ICNIRP STATEMENT

AMENDMENT TO THE ICNIRP "STATEMENT ON MEDICAL MAGNETIC RESONANCE (MR) PROCEDURES: PROTECTION OF PATIENTS"

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AMENDMENT TO THE ICNIRP "STATEMENT ON MEDICAL MAGNETIC RESONANCE (MR) PROCEDURES: PROTECTION OF PATIENTS"

The International Commission on Non-Ionizing Radiation Protection*

INTRODUCTION

ICNIRP PUBLISHED in 2004 a statement on the protection of patients undergoing medical magnetic resonance (MR) procedures (ICNIRP 2004). This statement was intended for use by international and national medical device regulatory authorities, MR users and health professionals, and those involved in the design and manufacture of MR equipment for clinical applications. Contraindications, precautions, and safety considerations for the patients were given. Recommendations on research with volunteers were also given.

Since publication of that statement, there have been further studies of the possible health effects of exposure to the high static magnetic field levels used in the new generation of MR systems (summarized by Noble et al. 2005 and AGNIR 2008) and in 2006 the World Health Organization (WHO) published a health risk assessment of static magnetic field exposure (WHO 2006). A revision concerning patient exposure to MR clinical procedures has been made by the UK Health Protection Agency (HPA 2008). In addition, ICNIRP has recently published revised guidance on occupational and general public exposure to static magnetic fields (ICNIRP 2009). These revised guidelines recommend that occupational exposure of the head and trunk should not exceed a spatial peak magnetic flux density of 2 tesla (T) except for the following circumstance. For work applications for which exposures above 2 T are deemed necessary, exposure up to 8 T can be permitted if the environment is controlled and appropriate work practices are implemented to control movement-induced effects. Further guidance was issued regarding exposure of the general public.

In the light of this updated static magnetic field guidance and of the continuing development of MR technology and its important and wide-ranging applications in clinical diagnosis (Gowland 2005), ICNIRP has decided to issue an amendment of the statement concerning patient exposure to static magnetic fields during these procedures. The advice concerning patient exposure to the switched gradient fields and radiofrequency (RF) fields recommended by ICNIRP (2004) remains current.

RATIONALE

The following is a brief summary of the conclusions regarding studies of the possible health effects resulting from exposure to static magnetic fields published since the ICNIRP (2004) statement. Most of the new studies have concerned laboratory investigations of effects induced during movement in and around MR systems of up to 7 T and the associated dosimetry regarding movement-induced electric fields and currents.

Dosimetry: movement-induced electric fields and currents

Time-varying magnetic fields induce electric fields and currents in living tissues in accordance with Faraday's law of induction. Such fields and currents may also be induced by movement in a static magnetic field. In particular, motion along a field gradient or rotational motion, either in a uniform field or in a field gradient, produces a change in flux linkage which induces an electric current, in contrast to linear motion of the body within a uniform static field. With regard to linear movement in a gradient field, the magnitude of the induced currents and associated electric fields increases with velocity of the movement and amplitude of the gradient. Calculations suggest that such induced electric fields will be substantial during normal movement around or within fields >2–3 T (Crozier and Liu 2005), and may account for the numerous reports of vertigo, nausea and flickering light sensations (termed magnetic or magneto-phosphenes) experienced by patients, volunteers and workers moving in the field (Schenck et al. 1992; Chakeres and de Vocht 2005; de Vocht et al.

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2006b). For a body moving at a constant speed of 0.5 m s^{-1} into a 4 T magnet, Crozier and Liu (2005) estimate the maximum induced electric field strength in the body to be approximately 2 V m^{-1} (WHO 2007). It should be noted that frequencies associated with body movement are likely to be less than 10 Hz, the frequency below which accommodation decreases the electrical excitability of nerve tissue due to the slow inactivation of the voltage-gated sodium ion channels (Bezanilla 2000).

Laboratory studies

The conclusion of ICNIRP in 2004 regarding a lack of effects whilst stationary in a static field of 8 T has been confirmed in an MR study in which the static field component was 9.4 T (Atkinson et al. 2007) where no change was seen in heart rate or systolic blood pressure or in other measures of vital functions.

Several studies have reported that individuals exposed to static magnetic fields above 2–3 T experience transient sensory effects associated with motion in a static field gradient such as vertigo, nausea, a metallic taste, and magnetic phosphenes when moving the eyes or head (Schenck et al. 1992; de Vocht et al. 2006a and b; Atkinson et al. 2007). However, the occurrence and severity of these symptoms can be decreased by slowing the rate of motion of an individual through the magnetic field gradient (Chakeres and de Vocht 2005).

The theoretical and experimental basis for magnetic-field-induced vertigo experienced by people working in and around strong static magnetic fields has been investigated in some detail by Glover et al. (2007). Movement of volunteers into the bore of a 7 T whole-body magnet at a speed of 0.1 m s^{-1} resulted in a sensation of rotation (pitch forwards or backwards) in some but not all of the subjects. The direction of apparent rotation was reversed when the orientation of the subject was reversed in relation to the field, e.g., by moving from a supine to a prone position, suggesting an effect of induced current on the neural output of the vestibular system. Head movement within the homogeneous (zero gradient) field at the center of the magnet resulted in mild to severe vertigo-like effects, and in some cases nausea, for up to 30 minutes.

In contrast to movement-induced effects, postural sway was increased in some (less than 50%) of the subjects standing stationary adjacent to the MR scanner in a field of ~0.8 T. The effect is thought to be consistent with differences in magnetic susceptibility between the calcite crystals that comprise the otoconia of the vestibular organ and the surrounding fluid.

Sensitivity to these effects varies considerably between individuals. Thresholds for motion-induced vertigo in sensitive people were estimated to be of the order of 1 T s^{-1} for greater than 1 s, and of a field-gradient product of 1 T^2 m^{-1} for postural sway. The long integration times required for these effects to become apparent are indicative of the relatively low frequency response (0.4–4 Hz) of the vestibular system (Grossman et al. 1988; Pozzo et al. 1990; MacDougall and Moore 2005).

In conclusion, current information does not indicate any serious health effects resulting from acute exposure to static magnetic fields up to 8 T. It should be noted, however, that such exposures can lead to potentially unpleasant sensory effects such as vertigo during head or body movement.

Epidemiological studies

ICNIRP (2004) noted that there have been no epidemiological studies performed to assess possible long-term health effects in patients (or volunteers) and recommended that such research be carried out, particularly on individuals such as volunteers with high levels of exposure. It remains the case that there is no specific information regarding possible long-term health effects. Mechanistic considerations however, suggest that any effects are likely to be acute.

RECOMMENDATIONS

ICNIRP notes that it is the responsibility of medical doctors to balance the risk and benefit to a patient undergoing an MR examination. It remains the case that, as noted by ICNIRP (2004), very little is known about the effects of static magnetic fields in excess of 4 T on the growth and development of fetuses and infants, and therefore some caution may be warranted regarding their imaging above 4 T.

The three-tier approach used previously by ICNIRP (2004) is still considered to afford adequate levels of protection to patients as well as provide no hindrance to routine clinical imaging. Additionally, it provides flexibility for research and for further development of diagnostic procedures. These tiers were, in summary:

- Routine MR examinations for all patients (normal operating mode);
- Specific MR examinations outside the normal operating range, where discomfort and/or adverse effects for some patients may occur. A clinical decision must be taken to balance such effects against foreseen benefits; exposure must be carried out under medical supervision (controlled operating mode); and
- Experimental MR procedures, at levels outside the controlled operating range, for which special ethical approval may be required in view of the potential risks (experimental operating mode).

It is recommended that until further information becomes available, the limits on static magnetic field exposure recommended by ICNIRP (2004) should be as follows for each operating mode:

- For the normal operating mode there should be an upper limit for whole-body exposure of 4 T, in view of uncertainties regarding the effects of higher fields, including effects on fetuses and infants;
- For the controlled operating mode, there should be an upper limit for whole-body exposure of 8 T. ICNIRP considers that the exposures permitted under the controlled operating mode should be based on levels for which there is appreciable human evidence, and should not go higher than this; and
- For the experimental operating mode above 8 T, a progressively cautious approach is suggested for increasingly high magnetic flux densities due to uncertainties regarding possible effects of flow potentials on heart function. In the light of these possible effects, it is concluded that patients should be exposed to such fields only with appropriate clinical monitoring.

There is a need to ensure that patients are moved slowly into the magnet bore, to avoid the possibility of vertigo and nausea. Thresholds for motion-induced vertigo have been estimated to be around 1 T s^{-1} for greater than 1 s; avoiding these sensations is likely to afford protection against other effects of induced electric fields and currents that arise as a consequence of motion in a static magnetic field.

During the preparation of the statement, the composition of the International Commission on Non-Ionizing Radiation Protection was as follows:

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