CHAPTER 16
Safety

While considered to be a relatively safe imaging technique, MRI is not without risks. Its use in humans is regulated by healthcare committees of national governments. For example, the US Food and Drug Administration (FDA) has ruled that MRI scanners are Class II medical devices subject to the regulations defined in 21 CFR 892.1000 (US Government, 2008), the same classification as most X-ray-based imaging devices. Operational limits for MRI for most countries are derived from those established by the International Electrotechnical Commission (IEC), with Japan and Italy having separate regulations.

One area where frequent questions arise is pregnancy, both of patients and of workers. While additional research in the area is warranted, there is currently no indication of any adverse biologic effects to the fetus or mother from exposure to the MRI hardware during scanning at any time during the pregnancy (Kanal et al., 2007; Shellock and Crues, 2004). The current recommendations for scanning of pregnant patients is based on the clinical problem under examination and whether MRI is the most appropriate imaging modality to use. Nevertheless, it is prudent to minimize exposure to the MRI scanner during pregnancy, both for patients and health care workers.

There are five general areas where MRI-specific safety precautions are warranted: base magnetic field, cryogens, gradients, RF power deposition, and contrast agents. Depending on the particular scanner and clinical scan in question, one or more of these areas may not be relevant (e.g., a permanent magnet scanner that has no cryogens or a clinical study that does not use contrast media). Manufacturers attempt to minimize any risks through hardware and software limitations on scanning, but some risks cannot be controlled by the manufacturer. Our intention in this section is to describe the potential risks associated with MRI, both for patients and workers, and indicate the current guidelines to minimize these risks.

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16.1 Base magnetic field

The first area where precautions should be exercised is the base magnetic field, regardless of its field strength. The examination room in which the magnet is located should have restricted access. Any metal near the magnet should be nonmagnetic (diamagnetic response). Metal items such as stethoscopes or pens may be attracted to the magnet, causing possible injury. Breathing gases used for sedated patients should be either built into the wall or supplied from nonferrous tanks. Electrical equipment must be protected or shielded from the magnetic field in order to function properly. Patients with surgical implants or metal fragments in their bodies as a result of trauma or occupation (e.g., sheet metal workers) should be scanned only if there is no risk to the patient should the implant or fragment move during the procedure. Patients with magnetic pacemakers, or ferromagnetic intracranial aneurysm clips, or neurostimulators should not be scanned under any circumstances due to the risk of patient injury. The magnetic properties of various medical implants have been extensively described by Shellock and coworkers (Shellock and Spinazzi, 2008).

It is also important to realize that the magnetic field of all magnets extends in all directions away from the center of the field, including vertically. The amount of fringe magnetic field (the portion outside the magnet housing) is a very important consideration in siting an MRI system. The fringe field is greatest near the magnet parallel to the field (typically in the *z* direction) and decreases with increasing distance away from the magnet. The fringe field is also larger for higher field magnets. A low-field magnet has a very small fringe field, making it easier to use standard patient monitoring equipment. High-field systems are often manufactured with magnetic shielding of different types to reduce the fringe field. This shielding may surround the magnet (passive shielding), be generated by a second set of superconducting magnet windings surrounding the main field (active shielding), or be built into the wall (room shielding). Two distances are of concern regarding the fringe field. The 0.5 mT (5 G) distance is considered the minimum safe distance for persons with conventional pacemakers. This distance prevents interference of the pacemaker operation by the magnetic field. An important study describes MRI-compatible pacemakers (Sommer et al., 2006; Nazarian et al., 2006) that have been developed and are in clinical use in Europe. The 0.1 mT (1 G) distance, the nominal distance for other equipment that uses cathode ray tube monitors, prevents distortion of the image on the monitor by the magnetic field. The actual distances are installation- and equipment-specific. Contact the manufacturer regarding individual situations.

16.2 Cryogens

Most MRI magnets are manufactured with wire that becomes superconducting when immersed in liquid helium, an example of a cryogen. Cryogens are very cold liquids, specifically helium or nitrogen, which are used in superconducting magnets to maintain the magnetic field. These liquids boil at temperatures well below 0 °C (helium at –270 °C, nitrogen at –196 °C). During refilling of the magnets with these liquids, contact with the transfer line can cause frostbite. In addition, the occurrence of a quench or spontaneous discharge of the magnet

will cause the energy within the magnet windings to heat up the interior of the magnet. This heat will cause the helium liquid to boil, increasing its volume by three orders of magnitude. Manufacturers connect exhaust pipes to vent this gas to the exterior of the building so that the gas will escape harmlessly. However, should this vent become occluded, the gas will escape into the scan room, displacing the oxygen. In the event of a quench, all personnel and patients should evacuate the scan room.

16.3 Gradients

One area of concern with gradients is the potential for the stimulation of nerve tissue produced by the change in $\boldsymbol{B}_0$ caused by the gradient. If the change in $\boldsymbol{B}_0$ is large and rapid enough (represented by the quantity dB/dt), then nerve stimulation may occur. The greatest area for this is at the edge of the gradient coil, as this is where the gradient amplitude change is greatest. This corresponds to the entrance to the bore for a solenoidal magnet. Manufacturers are required by the governing regulatory organizations (FDA, IEC, etc.) to limit dB/dt so that no cardiac stimulation occurs due to the gradient pulsing. Because of the directional nature of the gradients and the nerve tissue, scan protocols may be limited in one direction more than another to reduce the potential for stimulation. Limitations in a scan protocol are most frequently encountered when rapid gradient pulsing is used, such as in echo planar sequences, or gradient echo sequences with a small FOV and short *TR*, as in cardiovascular imaging.

A second area of concern with gradients is acoustic noise. The gradients are generated by electrical currents and a mechanical force is produced in the gradient coil winding as a result of interactions with the base magnetic field. This process is the same as used in a loudspeaker connected to an audio amplifier. The amount of noise generated in an MR scan depends on the rate and strength of gradient pulsing. Different pulse sequences will create different amounts of acoustic noise (e.g., spin echo versus echo planar imaging). Also, certain operator parameters will affect the volume; for example, small FOV, thin slices, short *TR*. In many cases, hearing protection for the patient may be advised.

16.4 RF power deposition

Although MR is considered a relatively safe imaging technique, the *T1* relaxation process converts the absorbed RF power to heat inside the patient. Manufacturers are required by the governing regulatory organizations (FDA, IEC, etc.) to have two monitors, either hardware or software, to limit the RF power deposited in a patient (IEC). This is

to ensure that excessive patient heating does not occur over both the excited tissue volume (localized) and the entire patient (whole body). To accomplish this, the specific absorption rate of energy dissipation or SAR is monitored. The SAR is measured in watts of energy per kilogram of patient body weight ($W\,kg^{-1}$). MRI systems are designed to operate at or below the SAR guidelines, which are set to limit the core body temperature rise to approximately 1 °C or less, with slightly higher elevations allowed for regional examinations. For low-field scanners, the SAR seldom limits the measurement protocols. For high-field scanners, the SAR limits have a significant effect on the number of slices or saturation pulses that can be applied to the patient within a scan. The major challenge is in the estimation of the amount of tissue exposed to the RF energy. This depends on the nature and transmission profile of the transmitter coil as well as the patient size. Consult the manufacturer for specific details on the SAR monitoring system that is incorporated into a particular scanner.

16.5 Contrast media

In general, MR contrast agents have a relatively good safety record. Adverse reactions to the presence of the media have been rare. However, there have been reports of nephrogenic systemic fibrosis (NSF) occurring in patients with acute or class 4 or 5 chronic renal failure when administered gadolinium-based contrast agents (Kuo et al., 2007). While not present in all cases, most of the patients who developed NSF were given high dosages (frequently used for angiographic studies) of nonionic agents. The hypothesis is that the stability of these compounds, both kinetic and thermodynamic, is less than for the ionic linear and macrocyclic agents. As a result, unchelated gadolinium is present in larger concentrations, leading to increased deposition in tissues, primarily the skin. The US FDA issued a "black box" warning (US Food and Drug Administration, 2006) recommending against the use of gadolinium-based contrast media for patients with renal insufficiency unless the diagnostic information is essential and cannot be obtained using a noncontrast technique.

A second group of patients for which contrast media is not recommended is pregnant patients. While there are no studies to suggest that there is a risk to the fetus by contrast media, caution should be used in performing these studies. Bone deposition is a potentially serious complication of gadolinium contrast use in the fetus and children, as gadolinium is a calcium analog and can be taken up in bone. Nonionic linear agents should not be used for these patients.