

# NON-IONIZING BIOLOGICAL EFFECTS AND SECURITY ISSUES IN MAGNETIC RESONANCE

## EFFECTOS BIOLÓGICOS Y ASPECTOS DE SEGURIDAD DE LAS RADIACIONES NO IONIZANTES EN LA RESONANCIA MAGNÉTICA

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### PALABRAS CLAVE (DeCS)

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### SUMMARY

*Objective:* To review the deterministic biological effects of static, dynamic and dependent magnetic fields used in clinical magnetic resonance imaging (MRI). *Methods:* The suggested limits are referenced depending on the different MRI applications, as well as their possible biological effects. In addition, safety aspects which must be taken into account when areas that include this diagnostic technique are shown. Lastly, a short description of the important items for the regulatory authorities to consider when facing these types of test with non-ionizing radiation is discussed. *Conclusions:* Even though there is no agreement in the literature about the biological risks, risks do exist due to the presence of high magnetic fields. Specific precautions should be taken in terms of proper facilities and qualified personnel, as well as an appropriate legislation which does not exist in Colombia.

### RESUMEN

*Objetivo:* Hacer una revisión, en español, de los efectos biológicos determinísticos de los campos magnéticos estáticos, dinámicos y de radiofrecuencia, propios de los exámenes de resonancia magnética (RM) en hospitales. *Metodología:* Se hace referencia a los límites definidos dependiendo de los distintos usos de la radiofrecuencia en un examen de RM y sus posibles efectos biológicos. Además, se muestran los aspectos de seguridad que deben tenerse en cuenta cuando se diseñan zonas que incluyan esta técnica diagnóstica. Finalmente, se hace una breve revisión de los temas que deben tener en cuenta los entes reguladores ante este tipo de exámenes con radiaciones no ionizantes. *Conclusiones:* A pesar de no ser determinantes los estudios sobre riesgo biológico, sí hay riesgos, principalmente por la existencia de altos campos magnéticos, que aconsejan tener ciertas precauciones en cuanto a instalaciones y personal calificado, así como una legislación acorde, de la que, por otra parte, carece Colombia.

### Introduction

Non-ionizing radiations are part of the electromagnetic spectrum and they have a sufficiently wide wavelength so that their interaction with the tissue does not cause the creation of ionic pairs (Compton effect,

photoelectric, etc.): therefore, the consequences are different from those studied in conventional radiobiology.

Magnetic resonance (RM) procedures are considered safe from the viewpoint of radiological protection; however, the non-stochastic biological effects which

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have been observed during tissue interaction with constant, variable, and electromagnetic magnetic fields have led to a thorough study of these phenomena. Multicentric revisions in which most exposure limits and recommendations are based on have been performed by the International Commission of Non-Ionizing Radiation Protection (ICNIRP).

ICNIRP has concluded that clinical evidence regarding the association between the possible carcinogenic effects and the levels of radiation is insufficient in order to provide a clear base of exposure limits (1). Therefore, their recommendation guides are based on short-term deterministic effects, such as the induction of magnetophosphenes, the stimulation of peripheral nerves and muscles, burns, and increases in bodily temperature.

## Biological effects of MR

In the specific case of magnetic resonance, biological effects come from the use of constant magnetic fields, variable magnetic fields, or radiofrequency gradients and impulses. Following is a brief description of the biophysical interaction mechanisms and the exposure limits for each one of them.

## Constant intense magnetic fields

The three interaction mechanisms which are present with the constant magnetic fields are described from a biophysics perspective.

The first mechanism, magneto-mechanical, explains the alignment and transfer of molecular magnetic moments with the external magnetic field, which is a dependent factor both in the intensity of the external magnetic field as well as its variation in respect to position ( $B\text{-dB/dx}$ ). For example, the alignment of the rhodopsin molecules (components of the retina rods) with very intense magnetic fields creates a mechanical stress which causes false excitations which in turn lead to the induction of magnetophosphenes (2).

It has been suggested that these types of interactions can affect the coagulation processes when aligning fibrinogen (3) and that blood flow can be affected by the ordering of oxygenated erythrocytes (4). In the human body, however, the thermal energy in which these molecules are immersed in causes thermal movement (Brownian) to prevail, which makes this a negligible phenomenon (2). A study with intense magnetic fields (5) showed that induced force is only 1% of the intensity in a 4T field.

The second interaction is magnetic-hydrodynamic interaction, which analyzes the interaction of the magnetic field with blood flow. This type of analysis evidenced that the change in vascular pressure is less than 0.2% and showed that there are no significant changes in the circulatory system for fields under 10T (6). Similarly, it was found that volunteers who were subjected to one hour in 8T fields did not show changes in systolic or diastolic pressure, neither in the respiratory pattern nor in cardiac frequency (7).

Additionally, the flow of ions in blood vessels which are subject to a magnetic field will cause an electrical impulse in them. The overlapping of this induced potential modifies the amplitude of the T-wave in an electrocardiogram (ECG). However, these potentials are much lesser than the limits induced by cardiac stimulation (8). Similarly, the potential of action in peripheral nervous fibers will be altered, but a very intense field is required in the range 24T in order to reduce the neuron conduction by 10% (9).

Experimental measures with fields of up to 2T did not show significant effects in the functioning of peripheral nerves when studied in mammals (10). Lastly, modifications in the results of electroencephalographic studies with fields over 9.1T were observed, but they were transitory and reversible in less than 30 minutes (10), and the vital signs were not altered with 8T (11).

The third mechanism shows the magnetic effects in chemical reactions. This explains the modification of kinetics in the reactions which use radicals as intermediate products. The direct effect occurs in ions with their linkages (12). However, in an environment with a viscosity similar to water, very intense magnetic fields (approximately 10 million Teslas) would be necessary in order to produce a Lorentz force comparable to the linkage energy of ions (2). For example; in order to cause damages in DNA, eV\* type energies are required, and a magnetic field of the tesla type which interacts with electronic spines is also needed, only generating eV microns type energy ( $\mu\text{eV}$ ). The most visible physical effect with 2T fields is transitory vertigo due to the movement of the body inside of the magnetic field (7).

Based on this type of evidence, ICNIRP divides exposure into normal, controlled, and experimental, depending on the intensities they are subject to, recommending the exposure limits for occupational personnel and the general public. This is described in table 1.

**Table 1. Operational limits of constant magnetic fields**

Mode of operation	Bo
Normal	< 2T
Controlled	Entre 2T y 4T <sup>a</sup>
Experimental	> 4T
Occupational Personnel	Límite de Bo
Exposure of the head and the trunk	2T
Exposure of limbs	8T
General public	400 mT <sup>b</sup>

a. The upper limit of controlled exposure is due to a lack of information on the possible effects to higher fields.

b. The limit for the general public is obtained when applying a reduction factor of 0.2 for occupational limit.

Source: Reiser MF, et al., 2008 (13); ICNIRP, 2009 (14).

## Variable magnetic fields

The variable magnetic fields analyzed in this section are related to the gradients of the magnetic fields and to the changes in the time when these are used. The gradients of the MR magnetic fields are generally two magnitudes under the fixed ones. This type of electromagnetic radiation has a low frequency and therefore, it deposits small quantities of energy. Due to this, its interaction is considered an athermal interaction (15,16).

\*eV: electron volt; energy measure unit. Nuclear and atomic interactions are usually expressed in this unit.

However, their effects must be considered given that there are phenomena associated with these effects which have significant biological consequences. The most important phenomenon is Faraday induction, given that the current which is induced has a frequency of under 100 kHz. In this range of frequencies, the conductivity of the cell membrane is

several magnitudes lower than in the intra and extra cellular fluid, which leads to an induction of a potential through the cell membrane. When the induced voltage is over the threshold, it can stimulate the nervous and muscle cells (13).

From the safety viewpoint, the first outcome to be considered is cardiac fibrillation given that it can cause death. On the other hand, peripheral nervous stimulation is a practical concern since it can cause the test to be uncomfortable, or an intolerable stimulation can interfere with the total development of the test (7).

The factor which can cause the mentioned currents appears during an MR sequence when the gradients are turned on or off, that is to say, variations of the magnetic field over time (dB/dt). High field gradients will be required, in the range of 6000 T/s to reach the stimulation of the myocardium (17,18). Given that the ranges of clinical operations are found well below this value, it is not considered a contraindication. For peripheral nervous stimulation, studies in humans have established a limit of approximately 200 T/s (2).

One must consider that gradients depend on the shape of the impulse, their duration and repetitions (2). For example, calculations of parasitical currents suggest that nervous and cardiac stimuli can be avoided with 20 T/s for single monophasic impulses and for repetitive impulses over 3 ms (19).

The perception thresholds must be determined by the manufacturer for all types of gradients and the sequences must be designed in such a way that they do not exceed the peripheral nervous stimulus (20). Usually, the maximum value is between 50-100 T/s, which is safe and comfortable for volunteers (2). FDA does not suggest a numeric value as a limit, but it recommends patient monitoring in order to proceed in case of pain due to stimulation of the peripheral nerves (7). On the other hand, MHRA, the regulatory authority in the United Kingdom, suggests a limit of 20 T/s (21).

The changes in the magnetic field also cause movements in the physical parts of the equipment which causes uncomfortable noises for the patient. Even if they are not lethal, they can influence the quality of the image, depending on the type of experiment (22), or they can even touch the limits allowed for exposure (7).

## Radiofrequency impulses

The frequency of RF fields used in MR is under a dozen MHz. For these frequencies, the conductivity of the cell membrane is comparable to intra and extra cellular liquid, which implies that it does not induce voltage through it (13). On the other hand, the energy deposit in this range causes an increase in tissue temperature. Said increase not only depends on the characteristics of incident radiation but also on the tissue, specifically its thermal conductivity and its microvascular flow (perfusion).

The energy deposit is characterized by energy absorbed by unit of mass and time, also known as specific absorption rate (SAR). It is related to the induced current  $j$ , the magnitude of the electrical field  $E$  and the density of the irradiated tissue  $\rho$ , through the expression:

$$SAR = \frac{j \cdot E}{\rho} = \frac{\sigma \cdot E^2}{\rho}$$

The theoretical and experimental considerations reveal that the absorption of RF in the body reaches a maximum level when the wavelength ( $\lambda$ ) is similar to bodily size. Unfortunately, the  $\lambda$  of the RF fields used in MR is within this range (1). Due to this reason, one must pay attention to the energy deposit, given that an elevated thermal increase can lead to biological damages or modifications.

Literature reports that adverse effects have not been found for bodily exposures if the increase in temperature is under 1 °C. In the case of children or persons with cardiac circulatory disabilities, the increase must not be over 0.5°C. With respect to localized heating, it is reasonable to assume that adverse effects will be avoided if the localized regions do not exceed 38°C in the head, 39°C in the trunk and 40°C in the limbs (23, 24).

A study with 50 volunteers exposed to 0.4-1.2 W/kg showed an increase of 0.2 °C in its temperature, without presenting changes in blood pressure or cardiac rhythm (25). However, faced with the difficulty of measuring the thermal increments in MR studies in vivo, mathematical studies have been developed which enable the estimate of thermal increases in function of SAR.

For example, it has been calculated that during an exposure with a SAR of 5 W/kg of the complete body of a patient with normal thermoregulatory capacity, its temperature will increase at a maximum of 0.6 C depending on environmental conditions (26). One must mention that these models are based on the classic nature of electromagnetic radiations, and that a quantic analysis is recommended (7).

Based on these types of models and on clinical evidence related to a thermal increase, ICNIRP (1) recommends SAR limits in such a way that they do not exceed temperatures which are proven to cause complications. Table 2 shows some of these recommendations for total and partial bodily irradiation (head).

**Table 2. SAR limits for volunteers and patients who undergo MR procedures with an environmental temperature under 24°C**

Modo de operación	The entire body SAR (W/kg)
Normal	2
Controlled	4
Experimental	> 4
Any region (except the head) SAR (W/kg)	Head SAR (W/kg)
2-10	3,2
4-10	3,2
> 4-10	>3,2

Source: ICNIRP, 2009 (4)

The International Electrothermal Commission (IEC) recommends that when the limits of controlled exposure (4.0 W/kg) are exceeded, the system must alert the operator found in an experimental or research mode (27).

## Embryonic development

Significant effects on pre and post natal development were not observed in exposures of approximately 1 T in rodent fetuses in the uterus (28, 29). On the other hand, there is no evidence of growth alterations or reproductive changes when rates are subject to field gradients (30). Even

though it is known that maternal heating in mammals causes abnormalities in fetal and embryonic development (31, 32), the transitory effects of RF potency do not increase maternal temperature over 39°C. Adverse effects of its exposure which affects a human fetus are not expected.

### Technical safety aspects

One must be especially careful not to perform MR tests in patients with activated implants through electronic means, whether they are magnetic or mechanical, which functioning can be interfered by the action of the produced electromagnetic fields.

Therefore, patients with an internal cardiac pacemaker, implantable cardiac defibrillators, cochlea implants, neural stimulators, bone growth stimulators, medication-infusing electronic pumps and other similar devices which can be negatively affected by the electromagnetic fields must not undergo this type of test (33).

### Installation

In order to avoid damages or accidents caused by intense magnetic fields, the World Health Organization (34) recommends that the space destined for MR equipment is divided into 4 areas, described as follows (35):

**Area I:** Dedicated to the general public, outside of the influence of the MR equipment magnetic field.

**Area II:** It is a communicator between area I, which is controlled, and area III, which is controlled. It is outside the magnetic field influence of the MR equipment. It can be accessed freely, but it does not have free circulation. In this area, patients are received and are asked security questions before reaching area III, where they will be under the effects of the MR equipment magnetic field.

In this area, there will be an intensity of the magnetic field equal to or lesser than 0.5 mT.

According to specific recommendations of the Medicines Health-care products Regulatory Agency (36), it is recommended that a space is reserved in area II for lockers or cabinets so that patients and workers can leave their belongings in a secure area which can potentially be damaged or can interfere with the magnetic field of the MR equipment.

**Area III:** In this area, the effects of the MR equipment magnetic field can cause wounds due to the movement of ferromagnetic objects (such as pressure gas bottles), or it can also damage some electronic equipment (from pacemakers to measurement equipment of the constants of the patients), as well as damage memory or bank cards.

In this area, one must be very careful with ferromagnetic materials. These materials must be avoided as much as possible. A magnetic field intensity of between 0.5 mT and 3 mT can be present (which is found between the values suggested by ICNIRP (table I).

**Area IV:** This area is exclusively dedicated to MR equipment. It must always be inside of area III. Because it contains the magnet, area IV must be screened with electromagnetic waves. There are two reasons for this: contain the maximum MR equipment magnetic field, as well as prevent other frequencies which alter both MR acquisition and the homogeneity of the MR equipment magnetic field from entering. The construction of a Faraday cage is recommended in order to achieve

this shielding. Their characteristics (which will be further indicated) depend on the geometry of area IV and the type of magnet to be used. Access to ferromagnetic metals must be prohibited in this area, unless absolutely necessary. Given the case, it must be managed with extreme care. There will be a magnetic field intensity of less than 3 T in this area. The magnet and the required magnetic compatible equipment will be placed in area IV.

### Shielding

Shielding occurs in two parts. The first part is the shielding proper of the magnet, which depends on the MR equipment to be used. The second part is the one that must be installed in the room which holds it, that is to say, area IV.

This type of shielding is achieved by covering the entire area IV with a sheet of metal. A wooden structure or stainless steel structure covered with copper sheets (approximately 2 mm thick) can be used. The sheets must be united by joints which enable the electrical conduction in the entire union. The attenuation of the signal must be 100 dB for a frequency of 100 MHz. The rest of the isolating layers and the necessary structures will be installed outside of this copper sheet.

The shielding must not cover some ventilations ducts in the area in order to maintain adequate atmospheric pressure through special grilles. Cable connectors must also be present for said effect; such as ducts for nitrogen, helium, and medicinal gases in case they are required. Lastly, the technologist window must have a copper net to contribute to the shielding, as well as the door, which must be covered by copper tabs so that it acts as a conductor when closed.

### Legislation

#### International recommendations

The OMS is not a regulatory agency. Due to this, it only recommends States to regulate these types of equipment according to the following criteria (34):

- Adopt international scientific standards in order to limit human exposure.
- Take protection measures for scientific, medical, or industrial usage of the magnetic fields (distance criteria, administrative controls, inventory, etc.).
- Consider the issuance of licenses for MR equipment with fields over 2 T in order to ensure protective measures.
- Finance the investigation of the MR security field in order to complete the knowledge gaps in this field.
- Have a database of the MR equipment in order to have a control of the exposure of the occupationally exposed personnel and the patients.

#### Latin American regulation

At the Latin American level, the OPS, as a branch of the OMS, does not have regulatory measures of the possible risks of the MRI equipment; therefore, it covers recommendations in an indirect manner, for example in the case of maintenance (27) and/or the formation of Medical Physicians jointly with OIEA (38). In this last report, it is recommended that postgraduate experts for quality control and assurance are present, as well as having people “responsible of evaluating the biophysical risks of the MR equipment”.

Regulation in Latin America is varied and does not always cover a direct control in medical applications. It is usually based on technical standards in order to prevent risks in the ever-increasing framework of wireless or cellular technology (39).

The limits were determined, at first, by following the recommendations of the American Standards National Institute (40) or of the ICNIRP (1). In 1991, ANSI recommended a limit of occupational exposure of 1 mW/cm<sup>2</sup> for frequencies from 30 to 300 MHz (41), which was adopted by some Latin American countries such as Bolivia (42). However, generally speaking, an abridgement between ANSI (43, 44) and ICNIRP is sought (see the case of Argentina [45], Brazil [46], Chile [47], Costa Rica [48] or Ecuador [49]).

### Colombian legislation

In the case of technical limitations in Colombia, the recommendation of the International Telecommunications Union (abbreviated UIT in Spanish), based on technical standard K52, is followed (50). However, the clinical regulatory body is the Ministry of Health and Social Protection. Its mission statement is to: guarantee health assurance and the access of the population to health promotion strategies, prevent illnesses, and provide other health services and economic benefits, according to the fundamental principles of efficiency, universality, and solidarity, with the purpose of improving the health and quality of life of the Colombian population (51). However, there is no specific legislation related to non-ionizing radiations, particularly for MR equipment.

A first approach with a specific regulation can be referenced in Resolution 4445 of 1996 of the Ministry of Health (52): "in which regulations are dictated for the compliance with the content of Title IV of Law 09 of 1979, referring to sanitary conditions that hospitals and similar establishments must comply with".

Numeral 6 of article 33 (of support services for diagnostic and treatment activities-generalities) mentions medical imaging services. Section 6.3 says the following regarding MR: Magnetic Resonance: It is the environment which is destined for the performance, processing and interpretation of studies which are carried out through the variation of magnetic fields which are translated into images. It requires protection against magnetic fields, with a coverage called Faraday cage.

The previous points prove the deficiencies in the definition of the necessities, given that the risks for the general public, for the patient and the personnel which is occupationally exposed are not considered. Therefore, the recommendations established by OMS must be complied (34).

In the framework of the conditions which regulate hospital services, the 2006 resolution (53) which regulates the quality and maintenance of radiological services through the enabling of services, among other points, does not contemplate the international OMS recommendations, and leaves the centers to be in charge of the MR security criteria. Recently, this 2006 resolution was completed with the 2013 resolution (54). Even though the 2013 resolution expands the radiological protection of ionizing radiations, it also leaves the MR international criteria aside.

### Conclusions

Although several investigations specifically geared towards the study of MR potential biological effects have been performed, the results

of these studies have been predominantly negative, which supports the more widespread opinion that there are no important health risks associated with the usage of this image diagnostic modality.

However, short-term non-stochastic effects must be taken into account when: the external magnetic field intensity is to be selected in sequences which imply the usage of magnetic field gradients, as well as implying the energy deposited/unit of mass by the radiofrequency impulses, in order to prevent transitory complications or slight burns which can turn the test into an uncomfortable procedure.

One must not forget that the most common problems when a person undergoes an MR exam are: acoustic noise and claustrophobia.

The design of MRI shields must consider the limitations of the constant, variable, and electromagnetic fields for occupational personnel and the general public. Because of this, the design must be divided into areas which satisfy said requirements.

The lack of specific regulations leads to joint efforts to achieve clear legislation which adjusts to the socioeconomic reality of the country. Therefore, the research, inquiry, and disclosure of the effects of non-ionizing radiations are valuable tools for regulatory bodies as they strive to define health public policy guidelines.

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