

Patient Monitoring System for MRI

An Evidence-Based Analysis

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I. BACKGROUND

I.1 Clinical need

In the past few years, the indications to perform MRI have increased markedly. The wider availability and increasing use of MRI equipment, however, has led to a number of problems. MRI investigations are lengthy; therefore, many patients, particularly children, cannot tolerate the procedure without sedation or general anesthesia. Many children either have difficulty remaining immobile during the MRI procedure or become frightened by the MRI equipment. Some adult patients who undergo an MRI procedure experience emotional distress that can range from mild anxiety to a full-blown panic attack. Several studies have shown that 14% to 20% of adult patients require sedation to tolerate MRI. (1,2) Patients' lack of immobility and distress contribute to adverse health outcomes, compromise the quality of images and decrease the efficiency of the imaging facility due to delayed or cancelled examinations.

The MRI procedure poses little risk to the patient, but investigators have highlighted the risk of life-threatening adverse events related to sedation of children or adults for diagnostic procedures. (3–6) Of greatest concern is the risk of respiratory depression and hypoxemia that potentially have long-term effects. Patients under sedation may become unable to respond or alert the MRI technologist about respiratory problems, cardiac distress or other changes in physiological status.

With the use of sedation and anesthesia, it is necessary to monitor cardiorespiratory parameters during the procedure and to provide an equivalent standard of care as that provided in the operating room.

The Safety Committee of the Society for Magnetic Resonance Imaging has published guidelines and recommendations concerning the monitoring of patients during MRI procedures. (7) This information indicates that all patients who are sedated for MRI procedures should be physiologically monitored and supported by the appropriate means. Guidelines issued by the Joint Commission on Accreditation of Healthcare Organizations indicate that patients who receive sedatives or anesthesia require monitoring during the administration and recovery from these medications. Also, it is well recognized that injured or critically ill patients can sustain central nervous system or cardiopulmonary complications and should be carefully monitored during the MRI procedure.

Conventional monitoring equipment and accessories are not designed to operate in an MRI environment. Because of the strong magnetic field generated by the MRI—thousands of times greater than that of the earth's magnetic field—any items in the MRI environment that contain ferrous materials become potential dangerous projectiles that could injure the patient. However, various physiologic monitors have been developed for use in an MRI environment. It is also necessary to have various non-magnetic devices and accessories available for emergencies including an oxygen cylinder, laryngoscope, aspirator and other emergency equipment that is appropriate for the MRI environment.

I.2 The technology

I.2.1 Monitoring

Monitoring is the continuous observation of the patient's vital signs for the purpose of identifying changes in physiological parameters and preventing undesired events. The objective of monitoring is to ensure that the patient's basic cardiopulmonary parameters and temperature are safely maintained.

I.2.2 Principles of MRI

The standard unit of measurement of the magnetic field strength is Tesla (T). One T is equal to 10,000 Gauss (G). The earth's magnetic field strength at the surface is 0.5 G to 2.0 G. MRI systems

have field strength of 0.15 T to 2.0 T. The quality of the images is directly related to the strength of the magnetic field.

I.2.3 Definition of the MR environment

The MR environment is the vicinity of the MR scanner. It includes the region from the centre of the magnet bore out to the 5 G (0.0005 T) line. Beyond the 5 G line, the level of magnetic field is generally considered to be safe.

I.2.4 Characteristics of the MR environment

The MR environment is characterized by the presence of the following:

- Static magnetic field commonly in the range of 0.2 T to 2.0 T. Lower and higher fields are also in use.
- Gradient magnetic field (the rapidly changing magnetic field) used during imaging.
- Radiofrequency (RF) pulses.

I.2.5 Fringe field of MRI

The fringe field of MRI is the magnetic field that extends beyond the margins of the MRI equipment. The magnetic field strength decreases proportionally with the distance from the magnetic bore.

Within the fringe field of the MRI, the static magnetic field is always present, and there are changing magnetic fields that occur during imaging. A magnetic field strength of 5 G causes electrical equipment and pacemakers to malfunction and erases magnetic tape on credit cards. At a field strength of approximately 50 G, ferromagnetic objects become attracted toward the magnet.

I.2.6 Regulatory status

Health Canada has issued licenses to 3 MRI-compatible patient monitors:

1. Datex-Ohmeda S/5 Monitor System made by Datex-Ohmeda: License #14266
2. Maglife C Plus made by Schiller: License #4222
3. Millennia Vital Sign Monitoring System made by Invivo Research: License #61946

Table 1 shows information for MRI-compatible patient monitors available in Canada.

Table 1. MRI-compatible patient-monitoring systems in Canada

	Datex-Ohmeda	Maglife C Plus	Millennia
Compatibility with MRI scanner	Up to 1.5 T	Up to 3.0 T	Up to 3 T
Limitation	Must be used outside of 2 mT	Must be used outside of 40 mT	Can work in 0.5 T
Feature	ECG Pulse oximetry (SpO ²) Capnography Non-invasive blood pressure 2 invasive blood pressure 5 anesthetic agents	ECG Pulse oximetry (SpO ²) Capnography Non-invasive blood pressure 2 invasive blood pressure 5 anesthetic agents, temperature monitoring	ECG Pulse oximetry (SpO ²) Capnography Non-invasive blood pressure 2 invasive blood pressure 5 anesthetic agents

*T refers to Tesla; mT refers to milli Tesla; ECG refers to electrocardiography; pulse oximetry (SpO²) refers to the arterial oxyhemoglobin saturation; capnography refers to the measurement of carbon dioxide.

II. LITERATURE REVIEW

II.1 Objective

The objective of this health technology policy assessment was to identify issues related to the interaction of the MRI environment and patient-monitoring systems.

II.2 Methodology

To review the published literature on MRI-compatible patient-monitoring systems, we searched MEDLINE, EMBASE, MEDLINE In Process and other Non-indexed Citations from January 1, 1996 to October week 4, 2003.

II.3 Results of literature search

The search yielded 145 citations on patient-monitoring systems for MRI. Fourteen publications, including letters and comments, were selected for review. (8–21)

II.4 Assessment of evidence

The assessment of the evidence discusses the safety and compatibility of patient-monitoring systems designed for use in the MR environment.

II.4.1 Management of patients during MRI

Patients undergoing MRI examination can benefit from sedation or anesthesia because 1) it allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort or pain and 2) it may expedite procedures that require the patient to be immobile. Inadequate sedation can be costly in terms of quality of the images, inconvenience to the patients and families, and increased use of professional time.

II.4.1.1 Depth of sedation

The American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists developed practice guidelines (22) for sedation and analgesia by non-anesthesiologists. The guideline describes 3 levels of sedation and general anesthesia as follows:

Minimal sedation (anxiolysis) is drug-induced sedation during which patients respond normally to spoken commands. In this state, patients' cognitive function and co-ordination may be impaired, but cardiovascular and ventilatory functions are unaffected.

Moderate sedation/analgesia (conscious sedation) is the drug-induced depression of consciousness during which patients respond purposefully to spoken commands. In this state, cardiovascular function and spontaneous ventilation are not impaired.

Deep sedation/analgesia is the drug-induced depression of consciousness during which patients cannot be easily aroused, but will respond to painful stimulation. In this state of consciousness, cardiovascular function is usually maintained, but ventilatory function may be impaired; therefore, patients may require assistance in maintaining a patent airway.

General anesthesia is the drug-induced loss of consciousness during which patients cannot be aroused. Patients' cardiovascular function may be impaired, and they may need airway maintenance and ventilatory assistance.

According to the guidelines of the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists, (22) non-anesthesiologists who perform sedation and analgesia in a variety of settings must be able to rescue patients from any level of sedation, because the sedation may become deeper than initially intended. Appropriate monitoring of the vital signs has been considered as an essential component of patient care and should be maintained for all sedated or anesthetized patients.

II.4.1.2 Management of patients with underlying medical conditions during MRI

Critically ill patients, such as those transferred from the emergency room or intensive care unit, require full monitoring during imaging investigations. In addition, certain types of patients are at increased risk for developing complications associated with sedation or anesthesia during MRI procedures. Patients with serious underlying medical conditions, such as severe cardiovascular or pulmonary disease, and patients with sedation-related risk factors, such as difficult airway, morbid obesity and sleep apnea, are at increased risk of respiratory depression or hemodynamic imbalance. For these patients, close monitoring of vital signs is essential, and the presence of an appropriate medical specialist will decrease the risk of adverse outcomes.

II.4.1.3 Management of pediatric patients during MRI

II.4.1.3.1 American Academy of Pediatrics Committee on Drugs Guideline

The American Academy of Pediatrics Committee on Drugs has provided a uniform guideline (23) for observing and caring for children who need sedation for a diagnostic or therapeutic procedure regardless of where the procedure is performed. According to the Committee on Drugs guidelines, age- and size-appropriate equipment and medications to sustain life should be available and checked before sedation. All patients sedated for a procedure must be continuously monitored for cardiorespiratory status, and the individual responsible for monitoring should have no other responsibilities.

II.4.1.3.2 General anesthesia versus sedation for MRI examination

For children undergoing MRI examinations, the administration of sedation or anesthesia may be necessary to achieve the degree of co-operation or immobilization necessary to complete the

examination. It has been shown that an MRI procedure is more successful for children who have general anesthesia.

A prospective study (24) of children who were sedated (n=922) or given general anesthesia (n=140) for MRI or computed tomography scanning showed that sedation was inadequate for 18% of children, and MRI procedure was aborted as a result of inadequate sedation in 9.6% of* children. This study showed that the age of the child and the severity of the illness influence the success of the sedation. Sedation was inadequate more commonly in children who were classified as ASA III-IV1* than those who were classified as ASA I-II* (24% and 15% respectively, p=0.04). Children for whom sedation failed were older than those with who had a successful examination. A logistic regression analysis showed that age was the only variable predictive of inadequate sedation (p=0.0005) and failed sedation (p=0.004).

II.4.2 Issues in the MRI environment

II.4.2.1 MR safety and MR compatibility

It is possible that a metal object that shows weak ferromagnetic qualities when exposed to a 1.5 T MR system may show substantial magnetic field interaction when exposed to an MR system operating at a higher static magnetic field strength. Therefore, it is important to appreciate the differences between MR safety and MR compatibility. According to the United States Food and Drug Administration (USFDA), Center for Devices and Radiological Health, these terms are defined as follows:

MR safe: This term indicates that the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individual, but may affect the quality of diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the term “MR safe,” since a device that is safe under one set of MR conditions may not be so under more extreme MR conditions.

MR compatible: This term indicates that the device, when used in the MR environment, has been demonstrated to neither substantially affect the quality of diagnostic information nor have its operations affected by the MR equipment. Once again, the terms under which the device was tested must be known. It should be noted that compatibility cannot be addressed in isolation from safety.

These are important issues for patient monitors in the MRI environment and have been discussed in the literature.

II.4.2.2 Interaction of the monitor with MR scanner

II.4.2.2.1 Liquid Crystal Display screens and microprocessors

Liquid Crystal Display (LCD) screens or microprocessors in patient-monitoring systems may produce RF interference that affects MR image quality. Light-emitting diodes and LCD terminals are electrically turned on and off at a high frequency. The resulting interference can be radiated either directly into the imaging area or can be conducted through patient interface connections such as electrocardiogram (ECG) leads into the imaging field and cause distortion of the images. Locating

*Physical status of patients as classified by the American Society of Anesthesiologists [ASA]

<u>ASA classification</u>	<u>Patient's physical status</u>
I	Normal and healthy
II	Mild systemic disease
III	Severe systemic disease that limits activity but is not incapacitating
IV	Systemic disease that is incapacitating and a constant threat to life
V	Survival for more than 24 h not expected, with or without operation

the monitoring unit outside the MR room, or shielding RF may prevent the interference. For patient-contact devices such as ECG monitors, there are safety guidelines that must be followed.

II.4.2.2.2 Equipment with sensors and detectors

Sensors and detectors, such as those used in pulse oximetry, are an additional source of interference that can be picked up by the MR receiver coil and cause distortion of the images. Shielding of the sensor can prevent this.

II.4.2.2.3 Equipment containing ferromagnetic materials

Ferromagnetic materials close to the magnet can disturb the homogeneity of the static magnetic field and produce distorted images. Patient-monitoring equipment located in the scan room can also affect the magnetic field homogeneity. Power supply transformers can contain sufficient magnetic material to result in the distortion of the magnetic field.

II.4.2.3 Interaction of the MR scanner with the monitor

II.4.2.3.1 Influence of the static field on motors

The fringe field of the MR system may saturate the magnet in the motors of some equipment. Saturation can cause the motor to stop, slow down or accelerate so that the motor burns out. (16)

Similarly, electronic circuitry may contain components that are affected by static magnetic fields (e.g., transformers, switches, relays).

II.4.2.3.2 Effect of the gradient magnetic field

ECG leads create an electrical loop and the pulsing gradient magnetic field generates a circulating current within this loop. This can result in a voltage several times the magnitude of the R wave and incorrect triggering of the ECG equipment.

II.4.2.3.3 Effect of RF

The RF field can affect ECG and pulse oximetry equipment when they are situated within imaging environment. RF energy can easily couple into the leads and the input amplifier, resulting in momentary losses of the monitor signal.

II.4.2.4 Safety hazards for patients and MR staff

II.4.2.4.1 Effect of the static magnetic field

The static field produced by the MR system can influence the safety and effectiveness of a device or piece of equipment. MR systems operating in clinical and research settings have static magnetic fields as low as 0.6 T (600 G) to as high as 8.0 T (80,000 G). Therefore, MR-compatible products should be tested under actual conditions of use. Small MR systems designed for specific applications, such as extremity imaging, may have very well contained magnetic fields: approximately 5 G within 6 inches from the magnet bore. (16)

II.4.2.4.1.1 Missile effect

When ferromagnetic materials are brought near the magnet, a serious hazard can be caused by the potential “missile effect.” The attractive forces increase rapidly as the object nears the magnet, producing a force that can displace even very large objects and pull them toward the magnet.

Despite safety warnings issued by the manufacturers, there are numerous stories of ferromagnetic objects being pulled into MRI equipment. This phenomenon can injure or kill an individual inside or outside the magnet, can cause serious damage to the magnet and can smash the RF imaging coils.

II.4.2.4.1.2 Effect on biomedical implants or devices

Patients who have metal fillings, ferromagnetic clips or pins in their body, neurostimulators, defibrillators and cochlear implants cannot be imaged with MR. Ferromagnetic metal implants or foreign bodies can be twisted and pulled by the force of magnets and cut or seriously damage surrounding tissues. Nor can patients using pacemakers be imaged because a strong magnetic field can induce currents in the pacemaker circuitry that cause it to fail and possibly cause death.

However, most implantable devices are now made of titanium or other metals that allow MRI examination without causing injury to the patient. (10)

II.4.2.4.2 Risk of patient burns caused by heating

Devices such as ECG electrodes and leads, pulse oximetry sensors and metallic components, connectors, cables and surface coils have the potential to become hot enough to cause burns when they are exposed to the changing gradient magnetic fields and the RF currents in the MRI environment. Conductive leads can be replaced by carbon fibre leads to minimize the possibility of burns, prevent image degradation and ensure proper functioning of the ECG monitor.

II.4.3 Report of ferromagnetic objects crashing into the magnet bore

The USFDA Medical Device Reporting and the Emergency Care Research Institute's (ECRI) Health Devices Alerts databases contain reports on several instances in which ferromagnetic objects have crashed into or been pulled into the bore of MR systems. The objects involved in these incidents include intravenous poles, oxygen cylinders, a helium cylinder, a mop bucket, a laundry cart, a chair, a ladder, a patient lift, a light fixture, a pulse oximeter transformer, traction weights and parts of a forklift. A widely reported tragic incident occurred in July 2001 in an MRI scan room near New York. An oxygen cylinder was pulled by the magnet and crashed to the head of a young boy who was undergoing MRI examination. This unfortunate incident was fatal and the details have not been disclosed.

II.4.4 Reports of pulling objects that appear safe

In several instances reported in the literature, sandbags have been pulled into MRI equipment. The ECRI's Hazard Report indicates that not only the devices that contain ferromagnetic elements become projectiles in the MR environment, but also devices that appeared to be safe were attracted to the magnet. An ECRI Hazard Report published in July 1998 indicates an incident in which a sandbag was attracted by the MR system. Apparently, some sandbags contain ferromagnetic pellets and are not safe in the MR environment.

II.4.5 Reports of pulling MRI-compatible equipment

A report (17) from the Royal Victoria Hospital in the United Kingdom indicates that an MRI-compatible patient-monitoring system was rapidly attracted towards the bore of the 1.5 T magnet when the monitor was being moved to its operational position. The monitoring equipment weighed 25 kg and measured 45 cm x 35 cm x 45 cm. The equipment became lodged in the mouth of the magnet. The force of attraction was so great that it took 5 people to extract the monitor from the magnet.

We contacted Dr. Farling, who reported this incident, to identify the make of the monitor. The monitor was a Schiller Maglife C Plus, supplied by Amazon Medical.

II.4.6 Reports of fires and burns due to ECG electrodes

Kugel et al (21) reported that a high voltage induced at the position of the ECG electrodes resulted in heating and an open flame. In this experience, the ECG signals were guided through standard cabling that was delivered with the monitor marked as MR compatible. During the scanning, the patient suddenly cried for help, and the anesthesiologist noticed a flame of approximately 3 cm arising from the patient's shirt close to the position of ECG electrodes. The anesthesiologist bent towards the patient into the magnet bore and extinguished the flames with his hands. The scanning was immediately discontinued and the patient pulled out of the magnet bore. The incident caused second to third degree burns at the position of the ECG electrodes.

II.5 Future MRI systems

The safety and effectiveness of a device suited to a particular MR environment cannot be guaranteed for future MR systems. Specifications and performance characteristics of MR systems continually change to achieve higher performance. Products for use in the MR environment that were manufactured by a company other than the original manufacturer should be tested under the new conditions.

III. SUMMARY & FINDINGS

- ® The increasing use of MRI has led to an increased demand for sedation and monitoring during the procedure.
- ® A broad range of patients requires full monitoring of physiological parameters during the MRI examination.
- ® Most children undergoing MRI examination require deep sedation or general anesthesia to render them motionless during the MR procedure.
- ® Airway management may become necessary for some children who need assisted ventilation or are at risk of airway obstruction.
- ® Remote access to the patient is a major challenge in MRI examinations; therefore, monitoring is essential to the patient's care.
- ® Patients undergoing sedation for MRI examination may sustain central nervous system or cardiopulmonary complications, so require monitoring of physiological parameters.
- ® Full monitoring includes ECG, pulse oximetry, non-invasive blood pressure, invasive blood pressure, capnography, and temperature.
- ® Most of the standards of care adopted by the American Society of Anesthesiologists can be met in the MRI environment.
- ® Hazards and adverse events in the MRI environment must be acknowledged.
- ® Patient monitoring systems for MRI must meet the safety and compatibility requirement set by the FDA.

® Issues in the MRI environment include:

Interaction of the monitor with MR scanner

Interaction of the MR scanner with the monitor

Safety hazards for patients and MR staff

® Safety hazards that immediately affect the patient include the “missile effect” and the “possibility of burn”.

- A serious hazard can be caused by the displacement “missile effect.” This phenomenon can injure or kill an individual inside or outside the magnet.
- Devices such as ECG electrodes and leads, pulse oximetry sensors and metallic components, connectors, cables and surface coils have the potential to become hot enough to cause burns to the patient.

® The efficiency of imaging facility can be affected by:

- Delayed or cancelled examinations due to incidences caused by the interaction.
- Delayed or cancelled examinations due to the damage to the MR system.
- Delayed or cancelled examinations due to distorted images.

The main sources of interaction that cause distortion of the images are:

- LCD screens or microprocessors in patient-monitoring systems.
- Sensors and detectors, such as those used in pulse oximetry.
- Devices containing Ferromagnetic materials which can disturb the homogeneity of the static magnetic field and produce distorted images.
- Incorrect ECG monitoring and loss of monitor signals when affected by the gradient magnetic field.
- Saturation of the motors in some equipment by the magnetic field which can cause the motor to stop or to burn.

® It is the responsibility of the health care facility to ensure MR safety and compatibility of new equipment, such as patient-monitoring systems, with the MR environment.

® Equipment intended to be used in MR environment must be tested under actual conditions of use.

® MR compatible monitors and other technologies used in the MR environment must comply with Health Canada licensing and manufacturer safety and compatibility specifications.

® Appropriate attention should be paid to the safety of the MR procedure for each patient.

® Since specifications and performance characteristics of specific MR systems continually change to achieve higher performance, products for use in the MR environment manufactured by the other manufacturers should be tested under the new conditions.

® Today’s safety and effectiveness of a device in specific MR environments cannot be guaranteed for future MR systems.

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