Patient Safety in Radiology

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Learning Objectives

- Recognize the importance of multidimensional patient safety issues in radiology.
- Discuss the level of awareness of radiation protection in the different categories of health care workers and among patients.
- Explain MRI hazards and identify their preventive approaches.
- Analyse the clinical use and adverse effects of contrast media and the management of contrast agent-related risks.

22.1 Introduction

Medical imaging (in short radiology) includes diagnostic and interventional procedures and has an essential role in the diagnosis and treatment of diseases. The objective in this field of medicine is focused on providing diagnostic and therapeutic benefit to the patients along with protecting them from the possible hazards associated with the procedures. By continuously upgrading imaging technologies and improving imaging modalities, such as ultrasonography, X-ray-based imaging (radiography, fluoroscopy, and computed tomography), magnetic resonance imaging (MRI), and interventional radiology, safety has become more and more crucial. The potential hazards in radiology for the patients and the staff are multidimensional:

- some possible errors could take place during handling the patients, acquisition of imaging, or image reporting that could be harmful to the patients. The examples of these errors include the wrong patient, site, or side during image acquisition, diagnostic errors of perception or interpretation of imaging, and transcription errors in radiology reports [1, 2]
- the potential hazards and side effects of unique aspects of medical imaging such as ionizing radiation, the strong magnetic field of MRI, and the contrast agents are critical issues in radiology safety.
- considering the ubiquitary diffusion of information technology in medical imaging, cybersecurity strategies are becoming necessary to avoid incidents that could threaten patient safety [3].

In radiology, like the other medical fields, new approaches to patient safety are needed: a patient-

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centered approach and a high-tolerance system vis-a-vis the errors rather than eliminating them by individual blaming [1]. Team working and continuous training about radiology hazards and their prevention are essential for all radiology professionals, to improve the system quality and to provide radiology safety for the patients and the staff [4].

In this chapter, we will discuss the main radiology safety aspects: radiation protection, MRI hazards, and contrast agent-related risks.

22.2 Radiation Protection

"Radiation protection" includes all measures useful to ensure the protection of man and the environment against the hazards of ionizing radiation. In medical imaging, X-ray-based modalities, especially computed tomography (CT), are the main area of concern for radiation exposure and its biological effects [5]. Indeed, radiation from imaging procedures comprises a significant amount of exposure to the general population.

Radiation effects can be classified as follows: (1) somatic effect (appears in the person exposed) and genetic effect (emerges in the offspring); (2) deterministic effect (with a radiation threshold level, such as burning) and stochastic effect (without a radiation threshold level). Stochastic effects are the most significant matter of concern of radiation exposure in radiology [5]. These effects can arise from exposure to low-level ionizing radiation which is responsible for long-term disease induction (both cancer and non-oncological diseases). The linear no-threshold model states that any exposure to ionizing radiation, however small, has the potential to cause harm [6].

Several papers have shown a small but significant increase of cancer risk in children and young patients with previous exposure to CT scans [7] paralleled by a measurable increase in radiation-induced DNA damage following several radiologic examinations [8].

The European Commission issued guidelines on radiation protection education and training of medical professionals in the European Union that recommend [9]:

- a course on radiation protection should be included in the basic curriculum of medical and dental schools
- continuing education and training after qualification should be provided, and, in the special case of the clinical use of new techniques, training should be provided on these techniques and the relevant radiation protection requirements
- knowledge of the advantages and disadvantages of the use of ionising radiation in medicine, including basic information about radioactive waste and its safe management, should be part of radiation protection education and training for medical students.

However, several studies have reported an alarming lack of knowledge among health professionals about radiation protection issues and radiation doses of commonly performed imaging procedures [10–12]. For example, the overall radiation doses associated with various imaging modalities are underestimated by a substantial number of professionals, and in some cases, professionals are unable to correctly differentiate between ionizing and nonionizing radiation-based imaging techniques [13]. Furthermore, patients' knowledge of the risk associated with radiation exposure is generally low. They should be better informed concerning the dose and the potential risk of medical radiation [14]. The referring physicians, as well as radiologists, have the responsibility to communicate dose information to patients in an easily understandable and useful way.

The European Directive BSS 59/13 is an essential document in this field, which has forcefully restated the importance that all stakeholders are informed and committed to the reduction of unnecessary exposure of patients during imaging procedures [15]. Article 57, which deals with the responsibilities, explains the requirements to optimize the radiation dose and to provide information to patients. It is emphasized that the professionals have to provide adequate information to the patient or his/her representative, and have to ensure that he/she is aware of the benefit and the risk of radiation based procedures [15].

The radiographers play a vital role as the last gatekeeper in the radiation protection chain. To do so radiographers should [13, 15]:

- be provided with intensive education programs on typical doses for each type of examination, risk/benefit analysis and biological effects of radiation
- attend obligatory radiation safety courses during their undergraduate studies, as well as postgraduate radiation protection and radiation safety training
- attend updating courses about new technologies and devices which can limit radiation dose without compromising image quality
- be familiar with software which allows radiation dose monitoring of the procedures carried out in the daily activity (DMS: Dose Management System)
- participate in projects of radiological procedures benchmarking
- be included in multidisciplinary teams to set up and periodically review diagnostic reference levels both for adult and paediatric patients.

A poorly informed radiographer can put the patient at a higher risk by not optimizing the pertinent imaging parameters. For instance, during CT imaging, it is crucial to select the correct tube voltage and current rotation time, depending on patient age and diagnostic query. Further to this, the use of automated tube current modulation and correct patient centering on the CT table have proved useful in lowering radiation dose while preserving diagnostic image quality. The localizer radiograph shows a significant influence on radiation exposure but with different outcomes depending on the manufacturer of the CT scanner [16].

Radiologists and radiographers should have a thorough understanding of these differences to assure patients the best examination in terms of a correct trade-off between radiation dose and image quality. Moreover, particular attention should be given to ensure that radiation dose variability is minimized in patients undergoing repeat CT examination [17]. Because of the strict correlation between image noise and radiation exposure, the iterative reconstruction approach has the potential to be employed with data acquired at lower radiation doses while preserving clinical information [18].

All this highlights the importance of education and awareness of the operators. The lack of awareness represents a small risk for individual patients; however, the danger becomes significant when considered at a population level. Un-awareness may depend on [13, 19]:

- lack of proper preparation during university courses
- inadequate training for staff already in employment, and lack of interest, especially of the senior staff
- growth of technological complexity, which requires a continuous update of the knowledge of the radiological staff
- lack of accountability, i.e. dose performances are seldom evaluated.

Comprehensive and well-coordinated actions must be set up to increase awareness of radiation risks and to promote education and knowledge in radiation protection. This is why information campaigns such as Image Gently®, Image Wisely®, and the more recent Eurosafe Imaging campaign have paid specific attention to the fundamental role of staff training in radiation protection, emphasizing the role of effective multi-professional cooperation [20].

22.3 Magnetic Resonance Imaging (MRI) Hazards

Magnetic resonance imaging (MRI), as a nonionizing radiation modality, poses unique hazards to the patients and the staff. These hazards are mainly related to the static magnetic field (SMF), the gradient magnetic field (GMF), and the radiofrequency (RF) field. The interaction between these three components and human body tissues, as well as ferromagnetic objects/devices, presents the more relevant safety concerns. Other MRI safety issues include: gadolinium-based contrast media, cryogen-related issues,

metallic implants, pregnancy, and paediatric examinations.

The following paragraphs will briefly explain the hazards and safety issues of MRI in further detail.

22.3.1 Static Magnetic Fields (SMF)

Biological effects on the human body: The SMF strength used in clinical applications is typically between 0.2 and 3.0 T; however, the clinical utilization of 7 T MRI is increasing. Magnet strengths as high as 17.5 T are currently being used in research [21]. There is no evidence indicative of significant or permanent biological effects of the SMF on the human body [22]. However, patients within a strong magnetic field (7 T or above) can undergo transient symptoms including nausea, vertigo, tinnitus, hearing loss, nystagmus, motion disturbances, dizziness, and a metallic taste [23]. For certain occupations, such as a surgeon, during an operation within an open MRI device, the occurrence of these acute symptoms may present a safety threat for patients [24]. Simultaneous exposure to SMF and low-frequency movement-induced time-varying magnetic fields from a 7 T MRI can result in neurocognitive effects such as reduced verbal memory and visual acuity [25]. There is no consensus in the scientific literature regarding the ability of SMF to damage DNA, to be carcinogenic, or to have other biological effects [21, 26].

Translational force and torque on ferromagnetic objects: Torque (twisting force) and translational magnetic force (the force that causes a magnetic object to move toward a magnet) are the results of the interaction between the SMF and ferromagnetic objects, which are proportional to the strength and spatial gradient of the magnetic field (MF), respectively [22]. Objects which may be affected by these forces include implanted medical devices—such as surgical sutures, stents, clips, prostheses, and cardiac pacemakers—and unintended metallic foreign bodies. These forces can dislodge the objects resulting in injury to the patient or may even be fatal if located in dangerous anatomic zones such as aneurysm clips [21, 27]. The compatibility of MRI with any implant and medical devices has to be evaluated before entering into the MRI environment. Therefore, it is necessary to perform accurate and thorough screening procedures for patients and other individuals to avoid all the MR non-safe objects entering the MR environment (see Sect. 22.3.4 below).

All patients who are suspected of having ferromagnetic foreign objects within their bodies must undergo further investigation. For example, in patients with a history of orbital trauma, orbital radiography is recommended to exclude possible intraocular metallic foreign body before MR examination [23, 28].

Projectile injury: The projectile or missile effect is a dangerous event caused by the attraction of ferromagnetic objects (external to the patient) by the SMF. Accelerated movements of medical support equipment such as oxygen tanks, cylinders filled with anesthetic gas, intravenous stands, beds, and chairs towards the magnetic bore can cause patient injury and damage to the hardware [22, 27]. To prevent projectile injuries, all patients and non-MR personnel must pass device and object screening before entering the MR environment [28]. There should be restrictions into the MR zone in order to preserve a safe environment. Hence, the accessibility of the MR site is classified into four zones according to the potential risk of danger: zone I (freely accessible to the public), zone II (the interface between zone I and the strictly controlled zones), zone III (in which free access by unscreened non-MR personnel or ferromagnetic objects can result in serious injury), and zone IV (MR unit magnet room: the presence of the individuals in this zone is subject to direct visual observation of MR imaging personnel) [28].

22.3.2 Gradient Magnetic Fields (GMF)

Nerve and muscle stimulation: The fast-switching gradient magnetic coils used within the MR unit produce spatial information [21]. The time-varying (gradient) magnetic field

induces tiny currents in the peripheral nerve cells and muscle fibers resulting in a sensation of tingling or pain. The U.S. Food and Drug Administration (FDA) does not provide a specific number for dB/dt to avoid peripheral neurostimulation and only requires to operate below levels that may result in adverse effects [27]. Another potential side effect of GMF is magneto-phosphenes, the perceived flashing sensation in the eye, due to stimulation of the retina/optic nerve. Current MR systems operate below the threshold for cardiac stimulation or ventricular fibrillation [22]. GMF may also induce electronic currents in conductive materials which may be hazardous for patients with electronically active devices like cardiac pacemakers or neurostimulators that can undergo temporary or permanent malfunctioning [29].

Acoustic noise: Due to the rapidly switching currents in the coils, another effect of GMF is the production of acoustic noise. Hearing protection devices should be provided for all patients during MR examinations with noise pressure exceeding 99 dB to avoid acoustic injuries [28].

22.3.3 Radiofrequency (RF) Magnetic Field

Thermal injury and burns: The RF coil produces the RF magnetic field (in the order of μT), which excites nuclear magnetization inside the body and receives nuclear MR signal which is used to form the images [21]. The absorbed RF energy by the human body may result in whole-body or localized tissue heating. Heat stress and heat exhaustion might be produced due to excessive body heating, and in certain conditions, localized RF burns may occur because of intense heat transmission. The level of RF energy deposited into body tissues can be quantified by the Specific Absorption Rate (SAR, W/kg) and Specific Energy Dose (SAD, J/kg). SAD can be calculated by multiplying the SAR with the duration of exposure to the RF power [23]. Patients who have the highest risk of experiencing dangerous levels of whole-body heating include those with thermoregulatory dysfunctions such as obesity, diabetes, old age, and those unable to sense or communicate an increase in temperature [21, 23]. Therefore, it is essential to maintain the core body temperature below 40°C, and it must not increase more than 1°C to ensure patient safety [30]. The FDA recommends that the maximum level of SAR for individuals with normal thermoregulatory function should be: 4 W/kg for the whole body over 15 min, 3 W/kg to the head, and 8 W/kg for any 1 cm^3 of tissue (e.g., in the extremities) over 5 min [22]. Recent data proposed that the SAD should be below 4 kJ/kg to prevent an excessive core temperature rise of 1.3°C, which is the updated threshold limit [30]. The other safety points are to keep the temperature in the MRI system below 22°C, to avoid the use of blankets, to consider active cooling, and to provide rest (cooling-off) periods for patients in the case of higher SAD or prolonged MR examinations [23, 30].

The RF magnetic field induces the current in conducting objects, primarily those with an elongated shape or those with a loop of a specific diameter. This interaction between the RF field and conducting objects can produce excessive heat, which may lead to thermal injuries or burns of adjacent tissue [30]. Hence, conductive objects such as implants, medical devices, wires, leads, sensors, and jewelry, can be problematic. Another important recommendation is to remove all clothing of the patients and to use MR-safe clothing during the MR examination [23]. Moreover, it is recommended to use cold compresses or ice packs in areas at high risk of burning, for example, where leads are placed on the skin or extensively tattooed areas [28]. Localized burns can also potentially be caused by conductive loops resulting in excessive energy deposition due to skin-to-skin contact, for example, thigh-to-thigh contact. In order to prevent these kinds of injuries, thermal insulation should be placed in areas with risk of skin-to-skin contact. Finally, it is mandatory to use insulation pads between the patient and the RF coils to reduce the risk of burns [27].

22.3.4 Implants and Devices

Potentially relevant MR safety hazards can occur as the result of magnetic field-induced movement and dislodgment of ferromagnetic objects, induction of electrical currents, excessive heat production, and misinterpretation due to imaging artifact [30]. Moreover, the MR electromagnetic field may interfere with the regular operation of electronically active devices such as cardiac pacemakers, implantable cardioverter-defibrillators, neurostimulators, implanted medication pumps, and cochlear implants. Non-clinical testing is required for all medical implants and devices to determine their safety in the MR environment [30]. Three types of labeling—typically provided by the device manufacturer—apply for the implants/devices according to either the scientifically based rationale or device testing data: MR safe (no known hazards), MR non-safe, and MR conditional [31]. MR conditional devices are objects that are tested and considered safe only under specific MR conditions. Information on these conditions, including maximum SMF, maximum spatial magnetic field gradient (dB/dx), and the maximum whole-body averaged SAR, are provided by the device manufacturer [30, 32].

Effective screening to identify possible implants/devices within the patients is necessary before the MR examination to preserve a safe MR environment. In the patient with implants/devices, it is essential to obtain the MR safety information of the implant/devices to document its compatibility with the MR environment [29].

With the development of new technologies and devices, adherence to continuously updated guidelines is crucial. Fortunately, large databases exist that provide updated safety ratings and recommendations for medical devices, and manufacturers publish MR safety information on their websites [33, 34].

22.4 Contrast Agent-Related Risks

Contrast agents (CA) are frequently employed to improve radiology diagnostic capacity in certain indications. Although these agents generally considered safe, they can cause some adverse effects ranging from minor reactions to severe life-threatening events [35]. These agents include:

- Iodinated contrast agents for X-ray-based studies (radiography, fluoroscopy, CT).
- Gadolinium-based contrast agents (GBCA) for MRI.
- Microbubbles for ultrasonography.

The side effects of CA consist of acute adverse events, injection site problems such as CA extravasation, or the adverse effects related to a specific group of CA such as nephrotoxicity, thyrotoxicity, and systemic nephrogenic fibrosis. The general considerations and precautions related to the contrast-enhanced examinations to provide patient safety are summarized as follows.

22.4.1 Patient Selection

The best prevention of CA adverse effects is to avoid applying them. The referring physicians and the radiologists should always consider the risk-to-benefit of applying CA for the patients, assure about the real indication, and consider the possible better alternative diagnostic imaging without CA [35].

22.4.2 Identify the Risk Factors and Contraindications

It is necessary to obtain the medical and drug history of the patients before performing a contrast-enhanced examination. One example is the history of prior allergic-like reactions to CA, asthma, or allergies that could increase the risk of allergic-like contrast reactions and if necessary premedication should be prescribed with corticosteroids or changing the CA within the same CA group. Another example is the history of renal diseases: in these patients creatinine level should be obtained before administration of iodinated CA or GBCA. Drug history of using metformin (hypoglycemic agent) should be considered before the administration of iodinated

CA and in case of reduction of renal function temporary discontinuation of metformin is recommended.

22.4.3 Safe Injection of Contrast Agents

The injection of CA either by hand or by power injector can cause complications following contrast extravasation or air embolism. The health care professional performing the injection has to evaluate intravenous access, verify the catheter size, monitor the flow rate of injection, and adjust the power injector carefully for preventing the potential adverse events [35, 36].

22.4.4 Allergy-Like and Chemotoxic Reactions

These adverse reactions can occur following intravascular administration of any group of CA, specially iodinated CA and GBCA [35]. Most of these reactions are acute and occur in the first hour after contrast administration (many in the first 5 min), but in rare cases, there are delayed reactions after injection of iodinated CA [36].

The acute adverse events can be chemotoxic or allergy-like (idiosyncratic) reactions. They are classified into three severity categories: mild, moderate, and severe. Most of the acute adverse reactions are mild, but severe life-threatening reactions can rarely occur. Chemotoxic reactions are related to molecular and chemical characteristics and are frequently dose and concentration related. Vasovagal reactions and cardiovascular effects (especially in patients with underlying cardiac disease) and symptoms of warmth, metallic taste, and nausea/vomiting are examples of chemotoxic reactions [36]. Allergy-like reactions are independent of dose. The symptoms can include urticaria, pruritus, cutaneous edema, or rare anaphylactic reaction. The most important risk factor for an acute adverse reaction to CA is a previous reaction, and a prophylactic corticosteroid injection is indicated. A history of asthma and atopy can result in a mildly increased risk of acute adverse reactions [35]. The other risk factors include more massive doses, increased rate of administration, the use of higher osmolar nonionic CA, and intra-arterial (vs. intravenous) administration [37]. The properties of GBCA that increase the risk of acute allergic reactions are ionicity, protein binding, and having a macrocyclic structure [38].

The considerations required for ensuring the minimal contrast-related acute adverse events and their proper management are:

- providing enough education and training of the health professionals involved in CA side effects, their risk factors, and treatment
- screening the patients for detecting possible risk factors
- using nonionic CA whenever possible
- considering premedication in high-risk patients
- ensuring the availability of emergency and resuscitation equipment
- monitoring the patients and providing accessible communication between them and the radiology staff before, during, and after the injection [37, 39].

22.4.5 Adverse Events Related to Iodinated Contrast Agents

Nephrotoxicity: Iodinated contrast agents (ICA) can cause acute kidney injury or worsen pre-existing chronic kidney disease [40]. This effect is known as contrast-induced nephropathy (CIN). However, post-contrast acute kidney injury (PC-AKI) is a general term and describes any sudden deterioration in renal function within 48 h following the intravascular administration of iodinated contrast, regardless of the cause [35]. The pathophysiology of CIN is not precisely understood [40].

The critical risk factor is pre-existing severe renal insufficiency (eGFR <30 ml/min for intravenous, eGFR <30–45 ml/min for intra-arterial injection). Other risk factors include age >70 years, dehydration, diabetes mellitus, hypertension requiring medical therapy, nephrotoxic medication, and metformin or metformin-containing drug combinations [39, 40]. ICA with

high osmolality, high viscosity, large doses, and multiple contrast injections within 48–72 h entail further risk [40].

- Follow the recommendations to prevent ICA-related nephrotoxicity [35, 39, 40].
- A baseline serum creatinine should be available or obtained before the injection of contrast medium in all patients considered at risk for CIN.
- Alternative imaging without using ICA (if possible) should be applied in high-risk patients.
- Volume, osmolality, and viscosity of the ICM should be as low as possible if the injection of ICA is necessary.
- Nephrotoxic treatments should be discontinued.
- Hydration before the injection of ICA in high-risk patients is extremely important.
- The use of antioxidants, such as statins or *N*-acetylcysteine, may be useful.

Thyrotoxicity: ICA can develop thyrotoxicosis in patients with a history of hyperthyroidism [35].

22.4.6 Adverse Events Related to Gadolinium-Based Contrast Agents (GBCA)

GBCA are MR contrast media. Different kinds of GBCA are available, with different chelate chemistry, viscosity, and osmolality. According to these properties, GBCA can be macrocyclic, linear, ionic, or nonionic [38]. In the following paragraphs, two main side effects of GBCA will be presented.

Nephrogenic systemic fibrosis (NSF): NSF is a rare and serious disease, related to the exposure of GBCA in patients with impaired renal function. It primarily involves the dermal/sub-dermal tissues but can also involve other organs such as lungs, heart, skeletal muscles, and esophagus. Most cases of NFS are reported in patients with severe chronic kidney disease (CKD4, eGFR 15–29 ml/min/1.73 m^2) and end-stage CKD (CKD5, eGFR <15 ml/min/1.73 m^2). Risk factors for developing NSF, include renal failure (acute or chronic), the pre-existing pro-inflammatory state of these patients, and type, dosage, and frequency of GCBA administration [41, 42]. The higher the dose of GBCA, either administered in a single dose or cumulative dose of multiple administrations, the higher is the risk of NFS [41].

The formulation of GBCA is an essential factor in developing NFS. Most reported cases of NFS are due to exposure to gadodiamide, gadopentetate dimeglumine, and gadoversetamide. The American College of Radiology Committee on drugs and contrast media, the European Medicines Agency, and the U.S. FDA have classified GBCA groups based on their risk for developing NFS [35, 42].

Therefore, low-risk GBCA and the lowest possible dose should be used in patients with renal insufficiency to prevent the development of NFS. For dialysis-dependent patients, a full 4-h dialysis session should be considered [35, 41, 42].

Tissue deposition of GBCA: GBCA can be deposited in some tissues, i.e., the brain, in patients with multiple exposures to GBCA. Linear GBCA are responsible for most reported cases of brain GBCA deposition, which can be seen as high T1 signal intensity in the dentate nucleus and globus pallidus. Although no neurological adverse effects of GBCA deposition have been reported, further evidence is needed before excluding any harmful consequence of such deposition [43].

22.5 Conclusion

Other aspects of patient safety in medical imaging, such as cybersecurity, radiology safety in children or pregnant women, and safety in interventional procedures are not addressed in this chapter. The aim of the chapter is to provide a basic coverage of the main safety concerns related to medical imaging that may be useful for further improving radiology as an enabling medical specialty [44].

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