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Magnetic Resonance Safety

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Abstract

Magnetic Resonance Imaging (MRI) has a superior soft-tissue contrast compared to other radiological imaging modalities and its physiological and functional applications have led to a significant increase in MRI scans worldwide. A comprehensive MRI safety training to protect patients and other healthcare workers from potential bio-effects and risks of the magnetic fields in an MRI suite is therefore essential. The knowledge of the purpose of safety zones in an MRI suite as well as MRI appropriateness criteria is important for all healthcare professionals who will work in the MRI environment or refer patients for MRI scans.

The purpose of this article is to give an overview of current magnetic resonance safety guidelines and discuss the safety risks of magnetic fields in an MRI suite including forces and torque of ferromagnetic objects, tissue heating, peripheral nerve stimulation and hearing damages. MRI safety and compatibility of implanted devices, MRI scans during pregnancy and the potential risks of MRI contrast agents will also be discussed and a comprehensive MRI safety training to avoid fatal accidents in an MRI suite will be presented.

Keywords: Magnetic Resonance Imaging (MRI), Safety, Magnetic Fields, Implants, Pregnancy, Contrast Agents

Introduction

The increasing clinical demand for Magnetic Resonance Imaging (MRI) with its superior soft-tissue contrast compared to other radiological imaging modalities and potential physiological and functional applications has contributed to the installation of almost 30,000 MRI scanners worldwide. Therefore, more and more healthcare professionals need to be trained in MRI safety to protect patients and other healthcare workers from the potential risks of MRI [1,2]. It is also important that radiologists, referring physicians and MR technologists are able to evaluate MRI safety and compatibility of medical devices and implants because they are often the first health care professionals who will talk to a patient about an MRI exam, potential risks, and MRI safety [3].

Radiologists are well trained about MRI appropriateness criteria but they require support from referring physicians to estimate the risks and benefits of MR imaging procedures [4]. Especially referring physicians who know details of a patient's medical history can improve the MRI safety screening process when they are aware of the risks of an MRI scan by pre-screening their patients before an MRI exam [5]. This is particularly important in high-risk patients and in patients with new implants that have not yet been tested for MRI compatibility [6,7].

An expert panel has developed the American College of Radiology (ACR) Guidance Document for Safe MR practices [8]. The following sections will review potential bio-effects and risks of the magnetic fields that interact with patients and health care professionals in an MRI suite [9].

Magnetic Fields in an MRI suite

There are three major magnetic fields in an MRI suite that that have potential safety risks [10–14]:

1. The static magnetic field B_0 of clinical MRI scanners that ranges from 0.2T to 3T [15–17]. B_0 is orders of magnitudes larger than the magnetic field of the earth and can torque, attract and accelerate ferromagnetic objects in direction of the opening of the bore of an MRI scanner. B_0 can also interfere with implanted devices such as pumps and pace makers [18–26,1,27,28,2,29,30,15,31,12,16,32–47,7,48–62,11,63–73].
2. The radiofrequency (RF) field B_1 that is in the order of μT [74,30] and is produced by RF-coils. It can potentially cause tissue heating, especially when implants are present [19,75–89,16,90–100,4,101–103,10,104–116,69,117].
3. The magnetic field gradients with amplitudes in the order of 100 mT/m and with slew rates up to 200 mT/m/ms [63,118]. The fast switching gradient fields are applied for spatial encoding of the MRI signal and can cause peripheral nerve stimulation and

implant heating. They are also responsible for the noise in the MRI scanner room, which can reach levels of 100 dB or more and potentially lead to hearing damages [74,119–121,118,122–126,30,31,127,128,16,90,129,37,130–133,57,58,134,135,69].

MRI Zones

In the ACR guidance document on MR safe practices from 2013 four different zones are suggested around the MRI scanner [136,137]. The access to these zones is restricted in MRI facilities and hospitals and the boundary of each zone in this four-zone safety system is defined by its purpose and distance from the MRI scanner [30]. Some zones may extend into other areas or floors of the facility due to the three dimensional extend of the magnetic field [138].

Zone I includes all areas freely accessible to the general public where the magnet field poses no hazards, such as the entrance to the MR facility.
Zone II is located between Zone I and the more restrictive Zone III. In Zone II patients are under general supervision of MR personnel. Zone II often includes the reception area, dressing rooms and MRI screening rooms.
Zone III is access-restricted by physical barriers such as doors with coded access. Inside Zone III, only approved MR personnel and patients that have undergone MRI screening are allowed. The MR control room is in Zone III.
Zone IV is the room where the magnet is located. Access to Zone IV should only be possible by passing through Zone III. Zone IV is designed so that the walls of magnet room contain the five 0.5 mT line (or 5 Gauss) line of the fringe field of the magnet.

The 5 Gauss line of an MRI suite defines a border to an area in which the magnetic field could affect implanted devices such as pacemakers [7]. Special warning signs about the strong magnetic field and its associated hazards need to be set up in the MRI facility. An MR safety program should be established to train employees about the dangers of the magnetic fields in the MRI suite [139] and to warn about potential interferences of the magnetic fringe field with implanted devices [140].

Attractive forces and torque on ferromagnetic objects by the static magnetic field B_0

The static magnetic field B_0 of an MRI machine attracts ferromagnetic objects and accelerates them toward the center of the bore of the MRI scanner. Ferromagnetic objects such as coins, hairpins, steel oxygen tanks or scissors can be accelerated or torqued by B_0 [4,10] and become dangerous projectiles [51]. The MRI safety program of the facility needs to warn about the misconception that larger objects will resist attraction to the field and need to emphasize the relationship between object size, material components, and projectile risk. Insufficient MRI safety training of ancillary medical personnel has led to fatal accidents when medical and other equipment was accelerated into the bore of the magnet [50,51].

Thermal effects induced by the radiofrequency field B_1

Physicians and MRI technologists need to be aware of the bio-effects of radiofrequency fields [99] because RF-fields can cause tissue heating in the human body [100,105]. The specific absorption rate (SAR) is a measure of the RF-power absorbed per mass of tissue and has the units of watts per kilogram (W/kg) [75]. The absorbed RF-energy is transformed into heat in the human body [141,110] and especially infants, children and patients with thermo-regulatory disorders might experience an increase in the body core temperature due to RF-induced heating during an MRI exam [76,141,114,142].

A proper preparation of each patient before an MRI exam is necessary to avoid burns even for patients without implants. The Guidelines to Prevent Excessive Heating and Burns Associated with Magnetic Resonance Procedures [143] recommend to

1. remove metallic objects contacting the patient's skin (e.g., jewelry, drug delivery patches with metallic components),
2. use insulation material of 1 cm or thicker to prevent skin-to-skin contact and the formation of closed-loops from touching body parts,
3. allow only devices, equipment, accessories (e.g., ECG leads, electrodes), and materials that have been thoroughly tested and determined to be MRI safe [6,144,7].

Peripheral nerve stimulation and hearing damage caused by the gradient system

The time-varying fast-switching gradient magnetic fields may stimulate nerves or muscles in patients by inducing electrical fields [121]. There are multiple factors influencing the interactions of gradient fields with biological tissues and they depend on the frequency of the gradient field, the maximum and average flux densities, the presence of harmonic frequencies, the waveform characteristics of the signal, the polarity of the signal, the current distribution in the body, the electrical properties, and the sensitivity of the cell membrane [119–121,118,126,31,128,37,131,133,63,134]. The acoustic noise during an MRI exam is also caused by the gradient system [121,118]. Head phones and earplugs are essential hearing protections for patients during and anybody present during an MRI examination [37].

MRI screening procedures

MRI screening before any MRI exam is indispensible and evaluates the magnetic and geometric properties of implants or foreign bodies, and their potential interactions with the magnetic fields in an MRI system [16,145,51,4,10,146,147]. Before anybody is allowed to enter the MRI suite, it is essential to remove all objects that could potentially interact with the magnetic fields [50,51,58,11]. It is recommended that patients will wear gowns in the MRI environment to avoid metallic fasteners, loose metallic components, or metallic threads on clothing in the MRI suite [148].

Implanted Devices

It is essential for any referring physician, radiologist or MR technologist to know where to find details about the MRI safety and compatibility of medical implants and devices [7,6,144]. Frank Shellock, Ph.D. and his team work on MRI safety and have published several books and a searchable on-line catalog that lists MRI-safe devices and MRI-safe implants with their allowed magnetic field strengths and gradient limitations (http://www.mrisafety.com/TheList_search.asp) [100,4,101–103,58,10,104,59,105,60,106,107]. When a patient with implants is scheduled for an MRI exam it is vital to understand that the injury risk increases with the proximity of the implants to vital vascular, neural or soft tissue structures [58]. Implants, medical materials, and devices from the US and Europe that were manufactured in last three decades are made from non-ferromagnetic materials and are usually labeled *MR safe* or *MR conditional* [100]. Other implants or devices have to be considered *MR unsafe* and are contraindicated for an MRI scan. Interactions of these objects with the magnetic fields can cause severe artifacts and heating [7]. Even non-ferromagnetic implants can cause heating due to eddy currents that propagate in metals exposed to oscillating magnetic fields [102,103]. Especially orthopedic implants such as external fixation systems can cause heating in an MRI scanner [6,144,7,145,149,4,103,10,107] and some of the new implants or devices have not been tested or labeled for MRI compatibility [150]. It is therefore essential to establish a close collaboration between the radiology team, the ordering physician, and the physician who placed the implant [13].

MRI during Pregnancy

The practice guidelines collaboratively developed by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) recommends no special consideration for any trimester in pregnancy [151] since there is no evidence in the current literature for deleterious effects of MR imaging at 1.5 T on the developing fetus [152–154]. The risk to benefit ratio to perform an MR scan on a pregnant patient needs to be evaluated by a level 2 MR personnel-designated attending radiologist [139,151]. The radiologist should discuss and agree with the referring physician to perform the magnetic resonance imaging exam. Patients can then undergo an MRI scan in any stage of the pregnancy and the following statements should be added to the radiology report or to the patients' medical record [151]:

1. The information requested from the MRI study cannot be acquired by ultrasonography.
2. The data are needed to potentially affect the care of the patient or fetus during the pregnancy.
3. The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.

The ACR Manual on Contrast Media recommends that each case should be reviewed carefully by members of the clinical and radiology team and gadolinium based contrast agents should be administered only when there is a potential significant benefit to the patient or fetus that outweighs the possible but unknown risk of fetal exposure to free gadolinium ions [136]. Gadolinium based contrast agents are consequently classified as pregnancy class C drugs because potential benefits may warrant the use in pregnant women despite potential risks [8,155].

MR Contrast Agents

FDA approved MRI contrast agents are gadolinium chelates with different stability, viscosity, and osmolality [156].

Radiologists and MRI technologists should be aware of adverse effects of gadolinium based contrast agents. Gadolinium chelates are in general well tolerated and acute adverse reactions are observed with a lower frequency than after the administration of iodinated contrast media [157]. The reported frequencies of all acute adverse events after an injection of 0.1 or 0.2 mmol/kg of gadolinium chelate range from 0.07% to 2.4% [156,158]. Coldness at the injection site, nausea with or without vomiting, headache, warmth or pain at the injection site, paresthesias, dizziness, and itching are potential adverse effects after the administration of gadolinium chelates [159,160,157,161–167,158,156,168–170]. Severe allergic reactions including rash hives, urticaria and bronchospasm range from 0.004% to 0.7% [160,161]. Severe, life-threatening anaphylactoid or nonallergic anaphylactic reactions are exceedingly rare with frequencies between 0.001% and 0.01% [160,162,164,168]. In an accumulated series of 687,000 doses there were only 5 severe reactions and fatal reactions to gadolinium chelate are extremely rare [156,160,157,161].

Nevertheless, it is important to know that Gadolinium chelates administered to patients with acute renal failure or severe chronic kidney disease can result in a syndrome of nephrogenic systemic fibrosis (NSF) [159]. There are no reports of NSF in patients with normal kidney function, therefore, the U.S. Food and Drug Administration (FDA) requires that manufacturers include a boxed warning on the product labeling of all gadolinium-based contrast agents that patients with severe kidney insufficiency who receive gadolinium-based agents are at risk for developing NSF [157,160].

Claustrophobia during MRI exams

Patients can become claustrophobic during an MRI scan and refuse to complete the exam especially when they are not well informed about the procedure [171,172]. Larger bore sizes and Open MRI systems can help to reduce claustrophobia [173,174]. Referring physicians can help to reduce claustrophobia by discussing the details of the MRI procedure with the patients before their exam [175,176].

Sedation and Anesthesia for MRI exams

Non-compliant patients such as children or claustrophobic adults may require sedation or anesthesia during an MRI exam because MRI scans often require long scan times and are sensitive to motion [177]. Patients with pain can benefit from pain management to help them to remain motionless during the MRI exam. An MRI safety program should emphasize specific risks and benefits of sedation, anesthesia, and pain management in these patients [178].

MRI Safety Training and Emergency Procedures in an MRI Suite

All personnel working in the MR environment need to be trained with a comprehensive MRI safety course [13]. For new employees who will work in the MR environment this course should be included in the employee orientation program and be repeated annually. The MRI safety training should include the presentation of technical and medical background of MRI safety. Hands-on demonstrations of missile effects of ferromagnetic objects can help to better understand and experience the dangers in an MRI suite [9,13]. Detailed screening procedures of patients with a questionnaire for ferromagnetic objects, implants, devices, body piercing, allergies to MRI contrast agents, kidney disease, pregnancy, breast feeding and also the screening of patients that have a history injuries by a metallic foreign body such as bullets, shrapnel, or other type of metallic fragments help to avoid severe accidents in an MRI suite. An important topic to discuss in an MRI safety course are severe burn wounds that were experienced by patients when limbs or other body parts of the patients were in direct contact with transmit RF coils of the MR systems or when skin-to-skin contact points were responsible for these injuries. The safety course needs to warn about high acoustic noise levels of the gradient system during an MRI scan and the potential noise reduction with earplugs and headphones to avoid potential hearing damage. Videos from quenching magnets can help to understand how powerful a sudden loss of the superconductivity of the magnet might be and emergency procedures during a quench should be discussed. It is important that medical personal entering the MRI scanner room to evaluate the patient, administer medications or interventions need to be trained in emergency procedures in an MRI suite [140]. Healthcare professionals need to know which objects can be brought into the different MRI zones in order to prevent fatal injuries and medical equipment failure and how to remove a patient from the MRI magnet room to resuscitate or treat the patient in emergency cases [145].

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