Safety of MRI in patients with implanted deep brain stimulation devices

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ABSTRACT

Objective: To survey the safety of MRI in PD patients implanted with DBS devices. Background: MRI in patients with DBS implants is useful to confirm electrode placement, optimize programming and investigating complications. However, several medical centers do not perform MRI studies in DBS patients because of safety concerns. The safety profile of MRI in DBS patients has not been documented in large clinical series. Methods: 42 NPF Centers of Excellence (COEs) were asked to complete a questionnaire on MRI use and DBS. Results: Investigators from 40 of 42 (95%) NPF COEs completed the survey and 23 (58%) reported that they were currently performing brain MRI in DBS patients, while 3 (7.5%) had done it in the past. The 17 COEs currently not performing post-operative MRI for DBS listed the following reasons: 1) industry guidelines and/or warnings (53%); 2) decision deferred to outside department (29%); 3) liability/risk/safety (18%); 4) no active DBS program (18%); 5) no available MRI (12%); and 6) insurance and reimbursement concerns (6%). A total of 3304 PD patients with one or more DBS leads had a brain MRI scan, and 177 DBS patients had MRI of other body regions. In one case MRI was associated with an IPG failure without neurological sequelae after IPG replacement. No other complications were reported. Conclusions: these data provide evidence for a favorable risk/benefit ratio for brain MRI in patients with DBS implants. Further studies will need to address whether a re-assessment of more restrictive recommendations (i.e. very low SAR values) may be warranted.

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Introduction

Deep brain stimulation (DBS) has emerged as the most effective and safe surgical intervention in the treatment of a variety of movement disorders, including Parkinson’s disease (PD), essential tremor (ET), and Tourette syndrome (TS), as well as other neurological and psychiatric disorders (Halpern et al., 2007; Limousin and Martinez-Torres, 2008; Yu and Neimat, 2008). Although pre-operative imaging studies and intra-operative microelectrode recordings have been used to guide the position of the electrode to the appropriate target nucleus, post-operative confirmation of the electrode placement is desirable in order to verify the location and to rule out surgical complications. This information is also useful to optimize subsequent programming and to investigate long-term complications. Currently used MRI scans, however, generate powerful electromagnetic fields that can produce potentially hazardous interactions with implanted components of the DBS system. Some of these interactions, especially heating, can lead to serious injury. Diathermy treatment, which involved pulse-modulated radiofrequency to the maxilla, in a 70-year-old patient with PD implanted with a DBS device, resulted in permanent diencephalic and brainstem lesions and a vegetative state (Nutt et al., 2001). This tragic complication probably resulted from induction of radiofrequency current and heating of the electrodes, leading to the edema surrounding the DBS electrode. Complications have been also rarely reported in patients with implanted DBS following MRI scans of their head, such as transient dystonia and ballism of one leg (Spiegel et al., 2003) and of other parts of the body, such as the lumbar spine (Henderson et al., 2005; Rezai et al., 2005).

Although computed tomography scans, rather than MRI, have been recommended by some, several studies have concluded that, if appropriate safety measures are employed, standard MRI (Tronnier et al., 1999; Jech et al., 2001, Larson et al., 2008) and even functional MRI scans (Arantes et al., 2006) can be safely performed in patients with implanted neurostimulation systems. The main manufacturer of DBS devices, Medtronic, recommends limiting the scan to the head...
region using specific absorption rate (SAR) to 0.1 W/kg which is well below the permitted whole-body SAR limit of 4 W/kg for patients without DBS devices. Following such stringent SAR recommendations, however, is problematic and several centers do not perform MRI studies in DBS patients because of safety and liability concerns. Despite these concerns, there is paucity of data regarding the safety of MRI scans performed in PD patients implanted with DBS devices. The primary aim of this study was to survey safety of MRI scans performed in PD patients implanted with DBS devices in Centers of Excellence (COEs) of the National Parkinson’s Foundation (NPF). The findings may be useful in assessing the current practice and risks, and perhaps modifying current guidelines for the use of MRIs in patients with DBS.

Methods

A survey was commissioned by the DBS Study Group of the National Parkinson Foundation (NPF) to investigate current practices and attitudes toward performing MRI in PD patients implanted with DBS electrodes. MT, JJ and MSO developed the nine-question survey (see Appendix). Forty-two NPF COE were contacted via e-mail and asked to complete the survey. Clarifications were obtained by e-mail and/or personal communication. The results were tabulated on an Excel spreadsheet and descriptive statistics performed.

Results

Investigators from 40 of 42 (95%) NPF COE completed the survey. No reason for non-participation in the survey was offered by the two non-responders. Five responders (12.5%) were private medical centers, and the rest of the cohort were academic or academic-affiliated centers. The responding centers represented a widespread geographical area and were distributed as follows: United States (n = 28), Canada (n = 5), Europe (n = 5), Australia (n = 1), and Asia (n = 1).

Of those returning results, 23 (58%) reported that they were currently performing brain MRI in patients with DBS, while 3 (7.5%) had done it in the past; 5 (13%) were currently performing MRI of other body parts (besides the brain), and 2 (5%) had performed MRI on other body parts in the past. One center was performing only cervical spine MRIs, while the others had also imaged other body parts, including the shoulders, lumbar spine, knee and upper limbs. The 17 centers (42%) currently not performing MRI for DBS listed the reasons for not using post-operative imaging as: 1) industry guidelines and/or warnings (53%); 2) defer clinical decision to outside department (29%); 3) liability/risk/safety (18%); 4) no active DBS program (18%); 5) no available MRI (12%); and 6) concerns about insurance and reimbursement (6%).

A total of 3304 PD patients with one or more DBS leads had a brain MRI scan, and 177 DBS patients had MRI of other body regions. Twelve centers reported to have performed less than 50 brain imaging studies, seven centers performed between 50 and 200 studies, five centers performed between 200 and 400 brain MRIs and two centers accounted for over 400 brain studies. One center reported experience with over 100 body MRI studies. A variety of imaging protocols and MRI manufacturers were utilized (Table 1), and field strength was 1.5 T except for a single center that used a 1.0 T magnet.

One complication was reported where a brain MRI was associated with an implantable pulse generator (IPG) failure (the DBS target was not provided). In this case, the MRI manufacturer was General Electric and the magnet strength 1.5 T. No further details are available, both regarding MRI parameters used and the type of IPG defect that was detected. The defective device was replaced in this single patient and there were no neurological sequelae. No other complications have been reported.

In general, all 23 positive responders felt that it was safe to perform post-operative MRI in DBS-implanted patients (Fig. 1), with four of them specifying “brain only”. Of these, 20 would not perform MRIs unless a transmit-head-receive coil was available (three would do it anyway and one possibly); 15 would not perform MRIs if scanning equipment had not been inspected to meet Medtronic recommended safety specifications and 19 would still perform an MRI if the DBS patient presented an IPG implanted in the abdomen or below the usual subclavicular location (three specifying “brain only”). Regarding the specific safety procedures, all 24 centers turned the stimulator off, 23/24 set the amplitude parameters to 0.0 V and two set the IPG to a bipolar configuration; 18/24 centers check impedance and current drain for continuity; and only 13/24 centers obtained a consent from the DBS patient before performing MRI.

![Fig. 1. Post-operative MRI obtained to confirm proper lead position in a patient with a good clinical outcome following bilateral subthalamic nucleus (STN) DBS. Sagittal (A), coronal (B) and axial views (C) confirmed STN placement and ruled out intracerebral bleeding. The images were obtained from Baylor University after turning the device to 0.0 V and switching the impulse generator off. The MRI machine was a Siemens 1.5 T and the sequence was a T1 MP-RAGE.](image-url)
Our survey of 42 international NPF COEs shows an extremely low rate of complications following over 3000 brain MRIs and 177 body MRIs. Only one problem was reported, which concerned a hardware-related complication with no neurological sequelae. The surveyed NPF COEs were geographically widespread and reflected clinical standards from North America, Europe, Asia and Australia. Twenty-three centers, representing 58% of the surveyed NPF COEs, felt that it was safe to perform brain MRI in DBS patients, using certain basic precautions (e.g. transmit-head-receive coil, stimulator turned off, amplitude parameters set to 0 V). The 17 NPF COEs not performing MRIs cited in the majority of case industry guidelines and/or warnings, which are based on two complications reported in the literature. Current standards recommend the use of a 0.5 to 1.5 T MR system with send/receive head radiofrequency coil only with specific absorption rate (SAR) up to 0.1 W/kg. These recommendations are fairly restrictive and basically limit the application of MRI technology in DBS patients to head studies.

A PubMed search for published articles dealing with DBS and MRI safety revealed only few papers specifically concerning this topic (Table 2). MRI safety concerns in DBS patients include the possible occurrence of skin and scalp burns (heating), magnetic field interactions, induced currents, functional disruption of the devices, and temporary or permanent injury to the patient, including transient dystonia, paralysis, coma or even death (Rezai et al., 2004, Patterson et al., 2007). The use of strict MRI technical guidelines has been instituted after reports of two safety accidents (Fig. 2) (Table 2), which are worth a detailed review. The first case described a PD patient with externalized leads, a practice seldom used nowadays in clinical practice. After undergoing a brain MRI with 1.0 T scanner and head TR coil, he developed ballistic and dystonic movements that lasted 17 months and were attributed to a presumed lesion of the nucleus subthalamicus, which however was never documented (Spiegel et al., 2003). The second incident was reported in another PD patient with abdominal wall IPG, which — similar to the case above — is a placement currently seldom used. Following a lumbar MRI with a 1.0 T scanner and whole-body RF coil, he developed altered mental status. A brain lesion around the implanted lead was documented and attributed to thermocoagulation (Henderson et al., 2005).

Table 2

<table>
<thead>
<tr>
<th>Reference</th>
<th>Age and diagnosis</th>
<th>Target</th>
<th>IPG location</th>
<th>Procedure</th>
<th>Neurological event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiegel et al., J Neurosurg 2003;99:772–4.</td>
<td>73, PD</td>
<td>STN</td>
<td>Externalized leads not connected to IPG</td>
<td>Brain MRI T-R head coil 1.0 T</td>
<td>Dystonic/ballistic left leg movements</td>
</tr>
<tr>
<td>Henderson et al., Neurosurgery 2005;57:E1063.</td>
<td>56, PD</td>
<td>STN</td>
<td>One lead connected to abdominal IPG and other connected to subclavicular IPG</td>
<td>Lumbar MRI T-R body coil 1.0 T</td>
<td>R hemiparesis, aphasia, obtunded sensorium due to subacute hemorrhage</td>
</tr>
<tr>
<td>Nutt et al., Neurology 2001;1384–1386.</td>
<td>70, PD</td>
<td>STN</td>
<td>Subclavicular IPG</td>
<td>Diathermy to maxilla</td>
<td>Permanent diencephalic and brainstem lesions (vegetative state)</td>
</tr>
</tbody>
</table>

PD: Parkinson’s disease; STN: subthalamic nucleus; IPG: implanted pulse generator.

Discussion

Our survey of 42 international NPF COEs shows an extremely low rate of complications following over 3000 brain MRIs and 177 body MRIs. Only one problem was reported, which concerned a hardware-related complication with no neurological sequelae. The surveyed NPF COEs were geographically widespread and reflected clinical standards from North America, Europe, Asia and Australia. Twenty-three centers, representing 58% of the surveyed NPF COEs, felt that it was safe to perform brain MRI in DBS patients, using certain basic precautions (e.g. transmit-head-receive coil, stimulator turned off, amplitude parameters set to 0 V). The 17 NPF COEs not performing MRIs cited in the majority of case industry guidelines and/or warnings, which are based on two complications reported in the literature. Current standards recommend the use of a 0.5 to 1.5 T MR system with send/receive head radiofrequency coil only with specific absorption rate (SAR) up to 0.1 W/kg. These recommendations are fairly restrictive and basically limit the application of MRI technology in DBS patients to head studies.

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Fig. 2. T1 MRI Image sequences were obtained in two patients referred from outside institutions for evaluation of “DBS failures.” The scans were obtained using a Signa HDx GE 1.5 T MRI scanner, and a T1 sequence with 1 mm slice thickness. The MRI images provide examples of suboptimal/misplaced leads. In panels A–C the intended brain target was the globus pallidus interna (GPI). Imaging revealed that the leads were placed too shallow (green arrows). Panels D–F reveal placement of the subthalamic (STN) nucleus DBS leads that were too deep. In both cases the patients clinically had suboptimal responses to DBS. The images were obtained from the University of Florida after turning the device to 0.0 V and switching the impulse generator off.
A recent retrospective single-center study reviewed data from 405 patients with 746 implanted DBS systems who underwent a total of 1071 MRI procedures (some of which were included in our survey). The authors reported no adverse events in any of the patients included in the study, despite SAR ranges between 0.1 and 3.0 W/kg and conclude that the current 0.1 W/kg SAR recommendation may be unnecessarily low (Larson et al., 2008). Phantom head studies with various clinically relevant pulse sequences showed temperature elevations within an acceptable physiologically safe range (Bhidayasiri et al., 2005), which may be reduced using small, concentric loops placed around the burr hole, allowing for a wider range of clinical scanning sequences at 1.5 and 3 T in patients with DBS implants (Baker et al., 2005). However, the clinical approach to MR imaging in patients with DBS remains controversial due to lack of extensive safety data and research when MRI is used with implantable neurological and cardiac stimulators. Recent cardiac reports also suggest that MRI may not be an absolute contraindication in patients with cardiac pacemakers (Prasad and Pennell, 2004).

The retrospective nature of this study and the lack of details regarding issues such as specific SAR measurements and the type of coils used clearly limit the interpretation of our survey results. However, this large and positive experience seems to indicate that DBS centers around the world are quite comfortable performing brain MRIs following basic recommendations and using a head-receive coil in 1.5 T magnets, when the IPG is in the typical subclavicular placement, turned off with the voltage set to zero (Larson et al., 2008). There is less consensus on the safety of MRI of other body areas and the sample collected by our survey is not sufficient to rule out the possibility of rare complications. We do not want to engender a false sense of security and safety for clinicians and radiologists, however our data does suggest a favorable risk/benefit ratio for brain MRI in patients with DBS when basic precautions are implemented. Further studies will need to address whether a re-assessment of more specific and restrictive recommendations (i.e. very low SAR values) may be warranted.

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**Conflict of interest**

The authors declare that there is no conflict of interest.

**Appendix 1: NPF survey of MRI use with DBS**

1. **Does your center perform MRI on patients who have implanted Deep Brain Stimulation (DBS) devices?**
   - **YES**
   - **NO**
   
   If **NO**, please list reasons why not and then stop here.
   **Reasons why not__________________________**

2. If the answer to question #1 is **YES**, please indicate whether
   - A. The center that performs the MRI is
     - Private hospital
     - University hospital
     - Independent MRI facility

3. The center performs
   - a. **MRI**
   - b. **MRI of other body parts**?  
   - **YES**
   - **NO**

   If **YES** please specify which body part(s)__________________________

4. Do you use a specific MRI protocol for DBS patients? Please indicate all that apply:
   - a) **T1-FLAIR**
   - b) **T1-mprage (Siemens)**
   - c) **T1-3d fast SPGR (GE)**
   - d) **T1-3d tfe (Phillips)**
   - e) **T2-FLAIR**
   - f) **T2 TSE**
   - g) **T2 inversion**
   - h) **FLAIR**
   - i) Fast Spin Echo/Inversion Recovery
   - **Other__________________________**
4. Please indicate the technical features of your MRI scanner (check all that apply):
   Manufacturer
   GE ______
   Siemens ______
   Philips ______
   Others ______________________
   TESLA ______
   0.5 ______
   1.0 ______
   1.5 ______
   3.0 ______

5. How many DBS patients has your center scanned? Please be as precise as possible
   Brain MRI ______
   Body MRI ______

6. Did your center observe any complication(s) attributable to MRI scan(s)?
   YES ______
   NO ______
   If YES, then
   How many? ______
   DBS target ______
   Type of complication (please specify) ____________________________
   What was the outcome? ________________________________________
   Did you report the complication and if so to whom? ______
   MRI procedure (e.g. brain, body part, etc.) ______________
   MRI Manufacturer ______________________
   TESLA ______

7. Do you feel that it is safe to perform post-operative MRI on your DBS patients?
   YES ______
   NO ______
   If NO, then why not? ________________________________________

8. Would you do post-operative MRI in the following scenarios (with a DBS patient)?
   a. No transmit-receive head coil
      YES ______
      NO ______
   b. An abdominally implanted impulse generator or an impulse generator below the usual subclavicular location
      YES ______
      NO ______
   c. If the MRI machine has not been inspected to meet Medtronic recommended safety specifications
      YES ______
      NO ______

9. Do you follow the following procedure before MRI? If not, please explain.
   a. Set the amplitude parameter to 0.0
      YES ______
      NO ______
   b. Check the impedance and current for continuity
      YES ______
      NO ______
   c. Turn the stimulator OFF
      YES ______
      NO ______
   d. Obtain a consent form from the patient
      YES ______
      NO ______

10. (Optional):
    Comments: __________________________________________________

References


