Standardized Approaches to MR Safety Assessment of Patients with Implanted Devices

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KEYWORDS

• MR imaging • Safety • MR safety • Standardization • Magnetic fields • RF fields
• Gradient magnetic fields

KEY POINTS

- MR imaging is unique in that instead of using only 1 energy source, 3 distinct fields/energy sources are used to generate every MR imaging image/study.
- Each field/energy source is associated with its own unique safety risk(s) for humans, especially for those in whom there are implanted devices or foreign bodies.
- Each field/energy source, and therefore attendant risk potentials, is located within the MR scanner and patient in a spatial distribution pattern that is (a) not homogeneous and (b) unique to each field/energy source.
- The location of greatest risk associated with a given MR imaging field or energy source can be physically quite remote from the anatomy being imaged.
- A standardized approach to assessing and even beginning to quantify risk of a device/foreign body patient undergoing an MR imaging examination is achievable and is outlined in this article.

INTRODUCTION

For more than a century, diagnostic radiology has been based primarily for taking a radiograph energy source and directing it so that at least part of the radiographs produced by this source would irradiate an anatomic region to be evaluated. Some of the radiograph photons shined at the anatomic region of interest would be absorbed, reflected, and/or deflected predominantly by the electrons within the tissues so irradiated. Others managed to successfully pass through the irradiated tissues unscathed. The greater the number of radiograph photographs that successfully struck the receiver on the other side of the patient being studied, the blacker that region of the image would appear, and vice versa. In this fashion, we would probe predominantly relative electron density on all radiograph-based studies. Anatomy with greater relative electron density, such as electron-rich bone or iodine-containing contrast agents, would appear whiter, whereas electron-poor regions, such as lung and air, would appear darker.

There are several known risks associated with exposure to ionizing radiation, with the dominant one being the potential to induce mutations/carcinogenesis. One way that diagnostic radiology manages this risk is to routinely only expose the anatomy to be examined to such ionizing radiation. For example, in the process of acquiring a chest radiograph, the transmitted energy is collimated in such a way as to only irradiate or expose the chest to this ionizing radiograph beam. Although the target volume to be examined is

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indeed exposed to this energy, collimation ensures minimal to no significant exposure to, for example, the radiograph-sensitive gonads while acquiring that chest radiograph.

Also inherent to such radiograph studies is the fact that the region that IS exposed to ionizing radiation is quite homogeneously exposed, such that the sides and middle of the irradiated volume are exposed to very similar levels of ionizing radiation, in both in energy levels (kV) and quantity/duration (mA·s). Furthermore, it is obvious to all that there is no "exposure" of the patient to this ionizing radiation unless we are actively "taking the picture." Before and after the actual "exposure," there are no ionizing radiation safety considerations associated with the (inactive) radiograph equipment.

This comfortable and familiar model has been integrally associated with diagnostic radiologists since our specialty began over a century ago. One energy source, one associated set of risks from that energy exposure, homogeneous irradiation of (and only of) the anatomy to be evaluated, any associated potential risks are restricted to (and only to) the tissue being examined, and of course the patient's tissues are only exposed to this diagnostic energy while the system is activated for diagnostic imaging purposes. Between patients, there is no such energy produced, because the energy source is inactive, and therefore, no associated risks about which to be concerned.

It is precisely this clean, neat, predictable paradigm that was broken with the introduction of diagnostic MR imaging. MR imaging provides soft tissue contrast in a literally unprecedented manner. However, much of the science underlying the MR imaging process is foreign and entirely non-intuitive to many radiologists. Indeed, the name of our profession itself - radiology - underscores its dependence upon x-rays and ionizing radiation-based imaging - and not one based on magnetic fields.

MR imaging introduces several significant and quite nonintuitive changes into the ionizing radiation–based safety risk assessment model described above. With MR imaging, we are no longer dealing with a single energy source; rather, multiple energy sources are required to produce these powerfully diagnostic images. Furthermore, each of these energy sources is associated with its own risk or set of risks, and these differ from those of each of the other energy sources used in diagnostic MR imaging studies. In addition, the spatial distribution of these energy sources is not only heterogeneous, but each of the various fields or energies used in the MR imaging process has its own unique spatial distribution pattern. To make matters worse, the *temporal* distribution of these energy sources also differs among the various energies and fields used in the MR imaging process. Some are present only during active imaging; others are present even when no imaging is taking place. In fact, some of these energies may be present even when the system is apparently inactive and "off," when no patients are being examined, and the site itself is powered down for the night!

With MR imaging, our comfortable safety model is dramatically modified (**Table 1**). To safely perform MR imaging on our patients, we have to learn an entirely new paradigm and must be able to logically apply that new algorithm and understanding to patient and device safety evaluations. That has proven to be both daunting and frustratingly nonintuitive for most of its practitioners.

This article focuses on precisely this algorithm. It would require a textbook to provide the details and nuances of each energy, their myriad associated risks, their unique spatial distributions subtleties, and their customized risk mitigation strategies. However, the purpose of this exercise is to provide an outline of the major underlying issues followed by an algorithm that can be successfully applied toward systematically assessing and even pseudo-quantifying the risks associated with MR scanning of patients with implanted devices, implants, and/or foreign bodies.

ENERGIES/FIELDS

Every MR imaging study uses 3 different energies or fields that can be broken down into 4 fields, as follows.

Static Magnetic Field (Bo)

Intrinsic in the clinical MR imaging process is the requirement to magnetize the hydrogen nuclei of the tissues being imaged. This process is accomplished by exposing the patient to a powerful static magnetic field, commonly referred to as the Bo magnetic field. The most commonly used static magnetic field strengths used in clinical MR imaging today are 1.5 T followed by 3 T. This static magnetic field Bo can be thought of as having a "frequency" of zero, because it never changes before, during, or after the patient undergoes their MR imaging study.

Static Magnetic Field Gradient (dB/dx)

As one approaches the MR scanner, the strength of that MR scanner's static magnetic field increases. One could thus map the *spatial rate of change* of the magnetic field that envelopes that MR scanner, where the spatial rate of change of

Table 1
Differences between radiograph/computed tomography- and MR imaging-based risk assessments

Modality	Radiograph/Computed Tomography	MR Imaging
Number of fields and/or energy sources	1	3 (4)
Associated risks	All associated with ionizing radiation (carcinogenesis, cataractogenesis)	Varied, with unique risks associated with each energy or field used in the MR imaging process
Irradiation pattern	Homogeneous through the anatomy being evaluated	Heterogeneous and homogeneous throughout the anatomy being evaluated, and heterogeneous outside of the volume being evaluated
Potential risk exposure	Only the anatomy/volume being evaluated	Tissue and structures within as well as physically quite distant from the anatomy/volume being evaluated
Temporal associations of potential risks	Only during active imaging	Some are only present during active MR imaging; others are active at all times, whether the system is imaging or even "on" or not

the magnetic field as one gets closer to the scanner increases the closer one gets to the scanner itself. For example, at the entrance to the room containing the MR scanner, with each centimeter one approaches the scanner opening, the magnetic field might get 1 G stronger. However, at close proximities to the MR scanner with each centimeter closer that one gets to the scanner, the magnetic field might measure 1000 G stronger! Thus, the spatial rate of change, or dB/dx, associated with the Bo static magnetic field of that scanner can be mapped out and is stronger in certain locations in the room and in the magnet bore than in other regions. Of course, because the Bo magnetic field is, by definition, static or constant, this spatially changing dB/dx magnetic field gradient is also static and does not change over time, hence, the name fixed spatial magnetic field gradient, or magnetic spatial gradient, or fixed field gradient, or spatial field gradient. One could say that it has a "frequency" of zero, because it never changes, just as the "frequency" of change of the static field Bo is zero.

Time-Varying Magnetic Field (Imaging) Gradients (dB/dt)

Time-varying gradient magnetic fields are used for multiple purposes in MR imaging, but one of their most critical functions is to enable spatial localization of the signals detected in the MR imaging process. These magnetic fields, produced by 3 sets of orthogonally oriented spatially coregistered gradient coils, vary in strength in a fixed manner across 1 axis in space. Thus, when a transverse gradient is activated, it generates a magnetic field that is, for example, stronger on the left of the patient in the scanner bore and weaker on the right of that patient at the same time. Further, the rate at which that magnetic field changes from stronger on the left to weaker on the right is fixed and constant. A magnetic field that changes in this fashion would be referred to as a linear magnetic field gradient. Linear gradient magnetic fields are turned on and off thousands or tens of thousands of times during a typical MR imaging sequence.

Time-Varying Radiofrequency Magnetic Fields (B1)

Time-varying radiofrequency (RF) oscillating magnetic fields are irradiated into the patient's tissues in order to effect resonance with the patient's hydrogen nuclei exposed to that MR scanner's Bo magnetic field. It is this resonance that results in the tissues absorbing some of this RF irradiated energy and becoming "excited," and it is manipulation and ultimate detection of this excited energy and how it returns to its baseline that we detect. Detecting how different tissues uniquely handle this resonantly absorbed energy is one of the most basic methods used in the MR imaging

process to differentiate and contrast various tissues from each other. This B1 energy is itself oscillating at millions of times per second, and hence, the name *radiofrequency* (the precise frequency of which is determined by the strength of the Bo magnetic field of that particular MR scanner). Furthermore, this same RF magnetic field is itself transmitted as pulses, and dozens or hundreds of such pulses may be transmitted per second (depending on the precise MR imaging study design). Thus, technically, the RF (B1) energy is an RF oscillating magnetic field B1 that is itself modulated at extremely low-frequency rates.

DESCRIPTION OF ASSOCIATED RISKS

Each of the above 4 energies or fields is associated with its own risk or set of risks. The predominant ones are included in later discussion. Please note that potential biologic risks, such as mutagenicity/carcinogenesis or acoustic noise, are beyond the scope of this article and will not be discussed herein.

Static Magnetic Field (Bo) and Static Field Gradient (dB/dx) Associated Potential Risks

Because the Bo and dB/dx magnetic fields are constant, the risks associated with the Bo and dB/dx magnetic fields are themselves also always present, even when the MR scanner is "off" and not being used for imaging. The main risks associated with a static magnetic field Bo and its associated static field gradient dB/dx include those associated with induced forces on ferromagnetic materials/objects within that field. Such forces include the following:

1. Torque: Ferromagnetic objects in the field with asymmetric aspect ratios experience a force that would tend to align their long axes parallel to the lines of force associated with that field. The stronger the Bo static field to which such a ferromagnetic material/device is exposed, the stronger the torque related forces.
2. Translation: As one first approaches an MR scanner's magnetic field, ferromagnetic objects approaching the MR scanner would experience a pulling force that would translate or "slide" that object toward the magnet opening. This force is itself determined (among other factors) by the strength of the static field Bo at the location where the ferromagnetic object is found as well as the static field gradient dB/dx across the ferromagnetic object at that position in space. In general, the stronger the static magnetic field Bo (until magnetic saturation is achieved in the ferromagnetic material/object) and the greater the spatial fixed gradient (dB/dx) across the object, the stronger the displacement translational, or "missile effect," related forces attempting to displace the object toward the higher field strength (greater dB/dx) locations.
3. Device modification/alteration: Incapacitation or alteration of the function of a device may result from exposure of that device to strong static magnetic fields Bo and/or static magnetic field gradients dB/dx. This is another risk associated with Bo and dB/dx distinct from that of physical harm from torque or translational forces experienced by ferromagnetic materials exposed to these fields.
4. Lenz's forces: Even if material is NON-ferromagnetic, electrically conductive material moved through static field gradients can result in induced voltages and currents within the moved material. These in turn can secondarily generate magnetic fields that oppose the original motion vector. Thus, there are grossly detectable forces on electrically conductive materials even if they are nonferromagnetic, such as aluminum, that are moved through the static magnetic fields associated with an MR scanner. The more rapid the movement, the greater the strength of these induced Lenz's forces. Thus, rapid motion of certain devices or implants in the immediate vicinity of the entrance to the MR scanner can result in grossly detectable forces on almost any metal devices, implants, materials, or foreign bodies. These may vary from barely perceptible induced forces to overt dislodgement of the implant.

Imaging Gradients (dB/dt) Associated Potential Risks

There are several risks associated with time-varying gradient magnetic fields dB/dt. For example, the auditory sounds or noises associated with the MR imaging process can be sufficiently strong to result in hearing loss. However, as the focus of this article is implant safety, these will not be further elaborated upon here. Furthermore, although heating of implants from exposure to sufficiently strong and prolonged dB/dt is possible, at today's exposure values these are typically minor levels of heating and are not generally a major safety issue associated with dB/dt energies.

The primary risk associated with dB/dt energies is that of inducing neuroexcitation of nerves exposed to sufficiently strong/long time-varying dB/dt, or imaging gradients. Such excitation would be expected to be accompanied by excitation of

whatever was at the distal end of the excited nerve. If it would be a muscle, then twitching of that muscle might result. If the heart would be found at the end of that nerve, such neuromuscular excitation or "twitching" would be referred to as an arrhythmia. The likelihood of such arrhythmogenesis would be greatly potentiated if a wire or lead would be in the volume exposed to time-varying dB/dt energies, focusing those induced electrical fields at the tip of that wire or lead where the heart muscle is found.

Radiofrequency (B1) Associated Potential Risks

By far, the single major risk associated with tissues exposed to irradiated RF energies is that of power deposition or heating. Diffuse patient heating and core hyperthermia is one such potential risk, but once again, because this article deals with implant safety, that will not be further dealt with herein. Focal heating, however, can also result from RF irradiation, and that can be of sufficient magnitude to result in thermal injury/burns. It is important, however, to understand that it is not the transmitted time-varying oscillating B1 magnetic fields that heat the tissue. Rather, these transmitted B1 magnetic fields in turn induce time-varying electrical (E) fields, and it is these E-fields that can produce focal energy/heat deposition sufficient to result in thermal injury or burns. Accurately assessing implant/device safety in MR environments absolutely requires a recognition of the above, because this is what is responsible for the potential to induce burns at locations that might be physically quite remote from the B1 irradiated volume. In this regard, wires or leads exposed even in part to the transmitted RF (B1) energies may be uniquely efficient in focusing or concentrating these secondarily induced electrical fields at and just beyond the tip of these leads, an ideal setup for an RF-induced thermal injury or burn.

SPATIAL LOCATION OF ENERGIES/FIELDS AND, THEREFORE, RISKS

Static Field (Bo) Associated Potential Risks: Torque

The static magnetic field of MR scanners is always homogeneous and near its maximum strength in the region in which MR imaging is performed. Therefore, torque-related forces are always strong or near maximal at the center of the MR scanner where imaging is performed.

The spatial distribution of the Bo static field for a typical 1.5-T superconductive MR scanner is depicted in **Fig. 1**.

Static Field Gradient (dB/dx) Associated Potential Risks: Translational Forces, Lenz's Forces, Device Function Alteration/ Incapacitation

The homogeneity of the magnetic field in the volume in which MR imaging is performed means that the spatial field gradient (dB/dx) is at or near zero in the center of the scanner. Therefore, translational or missile-effect forces are ironically *weakest* in the center of the MR scanner. However, these forces reach maximal values as one approaches the physical ends/borders of the magnet coils of the MR scanner (regardless of whether the field is horizontal or vertical). For cylindrical bore configuration superconductive MR scanners, this means that the greatest translational forces are near the entrance to (and exit from) the bore, radially peripherally at the plastic faceplate of the scanner itself. For vertical field systems, the greatest dB/dx and therefore vertically oriented translational forces are typically also located near the radial outer edges of the scanner "plates" and are least and weakest in the (radial) center of the scanner. The spatial distribution of the dB/dx static magnetic field gradient for a typical 1.5-T superconductive MR scanner is depicted in **Fig. 2**.

Imaging Gradient (dB/dt) Associated Potential Risks: Neuromuscular Excitation

The shape of the 3 orthogonal imaging gradients is such that they tend to increase as we approach the left-right, anteroposterior, and superoinferior margins of the gradient coils themselves. Similar to a see-saw in a child's playground, the greatest change per unit time is at the ends of the produced magnetic field gradient/see-saw, and the smallest change per unit time is at its center. The center of the 3 gradient coils is physically coregistered to the center of the Bo magnetic field. Thus, the smallest dB/dt is at the center of the scanner, right where we positioned whatever anatomy of interest it is that we are imaging. At the radial periphery of the scanner are the strongest X (transverse) and Y (anteroposterior) gradients, and (depending on the design of the gradient coils) roughly 35 cm superior and 35 cm inferior to the center of the scanner is where the superoinferior gradient dB/dt maxes out. Thus, implanted or abandoned wires or leads in these positions would have the greatest induced voltages and currents from time-varying gradient dB/dt magnetic field, and therefore, the greatest potential for neuromuscular excitation is found at these locations.

Note that direct neuromuscular excitation of peripheral nerves, or peripheral nerve stimulation (PNS), is what is targeted by regulatory agencies.

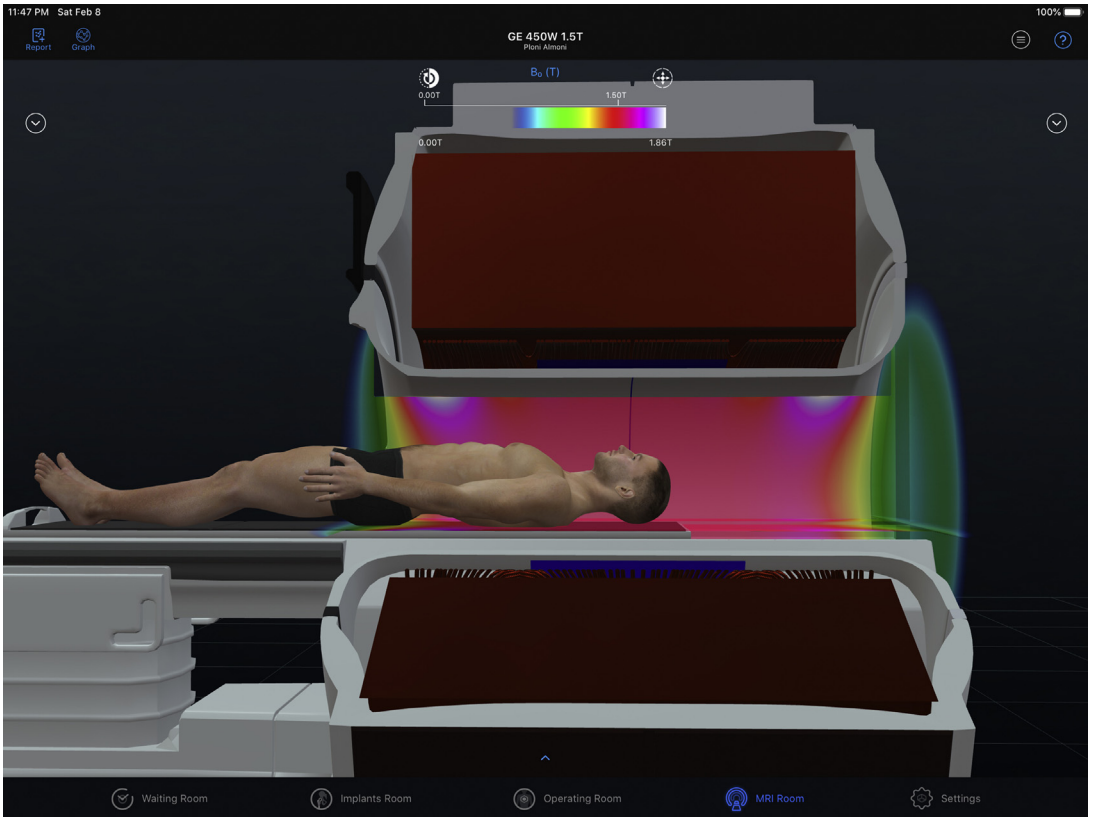

Fig. 1. Figs. 1–4 are 3-dimensional depictions of (for illustration purposes) a GE Healthcare 1.5-T 450-W MR scanner. For teaching purposes, the right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed 3 dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the static magnetic field Bo are depicted. (*Courtesy of* Dr Kanal, created using the MagnetVision app that he created, Advanced Magnetic Analytics, LLC.)

PNS itself is not typically harmful per se. However, PNS is achieved at lower levels of neurostimulation than is cardiac muscle stimulation. Therefore, if we do not see/experience PNS, we would not expect to be near cardiac stimulation thresholds. All this changes, however, if there is a wire or lead in the heart. This wire or lead has the potential to temporally and spatially focus induced electrical fields at the tip of the lead and can thus markedly potentiate arrhythmogenesis. Consider the situation of an abandoned cardiac lead where at least part of this lead is exposed to the dB/dt magnetic fields. The study may be centered on the L4 vertebral body for a lumbar spine study, but 35 cm or so superior to this location an abandoned lead in the heart may be exposed to maximal (superoinferior) dB/dt magnetic fields. Such a patient might therefore be exposed to significant arrhythmogenic stimulation despite the fact that the study in question is centered on anatomy that is physically remote from the heart and its abandoned lead.

The spatial distributions of the dB/dt time-varying imaging gradient magnetic fields for a typical 1.5-T superconductive MR scanner are depicted in **Fig. 3**.

Radiofrequency (B1) Associated Potential Risks: Thermal Injury/Burns

The transmitted RF (B1) oscillating magnetic fields induce time-varying electric (E) fields in electrically conductive materials, such as patient tissue. At locations of greater B1 magnitudes, there is the potential for greater induced E fields. B1 magnetic field maps associated with transmitting RF coils are dependent on many factors, including the shape and design of the transmitting RF coil. However, for typical birdcage coil designs, the greatest B1 fields are generally located radially nearest the physical edges of the coil itself, as well as at the superoinferior borders of the transmitting RF coil. There can be extremely rapid decay of B1 amplitude as one leaves the edges of the transmitting

Fig. 2. The strength and spatial distribution of the static/fixed spatial magnetic field gradient dB/dx. Notice that in the homogeneous static magnetic field at the center of the MR scanner, the strength of the dB/dx and therefore potential translational forces on ferromagnetic materials and objects are minimal. The greatest translational forces scale with the dB/dx of this magnet, which maximizes near the radial extremes/borders at the entrance (and exit) to the MR scanner bore. (*Courtesy of* Dr Kanal, created using the MagnetVision app that he created, Advanced Magnetic Analytics, LLC.)

RF coil and heads toward the radial center of the coil. Indeed, the designs are typically such that the central volume of transmitting RF coils has moderately homogeneous B1 fields, but are quite heterogeneous and significantly higher amplitudes at the extreme radial periphery of the coils. Recall, however, that it is not the B1 fields that are responsible for focal thermal injury/burns, but rather the secondarily induced e-fields. Therefore, the greatest induced e-fields tend to be at the radial periphery of these birdcage transmitting RF coils. However, once again, there is a significant exception to this rule: Should there be an electrically conductive tissue pathway, device, object, or foreign body, and especially, if there is a wire, that is exposed even in part to the transmitted B1 fields, these can be exceptionally efficient at concentrating secondarily induced e-fields at the tip of the wire or lead. Such tissue heating just distal to the lead tip could result *even if the tip of that wire is physically quite removed or distant from the volume that underwent primary RF (B1) irradiation!*

The spatial distribution of the transmitted time-varying oscillating RF (B1) magnetic fields for a typical 1.5-T superconductive MR scanner's body coil is depicted in **Fig. 4**.

STANDARDIZING THE APPROACH TO MR SAFETY ASSESSMENT FOR PATIENTS WITH IMPLANTS, DEVICES, AND FOREIGN BODIES

It is known that there may be very small risks associated with computed tomographic (CT) scanning of some models of active implanted cardiac devices.[1] Assume a pacemaker patient needs a head CT study. In assessing the risks of proceeding, the provided Food and Drug Administration guidance is quite straightforward: "The probability of x-ray electromagnetic interference is lower when radiation dose and particularly the radiation dose rate are reduced.

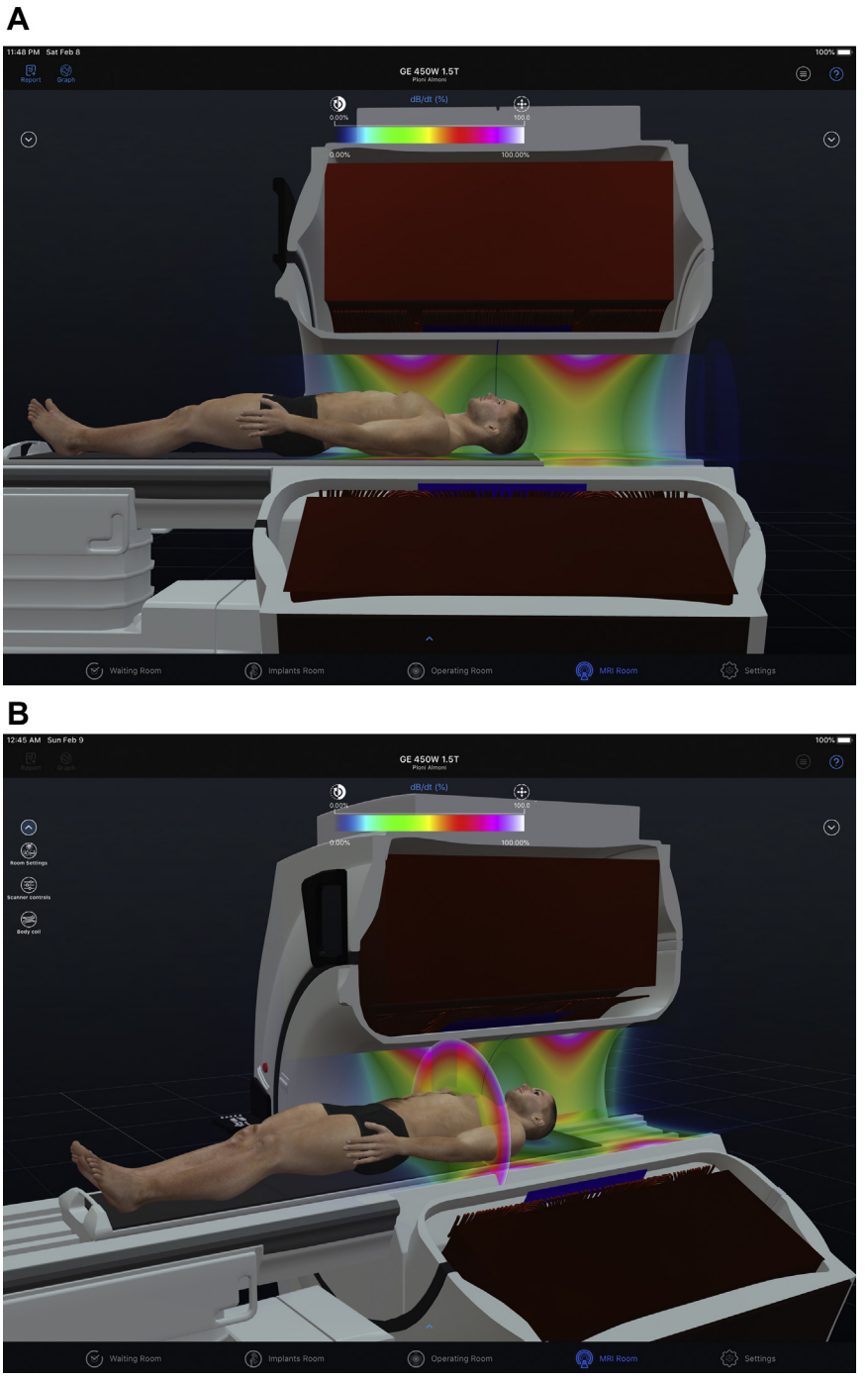

Fig. 3. (*A*) The strength and spatial distribution of the time-varying imaging gradient magnetic fields dB/dt. Note that when centered on the pituitary gland/brain the greatest dB/dt forces are over the chest of this patient, right where a cardiac pacemaker might be positioned. (*B*) The 3-dimensional nature of the 3 orthogonally oriented gradient magnetic fields, which increase in strength as the radial and superoinferior distance from center increases, and approaching the physical margins of the 3 gradient coils. (*Courtesy of* Dr Kanal, created using the MagnetVision app that he created, Advanced Magnetic Analytics, LLC.)

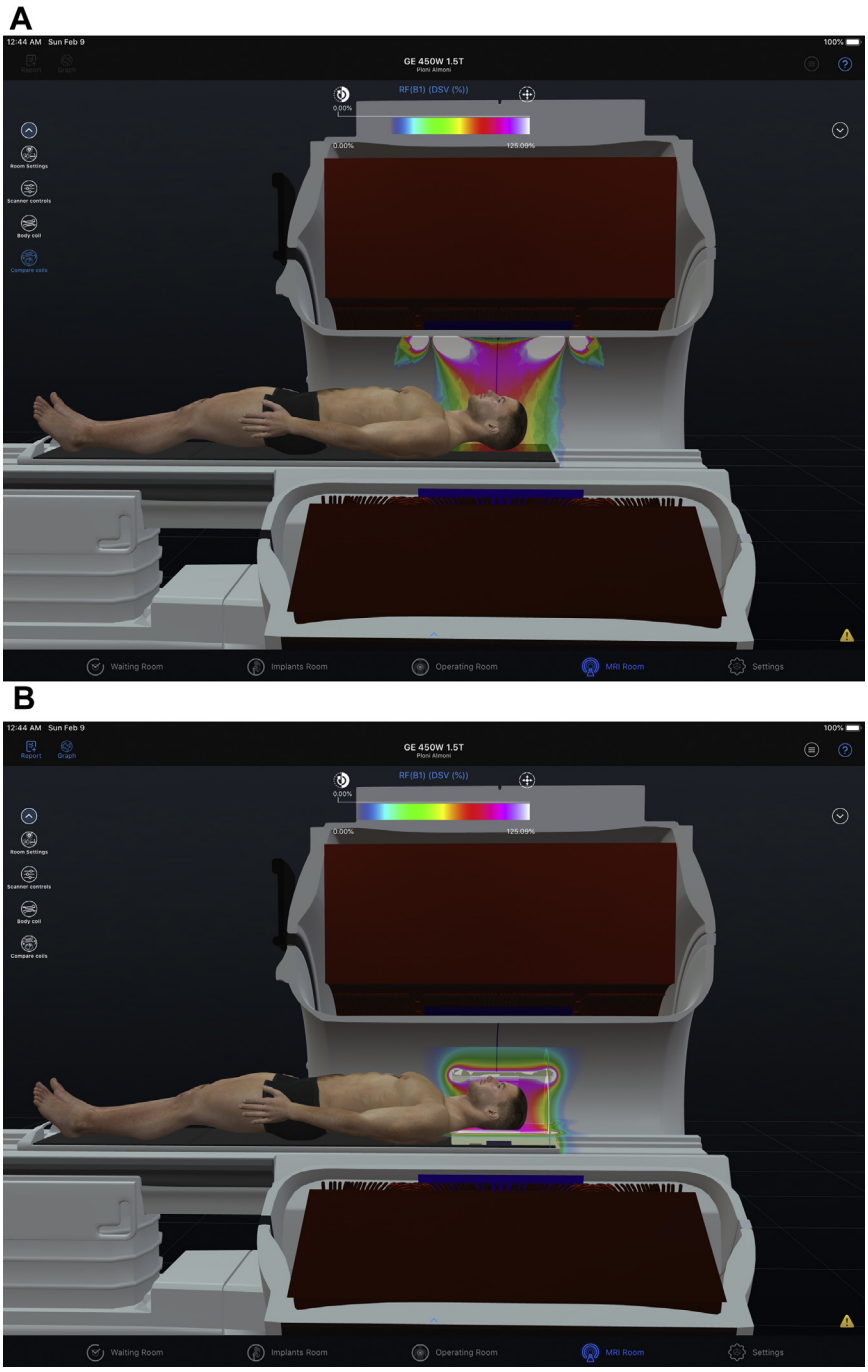

Fig. 4. (*A*) The spatial distribution of the transmitted RF (B1) oscillating magnetic fields with the body coil of this scanner being used as the RF transmitter hardware. (*B*) Note how the transmitted RF fields cover a smaller volume when a transmit-receive head coil is used for RF transmission in this same scanner. (*Courtesy of* Dr Kanal, created using the MagnetVision app that he created, Advanced Magnetic Analytics, LLC.)

Interference can be completely avoided when the implantable device is outside of the primary x-ray beam of the CT scanner." In other words, if you do not irradiate the device, there is no increased risk from CT scanning of such devices! As a famous self-defense instructor once taught, the best defense against a blow is to not be there when it lands.

Note that a risk was detected, and a means was implemented, to mitigate this risk to acceptable levels, thus permitting one to proceed with the requested head CT study on this pacemaker patient. The general algorithm of risk assessment has always been to (a) identify the potential risk(s) from the energy to be used for the requested examination; (b) quantify the risk to the patient/fetus/device for the requested study; then (c) either accept the potential benefit as being substantially greater than the perceived risk OR find a way to mitigate the potential risk back down to acceptably low levels (such as by ensuring that the fetus or implant were not exposed to the energy in question), and safely proceeded with the requested examination. Alternatively, cancel the examination if the potential risk is greater than the potential benefit of the study.

We have seen that MR imaging does not use one, but rather several, energy sources, each with its own associated potential risks and spatial and temporal distributions. Thus, to determine the safety of proceeding with a requested MR imaging examination on a patient in whom there is an implanted device or foreign body, it would be logical to follow the model that we have successfully used above. However, a few modifications are needed to accommodate the fact that multiple energy sources are used in MR imaging:

1. Identify the energy source and its associated potential risks;
2. Assess if the implant/foreign body would be exposed to this energy and therefore its associated risks;
3. Determine if these risks are acceptably low are not;
4. If the risks are at a concerning level, determine if any actions might be undertaken to mitigate those risks to acceptably low levels (relative to the potential benefit of proceeding with the examination in that same patient);
5. Repeat steps 1 to 3 for each of the energy sources used in the MR imaging process;
6. Repeat steps 1 to 5 for each implant, device, and/or foreign body in that patient.

If at any time through this process the potential risks significantly exceed the potential benefit of proceeding with the requested MR imaging study and cannot be mitigated, the examination should likely be canceled. If there are no or low risks from a given energy, and/or if risks might be present but can be successfully mitigated by some interventions effected by the user/operator, proceed with evaluation of the next energy to be used. This process is then repeated until all energies are considered, and no significant risks remain. This entire process is then repeated for all implants, devices, and/or foreign bodies in the patient. If no significant risks remain for any of the energies for any of the implants/foreign bodies in that patient, the potential benefit would likely exceed the low detected cumulative risks of proceeding.

Example 1

A 208 cm 32-year-old male semiprofessional basketball star with an abandoned left subclavian vein to inferior vena cava cardiac lead is requested to undergo an elective 1.5-T MR imaging examination of his right knee for a possible medial meniscal tear. Application of the above described standardized approach to risk assessment would produce the following (assessment questions in *italics*, responses in **bold**):

Energy #1: **Static field Bo**.

Associated risks: **Torque and translation**.

Is the device significantly exposed to this energy/field for the requested study? **Yes**.

Does the device exhibit significant ferromagnetic properties? **No; therefore, no significant associated torque (or translation) risk**.

Risk assessment for this energy: LOW.

Energy #2: **Static field gradient dB/dx**.

Associated risks: **Translation, Lenz's forces**.

Is the device significantly exposed to this energy/field for the requested study? **Yes**.

Does the device exhibit significant ferromagnetic properties? **No; therefore, no significant associated translational risk**.

Is the device electrically conductive? **Yes; therefore, there are potential Lenz's (displacement) forces**.

Can steps be taken to mitigate Lenz's forces? **Yes, move patient slowly through dB/dx fields**.

Risk assessment for this energy: LOW.

Energy #3: **Imaging gradients dB/dt**.

Associated risks: **Neuromuscular excitation/arrhythmogenesis**.

Is the device significantly exposed to this energy/field for the requested study? Recognizing the physical distribution of the dB/dt gradient fields relative to this implant in this patient positioned and centered as they will be for this study, **no, not for the requested study/patient dimensions and positioning; therefore, very low risk of arrhythmogenesis**.

Risk assessment for this energy: LOW.

Energy #4: **Transmitted RF (B1)**

Associated risks: **Thermal injury/burns**.

Is the device significantly exposed to this energy/field for the requested study? **No, not if a**

local transmit/receive extremity coil is used for RF transmission for the requested study/patient positioning; therefore, very low risk of thermal injury/burns.

Risk assessment for this energy: LOW.

Thus, it would seem that for the requested study, for this particular patient, for this particular study requested, for this particular device/implant/foreign body, for the specific MR hardware to be used, the potential risk of proceeding may be quite low.

Example 2

A 173 cm 94-year-old male patient with a suspected ferromagnetic jagged 13-mm foreign body (shrapnel injury from World War II) in the right chest just lateral to the right pulmonary hilum is requested to undergo a 1.5-T MR imaging examination of the lumbar spine for severe low back pain and a left L5 radiculopathy. Application of the above described standardized approach to risk assessment would produce the following:

Energy #1: **Static field Bo**.

Associated risks: **Torque and translation**.

Is the device significantly exposed to this energy/field for the requested study? **Yes**.

Does the device exhibit significant ferromagnetic properties? **Presumed YES; therefore, significant presumed associated torque (and translation) risk**.

Can steps be taken to mitigate torque forces? **NO**.

Torque risk assessment for this energy: HIGH.

Energy #2: **Static field gradient dB/dx**.

Associated risks: **Translation, Lenz's forces**.

Is the device significantly exposed to this energy/field for the requested study? **Yes**.

Does the device exhibit significant ferromagnetic properties? **Yes; therefore, significant presumed associated translational risk**.

Can steps be taken to mitigate torque forces? **NO**.

Is the device electrically conductive? **Yes; therefore, there are potential Lenz's (displacement) forces**.

Can steps be taken to mitigate Lenz's forces? **Yes, move patient slowly through dB/dx fields**.

(Translational) Risk assessment for this energy: HIGH.

Energy #3: **Imaging gradients dB/dt**.

Associated risks: **Neuromuscular excitation/arrhythmogenesis**.

Is the device significantly exposed to this energy/field for the requested study? **Yes, but short electrical length and position in right mid chest lateral to the right pulmonary hilum and not in/contiguous with the heart reduce risk for arrhythmogenesis**.

Risk assessment for this energy: LOW.

Energy #4: **Transmitted RF (B1)**

Associated risks: **Thermal injury/burns**.

Is the device significantly exposed to this energy/field for the requested study? **Yes, but short electrical length and central position in the chest/bore significantly decrease risk of thermal injury/burns**.

Risk assessment for this energy: LOW.

For this requested study, for this particular patient, for this device/implant/foreign body, for the specific MR hardware to be used, the potential risk of proceeding may be quite high from torque/translation of a jagged metallic piece of World War II shrapnel next to major pulmonary vasculature and the lung parenchyma itself. One might well consider canceling the requested study as the potential life-threatening risk of proceeding would far exceed the potential diagnostic benefit of a lumbar spine MR imaging for radiculopathy.

We can see how changing ANY of these clinical parameters (eg, requested study is a head or cervical spine MR imaging instead of knee, or different implant, or different patient/body habitus) requires us to start from scratch and perform a new safety assessment, because the answers and therefore risk quantification levels are specific to each presenting clinical situation.

SUMMARY

MR imaging is unique in that multiple energy sources are used to generate every MR study. The relative spatial distributions of these energies and their associated risks are unique to each energy/field. We can standardize our process of attempting to assess and pseudo-quantify the risks associated with MR imaging in patients with devices and/or foreign bodies by

1. Evaluating the potential risks of proceeding with the requested MR imaging study for each MR imaging energy/field for that implant/device/foreign body;
2. Attempting to mitigate any detected risks that might be present for any of the MR imaging energies/fields relative to that implant/foreign body;
3. Repeating this process for each implant, device, and/or foreign body in our patient and assessing final cumulative risks of proceeding with the requested MR imaging study.

By comparing the potential benefit against the final cumulative risks of proceeding with the

requested MR imaging study, we will be able to provide the patient with an informed and scientifically sound benefit-risk ratio about the safety of that particular requested MR imaging study, in that patient, on that MR scanner hardware.

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DISCLOSURE

The authors have nothing to disclose.

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