MRI Safety Update: 2012

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Preventing accidents and injuries in the MRI suite

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Major effort today to improve patient safety

Headlines:

Be more efficient!

Team Approach to MRI safety is needed in current environment...

• Improve MRI safety – everyone agrees but how and at what cost (time, $, people)?
• Image more patients, patients with devices,
• Image more complex cases, and patients who require substantial medical support (pumps, monitoring, nursing, anesthesia personnel)
• Add late/second/long shifts… train on weekends,
• Radiology will support 24/7 coverage …

This “access pressure” can affect safety…we must train ourselves and our teams to prevent mistakes!
Objectives

• To know the safety issues within MRI and the concerns cited by the Joint Commission.
• To know the safety items presented in the ACR Guidance Document for Safe MRI Practice
• To understand the strengths and limitations of ferromagnetic detectors (FD) and how they can be used and sited in MRI suites.
• To be able to interpret information about conditional implanted devices and implement safe MRI scanning strategies.


http://www.acr.org

Look for new 2012 version of this document!

- Static field related issues
  - Translational and rotational forces on ferromagnetic materials
- Time varying magnetic field related issues
  - Induced Voltage, auditory and thermal issues
- Personnel qualifications and training
- Site access limitations
- Pregnancy related issues
- Guidelines for Claustrophobia, anxiety, sedation, analgesia, and anesthesia
- Contrast agent safety
- Device safety
- MRI siting considerations and emergency planning

MRI Safety: Distilling it down

B0 effects
- Attraction force and torque, always on
- Maximum spatial gradient location (measure or vendor info)

RF Effects
- Heating, SAR
- (Testing, simulation, vendor info)
- Body transmit versus T/R coil

Gradient Effects dB/dt
- Noise (ear plugs)
- Peripheral Nerve stimulation
- Discharge batteries (active devices)

MRI Scanning modes
- Normal, 1st Control
  - Adjust/control SAR and dB/dt

Implanted Devices (limits, labeling)
- Gad Contrast/ Renal function/pregnancy
  - www.coppermoonshineatolls.com

Static Magnetic Field, B0
Magnetic field Spatial Gradient

The magnetic attraction of a magnetic dipole is driven by the gradient of the field:

\[ F = (\nabla \times \vec{B}) \times \vec{B} \]

Note: the regions at the magnet bore have the highest force and depend upon \( B_0 \) and magnet design!

Ref: Dr Mark Keene

Example: Spatial Gradient Effect

- No force and operational against 1.5T and 3T magnets
- Attracted and not operational against 1.5T short length, large bore magnet (Espree)
- Magnet design makes a difference!

Anesthesia machine designed for MRI environment
Example: Device Maximum Spatial Gradient

- **Formula 418 Balloon Expandable Biliary Stent**
  Nonclinical testing has demonstrated that the Formula biliary stent is **MR Conditional**.
- A patient with this stent may undergo MRI immediately after placement under the following conditions:
  - Static magnetic field of 3.0 T or less
  - **Maximum spatial gradient magnetic field of 720 gauss/cm**
  - Maximum whole-body averaged SAR) of 3.0 W/kg for 15 minutes of scanning
  - In nonclinical testing, the Formula biliary stent produced a temperature rise of less than 1°C at an SAR of 3 W/kg for 15 minutes of MR scanning in a 3 tesla system (Excite, Software G3.0-052B, GE Healthcare).

http://www.cookmedical.com/di/productMri.do

Practical Prevention Methods

- Screening of patients (Safety form, verbal)
- Annual Training (in and outside of MRI)
- Use of ferromagnetic detectors
- Control of MRI suite via locks, training requirements
- Remove ferromagnetic items from MRI area

The static magnetic field (B0) in MRI is the primary cause of the following safety concern during patient care?

<table>
<thead>
<tr>
<th>%</th>
<th>1. Peripheral nerve stimulation</th>
<th>2. Electrical current formation and tissue heating</th>
<th>3. Attraction and torque of ferromagnetic material and objects</th>
<th>4. Ionizing radiation build up during scanning</th>
<th>5. Shim volume aperture size limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Answer

1. Peripheral nerve stimulation
2. Electrical current formation and tissue heating
3. Attraction and torque of ferromagnetic material and objects
4. Ionizing radiation build up during scanning
5. Shim volume aperture size limitation


RF Effects

RF Excitation

• Body coil (bird cage typical) is commonly used for imaging
• We image with the magnetic component of the field.
• What happens to the electric field (heating)?
RF Energy Deposition & Heating

- E fields can induce electric current (i) in loops of conducting materials (i flows from high to low E field).
- Patients are conductors, heating results from current flow.
- Current at high impedance points can induce burns, e.g. wire tip, patient loops.

RF: What is SAR?

SAR = Specific absorption rate (Watts/kg)

W/kg = Energy per unit time per kg of tissue

Power is proportional to flip angle²

(Sequences play out more/less RF per unit time: e.g. GRE vs. TSE/FSE)

Tx/Rx coils (head, knee, wrist, foot) use less power, are limited to local volume and yield low SAR

All scanners limit the SAR delivered to patients using FDA or IEC limits.

IEC 60601-2-33 SAR Limits

<table>
<thead>
<tr>
<th>Body Region→</th>
<th>Whole Body SAR</th>
<th>Partial Body SAR</th>
<th>Head SAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Region→</td>
<td>Whole Body</td>
<td>Exposed Body Part</td>
<td>Head</td>
</tr>
<tr>
<td>Operating Mode↓</td>
<td>W/kg</td>
<td>W/kg</td>
<td>W/kg</td>
</tr>
<tr>
<td>Normal</td>
<td>2</td>
<td>2-10*</td>
<td>3.2</td>
</tr>
<tr>
<td>First Level Controlled*</td>
<td>4</td>
<td>4-10*</td>
<td>3.2</td>
</tr>
</tbody>
</table>

This table is based on an averaging time of 6 min. For short term SAR, the limits over any 10s period shall not exceed three (3) times the stated values.

* Monitoring required.
RF Coils Can Affect SAR

- Is this head coil Transmit/Receive or Receive only? (Most are receive only…)

Scanning Parameters and Operating Mode affect SAR

MRI is often First level operation, but Normal Mode is recommended in IEC standard for:
- Pregnant women
- Children weighing less than 20 kg
- Non-communicative patients, who are not being physiologically monitored
- Patients with certain implanted devices such as Vagal Nerve Stimulator
RF Warming Prevention Methods

• Keep scan room cool
• Bore fan turned on
• Place pads between arms and bore
• All patients get squeeze ball and instructions
• Temperature and humidity meters used in all scan rooms

B1rms versus SAR

The use of B1rms (RF amplitude rms) may be another useful measure of the potential for implant heating

SAR and other heating parameters are proportional to the square of B1rms.

MRI vendors will provide B1rms information for sequences

Device manufacturers may specify a maximum value for B1rms for their implants.

The radiofrequency field (B1) in MRI is the primary cause of the following safety concern during patient care?

0% 1. Peripheral nerve stimulation
94% 2. Electrical current formation and tissue heating
0% 3. Attraction and torque of ferromagnetic material and objects
0% 4. Ionizing radiation build up during scanning
0% 5. Extremely loud noise during scanning
Answer
1. Peripheral nerve stimulation
2. Electrical current formation and tissue heating
3. Attraction and torque of ferromagnetic material and objects
4. Ionizing radiation build up during scanning
5. Extremely loud noise during scanning


Time Varying Gradient Fields (dB/dt)
- Spatially encode Z, Y, X
- Can be loud!
- dB/dt limited by physiology - peripheral nerve stimulation (PNS)
- Operating mode controls dB/dt
- Can affect active devices, possible to discharge batteries...

Gradient Switching in Spin Echo

Gx
Gy
Gz
RF
TE
0 5 10 15 20 25 30

Time (ms)
Imaging Gradients

• Imaging sequences can use different dB/dt (e.g. SE vs EPI based DTI sequences)
• Gradients have rise times, and are not instantaneous
• Rise Time of each depends on hardware and software
• Slew Rate (SR) = Gradient Amplitude/Rise Time
• dB/dt can induce current in peripheral nerves causing sensation (discomfort or pain)

The gradient magnetic fields switching rate (dB/dt) in MRI is the primary cause of the following safety concern during patient care?

- Peripheral nerve stimulation: 94%
- Electrical current formation and tissue heating: 0%
- Attraction and torque of ferromagnetic material and objects: 0%
- Ionizing radiation build up during scanning: 0%
- Shim Volume aperture size limitation: 6%

Answer

1. Peripheral nerve stimulation
2. Electrical current formation and tissue heating
3. Attraction and torque of ferromagnetic material and objects
4. Ionizing radiation build up during scanning
5. Shim volume aperture size limitation
Sentinel Event Alert

- Five MRI related cases – 4 deaths
- Two levels of screening for patients prior to MRI
- All device history and data reviewed prior to MRI
- Staff training, Annual training
- Projectile effect prevention
- Device failure
- Burn prevention
- Hearing protection
- Cardiac Code plan
- MRI compatible equipment (include labeling)
  - extinguishers, O2 tanks, monitors, pumps…

MRI Labeling- Oxygen Tank 101

MR unsafe

MR safe
Manufacturers of MRI equipment rely on using weight and friction to prevent projectile accidents.

Some equipment has unavoidable ferromagnetic components, e.g. Patient monitors.

Other equipment (e.g. gurneys, chairs, IV poles) have ferromagnetic components to avoid the inconvenience of designing them out and to reduce manufacturing cost.

MRI equipment that contains ferromagnetic components are designated “MR Conditional”.

Conditions can include limits to B0, spatial gradient, RF power, dB/dt, operating mode, monitoring, staffing...

### MR Conditional Equipment

**MRI conditional device labeling indicates:**

1. Devices that cannot be allowed to enter zone 4.
2. Devices that have several features and conditions of operation.
3. Devices that are always safe to scan in MRI
4. Screening methods to be used prior to entering zone 3
5. Devices that can be scanned in MRI if specific conditions are met.

### Answer

1. Devices which cannot be allowed to enter zone 4 of the MRI suite.
2. Devices that have several features and conditions of operation
3. Devices that are always safe to scan in MRI
4. Screening methods to be used prior to entering zone 3
5. Devices that can be scanned in MRI if specific conditions are met
Ferromagnetic Detection (FD)

- Ferromagnetic materials perturb the local magnetic field.
- Field perturbations follow the object as it moves.
- A high sensitivity magnetic gradiometer senses the environmental field gradient.
- Ferromagnetic detectors are sensitive only to changing magnetic field gradients.
- A moving field perturbation triggers a visual/audible alarm.

Ref: Dr Mark Keene

Ferromagnetic Detection Systems

- Sensitive magnetometers can detect changes in the local magnetic field
  \[ V = -A \frac{\partial B}{\partial t} \]
- Patient must be moving
- Ferromagnetic metal distorts field, exceeds allowable threshold

Ferromagnetic Screening

- Patient walks toward device, turns then walks away
- Keys, other ferromagnetic metal are detected
Notes about FD Systems
Ferromagnetic detection systems are not a replacement for standard MRI safety rules and protocols (such as in ACR Practice Guideline).

They can be an important adjunct to provide a final check prior to entering the room or the last stage in the patient screening process.

JCAHO now requires new MRI sites to incorporate FD equipment site preparations at each MRI suite (power, access)

FD System Placement / Planning

- Patient flow
  - Change into gown
  - Move to FD screen
  - Move to sub wait
  - Move to scanner
- Placement
  - At scan room door
  - At entry alcove?

FD Placement/MR Zones

- Prior to zone 4
  - Max protection but affected by operator, door
- Prior to zone 3
  - Leaves access to zone 4 open
- Screen in zone 2
  - Convenient, but possible to pick up objects post screen
One Month FD Experience

• Initial equipment training, rated very highly by MRI technologists
• Site not ideal (retrofit)
  – FD detects technologist movement at op console
  – Sensitivity high – alarms set off by technologists (ferromagnetic metal in shoes, clothing)
  – Alarm triggered often by staff
  – Alarm ignored by cleaning crew (experienced crew in MRI but untrained in FD response)
    • Cleaning mop attracted into 3T magnet
    • No one hurt, crew member “I knew but thought I could hold on to it”

Why Accidents Occur – Can Training and Safety Devices Help?

• Faults in process… improve with review and use?
• Deliberate disregard of safety protocols by staff.
  “I know better than …”
• Ignorance of safety protocols due to lack of training (cleaners, maintenance, staff from other departments).
• Unintentional disregard of safety protocols by staff.
  Lapses in concentration or focus/ wrong decisions / mistakes …

Ferromagnetic detectors can be used to:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>1. Screen patients for objects with high SAR.</td>
</tr>
<tr>
<td>80%</td>
<td>2. Detect an object that may be attracted to the magnet.</td>
</tr>
<tr>
<td>0%</td>
<td>3. Detect when vibrations affect magnet signal stability.</td>
</tr>
<tr>
<td>0%</td>
<td>4. Evaluate ionizing radiation levels during scanning</td>
</tr>
<tr>
<td>20%</td>
<td>5. Screen patients for dB/dt fluctuations that are beyond normal limits</td>
</tr>
</tbody>
</table>
Answer

1. Screen patients for objects which may have high SAR.
2. Detect an object that may be attracted to the magnet.
3. Detect when vibrations affect magnet signal stability.
4. Evaluate ionizing radiation levels during scanning.
5. Screen patients for dB/dt fluctuations that are beyond normal limits.

**MR Environment Medical Device Concerns**

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm

<table>
<thead>
<tr>
<th>Component of MR Environment</th>
<th>Medical Device Concern</th>
<th>Potential Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Magnetic Field (always on)</td>
<td>Rotational force (torque) on object</td>
<td>Tearing of tissues Rotation of object in order to align with field</td>
</tr>
<tr>
<td>Static Magnetic Field Spatial Gradient (always on)</td>
<td>Translational force on object</td>
<td>Tearing of tissues Acceleration of object into bore of magnet “missile effect”</td>
</tr>
<tr>
<td>Gradient Magnetic Field (pulsed during imaging)</td>
<td>Induced currents due to dB/dt</td>
<td>Device malfunction or failure</td>
</tr>
<tr>
<td>Radio Frequency Field (pulsed during imaging)</td>
<td>RF induced currents resulting in heating</td>
<td>Patient burns (thermal and electrical)</td>
</tr>
<tr>
<td>Radio Frequency Field (pulsed during imaging)</td>
<td>Electromagnetic interference- active device</td>
<td>Device malfunctions Induced noise (monitoring devices)</td>
</tr>
</tbody>
</table>

Vagal nerve stimulator

- Being used for treatment resistant epilepsy, as well as depression
- Heating at lead tip could damage vagus nerve
- Conditional: Head scan possible with proper precautions (T/R coil, 1.3 W/kg SAR)
Deep Brain Stimulation

- Being used for treatment of tremors
- Heating at lead tip could damage brain tissue
- Conditional: Head scan possible with proper precautions (T/R coil 0.1 W/kg SAR)

New MR Conditional Pacemaker

- Medtronic Revo MRI SureScan Pacing System
  - Special wires
  - Special pacer
- Patients may call it "MRI safe", but it is Conditional

Revo Radiology MRI Conditions 1

- B0: Horizontal, cylindrical bore 1.5T MRI
- Gradient systems with maximum gradient slew rate of ≤ 200 T/m/s) must be used
- Normal Operating mode:
  - Whole-body-average SAR ≤ 2.0 W/kg
  - Head SAR < 3.2 W/kg
- The patient positioned such that the isocenter is superior to the C1 vertebra or inferior to the T12 vertebra (note T spine/chest not covered)
Revo Radiology MRI Conditions 2
• Proper patient monitoring (two people)
  – Visual and verbal contact
  – ECG and pulse oximetry (plethysmography).
• Training requirements:
  • A health professional with cardiology SureScan training must be present during the programming of the SureScan feature
  • A health professional who has completed radiology SureScan training must be present during the MRI scan

MRI Scanning with Revo
• If all conditions are met (1.5T, Normal Mode, 2 W/kg SAR, proper body location and monitoring by two trained people),
  – Lead heating will not be significant
  – Pacing device will not be affected by MRI
  – Pacing device programming will remain intact

A new pacemaker has conditional MRI labeling that indicates:

0%  1. Safe MRI scanning is allowed under all MRI operating modes and device settings.
0%  2. Under no MRI conditions is the device safe in MRI, pacemakers are a contraindication in MRI.
5%  3. Second level operating mode is used for scanning this device when under appropriate supervision.
95%  4. Specific limitations of MRI operation, device setting, body location and monitoring to allow safe scanning.
0%  5. Device must be located outside of the maximum spatial gradient defined by the equipment manufacturer.
Answer
1. Safe MRI scanning is allowed under all MRI operation modes and device settings.
2. Under no MRI conditions is the device safe in MRI, pacemakers are a contraindication in MRI.
3. Second level operation mode is used for scanning this device when under appropriate supervision.
4. Specific limitations of MRI operation, device setting, body location and monitoring to allow safe scanning.
5. Device must be located outside of the maximum spatial gradient defined by the equipment manufacturer.

Conclusions
• Many lethal safety issues are present within the MRI environment.
• The Joint Commission has raised concern and endorses the strategies presented in the ACR Guidance Document for Safe MRI Practice 2007.
• Ferromagnetic detectors have an evolving role and are a new tool to improve site MR safety screening for ferromagnetic objects.
• Many devices have MRI conditional labeling, and can be imaged in MRI only if all the conditions are met/followed.

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