede DBS therapeutic effect. Importantly, the MRI images can provide much more

TABLE 1. Clinical case reports depicting the safety of postoperative MRI imaging of DBS electrodes at higher specific absorption rate (SAR) values

Group	Patients	MR strength (T)	Coil	SAR (W/kg)	Scan sequence	Hardware	Adverse events
Dormont et al[27]	5	1.5	-	-	T1W SE 3D Soiled GE 3D TOF	-	None
Spiegel et al[8]	1	1.0	T/R Head	-	Sagittal and Coronal SE	Externalized bilateral leads Kinetra	Transient hemiballismus
Henderson et al[7]	1	1.0	T/R Body	Whole body: 0.57-1.26 Local body: 3.92	-	Bilateral Soletra	Permanent neurological deficit
Kovacs et al[36]	34	1.0	T/R Head	<0.20	T1W MP-RAGE T2W SE	Soletra	None
Larson et al[9]	405	1.5	T/R Head	<3.0	T2W FSE 3D GE IR FSE	Itrel, Soletra, Kinetra, Libra	None
Vasques et al[44]	161	1.5	T/R Head	Whole body: <1.9	3D T1W FSE 2D SE	Itrel, Soletra	Two hardware failures
Tagliati et al[37]	3481	1.0 and 1.5	Various	-	Various	Various	One hardware failure
Chhabra et al[45]	64	1.5	R head	<0.8	T1W SE T2W FSE IR FSE	Itrel, Soletra	None
Fraix et al[38]	570	1.0 and 1.5	T body, R head	<4.0	3D T1W FSE T1W and T2W SE	Itrel, Soletra, Kinetra	None
Nazzaro et al[10]	249	1.0 and 1.5	T/R Head	0.16-3.13	T1W 3D T2W SE T2W Turbo IR	Itrel, Soletra	None
Weise et al[39]	211	1.5	T/R Head	0.8-0.9	T2W SE with IR	Kinetra	None
Zrinzo et al[11]	223	1.5	T/R Head	<0.4	T2W FSE DSE T1 Volume	Soletra, Kinetra	One transient neurological event

This table has been modified with permission from Zrinzo et al.[11]
Body, body coil; DSE, dual spin echo; FSE, fast spin echo; GE, gradient echo; Head, head coil; IR, inversion recovery; MP-RAGE, magnetization prepared-rapid gradient echo; R, receive; SE, spin echo; T, transmit; TOF, time of flight; W, weighted.

detail about the specific electrode placement and contact point location within anatomical structures.[27]

Diagnostic Imaging in the Presence of Electrodes

The focus of the discussion has been on the localization of DBS electrodes, but diagnostic imaging should also be addressed. MRI scans are the modality of choice over CT scans when imaging brain tumors[29] and strokes[30] because of the better tissue discrimination and greater sensitivity to early symptom detection.[31] Currently, the industry SAR recommendations are jeopardizing clinical diagnostic MRI scans. If an MRI is required for diagnostic purposes in the presence of electrodes, it cannot always be performed adequately at the reduced SAR values depending on the scan sequence required. Furthermore, MRI offers a number of advanced scan sequences that can be performed to identify different brain structures such as GRE sequences, susceptibility-weighted imaging (SWI), diffusion-weighted imaging (DWI), perfusion imaging and Magnetic Resonance (MR) spectroscopy.[32] Various MRI sequences provide invaluable diagnostic information and should not be avoided if the scan parameters are not below the industry SAR recommendations.

For instance, in the event of an acute stroke, the early detection of blood may be crucial for optimal recovery. Several studies have demonstrated the sensitivity of GRE scan sequences in measuring intracerebral hemorrhage (ICH) over CT scans.[30,33] The SAR values of GRE sequences are lower than FSE sequences because of the unneeded 180° flip angle and a flip angle usually below 90°.[34] In a phantom study, it was found that GRE sequences produce a local head SAR values around 0.5 W/kg.[13] The most widely used scan for ICH is a DWI sequence, which makes employs a fast GRE. Recently, the SWI sequence has been used for visualizing ICH. The SWI scan uses the magnetic susceptibility differences between the tissue of interest and the surrounding tissue, which is caused by substances such as iron, hemorrhage, or calcium.[35] DWI is powerful at detecting acute ICH, but SWI can be used as an adjunct to localize the affected brain tissue

further. SWI is so sensitive that it can detect minute micro-bleeds, which is important when considering thrombolytic agents.[35] The SWI sequence uses a GRE sequence with postprocessing, which means a SAR value of ~0.5 W/kg is obtained.

Discussion of Case Reports

The SAR recommendations put forth by industry are problematic because the specific scan parameters needed for accurate localization of DBS electrodes and diagnostic imaging tend to produce much higher SAR values. Several centers routinely perform postoperative MRI scans with DBS electrodes at higher SAR values than the product labelling.

Patient injuries from MRI scan procedures have contributed to the industry recommendations on postoperative MRI scanning of DBS electrodes. An in-depth literature search revealed that 6 adverse events have been reported, and only 1 event caused a permanent impairment (see Table 1). There were 2 adverse events that contributed to the reduction in the recommended SAR value. Spiegel and colleagues[8] reported the first event in which transient dystonia occurred in a 73-year-old patient who had undergone postoperative MRI imaging with externalized DBS electrodes. There were several red flags with this report, such as not reporting the SAR value and the fact that the externalized leads may have had broken contacts or may have been uninsulated (exposed to higher RF).[36] The second adverse event occurred in 2005 when a 56-year-old patient underwent bilateral STN-DBS and had the implantable pulse generator placed into the abdomen so it did not interfere with the butt of his rifle.[7] The patient underwent an MRI for back pain and immediately after the MRI the patient developed a right-sided hemiparesis resulting from a hemorrhage in the left thalamus adjacent to the tip of the DBS electrode.[7] Taken together, the case reports are more likely the result of user error and have very little to do with SAR values. However, Medtronic adjusted the maximum recommended SAR following the second patient injury report in 2005. The limited reports of adverse events following postoperative MRI scanning strongly suggest that MRI scanning of DBS electrodes is well tolerated. The possibility of performing less restrictive scan sequences with higher SAR values has been explored extensively (Table 1).

Table 1 shows that many centers have not let the recommendation for a low SAR value stop the use of scan sequences that produce higher SAR values. These centers routinely use scan sequences that produce higher SAR values than recommended such as FSE and GRE sequences with no adverse events.[9,10,13,37,38] Following an extensive literature search, it was found that more than 5,400 individuals with implanted DBS devices have had a postoperative MRI scan at higher SAR values than what is recommend by industry (Table 1).

Larson and colleagues[9] reported that their center routinely performed T2-weighted FSE and inversion recovery FSE scan sequences with SAR values well above the industry recommended values. They used a 1.5T MRI machine with a transmit/receive head coil and had scanned more than 400 individuals with bilateral DBS electrodes.[9] The SAR values varied depending on the scan sequence, but were reported to never exceed 3.0 W/kg. Within the case report, they listed a random patient SAR value of 1.4 W/kg.[9] The authors, although giving proper caution, concluded that the industry-recommended SAR value is unnecessarily low and that the restrictions discourage or prevent postoperative MRI imaging from occurring.[9] Tagliati and colleagues[37] surveyed 40 National Parkinson's Foundation Centers of Excellence (COEs) on their typical postoperative DBS MRI procedures. It was found that only 23 of the 40 COEs routinely performed postoperative MRI of the DBS electrodes.[37] The 17 COEs that did not perform the MRI reported the main concern was with industry guidelines and warnings.[37] A total of 3481 patients were scanned at the 23 COEs, and only 1 adverse event was reported. The reported adverse event was hardware failure, which was not linked to the imaging routine itself.[37]

Nazzaro and colleagues[10] conducted a large retrospective cohort study to examine the implementation of T2-weighted postoperative MRI scan sequences in 249 DBS patients All scan sequences in the study produced a higher SAR value than industry recommendations with no reported adverse events. In general, the reported studies maintain the postoperative MRI SAR value below 1.0 W/kg while still obtaining high-quality MRI images. Weise and colleagues[39] conducted a retrospective study with 211 DBS patients who underwent at least 1 postoperative MRI scan. This center routinely uses a T2-weighted FSE with inversion recovery with a SAR value of 0.8 W/kg.

Other centers have continued to report the use of postoperative MRI imaging of DBS electrodes above industry recommendations. Unfortunately, most of the industry MRI recommendations are based on in vitro testing of homogenous tissue and phantom models. Homogenous models are commonly used for modeling malignant tumors,[40] but do not accurately predict the SAR distribution within the heterogeneous distribution of tissues with varying electrical properties.[41,42] Ullman and colleagues[42] conducted a literature review of the DBS Brain Tissue Network for MRI-related adverse events. Furthermore, they performed 3T MRI scans on 4 postmortem brains with DBS leads. They did not observe any pathological findings as a result of the MRI within the DBS brain tissue database.

After 12 hours of extensive 3T MRI imaging of the postmortem brain tissue, there were no noticeable tissue changes.[42]

Conclusion and Recommendations

Patient care is of utmost importance, which includes both safety and effective clinical management following the implantation of the DBS device. The current viewpoint advocates for optimal clinical management of patients receiving DBS intervention. The concern for electrode heating should not be disregarded, as reports have demonstrated a relationship between RF and electrode heating.[13,43] However, restricting SAR to unnecessarily low levels and sacrificing appropriate MRI scanning should be avoided. The extensive patient data presented in Table 1 supports the notion that the industry-recommended SAR value may pose a greater threat to clinical management rather than being mindful of patient safety.

Based on the extensive literature search, the scan sequences that provide the most valuable information required for electrode localization are T2-weighted FSE, inversion recovery FSE, and 3D T1-weighted GRE. GRE scan sequences are invaluable when considering diagnostic imaging. Scan sequences using GRE, DWI, and SWI have been performed safely in individuals with DBS electrodes despite having slightly higher SAR values than industry recommendations.

The recommended scan sequences for electrode localization and diagnostic imaging produce SAR values that exceed the industry recommendations. Given that industry reduced the recommended SAR value from 0.4 W/kg to 0.1 W/kg based on user error, a minimum of 0.4 W/kg can be used. The maximum SAR value is more difficult to determine, as this value depends on user experience. The extensive review of literature demonstrates that several centers can obtain useful MRI images at SAR values not exceeding 1.0 W/kg. Furthermore, it has been demonstrated that no significant temperature increases are experienced at SAR values less than 1.2 W/kg.[13] Given that more than 1000 patients have been scanned at SAR values over 1.0 W/kg without an adverse event, an MRI scan that produces a SAR value less than 1.0 W/kg should not pose a significant risk. It is recommended that scan parameters should be planned per the scan type first, then modifications should be made to reduce SAR to below 1.0 W/kg. If your center performs MRI in the presence of electrodes, it is encouraged that the scan sequences and SAR values are reported during publication. This information will be invaluable going forward, especially given the limited number of reported values currently in literature. Postoperative MRI in the presence of DBS electrodes is crucial for the well-being of the patient, and the avoidance of such scan sequences should not occur because of industry recommendations. ■

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