SHORT COMMUNICATION

SAFETY CONCERNS RELATED TO ULTRA HIGH FIELD MAGNETIC RESONANCE IMAGING

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ABSTRACT

Over the past three decades, magnetic resonance imaging (MRI) technology has seen tremendous improvements. Ultra high field imaging systems are now increasingly being used in clinical practice as they provide higher resolution and image contrast. However, evaluation of safety risks of MR systems for human exposure at such high fields should be the first priority to demonstrate their long term feasibility. This article reviews potential safety issues for patients, research volunteers and technicians present in the ultra-high field strength MR systems.
Keywords: Magnetic Resonance Imaging; MRI Safety; Ultra High Field Strength Imaging

Abbreviations: FDA: Food and Drug Administration; MRI: Magnetic Resonance Imaging; SAR: Specific Absorption Rates

Introduction

Magnetic resonance (MR) imaging has established itself both as a diagnostic as well as a research tool of choice in many areas of health sciences because of its ability to provide excellent image quality and speed of imaging. Improving the same two factors i.e. image resolution and temporality, has been the main focus of studies and techniques aimed to bring in new advancements in MR imaging systems. As a result, several modalities of MR imaging system e.g. gradients, and pulse sequences,have been manipulated to achieve several modes and sequences like diffusion weighted imaging, diffusion tensor imaging,[1] MR spectroscopy,[2] and dynamic contrast imaging. Moreover, increasing the magnetic field strength is also of great value as it increases the signal to noise ratio (SNR) and contrast to noise ratio (CNR) especially helpful for techniques like MR spectroscopy and functional MRI. However, ultra high field MR systems (≥7T) have their own safety con-cerns, which need to be addressed in order to implement these MR systems in research and clinical fields. This article will review potential safety issues as reported by previous studies and will discuss guidelines related to these safety issues.

Organizations providing guidelines for safe MRI practices:

In view of emerging applications of MRI techniques, several organizations have established guidelines regarding different aspects of patient safety undergoing MR imaging. These include Food and Drug Administration (FDA) guidelines,[3] which sets limiting criteria for several parameters like main static field, specific absorption rate (SAR), gradient fields rate of change and sound pressure level and International Electrotechnical Commission (IEC), which has esta-

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blished modes[4] i.e. normal operating, controlled and research/experimental (second) to ensure that adequate medical supervision is provided at MR imaging parameters at high values. Similarly International Commission on Non-Ionizing Radiation Protection (ICNIRP) provides guidance on health effects of non-ionizing radiations.[5] Other guidelines include Safety guidelines by American College of Radiology (ACR),[6] Medicines and Healthcare products Regu-latory Agency (MHRA) and American Society of Testing Methods (ASTM). The safety standards set by these guidelines will be discussed along with safety parameters of MR imaging system.

Identification of potential safety concerns requires thorough understanding of basic principles of MR imaging.[3] Briefly, magnetic resonance imaging (MRI) is based upon the principle of magnetic resonance whereby nuclei of atoms possessing ferromagnetic and paramagnetic properties are partially aligned by a strong magnetic field (B0) which can be flipped using radio frequency waves (transmitted through radio frequency (RF) coils) in the presence of gradient field (GSS) (produced through gradient coils for spatial encoding of magnetic field). This flipping of nuclei will subsequently result in their oscillations in the magnetic field ultimately reaching equilibrium point with simultaneous release of energy in the form of electromagnetic waves which are received by receiver radio frequency (RF) coils and these radio signals are then used to form detailed body images using different software. In short there are three types of magnetic fields involved in MR imaging system and increase in their strengths can have unique safety concerns in living organisms. Other potential safety issues which are common to all field strengths may arise from the use of contrast agents, anesthetic agents, breath holding spells, implanted devices with magnetic properties, and certain factors present in the surrounding environment e.g. the design of MR imaging machine itself.

Safety concerns related to static magnetic field (B0):

Static Magnetic field (B0) is probably the most important magnetic field regarding safety issues as it is responsible for the force and torque on human body at the nuclear level. This force, however, is also applicable to implanted devices and metallic objects. Increased field strengths exert more force on these objects which can be greater than 100000 times the force of gravity.These implants and metallic objects can be dislodged, lifted, rotated or disrupted. Moreover, RF wavelengths at 7T become shorter and are more prone to resonate with those of metallic objects causing energy exchange and heating.[9] Current FDA guidelines consider main static field strengths less than 8T to be non-significant risk in adults, while field strengths greater than 8T need investigational device exemption (IDE). A recent study showed that deflection angles of metallic dental implants were significantly larger at 7T than at 3T MR system.[7] Temperature increases were also significant but still less than 1°C in this study. Therefore meticulous safety screening precautions should be taken prior to ultra-high field MR imaging, searching for all implanted devices or other objects like surgical clips, arterial lines, stents, needles, dental prostheses, body piercings and rings, regardless of their size.

Apart from the studies identifying effects of force created by static magnetic field on human body and metallic objects (devices and implants), several studies have also been done to evaluate structural, physiological and pathological effects of Ultra high field MRI system on human body. One study showed that vital sign parameters (Diastolic blood pressure, heart rate, respiratory rate, body temperature and pulse oxygenation levels) did not change significantly during MRI procedure except for systolic blood pressure.[8] Another study[9] also showed no significant short term changes in vital signs, cardiac function and cognitive function. A 2011 meta-analysis[10] analyzing the effects of static magnetic fields on cognition, vital signs, and sensory perception supported the non-significant effect of static magnetic field on vital signs. However, sensory perception, as reported in previous studies[11-13] was significantly impaired with dizziness or vertigo being the most common symptom reported. Vertigo is believed to be caused by magnetic field induced currents produced in endolymph due to head movement in MR system.[14] Theysohnet. al (2014) further quantified the effects of ultra-high field strength imaging at 7T on vestibular system using sway path and body axis rotation tests and showed more temporary side effects e.g. vertigo at 7T system compared to 1.5 T and 3 system.[15] Vertigo and postural instability were even present after exiting the MR system, therefore, fall

precautions should be taken for individuals after 7T MR imaging. Other sensory modalities impaired in MR imaging are subjective sensation of metallic taste, nausea and light flashes,[15,16] allof which are also believed to be the result of static magnetic field induced currents. These currents are produced due to body movements e.g. head movements within the bore of MRI machine especially at high gradient fields, gradient field velocity. Therefore, body movements should be minimized while MR imaging especially at high field strengths which can further lower the side effects related to induced currents.
Effects of static magnetic field on special sensory system, cognition and behavior have also been studied[12,17,18] and results show no significant effects on cognition although eye hand coordination and visual contrast sensitivity show slight impairment. These results are also supported by a 2013 study[17] by Heinrich et al, who took a larger sample size with adequate matching and standardization, showing insignificant effects of static magnetic field at different field strengths even for eye hand coordination and visual contrast sensitivity. Hence, we can conclude that MR imaging at 7T appears to have no effect on cognition and behavior.

Safety Concerns related to gradient field:
Unlike static magnetic field, gradient field strength remains the same in ultra-high field strength imaging, so the side effects of gradient field strength in 7T MRI systems should also be the same as in low field strength systems i.e. peripheral nerve stimulation and acoustic noise production. Peripheral nerve stimulation depends upon the rate of change of gradient fields (dB/dt levels),[19] however Theysohn et al (2008)[12] reported significantly increased frequency of twitching (a physical sign of peripheral nerve stimulation) at 7T MRI. But, this could also be attributed to paresthesia caused by peripheral nerve compression. Initial dB/dt limit proposed by MRDD (Magnetic resonance diagnostic devices) guidance was 20T/sec for pulse duration over 120 microseconds[30] which was relaxed owing to clinical potential of MRI at dB/dt levels greater than 20T/sec. Now, MRDD guidance recommends volunteer studies for stimulation thresholds at different pulse durations and axes to limit dB/dt levels at 80% level of stimulation threshold in normal mode and at 100% level of stimulation threshold in first level controlled mode.Theyson et al (2008) also proposed that the dB/dtlimit could be increased to 120% level of stimulation threshold as peripheral nerve stimulation was still 2.9% which was less than the 5% limit set by FDA/IEC.[29]
Acoustic noise, another safety issue caused by gradient magnetic field, is produced through interaction of gradient and static magnetic fields causing vibrations of gradient coils governed by Lorentz forces. This noise can reach the levels of 126d band may cause multiple side effects from anxiety to partial hearing loss.[20] Therefore, effective noise reduction procedures are required at ultra-high field strength imaging as noise level increases with increase in strength of static magnetic field. Several studies have shown that both passive and active noise control procedures can reduce sound levels.[21,22] Furthermore, development of quiet MRI sequences by optimizing standard clinical turbo spin echo (TSE) and gradient echo (GRE) sequences can further reduce the noise level.[23]

Safety Concerns Related to Radiofrequency Field:
Radiofrequency field is another aspect of MRI system which has known safety issues, most important being radiofrequency (RF) induced heating.[24] Radiofrequency coils transmit high energy waves to nuclei for spin flip, but a lot of energy is also dissipated in the form of heat due to resistive nature of body tissues. Ultra high field strength imaging e.g 7T systems are particularly more hazardous because the incident wavelengths are shorter and more prone to resonate which can result in maximal energy transfer and subsequently heat generation leading to an increase in core body temperature. A major limitation of 7T MRI system, rotating magnetic field (B1) inhomogeneities, is also related to heating as it creates inhomogeneous distribution of signal and SAR (specific absorption rate) intensities, which results in localazied temperature increases, so called ‘hot spots’. Unlike, core body temperature increase, hot spots may be anywhere in the body and may be more difficult to localize and cool down. Luckily, the heating effect of RF field occurs more at the surface, which is easier to dissipate and thermoregulatory mechanisms are likely to further mitigate the RF induced temperature changes. Nevertheless, specific absorption rates (SAR) should be calculated and brought within FDA/

IEC guidelines, which limits SAR according to the body part being examined i.e. 4 W/kg whole body for 15 minutes, 3W/kg averaged over the head for 10 minutes, 8 W/kg in any gram of tissue in the headortorso for 15 minutes, or 12 W/kg in any gram of tissue in the extremities for 15 minutes.[30] Kangarlu et al (2003) measured radiofrequency induced temperature increases in a head phantom and confirmed the theoretical field inhomogeneites leading to hot spots as well as rise in core temperature, however, the temperature increases observed were all within FDA limits.[25] Some pulse sequences e.g. fast spin echo and magnetization transfer contrast may achieve SARs beyond the limits proposed by FDA/IEC guidelines. This issue has led to several other studiesaimed at reducing the parameters like repetition time, TR, and number of slices, and developing new pulse sequences which operate at SARs within fda/IEC limits. Variable rate selective RF pulse sequences[26,27] were designed to achieve peak RF power control which were further optimized for parameters like time[28] and acoustic noise.[29] To reduce the local field inhomogeneities and SAR, Zelinski et al (2009) suggested the use of parallel transmission of RF pulses for inner volume excitation and suggested model based evaluation of the individual target patterns.[30] However, designing parallel transmission RF sequences requires control over transmitter power and SAR, which was achieved by Guerin et al (2014) who proposed a design algorithm allowing the design of small flip-angle pTx spoke pulses with explicit control for local SAR, global SAR, maximum and average power on each channel.[31] Other techniques for parallel transmission of RF pulses at low peak RF power have also been developed[32,33] but their clinical applicability along with safety benefit is yet to be studied.

Conclusion

Ultra high field imaging is an emerging technique in diagnostic/interventional radiology with wide clinical applications and adequate safety profile. Nevertheless, all safety measures should be taken to ensure safety of patients and research volunteers. Safety guidelines by relevant organizations (FDA/IEC) should be used as a standard and strictly followed. At present, it appears that thereare no unique safety concerns at ultra-high fields (7T systems) when compared to low field systems like 1.5 T and 3T but common side effects can be more severe at high fields e.g. force on metallic objects, acoustic noise production, and radiofrequency induced heating. These should be handled by practicing more effective measures at ultra-high field strengths e.g. strict evaluations to search for contraindications to MRI (implants etc.), use of effective anti-noise apparatus, and utilizing RF power/SAR controlled pulse sequences. Finally, studies should be done for better evaluation of MRI safety and its emerging techniques. Newer techniques e.g. parallel transmission designs should be developed and optimized to make MR imaging a safer, faster and a reliable tool for healthcare.

Conflict of Interest:
Authors declare that no conflict of interest exists in writing of this article.

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