MRI Safety Protocol for Deep Brain Stimulation (DBS) Devices

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Introduction

- Deep Brain Stimulation (DBS) involves the implantation of electrodes into specific cortical targets to modulate neural circuitry in patients with Parkinson's disease, essential tremor, dystonia, and epilepsy. [1]
- It is estimated that roughly 70% of the 200,000 patients with implanted DBS devices will require an MRI within ten years of implementation.
- The most well-studied risks of performing MRI with implanted DBS devices include device heating, induced currents, pulse generator dysfunction, and magnetic field-induced device movement. [2]
- Past case reports that illustrate the potential harm in performing MRIs in patients with DBS lead to harsh warnings and safety guidelines put forth by the DBS manufacturers themselves.
- The PROMeNADe Trial highlights the utility of developing a workflow to understand the eligibility and safety of using MRI in patients with cardiothoracic implantables. [3, 4] A similar need exists for patients with DBS devices.
- Determining device specific MRI eligibility and ability to adjust scan parameters when necessary to conform to MRI conditional manufacturer guidelines is also a challenge for many imaging centers, which potentially limits patient access.
- In their study of 42 NPF Centers of Excellence (COE) Tagliati et al revealed that:
  - Nearly half of surveyed centers failed to perform MRIs on DBS patients because of manufacturer warnings/guidelines.
  - Two of the top five reasons for which centers did not perform MRIs on DBS patients included industry guidelines and/or warnings and lack of an active DBS program.
  - 13% of centers performed body MRIs on patients with DBS.
  - In the centers that performed MRIs on patients with DBS, 3,304 patients underwent brain MRIs and 177 patients underwent body MRIs. Only one adverse event occurred: implanted pulse generator failure without sequelae. [5]
- Many studies have been performed to standardize and improve stringent guidelines for MRI use with little utility because of compromised generalizability. [6]
- Imaging departments should strive to have well-developed MRI safety protocols for patients with DBS devices (and other implantable devices) in order to ensure patients are receiving the imaging required to deliver competent care.

Purpose

Herein, our objective is to describe a standardized protocol of assessing a patient for an MRI scan both within and outside of DBS device labeling guidelines. In our presentation, we will also address the benefits and risks of performing modified MRI exams on DBS patients as well as future directions for DBS and MRI safety.

Methods

For this study, we consulted the expertise of two radiologists from the MRI safety department of a single institution to discuss the common challenges/roadblocks that providers face when trying to perform MRIs on patients with DBS. We also conducted a literature search on current technological initiatives to improve MRI safety for DBS patients.

Safety Protocol

Figure 1. MRI Safety Protocol for DBS devices

Discussion

- MRI is a powerful tool utilized post-operatively to evaluate DBS device placement and evaluate pathologies in patients with existing DBS devices. As prior cases have shown neurological complications arising secondary to radiofrequency lesions via thermal damage, MRI safety is a valid concern. [7-9]
- As DBS complications may arise due to deviations from manufacturer guidelines, MRI safety protocols and readily available guidelines may streamline and alleviate the risks of MRI use and allow better access for patients.
- The proposed MRI safety protocol (Figure 1) outlines three phases after placing an MRI order: (1) screening for DBS patients, (2) evaluation and subclassification of device type, and (3) execution of the MRI with considerations for manufacturer, hospital, and Radiology team guidelines.
- The current protocol will tentatively be implemented at Kaiser Permanente LAMC and surveyed for feasibility, complications, and usability with the hopes of implementation at additional facilities.
- Future goals include composing a database to condense manufacturer guidelines and other pertinent scanning information for various devices into a centralized location accessible to the Radiologists and MRI technologists.
- Technological improvements with future DBS devices can further improve patient access and eligibility for MRI through less restrictive MRI conditions or potentially MRI safe devices in the future. Implementing improved device screening with EMR chart flagging (ex. allergy alerts), "smart devices" with automatic safety settings or communication with MRI scanners, or "device phone apps," may also improve patient awareness and provide rapid device information and safety instructions. [7-9]
- Limitations in the safety protocol may arise from differing preexisting hospital regulations and protocols for imaging. Additional limitations may occur based on individual patients, manufacturers, devices, and hospital cases.

Conclusions

- MRI safety and access is particularly important for patients with DBS devices due to the growing need for post-implantation patient imaging.
- Although manufactures have identified the necessary device parameters to be "MRI conditional", this process can be confusing and challenging for patients, providers, and imaging centers leading to bottlenecks in hospital imaging workflows.
- Our protocol aims to guide and coordinate imaging personnel so that more patients are able to obtain necessary imaging in a safe and efficient manner.

References