

MRI Safety at 3T versus 1.5T

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Abstract

The purpose of this article is to educate medical professionals on the safety concerns that arise when a healthcare organization converts from a 1.5 Tesla MRI scanner to a 3 Tesla MRI scanner. This article explains the differences between the two systems and the safety concerns associated. One of the obstacles that an MRI Technologist endures is that some implanted materials that have been considered safe for many years are now contraindicated on a 3T system. At a minimum the standard has changed. I will provide examples of why safety awareness needs to heighten in this environment. The findings show that even though there are new challenges associated with medical advancement in stronger magnetic field scanners, most patients can still be scanned safely in these environments. There are safety texts and online references that provide up to date information about almost every implant and the level at which that implant is considered safe, which helps to alleviate some of the associated stress healthcare professionals face every day in an MRI environment.

Introduction

Patients that could once be scanned safely in a 1.5Tesla (T) MRI scanner are now facing more rigorous screening when attempting to be scanned at medical centers that have traded in their 1.5T system for a newer 3T scanner in an attempt to achieve higher quality imaging quicker than ever before. Some facilities have replaced existing 1.5T scanners to be abreast of the new technology not realizing some revenue may be lost due to the safety differences associated with the two systems. With stricter safety guidelines work flow is hindered which in turn makes a facility less productive. One of the challenges is that the MRI safety committee has only tested a limited number of the foreign bodies a patient could potentially have. Frank G. Sherlock, Ph.D. provides the only comprehensive database that includes objects tested relative to the MRI environment. Over 1,800 objects have been tested and more than 600 have been

tested at 3Tesla. As a result, a large number of implants such as some stents that were at one time considered safe for 1.5 T have not all been cleared for the 3T systems. A high percentage of patients have some type of implant, therefore, the transition for the MRI Technologists is challenging, when all the safety rules that the MRI users have been so accustomed to suddenly change with a new system install. Implants are not the only safety concerns with a higher field system; the FDA restricts the amount of heat that can be induced in a given human tissue. The accepted levels are reached more quickly in 3T scanning, which results in longer scan times to enable the tissue enough time to cool to an allowable level. The supporting equipment for the MRI suite has to be MRI compatible in order to function properly inside the scan room, which is also more expensive. MRI equipment can range from special monitors, intravenous pumps, pressure injectors, and ventilators. Most equipment was designed as 1.5T compatible. When transitioning to a higher field system, sites are finding that new equipment, more rigorous site planning, and more stringent safety measure are in order to support the new innovation in a safe manner.

Literature Review

Magnetic resonance imaging began to make an impact in the clinical practice in the mid 1970's. The most common MRI scanners operated at field strengths of 0.6 T (Tesla). Eventually, advances made high field MRI feasible and systems operating at 1.5 T have become the clinical standard (Tanenbaum 2005). Five years ago 3T systems were for advanced research only and today they are appearing in both hospitals and outpatient facilities throughout the country. When you combine the growth in MRI scanners and increase in magnet strength, the risk factors multiply in the MRI environment. Another consideration Emanuel Kanal MD (Founding Member, Board Member, Officer, and/or Member of numerous national and international professional societies, and serves as a consultant to the FDA on MRI safety issues) says is the number of new practitioners in the MRI environment. The volume of examinations has increased and many exams are being performed by practitioners that are new to the modality. "While we always have had safety guidelines, the increased numbers of MRI practitioners and the increased number of patients involved in these procedures all increase the likelihood of mishaps occurring in the MRI environment" says Kanal (Harvey 2004). Market data late in 2004 indicated that 3T systems made up 25% of new high field MRI scanner purchases. The higher quality images and faster scan times made available with the higher field MRI scanners is so significant that most if not all imaging facilities will make the change soon if it not in the near future. The shift in interest from 1.5T to 3T as a research device to clinical practice validates what was once considered very high field MRI is now practical and potentially superior to 1.5T for clinical indications throughout the body (Tanenbaum 2005).

The clinical use of 3 Tesla MRI systems for brain, musculoskeletal, body, cardiovascular, and other applications is increasing worldwide. Because previous investigations performed to determine MRI safety for implants and devices used mostly MRI systems with static magnetic fields of 1.5 Tesla or less, it is crucial to perform ex vivo testing at 3 Tesla to characterize MRI safety for these objects, especially with

regard to magnetic field interactions. Importantly, a metallic object that displayed “weakly” ferromagnetic qualities in association with a 1.5 Tesla MRI system may exhibit substantial magnetic field interactions during exposure to a 3 Tesla MRI system (Shellock 2008).

With the increasing advent and use of 3.0 Tesla and higher strength magnets, users need to recognize that one should never assume MRI system compatibility or safety information about a device if it is not clearly documented in writing. Decisions based on published MRI safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields (Barkovich, Bell, & Kanal 2007).

Magnetic field strengths are measured in units of gauss (G) and Tesla (T). One Tesla is equal to 10,000 gauss. The main magnetic field of a 1.5 T magnet is about 30,000 times the strength of the earth's magnetic field. The main magnetic field of a 3T system is 60,000 times the earth's magnet field. The strength of electromagnets used to pick up cars in junk yards is about the field strength of MRI systems with field strengths from 1.5-2.0T. It is strong enough to pull fork-lift tines off of machinery, pull heavy-duty floor buffers and mop buckets into the bore of the magnet, pull stretchers across the room and turn oxygen bottles into flying projectiles reaching speeds in excess of 40 miles per hour. Deaths have occurred from trauma as a result of these effects. Smaller objects such as pagers, bobby pins and pens have been known to be pulled off the person carrying them (Woodward 2001). The 3T field is twice the strength of the 1.5T field and many practitioners do not take this into account when they are performing scans and procedures. When magnetic forces reach this high of a level it is difficult to determine at what point an object will become a hazardous or deadly projectile (Harvey 2004). In order to help reduce the risks of projectile accidents, ferrous objects and devices are typically prohibited in proximity to the MRI scanner, with non-ferromagnetic versions of many tools and devices typically retained by the scanning facility. Patients undergoing MRI examinations are required to remove all metallic objects, often by changing into a gown or scrubs.

Despite the fact that the 3T system looks identical to the 1.5 the similarity does not mean equal site considerations. Frequent injuries in the MRI suite and equipment damage are caused by the introduction of magnetic metals into the magnet room. The active shielding on most new 3T systems does a great job of restraining the magnetic field. The FDA 5 gauss exclusion zone can still be sited completely within the moderate size magnet room, despite the doubling of the power. On the down side, even though the exclusion zone can often be contained the fringing field for these magnets spills farther than that of the 1.5 system. The extended fringe field may interfere with nearby CT, PET, and other imaging equipment that was not affected by the half powered unit. If the active shielding were to fail even for a short period of time and the primary magnet remained, the magnetic field will suddenly bloom to several times its normal size. The increased size of the bloom field could have life-threatening consequences compared to

a 1.5T system (Gilk 2005). Active shielding is excellent; however it increases the rate at which the field strength increases as you approach the magnet. In a 1.5 scanner one might be able to take a wheelchair closer to the scanner with a steady gradual pull. In a 3T scanning environment a slight pull may turn into suddenly ripping the chair from your hands and slamming it down the bore of the magnet (Gilk 2005).

The potential benefits of MRI are abundant, however there are dangers in the environment that must be acknowledged and respected. The invisible force associated with these systems can be extremely dangerous if proper precautions and facility planning is not taken. These hazards may be attributed to one or more combinations of the three components that make up the MRI environment. Strong static magnetic fields including its associated spatial gradient, pulsed gradient magnetic fields and pulsed radio frequency (RF) fields are potential hazards when patients and medical devices are placed within the MRI environment (FDA 1997).

The gradient magnetic field is responsible for the ambient noise associated with MRI. The International Electrotechnical Commission (IEC) and the U.S. Food and Drug Administration limit permissible sound levels to 99 dBA (FDA 1997). The field strength and the length of the magnet bore are factors that influence sound pressure levels. The noise associated with the gradient fields increase with field strength. The noise level in a 3T system approaches twice that of the 1.5T system and can be in excess of 130 dBA. Higher gradient performance at 3T scanning also causes higher sound pressure levels. In addition, the new shorter bore systems sold today are louder than the older long bore systems (Tanenbaum 2005). The use of some type of compatible hearing protection such as ear plugs or headphones, should not only be made available to patients, it should be required.

The pulsed Radiofrequency fields can induce current resulting in heating of the body, which in turn can cause patient burns. Specific absorption rate (SAR) is a measure of energy deposited by an RF field in a given mass of tissue. SAR is established by the international Electrotechnical Commission (IEC) and the Food and Drug Administration to not exceed 8 watts per kg (W/kg) of tissue for any 5 minute period or 4 W/kg for a whole body averaged over 15 minutes. The doubling of the field strength from 1.5T to 3T leads to a quadrupling of the SAR, hindering scanner performance (Tanenbaum 2005). Unregulated absorption can lead to injury. "The heating potential is notably higher and more significant at higher field strengths than at lower fields," says Kanal. "If anything, one would be even more concerned about heating at higher fields than at lower fields" (Harvey 2004).

The Static magnetic field is a component of the MRI environment which is always present even when the scanner is not imaging. This static magnetic field is typically between .2 and 2Tesla (5,000 to 20,000 gauss) measured in the center of the magnet bore. This strong magnetic field strength drops off rapidly with distance away from the magnet, producing a large spatial gradient. As a result of the large gradient, ferrous objects introduced into the field are accelerated and can quickly become dangerous projectiles. Dislodgment or malfunctions of the implanted device, tearing of tissues, and

acceleration of the object into the bore of the magnet, are all safety concerns associated with a high static magnetic field (Woodward 2001).

When using radio frequency coils, monitors, electronic devices, or any object that is a conductive material, injury can occur to the patient, such as tissue heating and burns, but this tends to be problematic primarily for objects made from conductive material that have elongated shapes such as leads, guide wires, and certain types of catheters. Because, excessive heating and burns have occurred in association with implants and devices that have an elongated configuration or that form conducting loops, patients with these objects should not undergo an MRI procedure at 3T until ex-vivo heating assessments are performed to determine the relative risks (Shellock 2008). A child received a burn to the right hand from an ECG cable, the child was anesthetized during the procedure, and a skin graft was required to treat the affected area. A patient received a 1.5"X 4" blistered burn to the left side of the back near the pelvis from an ECG gating cable. A similar burn occurred to a patient from a pulse oximeter that was left attached during a MRI procedure which also required a skin graft (FDA 1997).

MRI associated accidents, many life threatening or fatal, are still occurring and this has caused concern in the radiology community. In order to reduce the risk, the American College of Radiology has issued an updated version of the 2004 White paper on MR safety called ACR Guidance Document for Safe MR Practice 2007. This document covers every aspect of MRI safety, from the design of the MRI suite to the qualifications of the personnel screening patients and what to do in the case of an emergency. There are many issues that can impact MRI safety that should be considered during site planning for a given MRI installation. These have historically not been dealt with in the prior versions of the ACR MRI Safe Practice Guidelines. For the first time, they are included in this article, as separate appendices, sections that address such issues as well, including cryogen emergency vent locations and pathways, 5-gauss lines, siting considerations, patient access pathways, etc. (Barkovich et al. 2007). Personnel who work in or near a magnetic resonance imaging facility should read and practice under the guidance of this document; it also contains information that may be useful for non-radiology personnel. Nursing staff typically prepare in house hospital patients for MRI procedures; this document provides information on how to manage some the potential risks such as aneurysm clips, pacemakers, dermal drug delivery patches and gadolinium-based contrast agents.

The most considerable safety concern in the MRI environment is the effect of the magnetic field on medical devices and implants. Just as some equipment is not transferrable from 1.5T to 3T, some medical devices that are safe at 1.5T are not safe at 3T. Problems presented by 3T systems for metallic implants include translational attraction and torque. Translational attraction is what has been referred to as the projectile effect, when an object moves towards the magnet at a high rate of speed. Torque, as it relates to MRI is the shifting or twisting of the medical device or implant inside the patient's body. The movement is caused by the static magnetic field and can cause discomfort, injury or death if the implant is displaced (Harvey 2004).

In 2003, a New Mexico woman sued a Los Alamos hospital, claiming the magnetic pull of an MRI scanner caused an oxygen tank to hit her in the back. In 2001, Michael Colombini, 6, was killed while undergoing an MRI when an oxygen tank flew out of the hands of an anesthesiologist toward the machine, hitting him in the head. In 1992, a 74-year-old woman hemorrhaged and died after an aneurysm clip in her brain shifted while she was on a table preparing for an MRI procedure. Dr. Emanuel Kanal, who helped write the MRI safety guidelines for the American College of Radiology, says dozens of similar accidents occur each year due to "pilot error." "It's my opinion that the majority of the incidents that have occurred have been as a result to what I referred to as pilot error or how the procedure was performed," Kanal said. "I believe there is a strong "it couldn't happen here" mentality. I don't believe people are quite aware of the potential problems that can occur or the substantial severity that could occur." (ABC News 2005). There was an incident reported to the FDA of a patient receiving blistered burns to the left thumb and left thigh that was touching the side of the bore, the incident occurred because the MRI operator input an inaccurate patient weight resulting in an incorrect SAR value (FDA 1997).

There are safety protocols and procedures in place at virtually every MRI facility including hospitals and out-patient centers. The screening of patients should and usually does begin with a phone call interview before he or she arrives at the imaging center. Patients are then screened by the MRI facility employees before entering the MRI environment and are asked to remove all loose objects by a qualified healthcare professional; however patients somehow still manage to reach the entrance to the MRI scan room with metallic objects on their person. A study was performed to test a new ferromagnetic detector. The test population consisted of non-selected, ambulatory, outpatients and inpatients who were instructed to remove all loose metallic objects prior to MR imaging. Some of the subjects chose to wear their clothes while others wore hospital gowns. Testing was done using the FerrAlert™ (Kopp Development, Florida) ferromagnetic detector which was calibrated to sound an alarm when it detected an object the size of a 2 cm x 1 mm ferromagnetic safety pin. Data from 228 patients was reported. 44.30% (101/228) patients were detected to have some type of ferromagnetic object(s). Of these, 8 patients had surgical prosthesis as the cause for the alarm. In 92 patients, the ferromagnetic foreign body was identified, removed, and the patients were rescreened. In one patient, the system failed to detect a metallic safety clothing pin during rescreening which was found as an artifact on the study. The cause of the alarm was not identified in one patient. 55.7% (127/228) patients had no ferromagnetic materials detected and had uneventful studies (Thomas & Kanal 2005).

As an adjunct to conventional screening practices used for identifying potential missile threats, MRI safety experts are now recommending the use of ferromagnetic-only detectors specifically developed for use in MRI facilities. These devices identify only ferromagnetic objects that can be attracted to MRI machines and, unlike conventional metal detectors, do not alarm on aluminum, titanium, brass or other metals that are not magnetically attracted (Joint Commission 2007).

The Joint Commission has released an alert that MRI accidents are on the rise. Joint commission is persuading hospitals to take a look at their processes that are in place to prevent such accidents. There have been close to 400 MRI accidents reported to the FDA, the majority of the accidents were from burns, only 10% were from the missile effect category. The increase in accidents is due to many factors and an increase in field strength in newer magnets is one of them. Heating accidents can be a result of improper positioning or incorrect setting on the particular scanner. Implants such as pacemakers and aneurysm clips can be unsafe when exposed to a time varying magnetic field. Lack of educational material on the major differences between the 1.5 T MRI systems and the 3T MRI systems is also a problem with staff not treating the newer machines more cautiously. Metal objects can and do become airborne when brought into a MRI scan room (Joint Commission 2008). Unfortunately, MRI accidents do occur regularly, though the vast majorities go unreported. The concealment of these accidents serves to reinforce an artificial sense of security within the industry. "Hopefully, it won't take another death for hospitals and imaging centers to warmly embrace the ACR 4 zone principles, because if there is another high profile accident, MRI may feel the bridle of state imposed regulation for the first time" (Gilk 2005).

Conclusion

As with any advance in technology, caution must be taken into account. All of the unknowns with any new innovation should be explored thoroughly. For the new 3T MRI system users, as well as the existing 1.5T users, the take home message is that those who regularly work with these high field magnets need to be vigilant with the MRI safety protocols. This is especially the case when healthcare personnel are directly responsible for the safety of outside persons entering the magnetic environment. As a result of some mishaps with magnetic objects being inadvertently or unknowingly taken into the magnet room, more strict safety measures should be taken into consideration. Automatic locking doors with badge access, ferromagnetic metal detectors, and professional education are some steps that can be taken to decrease MRI accidents. Proper resources and professional discipline to never assume safety of an object in the MRI suite is crucial. When the question arises whether to install a 3T MRI system in the place of a lower field system, each department will have to consider whether the desire for a higher-field scanner is worth the necessary adjustments required to successfully upgrade.

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