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No Adverse Effects following Off-Label Magnetic Resonance Imaging in a Patient with Two Deep Brain Stimulation Systems: A Case Report

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Abstract
Magnetic resonance imaging (MRI) in patients with implanted deep brain stimulation (DBS) systems is subject to strict guidelines in order to ensure patient safety. Criteria include limits on the number of implanted leads. Here, we describe the case of a 29-year-old patient with generalized dystonia implanted with 4 DBS electrodes and 2 implantable pulse generators, who had an off-label spinal MRI without regard for manufacturer guidance yet suffered no adverse effects. This suggests that manufacturer guidelines might be overly restrictive with regards to limits on implanted DBS hardware. Further research in this area is needed to widen access to this fundamental imaging modality for patients with DBS.

Introduction

Deep brain stimulation (DBS) systems use an implantable pulse generator (IPG) connected by extension leads to intracranial electrodes to modulate neural function. They are commonly used to deliver neuromodulation therapy for movement disorders, epilepsy, chronic pain, and some psychiatric conditions, with generally accelerating uptake as the technology matures and the scope of conditions treated widens. It is estimated that over 160,000 patients have undergone DBS surgery in the last 30 years, with approximately 12,000 patients now receiving the treatment annually [1].

Despite its clinical success, DBS presents a radiological challenge. Historically, DBS systems have been deemed largely incompatible with magnetic resonance imaging (MRI), owing to risks including electrode heating, electrode displacement, induced currents, and IPG dysfunction [2]. Following several MRI-related adverse events in patients with DBS systems, a US Food and Drug Administration warning was issued in 2005, and DBS manufacturers issued stringent MRI guidelines. These include MRI parameters as well as limits on the number of implanted devices and leads.

In this report, we present the case of a generalized dystonia patient with 2 separate DBS systems implanted, comprising 4 leads and 2 IPGs. The subject had an unsanctioned lumbar spine MRI yet suffered no adverse effects detectable either clinically or radiologically. To the best of our knowledge, this is the only case in the literature of an MRI scan on a patient with two DBS systems.

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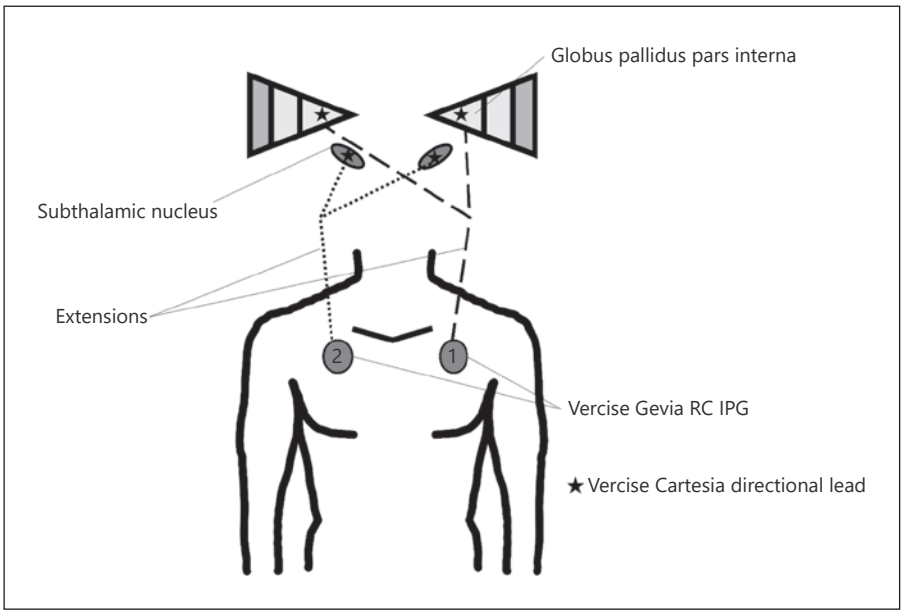

Fig. 1. A diagrammatic representation of the rechargeable (RC) IPG and lead configuration in the patient. The first IPG is situated in a left prepectoral subcutaneous pocket and routed to bilateral globus pallidus pars interna leads via extensions. The second IPG is situated in a right prepectoral subcutaneous pocket and routed to bilateral subthalamic nuclei leads via extensions.

Performing this MRI scan on this patient outside manufacturer guidelines was an error that clearly presented a potential risk to patient safety. It is paramount that MRI departments remain aware of vendor guidelines to prevent such incidents. However, as in this instance the patient, fortunately, came to no harm, it presents an opportunity to discuss DBS manufacturer guidelines for MRI and the extent to which they may be safely relaxed.

Case Report

A 29-year-old male was diagnosed with severe childhood-onset generalized dystonia. He first underwent DBS surgery in our department in September 2017, in which bilateral electrodes were implanted into the globus pallidus pars interna bilaterally. The system comprised two Vercise Cartesia™ directional leads (Boston Scientific, Marlborough, MA, USA), each connected to 55 cm extensions that were tunnelled to a Vercise Gevia™ rechargeable IPG (Boston Scientific) placed in a left pectoral subcutaneous pocket.

Some improvement was seen in truncal and cervical dystonia as well in speech disturbances due to oromandibular dystonia. However, the limbs and hands, in particular, remained affected, and the decision was taken to perform a second DBS surgery in July 2019. Here, the subthalamic nuclei were targeted bilaterally, with a further two Vercise Cartesia™ directional leads connected to a second Vercise Gevia™ IPG in a right pectoral subcutaneous pocket with 55 cm extensions (Fig. 1). Both systems were switched on and resulted in a general improvement in dystonic movements, speech, and gait by January 2020.

In November 2020, the patient developed right groin pain that developed into a shooting back pain over several months. In June 2021, while travelling abroad, an exacerbation of this pain prompted him to seek medical attention. He underwent a 1.5 Tesla MRI scan of his lumbar spine that was performed in a private clinic without regard to his DBS devices, which were left turned on. Sequences performed included T1, T2, and T2 short tau inversion recovery. This imaging was contraindicated on several counts according to manufacturer ImageReady™ MRI guidelines, which specify that MRI scans should be performed under specific MRI parameters neither without enabling "MRI mode" on the IPG nor

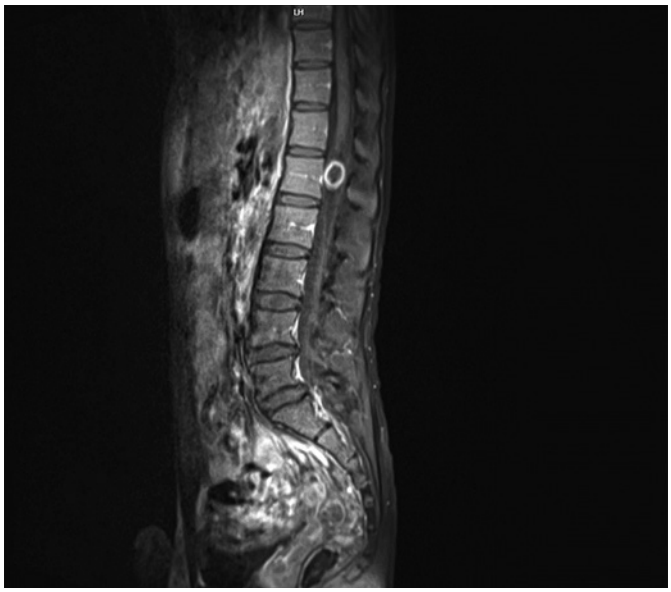

Fig. 2. Sample T1-weighted with contrast image from the unsanctioned lumbar spine MRI, showing the L1 intradural tumour and adequate diagnostic quality.

Table 1. MRI parameters in the patient's lumbar spine MRI compared to Boston Scientific ImageReady™ MRI Guidelines for Vercise Gevia DBS systems

MRI or DBS system parameter	Patient scan parameter	Manufacturer criterion	Was manufacturer criterion met in patient?
IPG placement	IPGs in prepectoral subcutaneous pockets	IPG implanted in subclavicular/pectoral region	✓
Lead extension placement	Extensions routed on same side of body as IPGs	Extensions routed on same side of body as IPG	✓
DBS leads, *n*	4	≤2	✗
IPGs, *n*	2	≤1	✗
MRI mode status	Not enabled	Enabled	✗
MRI static magnet strength, T	1.5	≤1.5	✓
MRI spatial field gradient, T/m	11	≤40	✓
MRI gradient slew rate, T/m/s	125–200	≤200	✓
SAR, W/kg	1.09–1.78	≤0.1	✗
B1+rms, μT	2.80–7.08	≤2.0	✗
Echo time, ms	T1: 13 T2: 89–97 T2 STIR: 70–103	None specified	N/A
Repetition time, ms	T1: 500–568 T2: 3,070–6,903.6 T2 STIR: 3,500–5,820	None specified	N/A
Slice thickness, mm	T1: 3–4.5 T2: 4.5 T2 STIR: 4	None specified	N/A
Flip angle, °	150–180	None specified	N/A
Total acquisition time, mins:seconds	31:58	≤30:00	✗
MRI model	Siemens Avanto	None specified	N/A

Values were extracted from image DICOM headers. SAR, specific absorption rate; B1+rms, B1+ root mean square; IPG, implantable pulse generator; DBS, deep brain stimulation; STIR, short tau inversion recovery.

in patients with more than 2 DBS leads or more than 1 IPG (see Table 1) [3]. Notably, the specific absorption rate (SAR) and B1+ root mean square (B1+rms) also exceeded recommended values.

The MRI was of diagnostic quality and revealed a round well-circumscribed enhancing lesion within the spinal canal at the level of the L1 vertebral body, in keeping with a benign intradural extramedullary tumour (Fig. 2). Following the scan, the patient contacted our department and was commenced on dexamethasone 2 mg twice daily for 1 week and 2 mg once daily afterwards to temporarily manage tumour-related symptoms. The L1 intradural tumour was completely resected with histopathology confirming a World Health Organization grade 1 schwannoma.

The patient reported no new problems during or after the MRI scan. On examination in clinic 4 weeks after the MRI, there were no changes found compared to the patient's neurological baseline. In keeping with his usual dystonia, there was increased upper limb tone, brisk reflexes, and a dystonic gait. There were no focal motor or sensory deficits. He has reported no problems since. A CT head with contrast (Fig. 3) performed on the same day identified no adverse changes relating to the DBS electrodes. Impedances for both devices were within standard operating ranges throughout including at baseline and last follow-up (online suppl. Table; for all online suppl. material, see www.karger.com/doi/10.1159/000525538).

Discussion

As use of DBS increases globally, so too will the need to safely and accurately image this patient cohort. Stringent MRI eligibility criteria for DBS patients were put in

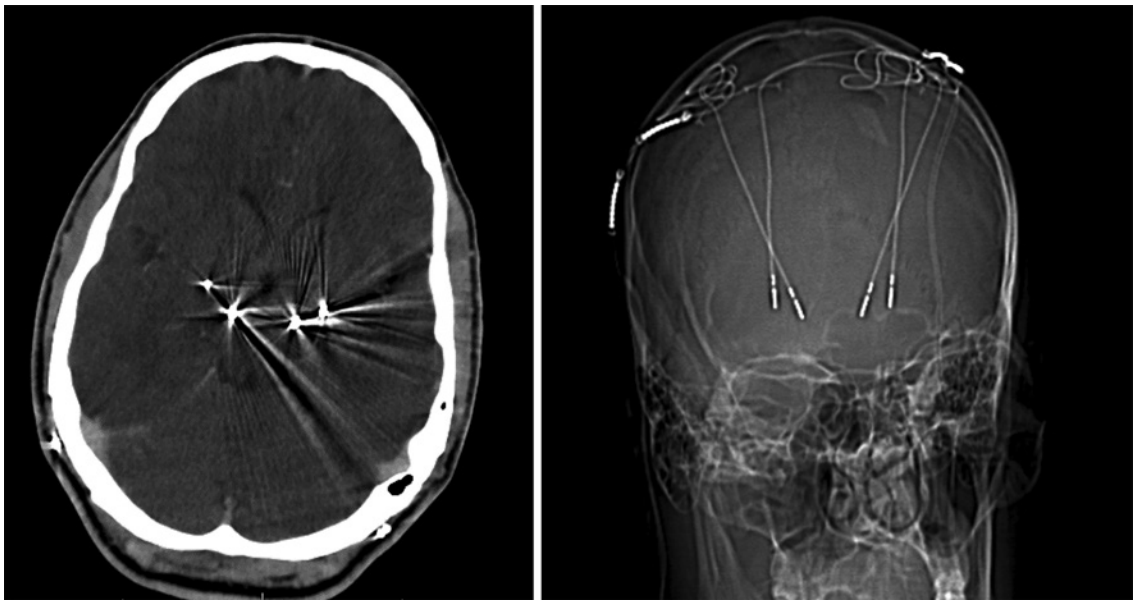

Fig. 3. CT images obtained 4 weeks after MRI demonstrating the four electrodes in situ and no evidence of MRI-related complications.

place following early case reports of adverse outcomes. These have largely gone unchallenged and have led to understandable reluctance to perform MRI scans in DBS patients. Indeed, Tagliati et al. found that only 48% of hospitals surveyed were performing head MRIs in DBS patients and only 13% were performing MRIs of other body parts in this patient cohort [4]. Thus, MRI access is typically restricted to specialist centres where specific protocols can be prescribed. This situation is further compounded by discrepancies between guidelines from DBS and MRI manufacturers, which serve to highlight the systemic nature of the lack of clarity over this problem [5].

While MRI in DBS patients must be treated with due caution, it is also important to ensure that these guidelines are proportional to clinical risk. As with all medical investigations, MRI in patients with DBS comes with risks and benefits that must be carefully evaluated. The primary risks for patients with DBS undergoing MRI are radiofrequency-induced electrode heating and IPG hardware malfunction. These can result from the interaction between the magnetic fields inherent to MRI and ferromagnetic material or circuitry within the DBS leads and IPG. These risks are determined by factors such as MRI acquisition parameters (most notably SAR and B1+rms), the body region being imaged, electrode configuration, and materials used in the DBS hardware.

To date, documented in vivo adverse effects of MRI in DBS patients include hardware failures [4, 6], transient neurological events [7, 8], and permanent neurological deficits [9]. Phantom studies, primarily concerning electrode heating, have produced mixed results, with widely varying estimates of electrode temperature increases of <1°C to >25°C [10–12]. Computational models of DBS-MRI interactions present another method to investigate safety guidelines and have provided useful insights into the relationship between electrode heating and risk factors such as SAR and lead trajectory [13, 14].

By contrast, retrospective studies of MRI scans performed in patients with DBS have found low rates of complications, even with an SAR outside manufacturer recommendations and as high as 3 W/kg [15]. A single-centre study of 1,071 MRI events across 405 patients found no adverse events [15], and an overlapping multi-centre study of 3,481 patients found only one hardware failure with no associated neurological sequelae [4]. A recent prospective study of 102 patients undergoing either 1.5T or 3T functional head MRI found no adverse events, despite the 73 3T sequences being outside manufacturer guidelines [16]. Notably, these scans were only performed after local safety testing.

Whilst most research has concerned DBS safety in head MRI, a recent prospective study focussing on spinal MRI similarly found that sequences can be safely taken outside manufacturer SAR guidelines after prior in vitro safety testing [17]. Sixty-seven sequences taken across 9 patients with Medtronic DBS systems produced no de-

tectable adverse effects. Notably, the study also demonstrated a steep safety gradient along the spine, with lumbar spine MRI causing no appreciable electrode heating. From these data, the authors extrapolated a theoretical maximum safe SAR of 25.6 W/kg for lumbar spine MRI, which is far in excess of that necessary for conventional MRI. Indeed, this may provide some explanation for the lack of adverse effects in the case of our patient, with a maximum scan SAR of 1.78 W/kg.

Overly restrictive guidelines reduce access to a fundamental imaging tool in a patient population with a greater demand for such imaging. Up to 75% of movement disorder DBS patients will require an MRI within a decade of DBS surgery [18]. It seems that a safe approach to expanding eligibility is to interrogate each manufacturer criterion in turn to elucidate to what extent each can be safely relaxed. In this way, DBS MRI guidelines may find precedent in the stepwise relaxation and adjustment of MRI guidelines seen in the analogous technology of cardiac pacemakers [19, 20]. Current work to broaden MRI usage in patients with DBS is taking many forms, including reducing ferromagnetic material in hardware, phantom studies, computational models, and patient cohort studies [8, 10–15, 17, 21].

This case report illustrates that it may be possible to safely perform MRI scans in patients with more DBS hardware than previously allowed: up to 4 leads and 2 IPGs. It adds to the growing body of literature supporting the use of MRI in DBS patients where there is sufficient clinical need, even outside manufacturer specifications for parameters such as SAR and b1+rms [2, 8, 15, 17]. This mounting evidence combined with increasing uptake of DBS should provide further impetus to challenge and relax DBS MRI safety protocols, ultimately moving towards equal access to MRI for patients with DBS.

Statement of Ethics

Ethical approval was not required for this study in accordance with local/national guidelines. Written informed consent was obtained from the participant for publication of the details of their medical case and accompanying images.

Conflict of Interest Statement

Francesca Morgante: speaking honoraria from Abbvie, Medtronic, Bial, Merz, International Parkinson's disease and Movement Disorder Society; advisory board fees from Boston Scientific, Merz, and Bial; consultancies fees from Boston Scientific; research support from Boston Scientific, Merz, and the NIHR; royalties from Springer. Erlick Pereira: speaking honoraria from Boston Scientific; research support from the NIHR; royalties from Elsevier and Oxford University Press. Michael Hart: speaking honoraria from Boston Scientific; research support from the Royal College of Surgeons of Edinburgh. All other authors do not have any disclosures.

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Author Contributions

James Hayley contributed as primary author of manuscript, gathering data for case report, communication with participant, making substantial contributions to conception of the work and drafting and revising work for intellectually important content, giving final approval of version to be published, and agreeing to accountability for accuracy and integrity of work. Michael G. Hart and Abteen Mostofi contributed by gathering data for case report, making substantial contributions to conception of the work and drafting and revising work for intellectually important content, giving final approval of version to be published, and agreeing to accountability for accuracy and integrity of work. Francesca Morgante and Erlick A. Pereira contributed as neurologist and neurosurgeon, respectively, responsible for care of case, communication with participant, making substantial contributions to conception of the work and drafting and revising work for intellectually important content, giving final approval of version to be published, and agreeing to accountability for accuracy and integrity of work.

Data Availability Statement

All data generated or analysed during this study are included in this article and its online supplementary material. Further enquiries can be directed to the corresponding author.

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