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Safety of MRI at 1.5 Tesla in Patients with Implanted Sacral Nerve Neurostimulator☆

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Abstract

Objectives: Sacral neuromodulation has become an established method to treat voiding dysfunction. Currently the use of implanted sacral nerve stimulators is becoming more popular worldwide. Magnetic resonance imaging (MRI) is an important diagnostic tool for many medical and neurological disorders. Many radiology centers do not perform MRI examinations on patients with implanted sacral nerve stimulator. The basis for this policy is that potential hazards such as motion, dislocation or torquing of the implanted pulse generator (IPG), heating of the leads, and damage to the IPG may occur, resulting in painful stimulation. In contrast, many studies conducted on MRI at 1.5 Tesla in patients with implantable devices have found the examination to be safe if the area to be imaged is out of the isocenter of the MRI scanner and other precautions are taken.

Methods: Eight MRI examinations at 1.5 Tesla were conducted in areas outside the pelvis on six patients with implanted sacral nerve stimulator (InterStim® neurostimulator; Medtronic, Inc, Minneapolis, MN, USA). Implanted pulse generators were examined before and after MRI procedures. All patients had their parameters recorded; then the IPGs were put to "nominal" status. Patients were monitored continuously during and after the procedure. After the MRI session, the site of the implanted device was examined and changes were reported. Devices were then re-programmed to their previous setup with the use of a programmer (model 7432; Medtronic, Inc). Voiding diaries were collected after MRI procedures and compared with previous records.

Results and conclusion: During the MRI session, no patient showed symptoms that required stopping the examination. There was no change in perception of the stimulation after re-programming of the implanted sacral nerve stimulator, according to patients' feedback. Devices were functioning properly, and no change in bladder functions was reported after MRI examinations. Finally, we hope that presenting these cases will encourage performance of more comprehensive studies on implanted sacral nerve stimulators on a larger patient population in the near future.

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1. Introduction

MRI is a safe, non-invasive and essential diagnostic tool [1]. Implanted sacral nerve stimulators are a new and rapidly evolving therapeutic modality for a variety of causes of bladder dysfunction [2–5]. Currently the number of patients who have bladder neurostimulator is growing rapidly. For many patients, their conditions often necessitate magnetic resonance imaging (MRI) examination. However, the current practice is to contraindicate patients with implantable devices [6,7]. Concerns regarding potential hazards for performing MRI with implantable devices include: motion, dislocation of the neurostimulator, changes to the neurostimulator program and damage to the neurostimulator components that may be caused by static or pulsed magnetic fields. Voltages and currents in neurostimulator leads induced by pulsed gradient magnetic fields and/or pulsed radio-frequency (RF) fields may result in pain stimulation. Another concern is heating in neurostimulator leads, which is due to the electromagnetic RF field and is strongly affected by the electrode configuration, the type of RF coil and the specific absorption rate (SAR) of the MR image [1,8–10]. In contrast, many studies conducted on patients who underwent MRI examinations with implantable devices showed no clinical adverse effects [11–13]. Furthermore, the work by Sommer et al. adds to the mounting support that, if highly specific guidelines are followed, MR procedures may be performed safely in patients with implantable devices [14].

2. Methods

2.1. Patients

Six patients with the implanted IPG model ITRELL III® (Medtronic, Inc, Minneapolis, MN, USA) were subjected to MRI examination and underwent a total of eight MRIs. All patients had the IPG implanted under the skin of the buttock. The electrodes were located in the right third sacral foramen in four patients and in the left third sacral foramen in the remaining two. All patients had voiding dysfunction characterized by urge frequency that was controlled by the implanted sacral nerve stimulator. The sacral nerve stimulators had been implanted for 2 to 4 years with an average of 2.5 years. All patients were followed with regular visits and had their voiding diaries recorded every 6 months during the first year post-implant and then once yearly. Five examinations were performed on the brain, while the other three were on the cervical and thoracic vertebrae for neurological reasons. The MRI tests were requested by the patients' neurologists for medical reasons. Patients were counseled regarding the risks of the MRI by their radiologists; informed consent was obtained in all patients after proper counseling regarding the procedure, complications, current recommendations of safety and the value of MRI examination. All MRI studies were performed with the use of an MR system operating at a static magnetic field strength of 1.5 Tesla (GE Signa CV/I; General Electric Medical Systems, Milwaukee, WI, USA) and running 9-x software.

2.2. MRI examinations

Implanted pulse generators were examined before and after the MRI procedure. All patients had their IPG stimulation parameters recorded; then the IPGs were set at ''nominal'' status (settings at which the devices were shipped by the company). The parameters recorded in the nominal setup were amplitude of 0 volt and output set at ''off''. Before the MRI session, patients were requested to report any sensation of heat emanating from the site of the IPG. Moreover, patients were discouraged from taking medications that might affect awareness. During the examination, continuous monitoring for symptoms of heating at the site of the device was performed through verbal contact with the patients. After the MRI session, the site of the IPG was examined and changes were reported. Patients were asked about any abnormal sensation during the MRI session. IPGs were then reprogrammed to their previous setup with the use of a programmer (model 7432; Medtronic, Inc).

2.3. Patient follow-up

Patients were given a voiding diary to fill out for 4 days. The diaries were collected after the MRI procedure and compared with previously recorded data. The voiding diaries were recorded for a minimum of 3 days and a maximum of 7 days after the MRI sessions. Each patient was requested to record the following bladder parameters: voided volume in milliliters, post-void residual urine in milliliters (if applicable), frequency of urination per 24 h, sense of urgency and episodes of urinary incontinence including the number of protective pads used per 24 h.

3. Results

3.1. Patient examinations

None of the patient reported torquing, heating sensation or any other unusual symptoms during MRI that would have required stopping the examination. The MR images were not affected by the presence of an IPG that was located away from the imaged anatomical part. There was neither a heating sensation at the site of the IPG nor dislodgment of the electrodes on the basis of patients' perceptions of the stimulation site. IPG devices showed no evidence of malfunctions as evidenced by a battery index of ''OK'', and the devices were reprogrammed according to the values used before the MRI procedures. In all patients, the

stimulation parameters recorded varied from 2 to 5 V in amplitude, 10 pulses per second in frequency and 210 μs in pulse width. No patient mentioned a change in perception of the stimulation once the IPG was reprogrammed to the pre-MRI stimulation parameters.

3.2. *Patient follow-up*

Data collected from voiding diaries 3 to 7 days after the procedure did not show any significant change in bladder parameters that could have been due to the MRI examination, as evidenced by comparing pre-MRI parameters with those in the latest voiding diaries.

4. Discussion

Magnetic resonance imaging is an essential diagnostic tool. In many instances, it has been the best available test to diagnose many medical disorders. Preventing patients from having this important tool might seriously affect our ability to establish a correct diagnosis, which in turn would affect the quality of care provided. Sacral root neuromodulation is a treatment modality approved by the United States' Food and Drug Administration (FDA) for patients with chronic voiding dysfunctions in the form of urinary urge incontinence, urgency frequency syndrome or voiding difficulty with either incomplete or complete retention [15]. Thousands of patients with bladder dysfunction have implantable bladder neurostimulators that indeed have improved their symptoms and their quality of life. Of those patients, many need MRI examinations for various clinical indications. The current policy of many radiology centers is to contraindicate MRI for patients with implantable devices including bladder neurostimulators. There are many concerns for MRI use in patients with implantable devices such as torquing, malfunction of the device and heating of the lead tip.

4.1. *Concerns associated with static magnetic field*

Owing to the attraction of a magnet, any ferromagnetic object close to the magnet will experience a magnetic pull and/or rotating torque. According to the manufacturer of InterStim® bladder neurostimulators, implanted leads and extensions should not experience magnetic field–related mechanical forces since they are made from nonmagnetic material. However, the neurostimulator contains a small amounts of ferromagnetic material; nonetheless, MRI safety testing conducted with the use of an MRI system with a static magnetic field of 1.5 Tesla, patient-equivalent phantoms and various device configurations showed that the magnetic forces acting on the Activa® neurostimulator (Medtronic, Inc; Activa® is similar in structure to the InterStim® neurostimulator) were less than the force of gravity [10,16].

4.2. *Concerns associated with malfunction of the device attributable to exposure to the electromagnetic fields of an MR system*

Exposure to a high magnetic field potentially could cause pain or discomfort to the patient or damage to the nerve fibers at the site of the implanted electrodes. Several studies conducted on pacemakers, implantable cardioverter defibrillators, and neurostimulators have not shown major malfunctions, while others reported some malfunctions after MRI examinations [11,18].

4.3. *Concerns associated with heating of the electrodes*

Achenbach et al. reported that a temperature increase occurred at the tip of the pacing electrode [7]. However, Rezai et al. reported that temperature elevations at the distal end of a deep brain stimulation electrode of 25.3 °C occurred after 15 min of MRI and noted that the use of clinically relevant positioning techniques for the neurostimulation system and MR parameters used for imaging the brain generated little heating [18]. Furthermore, Martin et al. reported in 2004 that they found no evidence that increases in SAR increase the likelihood that the pacemaker lead would heat and cause subsequent threshold changes [12]. In the case of sacral nerve neurostimulators, a variety of symptoms could develop if the leads are heated (eg, urgency with pelvic pain, urinary frequency, incontinence for stool or urine and possibly sexual dysfunction in both women and men).

Specific absorption rate, defined as the amount of RF power absorbed per unit of mass of an object (indicated in W/kg), has been used by many investigators as an indirect measure of RF energy to predict the temperature change in implantable devices and, perhaps, to report safety recommendations [17,19]. Baker et al. recently reported that SAR, as recorded at an implantable conductive device, was profoundly different between two different generation 1.5-Tesla MR systems (ie, a specific scanner hardware running a specific software version) from the same manufacturer. They concluded that SAR estimates are not reliable as a methodology of determining power delivery across MR system types [20].

In deep brain neurostimulators, reports have shown a reasonable possibility for heating attributable to excessive MRI–related heating of brain neurostimulators. Recently, Rezai et al. [18] conducted a study in which some clinical scenarios were simulated to perform MR procedures at 1.5 Tesla on gel-filled phantoms. They found that temperature increased under certain conditions; moreover, factors that affected temperature increase included location of the neurostimulator, the RF coil and the SAR used during the MR examination. Finally, the authors stated that heating is not a major concern as long as the guidelines are conducted strictly. In a separate study, Finelli et al. reported a similar conclusion [21]. Experience from pacemakers has showed that more than 200 patients with a cardiac pacemaker have undergone MR procedures safely [22].

Another safety concern for patients with implantable devices is the anatomical part of the body to be scanned. In 2001, Luechinger et al. showed that torque in pacemakers during brain imaging is very minimal; moreover, it has been suggested that, if patients are positioned so that the implantable device does not enter the magnet bore, no significant interaction occurs [11]. Furthermore, Sommer et al. have showed a significant decrease in temperature in leads of the pacemaker when the center of the region to be imaged was located 30 cm or farther from the center of the lead loop [14].

Voiding diaries have been used as an instrumental tool for capturing the voiding function in a quantitative manner. All patients with the InterStim® system have to record their voiding pattern in the diaries once every 6 months for the first year after the implant of the device and yearly thereafter. In the current study, voiding diaries recorded after the MRI session were compared with the latest diary recorded. Minimal migration of the stimulating electrode lead would have been noticed in the patients' perception of the site of stimulation. Such changes would be depicted in the voiding parameters recorded in the voiding diaries. None of the patients in the current study has shown significant changes in their voiding parameters. This finding denotes that there was neither mechanical torque nor displacement of the electrode lead.

Recent studies have demonstrated that implanted neurostimulators and other similar devices may be present in patients who have MRI procedures, as long as specific precautions are followed [17,23,24]. Very recently, however, the FDA issued a public health notification titled *MRI-Caused Injuries in Patients with Implanted Neurological Stimulator*, which provides sources for the most current recommendations, how to report an adverse effect, and ways to obtain more information [25]. In addition, Medtronic, Inc, currently is in the process of finalizing a revision for their safety guidelines regarding MRI examinations in patients with implanted bladder neurostimulator. Their current official statement, however, advises against performing MRI examinations in the abovementioned patients.

5. Limitations

The analysis included only a limited number of patients because of the current recommendations against performing MRI examinations for patients with implantable devices. Technical details such as SAR values and the position of the stimulator leads in relation to the RF antennae were not available for those examinations because the examinations were done for medical necessity and those values were not recorded in patients' files. The possibility of adverse effects occurring during MRI examinations could not be ruled out completely because of the subjective nature of the evaluating process; nevertheless, long-term follow-up for those patients has shown clearly that no significant difference in outcome for those patients occurred that could be attributed to an adverse effect during their MRI examinations.

6. Conclusion

Finally, we are aware of the controversial nature of this issue, as well as the fact that the inability to illicit an adverse effect does not mean necessarily that it is not present. We, however, wish that presenting those cases will encourage performance of more comprehensive studies on implanted sacral nerve stimulators in the near future and that clear safety guidelines will be established.

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Editorial Comment

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This article deals with an important clinical issue with potential severe medical and legal complications. Sacral nerve stimulation treats functional disorders that might originate from masked, underlying neurogenic disease. It is important that urologists learn to focus on symptoms and signs of neurogenic diseases. All urologists implanting these devices will encounter situations in which magnetic resonance (MRI) is mandatory. It is reassuring that this report shows MRI in an implanted patient is feasible as no other literature is available. The authors cite a 2002 article by Rezai et al. on heating of leads by MRI, which concluded with safety guidelines [1], but, in 2005, this same author reports that a severe neurogenic deficit (radiofrequency lesion) occurred after lumbar spine MRI in a patient with deep brain stimulation [2]. Although we stimulate another region of the body, we have to weigh each decision to perform MRI in an implanted patient.

We recently performed a ''1992–2005 Maude'' research on cited complications after MRI in patients with an implanted pulse generator [3]. We found 64 reports on MRI in patients with a pulse generator, 30 reports on complications of MRI and pulse generators and 7 cases of epilepsies occurring after setting the pulse generator at ''off''. There were 23 reports on device malfunctions of the pulse generator ($n = 21$) or the lead ($n = 2$). In 3 cases it was specified that the pulse generator was set at ''off'' and in 1 case it was left at ''on''. None of the ''Maude reports'' or the literature reports discussed sacral nerve stimulation.

In conclusion, even if this article is reassuring, we have to weigh the decision of performing an MRI in an implanted patient and set the pulse generator at ''off'' before each MRI.

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