Health and Welfare Canada
Santé et Bien-être social Canada

Safety Code 26
Guidelines on Exposure to Electromagnetic Fields from Magnetic Resonance Clinical Systems

87-EHD-127

Canada

SAFETY CODE – 26

GUIDELINES ON EXPOSURE TO ELECTROMAGNETIC FIELDS FROM MAGNETIC RESONANCE CLINICAL SYSTEMS

Environmental Health Directorate

Health Protection Branch

Published by authority of the

Minister of National Health and Welfare

87-EHD-127

Également disponible en français sous le titre
Code de sécurité - 26 Lignes directrices sur l'exposition aux champs électromagnétiques provenant d'appareils cliniques de résonance magnétique

PREFACE

Magnetic resonance imaging (MRI) and recently also magnetic resonance spectroscopy (MRS) have been gaining a widespread acceptance and many applications in clinical settings. These imaging devices utilize three types of fields, namely, the static magnetic field, the time-varying magnetic field and the radio-frequency (RF) field. Since each of the fields produced by MRI or MRS devices, if of a sufficient intensity, can produce detrimental biological effects, questions have been raised regarding the safety of these devices. Guidelines on device characteristics and patient and operator exposure have been published in some countries (the United States, the United Kingdom, the Federal Republic of Germany).

This document briefly reviews biological effects of various fields used in magnetic resonance devices and provides general guidance on exposure levels to the patient and to the operator. The levels cited should not be considered as strict limits which if exceeded would result in a dangerous situation, but rather indicate the presently established levels below which potential hazards, if any, are considered minimal, if any. Higher exposure levels may still be safe, depending on various factors. For patient exposures exceeding the specified safe limits, the usual risk-benefit assessment has to be made.

This document was prepared by Dr. M.A. Stuchly, and reviewed by Mrs. D.A. Benwell, Dr. S.S. Mohanna, and Dr. M. Smith of the Bureau of Radiation and Medical Devices. Numerous valuable comments were provided by Dr. M.J. Bronskill, of Princess Margaret Hospital, Toronto, Ontario; Dr. L.D. Brown, Saskatchewan Labour, Regina, Saskatchewan; Mr. T.E. Dalgleish, Nova Scotia Department of Health, Halifax, Nova Scotia; Drs. D.J. Dorst, R.L. Nicholson and F. Prato of St. Joseph's Hospital, London, Ontario; Mr. B. Phillips, British Columbia, Ministry of Health, Vancouver, British Columbia; Dr. A.M. Sourkes, Manitoba Cancer Foundation, Winnipeg, Manitoba; Dr. R.T. Thompson, Victoria Hospital, London, Ontario; and Mr. J.M. Wetherill, Alberta Workers' Health, Safety and Compensation, Edmonton, Alberta.

Interpretation and further details of the recommendations of this safety code may be obtained from the Non-Ionizing Radiation Section, Bureau of Radiation and Medical Devices, Environmental Health Directorate, Health Protection Branch, Ottawa, Ontario, K1A 0L2.

TABLE OF CONTENTS

1. INTRODUCTION

In recent years magnetic resonance (MR) has emerged as a diagnostic tool for clinical in vivo imaging (MRI) and spectroscopy (MRS). Magnetic resonance clinical imaging offers important advantages which have stimulated rapid development of various systems and applications. Information is obtained on chemical and structural body properties and their pathology which in some cases cannot be obtained by other imaging modalities such as computerized tomography (CT) or ultrasound. Other advantages include the availability of images of the body in any cross-sectional orientation without loss of image quality, and the possibility of identification of vascular structures without introduction of an intravenous contrast agent[32].

Magnetic resonance devices use a strong magnetic field, a time-varying magnetic field and a radiofrequency (RF) field to obtain images of the body in selected planes. The physical properties utilized are the magnetic moment and spin properties of specific nuclei contained in biological molecules. The most common nucleus for imaging is the single proton hydrogen atom but imaging using other nuclei is being developed. Properties of such nuclei is phosphorus (^{31}P), carbon (^{13}C), sodium (^{23}Na) and others are used for in vivo MRS.

As with any technology, even when beneficial in medical applications, it is necessary to consider carefully the potential health hazards and to develop and implement proper safety precautions. There are several safety factors that have to be considered with respect to clinical use of MR for human beings. In this safety code biological effects of fields used in MR are briefly reviewed. Information is also given on guidelines regarding MR in other countries. General guidance is provided regarding what patient and operator exposure levels are considered safe at the present time. Advice is also provided with respect to cardiac pacemakers and metallic implants. However, other safety issues not directly related to human exposure to electromagnetic fields are not addressed here. These include possible injury by flying projectiles (because of the forces acting on ferromagnetic objects in the static magnetic field), injury due to cryogenic magnet quench, and electromagnetic interference

by MR fields with other medical devices (e.g. ECG monitors). Advice regarding these problems is given in another Health and Welfare publication[23].

2. EXPOSURE LEVELS FOR TYPICAL DEVICES

Presently available commercial human imaging systems produce a magnetic field inside the magnet bore with flux densities ranging from 0.02 T (Tesla) to 2 T, depending on the system. The magnetic fields are produced by a permanent magnet, by a resistive magnet (only below 0.3 T), or by a superconducting magnet. Outside the magnet bore the magnetic flux densities decrease with distance away from the magnet.

The magnetic flux density outside the system depends on the field strength of the magnet as well as the system design (the bore size, shielding, etc.). Measurements around the FONAR QED-80 imaging system (0.04 T) indicate that the magnetic flux density changes from 0.04 T in the imaging volume to 0.6 mT at the end of the patient table[2]. The level in the control room was about 0.4 mT[2]. Measurements performed by the Bureau have shown that for a 0.15 T MRI system (Teslacon Technicare, TM) the magnetic flux density at the entry to the magnet is 0.1 T, decreasing to 15 mT at a distance of about 1 m from the surface of the magnet housing, and to less than 1 mT at 3 m. For a 0.5 T MRI system (Philips Gyroscan, 515) the magnetic flux density at the magnet entry is about 0.12 T, 30 mT at a distance of 1 m, and 3 mT at 3 m from the surface of the magnet housing. For a 1.9 T MRS system (Oxford Research TMR 32/20) with a small bore (0.26 m) the magnet flux density at the entry is about 0.8 T, decreasing to 12 mT at a distance of 1 m, and less than 1 mT at 3 m.

Time-varying magnetic fields are superimposed on the static magnetic field to obtain spatial information in MR imaging and spectroscopy devices. These fields are of low magnitude compared with the static field.

RF fields are produced inside the magnet bore by transmitting coils. The RF fields are pulsed, and various pulse sequences are used by different systems. Several sequence options are available in each system. The frequency of RF fields depends on the strength of the static magnetic field. In MRI systems imaging protons the frequency ranges from about 6.4 MHz for a 0.15 T system to about 85 MHz for a 2 T system. Various frequencies are used in MRS. The average RF power or MR systems varies from a few to a few tens of watts (W). The peak RF power of the pulses may reach a few kW. Outside the magnet housing, intensities of RF fields are very low. Measurements by the Bureau performed for 0.15, 0.5, and 1.9 T systems have indicated that the RF magnetic field strength is below 0.05 A/m (the sensitivity of the survey instrument used) anywhere outside the magnet housing.

On the basis of the available data it can be evaluated that operators of MR clinical devices are likely to be exposed to magnetic fields below 2 mT for long time periods. This is because the operator spends a lot of time at a console containing Cathode Ray Tubes (CRTs), which produce distorted pictures in magnetic fields above about 0.5 mT. The actual exposure level depends on the magnetic field and the siting of the system. For short periods of time, while placing the patient in the imaging device, the operators and other personnel may be exposed to much stronger fields. Hands and arms may be exposed to the nominal magnetic flux density of the system when placed inside the magnet bore.

3. EXPOSURE GUIDELINES IN OTHER COUNTRIES

In the United States, the Food and Drug Administration (FDA) of the Department of Health and Human Services published in 1982 “Guidelines for evaluating electromagnetic risk for trials of clinical NMR* systems”[14]. The guidelines are directed to sponsors, manufacturers and researchers of clinical MR devices, and

* NMR – Nuclear Magnetic Resonance

specify the levels of the fields which when exceeded require evaluation in terms of "significant risk". "Significant risk" does not mean that a device is too hazardous for clinical studies. The FDA guideline limits are:

(i) static magnetic fields – whole or partial body exposures of 2 T,

(ii) time-varying magnetic fields – whole or partial body exposures of 3 T/s, and

(iii) RF fields – exposure to RF fields that results in a specific absorption rate (SAR) that exceeds 0.4 W/kg as averaged over a whole body, or 2 W/kg as averaged over any one gram of tissue.

In the United Kingdom the National Radiological Protection Board recommended in 1984 that the following conditions be fulfilled during operation of MR clinical imaging equipment[1]:

(i) The static magnetic field should not exceed 2.5 T to the whole or to a substantial portion of the body for those exposed to the imaging process. Staff operating equipment should not be exposed for prolonged periods of time to more than 0.02 T to the whole body and 0.2 T to arms and hands. For short periods less than 15 min/h these limits are increased to 0.2 T for the whole body and 2 T to arms and hands.

(ii) The rate of change of magnetic flux density should not exceed 20 T/s for durations of change greater than 10 ms, and for shorter periods the relationship $(dB/dt)^2\ t < 4$ should be observed where (dB/dt) is the rms value of the rate of change of the magnetic flux density in T/s and t is the duration of change in s.

(iii) Exposure to RF fields should not result in a rise in body temperature of more than 1°C (whole body and in any gram of tissue). This may be ensured by limiting the mean specific absorption rate (SAR) to 0.4 W/kg in the whole body, and 4 W/kg in any gram of tissue.

The document also recommends that it might be prudent to exclude from MR imaging pregnant women during the first three months of pregnancy. Persons fitted with cardiac pacemakers and large metallic implants are also subject to special precautions, although they are not excluded from imaging.

In the Federal Republic of Germany, the Federal Health Office published in 1984 "Recommendations for the prevention of health risks caused by magnetic and high-frequency fields in NMR tomography in vivo and NMR spectroscopy"[22]. These recommendations are addressed to physicians using the equipment. The following limits are recommended (for the patient):

(i) a static magnetic field of 2 T (whole or partial body); for people wearing cardiac pacemakers exposures to the magnetic flux greater 0.5 mT should be avoided,

(ii) the time-varying magnetic field should not induce a current density exceeding 3 $\mu A/cm^2$ for switching times 10 ms and longer, and $30/\tau$_ $\mu/A/cm^2$ for shorter switching times, where τ (ms) is the switching time,

(iii) RF exposure should not result in a specific absorption rate (SAR) greater than 1 W/kg, as averaged over the whole body, and 5 W/kg as averaged over any kilogram of tissue, excluding eyes.

4. HEALTH EFFECTS OF MR FIELDS

General reviews of health effects of MR fields have been published[4-7,24,25,30]. In addition, comprehensive reviews of the biological effects of static magnetic fields[28], time-varying magnetic fields[29] and RF fields[11] are also available. Therefore, only a brief outline of biological effects of each of the three types of fields is given. A relatively limited number of studies have been reported on effects of MR exposures (all three fields), and these are reviewed here.

4.1 Static Magnetic Field

Static magnetic fields can interact with biological systems by exerting forces on molecules and cells having diamagnetic susceptibility. They can also affect enzyme kinetics and act on moving charges (including moving fluids). Molecules and some cellular structures such as retinal rods, DNA, and sickle cells are magnetically anisotropic, and therefore a force acts upon them in a static magnetic field, which tends to orient them with the field. Fields of the order of about 0.3 to 2 T have been reported to be effective in causing orientation in samples studies in vitro[4,6,7,30]. Enzymatic reactions can be affected by strong magnetic fields of the order of 20 T[6].

A static magnetic field exerts a force on a moving charge in the field. The force is directed perpendicularly to the direction of the field and the direction of the motion. Through this mechanism magnetic fields can distort current loops for nerve conduction (propagation of the action potential) and can cause a decrease in the conduction potential and a decrease in the conduction velocity. Strong fields above 24 T are required for this effect[6,30].

Another type of interaction involves moving conducting fluids such as blood flow and periodic movement of certain body parts e.g. chest and heart contractions. Motion of a conductor in a magnetic field results in induction of a potential across the conductor, or in the case of a human being across a blood vessel. The induced voltage depends on the magnetic flux density, the vessel diameter, blood flow rate and the orientation of the blood vessels with respect to the direction of the field. These potentials are detectable in ECG; however they are physiologically insignificant until a threshold for the depolarization of cardiac muscle fibers is reached. An approximate “worst case” calculation indicates that 2.5 T induces flow potentials of the order of 40 mV, which is the depolarization threshold for individual cardiac muscle fibers[24]. However, the calculated potential refers to the cross-section of the aorta, and much lower potentials are induced across individual cells[24]. The potentials induced by movement of cross-sections such as the thorax are much lower than those calculated for the blood flow[6].

The available scientific data on biological effects of static magnetic fields is rather limited and inconsistent[4-7,24,25,28,30]. On the basis of a number of carefully performed studies, the following important biological processes appear not to be affected by static magnetic fields up to approximately 2 T[30]: (1) cell growth and morphology, (2) DNA structure and gene expression, (3) reproduction and development, (4) bioelectric properties of isolated neurons, (5) animal behaviour, (6) visual response to photic stimulation, (7) cardiovascular dynamics, (8) hematological indices, (9) immune response, (10) physiological regulation and circadian rhythms. However, the scientific data base, at present, is not sufficient to assess the risk of exposure to higher static fields[30].

There have been very few human studies. Some evidence has emerged which indicates that occupational exposures of humans to up to 2 T for durations of a few hours do not seem to cause any adverse effects. Exposures to up to 0.5 T for prolonged periods of time did not result in any deleterious effects. These conclusions are drawn from a study of workers in nuclear physics laboratories[5,25]. Exposure limits of 0.01 to 0.03 T for 8h/day have been recommended for workers in nuclear physics laboratories in various countries[27], and can therefore serve as a reference level for MR operators. The guidelines permit, however, higher exposures for short periods of time.

4.2 Time-Varying Magnetic Field

Time-varying magnetic fields interact with biological systems primarily through induction of internal electric currents so called “eddy currents”. The magnitude of the current depends on the time rate of change of the magnetic flux density and on the radius of the current loop. The current loops are in planes perpendicular to the direction of the magnetic field. The threshold current densities for known biological effects have been established[5-7,24,25,30]. The effects include fibrillation, electroshock, induction of visual phosphenes, and initiation of impulses in nerve and muscle cells. The thresholds are functions of the rate of change of the magnetic flux density and the time duration of the applied time-varying field.

Current densities induced in a human body and its parts should be calculated by assuming a "worst case" radius loops, i.e. the largest realistic loop under practical exposure conditions.

Approximate threshold current densities in living tissues are as follows[30]: (1) 1 A/m^2 for cardiac fibrillation, (2) 10 mA/m^2 for reversible visual effects (magnetophosphenes), (3) 10-100 mA/m^2 applied chronically for irreversible alterations in the biochemistry and physiology of cells and tissues (e.g. current densities used in bone healing). Fields that induce current densities less than approximately 1-10 mA/m^2, which is the range of endogenous current densities (EEG, EKG) appear to cause few, if any, biological effects for non-chronic exposures[30].

Evaluation of the above thresholds and biological effects observed has led to the conclusion that human exposure to 3 T/s is of minimal, if any, health hazard[27], and was adopted in the U.S. recommendations[14]. The U.K. recommendation[1] of 20 T/s was based on an estimate that this rate of change of the magnetic flux induces a maximum of 0.3 A/m^2 in any part of the body, which is a factor of approximately 3 below the threshold for cardiac fibrillation. The F.R.G. recommendation[22] of 30 mA/m^2 corresponds approximately to 3 T/s[30]. The higher limits for short-duration pulses (less than 10 ms) in the U.K. and the F.R.G. recommendations are based on the relationship between the duration of the electric current flow and human response[1].

Recently, a study was performed to assess effects of pulsed magnetic fields on foetal development in mice[17]. Exposures ranged from 3.5 – 12 kT/s with pulse periods 0.33 – 0.56 ms. Exposures were of short durations during various stages of gestation. Some exposure conditions resulted in stimulation of superficial skeletal muscle. No adverse effects were observed on pregnancy, litter size and growth of off-springs of exposed mice as compared to controls[17].

4.3 Radiofrequency Field

Detrimental health effects from exposure to radiofrequency (RF) fields are associated with high rates of energy deposition.

Because the interactions of RF fields depend on the field frequency, type of field (electric, magnetic, far-field, near-field) and the body size and shape, a parameter called the specific absorption rate, (SAR) has been used to quantify the effects. The SAR is the dose rate, defined as the rate at which RF energy is imparted into a unit mass of the exposed biological body. The unit of the SAR is the watt per kilogram (W/kg). The SAR is usually spatially nonuniform within the human body. In the case of MR systems, the spatial distribution depends on the design of the transmitter coils, the frequency, and the shape, size and tissue type of the imaged object.

Exposure to RF fields at sufficient SARs results in local or whole-body temperature increases[11]. It has been estimated that a whole body average SAR between 1 and 4 W/kg for short durations (approximately 1 h) produces significant increases in human body temperatures, (about 0.5ºC at SAR = 1.4 W/kg) at ambient temperatures of 25 to 30ºC[11]. Higher increases in whole-body temperature can be expected in people having impaired thermoregulatory capability. Furthermore, local temperature increases in locations of high SARs may be much greater[11].

Effects of RF fields on various systems have been investigated and threshold limits in terms of the SAR and exposure duration have been established for several effects[11]. Many of the effects can be explained on the basis of general or localized heating. However, some of the effects are due to other non-thermal mechanisms. Several potentially significant effects have been documented at whole-body average SARs of 1 to 3 W/kg for prolonged exposures. These include: behavioral response alterations, promotion of cancer development in mice, a decrease in the number of Purkinje cells in the brain of rats, changes in endocrine gland function and blood chemistry, and reversible changes in hematologic and immunologic systems[11]. Furthermore, such non-thermal effects as changes in cellular energy metabolism in the rat brain and changes in calcium-ion efflux have been reported. The latter are for RF fields modulated at extremely low frequencies (i.e. frequencies between 1 and 300 Hz). RF fields resulting in higher SARs between 4 and 8 W/kg

have been shown to result in such detrimental effects in experimental animals as behavioral disruption, temporary sterility, and bradycardia[11].

Human data are very limited and not useful for the development of quantitative recommendations on safe exposure limits.

4.4 Magnetic Resonance Fields*

A few studies have been performed on cells and animals using MR fields. Practically none of these experiments have been corroborated by studies in more than one laboratory. No detectable mutagenic or cytotoxic effects were found in Chinese hamster ovary (CHO) cells exposed to MR fields of 0.35 T, 4.6 T/s and a peak SAR of 2.9 W/kg at 15 MHz (4 pulses of 5 ms duration)[26]. Under the same exposure conditions no chromosomal damage was found in CHO cells in culture exposed for 14 h[34]. Mice were exposed to MR fields of 0.7 T at an average SAR $\simeq$ 0.087 W/kg (estimated) for 1 h. No differences in chromosomal aberrations in bone marrow cells were found between the exposed and control mice[21].

Various bacterial strains were exposed to 1 T, 1 T/s and an average RF power of 0.097 W with no mutagenic or lethal effects found[31]. Human hymphocytes were exposed under the same conditions and no significant adverse chromosomal effects were observed[8]. Rats and guinea pigs were exposed to fields of 0.16 T and 2 T/s and a lack of changes in the blood pressure, heart rate and ECG was reported[33].

On the other hand, mice exposed to MRI fields (a 0.15 T system) failed to exhibit the normal nocturnal enhanced morphine analgesia during the mid-dark period. Animals exposed during the mid-light period had weaker response to morphine-induced analgesia. These results may reflect field-induced alterations in neuronal binding and/or changes in the pineal gland activity[19].

---

* Magnetic Resonance fields are defined as all three fields (static, time-varying magnetic field, and RF field) used in MR devices.

Experience with humans clinically exposed to MR fields is relatively small, as the devices have not been in use long enough to provide the opportunity for a long-term medical assessment of patients and volunteers[5,6,30]. A six-month follow-up of 181 patients and 70 volunteers did not find any changes in cardiac and neurological functions. However, the MRI device used in these studies had a static field of only 0.04 T. No visual or central nervous system effects were found in 118 patients whose heads were imaged by MRI[30].

4.5 Cardiac pacemakers and Metallic Implants

Cardiac pacemakers can be affected by each of the three types of fields produced by MR clinical devices. The static magnetic field affects the reed switch in programmable demand pacemakers and reverses them into asynchronous operation. The static field also exerts forces (torque) on ferromagnetic components within the pacemaker, which may result in a movement of the pacemaker. Six representative pacemakers from different manufacturers were investigated in MRI fields up to 0.5 T[20]. Minimum flux densities of the static magnetic field that altered reed switch position ranged from 1.7 to 4.7 mT depending on the pacemaker type. In this investigation the pacemaker was outside the human body. The reed switch returned to the original position when the pacemakers were removed from the field for magnetic flux densities of 1.3 to 3 mT. All six pacemakers experienced forces and torques when placed inside MRI systems operating at 0.5 T. The authors considered the torque on two pacemakers sufficient to result in significant movement of the pacemaker within the chest wall unless a sufficient degree of fibrotic tissue was present[20].

The time-varying magnetic field and radiofrequency field can interfere with the pacemaker circuitry. Most pacemakers employ protective measures against electro-magnetic interference (e.g. a titanium casing and a low-pass input filter[30]. When such interference occurs the pacemakers reverts into asynchronous operation.

For instance, 20 out of 26 pacemaker models investigated reversed to an asynchronous mode or exhibited abnormal pacing in 60 Hz magnetic fields of 0.1 to 0.4 mT (this corresponds to about 0.04 to 0.15 T/s)[30]. Furthermore, a time variation of 3 T/s caused unipolar pacemakers to recognize the induced voltage as a valid cardiac electrical signal[20].

Tests were performed on several pacemakers of various types in a 0.15 T MR system with a 6.4 MHz RF field produced by a transmitter operated at a maximum power of 1 kW with a pulse period from 130 to 500 ms[12,15]. In all pacemakers tested the static magnetic field caused reed switch closure resulting in asynchronous pacing at the programmed rate. An exception was a pacemaker which can be programmed to "magnet off" mode. This pacemaker continued normal operation in a magnetic field of 0.15 T for the in vivo tests (the pacemaker implanted in a dog)[15]. The authors conclude that conversion to asynchronous pacing is usually not a problem, but in some patients it may produce an arrhythmia.

Effects of RF pulsed fields varied for different pacemaker models and types. For some pacemakers the pacemaker rate was affected by the pulse rate of RF field, causing either a decrease in the rate[12] or an increase[15]. However, the operation of some models of pacemakers remained totally unaffected by the RF fields when tested in vivo[12,15]. In all cases the RF field caused artifacts in the ECG recording. However, these artifacts were found inconsequential for the operation of the heart. None of the pacemakers tested showed any alterations in programmed parameters or in the ability to be reprogrammed after they were removed from the RF field[15]. The authors recommend that patients with cardiac pacemakers should have their pacing activity monitored continuously during tests in a 0.15 T MRI device[12].

Metallic implants made of ferromagnetic and even diamagnetic materials experience force and torque in magnetic fields. All metallic implants are heated by the RF field and to a negligibly small degree by the time varying magnetic field used in MR systems.

Twenty-one aneurysm and other hemostatic clips and a variety of other materials were investigated for forces and torques experienced in MRI systems operating at 0.147 T and 1.44 T[18]. Sixteen clips were deflected by the fields, and for five aneurysm clips, forces and torques were considered sufficient to produce risk of hemorrhage from dislocation of the clip from the vessel or aneurysm, or cerebral injury by clip displacement. The level of risk depends on the degree of ferromagnetism and geometry of the clip, the field strength and gradient, as well as other factors such as the clip orientation relative to the field, the clip closing force, the condition of the vascular wall, tissues and structures close to the clip. Stainless steel alloys containing high percentages of nickel (10-20%) do not exhibit significant ferromagnetic properties. However, some stainless steels used for aneurysm clips and other clips have considerable ferromagnetism[18]. Clips made of tantalum or titanium are non-ferromagnetic[30]. In another study[3], 54 different types of surgical clips were characterized in a 0.15 T and 1.5 mT/m field. Nonmagnetic properties of tantalum and various austenitic stainless steel alloys and silver alloys were confirmed[3]. Several other types of aneurysm clips were examined, and recommendation was made against use of clips having a high martensite content[10]. Several types of magnetometers and metal detectors were investigated as possible preimaging screening devices[13]. Both types of devices are capable of detecting ferromagnetic clips imbedded in a patient[13].

Heating effects of time-varying magnetic fields and RF fields were investigated for surgical clips (steel and copper) and hip prostheses[9]. It was concluded that heating of surgical clips in MR systems is not significant, but large implanted metallic prostheses and rods might cause a problem due to heating under some circumstances and when very high RF fields are used[9].

A total of 305 MR examinations were performed in 236 patients with metallic implants[16]. Most examinations were in a 0.3 T system. Patients with cardiac pacemakers, electrical implants, prosthetic cardiac valves and aneurysm clips were

excluded from the study. The study was aimed at evaluation of image artifacts and possible adverse effects due to the metallic implants. The types of metallic implants were: surgical clips, central nervous system (CNS) shunting devices, tantalum mesh, craniotomy, sternotomy and other wire sutures, skin staples, and orthopedic devices (hip prostheses, knee prostheses, rods, plates, screws, pins and wires). Only two patients expressed complaints that could possibly, but not necessarily, be attributed to MR examination. In one case, a child with a CNS shunting device complained of pain behind the ear. In the other case a patient with a hip prosthesis complained of a burning sensation in the hip, knee and calf[16].

5. GUIDANCE ON EXPOSURES

5.1 Patients

Exposures in MR systems which do not exceed the following limits are considered of minimal, if any, health hazard:

(i) the static magnetic field: 2 T,

(ii) the rate of time change of the magnetic field: 3 T/s (rms),

(iii) RF field which does not cause an increase of body temperature (core or rectal temperature) of more than 0.5°C, and of any part of the body of more than 1°C. These limits are expected to be satisfied, if the specific absorption rates (SARs) do not exceed 1 W/kg as averaged over any 25% of the whole-body mass for exposures of durations longer than 15 min, and 2 W/kg as averaged over any 25% of the whole-body mass for exposures of durations of up to 15 min, where for the balance of the hour the person is not exposed to RF fields produced by the MR device.

Exposures in MR systems which exceed the limits specified are not necessarily hazardous, but a careful, individual evaluation should be done, as the presently available scientific data are not sufficient for providing general recommendations.

5.2 Operators

Operators of MR devices should not be continuously exposed to a magnetic flux density exceeding 0.01 T during the working day. Exposures to higher flux densities are permitted for short-time durations (about 10 minutes per hour); their number and duration should be minimized.

5.3 Special Considerations

Because of potential health hazards, as outlined in Section 4, special consideration should be given and precautionary measures employed when the following categories of patients are examined in MR systems:

(i) cardiac pacemaker bearers,

(ii) persons with metallic clips and other metallic implants,

(iii) pregnant women.

In cases where cardiac pacemaker bearers are examined in MR devices, continuous medical surveillance and corrective procedures should be available during the examination. However, since many cardiac resuscitation devices do not operate properly in fields above about 10 mT, they have to be used and the patient transferred outside the room where the MR device is located.

For persons with metallic clips and other metallic implants, an individual assessment of suitability for MR examination should be made: In cases where persons having large metallic implants are subjected to MR examination, they should be continuously monitored, and when discomfort is experienced around the site of the implant the exposure should be stopped immediately. Small metallic implants such as tooth fillings are not a problem in MR exposures.

There is no scientific basis to believe than an examination in a MR device that does not exceed the limits specified in paragraph 5.1 is hazardous to a pregnant woman. However, in view of the relatively limited experience with this clinical diagnostic modality, an individual assessment should be made for each pregnant patient.

REFERENCES

1. Advice on acceptable limits of exposure to nuclear magnetic resonance clinical imaging by the National Radiological Protection Board, U.K., Radiography, Vol. 50, No. 593, pp. 220, 1984.

2. Athey, T.W., Ross, R.J. and Ruggera, P.S., Magnetic fields associated with a nuclear magnetic resonance imaging system. Magn. Res. Imag., Vol. 1, pp. 149-154, 1982.

3. Barrafato, D., Helkelman, M., Magnetic resonance imaging and surgical clips, Canada J. Surg., Vol. 27, pp. 509-510, 1984.

4. Bernhardt, J.H. and Kossel, F., Recommendations for the safe use of NMR equipment. Clin. Phys. Physiol. Meas., Vol. 6, pp. 65-74, 1985.

5. Budinger, T.F., Health effects of in vivo nuclear magnetic resonance. IEEE Eng. Med. Biol. Magazine, Vol. 1, pp. 31-38, Sept. 1985.

6. Budinger, T.F., Nuclear magnetic resonance (NMR) in vivo studies: known thresholds for health effects, J. Comput. Assist. Tomogr., Vol. 50, pp. 800-811, 1981.

7. Budinger, T.F., Thresholds for physiological effects due to RF and magnetic fields used in NMR imaging. IEEE Trans. Nucl. Sci., Vol. NS-26, pp. 2821-2825, 1979.

8. Cooke, P. and Morris, P.G., The effects of NMR exposure on living organisms. II - A genetic study of human lymphocytes. Brit. J. Radiol., Vol. 54, pp. 622-625, 1981.

9. David, P.L., Crooks, L., Arakawa, M., McRee, R., Kaufman, L. and Margulis, A.R., Potential hazards in NMR imaging: heating effects of changing magnetic fields and RF fields on small metallic implants, Am. J. Roentgeonology, Vol. 137, pp. 857-860, 1981.

10. Dujovny, M., Kossovsky, N., Kossovsky, R., Valdivia, R., Suk, J.S., Diaz, F.G., Berman, S.K. and Cleary, W., Aneurysm clip motion during magnetic resonance imaging: in vivo experimental study with metallurgical factor analysis. Neurosurgery, Vol. 17, pp. 543-548, 1985.

11. Elder, J.A. and Cahill, D.F. (Eds.), Biological Effects of Radiofrequency Radiation. Report No. EPA-600/8-83-026F. U.S. Environmental Protection Agency, Research Triangle Park, NC, 27711, 1984.

12. Fetter, J., Aram, G., Homes, D.R., Gray, J.E. and Hayes, D.L., The effect of nuclear magnetic resonance imagers on external and implantable pulse generators. PACE, Vol. 7, pp. 720-727, 1984.

13. Finn, E.J., Di Chiro, G., Brooks, R.A. and Sato, S., Ferromagnetic materials in patients: detection before MR imaging. Radiology, Vol. 156, pp. 139-141, 1985.

14. Guidelines for evaluating electromagnetic exposure risk for trials of clinical NMR systems. Center for Devices and Radiological Health, Food and Drug Administration, U.S., 25 February, 1982.

15. Holmes, D.R., Hayes, D.L., Gray, J.E. and Merideth, J., The effects of magnetic resonance imaging on implantable pulse generators. PACE, Vol. 9, pp. 360-370, 1986.

16. Laakman, R.W., Kaufman, B., Hans, J.S., Nelson, A.D., Clampitt, M., O'Block, A.M., Haaga, J.R. and Alfidi, R.J., MR imaging in patients with metallic implants. Radiology, Vol. 157, pp. 711-714, 1985.

17. McRobbie, D and Foster, M.A., Pulsed magnetic field exposure during pregnancy and implications for NMR foetal imaging: a study with mice. Magn. Res. Imag., Vol. 3, pp. 231-234, 1985.

18. New, P.F.J., Rosen, B.R., Brady, T.J., Buonanno, F.S., Kistler, J.P., Burt, C.T., Hinshaw, W.S., Newhouse, J.H., Pohost, G.M. and Taveras, J.M., Potential hazards and artifacts of ferromagnetic and nonferromagnetic surgical and dental materials and devices in nuclear magnetic resonance imaging, Radiology, Vol. 147, pp. 139-148, April 1983.

19. Ossenkopp, K.P., Kavaliers, M., Prato, F.S., Teskey, G.C., Sestini, E. and Hirst, M., Exposure to nuclear magnetic resonance imaging procedure attenuates morphine-induced analgesia in mice. Life Sciences, Vol. 37, pp. 1507-1514, 1985.

20. Pavlicek, W., Geisinger, M., Castle, L., Borkowski, G.P., Meany, T.F., Bream, B.L. and Gallagher, J.H., The effects of nuclear magnetic resonance on patients with cardiac pacemakers. Radiology, Vol. 147, pp. 149-153, April 1983.

21. Prasad, N., Bushang, S.C., Thornby, J.I., Bryan, R.N., Hazlewood, C.F. and Harrell, J.E., Effect of nuclear magnetic resonance on chromosomes of mouse bone marrow cells. Mag. Res. Imag., Vol. 2, pp. 37-39, 1984.

22. Recommendations on preventing health risks caused by the magnetic and high frequency electromagnetic fields produced in NMR tomography and in vivo NMR spectroscopy. Bundes ges undheitsblatt, Federal Republic of Germany, Vol. 27, No. 3, pp. 92-96, 1984 (in German).

23. Recommendations to ensure protection of patients and operational personnel from potential hazards in proton NMR imaging. Environmental Health Directorate Publication No. 85-EHD-124, 1985.

24. Saunders, R.D. and Orr, J.S., Biologic effects of NMR. In Nuclear Magnetic Resonance, NMR, Imaging. Partain, C.L., James, A.E., Rollo, F.D., and Price, R.R. (Eds.), W.B. Saunders Co., Philadelphia, 1983, pp. 383-396.

25. Saunders, R.D. and Smith, H., Safety aspects of NMR clinical imaging. Brit. Med. Bull., Vol. 40, pp. 148-154, 1984.

26. Schwartz, J.L. and Crooks, L.E., NMR imaging produces no observable mutations and cytotoxicity in mammalian cells. Am. J. Roentgenology, Vol. 139, pp. 583-585, 1982.

27. Stuchly, M.A., Human exposure to static and time-varying magnetic fields, Health Physics, Vol. 51, pp. 215-225, 1986.

28. Tenforde, T.S., Biological effects of high DC magnetic fields. Report No. LBL-5954, Lawrence Berkeley Laboratory, University of California, 1981.

29. Tenforde, T.S., Interaction of time-varying ELF magnetic fields with living matter. In Biological Effects of Electromagnetic Fields. Polk, C., and Postow, E. (Eds.), CRC Press, Boca Raton, FL, 1986.

30. Tenforde, T.S. and Budinger, T.F., Biological effects and physical safety aspects of NMR imaging and in vivo spectroscopy. American Assoc. Physicist in Medicine Summer School on NMR In Medicine, 1985.

31. Thomas, A. and Morris, P.G., The effects of NMR exposure on living organisms. I - A microbial assay. Brit. J. Radiol., Vol. 54, pp. 615-621, 1981.

32. Vannier, M.W., Nuclear magnetic resonance imaging. Postgraduate Med., Vol. 76, No. 6, pp. 159-170, 1984.

33. Willis, R.J. and Brooks, W.M., Potential hazards of NMR imaging, no evidence of the possible effects of static and changing magnetic fields on cardiac function of the rat and guinea pig. Mag. Res. Imag., Vol. 2, pp. 89-95, 1984.

34. Wolff, S., Crooks, L.E., Brown, P., Howard, R. and Painter, R.B., Tests for DNA and chromosomal damage induced by nuclear magnetic resonance imaging. Radiology, Vol. 136, pp. 707-710, 1980.