MRI Safety

Safety Issue of Static Magnetic Field (1)

- Currently, typical MRI utilizes static field with strengths of 0.5 to 3 Tesla (FDA guideline is max 4 T for infants < 1 month and 8 T for others)
  - 1 Tesla = 10,000 Gauss
  - Magnetic field strength of the earth ~ 0.5 Gauss

Safety Issue of Static Magnetic Field (2)

- Any ferromagnetic substance taken into the MRI scanner room will be subjected to
  - **Missile effect** for loose objects
  - **Translational force** and **torque** for objects inside the body of patient.

Safety Issue of Static Magnetic Field (3)

- All non-MR personnel & patients entering the MRI scanner room must be screened. ACR recommends that non-emergent patients should be screened by two separate individuals.
- Consider using plain-film radiographic study to confirm the absence of metal fragments in critical parts of the body.

Safety Issue of Static Magnetic Field (4)

- All metallic objects brought into the MRI room must be certified '**MR Safe**', and use caution when such object is indicated as '**MR Conditional**'.
- Unknown objects must be tested with a strong handheld magnet (ACR recommends >1000 Gauss). Metal detector is not recommended.

Safety Issue of Static Magnetic Field (5)

- Zone 1: Reception area
- Zone 2: Screening interview area
- Zone 3: Control area, access restricted with key locks, passkey systems etc.
- Zone 4: MR scanner room
- MR personnel must have safety training, non-MR personnel cannot have independent access to Zone 3 or 4.

Safety Issue of Static Magnetic Field (6)

- Quenching of the magnet (cutting off electricity for the electromagnet) is **very** expensive and also hazardous due to the rapid expansion of the cryogen (-269 deg C).
- There is danger of asphyxiation, frostbite, etc. as well as fire hazard (due to liquefied air) in the MR room during quenching.

Biological Effect of Static Magnetic Field (1)

- There has been mention of dizziness and disorientation of personnel and patients as they move through a field of 4T or higher.

Biological Effect of Static Magnetic Field (2)

Electrodynamic force on moving electrolytes leads to electric potential across blood vessels (Hall Effect).

There is no clinically significant effect on heart rate, systolic and diastolic blood pressure, respiratory rate, core body temperature for static fields up to 8 T.

Biological Effect of Time-varying Magnetic Field (1)

- The time-varying magnetic field is produced by the rapid switching of magnetic gradients.
- This time-varying magnetic field **induces electric fields** in a subject according to Faraday's Law.
  - Produces nerve and muscle stimulation.

Biological Effect of Time-varying Magnetic Field (2)

- The peripheral nerve stimulation is a function of dB/dt (rate of change of magnetic field) and the duration of this pulse; this may cause discomfort.
- For a given duration of pulse, doubling the dB/dt that is the threshold for perception would cause an 'intolerable' stimulation

Biological Effect of Time-varying Magnetic Field (3)

- The primary concerns with regard to time-varying fields are cardiac fibrillation and brain stimulation.
- But study showed that the risk of cardiac stimulation in present day MRI gradient fields is negligible.

Biological Effect of Time-varying Magnetic Field (4)

- ACR recommends that presence of implanted **cardiac pacemakers** or implanted **cardioverter defibrillators** are **inadvisable** for routine MRI. (Several such patients have died during the examination even though many were okay).

Biological Effect of Time-varying Magnetic Field (5)

- In regard to brain stimulation, study found no effect of cognitive function from MRI gradient fields.
- Patients with implanted or retained wires in anatomically or functionally sensitive areas should be considered at higher risk.

Biological Effect of Radiofrequency Field (1)

- Radiofrequency energy deposited in the body during an MR examination will be converted into **heat**.
- '**S**pecific **A**bsorption **R**ate' (SAR) is defined as the average energy dissipated in the body per unit mass and time.
- This heat gain is countered by heat loss through sweat glands and cutaneous blood vessels.

Biological Effect of Radiofrequency Field (2)

- For whole-body exposures, no adverse health effects are expected if the increase in body core temperature does not exceed 1 deg C (0.5 deg C for infants).
- FDA guideline for max SAR is 4 W/Kg for whole-body imaging over 15 min, 3 W/Kg for head imaging over 10 min.

Biological Effect of Radiofrequency Field (3)

- Resonant circuitry can result in heating of the tips of wires or leads to temperature in excess of 90 deg C within a few seconds
- All unnecessary electrically conductive materials should be removed before imaging. All attached leads should be covered with cold compress or ice pack.

Biological Effect of Radiofrequency Field (4)

- Avoid any large conductive loops, including tissues (do not cross arms or legs in the MR, this forms a loop as well).
- Care should be taken to place thermal insulation between the patient and electrically conductive material.

Biological Effect of Radiofrequency Field (5)

- Some drug-delivery patches contain metallic foil and should be covered with ice pack during scanning.
- ACR also recommended that cold compresses or ice packs be placed on tattooed area during scanning.

Effect on Pregnant Patients (1)

- Thus far, there is no evidence of adverse effect of pregnancy outcome in women exposed to MRI during pregnancy.

Effect on Pregnant Patients (2)

- There is uncertainty in the RF dosimetry during pregnancy, it is recommended that exposure duration should be reduced to minimum and that only the normal operation level is used.

Effect on Pregnant Patients (3)

- Large doses of MRI gadolinium-based contrast agents have been shown to cause post-implantation fetal loss, retarded development, increased locomotive activity, and skeletal and visceral abnormalities in experimental animals.
- **ACR**: "MR contrast agents should not be routinely provided to pregnant patients."

Effect on Pregnant Patients (4)

- **International Non-ionizing Radiation Committee of IRPA** stated:

  "There is no firm evidence that mammalian embryos are sensitive to the magnetic field encountered in MR system. However …it is recommended that **elective examination of pregnant women** should be postponed until **after first trimester**."

Effect on Pregnant Patients (5)

- **ACR** stated:

  "Pregnant patients **can be accepted** to undergo MR scans at any stage of pregnancy **if** …. the risk-benefit ratio for the patient warrants that the study be performed…. It is recommended that pregnant patients undergoing an MR examination **provide written consent** to document that they understand the risks and benefits…"

Effect of Acoustic Noise (1)

- The noise occurs during the rapid alterations of currents within the gradient coil, producing significant Lorentz forces that induce vibrational modes at the coil.

Effect of Acoustic Noise (2)

- Transient hearing loss may occur following loud noise exceeding 100 dBA.
- 85 dBA is the threshold for permanent hearing loss following long term noise.
- FDA guideline is 99 dBA (140 dB peak), above which hearing protection should be worn.
- Noise exposure for the fetus is a concern.

ECRI Audio Conference
MRI Safety
Sept. 21 2005

Jason Launders, Emmanuel Kanal, Terry Woods
Frank Shellock (Q&A)

MAUDE data base 1995-2005

- MAUDE = Manufacturer And User facility Device Experience
- **389 incidents** related to MRI reported
- **9 Deaths**
- Incidents attributable to MRI technology: 302

  Other: 87
- NOT as safe as we think

Cause of deaths associated w/ MRI

- Pacemaker failure 3
- Insulin pump failure 2
- Aneurysm clip 1
- Neurostimulator 1
- Projectile 1
- Asphyxiation from Helium 1

Total **9**

Incidents related to MR technology

Coil burn	**117**	**39%**
Lead burn	60	20%
Body loop burn	36	12%
Other (e.g. implants)	31	10%
Projectile	**29**	**10%**
Acoustic injury	13	4%
Fire	12	4%
Internal heating	5	2%

Projectile incidents

- Among the 29 **Projectile incidents**, about half of those were due to **ENGINEERS**.
- These incidents are believed to be greatly under-reported (less than 10% of incidents have been reported)

‘Other’ Incidents

- Metallic implant failure / burn 12
- Infusion pump failure 8
- Pacemaker failure 7
- Aneurysm clip 2
- Neurostimulator 2

Reasons for coil burn

- Patients touching the bore (body coil)
- Little or no padding between coil and patient
- Electronic component failure
- Technologist error (wrong coil)

- **NOT necessarily** from electrical loops

PA-PSRS
(Pa Patient Safety Reporting System)

- **June 2004 – Sept. 2005**

  incidents related to MRI: 88

  serious events: none

- Screening error 33

  Contraindications during screening 28

  Contraindications during/after MRI 12

  Potential burns 3

  Potential projectiles 12

New FDA MR Safety Terminology

- MR Safe(Green)

- MR Conditional (Yellow)

- MR Unsafe (Red)

New ASTM MR Standards

(American Society for Testing & Materials)

Why new terminology?

- Previous '**MR Safe**' or '**MR Compatible**' items or devices may be 'safe' only under certain environment or magnet field strength.

  (Some devices safe in one magnetic field strength but fail in higher or lower magnetic field strength)
- These should be treated as '**MR Conditional**' until verified otherwise.

New and Changing Safety Issues

- Stronger magnets (3 T)
- Interventional MRI gaining popularity
- More and newer types of patient implants
- Larger patients

- **'Ferromagnet Detector'** is being developed.
- **'Modern Pacemaker'** may not be MR Safe. Thus far, there is no 'MR Safe' pacemaker approved by FDA. There may be 'MR Conditional' pacemakers.
- **Any** metallic implants such as **heart valves** or **stents** should be a concern for MR safety.
- Safety criteria include **shape** and **location** of implant. Presence of implant does not necessarily preclude MRI.

Conclusion

- Realize more than electrical loops cause burns.
- Ensure >**1/2" space** between patient and core
- Ensure **padding** between coils
- Maintain **contact** with patient and **stop** the examination whenever the patient reports heating.
- **Enforce screening**, even for engineers.
- Use magnets **>1000 Gauss** for screening purpose.
- Learn the **new terminology and signs**. Regard the old 'MR Safe' and 'MR Compatible' as 'MR Conditional'.