Safety Considerations in Interventional MR

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INTRODUCTION

MR imaging is an exceptionally powerful and safe imaging modality. In contrast to many of its radiological counterparts, the modality does not expose the patient or the operator to ionizing radiation and therefore avoids the principle safety concern in x-ray based imaging systems. The MR environment, however, is complex and contains aspects that pose substantial, but largely avoidable, safety hazards. Most notably, MR systems are always "on" in the sense that safety hazards exist even when the system is inactive. This is in contrast to virtually all other radiological systems and represents a substantial educational challenge for patients and personnel who work in and around MR suites.

In this lecture we address the many facets of MR safety and pay particular attention to the implications for interventional procedures. Many of the safety concerns related to MR imaging are heightened in the interventional setting as a result of the additional equipment and personnel that enter the MR environment. Thus, particular attention needs to be paid to suite layout and access, personnel training and screening, and equipment safety testing and labeling. The fundamental basis for safety concerns in MR imaging will initially be reviewed, followed by a summary of safety protocols that are commonly employed to minimize risk in interventional MR settings.

SAFETY CONCERNS OF MR SYSTEMS

Safety concerns arise from each of the three major sub-components of MR systems: (1) the static magnetic field (B_0) (2) time-dependent gradient fields (dB/dt), and (3) RF transmission (B_1).

B_0 - The most widely recognized safety concern with MR imaging relates to the presence of a large, invisible, static magnetic field. Magnets are most commonly designed to create a strong and homogeneous field within a modestly sized imaging volume, while maximizing openness and minimizing peripheral magnetic fields. The static magnetic field has several different regions, ranging from magnet isocenter to the magnetic fringe field, where relatively low magnetic fields extend over large areas. An important transitional zone occurs as you near the magnet, where the magnetic field increases rapidly, producing the potential for substantial deflection forces and torques. The magnitude of these forces is proportional to the spatial rate of change in magnetic field and the mass and magnetization of the magnetic object. The spatial rate of change in magnetic field is typically greatest near the magnet aperture, where the field strength is rapidly rising towards its eventual peak value. The spatial rate of change is further enhanced on tightly shielded magnets, which are designed to minimize magnetic fields outside of the magnet bore. Accordingly, magnetic fields are dampened in the periphery of these magnets, but the magnetic attraction near the bore is enhanced. Unfortunately, projectiles are not uncommon in MR suites. In the vast majority of cases these projectiles are small objects that are pulled from patients or staff as they approach the magnet. However, larger objects, including gas cylinders (1), floor waxing machines and chairs, have been reported that have resulted in serious injury and death. Protection from these types of accidents requires strict institutional policies and personnel adherence to the established safety and screening protocols.

The large static magnetic field of MR systems may pose a safety hazard to patients with internalized magnetic objects. Metallic implants and foreign bodies will experience the same forces described above and may move if not well seated in tissue. There is particular concern for metallic objects in the eye, which can produce ocular injury when exposed to high magnetic fields (2). There is further concern for implanted medical devices such as aneurysm clips (3), which experience deflection and force that may have devastating effects. An excellent and commonly used reference for determining the safety status of a wide range of implants and devices is maintained by Dr Frank Shellock and is available on-line (mrisafety.com) and in book form (4).

The cryogenic system of superconducting magnets poses a safety concern in the event of a quench. The rapid energy transfer from coil windings to the cryogenic liquid produces a large volume of helium gas that must escape the cryostat. MR systems are designed with vents to permit safe expulsion of these gases, but if this system fails then the gas will rapidly displace air in the magnet room. Thus, the magnet room should be equipped with outward opening doors and be rapidly evacuated in the event of a magnet quench.

dB/dt - The transient application of magnetic field disturbances during imaging induces electric fields and forces that create an assortment of other potential safety concerns including nerve stimulation and acoustic noise. The potential for nerve stimulation is dependent on both the strength and duration of the induced electric field (5). Since the strength of the magnetic field produced by gradient coils increases with distance from isocenter, nerve stimulation can occur in the periphery of patients or possibly in interventionalists as they lean into the magnet bore. Stimulation typically begins with a tingling sensation or twitching and can progress to become painful with relatively modest increases beyond the stimulation threshold (6,7). At sufficiently high levels nerve stimulation could potentially induce epileptic seizures or produce cardiac stimulation.

Acoustic noise in MR systems arises due to the activation and deactivation of the gradient coil system. Substantial forces in the gradient coil windings are induced when current levels change, making the wires want to twitch. This produces a small vibration in the structure in the same frequency range (~ kHz) as human hearing and is emitted as audible noise. The amplitude and frequency of the emitted noise is both a function of the MR system and the specific pulse sequence that is being performed, but can be appreciable. Patients within the magnet bore must wear hearing protection and anyone remaining in the magnet room during scanning must similarly consider ear protection. The necessity for ear protection is a function of the amplitude, frequency and duration of the acoustic exposure and agencies such as the Occupational Safety and Health Administration (OSHA) in the US set exposure limits.

B_1 - The primary concern with RF is heating related to absorption of this energy. While RF energy is not ionizing, the RF power that is transmitted into the patient will produce heat due to resistive loss that occurs within tissue. Standards have been established by the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC) that limit specific absorption rates (SAR) in tissues such that no thermal damage will be induced. However, these SAR restrictions inherently cannot account for the presence of conductive structures within the bore. In many instances there can be conductors associated with local RF receiver coils, EKG monitoring and other external objects in close contact with patients. These conductors can channel the RF transmit field and produce

substantially elevated focal deposition of RF energy, resulting in RF burns. MR compatible conductive devices that are within the bore are designed to limit this effect, but care must be taken to avoid the formation of an induction loop when setting up the patient. Implanted devices that contain conductors pose further complications that can be substantially more problematic and may preclude patients from undergoing an MR examination. Patients with cardiac pacemakers and implantable cardiac defibrillators (ICD's) are presently contraindicated for MR imaging, due largely to the potential for device malfunction and focal heating near electrodes. Other devices, such as deep brain stimulator (DBS) electrodes, are permitted to undergo MR imaging with very specific restrictions on SAR and the type of MR system and transmit RF coil.

ACR MR SAFE PRACTICE GUIDELINES

The potential safety concerns in an MR suite must be countered with processes and protocols that avoid or minimize the potential for adverse events. The American College of Radiology (ACR) formed a Blue Ribbon Panel on MR Safety to provide guidance and standards for safe MR examinations. These guidelines were initially published in 2002 and are regularly revised (8). The most recent installment was published in 2007 (9) and addresses the many facets of MR safety, from static magnet fields to MR contrast agents. This living document is an excellent resource and should be referred to when establishing institutional MR safety policies. It should be noted, however, that this reference primarily applies to conventional clinical MR systems, and therefore does not specifically consider niche applications such as interventional MR (10). This resource does address key features including:

MR Zones - The ACR standard utilizes the concept of different zones in MR facilities. Zone I is defined as freely accessible and having negligible MR related safety concerns. Zones II-IV have increasing safety concerns and therefore require progressively greater access restrictions and screening of equipment and personnel. This zone approach requires appropriately designed MR suites with access controls that are enforced and adhered to by staff. Further, protocols should be established for handling patients who experience cardiac or respiratory arrest in high risk MR zones. The primary aim of this protocol should be to provide the patient with the necessary acute life support while transferring them out of the area of magnetic risk. The magnet room itself should specifically be secured immediately after extracting the patient to avoid entry when code responders descend on the MR suite.

Patient and Personnel Screening - An integral part to the ACR guidelines is the screening process and this relies heavily on MR personnel, whom must be appropriately trained. Recommendations on screening are also available in a recent publication by Shellock and Spinazzi (11). Personnel training may be aimed at assuring the safety of the staff themselves (referred to as Level 1 MR personnel), or may be more extensive (Level 2 MR personnel). Level 2 trained personnel will assume responsibility for evaluating the safety of non-MR personnel and should have a broad understanding of the MR environment and how it may interact with humans, devices and equipment. Due to a variable sensitivity and lack of specificity, conventional metal detectors are not recommended at MR gateways. Ferromagnetic detection systems are now available and can be considered as an adjunct to the screening process.

Device and Equipment Screening - All equipment that is to enter Zone IV (magnet room) must be previously certified to be MR compatible and, where possible, labeled accordingly. Any non-MR compatible equipment within Zone III should be labeled as such and have physical restraints to prevent accidental introduction into Zone IV. For equipment where this is impractical, the device must be continually under the supervision of Level 2 MR personnel while within Zone III. Examples of non-MR safe equipment that may exist in Zone III include chairs, carts and pumps. A strong handheld magnet can be used to test for ferromagnetic materials, but should not be relied upon for establishing MR safety. It is further important to be aware of whether the equipment's MR certification of safety is established for the specific MR system (ie – is it safe up to 3T?).

OCCUPATIONAL HEALTH AND SAFETY

MR safety policies have by and large been focused on the patient within the bore of the magnet. This patient typically stands to benefit from the MR procedure and will only be exposed to the MR environment relatively briefly. Staff that work within an MR suite, however, are routinely exposed to the MR environment even if they never enter the magnet bore. Thus, there has been considerable interest in possible biological effects that could be attributable to exposure to this environment. Should a causal relationship between exposure to a particular aspect of the MR environment and some measurable health effect be demonstrated, then steps can be taken to limit this exposure and monitor for the effect. This is routinely done for staff operating equipment that emits ionizing radiation, as their exposure is monitored with a dosimeter and strict limits are placed on annual and lifetime exposure levels. Creating a similar paradigm in the MR environment is very challenging. Minimization of the potential for projectiles and the use of ear protection where appropriate are relatively straightforward examples of safety requirements that also directly affect staff. However, potential biological effects from the electromagnetic fields (EMF) of MR systems have not been definitively established and therefore it is not clear what, if any, safety measures are necessary.

The European Union (EU), however, in 2004 proposed a Physical Agents Directive that introduced occupational exposure limits for EMF's (12). This directive would require by law that all member states of the EU abide by their exposure limits. Exposure limits of particular concern to interventional MR (13) include a proposed static magnetic field "action value" of 0.2T and limits to time-variable magnetic fields comparable to that produced by gradients. The static magnetic field action value requires that employers take steps to assure that an exposure limit is not exceeded. However, the directive presently has not established this exposure limit, so the implications of this aspect remain uncertain. The proposed limits to the time varying magnetic field, however, are potentially much more problematic. Unlike RF exposure, gradient strength can be quite high near magnet openings and any procedure that involves the interventionalist reaching into the magnet during scanning will almost certainly substantially exceed the proposed exposure limit. This aspect of the directive remains very controversial and Hill et al (13) discuss the scientific background that went into developing the exposure limit. The controversy and implications on patient care have delayed implementation of the proposed EU directive from 2008, until 2012. The final language in this directive may play a key role in determining if and how interventional MR will be practiced.

SAFETY PROTOCOLS FOR THE INTERVENTIONAL MR SUITE

The interventional MR suite poses a particular challenge for establishing and maintaining MR safe practices. Each installation must design their site and establish procedures that place a strong emphasis on MR safety. They must further actively educate and train staff who will be involved in IMR procedures and continually refresh and emphasize the importance of adhering to established safety

protocols. Hushek et al have published safety protocol recommendations specific to interventional MR practices (14), which provides a nice overview of the special issues that must be considered.

IMR Suite Planning - Establishing a functional and defensible suite layout is key to safely and effectively performing MR guided interventional procedures. Each IMR suite is unique and may have to balance MR system requirements, space limitations, radiological and interventional system use, and variable applications. However, the ACR concept of MR Zones must be carefully considered when developing an IMR suite. The zone concept must be adapted to the special needs of an IMR system, where additional equipment and personnel will need to access Zones III and IV. Line of sight or video surveillance must be integrated to permit constant monitoring of the MR environment by Level 2 trained MR personnel. Consideration must further be made for anesthetic induction, transportation of anesthetized patients, scrub sinks, and room and staff sterility. Demarcation of the spatial extent of the magnetic fringe field (5 G or 30 G), either through physical walls, floor markings or ceiling mounted devices, is utilized in virtually all IMR installations and serves as reminder of the unique environment.

Staff Training - All staff that are involved with IMR procedures and may be required to enter Zones III or IV should be trained to Level 1 MR personnel and undergo regular training updates. It is important that these staff be aware of MR safety requirements as typically there will be insufficient Level 2 MR personnel to continuously track all aspects of IMR procedures. The larger number of staff that is associated with IMR procedures, however, creates its own safety risk as there exists the potential for untrained staff to pass through conventional screening. A relatively common method for minimizing this risk is to have uniquely colored surgical scrubs that are dedicated to the IMR suite. This scrub would ideally lack pockets to prevent the accidental introduction of loose ferrous objects. This concept has two principle advantages: (1) staff who transiently appear from other departments are easily identified and (2) the requirement to change into a specific scrub reinforces to staff the unique environment that they are entering and hopefully emphasizes the need for heightened safety awareness. Level 2 MR personnel must further work with anesthesia personnel to assure that patients entering the room under general anesthesia have been properly screened and prepared.

Patient Screening and Preparation - Patients scheduled to undergo an IMR procedure must initially undergo conventional screening to assure that they are not contraindicated for MR imaging. This should be performed as an integral part of surgical preparation and a Level 2 MR staff member must interview the patient prior to anesthetic induction. MR screening must continue when the anesthetized patient presents at the MR suite to assure they appropriately prepared to enter the MR system. Specific attention must be paid to the presence, and conformation, of any conductive leads that are attached to the patient. All unnecessary or unsafe conductors must be removed and the remaining leads run linearly from the patient, parallel to B0, and as far from the bore walls as possible. Insulation should further be provided between these wires and the patient to minimize the potential for thermal injury. Finally, the MR technologist should assure that ear protection is in place prior to MR scanning.

Equipment Certification - Interventional equipment that is specifically designed for use in an MR environment is becoming increasingly available. MR compatible versions may suffer some functional limitations and cost substantially more than their traditional counterparts, but should be utilized whenever possible. In instances where compatibility is yet to be established or unknown, then certification by an experienced MR physicist or engineer can be considered. This certification should follow the methods established by the American Society for Testing and Materials (ASTM, www.astm.org). They maintain standards for evaluating MR induced displacement forces (ASTM F2052-06), torque (ASTM F2213-06), and RF induced heating (ASTM F2182-02). They further have developed marking standards for indicating the conditions that are acceptable for devices in an MR environment (ASTM F2503-08). In situations where non-MR compatible, or unverified, equipment must be brought to the MR suite (Zones III or IV), then they should be constantly monitored and, whenever possible, physically tethered to avoid the possibility of entering an MR unsafe region.

SUMMARY

MR guidance of interventional procedures affords a host of potential benefits. The MR environment, however, is complex and poses challenges for staff and equipment. While MR imaging does not require ionizing radiation, there are safety hazards associated with the strong static magnetic field, incident RF energy, gradient fields and cryogenic system. Staff must be thoroughly trained in MR safety and patients and staff carefully screened prior to entering the MR environment. Vigilent adherence to pre-defined MR safety practices, such as those established by the ACR, provides the greatest likelihood of avoiding MR accidents. Ultimately, safety in an IMR setting can only be achieved by appropriate facility design, in depth personnel training, and careful screening of patients, staff, and equipment.

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