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REVIEWS AND COMMENTARY • REVIEW

Safety Considerations of 7-T MRI in Clinical Practice

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Although 7-T MRI has recently received approval for use in clinical patient care, there are distinct safety issues associated with this relatively high magnetic field. Forces on metallic implants and radiofrequency power deposition and heating are safety considerations at 7 T. Patient bioeffects such as vertigo, dizziness, false feelings of motion, nausea, nystagmus, magnetophosphenes, and electrogustatory effects are more common and potentially more pronounced at 7 T than at lower field strengths. Herein the authors review safety issues associated with 7-T MRI. The rationale for safety concerns at this field strength are discussed as well as potential approaches to mitigate risk to patients and health care professionals.

The increased adoption of MRI over recent decades has been marked by a steady rise in static magnetic field strength. Greater MRI field strength is accompanied by greater susceptibility effect, faster signal decay due to decreased T2 relaxation time, and signal-to-noise gains afforded by a larger excess of polarized hydrogen atoms. Notably, many safety considerations are more concerning at 7 T compared with lower field strengths.

MRI at field strengths higher than 3 T has gained acceptance from regulating bodies in recent years. The U.S. Food and Drug Administration (FDA) categorized MRI up to 8 T as a nonsignificant risk device for nonneonatal patients in 2003 (1), and in 2009 the International Commission on Non-Ionizing Radiation Protection found that no serious health effects had resulted from acute exposures at this field strength (2). In 2015, the International Electrotechnical Commission increased the static magnetic field limit for the first-level controlled operating mode (ie, requiring medical supervision) from 4 T to 8 T (3). In 2017, one vendor was given a CE, or "Conformité Européene," mark for its 7-T clinical system (Fig 1). The CE mark indicates that the 7-T MRI system conforms with health, safety, and environmental protection standards for products sold within the European economic area (4). Later that year, the U.S. FDA provided the first 510(k) clearance for a clinical 7-T MRI system (5).

As mentioned, 7-T clinical MRI is accompanied by additional concerns for patient safety. At 7 T, translational and rotational forces become more pronounced. Radiofrequency (RF) heating from induced voltages are of particular concern because, at 7 T, regions of tissue can absorb greater RF energy than permitted by limits already established at lower field strengths (6). Implanted devices such as cochlear implants, neuromodulation systems, and cardiovascular implantable devices may undergo interference, altered settings, malfunctions, or permanent damage at 7 T (7). Even if previously deemed acceptable for patients at 1.5 T or 3 T, implants, devices, and foreign bodies should be evaluated specifically for safety concerns at 7 T. Finally, bioeffects such as nystagmus, nausea, and motion disturbances are more common at 7 T than at lower field strengths (2).

The purpose of this article is to review 7-T MRI safety considerations relevant for human imaging. Considerations for reducing and avoiding safety issues at this field strength are also discussed.

Forces on Objects, Implants, and Devices during 7-T MRI

Attractive translational and rotational forces act on metals in the MRI environment. These forces depend on factors such as material composition, shape, and orientation. Rotational forces (torques) are proportional to the static magnetic field B_0, whereas translational forces are proportional to the product of B_0 and the spatial field gradient (SFG). The SFG is the change in the static magnetic field with distance from the MRI system; its regional value depends on B_0 and scanner shielding (8). Compared with 3-T MRI, the 7-T MRI fringe field (the magnetic field extending beyond the scanner) changes quicker as a function of distance from the magnet (ie, it has a steeper SFG, see Fig 2). Because B_0 and the SFG are greater at 7 T than at lower field strengths, translational forces on implants, devices, and foreign bodies at 7 T are greater than corresponding forces at 1.5 and 3 T. The stronger 7-T fringe field also tends to extend farther from the magnet center than the 3-T fringe field. As a result, stronger attractive forces may extend to greater distances from the magnet at 7 T.

Abbreviations

FDA = Food and Drug Administration, RF = radiofrequency, SAR = specific absorption rate, SFG = spatial field gradient

Summary

This review outlines the safety risks of and associated risk-avoidance strategies for clinical 7-T MRI.

Essentials

- Educating radiology personnel on identifying, understanding, and avoiding unwanted forces and heating in clinical 7-T MRI can reduce safety risks and prevent injuries.
- Understanding bioeffects that may manifest during clinical 7-T MRI is essential for their management.
- On October 12, 2017, the U.S. Food and Drug Administration provided 510(k) premarket clearance for clinical 7-T MRI.
- For 7-T MRI, stronger electromagnetic fields cause greater forces on metallic devices, increased potential for functional deficiency of active implants, and unpredictable radiofrequency heating due to the current lack of single-channel body radiofrequency transmit coils and the shorter resonant wavelength relative to lower magnetic field strengths.
- In a study of more than 3000 patients imaged with 7-T MRI, nystagmus, nausea, motion disturbances, dizziness, and other bioeffects were shown to be of some concern, with 38% of patients reported vertigo, 5.4% reported electrogustatory effects (metallic taste), and 1.2% reported magnetophosphenes (perceived flashing lights).

Figure 1: The 7-T MRI system (Magnetom Terra; Siemens Healthineers, Erlangen, Germany) currently approved for clinical use in the United States and Europe.

There are other forces in MRI beyond the aforementioned attractive translational and rotational forces. Electrical current is induced in conducting materials as they move through a changing magnetic field (eg, the SFG). These currents induce additional magnetic fields that generate Lenz forces opposing the object's motion (9). Lenz forces are greater on conductors moving through the stronger 7-T SFG relative to similar rates of motion through a 1.5- or 3-T SFG. Finally, although not yet reported at 7 T, rapid switching of MRI gradient magnetic fields may cause alternating torque that vibrates certain electrically conductive implants (10).

Mitigation of Force Risks during 7-T MRI

There are a variety of strategies that may be employed to avoid or reduce forces associated with clinical 7-T MRI. The zone restrictions and standardized screening described in the American College of Radiology guidance document (11) should be followed to avoid inadvertent admittance of ferromagnetic materials into the MRI scanner room. Potential projectile accidents can be avoided with use of 7-T MRI conditional patient support equipment (12) such as gurneys, wheelchairs, oxygen tanks, and intravenous poles, in addition to appropriate training, screening, assessment, and warnings.

Heating of Tissue and Implants during 7-T MRI

RF radiation (as used in MRI) can induce electric current in conductors that causes tissue heating primarily due to resistive losses. Metal implants and devices have high conductivity and low resistance to electric currents, which leads to minimal implant heating. However, surrounding tissue may be heated due to its relatively high electrical resistance.

Implants and devices that are associated with nominal heating at 1.5 and/or 3 T may trigger unsafe heating at 7 T. The proton resonance frequency at 7 T is approximately 298 MHz and the corresponding RF wavelength in tissue is approximately 11 cm, compared with 26 cm at 3 T and 52 cm at 1.5 T (13). Maximum heating potential in linear conductive implants can occur at half the RF wavelength; this amounts to a RF wavelength of approximately 5.5 cm at 7 T for certain physical configurations (14,15). Tests in wires at 1.5 and 7 T indicated maximum heating can occur at even shorter lengths (16,17). Thus, shorter metallic implants, devices, and foreign bodies have greater potential to heat and cause thermal injury at 7-T MRI compared with 1.5- or 3-T MRI. This can be especially problematic when employing stronger RF pulses because temperature has been demonstrated to increase with the square of the transmitted pulse power (16).

The specific absorption rate (SAR) provides an indirect measure of tissue heating that varies with B_0 field strength in a nonlinear fashion. Below 3 T, SAR increases with the square of B_0 (18,19). Above 3 T, SAR increases linearly with field strength (14,20). Above 5 T, SAR can even decrease as B_0 increases (21). However, regulatory limits on the applied SAR are the same regardless of B_0 field strength. Table 1 lists regulatory limits from the U.S. FDA (22) and the International Electrotechnical Commission (23). For normal operating mode, the whole-body SAR limit is set at 2 W/kg by both the FDA and the International Electrotechnical Commission. Currently, 7-T MRI only has local RF transmit coils, for which the International Electrotechnical Commission provides guidance of 10 W/kg local SAR in normal operating mode.

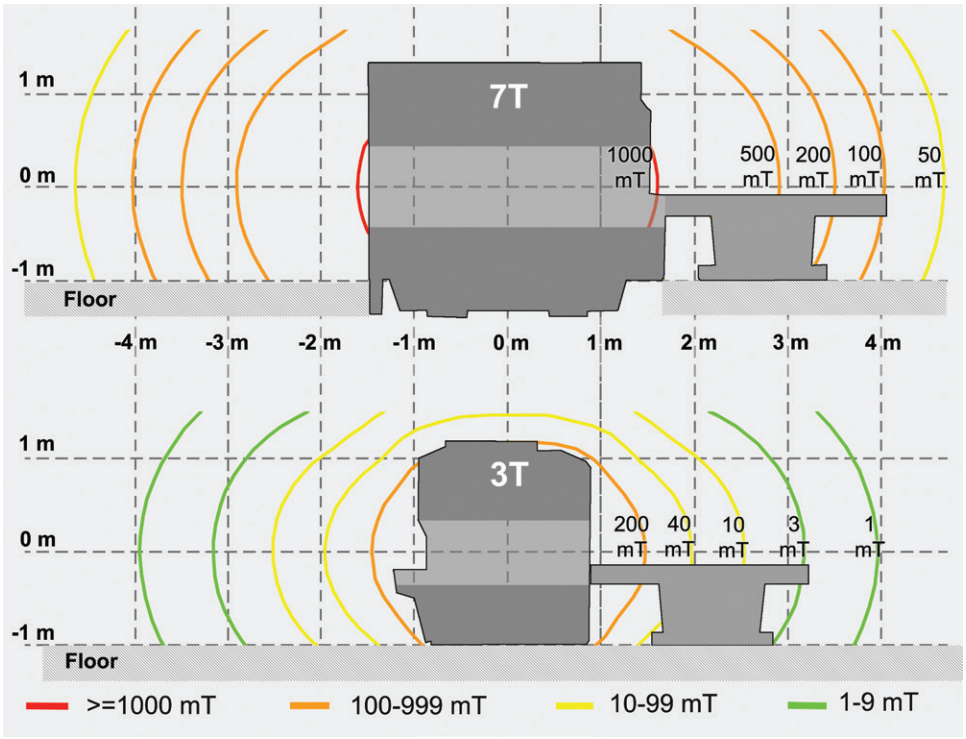

Figure 2: Comparison of fringe magnetic fields of two clinical MRI systems. Fringe magnetic fields are shown for (top) a 7-T MRI system (Magnetom Terra, Siemens Healthineers) and (bottom) a 3-T MRI system (Magnetom Skyra, Siemens Healthineers). Fringe field levels beyond the magnet are indicated by contours that are colored according to field strength ranges. These contours are also directly annotated with specific field strength values, with distance in meters indicated by dotted lines. Note: 1000 mT = 1 Tesla.

Monitoring RF-related heating in tissue at 7 T poses unique challenges relative to lower magnetic fields. The 1.5- and 3-T MRI systems are equipped with a large-volume, single-channel body coil for RF transmission. RF energy deposition for these coils is relatively straightforward to monitor and standardize due to the predictable single-source excitation. However, 7-T MRI research and clinical systems do not have a single-channel body RF transmit coil. Currently, the only option for 7-T RF transmission is using local, multichannel knee or head transmit-receive coils. RF energy deposition for these multichannel coils is difficult to monitor and standardize due to the added complexity of transmission from multiple sources. This is complicated by the relatively short (approximately 11 cm) 7-T RF wavelength in tissue. Shorter RF wavelengths can yield increased interference between waves and their reflections from boundaries or other RF coil channels, reducing RF penetration and increasing spatial RF (B_1) and SAR inhomogeneity relative to 1.5- and 3-T MRI (15,24).

Mitigation of Heating Risks during 7-T MRI

Tissue heating may be minimized by limiting RF power deposition and improving B_1 homogeneity to minimize regions of high SAR. This may be achieved by reducing RF pulse amplitude, duration, and/or frequency (25,26) or by employing dielectric pads (27). Multichannel transmission technology that modulates RF pulse waveforms and shims the B_1 magnetic field (28,29), readout segmentation with extended-length refocusing pulses (30), or fractionated dipole antennas (31) can also reduce SAR to limit tissue heating.

Implant and Device Safety during 7-T MRI

Approximately 300 metallic implants and devices have been tested at 7 T, a fraction of the more than 6000 metallic items that have been tested to date at 1.5 T and/or 3 T (32). Standardized methods for the evaluation of displacement, torque, and RF heating of passive implants were designed for 1.5- and 3-T scanners (33–36). As mentioned, the heating tests were developed for whole-body RF transmit coils, whereas currently only localized RF transmit coils (ie, head and knee coils) are available for clinical 7-T MRI. When coupled with the unique properties of the 7-T electromagnetic field relative to lower field strengths, it is apparent that 7-T–specific guidelines and further testing are needed to ensure safe 7-T imaging in the future.

Although methodology for 7-T testing to date has been variable, efforts are being made to evaluate a variety of devices. A summary of implant testing at 7 T is given in Table 2, listing implant type, testing results, and conditions (33–35,37). This table reveals the need for 7-T testing standardization that includes identification of each device's manufacturer, make, and model; execution of consistent testing protocols; and generation of reproducible results. Finally, note that all metallic implants will cause magnetic field inhomogeneity that leads to susceptibility artifacts in MRI.

There has been some debate among experts in the field regarding the safety of implants that are located beyond the immediate volume of the RF transmit coil. Currently, 7-T RF transmission is primarily limited to local head and knee RF coils, and the German Ultrahigh Field Imaging Network has accordingly provided recommendations that passive metallic implants that are distant from the transmitting RF coil and labeled "MR conditional" at 3 T can be safely scanned at magnetic field strengths higher than 3 T (54). It is true that the lack of commercial 7-T transmitting RF body coils permits reduction of RF heating risks by positioning implants remotely from a local transmitting coil. However, it is theoretically possible for low-resistance, conductive pathways within the volume of RF irradiation to propagate

Table 1: SAR Limits Recommended by the U.S. FDA and IEC

Organization and Operating Mode	Whole-Body Averaged SAR (W/kg)*	Body RF Transmit Head SAR (W/kg)	Local RF Transmit SAR (W/kg)		
			Head	Trunk	Extremity
FDA					
Normal	2[†]	3.2[‡]	…	…	…
First level	4[†]	3.2[‡]	…	…	…
IEC[§]					
Normal	2[‖]	3.2[‖]	10[‖]	10[‖]	20[‖]
First and second level	4[‖]	3.2[‖]	20[‖]	20[‖]	20[‖]

Note.—Normal operating mode = no outputs cause physiologic stress to patients; first-level controlled operating mode = one or more outputs cause physiologic stress to patients, requires medical supervision; second-level controlled operating mode = one or more outputs yield significant risk for patients, explicit ethical approval is required. FDA = Food and Drug Administration, IEC = International Electrotechnical Commission, RF = radiofrequency, SAR = specific absorption rate.

* Presently the FDA has not yet approved a 7-T system that employs RF transmission by means of a body coil.

[†] Averaged over 15 minutes.

[‡] Averaged over 10 minutes.

[§] The IEC recommends that SAR limits over a 10-second period not exceed twice any stated value.

[‖] Averaged over 6 minutes.

electric current to higher resistance regions remote from the irradiated region, regardless of RF frequency. Although this is a relatively improbable occurrence, it nevertheless presents thermal safety concerns when implants, devices, or foreign bodies are remote from the irradiated RF volume. The German report does offer some pertinent warnings regarding implants with a length scale similar to the resonant RF wavelength in tissue and regarding the possibility of the 7-T MRI scanner bore acting as a hollow circular waveguide for traveling waves (55) that could interact with distant implants (54).

Bioeffects

Patients undergoing MRI may experience biologic and/or physiologic effects as a result of their exposure to magnetic fields; many of these bioeffects are a 7-T imaging concern that are rarely considered at lower field strengths. Bioeffects caused by time-varying gradient magnetic fields, such as peripheral nerve stimulation and acoustic noise bioeffects, can be concerning at all clinical field strengths. Conversely, magnetic flux–induced bioeffects in the retina, tongue, vestibular apparatus, cardiovascular system, and brain that are barely detectable at 1.5 and 3 T may be noticeable at 7 T. The International Commission on Non-Ionizing Radiation Protection has thus recommended that symptoms such as vertigo, dizziness, nystagmus, magnetophosphenes, the electrogustatory effect, and neural and cardiac issues should be monitored carefully (2). Table 3 summarizes the experiences of subjects who underwent 7-T scanning as reported by means of survey-based studies; notably, vertigo for subjects on a moving table at 7 T was experienced by 1187 of 3147 subjects (37.7%) in a multisite cohort and by 346 of 573 subjects (60.4%) at one of those sites (56,57,59). Bioeffects will be described in turn and are classified as magnetic flux–induced bioeffects, peripheral nerve stimulation, acoustic noise bioeffects, or other bioeffects.

Magnetic Flux–induced Bioeffects

Recently, considerable effort has been spent in attempts to understand the bioeffects of changes in magnetic flux (the magnetic field passing through a surface) associated with 7-T MRI. As a patient passes through the SFG, as charged material passes through the static magnetic field, or even during time-varying gradient magnetic field applications, Lorentz forces are induced (60) in a variety of anatomic structures. Potential physiologic responses to these forces and their likelihood at 7 T are detailed below.

Cardiovascular System

Magnetohydrodynamic (ie, magnetism in electrically conductive fluids) forces can result from blood ions interacting with a magnetic field. These interactions can occur in MRI when a patient moves through the SFG. In addition, blood ions that flow through a static magnetic field can establish a flow potential that artificially elevates the T waves and ST segments on an electrocardiogram (8,61). Such blood ion motion in a magnetic field also induces a subsidiary magnetic field that generates forces opposing blood flow, which can increase systolic blood pressure (62) to a degree that depends on posture (63,64) and blood flow direction (65).

There is reason to believe that magnetic flux changes in the cardiovascular system are not a major concern for 7-T MRI. The World Health Organization has stated that the threshold for induction of minor heart rhythm, heart rate, and blood pressure changes are unlikely to occur at magnetic fields less than 8 T (66). In addition, investigators have reported no significant changes in blood pressure, respiration and heart rate, cardiac output, left ventricular and diastolic blood pressures, pulse oxygenation, and body temperature in animals, research volunteers, and patients with cerebral abnormality when scanning at 8 T (63,67). Studies have not yet been conducted in patients with compromised cardiovascular function (eg, heart failure, low

Table 2: Summary of 7-T MRI Implant, Device, and Foreign Body Testing to Date

Implant Type and Reference	Results
Two contrast material injectors, one RFID chip (32)	Approved
Twenty programmable shunt assistant valves (7)	Unintended pressure changes, many lost function
Thirty torsional magnetic microactuators (38)	No functional impairment when tested using animal 7-T MRI
Twelve dental retainer wires (17)	>45° deflection angle in six of the 12 wires Maximum temperature increases within a transmit RF head coil over 15 minutes at 16 W/kg SAR: 1.6°C for 4.7-cm-long wire in simulations and 1.4°C for 5.5-cm-length wire in experiment
Eighteen metallic items, including dental restorations and implants, abutments, and magnetic attachment keepers (39)	>90° deflection angle for two of 18 magnetic attachment keepers (all others <18°) Maximum temperature increases within a transmit RF head coil over 6 minutes: 1.5°C for one implant at 2.3 W/kg SAR and <1°C for all others at 1.2–2.23 W/kg SAR
Three intracranial fixation devices of varying diameter (40)	<7° deflection angles <1°C temperature increases measured within a transmit RF head coil over 20 minutes at 0.2 W/kg whole-body averaged SAR
Four extracranial neurosurgical implants (41)	<1°C temperature increases measured within a transmit RF head coil over 15 minutes at 10 W/kg SAR
Otolaryngological metal ventilation tube and wires, trachea support ring, nose dilator (42)	Nonstandardized testing showed motion but no significant heating of some implants in Petri dishes and water baths when using animal 7-T MRI
Twenty-three intraocular lenses with variable dyes, metals, and shapes (43)	< 1° deflection angles and <0.25°C temperature increases measured within a 6-cm-diameter transmit RF surface coil over 1 minute at 5 W/kg SAR
Ocular proton therapy markers (44)	<1° deflection angles
Two 32-electrode EEG caps (45,46)	Maximum temperature increases measured within a custom transmit RF head coil over 6 minutes at 10 W/kg SAR: 6.6°C in EEG paste and 3.8°C in phantom
Thirty-two–electrode EEG cap (47)	<0.4°C temperature increase measured within a 29-cm transmit RF head coil over 20 minutes at 2 W/kg SAR
Twenty peripheral stent-grafts (20–100 mm length) (48)	<33° deflection angles Maximum temperature increases measured within a custom transmit RF breast coil over 5 minutes at three times the local SAR maximum: <1°C in 14 of 20 grafts and <2°C in 40-mm-long grafts
Twenty-eight implants: clips, staples, stents, implants, screws, tissue markers, bullet (49)	>45° deflection angles in seven of 28 implants Moderate to high torque in 10 of 28 implants <1°C temperature increases measured in two aneurysm clips within a transmit RF head coil over 18.5 minutes at 3 and 1.5 W/kg SAR, respectively
Thirty-nine grafts, stents, intraocular lens, plates, nails, artificial joint (50)	>45° deflection angles in five of 39 implants Moderate torque in one of 33 implants <0.5°C temperature increase measured in eight implants tested within a transmit RF head coil over 15 minutes at 212% allowable SAR
Forty-six MRI support devices: gurneys, hampers, intravenous poles, ladders, tank holders, stools, table, walkers, wheelchairs (12)	No deflections observed for 13 items, results extrapolated to 33 similar items with lower magnetic susceptibility
Thirty-four ballistic objects: 31 bullets and three shotgun pellets (51)	No noticeable deflections in objects tested at 7 T
Four metal-containing intrauterine devices (52)	No device displacement or statistically significant temperature increases
Implants, tattoos (53)	Retrospective study of 230 subjects over 7.5 years revealed no reports of heating or forces

Note.—All heating experiments were conducted by using fiberoptic temperature probes in tissue-mimicking gel phantoms. EEG = electroencephalography, RF = radiofrequency, RFID = radiofrequency identification, SAR = specific absorption rate.

Table 3: Survey-based 7.0-T MRI Experiences

Reference	Study Design	Findings
Heilmaier et al (56) and Theysohn et al (57)	573 subjects underwent 7-T MRI, 166 of whom also underwent 1.5-T MRI. Authors assessed vertigo, electrogustatory effect, nausea, sweating, headaches, fear, magneto-phosphenes, tachycardia, and mental stability	1.7% of examinations (10/577) were incomplete due to nausea, pressure, or vertigo 11.9% of subjects (68/573) rated the examination as unpleasant, with head-first scans being more discomforting At 7-T relative to 1.5 T: Subjects generally experienced greater discomfort, especially vertigo, noise, and heating With a stationary table, all effects worse except sweating, headaches, and magnetophosphenes; 31.9% of subjects (183/573) reported a tiny amount of vertigo With a moving table, all effects were worse; 60.4% of subjects (346/573) reported a mild amount of vertigo (almost half of whom reported no vertigo with the stationary table)
Versluis et al (58)	101 subjects underwent 7-T examinations. Authors assessed dizziness, nausea, electrogustatory effect, heating, and acoustic noise.	3% of subjects (three of 101) reported an unpleasant experience Dizziness: 34% (34/101) felt dizzy going into the scanner 30% (30/101) felt dizzy coming out of scanner (more head-first) 14% of subjects (14/101) felt dizzy during imaging 11% of subjects (11/101) reported electrogustatory effect 33% of subjects (33/101) reported unpleasant acoustic noise One subject reported magnetophosphenes during the first 10 minutes One subject reported peripheral nerve stimulation
Rauschenberg et al (59)	3154 7-T examinations at four sites (including those from (56,57). Authors assessed site-dependent side-effects. Some examinations included slow manual table movement.	When mixed with approximately 10% (313/3467) of patients who underwent 9.4-T MRI: 82% (2843/3467) found the experience tolerable 7.6% (263/3467) reported discomfort 1% (35/3467) were unwilling to undergo further 7-T MRI 25% (867/3467) reported some mostly bearable side effects All 7-T bioeffects were rated worse during table movement: 37.7% of subjects (1187/3147) reported mild vertigo 19.3% of subjects (608/3147) reported moderate vertigo 5.4% of subjects (196/3147) reported electrogustatory effect 2.1% of subjects (66/3147) reported nausea 1.2% of subjects (39/3147) reported magnetophosphenes

ejection fraction) to determine if the magnetohydrodynamic effect can cause cardiovascular issues during 7-T scanning of this unique patient population.

Brain

Although most studies have reported no cognitive effects from exposure to the 7-T magnetic field, some have measured temporary deficiencies in visual and attention-related tasks performed in the 7-T fringe magnetic field that is depicted in Figure 2. Heinrich et al (68,69) examined visual processing and discrimination, hand-eye coordination, memory, attention, and reaction time and found that, aside from a slight effect on visual processing, B_0 field strengths up to 8 T did not significantly affect cognitive function. de Vocht et al (70) and van Nierop et al (71) analyzed effects on observed attention, concentration, and visuomotor, visual sensory, and visuospatial orientation in patients both stationary and moving near the magnet bore. They reported cognitive deficits in visuomotor speed (2%–7% average reduction per Tesla exposure over 64 patients), visual contrast thresholds (10% average reduction per Tesla exposure over 64 patients), visuospatial orientation (46.7% average deviation in line-bisection task per Tesla exposure over 30 patients), and attention and concentration (5%–21% average reaction time delays per Tesla exposure over 30 patients). Chakeres and de Vocht (64) measured transient episodes of sinus tachycardia during learning, retention, recognition, fluency, digit span forward, digit span backward, number-letter, and auditory–motor reaction time testing in

25 subjects, although they did not otherwise observe clinically significant neurocognitive effects in subjects at 8 T.

Vestibular Apparatus

The most prevalent and potentially concerning bioeffects at 7-T MRI relative to 1.5- and 3-T MRI are those occurring in the vestibular apparatus. Magnetohydrodynamic forces in the ionic endolymph of the vestibular apparatus have been postulated to arise due to electromagnetic induction from table or head movement in the magnetic field or from regional differences in magnetic susceptibility. Currently, the popular theory is that ionic endolymph motion in a static magnetic field induces magnetohydrodynamic forces (6,72). Regardless of origin, these forces in the vestibular endolymph lead to symptoms such as vertigo, dizziness, nausea, false feelings of motion, and transient nystagmus. Such bioeffects scale with the static magnetic field strength and are thus more prominent at 7 T than at weaker magnetic fields (56,72). Of particular concern is that motion sensations and nystagmus were reported to persist 2–30 minutes after patients were removed from the B_0 field (73). Table 3 shows that in one multicenter study (59), 1187 of 3147 subjects (37.7%) reported mild vertigo and 608 of 3147 (19.3%) reported moderate vertigo; in another study of 101 subjects (58), 34 reported dizziness going into a 7-T scanner, 30 reported dizziness coming out of a 7-T scanner, and 14 experienced dizziness during 7-T imaging. At one of the multicenter sites, 166 subjects also underwent 1.5-T examinations and overall reported greater motion disturbances when moving and stationary in the 7-T field (56).

Retina

Changing magnetic fields can induce current in the retina, which in turn can stimulate the optic nerve and cause the patient to perceive flashing lights. Some have postulated that these magnetophosphenes are caused by diamagnetic forces on retinal rods due to susceptibility anisotropy (74). The intensity of this phenomenon is proportional to the change in the magnetic field over a given amount of time, or dB/dt (6). Magnetophosphenes are thus more common at 7 T than at lower field strengths, especially as subjects' eyes move rapidly through the SFG (6). Regardless, Table 3 illustrates that, to date, few have reported experiencing magnetophosphenes. One multicenter study (59) found that only 39 of 3147 subjects (1.2%) perceived flashing lights, and one of the sites compared 166 subject examinations at 1.5 T and reported no increased prevalence at 7 T (56).

Tongue

Patients may complain of a "metallic taste" sensation when they move near the MRI scanner; this electrogustatory effect depends on the motion rate and direction with respect to the MRI magnetic field. Although the source of this phenomenon is not generally agreed upon (75), some have proposed that it could be related to the electrolysis of metallic dental fillings during translation through the SFG (63,76). Cavin et al (75) found that 12 of 21 subjects experienced metallic taste sensations when moving their heads in 7-T fields just outside the magnet bore. Table 3 conveys that, in a multicenter study (59), 196 of 3147 patients (5.4%) reported experiencing these sensations at 7 T. One of the centers found that the electrogustatory effect was more pronounced in the 7-T field for the 166 subjects who also underwent 1.5-T examinations (56).

Peripheral Nerve Stimulation

Induced voltages from time-varying gradient magnetic fields may result in inadvertent peripheral nerve stimulation that can be disconcerting or painful for the patient (77). There are little data on peripheral nerve stimulation associated with 7-T MRI and variable opinions as to whether it poses a greater risk than at lower field strengths. Some express concern that stronger gradients may be used to overcome the larger susceptibility effect at 7 T (78), although Kraff and Quick (79) noted that many 3-T scanners are capable of higher gradient amplitudes and slew rates for neurologic applications. Whether peripheral nerve stimulation poses a greater risk at 7 T than at lower field strengths thus depends on system functionality.

Acoustic Noise Bioeffects

The interaction of the static B_0 magnetic field with rapidly alternating currents in gradient coils yields coil vibrations; the subsequent impact of the coils within their mountings generates acoustic noise during MRI examinations. This can cause patient discomfort, communication difficulties, and/or temporary hearing loss shown to return to within 10 dB of baseline in 15 minutes (80). Guidelines from the U.S. FDA set maximum allowable sound pressure levels during MRI at 140 dB and at 99 dB root-mean-square average with hearing protection (22). Noise amplitudes depend on gradient amplitude, slew rate, pulse duration, and duty cycle, coil composition and geometry, pulse sequence parameters, and other environmental factors (81).

There is evidence to suggest that acoustic noise may be more of a concern at 7 T than at lower magnetic fields, although tests have been sparse with varied results. Budinger and Bird (74) theorized that the acoustic noise power scales nonlinearly with B_0 for a given gradient coil orientation. One study used simulations to compute a 6.3-dB increase in spectrally averaged sound pressure levels at 7 T relative to 3 T but computed a 2.4-dB decrease when a Lorentz damping term was included (82). Others have measured nominal to no change when echo-planar imaging pulse sequences were employed (83,84).

Other Bioeffects

There are other bioeffects of concern in MRI, although at this time no issues associated with 7-T MRI have been reported. Free radical concentration has been measured to increase when a magnetic field is applied, which can damage neighboring biomolecules (85). However, no effects have been reported in association with MRI (6,74). Magneto-orientation and magneto-mechanical translations of diamagnetic or paramagnetic materials in the body are thought to be too small to have a substantial effect on human subjects (6,8). A recent study using an ex vivo model measured mercury loss from dental amalgam–filled teeth in an artificial saliva solution when scanned at

7 T but not at 1.5 T (86); further studies validating this finding and determining how it may impact human subjects are warranted.

Mitigation of Bioeffects

There are methods to mitigate bioeffects. Because magnetic flux–induced effects increase with larger changes in the magnetic field over a given time, they may be mitigated by increasing the amount of time during which patients are moved through the SFG, both as they enter and as they exit the scanner bore. Careful patient evaluation and transport after 7-T examinations and before release can also mitigate risks associated with lingering vestibular issues. Acoustic noise perceived by the patient may be reduced with earplugs and headphones. In addition, scanning sequences using acoustic noise reduction techniques are currently offered by most vendors, although to date not all pulse sequences are available with such options. Antiphase noise cancellation (87), Lorentz force noise cancellation (88), and computer-aided gradient coil design (89) are other methods for reduction of acoustic noise.

Conclusion

After considering the safety issues that are unique to MRI at 7 T relative to lower magnetic field strengths, it is apparent that safety guidelines specific to this high field strength should be established. Many of the safety considerations discussed herein also apply to magnetic fields higher than 7 T, although the recent adoption of clinical 7-T MRI necessitates the standardization of 7-T–specific safety recommendations. The most concerning safety issues are the increased forces on metallic implants and the unpredictable radiofrequency-induced tissue heating that occurs at 7 T. Bioeffects such as vertigo, nystagmus, and magnetophosphenes are generally more prevalent and problematic at 7 T relative to lower field strengths, which also inspires special safety considerations. It is hoped that testing standards and the number of implants evaluated according to them will be updated to enable a greater number of patients with biomedical devices to have access to 7-T MRI. Regardless, it is the responsibility of the institution that installs a 7-T clinical MRI scanner to ensure patient safety both before and during the imaging process, and ideally to report adverse effects to add to the growing body of 7-T safety knowledge.

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