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Review article

Magnetic resonance imaging and gynecological devices☆,☆☆

Lúcia Correia[a,*], Ana Beatriz Ramos[b], Ana Isabel Machado[a], Duarte Rosa[a], Carlos Marques[a]

[a]*Maternidade Dr. Alfredo da Costa, Lisbon, Portugal*

[b]*Centro Hospitalar do Porto-Hospital Geral de Santo António, Oporto, Portugal*

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Abstract

Background: Performing magnetic resonance imaging (MRI) on women with gynecological devices is a completely accepted practice. The goal of our review is to assess how safe it is to perform MRI on women using contraceptive implants or devices.

Study Design: Literature review, searching in PubMed-Medline/Ovid for the following keywords: magnetic resonance imaging, intrauterine devices, Implanon® and Essure®.

Results: Though plastic devices do not represent a contraindication to the use of the technique, those including metallic components have been submitted to several tests, after which they were classified as *MR Conditional* (devices presenting no risks in MR-specific environments) by the Food and Drug Administration. Thus, the use of MRI can be safely advised to women with this type of device as long as the magnetic resonance equipment is ≤3.0 T.

Conclusions: Presently, there is no scientific evidence that contraindicates performing MRI on women with any kind of gynecological device. Therefore, this procedure is safe as long as it is performed under previously tested conditions.

Keywords: Magnetic resonance imaging; Intrauterine devices; Implanon®; Essure®

1. Introduction

Magnetic resonance imaging (MRI) is an increasingly popular imaging technique, having become one of the preferred techniques due to its several advantages over other methods, namely, (a) its multiplane capability, allowing for the capture of cuts or layers in all directions in space, (b) its high contrast resolution and (c) the absence of known harmful effects since ionizing radiation is not employed.

The differentiation of pelvic organs through contrast, an exclusive feature of MRI, has rendered it the technique of choice as far as exploring the pelvic cavity is concerned. The correct interpretation of MRI images requires an understanding of the basic mechanisms necessary for image formation. In its more basic form, MRI can be analyzed in terms of energy transference [1]. Magnetic resonance is the physical feature shown by the nuclei of some elements which, when submitted to a strong magnetic field and excited by radio waves of a particular frequency, will broadcast a radio signal, which can then be captured by an antenna and converted into an image [2,3].

Hydrogen atoms are the most common and the simplest in the human body since their nuclei consist of a single proton. This proton exhibits a feature called spin, which is essentially a rotational motion, similar to how the earth rotates around its own axis [2]. Thus, the magnetic field is the result of an electric charge in motion. Because of this behavior, the hydrogen proton is the most suitable for extracting MRI images due to its abundant presence in the human body and the capability to broadcast the strongest radio signal of all stable nuclei.

Under normal conditions, the protons in the body exhibit random orientation; however, if submitted to the influence of an external magnetic field, the spins become aligned in either the direction of the magnetic field or the opposite direction. In fact, the number of protons which become aligned with the magnetic field is a little higher than the rest. This fact results in a small magnetization, powerful enough to

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* Corresponding author. Praça das Flores N°3 2°Dto, 2526-419 Forte da Casa, Portugal. Tel.: +35 1934236134.

E-mail address: luciaaccorreia@gmail.com (L. Correia).

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broadcast an MRI signal [3]. When the radio frequency is turned off, the nuclei release themselves from the energy they absorbed. Each body tissue reemits radiation at a different rate, according to its own chemical composition and physical status. This radiation is then captured by an antenna, which converts it to electric current. Finally, the current is used to create the desired images. The variation in the several tissues' reemission times enables the creation of an image which shows the contrast between them.

It is important to point out the strength of the magnetic field created by the huge magnets present in MRI devices. Magnetic fields are usually measured in tesla units (T); another measurement unit normally used is the gauss (1 T=10.000 gauss) [3]. The magnets in use today in MR are in the 0.5–3.0-T range, or 5000 to 30,000 gauss. MRI uses gigantic magnets, which are capable of creating magnetic fields with an intensity varying from 0.2 to 9.4 T [4]. Nowadays, MRI for medical diagnosis employs devices ranging from 0.5 to 3.0 T. For comparison purposes, the earth's magnetic field is approximately 0.00005 T, exhibiting slight variations around the equator and the poles.

As is the case with other imaging methods, MRI is subject to several types of artifacts, which can compromise image quality and interfere in its interpretation. Thus, it is necessary to know the different types of artifacts, distinguishing them from anatomical variations and pathological processes. Artifacts can result from either data acquisition and treatment or the patient's own features [5]. One of the most relevant patient-related artifacts is the so-called magnetic susceptibility artifact. The magnetic susceptibility of a tissue showcases its capability to acquire self-magnetization when submitted to a magnetic field. Such acquired magnetization may be concordant (parallel) or discordant (antiparallel). In the presence of the former, it is said that a substance exhibits positive magnetic susceptibility, thus strengthening the resulting magnetic field. Such a substance is called paramagnetic (substances which show strong positive magnetic susceptibility are called superparamagnetic or ferromagnetic). In the presence of discordant (antiparallel) magnetization, the substances are classified as exhibiting negative magnetic susceptibility and are called diamagnetic. This magnetic susceptibility artifact is commonly found in the presence of air, metal, calcium or a concentrated gadolinic contrast medium. As far as the image is concerned, it can be identified as a hypointensity of focal signal, surrounded by a hyperintense halo, which can be associated to several levels of distortion in the surrounding tissue [5]. The size and shape of the artifact depend on the size, shape, orientation and nature of the metal, as well as the sequences used in the exam [6]. The artifact created by a ferromagnetic object is larger than that originated by a nonferromagnetic object [7] — the stronger the ferromagnetic nature of the object, the more intense the registered signal will be. Technically speaking, magnetic susceptibility artifacts are more prominent in gradient-echo and echo-planar sequences, and we may try to reduce them using a smaller voxel, shorter echo time, or larger bandwidth or even performing the exam with equipment featuring a lower-intensity magnetic field [6].

Due to the evolution and increasingly common usage of medical devices, some of which incorporate metallic components, the use of MRI in patients with such devices can lead to concern. Safety in the application of MRI on women using gynecological devices depends, essentially, on the device's structure.

For women using intrauterine devices (IUDs), pondered images in T2 allow us to observe three different areas of the uterus: the endometrium, with a high intensity signal; the junction area (junction between the endometrial mucosa and the myometrium), if we employ a low-frequency signal; and the myometrium, using a medium- intensity signal. IUDs must be correctly placed inside the uterine cavity and are visualized in MRI images as areas without signal — their shape depends on their orientation relative to the magnetic field. Being external to the patient's tissue, they are considered external devices. The description of the different materials present in IUDs will be approached more thoroughly throughout this paper, though we find it relevant, due to the aforementioned facts, to discuss the safety of MRIs in the presence of such devices, particularly those whose compositions include copper.

Since we favor the patient's well-being over image degradation, it is necessary to know the type of material being studied. In fact, in addition to the artifacts generated by metallic objects, which can decrease the diagnostic capability of MRI, when submitting a patient to an external magnetic field, we may cause dislocation, torsion or overheating of these devices, which in turn can provoke injuries [8].

Any complaint of pelvic pain should result in the immediate suspension of the exam. The most common, though seldom described, consequences include the burning of adjacent tissues, incorrect placement of contraceptive devices or, more seriously, uterine perforation in women using IUDs.

Recent studies reveal that gynecological devices generate minimal artifacts and that MRI can be safely performed since the majority of these devices do not exhibit relevant ferromagnetic proprieties.

Thus, this paper intends to review the literature on the topic of safety regarding the use of MRI on women with contraceptive devices or implants.

2. Material and methods

The authors researched in PubMed-Medline/Ovid using the following keywords: Magnetic Resonance Imaging, Intrauterine Devices, Implanon® and Essure®. This article presents the review of data published between 1985 and 2010 on the application of magnetic resonance on women using gynecological devices.

3. Results

3.1. Medical devices

The increasing use of MRI implied a greater demand for information regarding the safety of its application to patients with implants or other medical devices. As such, the Food and Drug Administration (FDA) has acknowledged the need for conduct studies in order to clarify these issues. Over the last few years, testing methods were developed by several organizations, e.g., the American Society for Testing and Materials (ASTM), in order to assess the presence of movement/deflection, torsion, a rise in the device's temperature due to radiofrequency or the creation of image artifacts. In 1997, the FDA's Center for Devices and Radiological Health (CDRH) proposed the first classification method, which splits devices into two groups: MR Safe (devices which have been shown not to increase the risk for patients, though potentially compromising the quality of diagnostic information) and MR Compatible (devices which do not increase the risk for patients and also do not compromise the quality of the diagnostic information collected). According to this terminology, testing "MRI safety" required in vitro tests in order to assess static magnetic field interactions, MR-related heating and, in some cases, induced electrical currents. In order to test "MR compatibility," the assessment and description of artifacts are also required, in addition to the above-mentioned tests [4,9].

After a while, the CDRH's classification method proved confusing, which could potentially lead to accidents and injured patients; therefore, as of August 2005, the ASTM published the classification method currently in use, which defines three groups [4,9]:

1. MR Safe: devices presenting no risks in all MR environments. This group includes devices made of nonconductive and nonmagnetic elements, e.g., plastic, silicone or glass devices.
2. MR Conditional: devices presenting no risks in MR-specific environments, under specific use conditions. Field conditions that define the MR environment characterization include static magnetic field strength, spatial gradient, time rate of change of the magnetic field, radiofrequency fields and specific absorption rate.
3. MR Unsafe: devices presenting risks in all MR environments. Performing MR in these cases is contraindicated. This group includes all electromagnetic devices.

Each group was represented graphically (Fig. 1).

The "MR Safe" icon can be represented by the acronym "MR" in green lettering inside a white square with green borders or by the acronym "MR" written in white over a green square. The "MR Conditional" icon consists of the acronym "MR" in black lettering inside a yellow triangle with black borders. The "MR Unsafe" icon consists of the acronym "MR" in black lettering over a white background inside a red circle with a red diagonal bar.

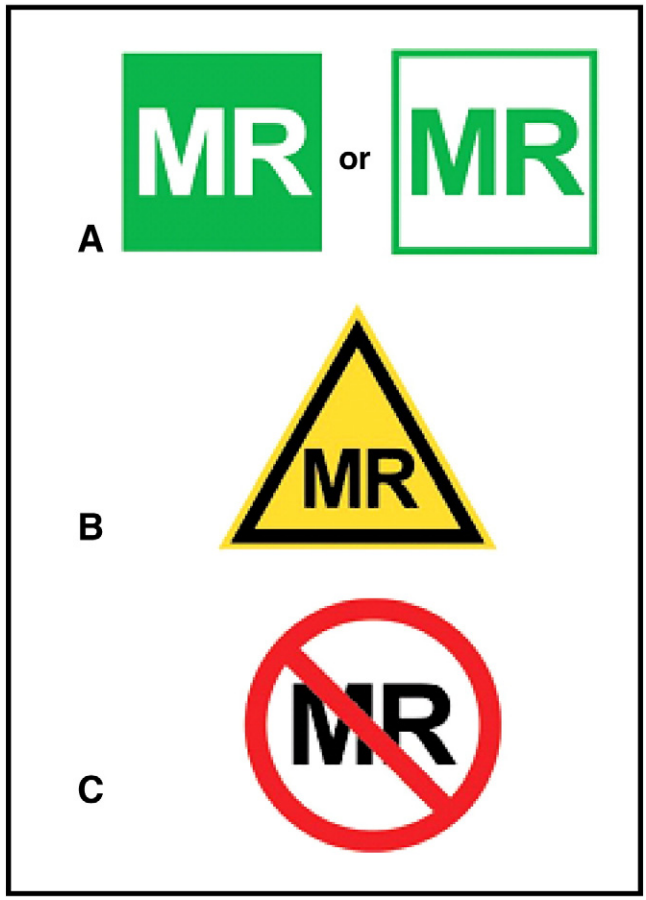

Fig. 1. Icons recommended by the ASTM. Legend: A, MR Safe; B, MR Conditional; C, MR Unsafe.

3.2. Gynecological devices

3.2.1. IUDs

IUDs are an effective contraceptive method used worldwide.

These devices can consist of nonmetallic elements, like the levonorgestrel-releasing intrauterine system (LNG-IUS) (Bayer HealthCare Pharmaceuticals Inc.), or a combination of metallic and nonmetallic elements. In the latter case, copper is the most commonly used metal.

Due to its polyethylene structure, the LNG-IUS is included in the group of MR Safe devices, according to the ASTM. Therefore, its use does not pose any risk to women in case MRI is performed.

Even though copper is not ferromagnetic, some concerns regarding the application of MRI on women using a copper IUD (Cu-IUD) have emerged since the presence of a device including a metal component in a patient submitted to MRI can lead to injuries deriving from its movement/deflection or from an increase in the device's temperature; in the Cu-IUD's case, this could result in

injuries to the endometrium, in addition to the possibility of generating image artifacts which would compromise the MRI's diagnostic capability [8].

Until the 1980s, healthcare providers' concerns, associated to a lack of guidelines and of previous studies, led many medical centers to contraindicate the performance of MRI in the presence of a Cu-IUD. However, due to the increasing use of MRI, women with Cu-IUD started to be submitted to this imaging technique when there was suspicion of pelvic disease or, more frequently, extrapelvic disease.

In 1987, Mark and Hricak [10] carried out in vitro and in vivo studies using RMI 0.35 T and 1.5 T on women with a nonmetallic IUD (Lippes Loop Intrauterine Double-S; Ortho Pharmaceutical, Raritan, NJ, USA) and a Cu-IUD (Cu-7; Searle Pharmaceuticals, Chicago, IL, USA) in order to assess the possible occurrences of movement, IUD temperature increase and generation of image artifacts during the MRI performance. They have concluded that performing MRI on those women was a safe procedure since there was no rotation or deflection of either metallic or nonmetallic IUDs, nor were there statistically significant differences in temperature, when compared to the placebo. Furthermore, no changes in image quality were recorded. Removing the IUD for the single purpose of performing a safe MRI was no longer justified. According to the same authors, and even though ultrasonography is still the main imaging methodology for the detection of a dislocated or extrauterine IUD, the MRI can be considered an alternative in cases where an ultrasonography is technically contraindicated or suboptimal, such as for overweight women or for those with a retroverted uterus.

Research in PubMed-Medline/Ovid using the keywords "Magnetic Resonance" and "Intra-Uterine Device" allowed us to find three more articles related to in vitro studies carried out in order to assess the safety of performing MRI on women with four different Cu-IUDs [11–13].

Using a 1.5-T MRI, Hess et al. [11] assessed the safety of three different IUDs — Multiload® CU375 (Nourypharma, Oberschleissheim, Germany), Nova-T® (Schering AG, Berlin, Germany) and Gyne-T® (Cilag, Sulzbach, Germany) — while Pasquale et al. [12] tested the ParaGard® CuT380A (Ortho-McNeil Pharmaceutical Corp., Raritan, NJ, USA). More recently, Zieman and Kanal [13] reassessed the usage safety of the ParaGard® CuT380A IUD on a 3.0-T MRI system.

The results obtained by the different authors corroborated and supported those of Mark and Hricak's studies [10], showing that the application of MRI on women using Cu-IUDs did not produce relevant effects (movement/deflection, torsion, temperature rise, image artifacts) which would contraindicate the use of MRI up to 3.0 T in women using this kind of device (Table 1). Hess et al. [11] recorded a maximum temperature increase in the IUD location that varied between 0.3 and 0.4°C.

Even though the presence of a metallic component may influence the image, due to the slight magnetic susceptibility of copper and the small size of the devices, the artifacts produced are not particularly relevant and do not interfere with the interpretation of the collected images [8,10].

IUDs are captured in MR images as no-signal zones inside the uterine cavity, assuming different structures according to the type of analyzed IUD and the cutting plane [10].

3.2.2. Essure®

The Essure® system (Conceptus Inc., San Carlo, CA, USA) consists of two metallic microimplants and is an increasingly popular female sterilization method. Each implant includes an internal stainless steel section, wrapped in polyethylene fibers, as well as an external section made of 26 expandable nickel and titanium spirals, with an initial diameter of 0.8 mm, reaching 1.5 to 2 mm in order to fit the

Table 1
Effects of MRI on women using Cu-IUD

Article	Year	Tests	Cu-IUD	MRI	Variables tested	Conclusion
Intrauterine contraceptive devices: MR imaging Mark and Hricak [10]	1987	In vitro	Lippes Loop Intrauterine Double-S Cu-7	0.35 T and 1.5 T	Movement Heat Artifacts	IUD does not move under the influence of the magnetic field, does not heat and does not produce artifacts in vitro or in vivo.
		In vivo	Retrospective review of six MR images of women with Cu-IUD			
Safety of intrauterine contraceptive devices during MR imaging Hess et al [11]	1996	In vitro	Multiload Cu 375 NovaT GyneT	1.5 T	Deflection Heat	Maximum temperature rise of 0.4°C.
Lack of interaction between MRI and the copper T380A IUD Pasquale et al [12]	1997	In vitro	CuT380A	1.5 T	Movement Torque Heat	There was no deflection, turning motion (torque) or temperature change. There appears to be no reason to exclude women with IUDs of the type examined from an MRI system or its environs.
Copper T380A IUD and MRI Zieman and Kanal [13]	2007	In vitro	Cu T380A	3.0 T	Deflection Torque Heating Artifacts	No significant deflection, torque, heating or artifact was found. No safety concerns regarding the use of the CuT380A IUD at 3.0 T, under the conditions of testing.

tubarian lumen. These microimplants are placed, via hysteroscopy, in the isthmic part of the tube, where they generate a foreign body reaction, resulting in the growth of fibrous tissue around the microimplants. Simultaneously, after a 3-month period, this leads to the fastening of implants and to an occlusion of the tubarian lumen, thus enabling definitive contraception [8].

The security of performing MRI on a woman using Essure® has raised some concerns due to its metallic constitution. After some ex vivo studies where several issues were tested, such as interactions with the magnetic field (torsion and deflection), temperature changes and the presence of image artifacts, Shellock [8] concluded that the use of Essure® did not increase the risk for the patients submitted to a 1.5-T MRI. Essure® was considered MR Safe in those conditions since no interactions with the magnetic field were identified and the maximum temperature change recorded was ≤0.6°C. Likewise, the use of these devices does not generate significant image artifacts, except when the studied region is exactly the same or is very close to the device's position — in this case, it may compromise the quality of the MR images. To overcome this problem, it might be necessary to optimize the MRI parameters in order to suit this particular device [4].

In 2002, while using a 3.0-T MR under the same circumstances, Shellock [14] concluded that the performance of MRI on a woman using Essure® was a safe procedure in vivo, though a 3° deflection angle was identified in vitro, as well as a slight torsion. However, there was no alignment towards the magnetic field. These changes are still within the limits defined by the ASTM in order to classify a device as MR Safe.

In MR images, the Essure® microimplants may be visible as linear losses of signal in the initial part of the tubes and in the uterine cornu region [15].

3.2.3. Contraceptive implant

The Implanon® (Organon USA Inc.) is a contraceptive implant approved by the FDA in July 2006. It is a small, 40-mm-long, 2-mm-thick rod made of soft and flexible plastic, with no metallic components, located inside an application system, which allows for the subcutaneous placement of the implant in the internal surface of the nondominant upper limb. It contains 68 mg of etonogestrel, spread through an ethylene–vinyl acetate core, which is surrounded by a thin, 0.6-mm membrane made of the same material. The prolonged release of etonogestrel allows for contraceptive effectiveness of up to 3 years [16].

The absence of metallic elements and its plastic composition both justify the classification of Implanon as an MR Safe device; that is, under no circumstances will its use pose a risk for women submitted to an MRI.

In the rare instances when it is not possible to clinically identify the location of the implant, the MRI is considered a second-line diagnostic examination after soft tissue ultrasound [17,18].

4. Discussion

MRI is an increasingly popular imaging technique, enabling the differentiation of organs and tissues by contrast through the use of radiofrequency waves. The generation of a magnetic field may have harmful effects, particularly when foreign metallic bodies are present inside the patients' bodies. The assessed effects consist of device movement/deflection, torsion, temperature rise and the creation of artifacts in the images obtained.

Even though most devices (e.g., prostheses, surgical clips) do not interfere with magnetic fields, some others are of an electromagnetic nature (e.g., electrodes for electrocardiography), and patients using the latter should not be submitted to MRI.

Improvement in the family planning field led to the introduction of several contraceptive methods, some of which include metallic components. In this review, we assessed the available information regarding the application of MRI on women who use some of the contraceptive methods available in our national market, both those devoid of metallic components (Implanon®, LNG-IUS) and those which include them (Cu-IUD and Essure®).

Nonmetallic contraceptive methods are considered MR Safe. Therefore, women using those devices can be safely submitted to any MRI environment.

Published studies on the application of MRI on women using Cu-IUD and Essure® have all concluded that it is a safe procedure, provided that the MRI is of a maximum of 3.0 T; thus, Cu-IUD and Essure® are classified as MR Conditional. The only identified effect was a slight increase in the temperature of the device and its surroundings — in vivo, these effects were shown to be nonsignificant. The use of specific MRI sequences allows for the capture of images with no artifacts that may compromise the diagnostic assessment.

Presently, there is no scientific evidence contraindicating the application of MRI on women who use the assessed gynecological devices.

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