High Field MRI: What Are the Special Safety Risks at Higher Fields?

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Introduction

In the last 10 years the use of MR-scanners with a magnetic field stronger than 3 Tesla ("Ultra-high field MRI", ie. UHF-MRI, defined as 7 - 9.4 Tesla in this presentation) has increased sharply, mainly driven by the fact that the three main manufacturers decided to develop 7Tesla MRI scanners for research purposes. More recently, also human 9.4 Tesla research MRI scanners are offered commercially. Over the last ten years, important improvements in hardware and imaging sequences at 7Tesla have led to a quality of fMRI, anatomical neuroimaging, cerebral angiography and spectroscopy clearly surpassing the quality routinely obtained at 3Tesla. This improved performance has resulted in the use of UHF-MRI not only in normal, young volunteers but also for clinical research in patients. When using UHF-MRI scanners in patient populations the amount of subjects having implants or a history of surgery increases sharply, resulting in a more urgent need of safety testing of common implants as well as a strong local implementation of safety procedures. In this presentation, the safety aspects of UHF-MRI will be discussed, both regarding normal volunteers, patients and workers.

Main magnetic field strength

To date, no important biological hazards of ultra-high field MRI to humans or animals have been identified (1-7). Potential risks that have been investigated include effects on cell reproduction, cell function, thrombolysis, nerve function, cardiovascular effects, body temperature change, magnetophosphenes, and cell alignment. Cognitive testing in the stray field of a 7 Tesla MRI scanner has shown no or only mild influence on specific cognitive domains including attention/concentration and visuospatial orientation, but these effects are thought to disappear quickly after exposure (8-10). The highest magnetic field MRI scanner approved by the FDA for clinical use is 3Tesla MRI. However, in 2003 the FDA declared MRI-scanners up to 8Tesla non-significant risk devices, implying that while IRB-approval is necessary for investigational use, it is unnecessary to apply for an investigational device exemption for MRI scanners up to 8Tesla. According to IEC guidelines, upto 3 Tesla is the normal operating mode, between 3 and 4Tesla the first and above 4Tesla the second level controlled operating mode (effectively requiring IRB-approval). However, an amendment (the second amendment) to increase the first level control operating mode to 8 Tesla is under discussion.
Since the force on ferromagnetic objects depends on $B_0 \cdot dB_0/dx$, and the static field gradients just outside of the bore of a passively shielded 7Tesla magnet are slightly smaller than a 3Tesla MRI scanner of the same vendor (11), the projectile effect will be only a bit stronger than on a clinical 3Tesla scanner. Moreover, because the magnetic field increases only quite gradually when moving towards the bore-opening, there is also a rather gradual increase in experienced force when entering the MR-suite with a ferromagnetic object; making the chance much higher that somebody recognises the danger before forces become too strong to refrain the object from flying into the scanner (note that this only holds true for a passively shielded magnet, for active shielded magnet this story is completely different). Rotational forces (torque) are approximately proportional to $(B_0)^2$ and will be therefore be stronger in a larger area around the scanner opening.

MRI in a research setting

Because UHF-MRI is mainly employed for (clinical) research purposes, frequently a zero risk policy needs to be enforced to ensure minimal risks for participants as dictated by IRB regulations. This has led to conservative safety regulations in many UHF-sites, effectively limiting the possibility of scanning elderly subjects (who have had more time to undergo invasive clinical procedures) and patients. Ironically, this will limit the possibilities for gathering evidence of the added value of UHF-MRI in clinical decision making as compared to clinical field strengths, making it therefore hard to convince local authorities to reconsider (too) strict safety guidelines due to a lack of possible benefits for the participant.
An informal questionnaire among UHF-sites by the high field studygroup of the ISMRM has shown large differences in safety procedures between sites as well as differences in local efforts of testing MR-safety of common implants. Publishing and central dissemination of test results could help to relax some of the probably overly conservative safety regulations in many UHF-sites.

Acoustic noise

As explained by Lorenz law, currents running through the gradient coils in the strong magnetic field will impose forces on the gradients themselves, leading to vibrations and noise. The amount of noise produced by an MRI scanner depends on the engineering of the gradient coil, the static magnetic field strength and the employed sequences, making direct comparisons with clinical systems difficult. EPI imaging was found to be only slighter louder at the bore-entrance of a 7Tesla scanner (105 dB) than on a clinical 3Tesla scanner of the same manufacturer (103 dB), although these sequences were not designed to be comparable (11). Probably, the more important difference with MRI scanners of clinical field strengh, is that head-coils for 7Tesla MRI are designed much more tight than head coils at 3Tesla, making it impossible to employ double ear protection (ear plugs and headphones) and one has therefore to rely solely on ear plugs. Disadvantage of the use of ear plugs is that their noise suppression depends highly on how well they are inserted and also that they can get dislocated during patient handling or scanning. Approximately a third of the participants to a 7Tesla MRI examination reported acoustic noise as an important distress (12).

Subjective acceptance of UHF-MRI

A few studies have accessed the subjective acceptance of 7Tesla MRI. Yang et al interviewed 18 normal subjects and 74 patients with cerebral pathology participating in an 8 Tesla MRI examination and they reported transient vertigo and nausea (in two subjects) as potential risks (13). Theysohn et al also found that vertigo during table-movements was the most important difference in subjective tolerance between 7Tesla and 1.5Tesla MRI, although the longer examination duration at 7Tesla was reported as more uncomfortable (14). Fulton et al have previously observed that the occurrence of dizziness decreased by decreasing the speed of the table motion (15). In the study by Versluis et al, dizziness (34% of subjects moving in and 30% of subjects moving out of the scanner), scanner noise (33%) and metallic taste (11%) were the most reported side-effects of an UHF-MRI examination. The overall experience was rated by 3% as unpleasant, 51% as neutral, and 46% as pleasant. In summary, all studies show little discomfort associated with a 7Tesla MRI examination, with dizziness the most important discomfort.

B_1 and SAR

The same guidelines are used for B_1-limitations and SAR calculations in UHF-MRI than at clinical field strengths. The biggest difference with 3Tesla MRI, is the more widespread use of multi-channel transmit setups, making SAR-monitoring a much more important and difficult challenge. Moreover, the smaller wavelength of the RF at 7Tesla imposes new challenges in defining guidelines to prevent significant (local) tissue heating. However, fundamentally the same restrictions hold at 7Tesla as at 3Tesla MRI.

Peripheral nerve stimulation

Since gradient switching is limited by the same IEC guidelines as clinical MRI scanners, the occurrence of peripheral nerve simulation (PNS) is not a big issue in UHF-MRI (14). Moreover, since TR is frequently limited by SAR at UHF, slower slew-rates can be considered in many sequences to decrease the risk of PNS and lowering the noise level at the same time.

Implants and screening of subjects

Tested implants at 7 or 8Tesla include: aneurysm clips (16), implants for ear-nose-throat surgery (17), upper eye implants (18), cranial fixation plates (19), dental wires (20), an EEG-cap (21), intraocular lenses (22), coronary stents (23), and extracranial neurosurgical implants (24) (see references for details on which implants were tested and whether they were found to be (conditionally) safe or unsafe). However, these publications differ with regard to how the safety tests were performed, on the interpretation of the data and the way of reporting, making it difficult to incorporate these studies into local safety protocols. One reason for differences in safety testing procedures, is the fact that in UHF-MRI it can no longer be assumed that the B_1-distribution is homogeneous. A second challenge is that a centralized overview of tested implants and the findings is lacking at the moment for UHF. Whereas for clinical MRI scanning frequently the website www.MRIsafety.com is used, this is not very helpful for UHF-MRI, since only three items are included that are tested at 7Tesla or higher (with an approved contrast agent injector as probably the most useful item).

Discussion and concluding remarks

The main difference in safety regulations of UHF-MRI compared to 3Tesla MRI, results from the fact that none of the commercially available systems are FDA-approved or CE-marked. This implies that all UHF systems are still investigational devices, requiring conservative safety policies and IRB-approval for all subjects scanned. Dizziness when moving through the strong magnetic field can be considered the most important side effect. Only limited safety testing of implants have been performed and the results are scattered over literature, making inclusion of these results into local protocols difficult. However, overall one can consider 7Tesla MRI examinations of a similar burden for participants than 3 Tesla MRI.

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