SAFETY OF THE PATIENT DURING IN VIVO MAGNETIC RESONANCE EXAMINATIONS. RATIONALE FOR THE INIRC/IRPA GUIDELINE.

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IRPA/INIRC is developing guidelines on safety of in vivo magnetic resonance (MR) diagnostic examinations,imaging (MRI) or spectroscopy (MRS), which involve exposure of the patient to static (SMF) and switched gradient (time-varying) magnetic fields (TMF), and radio frequency (RF) fields. The aim of this paper is to relate mechanisms of interactions, clinical endpoints and exposure conditions to safety concerns. Simplifications were made; more information can be found in Blank and Findl (1987), Tenforde and Budinger (1987), WHO-UNEP-IRPA (1987); quantities and units are defined in IRPA (1985). Current MR devices use SMF of 0.5 to 1.5 T, a few up to 5 T. TMF range from 1 to 10 mT with complex wave forms at frequencies from below 300 Hz up to a few kHz, and a time rate of change in magnetic flux density (dB/dt) up to 6 T/s. RF exposures occurr mostly in the frequency range from 4 to 200 MHz and result usually in a specific absorption rate (SAR) below 0.4 W/kg, examinations at higher SARs were also performed. MR examinations can be completed under one hour, and may be repeated a few times over the patient's lifetime. The considerations below refer only to such conditions, and do not apply to occupational or public exposure.

3 classes of interactions of SMF with living systems can be distinguished: 1. electro-, and magnetohydrodynamic, 2.magnetomechanical, 3. at the atomic and nuclear levels. Electrodynamic phenomena consist in the interaction of steady ionic currents with applied SMF according to Lorentz's force law. An electric (E) field is induced when an electrolyte flows through an insulated channel (eg. blood in a blood vessel), or a container filled with electrolyte (body, or body part) moves in the presence of SMF. The magnitude of induced potentials depends on the diameter of the vessel (size of container), flow (movement) velocity, the orientation and strenght of SMF. These also can deflect ionic currents within cells, and, in particular, conduction currents in excitable membranes of nerve and muscle cells. Magnetically induced potentials lead to changes in ECG at 0.1 T which increase with SMF strenght. Concerns were raised that at 2.5 T in adult healthy humans E field may reach depolarization potential for heart fibers, other calculations indicate that 10 T are still below fibrillation response levels. These are not known for patients with altered heart conduction because of disease or medication. Experiments on isolated neurons did not reveal any effects on conduction at 2 T, theoretical estimates indicate that 24 T are needed to deflect conduction currents. However, fields below 2 T may affect impulse propagation in asymmetric conductor loops, which may explain observed transient effects on acoustic induced potentials in the brain.

Theoretically, 10 T may restrict ion transport through the cell membrane. Magnetohydrodynamic effects consist in retardation of axial velocity of an electrolyte solution flowing through SMF. This leads to an increase in arterial blood pressure. Negligible hemodynamic perturbations are expected below 2 T, a 7% reduction of aortic flow velocity is expected in an adult human at 5 T. Magnetomechanical interactions do not play a role in biological mechanisms of concern, constitute however, the basis for the most hazardous aspect of MR: effects on ferromagnetic inclusions in the body and attraction of metallic objects by the magnet (see below). Interactions at the atomic and nuclear levels lead to interference with biochemical reactions, particularly those, which involve electron transfer processes via radical pair intermediates. Under MR examination conditions this mechanism is of little concern.

TMF induce potentials and circulating currents in accord with Faraday's law, i.e. effects can be discussed in terms of E field strengths and current densities (J). Their magnitude increases with the radius of the inductive loop and dB/dt. At low frequencies the interior of the cell is shielded, and the most likely site of interaction is the cell membrane. Many cell functions are affected even at low E and J values. Under MR examination conditions effects on the heart conduction system, muscle and nerve cells (electrical neuromuscular stimulation) are of concern. Thresholds for effects depend upon electrical and electrophysiological properties of tissues, and are frequency and waveform dependent. For MR TMF exposure conditions a general statement can be made that at J between 0.1 and 1.0 A/m^2 changes in the bioelectrical activity of the brain may occur, the threshold for sensory stimulation lying somewhere in this range. At J above 1 A/m^2 immediate health hazards exist, associated with the increasing possibility of inducing cardiac fibrillation (most quoted threshold 3 A/m^2, possibly lower in pathologic states) and continous (tetanic) muscle contractions. The most widely known effect of TMF exposure, magnetophoshenes, i.e. sensation of light flashes perceived during exposure of the head, is unlikely to occur under MR examination conditions.

Several mechanisms have been proposed for the interaction of RF fields, an established and noncontroversial one is dielectric heating. There is a wide concensus that exposure limits at frequencies above 100 kHz have to be established primarily from thermal considerations. Physiological considerations indicate that an increase of $1^{o}C$ in core temperature does not pose immediate health hazards to individuals with an unimpaired blood flow from the core to the skin, and normal evaporative heat loss through respiration and sweating. The increase in temperature during MR examination depends on RF energy depositon and the rate of heat loss. Nonuniformity of RF energy absorption in the human body may lead to an elevation of temperature over a limited volume (hot spot) not accompanied by an increase in core temperature.

The above mechanistic considerations supported by a large body of experimental data allow one to identify the cardiovascular, the central and the peripheral nervous systems as critical

ones for immediate adverse reactions due to SMF and TMF interactions. Tolerance to RF exposure is dependent upon the function of the cardiovascular and respiratory systems in thermoregulatory responses induced by systemic heating. Another limiting factor is the possibility of focal thermal injury due to RF hot spots. Thus physiological considerations seem to be suitable primary criteria for the evaluation of MR exposure conditions, from which secondary criteria in terms of physical parameters of exposure fields may be derived. IRPA/INIRC proposed the following guidelines for the assesment of MR safety:

SMF: No adverse effects have been observed nor are expected from exposures of the head and/or trunk to 2 T, or of the limbs to 5 T. Exposures of the head and trunk above 2 T require an assesment of the potential risk vs the likely benefit. Whole body exposures over 5 T may pose hazards for poeple with cardiovascular disease. Monitoring of cardiovascular function must be undertaken whenever exposures above 2 T occur. All exposures must be limited to fields below 10 T.

TMF: No adverse effects are expected when the dB/dt in the region occupied by the head or trunk does not exceed 3 T/s for the duration of change in magnetic flux density longer than 10 ms. For shorter periods dB/dt may be increased, provided that the product of $(dB/dt)^2$ and the duration of the change of magnetic flux density in seconds is less than 0.09. In the region occupied by the limbs dB/dt should not exceed twice the above values.

These values incorporate a safety factor of about 100 in respect to cardiac fibrillation threshold, and an even larger one in respect to peripheral neuromuscular stimulation. In the U.K. (NRPB, 1983) and the U.S. (Czerski and Athey, 1987) 20 T/s were indentified as a level at which no adverse effects are expected. At this level the safety factor for neuromuscular stimulation is about 3, and about 10 for cardiac fibrillation.

RF: For whole body or head and trunk exposures no adverse effects are expected if the increase in body temperature does not exceed $1^{o}C$, except for infants, pregnant women, and persons with cardiovascular deficits, in whom it is desirable to limit temperature increases to $0.5^{o}C$. IRPA/INIRC derived SARs for exposures of the head (4 W/kg limited to 60 Wmin/kg), trunk (8 W/kg limited to 120 Wmin/kg) and extremities (12W/kg limited to 180 Wmin/kg) at which temperature increases remain below these values. However, users of MR devices usually do not have the resources to determine RF energy deposition. Reliable and detailed data have to be obtained from the manufacturer.

A special case is the the examination during pregnancy and early childhood. MR in vivo studies of the fetus, pregnant women, newborn and infants should be limited to cases where direct benefit tothe patient will be derived in terms of diagnostic information not obtainable by alternate methods. The fetus may be sensitive to RF and magneetic fields. MRI is not not likely to provide useful information, so that examination of pregnant women during the 1^{st} trimester should be justified by benefits to the mother.

Exposure durations should reduced to mininum, and RF energy deposition should be kept at levels which minimize temperature increases, which should not exceed 0.5^{o}C.

Because of magnetic or RF interference examination of persons who have electrically, magnetically or mechanically activated implants (eg cardiac pacemakers) or rely on life support systems is contraindicated. Patientss with ferromagnetic aneurysm clips or metallic implants (eg intrauterine contraceptive devices, large hip prostheses) are also contraindicated.

A important aspect of MR safety are ancillary (collision and electromagnetic interference) hazards. The field near the magnet may be strong enough to pull ferromagnetic objects along the axis of the field. Thus, metallic objects can become dangerous projectiles. Various medical and non-medical equipment and magnetic data carriers may be affected. The extent of zones in which such hazards exist should be established, and warning signs posted. In view of such problems institution of resuscitation and intensive care of the patient in the examination room is impracticable. Proper emergency procedures should be developed.

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