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Investigating MRI safety practices in Greece. A national survey

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ABSTRACT

Purpose: Although the safety of clinical magnetic resonance imaging (MRI) has been discussed and analysed in great depth, safety-related incidents do still occur. In Greece, there are no previous studies exploring the employed MRI safety practices and policies. This study aims to explore the current status of MRI safety in Greece and to compare it to the well-established guidelines issued by the American College of Radiology. Specific changes in safety policies are recommended based on the results of the study.

Material and Methods: A quantitative methodological approach was followed for this study. Census sampling strategy was employed and specifically designed questionnaires were distributed to the entire population of MRI units currently operating in Greece. Statistical analysis was performed using descriptive statistics to analyse the findings. Pearson's chi-square test was used to evaluate relationships between variables.

Results: Out of 307 MR scanners currently operating within Greece, 104 valid responses were received (response rate 33.9%). 77 (74.0%) have implemented a zoning system, while 27 (26.0%) have not. Optimal signage of zone IV with a "the magnet is always on" sign exists only in 45 (43.3%) of MRI facilities. 94 (90.4%) have clearly marked zone III with appropriate sings, while 10 (9.6%) have not. However, access to zone III is strictly restricted by 48 (46.2%) participants. 90 (86.5%) units have clearly marked the area in which the magnetic field exceeds 5 Gauss (5 G). A statistically significant difference exists between hospital-based MRI units that have not clearly marked zone IV (28, 70%) compared to private sector units (31, 48.4%), p-value=0.031. 97 units (93.3%) provide patients with a pre-MRI written screening form, while 28 (26.9%) have implemented preliminary screening as a way of screening patients before scheduling MRI examinations. 7 centers (6.7%) use hand-held magnets for screening, while 97 (93.3%) do not use metal detection systems at all. 89 MRI centers (85.6%) are not equipped with MR-safe or MR-conditional fire extinguishers at all, 68 (65.4%) units are equipped with MR-safe stretchers and 42 (40.4%) with MR-safe wheelchairs. 85 (81.7%) are not equipped with

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MR-safe emergency resuscitation equipment, or MR-safe/conditional equipment such as ventilators (40, 26.1%), monitoring devices (47, 30.7%) and anaesthesia machines (20, 13.1%). A statistically significant difference was found in the frequency of MR-safe emergency resuscitation equipment of MRI centers in large cities (15, 29.4%) compared to small cities and islands (4, 7.5%), p-value=0.003, as well as between hospital-based units (14, 35%) and private sector outpatient centers (5, 7.8%), p-value=0.001. Regarding infection control measures, 87 units (83.7%) have seamless floorings and 99 use hand sanitisers (95.2%) but only 47 (45.2%) have hand-washing stations within the MRI departments. 85 (81.7%) units are equipped with an emergency exit as well as a specific plan for emergency situations (71, 68.3%). 59 (56.7%) are also equipped with alternative power outage, but only 13 (12.5%) perform drills on emergency response. There is a statistically significant difference in the frequency of performing emergency drills between hospital-based MRI units (9, 22.5%) and private sector outpatient units (4, 6.3%), p-value=0.014.

Conclusions: Most of the responders have generally employed optimal policies regarding pre-MRI screening methods and appropriate use of zoning system. However, there is a relative lack of MR-safe equipment and metal detection systems. In addition, some specific safety steps must be taken to enhance safety in terms of emergency preparedness and infection control. The recommendations of this study include the adoption of rigorous safety policies, education of healthcare professionals and greater provision of MR-safe safe equipment.

KEY WORDS

Magnetic Resonance Imaging/static field; Safety management; Health policy/ Greece

Introduction

Magnetic resonance imaging (MRI) has a great value in the diagnosis and management of many diseases, while during the last years an extensive use of this method has been noted in the clinical setting. Specifically, more than 30,000 MR scanners have been installed worldwide, with millions of examinations performed every year [1]. MRI safety is vital for ensuring the safety of both the patients and the MR personnel. Many potential risks are associated with clinical MRI, as the presence of strong static magnetic fields can potentially lead to an injury due to projectile effects. In addition, the time-varying gradient fields have a strong effect on humans [2]. Moreover, the ongoing increase in the use of various medical devices and implants within the human body has made the topic of MRI safety more complicated than ever, with increased potential risks associated with implants and foreign objects. Many safety events have been recently reported in the literature, while the United States Food and Drug Administration (FDA) reported a 310% increase within four years [3]. Moreover, the reported adverse events to the FDA were 30% more than in 2017. Similarly, a three-year review of the safety-related events within the United Kingdom showed a continuous increase from 2015 to 2017 [4]. The importance of explicit safety policies has been also augmented by the increased number of various medical devices and implants within the human bodies, as patient pre-MRI screening must be very careful to avoid harm. For instance, only in Germany there are more than 100,000 patients with cochlear implants [5].

Pre-MRI screening is the first step to ensure that access to the MRI area will be allowed only to eligible individuals. Many incidents have been reported due to defective screening procedures and undisclosed information regarding the presence of ferromagnetic materials. A recent study explored the events related to screening procedures and concluded that more than 25% of these events involved an object that was not safe to be brought into the MR environment [6]. The necessity for well-constructed patient screening forms and patient consent forms has been also justified and many textbooks suggest that this is a mandatory safety step before MRI examinations [7, 8]. In addition, the American College of Radiology (ACR) suggested the implementation of ferromagnetic

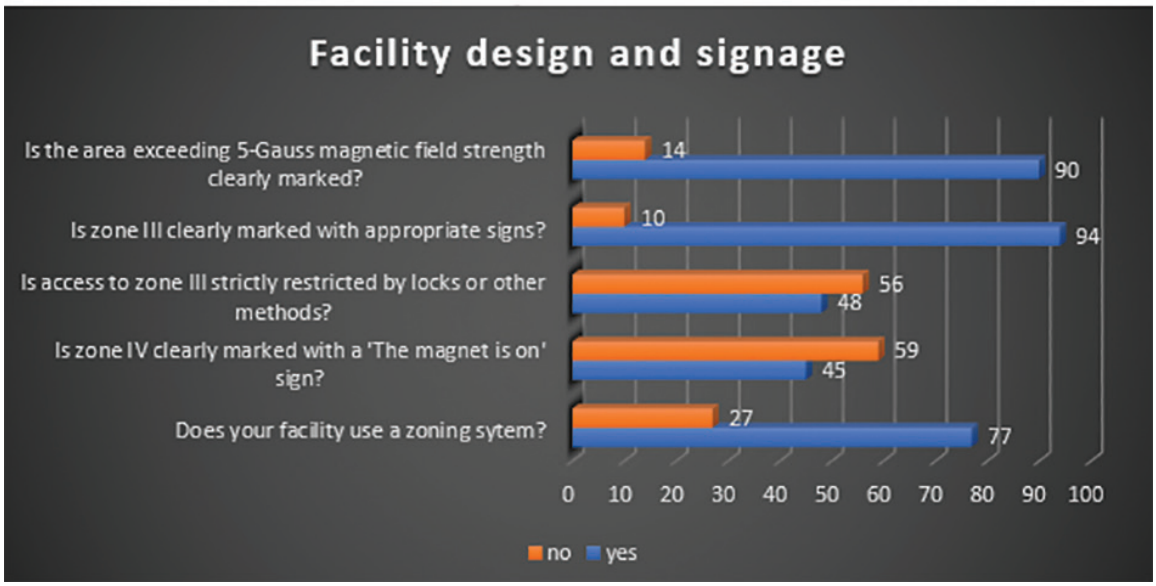


Fig. 1. *Overall frequency distributions of the responders regarding facility design and signage.*

detectors as a supplementary screening tool and many papers support this safety measure [9, 10].

Similarly, appropriate facility design and signage of MRI departments play an important role in MRI safety, as the nature and structure of these units require specific steps to enhance safety. A zoning system consisting of four independent zones with specific design and signage has been included in the ACR safety guidelines, and many papers have underlined the importance of this safety measure. In addition, it is clearly stated that all zones must be under the supervision of MR personnel [11]. Appropriate signage has been also suggested, with signs regarding the strong magnetic fields, "danger" warnings and a warning that the magnet is always on [12]. In Greece, the Greek Atomic Energy Commission (GAEC) has also issued a safety protocol suggesting the use of appropriate signage, with mandatory signs within the area where the magnetic field exceeds 5 Gauss [13].

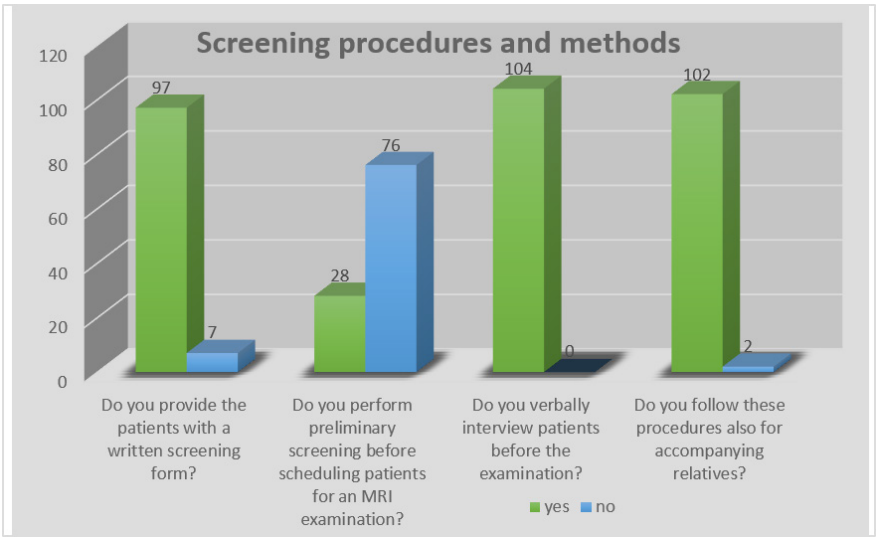
The ACR has underlined the importance of MR-safe equipment, while some projectile effects have been also reported in the literature [14]. Non-compatible equipment mistakenly brought into the MRI room or equipment mistakenly labeled as MR-safe, can result in projectile effects with potential injury. In addition, equipment needed in case of emergency, such as fire extinguishers or emergency resuscitation devices, must be also checked to be fully compatible with the MR environment.

Infection control measures must be also taken to minimise the potential risks of healthcare-associated infections, as it has been found that they affect over a million of patients every year [15].

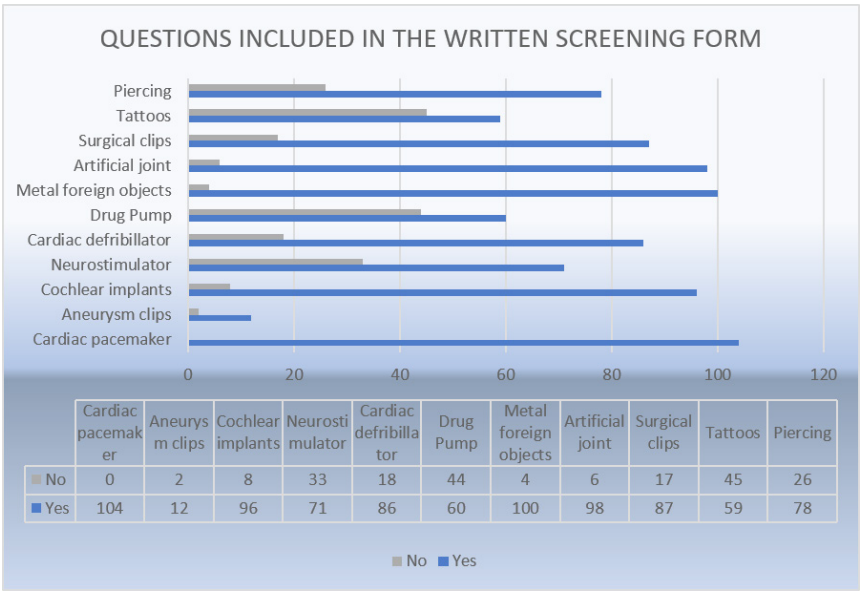
The potential risks associated with the administration of contrast media include adverse acute reactions related to allergies, the potential risk of nephrogenic systemic fibrosis (NSF) and gadolinium deposition to human tissues. Many acute reactions have been reported despite some papers reporting very low rates, such as 0.11% [16-19].

Emergency preparedness is another vital aspect of MRI safety, as many events can occur in the MR environment. Communication is thought to be the main challenge in developing emergency plans for radiological emergencies [20]. Many emergencies occur within the radiological departments, with most of them due to cardiac problems [21]. Consequently, emergency preparedness plans must be developed to respond immediately in case of fire, cardiac arrest, water damage or quench [11]. Local responders must be provided with appropriate education. In addition, drills must be performed on a frequent basis to ensure that the level of preparedness is optimal.

The aim of this study is to explore the employed safety practices among Greek MRI departments. This study focuses on safety issues related mainly to the static magnetic field. The rationale for this study was based upon the dramatically increased clinical applications of MRI in conjunction with the increased number of safety-related incidents. In Greece there are no previous studies



a.



	Cardiac pacemaker	Aneurysm clips	Cochlear implants	Neurostimulator	Cardiac defribillator	Drug Pump	Metal foreign objects	Artificial joint	Surgical clips	Tattoos	Piercing
No	0	2	8	33	18	44	4	6	17	45	26
Yes	104	12	96	71	86	60	100	98	87	59	78

b.

Fig. 2. a. *Frequency distributions related to pre-MRI screening procedures and methods.* ***b.*** *Frequency distributions regarding the questions included in the pre-MRI screening form.*

carried out regarding MRI safety. Moreover, Greece has more MR scanners per million inhabitants, compared to three European countries with similar population size [22]. Therefore, rigorous steps must be taken in order to enhance safety within the MR environment, as it has been confirmed that only rigorous safety policies can effectively reduce the incidence of safety-related events [23]. The lack of research regarding MRI safety in Greece, in conjunction with the relatively high number of safety-related events worldwide and the wide use of MRI applications within the country have justified the need for research to explore this field. In addition, the great value of adopting specific policies into a country to improve patient safety has been well-justified in the literature [24, 25].

Material and Methods

This study uses numerical data to confirm or reject the research question [26]. The census sampling method was chosen [27]. The target population of this study is the entire population of MR scanners within Greece. This was identified and resulted in 307 MR scanners, according to the statistics provided by the GAEC. All the MR scanners currently operating in Greece were included in the study

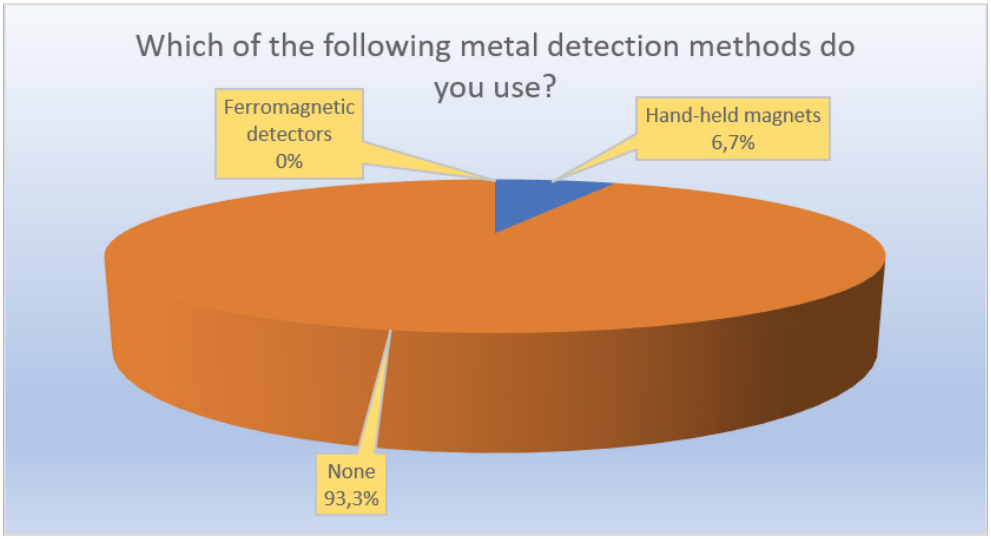


Fig. 3. *Distributions of the responders regarding supplementary screening methods.*

population, consisting of hospital-based (national health system or private) and private sector MR scanners.

The collection of data was achieved using a questionnaire, specifically designed for this purpose. The use of questionnaires as a data collection tool has been justified for measuring adoption of policies regarding other healthcare professions [28]. The questionnaire used for this study was a structured questionnaire with 26 closed questions with pre-coded answers. The ACR Guidance Document on MR Safe Practices was reviewed to identify the important aspects of MRI safety and the recommendations regarding implementation of specific policies [11]. In addition, most of these key themes have been included in similar studies investigating MRI safety practices and policies [29, 30].

The data collection process was initiated in March 2019 and was completed in July 2019. The questionnaires were distributed via e-mail to the participants, along with the accompanying information sheets and informed consent forms. The questionnaires were filled-in by MR technologists, Radiologists or Medical physicists, ensuring the relative background of the responders. A second attempt was made to access the MRI centers which had not responded to the first e-mail. Telephone reminders were also applied to the participants to ensure that they had received the questionnaires. The implementation of telephone reminders was decided as a method of increasing the response rate [26].

Data analysis was performed on the IBM SPSS Statistics software package, version 24.0, on a personal computer. Descriptive statistics were applied for the analysis of the findings. Graphs and tables were also used to present the results. Comparison between categorical variables was performed using the χ^2 statistical test [31].

Results

Out of 307 MR scanners currently operating in Greece, 104 valid responses were received, giving a response rate of 33.9%. Descriptive statistics of the responders are expressed as absolute (N) and relative frequency (%).

The first graph demonstrates the overall frequency distributions of the responders regarding facility design and signage **(Fig. 1)**. Out of 104 responders, 77 (74.0%) answered that they have implemented this zoning system in their facility, while 27 (26.0%) answered that they do not use this zoning system at all. Optimal signage of zone IV is not followed for the majority of the responders, as zone IV is clearly marked with a "the magnet is always on" sign only in 45 (43.3%) of the MRI facilities.

Regarding zone III, the vast majority of the responders have clearly marked zone III with appropriate sings, as 94 (90.4%) of them gave a positive response, while only 10 (9.6%) answered that they do not follow these guidelines. However, access to zone III is strictly restricted by key locks or other methods only in 48 (46.2%) of the participants. On the contrary, 90 (86.5%) of the units which participated in this study have clearly marked the area within the magnetic field exceeds 5 Gauss (5G).

Pearson's chi-square test was used to assess any possible differences that may exist between the optimal sig-

Table 1. Chi-square test for the evaluation of the relationship between optimal signage of zone IV and hospital-based/private sector outpatient MRI units.

	Is zone IV clearly marked with a "The magnet is always on" sign?					
	Yes		No		Chi-Square	p-value
	N	%	N	%		
Hospital-based units	12	30.0%	28	70.0%	4.662	0.031
Private sector outpatient units	33	51.6%	31	48.4%		

Table 2. Descriptive statistics for screening procedures and methods.

		N	%
Do you provide the patients with a written screening form?	Yes	97	93.3
	No	7	6.7
Do you perform preliminary screening before scheduling patients for an MRI examination?	Yes	28	26.9
	No	76	73.1
Do you verbally interview patients before the examination?	Yes	104	100.0
Do you follow these procedures also for accompanying relatives?	Yes	102	98.1
	No	2	1.9
Which of the following metal detection methods do you use?	Hand-held magnet	7	6.7
	None	97	93.3
Please specify which of the following questions have been included in your screening questionnaire	Cardiac pacemaker	104	100.0
	Aneurysm clips	102	98.1
	Cochlear implants	96	92.3
	Neurostimulator	71	68.3
	Cardiac defibrillator	86	82.7
	Implanted drug pump	60	57.7
	Metal foreign objects	100	96.2
	Artificial joint	98	94.2
	Surgical clips	87	83.7
	Tattoos	59	56.7
	Piercing	78	75.0

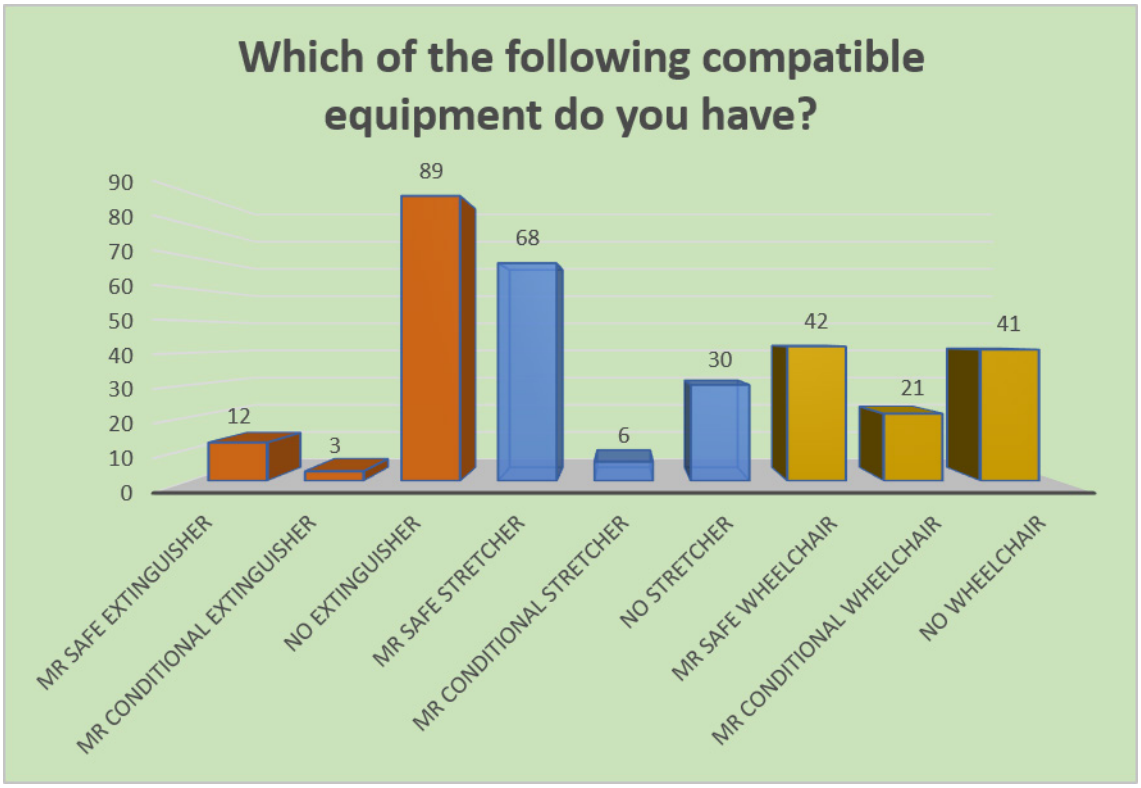


Fig. 4. *Frequency distributions related to the provision of MR-safe/MR-conditional equipment.*

nage of zone IV with a "the magnet is always on" sign and the MRI centers, depending on their operation within a hospital or a private sector outpatient center. Considering the depicted findings **(Table 1)**, the chi-square test indicates that there is a statistically significant difference among these variables (p-value=0.031). Specifically, 28 (70%) of the hospital-based MRI units reported that they have not clearly marked zone IV with this sign, compared to 31 (48.4%) of the private sector units.

Regarding the pre-MRI written screening form, the vast majority of the responders answered positively. Specifically, 97 (93.3%) of the participants provide the patients with a written screening form. On the contrary, only 28 (26.9%) of the responders have implemented preliminary screening as a way of screening patients before scheduling them for MRI examinations **(Fig. 2a)**.

Specific issues were also explored regarding the questions included in the written pre-MRI screening forms **(Fig. 2b)**. The overall descriptive statistics for screening procedures and methods are shown in **Table 2**. Generally, most of the responders answered positively at a high percentage regarding the questions included in the written screening form. The only exceptions stand for neurostimulators (71, 68.3%), implanted drug pumps (60, 57.7%) and tattoos (59, 56.7%), which in comparison were at a lower percentage.

Regarding any supplementary metal detection systems, only 7 (6.7%) out of 104 responders answered that they use hand-held magnets for screening, while 97 (93.3%) of the MRI units do not use metal detection systems at all **(Fig. 3)**.

Specific issues were explored regarding the provision of MR-safe and MR-conditional equipment at the units participated in this study. As the following graph depicts, the majority of the MRI centers (89, 85.6%) are not equipped with MR-safe or MR-conditional fire extinguishers at all **(Fig. 4)**. Regarding MR-safe stretchers and wheelchairs, 68 (65.4%) MRI units are equipped with MR-safe stretchers and 42 (40.4%) with MR-safe wheelchairs. In addition, most of the responders (85, 81.7%) answered that they are not equipped with MR-safe emergency resuscitation equipment, nor are they fully equipped with MR-safe/conditional equipment such as ventilators (40, 26.1%), monitoring devices (47, 30.7%) and anaesthesia machines (20, 13.1%). **Table 3** summarises the descriptive statistics for the frequencies of MR-safe equipment.

Table 3. Descriptive statistics for frequencies of MR-safe equipment.

		N	%
Fire Extinguishers	MR-safe fire extinguisher	12	11.5
	MR-conditional fire extinguisher	3	2.9
	No fire extinguisher	89	85.6
Stretchers	MR-safe stretcher	68	65.4
	MR-conditional stretcher	6	5.8
	No stretcher	30	28.8
Wheelchairs	MR-safe wheelchair	42	40.4
	MR-conditional wheelchair	21	20.2
	No wheelchair	41	39.4
Do you have MR-safe emergency resuscitation equipment?	Yes	19	18.3
	No	85	81.7
Which of the following MR-safe/conditional equipment do you have?	Ventilator	40	26.1
	Monitoring devices	47	30.7
	Anaesthesia machine	20	13.1
	None	46	30.1

Pearson's chi-square test was performed to evaluate any possible relationship between the percentage of centers equipped with MR-safe emergency resuscitation equipment and their geographical location **(Table 4)**. This resulted in a statistically significant difference in the frequency (p-value=0.003). Fifteen MRI centers located in large cities responded positively by 29.4% compared to 4 (7.5%) of the centers located in small cities and islands.

In addition, chi-square test was performed to assess possible relationship between MR-safe emergency resuscitation equipment and the nature of the MRI units (hospital-based units/private sector outpatient centers). **Table 5** depicts a statistically significant difference in the frequency (p-value=0.001). Specifically, 14 (35%) of the hospital-based units reported that they are equipped with such equipment, compared to 5 (7.8%) of private sector outpatient centers.

For the questions related to the administration of contrast agents and safety, it was noticed that the majority of the responders have employed screening procedures which include questions related to asthma, allergies and previous reaction to contrast agents, and also maintain appropriate medication to treat adverse reactions associated with contrast agents. In contrast, only 55 (52.9%) of the centers report adverse events to the responsible authorities.

Regarding steps taken to enhance infection control within the MRI units, the majority of the responders reported having seamless floorings (87, 83.7%) and also use hand sanitisers on a regular basis (99, 95.2%). However, only 47 (45.2%) reported having hand-washing stations within the MRI departments.

The majority of the responders reported that their unit is equipped with an emergency exit (85, 81.7%). Similarly,

Table 4. Chi-square test for the relationship between MR-safe emergency resuscitation equipment and centers located in/out of large city areas.

		Do you have MR-safe emergency resuscitation equipment?					
		Yes		No		Chi-square	p-value
		N	%	N	%		
Large city	Yes	15	29.4%	36	70.6%	8.321	0.003
	No	4	7.5%	49	92.5%		

Table 5. Chi-square test for the evaluation of relationship between hospital-based/private sector outpatient MRI units and the provision of MR-safe emergency resuscitation equipment.

	Do you have MR-safe emergency resuscitation equipment?					
	Yes		No		Chi-Square	p-value
	N	%	N	%		
Hospital-based units	14	35.0%	26	65.0%	12.185	<0.001
Private sector outpatient units	5	7.8%	59	92.2%		

most of them reported that they have developed a specific plan for emergency situations (71, 68.3%). Slightly more than half of the MRI centers (59, 56.7%) are also equipped with alternative power outage. On the contrary, only 13 (12.5%) of the responders perform drills on emergency response **(Table 6)**.

Pearson's chi-square test was performed to assess any possible relationship between the responders who reported that they perform drills on emergency response and the nature of the MRI units, based on whether they are hospital-based or private sector outpatient units. Considering the findings, the chi-square test indicates that there is a statistically significant difference in the frequency of the performance of drills in relation with these criteria (p-value=0.014). Specifically, 9 hospital-based MRI units responded positively (22.5%) in contrast to 4 private sector outpatient units (6.3%).

Discussion

The results of this study indicate an overall optimal use of zoning system among the MRI departments participated in this study, with the important exception of zone IV signage. Most of the centers not equipped with this sign were hospital-based MRI units. Reports showing significantly higher rates of safety-related incidents in inpatients strengthen the validity of this result. This was mainly attributed to the complexity and number of safety steps regarding inpatients, therefore safety-related events are more likely to occur [32]. Currently, there are no rigorous safety guidelines issued by the Greek government related to MRI facility signage, and this lack of legislation may have resulted in the above inconsistencies among Greek MRI departments. Specific legislation must be established in Greece to make the optimal zoning system mandatory for every MRI department. In addition, optimal communication between healthcare professionals, as well as development of MRI safety culture will certainly contribute to higher safety within the MRI sites.

In addition, the responders have employed optimal strategies regarding pre-MRI screening methods. The only exception is the low percentage of responders who reported that they use preliminary screening when scheduling the examination. It has been justified that

Table 6. Descriptive statistics for emergency preparedness.

		N	%
Have you developed a specific plan for emergency situations?	Yes	71	68.3
	No	33	31.7
Do you perform drills on emergency response?	Yes	13	12.5
	No	91	87.5
Does your site have an emergency exit?	Yes	85	81.7
	No	19	18.3
Does your site have an alternative power outage?	Yes	59	56.7
	No	45	43.3

preliminary screening is helpful for identifying underlying conditions which need further consideration, or for drawing attention to specific implants prior to examination [33]. Although preliminary screening is not recommended by the ACR, it may offer a potential advantage to MRI departments as a supplementary method of screening prior to patient's arrival. Moreover, this could also improve the workflow of the unit, as ineligible patients will be eliminated from entering the daily schedule.

However, the lack of ferromagnetic detection systems is thought to be crucial for patient and personnel safety, while neurostimulators, implanted drug pumps and tattoos must be integrated in the patient questionnaire. Also, the absolute lack of ferromagnetic detection systems raises serious concerns about the efficacy of patient screening in Greece. Therefore, it is suggested that this additional safety tool must be implemented in Greece to enhance safety. On the contrary, these metal detection tools cannot replace the thorough pre-MRI screening performed by MR personnel. It is the technologist's responsibility to ensure optimal screening and minimise the potential risks of magnetic fields to patients.

Regarding MR-safe emergency resuscitation equipment, a high lack of equipment was noted, with a statistically significant difference between MRI units. In terms of contrast agents and safety, an optimal performance was noted, with the exception of generally under-reported safety incidents. Regarding infection control measures, Greek MRI units employ generally good policies, except for in-site hand-washing stations. Finally, the level of preparedness must be improved, as most of the responders do not perform drills on emergency response, despite having a specific emergency plan.

Social research is associated with many biases, and this study has some specific limitations. Firstly, non-response bias arises from the fact that only 33.9% of the entire target population responded to this study. This minimises the effective sample size and invalidates the study to a degree, as the characteristics of the non-responders may differ from those of the responders. Hence, generalisation of the results to the wider population of interest cannot be achieved. In addition, many potential biases are associated with surveys, such as the trend of some responders to report the answers that the investigator would wish to, instead of their true answers. This is called social desirability and it is also a potential limitation of this study. Finally, another limitation of this study is the lack of knowledge regarding the persons who actually answered the questionnaire, as Radiologists, Medical Physicists and Technologists were all allowed to fill-in the questionnaires.

Consequently, specific steps must be taken in Greece

to raise the level of MRI safety among Greek MRI departments and to comply with the well-established guidelines by the ACR. The responsible authorities must issue rigorous legislation regarding MRI safety in line with the international standards. The managers of Greek MRI units are strongly encouraged to invest in new MR-safe equipment, mainly in terms of emergency resuscitation equipment, as well as the implementation of ferromagnetic detection systems. This will be an effective way of enhancing MRI safety of both the patients and healthcare professionals in Greece and minimising the potential risks of safety-related incidents. Further research is needed in Greece to explore the rate of incidents among Greek MRI units, as well as the level of safety-related education of professionals associated with MRI. R

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Conflict of interest

The authors declared no conflicts of interest.

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