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OFFICIAL JOURNAL OF THE
WORLD FEDERATION OF
NEUROSURGICAL SOCIETIES

Clinical Safety of Brain Magnetic Resonance Imaging with Implanted Deep Brain Stimulation Hardware: Large Case Series and Review of the Literature

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Key words

- Deep brain stimulation
- Magnetic resonance imaging
- Safety

Abbreviations and Acronyms

CT: Computed tomography
DBS: Deep brain stimulation
fMRI: Functional magnetic resonance imaging
IPG: Implanted pulse generator
MR: Magnetic resonance
MRI: Magnetic resonance imaging
PD: Parkinson disease
RF: Radiofrequency
SAR: Specific absorption rate
STN: Subthalamic nucleus



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Citation: *World Neurosurg.* (2011) 76, 1/2:164-172.

DOI: 10.1016/j.wneu.2011.02.029

Journal homepage: www.WORLDNEUROSURGERY.org

Available online: www.sciencedirect.com

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INTRODUCTION

Over 75,000 patients have undergone deep brain stimulation (DBS) procedures worldwide (28). Several centers use routine postoperative magnetic resonance imaging (MRI) to verify electrode lead location and screen for postoperative complications. MRI is also an important diagnostic tool that may be required if DBS patients develop additional unrelated symptoms. Additionally, functional MRI (fMRI) is a powerful research tool that may shed light onto the mechanism of action of DBS and lead to potentially important clinical discoveries. Safety of MR imaging in patients with implanted DBS hardware is therefore an important consideration.

■ **BACKGROUND:** Over 75,000 patients have undergone deep brain stimulation (DBS) procedures worldwide. Magnetic resonance imaging (MRI) is an important clinical and research tool in analyzing electrode location, documenting postoperative complications, and investigating novel symptoms in DBS patients. Functional MRI may shed light on the mechanism of action of DBS. MRI safety in DBS patients is therefore an important consideration.

■ **METHODS:** We report our experience with MRI in patients with implanted DBS hardware and examine the literature for clinical reports on MRI safety with implanted DBS hardware.

■ **RESULTS:** A total of 262 MRI examinations were performed in 223 patients with intracranial DBS hardware, including 45 in patients with an implanted pulse generator. Only 1 temporary adverse event occurred related to patient agitation and movement during immediate postoperative MR imaging. Agitation resolved after a few hours, and an MRI obtained before implanted pulse generator implantation revealed edema around both electrodes. Over 4000 MRI examinations in patients with implanted DBS hardware have been reported in the literature. Only 4 led to adverse events, including 2 hardware failures, 1 temporary and 1 permanent neurological deficit. Adverse neurological events occurred in a unique set of circumstances where appropriate safety protocols were not followed. MRI guidelines provided by DBS hardware manufacturers are inconsistent and vary among devices.

■ **CONCLUSIONS:** The importance of MRI in modern medicine places pressure on industry to develop fully MRI-compatible DBS devices. Until then, the literature suggests that, when observing certain precautions, cranial MR images can be obtained with an extremely low risk in patients with implanted DBS hardware.

Because there are concerns regarding the safety of MRI with DBS hardware in situ (18, 41), alternatives to MRI should be considered when possible. However, an image-guided and image-verified approach to DBS requires accurate verification of lead location within the intended target. Investigations other than postoperative MRI may not provide the required degree of accuracy and precision. Image fusion of postoperative computed tomographic (CT) images to preoperative MRI scans is open to fusion errors; mean errors of between 1.2 and 1.7 mm have been reported when using fusion algorithms, and larger errors of over 3 mm

may be expected in individual patients (30). Postoperative stereotactic CT or MRI prior to removal of the stereotactic frame are therefore preferable methods of lead localization (10, 32, 50). Unfortunately, the anatomical target cannot be directly visualized on CT; this method therefore relies on the assumption that anatomical structures have not moved relative to the final lead location within stereotactic space. MRI verification allows both electrode artefact and intended target to be visualized on the same image, and is therefore considered the gold standard in verification of lead location in the clinical setting (17, 33, 45, 53, 54). Postop-

erative MRI also provides the most comprehensive assessment of radiological complications after DBS because it is very sensitive to postoperative edema and hemorrhage.

The interactions between the electromagnetic fields of MRI machines and implanted DBS hardware are complex and have the potential to result in severe neurological disability or death. The static magnetic field, gradient magnetic field, and radiofrequency (RF) fields used for MRI may induce movement, heating, and electrical current within the implanted cables and electrodes or interfere with neurostimulator function (27). Phantom studies provide some insight into these effects but cannot replicate every potential interaction in the clinical setting (11, 23, 37, 47).

After isolated reported complications related to MRI, one DBS hardware manufacturer changed its recommended safety parameters (18, 41, 46). Current manufacturer guidelines are summarized in **Table 1** (27, 39, 40). Nevertheless, large numbers of MR examinations in patients with implanted DBS hardware have been performed without complications; many of these MRI scans were reportedly obtained with parameters outside current manufacturer guidelines.

Aims

We assess the safety of using MRI in patients with implanted DBS hardware in a large series of patients and examine the literature for clinical reports on safety of MRI with implanted DBS hardware.

METHODS

Our Case Series of MRI Performed with DBS In Situ

A prospective log of MRI scans performed in patients with implanted DBS hardware is kept at our institution. All complications potentially related to MR imaging are recorded, as are the imaging parameters. Records kept between the inauguration of the Unit of Functional Neurosurgery in November 2002 and June 2010 inclusively were analyzed. We defined an MRI examination as a single patient visit to the MRI scanner in which at least 1 acquisition was completed.

Management of Patients Before MR Imaging. Our image-guided approach to DBS

has been reported previously (12, 17, 20, 33). Inability to tolerate surgery under local anesthesia and continual movement of some patients requiring surgery for movement disorders, coupled with increasing reliance on verification of DBS lead location on postoperative stereotactic MRI, has led us to perform increasing numbers of DBS implant procedures under general anesthesia. After DBS lead insertion, 28-cm-long DBS leads were either capped or connected to a commercially available externalization kit (3550-05, Medtronic, Minneapolis, Minnesota, USA). The caps or connectors were tunneled to the parietal region (usually left), and the excess DBS lead was coiled around the relevant burr hole for between 1 and 3 complete turns. Externalization was performed via separate stab incisions; the noninsulated externalized wires were kept in isolation from each other and from the frame and secured to the forehead in loops with adhesive tape.

Implanted pulse generators (IPGs) were turned off prior to MR imaging, voltage set to zero, and bipolar settings applied according to default factory settings. The magnetic reed switch was disabled in those devices where this function was available.

MRI Parameters Used. MR images were obtained from a single 1.5-T Signa MRI scanner (software version Lx 9.1, General Electric, Milwaukee, Wisconsin, USA) using a head transmit/receive coil that did not extend over the chest to avoid RF exposure to areas outside the head and hence to minimize the area of the DBS circuit exposed. The MRI acquisition protocols were specifically designed to prevent the scanner-predicted head-average specific absorption rate (SAR) exceeding 0.4 W/kg while still providing adequate visualization of the target anatomy. The gradient slew rate (dB/dt) was less than 20 T/s for all acquisitions. The MRI imaging parameters used are presented in **Table 2**. The electrode artefact was noted on postoperative images, which were also examined for radiological complications.

Literature Search

An online PubMed search of the English language literature was performed on July 1, 2010, using the search parameters: (“MRI” or “magnetic resonance imaging”) and (“safety” or “adverse event”) and (“deep

brain stimulation” or “DBS”). The titles and abstracts of reports were reviewed, and relevant articles were selected. Further articles were selected based on quoted references. Publications on the safety of MRI with invasive EEG hardware were not considered further. Only articles that specifically commented on complications related to MR imaging or on the safety of MRI with implanted DBS hardware were selected for further analysis. When relevant publications from the same institution had been published, only the article with the most details relevant to MR imaging with DBS hardware in situ was selected.

RESULTS

Hardware, Anatomical Targets, and DBS Indications at Our Institution

MRI examinations were performed in patients who had 28-cm-long DBS leads implanted (models 3389 or 3387, Medtronic), except for 3 patients undergoing frameless stereotactic surgery when 40-cm versions of these DBS leads were used bilaterally and 3 examinations in patients who underwent implantation of bilateral pallidal leads 25 cm in length (model 6146, St Jude Medical, Plano, Texas, USA). DBS targets included the subthalamic nucleus, posteroventral motor and anteromedial limbic pallidum, ventrolateral motor and sensory thalamus, caudal zona incerta, periventricular/periaqueductal grey, posteromedial hypothalamus, and pedunculopontine nucleus. Indications for DBS included Parkinson disease (PD), dystonia, tremor of various non-PD and nondystonic origins (essential, posttraumatic, multiple sclerosis), gait freezing in progressive supranuclear palsy, Gilles de la Tourette syndrome, chronic pain syndromes, and trigeminal autonomic cephalgias.

Experience with MRI and DBS Hardware in Our Institution

MRI Sessions Performed. A total of 262 MRI examinations were performed in 223 patients with intracranial DBS hardware during the study period. Of these, 45 MRI examinations were performed in patients with intracranial DBS hardware connected to an IPG (Soletra or Kinetra, Medtronic). Typical head average SAR values for the gradient-echo localizer

Table 1. Current Manufacturer Guidelines Compared with Each Other and with the Protocol Observed in the Current Series

	Medtronic	St. Jude Medical	Current Series
	MRI should only be done if absolutely necessary, within the following guidelines	MRI should only be done if absolutely necessary, within the following guidelines	<i>Stereotactic MRI performed as routine after DBS lead implantation</i>
Hardware configuration	–	<i>Implant system components as close to the center line of the patient as possible</i>	–
	Avoid implanting IPG in the abdomen	Avoid implanting IPG in lower torso or abdomen	<i>IPG occasionally implanted in abdomen</i>
	–	<i>Avoid separation of the extension when implanting bilateral configurations</i>	Minimal separation of extension leads in bilateral implants
	–	<i>DBS lead coiled ≥ 3 times around burr hole</i>	<i>DBS lead coiled 1 to 3 times around burr hole</i>
Prior to performing MRI	Check neurostimulator function before MRI examination	Check neurostimulator function before MRI examination	Neurostimulator function checked before MRI examination
	If possible, do not sedate the patient and ask to alert technician of any unusual sensation	If possible, do not sedate the patient and ask to alert technician of any unusual sensation	<i>MRI performed in GA in >50% of patients</i>
Externalised systems	Wrap the external portion with insulating material	–	<i>No insulation material used</i>
	Keep the external portion out of contact with the patient	–	<i>Wires secured to patient's skin with adhesive plaster</i>
	Keep the external leads straight with no loops and running down the center of the head coil	–	<i>Wires looped, kept separate from each other and frame</i>
MRI parameters	Use only 1.5-T horizontal-bore MRI	Safety tests were only performed on 1.5-T machines	1.5-T GE Signa scanner
	Use only a transmit/receive head coil	Use only transmit-receive head coil	Transmit-receive head coil only
	<i>Limit the displayed average head SAR to 0.1 W/kg or less</i>	<i>Displayed local body SAR ≤ 0.22 W/kg (Brio); ≤ 0.4 W/kg (Libra/Libra XP)</i>	<i>SAR ≤ 0.4 W/kg</i>
	Limit the gradient dB/dT to 20 T/s or less	dB/dT limit = 20 T/s	dB/dT < 20T/s
If an IPG is present	Interrogate IPG: if a broken lead is suspected (high impedance), do not perform an MRI	Interrogate IPG: if a broken lead is suspected (high impedance), do not perform an MRI	Interrogate IPG: if a broken lead is suspected (high impedance), do not perform an MRI
	Turn stimulator output to off	Turn stimulator output to off	Turn stimulator output to off
	<i>Turn stimulation mode to bipolar</i>	–	Turn stimulation mode to bipolar
	Turn voltage amplitude to 0	Turn current amplitude to 0	Turn voltage amplitude to 0
	Disable magnetic (reed) switch if present	Disable IPG magnet (Brio)	Disable magnetic (reed) switch if present

Discrepancies between manufacturer guidelines and between guidelines and our protocols have been highlighted in italic bold lettering. DBS, deep brain stimulation; GA, general anesthesia; IPG, implanted pulse generator; MRI, magnetic resonance imaging; SAR, specific absorption rate.

ranged from 0.0039 to 0.0052 w/kg; for fast spin echo sequences, head average SAR was typically 0.3603 to 0.3916 W/kg.

A total of 239 MRI examinations were

performed during 227 consecutive, frame-based, image-guided DBS procedures (141 male; mean \pm SD age: 51.6 \pm 14.4 years). Only 2 of these procedures were not fol-

lowed by stereotactic MRI (technical reasons), and a nonstereotactic MRI was obtained by the first postoperative day. In 214 examinations, DBS electrodes had been

Table 2. MRI Protocols Used in the Current Series

Sequence	T2W-FSE (STN)	PDW-DSE (GPI)	T1 volume
Coil	Transmit-receive head coil	Transmit-receive head coil	Transmit-receive head coil
Scan plane	Axial/coronal	Axial/coronal	Volumetric
Image mode	2-dimensional	2-dimensional	3-dimensional
Image options	Flip angle: 90°	Flip angle: 90°	Flip angle: 30°
Scan timing	TE = 95 ms TR = 3000 ms	TE = 15 ms TR = 4000 ms	TE = 2.3 ms TR = 15.6 ms
Scan setup	Receive bandwidth: 20.83 kHz	Receive bandwidth: 15.63 kHz	Receive bandwidth: 15.63 kHz
Scanning range	Slice thickness: 2.0 mm, no gap Slices: 8	Slice thickness: 2.0 mm, no gap Slices: 15	Slice thickness: 2.0 mm, no gap Slices: 124
Acquisition matrix	(frequency): 256 (phase): 256	(frequency): 256 (phase): 256	(frequency): 256 (phase): 256
Phase field of views	1 250 mm	1 250 mm	1 250 mm
Number of excitations	4	4 (coronal), 3 (axial)	1
Contrast	No	No	No
SAR	<0.4 W/kg	<0.4 W/kg	<0.4 W/kg
Eco-train	9	7	N/A
Scan time	6:06	10:16 (coronal), 7:44 (axial)	5:21

DSE, dual spin echo; FSE, fast spin echo; GPI, globus pallidus internus; MRI, magnetic resonance imaging; N/A, not applicable; SAR, specific absorption rate; STN, subthalamic nucleus; TE, echo time; TR, time to repetition.

capped or externalized. DBS electrodes were connected to a previous IPG in 25 MRI examinations. One patient underwent a total of 5 MRI sessions with implanted DBS electrodes, 4 of which were with an implanted IPG in situ over the course of a few years. Nine patients underwent 3 MRI scans with DBS hardware in situ, of which 2 scans were with an implanted IPG. Three patients underwent 2 MRI scans with hardware in situ, of which 1 scan was with electrodes connected to an implanted IPG. Two patients underwent 2 MRI scans with brain electrodes not yet connected to an IPG.

Frameless surgery was performed in 3 patients who were unable to undergo surgery with the Leksell frame: the head was too large for frame placement in 1 patient and a pronounced thoracic gibbus prevented seating of the Leksell frame within the MRI cradle in the other two patients. Image-guided frameless DBS (Nexframe, Medtronic) with bilateral 40-cm DBS leads was therefore performed. Each pa-

tient underwent postoperative imaging with DBS leads in situ.

The additional 20 MRI examinations (9 patients, 3 male) were performed outside the context of the surgical procedure, in patients with an implanted IPG connected to the DBS electrodes, often to assess DBS electrode location in patients who had undergone surgery outside our program and sometimes to investigate other clinical concerns.

Adverse Events in Our Patient Series Related to MRI

One patient became very dyskinetic and agitated and his head moved during the immediate postimplant stereotactic MRI, which had to be terminated before completion of the scanning protocol. No abnormality was detected on the localizer sequence, and agitation resolved after a few hours. Nonstereotactic MRI was obtained before IPG implantation on the second postoperative day and revealed a hyperintensity suggestive of edema around the whole length of both electrodes (**Figure 1**). Head movement during the initial postop-

erative scan was thought to be the underlying cause. This patient had satisfactory improvement of PD symptoms with subthalamic nucleus (STN) DBS up to the last follow-up (5-years post surgery). There were no other clinical or hardware-related adverse events associated with MRI acquisition in any other patient.

Electrode Artefact Characteristics. On MRI, the electrode artefact is larger at the level of the bare contacts than at the insulated portion as reported previously (35, 52, 54). The artefact is larger than the electrode dimensions, and is recognized as a central signal void and surrounding hyperintensity on all MRI sequences that were used (52).

It was noted that the size of the artefact could vary between patients, and that in patients with bilateral electrodes, the right artefact was always slightly larger than the left, especially on proton-density images. The only exception was in those patients whose electrodes had been tun-

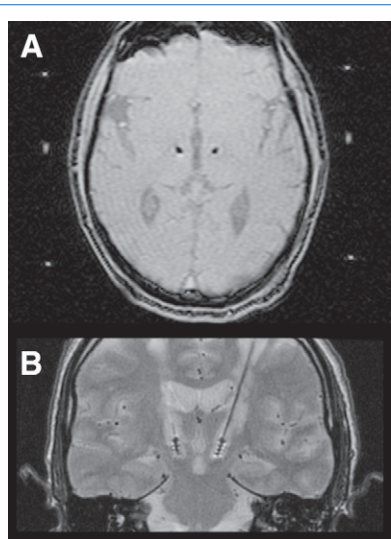


Figure 1. (A) Axial slice from localizer sequence of stereotactic MRI acquired immediately after electrode implantation. Large head movements occurred during further scanning, and the patient became agitated. The scan was terminated before full image acquisition. Agitation settled within a few hours. (B) Nonstereotactic MRI scan was performed on the second postoperative day in the same patient. Oblique coronal reconstruction through left electrode in T2-weighted sequence revealing significant edema along electrode track; at this point there was no further agitation. This patient continued to obtain a satisfactory improvement from STN DBS on PD symptoms 5 years after surgery. DBS, deep brain stimulation; MRI, magnetic resonance imaging; PD, Parkinson disease; STN, subthalamic nucleus.

neled to the right parietal region, where the left artifact was larger than the right (Figure 2).

Literature Review

Table 3 summarizes the clinical studies reporting on the safety of MRI in patients with implanted DBS hardware.

Case Reports of Adverse Events. There have been 4 reported adverse events while performing MRI scans in patients with implanted DBS hardware (Table 3). In 1 patient who underwent staged STN DBS, the ends of the externalized leads were fixed outside the transmit/receive head coil during an MRI scan of the brain at 1.0 T prior to IPG implantation (SAR not specified). Immediately after imaging, the patient developed dystonic and ballistic movements of

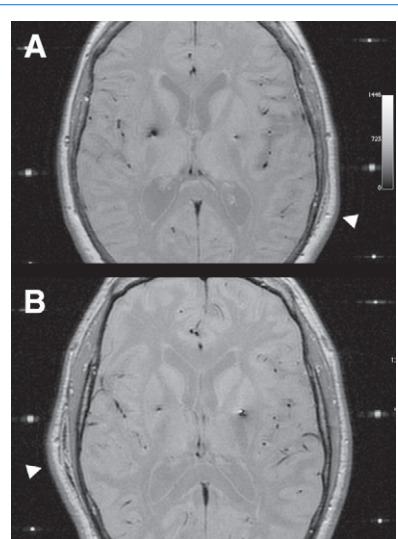


Figure 2. Axial proton-density stereotactic MR images at the level of the foramen of Monro in 2 different patients with dystonia; DBS lead artifacts can be seen en route to the posteroventral internal pallidum. (A) The capped leads were tunneled to the left parietal region (arrowhead), and the right DBS lead artifact is larger. (B) The capped leads were tunneled to the right parietal region (arrowhead), and the left DBS lead artifact is larger. We hypothesize that the greater number of coils around the lead ipsilateral to the capped lead exerted a greater choking effect on induced current, resulting in a smaller MRI artifact (see Discussion). DBS, deep brain stimulation; MRI, magnetic resonance imaging.

the left leg that settled completely after a few weeks (41). Another patient had undergone bilateral STN DBS for PD; the left electrode was connected to a Solettra IPG in the abdominal subcutaneous tissue and right IPG placed in subclavian location. A lumbar MRI scan at 1.0 T with a full-body coil was performed 7 months after surgery (mean SAR < 1.26 W/kg) and caused thermocoagulation of brain tissue 2 to 3 cm around the tip of the left electrode, resulting in severe permanent neurological disability. The operation mode of the neurostimulator during the scan was not reported (17, 18). The only reported complications of MRI at 1.5 T (General Electric, Milwaukee, Wisconsin, USA) are 2 associated IPG failures without neurological sequelae (44, 49). No other complications of MRI with implanted DBS hardware have been reported.

Safety of Structural MR in Patients with Implanted DBS Hardware. Early reports of MRI

with implanted DBS hardware discussed safety-related issues and reported no adverse effects in small numbers of patients (47, 48). Kovacs et al. (2006) published their experience with a 1.0-T MRI in 34 DBS patients (24). They suggested that resonant coupling of the RF pulses with implanted hardware is more likely to lead to heating in a 1.0-T than a 1.5-T magnet, but they did not encounter adverse effects in their series.

Larson et al. (25) in 2008 reported their experience obtaining 1071 MRI events at 1.5 T in 405 patients with implanted DBS hardware. No patients were scanned with externalized leads. Both body transmit/head receive and head transmit-receive coils were used, with SAR values well in excess of 0.1 W/kg and of up to 3 W/kg, without adverse events.

In 2008, Vasques et al. (49) reported on 226 MRI examinations under general anesthesia without adverse neurological or radiological sequelae. However, they did report 1 incidence of stimulator damage (Itrel III; Medtronic, Minneapolis, Minnesota, USA) after spinal MRI. In addition, the authors reported reset of stimulation parameters during cerebral MRI (Itrel III), a technical failure that is not infrequent with this device outside the context of MRI acquisition (49).

Ondo et al. (2005) initially reported that postplacement MRI was routinely performed in 23 of 36 North American centers that responded to a survey (31). In a further survey commissioned by the DBS Study Group of the National Parkinson Foundation, Tagliati et al. (44) in 2009 reported on the safety of MRI in PD patients with implanted DBS hardware. A total of 3304 PD patients with implanted hardware were reported to have undergone MRI of the brain, and 177 DBS patients had MRI of other regions. All 24 centers that replied to the survey switched the stimulators off, and 23 of 24 set the voltage to zero prior to imaging. The only adverse event reported was 1 IPG failure associated with imaging in a 1.5-T scanner.

Chhabra et al. (9) report on 192 MRI examinations during serial imaging of staged bilateral implantation in 64 patients; each patient underwent 3 MRI examinations with implanted hardware, the first after unilateral implantation without an implanted

Table 3. Clinical Studies Reporting on the Safety of Magnetic Resonance Imaging in Patients with Implanted Deep Brain Stimulation Hardware

Study	Number of MRI Events/Events with IPG	Number of Patients	Field Strength (T)	Coil	SAR Value (W/kg)	dB/dt (T/s)	Implanted Hardware	Adverse Events	Notes
Rezai et al., 1999 (38)	86/–	86	1.5	–	–	–	Itrel II	None	–
Tronnier et al., 1999 (47)	25/20	20	0.25 and 1.5	Transmit-receive head, transmit-receive body	–	–	Itrel II and III	None	–
Uitti et al., 2002 (48)	11/11	5	1.5	–	–	–	Itrel II	None	–
Spiegel et al., 2003 (41)	Single case report	1	1.0	Transmit-receive head	–	–	Externalised bilateral leads	Transient hemiballismus	Possible antenna effect from externalised leads
Henderson et al., 2005 (18)	Single case report	1	1.0	Transmit-receive body	0.57–1.26	–	Bilateral Soletra, one in abdomen	Permanent neurological deficit	Operation mode of Soletra unknown
Kovacs et al., 2006 (24)	34/34	34	1.0	Transmit-receive head	<0.2	<19.87 T/s	Soletra	None	–
Larson et al., 2008 (25)	1071/1071	405	1.5	Transmit-receive head and transmit body, receive head	<3.0	–	Itrel II, Soletra, Kinetra, Libra	None	–
Vasques et al., 2008 (49)	226/63	161	1.5	Transmit-receive head and transmit body, receive head	<1.9	–	Itrel II and III, Soletra	One hardware failure	–
Tagliati et al., 2009 (44)	–	3481	1.0 and 1.5	Various	–	–	–	One hardware failure	–
Chhabra et al., 2010 (9)	192/128	64	1.5	Receive only head	<0.8	–	Itrel II, Soletra	None	–
Fraix et al., 2010 (13)	631/61	570	1.0 and 1.5	Transmit body, receive head	<4.0	–	Itrel II, Soletra, Kinetra	None	–
Nazzarro et al., 2010 (29)	445/–	249	1.0 and 1.5	Transmit-receive head	0.16–3.13	< 10.43 T/s	Itrel II, Soletra	None	–
Weise et al., 2010 (51)	243/32	211	1.5	Transmit-receive head	0.8–0.9	<20 T/s	Kinetra	None	–
This study	262/45	223	1.5	Transmit-receive head	≤0.4	< 20T/s	Soletra, Kinetra	One transient neurological event	Patient movement during MRI linked to adverse event

DBS, deep brain stimulation; IPG, implanted pulse generator; MRI, magnetic resonance imaging; SAR, specific absorption rate.

IPG, the second during preoperative planning of the second side with an implanted IPG, and the last after implantation of the second side. They suggest that subgaleal coils in the DBS electrode choke the flow of induced current, reducing potential heating effects. Although they report the safe use of a receive-only head coil in this study on a 1.5-T MRI machine, they comment that their institution now uses transmit-receive head coils in view of the added margin of safety (9).

Fraix et al. (13) reported a large series of 631 MRI examinations in patients with implanted DBS hardware, including 61 with IPG and 4 MR imaging of the spine, without adverse events. Voltage was set to zero, but other therapeutic parameters were not adjusted prior to MRI. The reed switch of the Kinetra was disabled and

that of the Itrel II set to so-called normal amplitude; this function was not available on the Soletra. Nevertheless, they report that stimulation parameters remained unchanged after the scan, regardless of IPG used.

Nazzarro et al. (29) reported on 249 patients undergoing 445 brain MRI scan sessions, including many implanted with an IPG without adverse events.

Weise et al. (51) reported their experience of 243 MRI scans in 211 patients at 1.5 T using an RF transmit/receive coil with SAR values of up to 0.9 W/kg, including imaging of externalized leads and leads connected to an implanted IPG, again without adverse effects.

fMRI with Implanted DBS Electrodes. Rezai et al. (38) in 1999 reported the use of fMRI in

5 patients with implanted DBS electrodes. Jech et al. (21, 22) in 2001 reported performing fMRI studies in 4 PD patients. Hesselmann et al. (19) in 2004 reported a single case of intraoperative fMRI. Arantes et al. (2) in 2006 also performed fMRI studies in 4 patients. All of these studies were performed on 1.5-T machines in patients with unilateral implants that had been externalized prior to permanent IPG implantation, and stimulation was performed via an external impulse generator (Medtronic 3625) without adverse events. Stefurak et al. (43) in 2003 reported fMRI acquisition using a 1.5-T machine in a patient with bilateral externalized STN DBS electrodes, and Phillips et al. (34) reported the use of a 3.0-T machine to perform fMRI studies in 5 patients with

externalized bilateral STN DBS electrodes without adverse events.

DISCUSSION

The present report adds a large series of MRI examinations in patients with implanted DBS hardware to the literature. A total of 223 patients underwent 262 MRI examinations with average SAR values of ≤ 0.4 W/kg. Only 1 transient complication occurred, most probably related to large movements of the head during scanning. A literature review revealed that MRI scans have been obtained in over 4000 DBS patients with only 4 complications related to MRI acquisition reported: 1 transient and 1 permanent neurological complication, and 2 IPG failures.

Interaction of DBS Hardware with MRI

RF energy deposited in tissues during MRI can cause tissue heating and is primarily determined by a single factor: the SAR (1). The U.S. Food and Drug Administration specifies an SAR threshold for head MRI examinations of 3 W/kg averaged over the head for any period of 10 minutes. However, these SAR safety thresholds may not apply in DBS patients. Hardware coupling to the RF field may result in substantial focal heating that is influenced by the type and power output of the transmit RF coil, as well as the shape, orientation, and type of implant (4-6, 11, 23, 36). Significant heating may also occur at breaks points in the implanted hardware, and MRI should be avoided if this is suspected clinically (14). SAR values reported by commercial MRI scanners are approximations based on simple geometric tissue models, with unspecified underlying assumptions and margins of safety; scanner-reported SAR values may therefore vary among different MRI systems (6), leading some groups to perform calorimetric calibration of head coil SAR estimates (15).

Interaction with strong magnetic fields may result in movement of hardware, traumatizing the surrounding brain (27). Although components are designed with minimally magnetic materials, head movement during an MRI study may amplify this effect due to Lorentz forces on conducting structures. We hypothesize that this mechanism resulted in the single event of transient neurological symptoms in this study.

No further events have been noted upon careful observation of subsequent DBS patients during MR scanning. Notwithstanding variance from DBS manufacturer guidelines (27, 39, 40), our group and others have not observed any adverse events in DBS patients undergoing MRI under general anesthesia (26, 49).

Induced voltage within the lead system may also be induced by gradient magnetic fields generated during an MRI scan and is dependent on the rate of change of magnetic gradient pulses (dB/dT), loops in the DBS system, and location and orientation of the hardware with respect to the gradient coils.

The physical arrangement of implanted hardware clearly has an impact on MRI interactions (37). Kainz et al. (23) point out that increasing the number of extension cable loops around the IPG may increase the heating effect dramatically. On the other hand, phantom experiments have demonstrated that increasing the number of DBS lead loops around the burr hole significantly reduced induced temperature increases in a linear fashion (up to 50% in a 1.5-T machine with 2.75 loops, $P < 0.01$) (4). Although the mechanism is unclear, loops that lie within the transmit-receive coil are roughly perpendicular to the MRI magnetic field (B_0), which may choke the flow of induced current (4, 9). In our study, we noticed that in bilaterally implanted patients with a single dual channel IPG, the lead ipsilateral to the planned/actual IPG site created a smaller artefact on MRI. Both lead/cable connectors would be placed in the parietal region ipsilateral to the planned/actual IPG site. We hypothesize that the greater number of coils around the burr hole in the ipsilateral lead exerted a greater choking effect on induced current, resulting in a smaller MRI artefact.

These findings have clear implications on implantation techniques that may not be widely recognized by functional neurosurgeons and are not uniformly mentioned in current manufacturer guidelines.

Clinical Experience with Implanted DBS Hardware

Phantom studies have been very helpful in exploring the complex interaction between MRI and implanted hardware (3, 5-7, 11, 23). It is clear that great care must be taken before performing such studies in clinical

practice. However, it is difficult to propose universally applicable MRI safety guidelines in view of the variability in techniques of SAR calculation, the diversity of MRI systems and software employed, and the increasing number of available DBS hardware systems and methods of implantation. Published recommendations from manufacturers have tried to take all of these factors into account but are not consistent among manufacturers or devices, and have sometimes suggested parameters that severely restrict the quality of acquired images or result in significantly longer image acquisition times (27).

Only the accumulation of clinical experience will be able to provide a definitive measure of MRI safety. Literature reports suggest that the risk of permanent neurological complications is around 1 in 4000. We consider accurate documentation of electrode location an essential part of the surgical procedure, and the risk from stereotactic MRI is certainly less than the risk of surgery itself; it may even offer safety advantages over neurophysiological methods of electrode confirmation that rely on brain mapping with multiple brain penetrations (12). Both reports of adverse neurological outcomes occurred in the setting of a unique set of circumstances. The incidents involved 1.0-T machines, which use a different RF wavelength than the more commonly available 1.5-T machines. Field interactions between 1.0-T machines and DBS devices are less well characterized. A head transmit-receive coil was used in one event, a body transmit-receive coil in the other. SAR values were not reported in one study, and only estimated post hoc in the other. Externalized leads were straightened and fixed outside the coil in one instance, and an abdominal IPG of unknown operation mode was connected to the offending lead in the other. It is imperative that if further adverse events do occur, they are investigated thoroughly and comprehensively reported so that future similar events can be avoided.

Using a plastic or ceramic stylet during surgery would overcome the safety issues of MRI localization with implanted hardware (32, 42). However, this approach involves the use of intraoperative MRI or the routine reopening of the cranial wounds for final DBS electrode placement. In addition, a further MRI is required to provide radiological

documentation of final electrode contact location, and this approach does not address the issue of future MRI acquisition in DBS patients.

MRI after DBS lead implantation provides a sensitive assessment of potential surgical complications and is the gold standard in anatomical verification of lead location, short of autopsy. Structural MRI is an important diagnostic tool, and functional MRI may also open new insights into the mechanism of action of DBS. Notwithstanding manufacturer's guidelines, phantom studies and a limited number of clinical studies suggest that fMRI may safely be performed during active stimulation (2, 8, 14, 19, 21, 34, 38, 43). To our knowledge, fMRI with implanted IPG has not yet been reported. However, a phantom study has suggested that with adequate safety controls, fully implanted systems may even offer a significant safety advantage (8).

Physicians should be aware of the very real dangers of MRI in the presence of implanted DBS hardware and liaise closely with radiology and MR physicist colleagues to establish local practices and monitoring of MRI events. They should also be aware of the reality that the number of reported adverse neurological events in such situations is extremely low when sensible precautions are taken, and many thousands of MRI scans have been obtained with implanted MRI hardware without adverse consequences.

Finally, manufacturers should be aware of the importance of MRI in modern medicine and strive to develop MRI-compatible components that would eliminate the risks in obtaining clinically relevant MR images in DBS patients (6, 16).

CONCLUSIONS

Together with other large reported series, experience at our institution confirms that cranial MR images can be obtained in patients with implanted DBS hardware, including with implanted IPGs, without serious adverse events, when observing certain precautions. This does not imply that there are no safety concerns when performing MRI in patients with implanted DBS devices. The importance of MRI in modern medicine places pressure on industry to develop fully MRI-compatible devices. Until then, the literature suggests that functional

neurosurgeons may be able to further minimize potential risks of MRI acquisition in DBS patients by using longer leads that are then coiled around the burr hole and avoiding excessively long extension cables that would require excessive coiling of redundant length around the IPG.

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Conflict of interest statement: This work was undertaken at UCL/UCLH and was funded in part by the Department of Health NIHR Biomedical Research Centres funding scheme. The Unit of Functional Neurosurgery, UCL Institute of Neurology, Queen Square, London, is supported by the Parkinson's Appeal. Dr. Zrinzo, Dr. Hariz, Dr. Foltynie, and Dr. Limousin occasionally receive honoraria and travel costs for educational activities from the manufacturer of the devices used in this study. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

received 20 December 2010; accepted 11 February 2011

Citation: *World Neurosurg.* (2011) 76, 1/2:164-172.

DOI: 10.1016/j.wneu.2011.02.029

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CPC A81485