

PATIENT CARE
AND
MRI SAFETY

Module Seven

Biological Considerations

- There are no reported adverse biological effects of extended exposure to MRI.
- However, several inconsequential and reversible effects of electromagnetism can be observed.

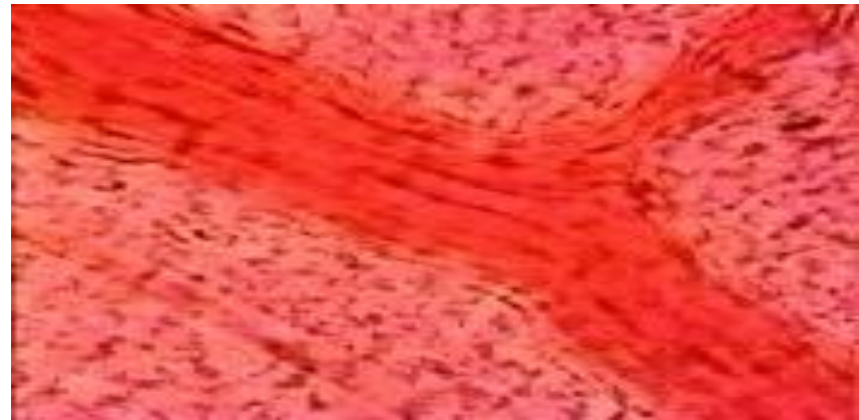


Static Magnetic Fields

- Many factors cause a risk when performing MRI on patients with ferromagnetic materials in their body:
 - strength of the static and gradient fields
 - degree of magnetism of the object
 - the mass of the object
 - the geometry of the object
 - the location and orientation of the object
 - the length of time the object has been in

Static Fields Below 2 T

- At fields below 2 T reversible abnormalities have been noted on ECGs.
- An increase in the amplitude of the T-wave due to the magnetohydrodynamic effect.
- When a conductive fluid, such as blood, moves across a magnetic field it results in the system triggering off the T - wave rather than the R-wave.



Heating

- Studies showed that patient exposed to field strengths of 1.5 T:
- 60 minutes - 0.1°C increase in body temperature
- 20 minutes - 0.03°C increase in body temperature

Static Fields above 2.0 T

- Some reversible biological effects observed at 2.0 T and above:
 - fatigue
 - headaches
 - hypotension
 - accounts of irritability

Static Fields above 2.0 T

- Some reversible biological effects observed at 2.0 T and above.
 - The effects of magnetic interaction energy and cell orientation.
 - Certain molecules (such as DNA) and cellular subunits (such as sickled red cells) have magnetic properties that vary with direction.
- FDA has cleared static magnetic field strengths up to 8 Tesla for clinical use in humans as “non-significant risk”.

Screening

- Metallic foreign materials within a patient must be identified before MR imaging.
 - Motion or displacement of these objects may result in injury to the patient.
 - We rely principally on clinical history.

MR Safe

- An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are comprised of materials that are electrically nonconductive, nonmetallic and nonmagnetic.
 - <http://www.usa.philips.com/healthcare/education-resources/publications/fieldstrength/mri-and-mr-conditional-implants>

MR Conditional

- An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
- Conditional 1 - 8
 - <http://www.usa.philips.com/healthcare/education-resources/publications/fieldstrength/mri-and-mr-conditional-implants>

MR Unsafe

- An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
- MR Unsafe 1 & 2
 - <http://www.usa.philips.com/healthcare/education-resources/publications/fieldstrength/mri-and-mr-conditional-implants>

Implanted Devices

- Electrically
- Magnetically
- Mechanically activated and
- Electrically conductive implanted devices
 - Certain implanted devices are not safe for MR imaging.
 - The function of such implants is impaired by the magnetic field, therefore patients with such devices should not be examined with MR.

Equipment

- A wide variety of MR-compatible monitoring devices are available.
- MR-compatible anesthesia machines and respirators are also available.
- An important point is that electronic monitoring devices are no substitute for direct monitoring.

Gradient Magnetic Field (Time-Varying)

- There is concern with nerves, blood vessels, and muscles that act as conductors in the body.
- Faraday's Law of Induction
 - states that changing magnetic fields induce electrical currents in any conducting medium.

Gradient Magnetic Field (Time-varying)

- Induced currents are proportional to:
 - the material's conductivity
 - the rate of change of the magnetic field and
 - the radius of the inductive loop.
- This effect is determined by factors such as:
 - pulse duration
 - wave shape
 - repetition pattern
 - the distribution of the current in the body

Biological Effects

- Vary with current amplitude range from:
 - reversible alterations in vision,
 - to irreversible effects of cardiac fibrillation,
 - to alterations in the biochemistry of cells and fracture union.
 - Visual effects may occur when retinal phosphenes are stimulated by induction from TVMF.

Acoustic Noise

- As current is passed through the gradient coils acoustic noise is created.
- Although within recommended safety guidelines, it can cause some reversible and irreversible effects.
- Communication interference, transient and possible permanent hearing loss.
- Earplugs are an acceptable prevention and should be used regularly.

Radiofrequency Fields (RF)

- Exposure to radiofrequency occurs as the hydrogen nuclei are subjected to an oscillating magnetic field.
- As the energy levels of frequencies used is relatively low, the predominant biological effect of RF irradiation absorption is the potential heating of tissue.

Specific Absorption Rate (SAR)

- MR systems cannot measure RF exposure, therefore it is necessary to measure the RF absorption.
- This is manifested as tissue heating and the patient's ability to dissipate excess heat.
- Energy dissipation can be described in terms of Specific Absorption Rate (SAR).

Specific Absorption Rate (SAR)

- SAR, expressed in Watts/kg, is a quantity that depends on:
 - induced electric field
 - pulse duty cycle
 - tissue density
 - conductivity
 - patient size
 - SAR is used to calculate expected increase in body temperature during an examination.

Specific Absorption Rate (SAR)

- In the US the recommended SAR level for imaging is:
- 4 W/kg for the whole body
- The SAR limit levels should never be exceeded.

RF Antennae Effects

- Radio frequency fields can be responsible for significant burn hazards due to electrical currents that are produced in conductive loops.
- Coupling of a transmitting coil to a receive coil may also cause severe thermal injury.

Pregnant Patients

- There are no known biological effects of MRI on fetuses. There are mechanisms that could potentially cause adverse effects.
 - Cell undergoing division, during the first trimester of pregnancy, are more susceptible.
 - FDA requires labeling of MR systems to indicate the safety of MR when used to image the fetus and infant.
 - However official guidelines have not been set.



Pregnant Patients

- In general, it has been suggested that any examination of pregnant patients should be delayed until after the first trimester.
- Then a written consent form should be signed by the patient before the exam.



Pregnant Employees

- MRI facilities must establish individual guidelines for pregnant employees in the magnetic resonance environment.
- The majority have determined that pregnant employees can safely enter the scan room and leave while the RF and gradient fields are employed.

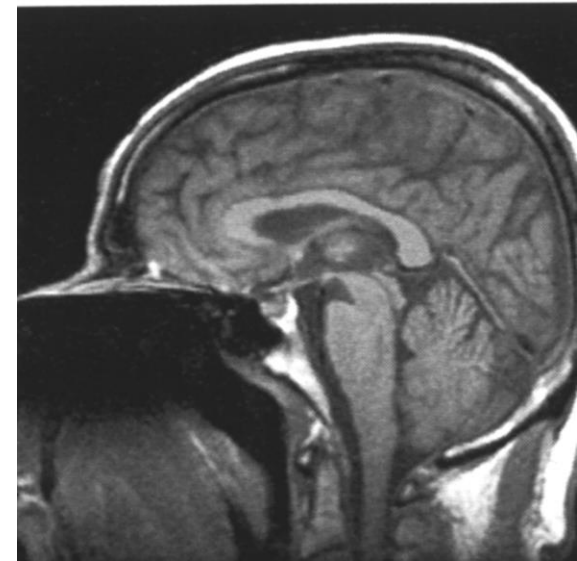
Implants and Prostheses

- Metallic implants pose serious effects which include:
 - torque
 - heating
 - artifact on MR images.
- Before imaging a patient, any surgical procedures the patient has undergone prior to the MR examination, must be identified.



Torque and Heating

- Some metallic implants have shown considerable torque when placed in the presence of a magnetic field.
- Heating experiments have not shown excessive temperature increases in implants.



Aneurysm Clips

- Some of the aneurysm clips tested displayed ferromagnetic qualities.
- Clip motion may damage the vessel, resulting in hemorrhage, ischemia, or death.
- It is recommended that the type of clip is emphatically non-ferrous and be identified before scanning.

Hemostatic Vascular Clips

Heart Valves

- Hemostatic Vascular Clips
 - Should be evaluated ex-vivo prior to the exam although none of the clips evaluated showed deflection.
- Heart Valves
 - Tests showed negligible deflection to the magnetic field. The deflection is minimal compared with normal pulsatile cardiac motion.
 - Although considered MR safe, careful screening for valve type is advised.

Intra-vascular Coils, Filters and Stents

- These devices usually become imbedded in the vessel wall after several weeks and are unlikely to become dislodged.
- Therefore it is considered MR safe to perform MR imaging provided a reasonable period of time has elapsed after implantation.

Otologic Implants

- Cochlear implants are attracted to magnetic fields and are magnetically and electronically activated.
 - They are mostly MR unsafe to MR exams.
- Many Otologic Implants are MR Safe or MR Conditional

Intra-ocular Ferrous Foreign Bodies

- It is not uncommon for metal workers to have metal fragments or slivers located in and around the eye.
- A study demonstrated that metal fragments as small as 0.1x0.1x0.1mm can be detected on radiograph and is sufficient enough to determine the risk to a patient.

Surgical Clips

- Abdominal surgical clips are generally MR safe because they become anchored by fibrous tissue.
- They can however produce artifact in proportion to their size and can distort the image.

Halo Vests and other Devices

- Halo vests pose several risk factors which include:
 - deflection and subsequent dislodging of the halo, heating due to RF absorption
 - electrical current induction within the halo rings
 - electrical arcing
 - severe artifact consequences.
 - Non-ferrous and non-conductive halo vests which are MR compatible are commercially available



Claustrophobia

- It is a condition that commonly affects patients, not a contraindication.
 - RF heating, gradient noise, and the confines of the magnet itself, add to the reaction.
- Reduce the incidence of claustrophobia.
 - Controllable air movement within the bore, good patient contact and education should help to reduce the reactions.
 - Open Architecture.

Gadolinium

- A rare earth metal or 'heavy metal'
- Toxic if not chelated.
- Ionic and Nonionic
- Shorten both T1 and T2 relaxation times

Current Applications

- Gadolinium has proven invaluable in imaging the central nervous system because of its ability to pass through breakdowns in the blood-brain barrier (BBB).

Current Applications

- tumor pre - and post surgery
- lesions with abnormal vascularity
- pre- and post-radiotherapy
- infection, infarction, inflammation
- liver (hemangiomas); renals
- post-traumatic lesions
- post-operation lumbar disc
- MR Angiography
- Previous Surgery
- History of Cancer

Contraindications

- Hematological disorders such as:
 - hemolytic anemia
 - sickle cell anemia
 - Pregnancy
 - Compromised renal function
 - GFR < 30
 - Acute Kidney Injury (AKI)

Contrast Reactions

- mild transitory headache
- nausea
- vomiting
- hypotension gastro-intestinal upset
- rash
- deaths have been reported.

Elimination of Gadolinium

- Approximately 80% of gadolinium is excreted by the kidneys in three hours.
- 95.5% eliminated primarily in urine within 24 hours
- 98% is recovered by feces and urine in one week.

Nephrogenic Systemic Fibrosis

- NSF is a disease that has been linked to gadolinium-based MRI contrast administration.
- FDA as of September 2010, has issued new policy regarding all gadolinium MRI agents updated in 2013 (ACR Guidance Document for Safe MR Practice: 2013)
- The revised labeling is specific to certain manufacturers however there are guidelines for all agents.

NSF – Black Box Warning

- The first black box warning was issued in 2007 to address the growing concern about the devastating disease.
- The warning requires screening of the patient prior to administration of any MR contrast agent.
- The warning also comes with utilization restrictions.

NSF

- According to FDA warnings these agents are not to be administered to patients with chronic, severe kidney disease (defined by a glomerular filtration rate (GFR) of less than 30 mL/min/1.73m²) or acute kidney injury.
- Patients are to be screened for acute kidney injury and other conditions that may reduce kidney function.

NSF

- The FDA now requires specific patient screening and kidney function tests for patients at risk for NSF before being administered a gadolinium with MRI.
- The requirements include avoiding administration for patients at risk, specifically those who would have problem eliminating the drugs...

NSF

- ...unless the diagnostic information from the contrast-enhanced MRI is essential and not available with non-enhanced MRI or other imaging modalities.
- Users are instructed to screen patients for acute kidney injury and other conditions that may reduce renal function.
- A GFR test is required for at risk patients.