

## Is MRI as safe as we think?

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### Abstract

Magnetic resonance imaging (MRI) is widely used as a non-invasive imaging modality for a wide variety of diseases and disorders. A patient placed in the MR machine for scanning is subjected to a powerful static magnetic field, rapidly varying gradient magnetic field, and radiofrequency field – in addition to the risk factors associated with gadolinium-based MR contrast agents. At present, there is no conclusive evidence for adverse biological effects in patients undergoing MRI. However, a clear understanding of the various bioeffects associated with MRI diagnostics is necessary to ensure the safety of patients as well as to justify its clinical use.

### Introduction

Magnetic resonance imaging was introduced as a clinical imaging modality by Lauterbur in 1972.<sup>1</sup> Since then, more than a hundred million diagnostic procedures have been completed worldwide, with relatively few major incidents or side-effects.<sup>2</sup> A potential health hazard of MRI is the influence of static, gradient and radiofrequency fields. Although guidelines have been laid for maximum permissible limits for each of these fields, they have been regarded as ‘...interim and somewhat arbitrary in nature.’<sup>3</sup> Numerous research studies conducted to date have failed to demonstrate any significant or unexpected hazards at currently used field strengths in clinical MRI; however, the data are not comprehensive enough to assume absolute safety.

#### Bioeffects due to static magnetic field

Extensive studies on the bioeffects of the static magnetic field in MRI diagnostics have been conducted over the past 30 years. Most of these studies concluded that exposure to static magnetic fields produces no significant bioeffects. Although there have been reports of harmful effects on isolated cells by static magnetic fields, no effect has been clearly verified as a scientific fact. The only well-established observation is the augmentation of T-wave amplitude and other nonspecific waveform changes on an electrocardiogram (ECG); these have been observed at static magnetic field strengths as low as 0.1 Tesla.<sup>4</sup> The increase in T-

wave amplitude is proportional to the intensity of the static magnetic field. Once the patient is removed from the magnetic field, these ECG abnormalities revert to normal. As no circulatory alterations appear in association with these ECG changes, no biological risks are believed to be connected with magneto-hydrodynamic effects in static magnetic field strengths up to 2 Tesla.<sup>4</sup> According to the latest guidelines from the USA's Food and Drug Administration (FDA), clinical MR systems using static magnetic fields up to 8.0 Tesla are considered ‘a non-significant risk’ for patients above the age of 1 month.<sup>5</sup>

#### Bioeffects due to time-varying gradient magnetic fields

During MR procedures, gradient magnetic fields may stimulate nerves or muscles by means of induction. At sufficient exposure levels, peripheral nerve stimulation is perceptible as ‘tingling’ or ‘tapping’ sensations. At gradient magnetic field exposure levels of 50 - 100% above perception threshold, patients may experience pain. At extremely high levels, cardiac stimulation may occur. However, the induction of cardiac stimulation requires exceedingly large gradient fields of a magnitude greater than those used for commercially available MR systems.

Studies performed on human subjects indicated that anatomical sites of peripheral nerve stimulation vary depending on the activation of a specific gradient (i.e. x-, y- or z-gradient).<sup>6</sup> Stimulation sites for x-gradients included the bridge of the nose, left side of thorax, iliac crest, left thigh, and lower back. Stimulation sites for y-gradients included the scapula, upper arms, shoulders, right side of thorax, iliac crest and upper back. Stimulation sites for z-gradients included the scapula, thorax, xyphoid, abdomen, iliac crest, and upper and lower back.<sup>6</sup> Typically, peripheral nerve stimulation sites were at bony prominences. According to Schaefer *et al.*,<sup>6</sup> since bone is less conductive than the surrounding tissue, it may increase current densities in narrow regions of tissue between the bone and the skin, resulting in lower nerve stimulation thresholds than expected.

#### Bioeffects due to radiofrequency fields

The majority of radiofrequency (RF) power transmitted for MR imaging is transformed into heat within the patient's tissue as a result of resistive losses.<sup>7</sup> The bioeffects associated with exposure to RF radiation are thus mainly related to the thermogenic effects. Many investigations have been conducted to characterise the thermal effects of MR-related heating. Investigators have quantified exposure to RF radiation by means of determining the specific absorption rate (SAR). The SAR is the mass-normalised rate at which RF power is coupled with biological tissue and is typically indicated in units of watts per kilogram (W/kg).<sup>8</sup> The relative amount of RF radiation that an individual encounters during an MR procedure is usually characterised with respect to the whole-body averaged and peak SAR levels. The SAR produced during an MR procedure is a complex function of numerous variables – frequency, the type of RF pulse used (e.g. 90° v. 180° pulse), the type of RF coil used,

repetition time, the volume of tissue contained within the coil, and other factors.<sup>8</sup>

With regard to RF fields, the FDA currently stipulates that MR procedures involving SAR values above the following levels are a significant risk:<sup>8</sup>

- 4 W/kg averaged over the whole body for 15 minutes
- 3 W/kg averaged over the head for 10 minutes
- 8 W/kg averaged over the head or torso per gram of tissue for 5 minutes
- 12 W/kg averaged over the extremities per gram of tissue for 5 minutes.

Response to MRI-related heating depends on physical, physiological and environmental factors; these include duration of exposure, rate of energy transfer deposition, patient's thermoregulatory system, the underlying health condition, and environmental conditions within the MR machine. Certain human organs, such as the testis and the eye, are particularly sensitive to elevated temperatures owing to their reduced capability to dissipate heat. These are potential sites for harmful effects if RF radiation exposure during MRI exceeds permissible limits.<sup>8</sup>

### Hazards associated with strong magnetic field

One of the most significant potential hazards around a magnet is the 'missile effect'. Magnetic objects in close proximity to a magnet can be drawn towards it with sufficient velocity to cause injuries. A hazard also exists for patients with ferromagnetic implants or foreign bodies as a result of movement or dislodgement of the objects<sup>9</sup> or their heating up as a result of current induction. Hence, patients with cardiac pacemakers, cerebral aneurysm clips, implanted electrodes (e.g. cochlear implants, bone growth stimulators), shrapnel, bullets, etc. should be kept away from the electromagnetic field of an MR machine.

### Safety considerations of MR contrast media

MR contrast media are gadolinium-based compounds with paramagnetic properties; they develop a magnetic moment and thus alter the image of hydrogen atoms in a magnetic field. Free gadolinium is toxic, so it is chelated with another compound that reduces its toxicity by altering its pharmacokinetics. Various MR contrast agents are available on the market – gadodiamide (Omniscan), gadopentetate (Magnascan), gadoteridol (Prohance), etc. – each with its own advantages and disadvantages. Excretion of gadolinium is mainly by the kidneys and to some extent by the liver. According to the American College of Radiology (ACR) guidelines, no patient may be administered MR contrast agents without authorisation from a duly licensed physician. The overall incidence of adverse reactions for MR contrast agents ranges from approximately 2% to 4%;<sup>10</sup> symptoms include nausea, emesis, urticaria, anaphylactoid reactions, hypotension, nonspecific ECG changes, injection site discomfort, localised oedema, taste change, etc. Transient elevation of serum iron and bilirubin has been observed on laboratory investigations. MR contrast media should therefore not be administered to patients with known or suspected sickle cell anaemia, renal failure or hypersensitivity to gadolinium. It was recently noted that a few patients developed a very rare disease – nephrogenic systemic fibrosis (NSF) – that is seen only in patients with severely impaired renal function;<sup>11</sup> it is associated with increased tissue deposition of

collagen, resulting in fibrosis and thickening and tightening of the skin, usually involving the extremities but possibly also any part of the body. Each of these patients had been administered a gadolinium-based MR contrast agent for MR imaging within a few weeks of the onset of the disease. Accordingly, the FDA recommends caution in administering gadolinium-based MR contrast agents to patients with moderate to end-stage renal disease, and also advises consideration of haemodialysis treatment immediately after administration of these agents to such patients. Furthermore, there is no concrete information regarding the safety of these agents in pregnant women, lactating mothers or children up to 2 years of age.

### Safety considerations for specific population subgroups

As mentioned, certain population subgroups (such as infants, pregnant women, lactating mothers, and patients with cardiac and renal failure and anxiety and panic disorders) require special precautions. Studies to date have not conclusively documented any deleterious effects of MR imaging on the developing fetus, but the evidence is not sufficient to presume absolute safety. As gadolinium-based MR contrast agents have been shown to cross the placenta, a decision to administer the contrast agent to pregnant patients should be accompanied by a well-documented and thorough risk/benefit analysis. Lactating mothers are advised to express their breastmilk and not breastfeed for 36 - 48 hours after MR contrast administration, as these agents have been shown to be excreted in breastmilk in very low concentrations. Infants and small children require sedation for MRI, primarily because of their inability to remain motionless during the procedure. Apart from the risks of sedation and anaesthesia, precautions are advised in administering MR contrast agents to infants <1 year old as their renal function is not completely developed. Proper explanation of the procedure, improvements in MR design and relaxation methods can be helpful in psychological problems associated with MR procedures.<sup>8</sup>

### Miscellaneous safety considerations

These include acoustic noise problems, asphyxiation and frostbite (an inadvertent system quench). During MR scanning, various acoustic noises are produced,<sup>12</sup> the primary source of which is the gradient magnetic field activation during the MR procedure. Problems associated with this noise include annoyance, heightened anxiety, and temporary and rarely permanent hearing loss.<sup>12</sup> Disposable ear plugs can be used to offer protection. In a case of system quench and release of helium and/or nitrogen gas all patients and health professionals should immediately evacuate the area.

### Risk to MR workers from long-term exposure

There are many reports in the literature that submit evidence of various adverse health effects associated with long-term exposure to electromagnetic fields, including elevated cancer risk and abortion rates. Although these observations have not yet been supported by empirical proof, the perceived occupational risk requires exposure monitoring in MR imaging workers.<sup>13</sup>

## Conclusion

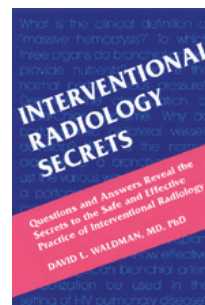
MRI, although a very useful clinical imaging modality, requires a clear

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knowledge and understanding of the various components of an MR system and its safety considerations, not only to ensure its prudent use for the benefit of patients but also to minimise the occupational risk to health care professionals and to provide efficient system operation.

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## Interventional Radiology Secrets



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