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Title:	No adverse effects following off-label magnetic resonance imaging in a patient with two deep brain stimulation systems: a case report		
Authors(s):	James Hayley (Corresponding Author), Michael G Hart (Co-author) Abteen Mostofi (Co-author), Francesca Morgante (Co-author), Erlick A Pereira (Co-author)		
Keywords:	Deep brain stimulation, Dystonia, Magnetic resonance imaging, Neuromodulation, Stereotactic surgery		
Туре:	Case Report		

Reviewer Response

1. "This suggests that safe limits on implanted DBS hardware in MRI might be higher than previously thought." I am not sure I fully agree with this conclusion of the abstract. I am not convinced it suggests it is safe but maybe it suggests that vendor guidelines might be overly restrictive, which limits MRI usage in patients that need it, and this should stimulate further work/research.

Dear Reviewer,

Thank you for your comment. We have amended the manuscript accordingly (page 1 lines 7-9): "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."

Case Report

NO ADVERSE EFFECTS FOLLOWING OFF-LABEL MAGNETIC RESONANCE IMAGING IN A PATIENT WITH TWO DEEP BRAIN STIMULATION SYSTEMS: A CASE REPORT

James Hayley MA(Oxon)^a, Michael G Hart PhD FRCSEd(Neuro.surg)^{a,b}, Abteen Mostofi PhD MRCS^{a,b}, Francesca Morgante MD PhD^{a,b,c}, Erlick A Pereira DM FRCS(SN)^{a,b}

^a Neurosciences Research Centre, Molecular and Clinical Sciences Institute, St George's University of London, London, United Kingdom

^b St. George's University Hospital, London, United Kingdom

^c Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy

Short Title: MRI with two deep brain stimulation IPGs

Corresponding Author:

James Hayley Neurosciences Research Centre, Molecular and Clinical Sciences Institute, St George's University of London Cranmer Terrace London, SW17 ORE, United Kingdom Tel: +447826230318 E-mail: m1801983@sgul.ac.uk

Number of Tables: 1

Number of Figures: 3

Supplementary material: 1 table

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Keywords: Magnetic resonance imaging, deep brain stimulation, neuromodulation, dystonia, stereotactic surgery

1 **ABSTRACT**

2 Magnetic resonance imaging (MRI) in patients with implanted deep brain stimulators (DBS) is subject 3 to strict guidelines in order to ensure patient safety. Criteria include limits on the number of implanted 4 leads. Here, we describe the case of a 29-year-old patient with generalized dystonia implanted with 4 5 deep brain stimulation electrodes and 2 implantable pulse generators, who had off-label spinal MRI 6 without regard for manufacturer guidance yet suffered no adverse effects. This suggests that 7 manufacturer guidelines might be overly restrictive with regards to limits on implanted DBS 8 hardware. Further research in this area is needed to widen access to this fundamental imaging 9 modality for patients with DBS.

10 **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.

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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.

Performing this MRI scan in 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.

33 CASE REPORT

A 29-year-old male was diagnosed with severe childhood onset generalised 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 55cm
extensions that were tunnelled to a Vercise Gevia[™] rechargeable IPG (Boston Scientific, Marlborough,
MA, USA) placed in a left pectoral subcutaneous pocket.

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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 55cm extensions (Figure 1).

Both systems were switched on and resulted in a general improvement in dystonic movements,speech and gait by January 2020.

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49 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 50 51 to seek medical attention. He underwent a 1.5 Tesla MRI scan of his lumbar spine that was performed 52 in a private clinic without regard to his DBS devices, which were left turned on. Sequences performed 53 included T1, T2 and T2 short tau inversion recovery (STIR). This imaging was contraindicated on several counts according to manufacturer ImageReady™ MRI Guidelines, which specify that MRI scans should 54 55 be performed under specific MRI parameters neither without enabling "MRI mode" on the IPG nor in patients with more than 2 DBS leads or more than 1 IPG (see Table 1)[3]. Notably, the specific 56 57 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 (Figure 2). Following the scan, the patient contacted our department and was commenced on dexamethasone 2 mg twice daily for one week and 2mg once daily afterwards to temporarily manage tumour-related symptoms. The L1 intradural tumour was completely resected with histopathology confirming a World Health Organisation (WHO) grade 1 schwannoma.

The patient reported no new problems during or after the MRI scan. On examination in clinic four 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 (Figure 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 (Supplementary Table).

72 **DISCUSSION**

As use of DBS increases globally, so too will the need to safely and accurately image this patient cohort. 73 74 Stringent MRI eligibility criteria for DBS patients were put in place following early case reports of 75 adverse outcomes. These have largely gone unchallenged and have led to understandable reluctance 76 to perform MRI scans in DBS patients. Indeed, Tagliati et al. found that only 48% of hospitals surveyed 77 were performing head MRIs in DBS patients and only 13% were performing MRIs of other body parts 78 in this patient cohort[4]. Thus, MRI access is typically restricted to specialist centres where specific 79 protocols can be prescribed. This situation is further compounded by discrepancies between 80 guidelines from DBS and MRI manufacturers, which serve to highlight the systemic nature of the lack 81 of clarity over this problem[5].

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83 While MRI in DBS patients must be treated with due caution, it is also important to ensure that these 84 guidelines are proportional to clinical risk. As with all medical investigations, MRI in patients with DBS 85 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 86 87 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 88 89 acquisition parameters (most notably SAR and B1+rms), the body region being imaged, electrode 90 configuration and materials used in the DBS hardware.

91

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 3W/kg[15]. A single-centre study of 1071 MRI events across 405 patients found no adverse events [15], and an overlapping multi-centre study of 3481 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.

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107 Whilst most research has concerned DBS safety in head MRI, a recent prospective study focussing on 108 spinal MRI similarly found that sequences can be safely taken outside manufacturer SAR guidelines 109 after prior in vitro safety testing [17]. 67 sequences taken across 9 patients with Medtronic DBS 110 systems produced no detectable adverse effects. Notably, the study also demonstrated a steep safety 111 gradient along the spine, with lumbar spine MRI causing no appreciable electrode heating. From these 112 data, the authors extrapolated a theoretical maximum safe SAR of 25.6W/kg for lumbar spine MRI, 113 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 1.78 114 115 W/kg.

116

117 Overly restrictive guidelines reduce access to a fundamental imaging tool in a patient population with 118 a greater demand for such imaging. Up to 75% of movement disorder DBS patients will require an 119 MRI within a decade of DBS surgery [18]. It seems that a safe approach to expanding eligibility is to 120 interrogate each manufacturer criterion in turn to elucidate to what extent each can be safely relaxed. 121 In this way, DBS MRI guidelines may find precedent in the stepwise relaxation and adjustment of MRI 122 guidelines seen in the analogous technology of cardiac pacemakers [19,20]. Current work to broaden 123 MRI usage in patients with DBS is taking many forms, including reducing ferromagnetic material in 124 hardware, phantom studies, computational models and patient cohort studies [8,10–15,17,21].

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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.

133 **STATEMENTS**

134 Acknowledgement: not applicable.

135 Statement of Ethics:

- 136 <u>Study Approval Statement:</u> Ethical approval was not required for this study in accordance with local/
- 137 national guidelines.
- 138 <u>Consent to Participate Statement:</u> written informed consent was obtained from the participant.
- 139 <u>Consent to Publish Statement:</u> written informed consent was obtained from the participant for
- 140 publication of the details of their medical case and accompanying images.

141 **Conflict of Interest:**

- 142 <u>Francesca Morgante:</u> Speaking honoraria from Abbvie, Medtronic, Bial, Merz, International
- 143 Parkinson's disease and Movement Disorder Society; Advisory board fees from Boston Scientific,
- 144 Merz and Bial; Consultancies fees from Boston Scientific; Research support from Boston Scientific,
- 145 Merz and NIHR; Royalties from Springer
- 146 <u>Erlick Pereira:</u> Speaking honoraria from Boston Scientific; Research support from NIHR; Royalties
- 147 from Elsevier and Oxford University Press.
- 148 Michael Hart: Speaking honoraria from Boston Scientific; Research support from Royal College of
- 149 Surgeons of Edinburgh.
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152 Author Contributions:

153 James Hayley: contributed as primary author of manuscript, gathering data for case report, 154 communication with participant, making substantial contributions to conception of the work and 155 drafting and revising work for intellectually important content, giving final approval of version to be 156 published, and agreeing to accountability for accuracy and integrity of work.

Michael Hart: 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.
 <u>Abteen Mostofi:</u> 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.
 approval 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: contributed as neurologist responsible for care of case, communication with

- 164 participant, making substantial contributions to conception of the work and drafting and revising work
- 165 for intellectually important content, giving final approval of version to be published, and agreeing to
- accountability for accuracy and integrity of work.
- 167 <u>Erlick Pereira:</u> contributed as surgeon responsible for care of case, communication with participant,
- 168 making substantial contributions to conception of the work and drafting and revising work for
- 169 intellectually important content, giving final approval of version to be published, and agreeing to
- accountability for accuracy and integrity of work.
- 171 **Data Availability Statement:** All data generated or analysed during this study are included in this
- article. Further enquiries can be directed to the corresponding author.

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FIGURE LEGENDS

Figure 1: A diagrammatic representation of the rechargeable (RC) implanted pulse generator (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 subcutaneous pocket and routed to bilateral subcutaneous via extensions.

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

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

Case Report

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James Hayley MA(Oxon)^a, Michael G Hart PhD FRCSEd(Neuro.surg)^{a,b}, Abteen Mostofi PhD MRCS^{a,b}, Francesca Morgante MD PhD^{a,b,c}, Erlick A Pereira DM FRCS(SN)^{a,b}

^a Neurosciences Research Centre, Molecular and Clinical Sciences Institute, St George's University of London, London, United Kingdom

^b St. George's University Hospital, London, United Kingdom

^c Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy

Short Title: MRI with two deep brain stimulation IPGs

Corresponding Author:

James Hayley Neurosciences Research Centre, Molecular and Clinical Sciences Institute, St George's University of London Cranmer Terrace London, SW17 ORE, United Kingdom Tel: +447826230318 E-mail: m1801983@sgul.ac.uk

Number of Tables: 1

Number of Figures: 3

Supplementary material: 1 table

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Keywords: Magnetic resonance imaging, deep brain stimulation, neuromodulation, dystonia, stereotactic surgery

ABSTRACT

Magnetic resonance imaging (MRI) in patients with implanted deep brain stimulators (DBS) 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 deep brain stimulation electrodes and 2 implantable pulse generators, who had 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.

Performing this MRI scan in 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 generalised 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 55cm extensions that were tunnelled to a Vercise Gevia[™] rechargeable IPG (Boston Scientific, Marlborough, MA, USA) 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 55cm extensions (Figure 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 (STIR). 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 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 (Figure 2). Following the scan, the patient contacted our department and was commenced on dexamethasone 2 mg twice daily for one week and 2mg once daily afterwards to temporarily manage tumour-related symptoms. The L1 intradural tumour was completely resected with histopathology confirming a World Health Organisation (WHO) grade 1 schwannoma. The patient reported no new problems during or after the MRI scan. On examination in clinic four 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 (Figure 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 (Supplementary Table).

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 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 3W/kg[15]. A single-centre study of 1071 MRI events across 405 patients found no adverse events [15], and an overlapping multi-centre study of 3481 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]. 67 sequences taken across 9 patients with Medtronic DBS systems produced no detectable 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 25.6W/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.

STATEMENTS

Acknowledgement: not applicable.

Statement of Ethics:

<u>Study Approval Statement:</u> Ethical approval was not required for this study in accordance with local/ national guidelines.

Consent to Participate Statement: written informed consent was obtained from the participant.

<u>Consent to Publish Statement</u>: written informed consent was obtained from the participant for publication of the details of their medical case and accompanying images.

Conflict of Interest:

<u>Francesca Morgante</u>: 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 NIHR; Royalties from Springer

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Author Contributions:

<u>James Hayley:</u> 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.

<u>Michael Hart:</u> 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. <u>Abteen Mostofi:</u> 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: contributed as neurologist 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.

<u>Erlick Pereira</u>: contributed as surgeon 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.

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FIGURE LEGENDS

Figure 1: A diagrammatic representation of the rechargeable (RC) implanted pulse generator (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 subcutaneous pocket and routed to bilateral subcutaneous pocket and routed subcutaneous via extensions.

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

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







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	~
Number of DBS Leads	4	≤2	X
Number of IPGs	2	≤1	X
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	X
B1+rms (µT)	2.80-7.08	≤2.0	X
Echo Time (ms)	T1: 13 T2: 89-97 T2 STIR: 70-103	None specified	N/A
Repetition Time (ms)	T1: 500-568 T2: 3070-6903.6 T2 STIR: 3500-5820	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	X
MRI Model	Siemens Avanto	None specified	N/A

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

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

IPG	Lead Location	Impedance before MRI (Ω)		Impedance after MRI (Ω)	
		Minimum	Maximum	Minimum	Maximum
1	Left GPi	965	4264	1051	5097
	Right GPi	1040	4336	1297	5159
2	Left STN	577	2230	1166	3821
	Right STN	607	2678	764	2139

Supplementary Table: Impedances before and after MRI for both DBS systems.

IPG 1 impedances before MRI were measured in September 2017. IPG 2 impedances before MRI were measured in July 2019. Impedances after MRI for both IPGs were measured in January 2022.

Minimum and maximum value refer to impedances from Vercise Cartesia[™] Directional Leads, connected to VERCISE Gevia Rechargeable IPG (Boston Scientific, Marlborough, MA, USA)

IPG= implantable pulse generator, MRI= magnetic resonance imaging, GPi= globus pallidus pars interna, STN= subthalamic nucleus