

A Review of Thermal MR Injuries

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Since its introduction into the clinical arena in the mid-1980s, magnetic resonance (MR) imaging has become an important diagnostic tool, not only because it is noninvasive and relatively safe, but also because it has shown increasing clinical applicability. The technology for MR imaging procedures has evolved considerably, resulting in systems with stronger static magnetic fields, faster switching of gradient magnetic fields and higher radiofrequency (RF) power.

Although MR imaging has proven to be a safe and effective modality when properly used, clinicians and regulators have become increasingly aware of the risks associated with this device, as well as the physical phenomena responsible for these risks. The number of MR imaging-related adverse events has increased steadily since the first years of clinical use (see Figure 1), which may be due to the increase in the number of MR procedures.¹ Skin injuries are the primary type of adverse events reported to the U.S. Food and Drug Administration (FDA). It is part of the FDA's mission to convey the risks of MR imaging by providing guidance

documents for safer use of MR and releasing public health notifications describing specific risks and actions for avoiding or reducing risks.^{2,3}

Health care and independent scientific organizations, such as The Joint Commission and the ECRI Institute, also have cited a heightened awareness of skin injuries related to MR imaging use and have called for greater caution during scanning. On February 15, 2008, The Joint Commission highlighted increasing patient safety issues with MR imaging by releasing a Sentinel Event Alert. This alert urged hospitals and ambulatory care centers to "pay special attention to preventing accidents and injuries during MRI procedures."⁴ The ECRI Institute cited MR imaging-related thermal injuries among its 2010 top 10 list of technology hazards. According to ECRI, these hazards are among the top safety issues in health care overall.⁵

Most of the adverse events that occur in practice are not due to system malfunctions, but to improper patient management (eg, positioning or considerations related to body size, weight and medical history) or improper use of the equipment before or during the imaging procedure. All members of the clinical team play an important role in preventing these adverse events.

This article presents a 12-year retrospective review of thermal injuries reported to the FDA's Center for Devices and Radiologic Health (CDRH) through its MedWatch program, including a summary of possible mechanisms responsible for MR imaging-related skin injuries. Although symptoms of most thermal-related injuries are not immediately noticeable by either the patient or clinician during or after the MR imaging, steps can be taken during the procedure to prevent them. This review also provides a list of guidelines to help clinicians minimize MR imaging-related adverse events.

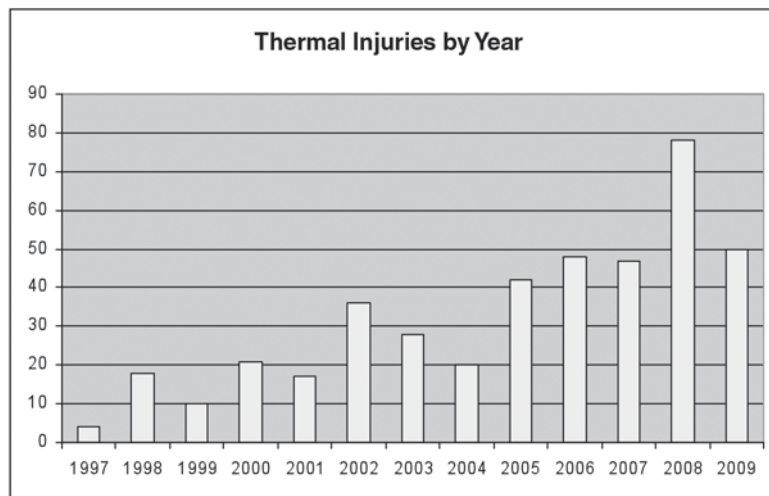


Figure 1. Thermal injuries by year. Source: the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database.

Mechanisms of Thermal MR Injury

In general, safety concerns related to MR-imaging systems arise from its high-power RF pulses that are emitted by the body coil and magnetic gradient field pulses. The RF pulses can induce currents in specific situations that are believed to be the origin of thermal injuries.

Interactions with metallic implants, pacemakers and external devices, such as pulse oximetry leads and electrocardiogram (ECG) cables, have been associated with MR imaging-related thermal injuries (see Box). However, even in the absence of metallic implants, the body can act as a conductor of current that may induce heating when parts of the body come into contact with each other and form a closed loop. For example, a patient lying supine with clasped hands, or a thumb touching the side of his or her leg during a scan, can form a closed loop that acts as a pathway for induced currents.

Review of Reported Adverse Events

Founded in 1993, MedWatch is the FDA's reporting system for adverse events. An adverse event is any undesirable experience associated with the use of a medical product.⁶ The MedWatch system collects adverse event reports primarily related to drugs and medical devices. Hospitals, consumers and patients can voluntarily report adverse events using FDA's 3500 form; manufacturers are required to report adverse events using FDA form 3500A. These reports are submitted to a database known as the Manufacturer and User Facility Device Experience Database System (MAUDE) and are subsequently reviewed by FDA analysts.⁷

Methods

We searched MAUDE data for reports received between January 1, 1997, and December 10, 2009, using MR imaging manufacturers' names and the FDA product codes for MR imaging systems. A keyword search was then used to locate events specific to thermal injuries. Keywords used included "burns," "blisters," "pain," "redness" and "erythema." The final subset of reports was exported to a spreadsheet for closer review. Reports not associated with thermal injuries obtained during MR imaging procedures were excluded.

The reports were then categorized by the primary location of the injury, the secondary location of the injury and the reported cause of the injury. The primary

Box

In October 2009, a 20-year-old man underwent a head and cervical spine magnetic resonance (MR) imaging scan following a car accident. During this scan, the patient was connected to a pulse oximeter for continuous monitoring. Immediately following the scan, he complained of burns on his hand where the pulse oximeter's finger grip was attached. Upon examination, the patient was diagnosed with second- and third-degree burns on his hand and fingers and had to undergo surgery for skin grafting to the burned areas.

location of injury was determined by the first body part mentioned as incurring a thermal injury. General anatomical terms were used to group similar reports (eg, torso, leg and feet). The reported cause of injury also was captured using simple terms such as "bore contact," "coil contact," "RF" and "burn" when it was available in the report narrative.

Results

The results of the MAUDE search produced 760 reports, which were narrowed to 468 reports after the keyword search was performed. Of the 468 reports, 419 were related to thermal injuries and are the focus of the following results.

Number of Thermal Injuries per Year

In spite of the increased awareness of thermal injuries related to MR imaging and the increasing numbers of studies and publications on the subject, the number of adverse events reported to the FDA grew steadily from 1997 to 2008. This increase may be partly due to a rising number of MR imaging procedures globally, as well as better reporting of MR imaging adverse events. In 2009, the number of thermal injuries reported actually decreased to almost 2007 levels. We hope this is due to heightened awareness of the causes of these injuries and not to underreporting.

Primary Location of Injury

Most thermal injuries involved the extremities (58%), including the arms, elbows and hands. This was followed by areas on the torso (19%), including the shoulder, back and hips (see Figure 2). Only 6% of the adverse events reported did not identify the primary location of the injury.

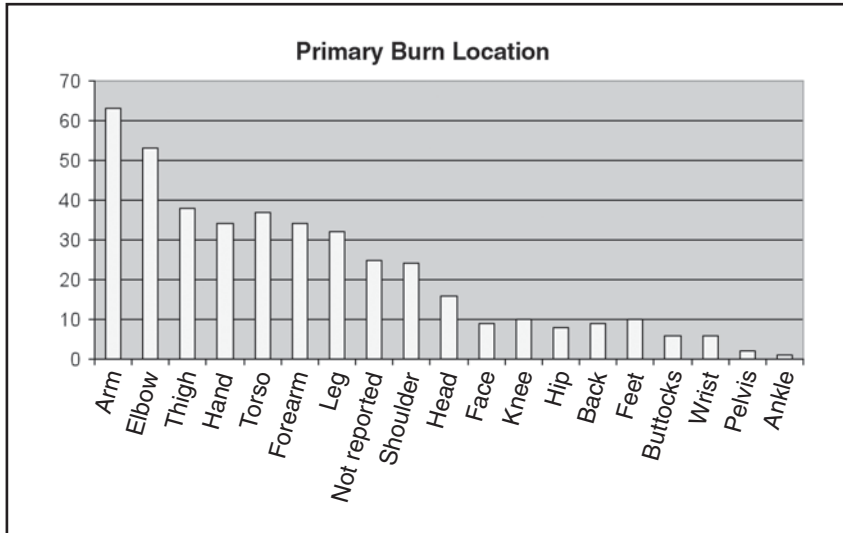


Figure 2. Primary location of injury. Source: the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database.

Reported Cause of the Injury

The majority of thermal injury reports also identified the cause of the injury (72%) compared with reports in which the cause was not identified (28%) (see Figure 3). The top 4 reported causes of thermal injuries included contact with either the MR bore (25%) or coil (14%), followed by contact with a foreign object (14%) or skin-to-skin contact (11%).

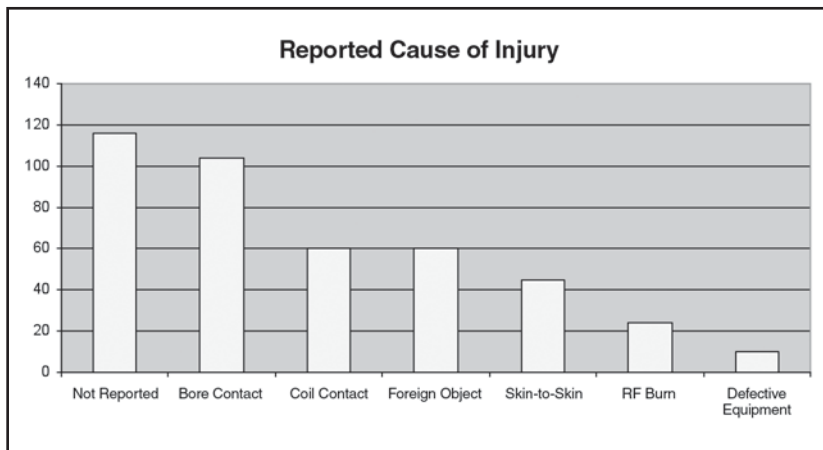


Figure 3. Reported cause of injury. Source: the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database.

Guidelines for Reducing Thermal Injuries

The following information for clinical staff using MR equipment was derived from a variety of guidelines and articles. This information may help clinicians take precautions to avoid adverse outcomes.

- Provide formal training for those who work near the MR imaging control room or equipment to ensure the safety of patients from all MR imaging-related injuries.^{8,9}
- Read the instruction manual before operating MR imaging equipment and performing scans on patients.⁹ Manufacturers of the MR imaging systems, as well as the coils, provide good information about the inner workings of their systems (eg, acceptable specific absorption rates, timely servicing of equipment and correct patient positioning).
- Regularly review and update facility policies and procedures on the safe use of MR equipment.⁸
- Before initiating a scan, ensure that the scanner has been properly maintained and is in working order, and the insulation, RF coils and other components are intact and well maintained.^{9,10}
- Thoroughly question patients about their medical history, particularly implanted devices. Documentation should note the device type and date implanted.⁸ Most implanted devices have undergone MR imaging safety testing. However, technologists also should follow their facility's policies and procedures to ensure that patients can safely undergo MR scanning.
- Thoroughly examine the patient's skin prior to MR imaging for permanent cosmetics or decorative tattoos and objects such as drug delivery patches, superficial metallic sutures, surgical scars and piercings. Examining surgical scars may help identify implanted devices.^{8,9}

- Instruct patients to avoid crossing their arms, legs, fingers or hands because these can form a large conductive loop and lead to thermal injury. Be aware that skin folds, such as those in the abdominal area and thighs, also may be prone to thermal injury.⁸
- Provide thermal insulation (eg, padding or air) to areas of the patient that are most likely to experience skin injuries (eg, areas of skin-to-skin or skin-to-machine contact). Use only the manufacturer-recommended insulation material at the recommended thickness. Place insulation material between the patient's skin and the local RF coils and pad the RF coils.⁸⁻¹⁰
- Communicate with clinicians caring for the patient and find out what electrical equipment can be removed during the scanning.⁸
- Only allow devices that are cleared for use with MR imaging to be attached to the patient during scanning, such as ECG cables and electrodes. If electrical equipment must remain in place during the scan, make sure that the electrical equipment contacts the patient's skin as little as possible and there aren't any loops in the device, such as those that can occur with cables. If contact between the cables or leads and the patient's skin cannot be avoided, cold compresses and ice packs have been recommended as a method for preventing thermal injury. However, caution should be taken with this method as well.^{8,9}
- Continually monitor the patient during the scan. If the patient experiences any sensations of overheating, such as discomfort, tingling or burning, stop the scan immediately.⁸ Although there may be no immediate sign of skin injury, delayed signs have been reported to the FDA up to 24 hours following the scan.
- Patients who are sedated, anesthetized or unconscious are at even greater risk of injury and should be examined carefully. Leads or cables should be repositioned after each imaging sequence.⁸
- If a skin injury occurs, follow the necessary steps to submit a medical device report.⁸ There are simple instructions on the FDA's website.⁶ Provide as much information as possible in the report, including the scan's duration, types of pulse sequences involved, the machine's field strength (eg, 1.5T or 3T) and the patient's distance from the bore and the coil. Accurate

tracking of adverse events is important because it ultimately improves patient safety.

Conclusion

Most thermal injuries caused by MR imaging occur in the extremities as a result of direct contact with the machine's components or from a closed loop formed by equipment or parts of the body. With increased awareness and ongoing education, the number of thermal injuries can be dramatically reduced. It is essential that MR technologists play a prominent role in maintaining a safe and effective MR imaging environment. ♦

References

1. Harris C. MRI procedure growth rate slows, study shows. AuntMinnie.com. www.auntminnie.com/index.asp?Sec=sup&Sub=mri&Pag=dis&ItemId=81355. Published June 5, 2008. Accessed May 27, 2010.
2. U.S. Food and Drug Administration. A primer on medical device interactions with magnetic resonance imaging systems. www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm. Draft released for comment on February 7, 1997. Updated June 18, 2009. Accessed October 30, 2009.
3. U.S. Food and Drug Administration. MRI safety. www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm135362.htm. Updated October 8, 2009. Accessed October 30, 2009.
4. Sentinel Event Alert: The Joint Commission. *Preventing MRI Accident and Injuries*. February 14, 2008.
5. ECRI: 2010 top 10 technology hazards. *Health Devices*. 2009;38(11):1-10.
6. U.S. Food and Drug Administration. What is a serious adverse event? www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm. Updated June 25, 2009. Accessed October 30, 2009.
7. U.S. Food and Drug Administration. How to report a problem (medical devices). www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm. Updated June 18, 2009. Accessed October 30, 2009.
8. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document for safe MR practices: 2007. *AJR Am J Roentgenol*. 2007;188(6):1447-1474.
9. Shellock FG, Crues JV. MR procedures: biologic effects, safety, and patient care. *Radiology*. 2004;232(3):635-652.
10. Dempsey MF, Condon B. Thermal injuries associated with MRI. *Clin Radiol*. 2001;56(6):457-465.

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