Screening the Patient: How To Deal with Individual Subject

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Introduction

Accidents in MRI occur in three main scenarios: metallic, ferrous objects are brought into the magnet room; patients with biomedical devices or implants that are not "MRI safe" are allowed into the magnet suite and into the bore of the magnet to undergo an MRI examination; and RF burns occur due to inappropriate use of coils, cables, monitoring equipment and/or breakdown in the function of hardware and/or software of the MRI system.

Why do MRI accidents occur? For these fundamental reasons: lack of adequate, recurring MRI safety training and education for the MRI staff, health care professionals (technologists and radiographers), and physicians; lack of an adequate number of qualified individuals to run the MRI facility effectively, efficiently and, most importantly, safely; poor design and/or implementation of policies governing access to the MRI facility; and a lack of financial support and allotment of time to ensure MRI safety processes and procedures take place on a regular basis.

In addition, to prevent accidents in the magnetic environment, all MRI staff, health care professionals including physicians must fully embrace and utilize continuously without exception several key MRI safety rules:

1 – Make no assumptions (e.g. "the doctor told me it was safe.")
2 – Trust no one
3 – Ask questions
4 – Screen the patient 4 times
5 – Know your RF coils
6 – No loops in cables or patients
7 – Keep the magnet room door closed
8 – Remain vigilant (watchful and alert)

Metallic, Ferrous Objects

The prevention of ferrous objects from being brought into the magnet room that are subsequently pulled into the magnet and possibly injuring a health care worker or patient is an ongoing process. Several policies and procedures must be developed that are specific to the type of MRI facility (hospital, free-standing clinic or research laboratory) to ensure they are realistic, will be utilized by all, and, most important, supported by those in charge.

The department or building in which the MRI facility is housed must be designed with magnet safety as a priority. Unfortunately, this is often overlooked due to limited finances and/or availability of space. This becomes "the accident just waiting to happen," which will drastically affect not only the MRI facility but also the entire medical institution with which it is affiliated.

An optimum design has been outlined in the ACR white paper on MRI safety identifying the different "zones" of a MRI facility and how each should be accessed and protected to prevent inappropriate equipment or personnel from becoming the accident

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in the magnet room. However, a magnet suite that was inappropriately designed in the beginning can be modified to provide an adequate level of safety. It will require an investment; but then it is important to remember that whatever the cost of renovating a MRI suite to improve safety, it will be negligible compared to the expense of almost any accident in the magnet room. The cost of an accident often includes much of the following: controlled quench or ramp down of the magnet to remove the ferrous objects (cryogen and labor costs); replacement of hardware and coils; magnet downtime (loss of patient revenue); magnet manufacturer service costs (labor); injury to health care workers and subsequent absence from work (and possible lawsuits); and injury (or death) to the patient and subsequent lawsuits. Several individuals have calculated the cost of an MRI accident to be several hundreds of thousands of dollars to several millions of dollars. In addition, once the accident reaches the media, the entire institution may experience a loss of revenue. After all, who wants to bring their spouse, child, parent or other loved ones to a medical institution whose health care professionals make mistakes of this caliber when dealing with human lives?

Restricted access, however, is only as good and as secure as the health care professionals and staff who monitor it. Training for all staff working in the MRI facility including physicians must be ongoing and regular. This is most critical for the MRI technologists and radiographers as they are the first line of defense, responsible not only for themselves and the patients but also for all the other staff and physicians who enter the magnetic environment. An adequate number of trained technologists or radiographers must be present to ensure safety is preserved across all shifts. In the past, there has been a lack of formally educated imaging technologists and radiographers to fill all the necessary jobs. As we experience a downturn in the economy, healthcare becomes less of a priority and the institution may reduce the number of qualified health care professionals. If this occurs in the MRI department, the risk of accidents increases significantly.

Appropriate signage must be placed throughout the MRI facility especially on the door leading into the magnet room and walls around that door. In addition to visual signs, a rug placed in front of the magnet room door provides a tactile warning as well as a sign for firefighters needing to crawl on the floor to avoid smoke during a fire. Lighted signs may result in confusion during a power outage incorrectly indicating that the magnet is not “on”. Metal detectors are never a good idea as their sensitivity is dependent upon the individual controlling them and, as human beings we may tend to rely too much on them. In addition, they cannot be used to detect internal biomedical devices or implants.

Special training must be available for any group of individuals who will enter the MRI facility and magnetic environment on an intermittent basis. This includes other health care professionals such as nurses and respiratory therapists as well as transportation, custodial services, engineering, fire department and police department personnel. There must be institution-wide procedures in place that require all of these individuals to have MRI-trained staff screen them using a form, accompany them into the magnetic environment, and remain with them at all times.

There must be a safety committee appointed for the MRI facility that sets policy and regularly evaluates safety and screening procedures including screening forms. At the very least, the safety committee is made up of one qualified technologist or radiographer and one MRI-trained radiologist or physician. Both of these individuals must be allowed time and financial support to maintain their MRI safety expertise by participating in MRI list servers and educational symposia. A member of the MRI safety committee performs the safety training for the MRI staff and other individuals and maintains policy and procedure documentation.

A thorough review of the completed pre-procedure screening form is an indispensable part of patient preparation. The technologist or radiographer who will be scanning the patient must be the last person who reviews the completed screening form; the person who visually and verbally screens the patient before they enter the magnet room; the person who takes the patient into the magnet room; and the person who positions the patient, accessories and equipment in the bore of the magnet.

All patients should be required to use gowns or scrubs provided by the MRI facility to prevent the introduction of any small items (keys, cell phones, paperclips, pocketknives, etc.) into the MRI environment. No items brought from a patient's home or from other departments in the hospital should be allowed into the magnet room including pillows, blankets or stuffed animals. Many of these seemingly benign objects have metal objects within.

Biomedical Devices and Implants

Strict policies must be in place including a comprehensive screening procedure for patients and others entering the MRI environment to prevent accidents as a result of exposure to the magnet (B_0) and/or RF electromagnetic fields (B_1). This begins with an appointment scheduling via telephone or email that includes a screening for the presence of major implants or devices that may require some investigation to ensure safety and that any 'conditional' areas are fully explored. This will save time and prevent a delay in the MRI schedule to confirm in advance if any devices or conditions are present. It will also prevent a rushed evaluation and decision for the patient to undergo the MRI examination that often results in an accident. The investigation may require conversations with one or more of the following: patient; patient's referring physician; surgeon; and family members (if the subject suffers from memory or age-related disorders such as Alzheimer's' Disease). Also required will be consultation of MRI safety reference books and websites, and device manufacturer websites to obtain necessary information concerning the safety and conditions under which the patient with the device or implant may be able to undergo the MRI examination.

Completion of a thorough pre-MRI examination screening form is required when the patient arrives at the MRI facility. If the patient cannot read the screening form, either a translator or translated form in their language must be available for the patient to accurately complete the screening form. If the patient is comatose or unable to comprehend the form, then a responsible family member or personal physician must be available to assist in the screening process. A visual screening of the patient's body may

need to be completed to rule out past surgical procedures such as the placement of a cardiac pacemaker.

The knowledge possessed by the MRI health care professionals and physicians is critical in this inquiry and analysis procedure to ensure patient safety and the accurate functioning of any active biomedical devices or implants post-MRI examination. Policies must be clearly understood by the MRI staff, health care professionals (technologists and radiographers) and physicians to ensure all individuals follow the same procedures during all shifts. For example, verbal approval from a referring physician or surgeon for a patient with an implant or device to undergo a MRI scan is never acceptable. Specific information about each implant and device must be known and documented appropriately. This includes: name of the manufacturer of the device; type, model or serial number; composition of material; date surgically placed; name of surgeon and hospital where surgery was conducted; and the condition or disease process the implant or device is correcting or supporting.

It is important that everyone involved in MRI safety fully embrace the current, accepted terminology describing the safety (or lack thereof) of any biomedical device or implant. Any confusion in something so basic should be avoided especially by those setting policies to protect patients and health care workers. The 'old' terminology included: "MR Safe", "MR Unsafe", "MR Compatible", and "Not MR Compatible". The 'new' terminology includes: "MR Safe", "MR Unsafe", and "MR Conditional". "MR Conditional" indicates there are conditions that must first be evaluated before the patient is approved to undergo the MRI examination. These conditions include the magnetic field strength, RF coil, gradient slew rate and maximum amplitude, SAR, and others dependent upon the implant or device.

Documentation of details should be conducted anytime a patient with an implant or device is approved for and undergoes the MRI examination. This should include the following information: the MRI scans conducted; SAR levels generated for each scan; the RF coil(s) used to transmit and receive; and the condition of the patient before, during and after the scanning. This information is critical if anything is discovered amiss following the examination or declared later by the patient.

The technologists and radiographers may be the individuals collecting all of the relevant and necessary data concerning the biomedical implant or device that is present. However, in all scenarios, it is the MRI radiologist or physician, who ultimately makes the decision for the patient is to undergo the MRI examination. This information should also be documented for each case including the signature of the approving radiologist or MRI physician and the names of the technologists or radiographers present.

Burns from RF Electromagnetic Fields

This may be the area of MRI accidents in which the least amount of attention is placed. This is most unfortunate because it is an area in which the technologists and radiographers must possess a complete, working knowledge of RF electromagnetic fields, RF coils, monitoring equipment, and how to prevent these accidents (patient burns) from occurring. If a MRI facility is employing staff who do not possess adequate training and education and yet are setting up the equipment for the MRI examination

and positioning the patient with RF coils and monitoring equipment, the risk of an accident in the magnetic environment is quite high.

Burns occur during MRI examination for several reasons: lack of knowledge on the part of the individual positioning the patient and operating the MRI system; inappropriate use of a RF coil; inappropriate positioning of the patient relative to the RF coils and monitoring cables; inappropriate positioning and placement of cables from all devices relative to other cables, coils and magnet system; use of monitoring equipment that is not compatible with that manufacturer's MRI system; use of electrodes that are not approved for MRI and/or use with that manufacturer's monitoring system; broken RF coils, cables or monitoring equipment; breakdown in safe function of some part of the MRI system; and others in which adequate information is not available to accurately identify the cause.

The technologist and radiographer must provide adequate instruction and information to the patient to ensure not only their compliance but also their partnership in the successful completion of the MRI examination. Visual and verbal communication with the patient must be maintained at all times. It must also be remembered that patient safety is more important that the completion of the MRI examination. Therefore, if a patient complains or communicates any difficulty or concern, it must be immediately investigated in the magnet room, at the magnet and not remotely from the control room. Comatose patients must be regularly checked in the magnet to ensure their safety during the MRI examination.

"One-quarter inch of air" and "no loops" are two good rules to remember to prevent burns during MRI examinations due to induced currents or failed hardware. MRI-safe pads and sponges must be used to provide this separation (one-quarter inch of air) between cables and the patient and between the patient and the bore walls and ceiling of the magnet. Separation from the RF body coil (bore walls and ceiling) is, of course, most important during scans in which the body coil is employed to transmit. Good habits, however, are formed by repetition. Padding patients also provides additional level of comfort encouraging 'motionless' scans. "No loops" means that there are no cables forming a loop with themselves, no cables forming loops with other cables, no cables creating a loop by touching the patient, and the patient must not form a loop with himself/herself through positioning of their extremities. Clasped hands, hands touching the hips, a hand against the forehead, or any scenario in which the patient forms a loop should be avoided to prevent patient burns in addition to peripheral nerve stimulation (PNS). In addition to patient instruction, sponges or pads are used to appropriately separate anatomy such as hands, knees, etc. Finally, it is important to remember that the larger the loop, the greater the risk for a burn to occur. Anything larger than the index finger and thumb creating a circle is a large loop. In addition, running the ECG cable from the patient out the far end of the magnet, turning and returning back through the magnet to the cable connection at the front of the magnet may be largest loop possibly ever formed in a magnet. And yes, it will induce a current in the loop which will result in a patient burn and/or damage to the MRI hardware.

The biggest challenge to ensure safety in the MRI is the ability to successfully multi-task: to simultaneously maintain focus on the patient and the magnetic

environment. This requires trained, knowledgeable, qualified individuals. This is especially crucial in the event that emergent care is required for the patient that is in the magnet, as all emergent care must take place outside of the magnet room. Timely removal of the patient from the magnet and out of the magnet room while maintaining a safe MRI environment during a crisis is our most difficult challenge.

Database for Reporting Accidents in the MRI Environment

Currently the FDA maintains the MAUDE database in which MRI facilities are to report accidents that occur:

It is estimated that only about 10% to 40% of incidents are reported. Many reasons exist for this lack of reporting: embarrassment; potential job loss; loss of professional reputation; loss of institutional revenue (if the news reaches the media); lack of knowledge that these accidents are not only required to be reported to the manufacturer and the FDA but within a specific amount of time; and others. In addition, the design of the database allows inconsistency and a general lack of organization in the details of MRI accidents that are reported.

A database that contains a majority of the accidents that occur in MRI facilities and requires comprehensive, well-organized methods of reporting has value in enabling one to accurately identify the areas in MRI safety where focus is needed, and to review the scope of MRI accidents that exist worldwide. It also provides evidence that can be used to ensure the financial support and the time necessary on an ongoing basis to maintain complete safety in the MRI environment for staff, health care professionals, and physicians and, most importantly, the patients.

Conclusion

An adequate number of knowledgeable, trained MRI staff, health care professionals (technologists and radiographers) and physicians are absolutely necessary to maintain a safe MRI environment. Limited access built into the design and patient flow within the MRI facility is critical. All of these require time and financial support. Any time one of these is reduced, the medical institution increases the risk of an accident in the MRI facility.

In healthcare, one's priority, whether health care professional or physician, is always the patient. Upon combining healthcare and the MRI facility, we must divide our attention, our priority, between the patient and the magnetic environment. If we are to ensure a MRI facility that is safe for the patients, MRI staff, health care professionals, physicians and the MRI equipment, we must successfully:

1 – Make no assumptions
2 – Trust no one
3 – Ask questions
4 – Screen the patient 4 times
5 – Know your RF coils
6 – No loops in cables or patients
7 – Keep the magnet room door closted

8 – Remain vigilant (watchful and alert)

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