How to Determine the MRI Safety and Compatibility of an Implant or a Medical Device?

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Purpose

The purpose of this exhibit is to give an overview on how to determine the MRI safety and compatibility of an implant or a medical device.

MR Safety Considerations

Magnetic Resonance Imaging (MRI) Tip for Scanning with Implants

- Follow your site’s process for scanning the patient
- Identify the manufacturer and model of any implants or medical devices assessed
- Review the MRI safety information in the device manufacturer’s labeling

- MR Safe. Patients with MR Safe devices have no known hazards.
- MR Conditional. For patients with MR Conditional devices, implant conditions should be matched with the MRI system information.
- MR Unsafe. Patients with MR Unsafe devices have a known hazard in all MR environments.

Fig. 1 MRI safety considerations when scanning patients with implants or medical devices includes the knowledge of MRI safety labeling for implants, medical devices, and other equipment.

MR Safety Labeling

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices, and accessories. Medical implants, medical devices, and other equipment used in or near the MR environment should be labeled as MR Unsafe, MR Conditional, or MR Safe.

Fig. 2 Medical devices can be categorized into three categories: MR Safe, MR Conditional, and MR Unsafe. The MR Safe label indicates no known hazards in all MR imaging environments. MR Conditional items have been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions including static magnetic field strength, spatial gradient, and time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). MR Unsafe items pose hazards in all MR environments. Many implants, materials, devices, and objects have been tested with regard to MR procedures and the MR environment. Frank Shellock and his team have published an extensive online list to determine information about specific miscellaneous implants and devices assessed at different field strengths.

A proper preparation of each patient before an MRI examination is necessary to avoid burns even for patients without implants. The Guidelines to Prevent Excessive Heating and Burns Associated with MR Procedures recommend:

- Remove metallic objects contacting the patient’s skin
- Use insulation material of 1 cm or thicker to prevent skin-to-skin contact and the formation of closed-loops from touching body parts
- Allow only devices, equipment, accessories (e.g., ECG leads, electrodes), and materials that have been thoroughly tested and determined to be MR safe.

Fig. 3 Dr. Emanuel Kanal has developed a detailed decision matrix to determine the MR safety for implants and devices that are not listed in the literature or on-line resources. This decision matrix includes a step-by-step analysis to determine MR safety.

Decision Matrix for MR Safety Screening

A detailed decision matrix with a step-by-step analysis to determine MR safety is displayed in Fig. 3.

The decision to determine the MR safety of an implant or device is the responsibility of the Magnetic Resonance Medical Director (MRMD) who is a physician and legally liable for safety in the MRI environment and the safe execution of the magnetic resonance examination. The MRMD will establish MR safety policies and guidelines of the site and will oversee all decisions regarding MR site access and site access restriction decisions.

An Magnetic Resonance Safety Officer (MRSO) will advise the MRMD and is charged with executing the MR safety practices as defined for the site by the MRMD. Additionally, a Magnetic Resonance Safety Expert (MRSE) can serve as a resource for the MRMD and MRSO in situations where the MRMD or MRSO need assistance with MR safety questions.

The American Board of MR Safety offers Magnetic Resonance Safety Certified™ (MRSC™) credentials for professionals charged with overseeing the safety of clinical and/or research magnetic resonance sites who demonstrate that they satisfy ABMRs requirements for such certification and qualification.

All personnel working in the MR environment need to be trained with a comprehensive MR safety course. 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 MR safety training should include the presentation of technical and medical background of MRI safety. Hands-on demonstrations of missile effects of ferromagnetic objects help to better understand and experience the dangers in an MRI suite.

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 MRI 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 personnel entering the MRI scanner room to evaluate the patient, administer medications or interventions need to be trained in emergency procedures in an MRI suite. Healthcare professionals need to know which objects can be brought into different MR 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.

Conclusion

Regular MRI safety training for staff, comprehensive screening forms and thorough patient evaluations, patient interviews before the exam, proper patient positioning, and constant visual and audio monitoring during the exam will improve the safety of patients and staff.

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