

Safety Assessment of the Operation of the Magnetic Resonance Imaging (MRI) System at 37 Military Hospital using the Specific Absorption Rate (SAR) Levels

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Abstract: In this present study, the Safety Assessment of the Specific Absorption Rate (SAR) levels of the operation of the Magnetic Resonance Imaging (MRI) System at 37 Military Hospital was done. The main aim of this research work was to verify whether all the specific physical parameters (a strong magnetic field, rapid-changing magnetic field gradients, and RF energy) as expressed in terms of SARs in the MR system are within the established limits set by the United States Food and Drugs Administrations (USFDA) and other international organizations. Protocols were developed to assess the radiological health and safety impact of some selected MR imaging procedures on patients. The parameter considered to be assessed was; Specific Absorption Rate (SAR); temperature rise in the body. The Smart brain and Routine lumbar Spine examination cards specific to brain and lumbar spine anatomy techniques were used. For brain examinations the T1W_SE sagittal PH, and the T1W_SE Tra_PH protocols gave the highest SAR values with a mean value 1.6 W/kg for 3 minutes. For the lumbar spine examinations, the T1W_TSE axial protocols exposed patients to the highest consistent SAR value of 2.8 W/kg. The T2W_TSE axial protocol gave the highest SAR value of 3.8 W/kg with a mean value of 3.1 W/kg with the highest exposure time of 4 min with a mean of 2.5 min. These SAR values were within the limits recommended by the United States Food and Drug Administration (USFDA). To optimize patient safety, local guidelines for safety assessment were developed which include; in house screening with a metal detector, filling in the screening form and ensuring that safety requirements are met before entering the MR room. The choice of protocols that minimize SAR values and strict compliance to safety protocols developed at the MRI facility therefore should be followed and continuously updated to achieve maximum safety for patient in and around an MRI facility.

Key words: Specific Absorption Rate (SAR), Magnetic Resonance Imaging, USFDA, T1W_SE sagittal PH, T1W_SE Tra_PH, T1W_TSE axial, T2W_TSE axial protocol

INTRODUCTION

Magnetic Resonance Imaging (MRI) is a major medical diagnostic tool. It makes it possible to visualize and analyze a variety of tissue characteristics, blood flow and distribution, and several physiologic and metabolic functions. Much of this power comes from the ability to adjust the imaging process to be especially sensitive to each of the characteristics being evaluated. The magnetic resonance imaging process uses a magnetic field and Radio Frequency (RF) signals to produce images of anatomical structures, of the presence of disease, and of various biological functions within the human body. MRI produces images that are distinctly different from the images produced by other imaging modalities (Perry, 2000).

Diagnostics radiology accounts for about 14% of the average annual effective dose from all sources including

natural radiation, whilst providing over 90% of that from all manmade exposures (UNSCEAR, 2000). This places MRI, a non-ionizing diagnostic tool on a higher advantage in terms of radiation protection among many other advantages that it has over X-radiation diagnostics. There are three main techniques for obtaining images of biological tissue. These are; Radiographic techniques, using x-rays (i.e., conventional X-ray and computerized tomography) Ultrasound techniques, using sound waves and Magnetic resonance technique, using radio frequency waves.

X-ray imaging often does not provide the high-contrast resolution necessary for meaningful diagnosis. In addition, the high levels of ionizing radiation required for obtaining clear images can adversely affect human tissue. High contrast areas, such as bone, are easily identified, but variations in soft tissue are not. The orientation of the patient is also crucial to avoid capturing confusing data.

Table 1: Specific Absorption Rate (SAR) levels for the various body parts in MR procedures

Averaging time		6 min				
Body Region	Whole body SAR	Partial body SAR	Head SAR	Local SAR		
	whole body	exposed body part	head	Head	Trunk	Extremities
Operating mode	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)	(W/kg)
Normal	2	2 - 10 (b)	3.2	10 (c)	10	20
1st level controlled	4	4 - 10 (b)	3.2	10 (c)	10	20
2nd level controlled	>4	>(4 - 10) (b)	>3.2	>10 (c)	>10	>20
Short term SAR	The SAR limit over any 10 s period shall not exceed three times the stated values					

This is because the X-ray passes through the entire object and therefore captures the image of objects both in front of and behind the desired plane of interest. One way around this confusion is to place the film inside the object, so only the desired plane of the object is captured. However, this procedure, similar to the one used in dental x-rays, is not always possible. Although ultrasound produces no adverse effects, it provides poor spatial resolution and is limited to parts of the body that provide a clear acoustic window between the external surface and the region of interest. An example of a problem area is the anterior spine, where small soft tissue areas are surrounded by bone. The physical size of the tissue is too small for ultrasound resolution, and the bony structure blocks meaningful imaging of tissues behind the bone. Ultrasound is often used for fetal imaging because the fetus is only surrounded by maternal soft tissue from the front.

Magnetic resonance imaging techniques are non-invasive, require no potentially dangerous radiation, and provide highly-contrasted images in virtually any orientation. MR also provides chemical information that cannot be measured with conventional radiography or ultrasonography. The MRI has the following distinct advantages; It is a non-invasive technique, It does not use ionizing radiation, Scanning is possible in any slice orientation (known as transversal, sagittal and coronal): with offset imaging in all directions, and slice angulations in any direction (known as oblique). MR imaging provides an excellent and unlimited choice of soft tissue contrast. Scanning can be synchronized with cardiac or respiration motion to remove unwanted artifacts in the images (Philips, 2009).

MRI is not an inherently dangerous process for either the patient or the MRI staff. However, the procedure does produce a physical environment and uses forms of energy that can produce injury or discomfort if not properly controlled. The potential sources of injury are not direct biological effects but interactions of the magnetic field with other objects, which in turn, might produce injury, and application of RF energy to the patient's body, which produces heat. During an imaging procedure a patient is subjected to the following: A strong magnetic field, Magnetic field gradients (that are rapidly changing with time), RF energy and Acoustic noise (produced by the gradients). There are potential hazards associated with

each of these if certain levels are exceeded or certain conditions exist. Safety measures and routine safety checks are therefore required to be adhered to by operators, medical physicists and managements of MRI facilities (Perry, 2000).

The levels of the strong magnetic field, the magnetic field gradients, the Radio Frequency energy (RF) and the acoustic noise could be ascertained by calculating the Specific Absorption Rate (SAR). In MRI, the rate at which energy (heat) is deposited in a unit mass of tissue is expressed in terms of the SAR in units of watts per kilogram of tissue. For specific tissue conditions, the rate of temperature rise will be proportional to the SAR. The SAR is determined by a combination of factors associated with the MR system and the acquisition protocol used. Each RF pulse delivers a quantity of energy to the body (Perry, 2000). Therefore the SAR is determined by the energy in each pulse and the rate at which the pulses are applied.

For instance, the United States Food and Drugs Administration (USFDA) have established the Specific Absorption Rate (SAR) values for each region of examination as in Table 1. The USFDA has further established that the (SAR) limit over any 10 sec period shall not exceed three times the stated values for any region of interest (IEC, 2010). Thus, any SAR value for a specific scan of a region of interest that rises three times above the stated value for that region in a scan time of 10 sec or more requires specific actions or decisions to be taken to ensure patient safety.

For many years, X-rays (CT scans, Fluoroscopy and Conventional X-rays) and Ultrasounds has been the most common diagnostic tools in medical imaging centres in Ghana. Medical imaging is one of the branches in the medical field and the scientific front in general that has seen a rapid advancement over the years. Throughout the years, there have been great advances in the medical technology available to diagnose various ailments. Radiological diagnosis, have also evolved, adopted and grown to accommodate these advances. There is therefore the need for Ghana to also stay in touch with the medical advancements in the developed countries. Thus, the commissioning of the state of the art MRI facility unit in the 37 Military Hospital on 7th September, 2009, the second of its kind in Ghana with the first been the Korle Bu teaching Hospital facility which became operational



Fig. 1: Philips MR systems achieve, release 2.6 level 12008-07-18 at the 37 Military Hospital

since 2006 was a welcoming relief. Hitherto, no safety assessment tests have been performed on any of the MRI facilities in Ghana to ascertain its compliance with international standards (USFDA/ ICNIRP). Hence, this work is the first of its kind in Ghana and would also serve as a basis for future research work on MRI safety assessment as well as provide a scientific data on the MRI facility to ascertain its compliance with the international safety standards and to produce a working protocol for patient safety.

The main aim of this research study was to verify whether all the specific physical parameters (a strong magnetic field, rapid-changing magnetic field gradients, and RF energy.) as expressed in terms of SARs in the MR system are within the established limits set by the United States Food and Drugs Administrations (USFDA) (IEC, 2010) and other international organizations.

The MR imaging techniques of interest were Serial axial T1 weighted (T1W), T2W and coronal Fluid Attenuated Inversion Recovery (FLAIR) for brain scanning and Serial sagittal T1W and T2W images and Axial T1W, T2W and FLAIR for lumbar spine scanning. Findings from this work will form the basis for establishing guideline levels patients.

MATERIALS AND METHODS

This study was carried out at the Magnetic Resonance Imaging-Unit of the 37 Military hospital, which is located in Ghana's Capital City, Accra from September 2009 to June 2010. The MRI machine is a Philips MR Systems Achieva, Release 2.6 level 12008-07-18 CE 0344 of model number 43000-574 and serial number 707703. It is a 1.5 Tesla three phase machine with a magnet number

TE. 150-3222. The machine with a mounted head coil as shown below in Fig. 1 is used mainly for diagnostic medical scans in MR radiograph.

Other hardware: There is more hardware needed to make an MRI system work. A very important part is the Radio Frequency (RF) chain, which produces the RF signal transmitted into the patient, and receives the RF signal from the patient. Actually, the receive coil is a part of the RF chain. The frequency range used in MRI is the same as used for radio transmissions. That is why this MRI scanner is placed in a Faraday cage to prevent radio waves to enter the scanner room, which may cause artifacts on the MRI image.

RF coil: The two main RF coils used for this work are the head coil and the spine coil as shown in Fig. 2a, respectively.

The control panel: The control panel as shown in Fig. 2b, consist of the patient monitor, the system unit, stand-alone printer, the back-up system unit and the close-circuit patient monitor.

Data acquisition control cabinet: Figure 2c, shows the data acquisition cabinet which consist of the main software that controls the operations of the MR scanner.

Gradient amplifiers: The gradient amplifiers as shown in Fig. 2d, consist of the x, y and z amplifiers that controls the spatial resolution of the MR images.

Liquid cooling cabinet: Figure 2e is the Liquid Cooling Cabinet (LCC). It controls the internal cooling system in



Fig. 2a: RF Coils used for this study



Fig. 2b: The control panel (including the processor)

the bore of the magnet to keep the Liquid helium (LHe) at -269 degrees Celsius (4.2 K)

Compressor Unit: The HC-8E Sumitomo Compressor (Fig. 2f), links the chiller unit and the LCC to ensure the correct temperature are maintained in the MR environment. It operated between 2000 and 3000 kPa throughout this study.

MRI software: The main imaging software used by the Philips MR Systems Achieva, Release 2.6 is the Dicom. The image viewer uses DicomWorks 1.3.5b. Two main exam cards were used for this study. They are the Smart brain and the Routine spine exam cards. Five protocols were used under each exam card for patient dose analysis. These are:

Smart brain:

- Longitudinal Relaxation time (spin-lattice) Spin Echo sequence (T1W_SE sag PH)

- Short TI inversion recovery Longitudinal Echo time transverse (STIR_LongTE Tra PH)
- Long repetition (TR) and echo time (TE) transverse (T2W_TSE Tra_PH)
- Short repetition (TR) and spin echo time (SE) transverse (T1W_SE Tra_PH)
- fluid attenuated inversion recovery and long repetition time (TR) coronal (FLAIR_LongTR Cor_PH)

Routine lumbar spine:

- Short repetition (TR), echo time (TE) fluid attenuated inversion recovery (T1W_FLAIR)
- Short repetition (TR) and turbo spin echo (TSE) axial (T1W_TSE axial)
- Long repetition (TR) and turbo spin echo (TSE) sagittal (T2W_TSE sag)
- Long repetition (TR) and turbo spin echo (TSE) sagittal (T2W_TSE sag)



Fig. 2c: Data Acquisition Control Cabinet (including the RF chain)



Fig. 2d: Gradient amplifiers



Fig. 2e: Liquid Cooling Cabinet (LCC)



Fig. 2f: HC-8E sumitomo compressor

- long repetition (TR) and turbo spin echo (TSE) axial (T2W_TSE axial)

Methodology: Since this was the first time a research project of this kind was being carried out in Ghana, close interaction and collaboration between radiology staff (MRI-staff), and investigator was essential for the success of this study. These practicalities necessitated participation of only one diagnostic department and a smaller focus of activities involving a few of the more common MRI examinations or those that had a potential for high SAR to patients.

These are lumbar spine and brain.

Safety assessment of the MRI system is considered at two levels:

- The design and construction of equipment and installations
- Day to day radiological practice (procedures)

This project focused on the second stages of the safety assessment process. The first stage centered on testing/verifying the various machine safety protocols and design of routine safety assessment protocol data sheet. The second stage involved safety assessment using SAR as the safety factor of the choice of imaging protocol.

The SAR values obtained was compared with the guidance levels set by the USFDA which as of now, is the internationally recognized regulatory body in SAR values for MRI scanners whilst the development of safety assessment protocols were compared with the safety guidelines issued by the IMRSE, ICNIRP and the maintenance protocol sheets of Philips Electronics N.V. Whilst it is expected that the study of the SAR values would be extended to cover the second facility at the Korle-Bu Teaching Hospital in future, the safety guidelines developed is applicable to the two facilities and subsequent ones that would be installed in the future.

Evaluation of SAR and Image quality: The safety assessment procedure requires evaluation of patient SAR and image quality. The SAR values taken were for those examinations that had high radiosensitive organs lying in the region of scan (e.g., Gonads in lumbar spine scans and the eye in brain scans). The assessments were made within a period of 36 weeks. This was followed by taking the necessary corrective actions.

Safety assessment:

Equipment: The following Safety Assessment tests were performed on MRI equipment according to the Philips system manual installation procedures:

- Scan stop bottoms
- Finger protection test

- Table test
- Hearing protection set
- Helium stability
- Airflow circuit
- Patient alarm test
- Remote Magnetic Monitor Unit (RMMU) battery test
- Examination room configuration
- Site conditions

The machine quality output was assessed with the head phantom of fluid concentration 1000 mL demi water. +770 mg CuSO₄.5H₂O and +1 mL arquad (1% solution) model number 4522 130 95954/080685W.

Patient: The patient safety facility on the equipment such as the patient observation system, Scan stop function, manual function patient support, patient ventilation inlet, hearing protection set for patient and patient alarm (Nurse call), metal detector (Ebinger hand held detector system, EBEX 611 and 612Z (model 4185) were all present and functional. MR compatible wheel chair was also available and functional for patient use. However, there was no MR compatible bed for bed patients, no written out patient screening forms for patients undergoing MRI scans as well as guidelines for; avoiding excessive heating, post-operative patients and patients with pacemakers.

Patient dose assessment: The choice of dose quantity for patient dose assessment depends on the type of examination performed. The measurement to be undertaken should be easy to measure, reflect radiological practice and obviously allow assessment on patients (Shellock *et al.*, 1994). The dose quantity that meets these criteria for MRI examinations is the SAR. The SAR can be accessed directly from the intrinsic computer software on the MRI scanner and in some cases by calculation through a mathematical model.

The dosimetric mode chosen for this study was the SAR obtained through the intrinsic computer software on the MRI scanner. The manufacture of the product, Philips Electronics N.V., has patented software that calculates the SAR value for each patient based on the specific protocols chosen. This makes use of the patients' weight, density of the volume to be scanned, the protocols chosen and other technical factors. The other technical factors included scan time, number of slices chosen, Number of Signals Averaged (NSA/NEX) and Number of Acquisitions (NAQ). These data are captured into the computer system by interactive software at the operator console. The sampling was done based on the patients presenting for examination and matching the criteria (brain and lumbar spine examinations with all ages).

The calculation is performed automatically by the system and is recorded by a data sheet (Appendix C). The values were recorded for brain and lumbar spine examinations.

Table 2a: Planned safety assessment test protocols

Planned safety assessment tests		HOSP/MRI	
System: MRI INTERA (ACHIEVA); Edition: December 2010			
Par.:	Paragraph name:	Results:	Remark:
1.	Safety test	Remarks:	
2.1.1	Scan stop, when "STOP SCAN" on the operator s console is pressed	Correct Yes✓/No	
2.1./3	Scan stop, when "STOP SCAN" on the front operator panel is pressed	Correct Yes✓/No	
2.2.1	Scan stop, when "STOP SCAN" on the rear operator panel is pressed	Correct Yes✓/No	
2.2.1	Scan stop, when RF door is opened	Correct Yes✓/No	Message on console
2.2.2	Finger protection test	Correct Yes✓/No	
2.2.3	Check table movement	Correct Yes✓/No	
2.2.4	Manual function patient support	Correct Yes✓/No	
2.2.5	Hearing protection set for the patient is available	Correct Yes✓/No	
2.2.6	Stable helium overpressure in the magnet	Correct Yes✓/No	
2.2.7	Airflow circuit; Patient ventilation inlet below false ceiling	Correct Yes✓/No	
2.2.8	Patient alarm tests (Nurse call) is operational and can be heard at the operator's console	Correct Yes✓/No	Listen to sound from console
2.2.9	Safety stickers are mounted	Correct Yes✓/No	Physical check
2.2.10.	ERDU checks have been passed	Correct Yes✓/No	Message on console
2.3.1	Pressure equalization grid available	Correct Yes✓/No	Message on console
2.3.2	Remote Magnetic Monitoring Unit (RMMU) battery test	Exchanged Yes✓/No	
		Correct Yes✓/No	Message on console
2.3.3	PFEI peripheral test	Correct Yes✓/No	Message on console
The following local required safety items have been implemented:			
Helium exhaust pipe inside RF-Enclosure			
2.4	Only the delivered helium exhaust pie sections are used	Correct Yes✓/No	Intack and in good condition
2.4.1./2	Check Helium venting system	Correct Yes✓/No	
2.5	Check of the RF coil	Correct Yes✓/No	
2.6	Check site condition	Correct Yes✓/No	Temperature, Humidity, Dust
2.7	Check for dust in hybrid box and QBC	Correct Yes✓/No	
2.8	Check impedance 50 Ohm QBC load	Correct Yes✓/No	
2.9	Artifact measurement	Correct Yes✓/No	
Planned safety assessment tests		HOSP/MRI	
System: MRI INTERA (ACHIEVA); Edition: December 2010			
3.	Examination room configuration	Remarks:	
3.1./2	Temperature, humidity and dust conditions are correct	Correct Yes ✓/No	
3.3.	Cryo cooler switch-off function is working	Correct Yes ✓/No	
3.4	Patient airflow circuit. The patient airflow opening is beneath the false ceiling in the examination room	Correct Yes ✓/No	
One of the following situations is realized:		Correct Yes /No	
RF door swings outward;			
RF door swings inwards and a measure is in place to avoid Overpressure;			
Overpressure grid (surface area >0.36 m ²) is available;			
Other measure realized.			
4.	Site conditions	Remarks:	
4.1.1	Safety markings are present at the site entrance	Yes/No✓	
4.1.2	MR compatibility of other equipment /devices/ accessories present in the room is OK	Yes✓/No	
4.1.3	Emergency run down unit is installed and functional	Yes✓/No	
4.1.4	Safety training for operators	Yes✓/No	
4.2.1	Safety training for hospital personal (cleaners, fire brigades, staff)	Yes/No✓	

Table 2b: Mean values for scan time and SAR compared with USFDA values for the 5 protocols commonly used in SMART Brain scan at the 37 Military Hospital

Scan protocol	Scan time (min)	SAR(W/kg)	USFDAW/kg
T2W_TSE Tra_PH	3.4	1.4	3
T1W_SE Tra_PH	3.2	1.6	3
FLAIR_LongTR Cor_PH	5.1	0.4	3
T1W_SE Sag_PH	3.2	1.6	3
STIR_longTE Tra PH	3.0	1.0	3

Table 2c: Mean values for scan time and SAR compared with USFDA values for the 5 protocols commonly used in Lumbar Spine scan at the 37 Military Hospital

Scan protocol	Scan time (min)	SAR W/(kg)	USFDAW/(kg)
T1W_TSE axial	2.3	2.8	8
T2W_TSE axial	3.0	3.1	8
T1W_TSE sagittal	2.3	1.9	8
T2W_TSE sagittal	2.1	1.9	8
T1W_FLAIR	5.2	1.0	8

RESULTS AND DISCUSSION

Safety assessment tests: Table 2a is the Safety Assessment measurement protocols developed for adoption at the MRI facility for routine and planned Safety Assessment tests.

General guidelines for screening of patients: One of the functions of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER) is to develop MRI safety guidelines and disseminate this information to the MR community in order to help ensure safety for patients, healthcare workers, and the other individuals in the MR environment. This is achieved by the Medical, Scientific, and Technology Advisory Board and the Corporate Advisory Board of the IMRSER, utilizing pertinent peer-reviewed, evidence-based literature and by relying on each member's extensive clinical, research or other appropriate experience (Shellock *et al.*, 1991) in line with this, the guidelines at Appendix B have been developed for adoption at the 37 MRI-unit subject to periodic reviews.

Guidelines to prevent excessive heating and burns associated with MR procedures: The use of radiofrequency coils, physiologic monitors, electronically-activated devices, and external accessories or objects made from conductive materials can cause excessive heating which may result in burn injuries to patients undergoing MR procedures. Heating of implants and similar devices may also occur in association with MR procedures. This turns to be problematic primarily for objects made from conductive materials that have elongated shapes such as leads, guidewires, and certain types of catheters (e.g., catheters with thermistors or other conducting components). There have been over thirty (30) reported cases of first, second and third degree burns that were experienced in patients in the United States of America. These were unrelated to equipment problems or presence of conductive external or internal implants or materials. (Review of data files from U.S. Food and Drug Administration, Center for Development and Radiological Health, Manufacturer and User Facility Device Experience Database, MAUDE) (CSRIMRI, 2010).

To prevent patients from experiencing excessive heating and possible burns in association with MR procedures, the guidelines at Appendix B are recommended for adoption at the Military hospital.

Guidelines for the management of the post-operative patient referred for a magnetic resonance procedure: There is controversy and confusion regarding the issue of performing a Magnetic Resonance (MR) procedure during the post-operative period in a patient with a metallic implant or device. Studies in the peer-reviewed literature

have supported that, if a metallic object is a "passive implant" (i.e., there is no electronically- or magnetically-activated component associated with the operation of the device) and it is made from a nonferromagnetic material (e.g., Titanium, Titanium alloy, Nitinol, etc.), the patient with the object may undergo an MR procedure immediately after implantation using an MR system operating at 1.5 Tesla or less as long as there are no inherent MRI-related heating issues (Allen *et al.*, 1991). In fact, there are several reports that describe placement of vascular stents and other implants using MR-guided procedures that include the use of high-field-strength (1.5 Tesla) MR systems (Gorny and Bernstein, 2008).

Guidelines for performing MRI in non-pacemaker dependent patients: Guidelines have been presented recently by the American College of Radiology (2007) and the American College of Cardiology/American Heart Association (2007) with regard to performing MR procedures in non-pacemaker dependent patients (ICNIRP, 2004). These guidelines are listed in Appendix A for adoption at the Military hospital.

Specific absorption rate: The findings of scan protocol scan time and SAR values generated from the MRI scanner at the 37 Military hospitals are illustrated in Appendix B for all the five (5) protocols used for lumbar spine and the brain scans.

A summary of the mean values for scan time and SAR compared with USFDA values for the 5 protocols used in Smart brain scan and the 5 protocols used in lumbar spine scans respectively are given in Table 2b and c, respectively

DISCUSSION

Specific absorption rate: Table 2b and c contain the range of SAR for 20 patients each for brain and lumbar spine for 5 different protocols of each examination. These includes for Smart brain examinations; T1W_SE sag PH, T1W_SE Tra PH, FLAIR Long TR Cor PH, STIR_long TE Tra PH and T2W_TSE Tra PH. The following 5 protocols were also used for the lumbar spine examinations; T1W_FLAIR, T1W_TSE sag, T1W_TSE axial, T2W_TSE sag and T2W_TSE axial.

The SAR for brain MRI using the Smart Brain Exam card gave the following SAR values for the 5 protocols used: The T1W_SE sag PH protocol gave 1.6 W/kg for all the 20 patients examined and in an average time of 3 min.

- The SAR value for T1W_SE Tra PH protocol gave 1.6 W/kg for all the 20 patients examined and in an average time of 3 min.
- The SAR value for FLAIR Long TR Cor PH protocol gave 0.4 W/kg for all the 20 patients examined and in an average time of 3 min.

- The SAR value for STIR_long TE Tra PH gave 1.0 W/kg for all the 20 patients examined and in an average time of 3 min.
- And finally the SAR value for T2W_TSE Tra PH gave 1.4 W/kg for all the 20 patients examined and in an average time of 5 min.
- The SAR values for the lumbar spine examinations using the Routine Exam card gave the following values for the 5 protocols used.
- The SAR value for T1W_FLAIR protocol gave 1.0 W/kg for all the 20 patients examined in an average time of 4 min.
- The SAR value for T1W_TSE sag protocol gave 1.9 W/kg for all the 20 patients examined in an average time of 3 min.
- The SAR value for T1W_TSE axial protocol gave 2.5 W/kg for all the 20 patients examined in an average time of 2 min.
- The SAR value for T2W_TSE sag protocol gave 1.9 W/kg for all the 20 patients examined in an average time of 2 min.
- The SAR for T2W_TSE axial protocol, ranged from 2.2 to 3.8 W/kg with a mean value of 3.1 W/kg the time also ranged from 1 to 4 min with a mean time of 2.5 min.

It is evident from the reported values in Table 2b and c that the SAR for all the protocols was relatively low as compared to the standards set by the USFDA. The Smart brain Exam card recorded an average of 99% in terms of consistency of SAR values and scan time. It gave a constant value for all patients examined in all the protocols for all ages and gender. The Routine Exam card for the lumbar spine examination also gave an average of 98% consistency in terms of SAR value and an average of 96% in scan time. The variation in SAR value occurred with the T2W_TSE axial protocol.

For brain examinations, the protocols with the highest SAR values were the T1W_SE sag PH, and the T1W_SE Tra_PH. They both recorded 1.6 W/kg at 3 min. This however, is within the accepted limit of 3 W/kg for head MRI in an average time of 10 min set by the USFDA as can be seen in Table 1. The FLAIR Long TR Cor PH protocol recorded the lowest SAR value in brain MRI scan.

Also for the lumbar spine examinations, the FLAIR protocol recorded the lowest SAR value of 1 W/kg. The sagittal protocols also recorded low and consistent SAR values of 1.6 W/kg whereas the axial protocols had the highest values with the T1W_TSE axial recording a consistent value of 2.5 W/kg and the T2W_TSE axial recording the highest value of 3.8 W/kg and a mean of 3.1 W/kg. The highest time recorded was 4 min and a mean time of 2.5 min. This however, is within the acceptable limit of 8 W/kg for 5 min as stipulated by the USFDA

(Table 2b). This variation can be attributed to operator manipulation of the NSA/NEX during scan and in effect the acquisition time. The lower the acquisition time the higher the SAR value, and the louder the background noise and also SNR worsens. This means patient suffers from loud noise whilst image quality is also compromised.

Though the protocols are generally within the acceptable limits, the use of low NSA/NEX values for lumbar spine axials must be discouraged since this will cause an increased heat radiation to the patient whilst increasing the background noise during scan which may be very uncomfortable to patients and has the potential of harming the ears. Image quality is also compromised when the scan time is reduced as a consequence of increased NSA/NEX.

CONCLUSION

This study aimed at assessing the safety of the operation of the MRI scanner at the 37 Military Hospitals by comparing the SAR values obtained during scanning with the USFDA values. From the assessment that was done at the 37 Military hospitals spanning within a period of 36 weeks, the following conclusions can be made.

Dosimetry is an essential element for the overall assessment of safety for a patient undergoing an MRI examination. In this study, the SAR for five different protocols for two Exam cards; Smart brain and Routine lumbar spine was determined for patients undergoing two different diagnostic procedures.

The estimated SARs were compared with the standards set by the USFDA/ICNIRP and it was observed that for brain examinations as well as the lumbar spine the values were 46.7 and 61.3% lower than the USFDA/ICNIRP levels respectively.

It was also observed that even though the SAR for lumbar spine was lower than the USFDA/ICNIRP levels, the protocols for axial images were higher. This was much noted in the T2W_TSE axial protocol which gave different values from one patient to another. It was realized that operators normally change the scan time for the T2W axials which accounted for the inconsistency.

Periodic monitoring of patients SAR should be routinely performed in all MRI-units as it helps identify operator related increase in SAR levels. This was particularly in this study as the automated protocols for Smart brain exam cards gave consistent and very low SAR values as opposed to the Routine exam card for lumbar spine where significant increase and inconsistency was observed in T2W_TSE axial protocols due to operator manipulation of NSA/NEX values. The use of these protocols have proven to be very reliable and can therefore be implemented for use in lumbar spine and brain MRI scans to ensure that the unit is operating at a maximum safety level.

Appendix A

General guidelines for screening of patients recommended for use at the 37 Military Hospital Mri-unit

- a. Each MR facility should appoint a safety officer (who is trained to understand the potential hazards and issues associated with the MR environment and MR procedure and be sufficiently familiar with the information contained on the screening forms for patients and individuals)
- b. Ascertain if patient has an implant that maybe contraindicated or requires special attention for the MR procedure (example, a ferromagnetic aneurysm clip, pacemaker, neurostimulation system, etc.)
- c. Ascertain if a patient presents a condition that require a special attention (example, pregnancy, disability, metallic body, etc)
- d. Present the patient with a screening form to officially document all the above concerns.
- f. Review the information on the screening form and conduct verbal interview.
- g. Address any concern that a patient may present after the verbal interview
- h. Find if patient has previous experience in MR environment. This helps to address claustrophobic tendencies and if there was any injury due to the MR environment
- i. Ascertain past and present medical records to ensure MRI contrast agent can be used without adverse contraindications.
- j. In case of females presented for MR examination of breast or OB/GYN, find out last menstrual period, use of oral contraception, hormonal therapy and fertility medication as these may alter tissue contrast on MR imaging.
- k. If MRI contrast would be applied in 'I' above, then enquire if patient is breastfeeding for nursing mothers.
- l. Before a patient is allowed to enter MR environment, ensure that patient has come out of his/her cloth except the one provided for at the facility and the patients own brief.
- m. No hair pins in cases of females, no watch, necklace, hearing aids, dentures, partial plates, keys, beepers, cell phones, eyeglasses, barrettes, jewelry, body piercing jewelry, paperclip, money clip, credit card, bank card, magnetic strip card, coins, pen knife, nail clipper, tools must enter the MR environment.
- n. In the event that a patient is comatose or unable to communicate, a qualified member of his family or accompanying physician should fill the screening form. Should this be inadequate, a skull or chest x-ray shall be performed to rule out any doubt before proceeding for the MR procedure.
- o. Apart from the MRI wheel chair, no other wheel chair or metal stretcher should be allowed to enter the MR environment.
- p. Metallic oxygen cylinders, monitors which are not MRI certified must not accompany a patient to the MR environment.

Guidelines to prevent excessive heating and burns associated with MR procedures recommended for adoption at the 37 Military Hospital Mri-unit

- a. Prepare the patient for the MR procedure by ensuring that there are no unnecessary metallic objects contacting the patient's skin (e.g., metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc.).
- b. Prepare the patient for the MR procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of "closed-loops" from touching body parts.
- c. Insulating material (minimum recommended thickness, 1-cm) should be placed between the patient's skin and transmit RF coil that is used for the MR procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient's skin and the body RF coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow

- d. pads or foam padding between the patient's tissue and the body RF coil of the MR system. This is especially important for those MR examinations that use the body coil or other large RF coils for transmission of RF energy.
- d. Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures.
- e. Carefully follow specific MR safety criteria and recommendations for implants made from electrically-conductive materials (e.g., bone fusion stimulators, neurostimulation systems, etc.).
- f. Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.
- g. Remove all non-essential electrically conductive materials from the MR system (i.e., unused surface RF coils, ECG leads, cables, wires, etc.).
- h. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.
- i. Keep electrically conductive materials that must remain within the body RF coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.
- j. Position electrically conductive materials to prevent "cross points". For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Notably, even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively-couple (without any contact or crossover) when placed close together.
- k. Position electrically conductive materials to exit down the center of the MR system (i.e., not along the side of the MR system or close to the body RF coil or other transmit RF coil).
- l. Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar device that is in direct contact with the patient.
- m. Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MR environment.
- n. Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.
- o. Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.
- p. Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.
- q. RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the RF coil.

Guidelines for performing mri in nonpacemaker dependent patients recommended for adoption at the 37 Military Hospital Mri-Unit

- a. Establish a risk-benefit ratio for the patient
- b. Obtain written and verbal informed consent
- c. Pretest pacemaker functions using appropriate equipment outside of the MR environment

- d. A cardiologist/electrophysiologist should decide whether it is necessary to program the pacemaker prior to the MR examination
- e. A cardiologist/electrophysiologist with Advanced Cardiac Life Support (ACLS) training must be in attendance for the entire MRI examination
- f. The patient should be monitored continuously during the MR procedure (e.g., blood pressure, pulse rate, oxygen saturation, and ECG)
- g. Appropriate personnel, a crash cart, and defibrillator must be available throughout the procedure to address an adverse event
- h. Maintain visual and voice contact throughout the procedure with the patient
- i. Instruct the patient to alert the MR system operator of any unusual sensations or problems so that, if necessary, the MR system operator can immediately terminate the procedure
- j. After the MRI examination, a cardiologist/electrophysiologist should interrogate the pacemaker to confirm that the function is consistent with the pre-examination state

Appendix B

Guidelines for screening of individuals (General Public) Recommended for adoption at the 37 Military Hospital

MRI- UNIT

- a. Before any non- patient individual (example, MRI technologist, physician, relative, visiting health professional, maintenance worker, custodial worker, fire fighter, security agent, etc.) is allowed into the MR environment, he/she must be screened by an MR safety trained health worker.
- b. If for any reason, the individual may become exposed to the electromagnetic field used for the MR procedure; this person must be screened as a patient.
- c. Make sure the individual does not carry any ferrous object into the MR environment
- d. Since such visitors are normally not stripped off their clothes, the use of the metal detector is required to ensure no ferrous metals are carried to the MR environment.

Appendix C: Values of specific absorption rate for all examinations under this study

1. Brain MRI

Table C1: Values for patient data (age, sex), time and SAR values for longitudinal relaxation time (spin-lattice) Spin Echo sequence for brain MRI using the smart brain examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T1W_SE sag PH									
1	30	M	1.6	3	S11	43	M	1.6	3
2	28	M	1.6	3	12	66	M	1.6	3
3	80	M	1.6	3	13	47	M	1.6	3
4	1	M	1.6	3	14	64	F	1.6	3
5	47	F	1.6	3	15	48	F	1.6	3
6	30	M	1.6	3	16	52	F	1.6	3
7	23	F	1.6	3	17	7	F	1.6	3
8	81	F	1.6	3	18	27	M	1.6	3
9	45	M	1.6	3	19	39	M	1.6	3
10	81	M	1.6	3	20	59	M	1.6	3

Table C2: Values for patient data (age, sex), time and SAR values for short TI inversion recovery Longitudinal Echo time for transverse brain MRI using the smart brain examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
STIR_LongTE Tra PH									
1	27	F	1.0	3	10	66	F	1.0	3
2	39	M	1.0	3	11	47	M	1.0	3
3	59	M	1.0	3	12	64	M	1.0	3
4	30	M	1.0	3	13	48	M	1.0	3
5	23	M	1.0	3	14	52	M	1.0	3
6	81	F	1.0	3	15	7	M	1.0	3
7	45	M	1.0	3	16	27	F	1.0	3
8	81	M	1.0	3	17	39	F	1.0	3
9	43	F	1.0	3	20	59	F	1.0	3

Table C3: Values for patient data (age, sex), time and SAR values for Imaging with long repetition (TR) and echo time (TE) for transverse brain MRI using the smart brain examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T2W_TSE Tra PH									
1	30	M	1.4	3	11	45	M	1.4	3
2	23	F	1.4	3	12	81	M	1.4	3
3	28	M	1.4	3	13	43	M	1.4	3
4	80	M	1.4	3	14	66	M	1.4	3
5	1	M	1.4	2	15	47	M	1.4	3
6	47	F	1.4	3	16	64	F	1.4	3
7	73	M	1.4	3	17	48	F	1.4	3
8	30	M	1.4	3	18	52	F	1.4	3
9	23	F	1.4	3	19	7	F	1.4	3
10	81	F	1.4	3	20	27	M	1.4	3

Table C4: Values for patient data (age, sex), time and SAR values for imaging with short repetition (TR) and spin echo time (SE) for transverse brain MRI using the Smart brain examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T1W_SE Tra_PH									
1	30	M	1.6	3	11	43	M	1.6	3
2	28	M	1.6	3	12	66	M	1.6	3
3	80	M	1.6	3	13	47	M	1.6	3
4	1	M	1.6	3	14	64	F	1.6	3
5	47	F	1.6	3	15	48	F	1.6	3
6	30	M	1.6	3	16	52	F	1.6	3
7	23	F	1.6	3	17	7	F	1.6	3
8	81	F	1.6	3	18	27	M	1.6	3
9	45	M	1.6	3	19	39	M	1.6	3
10	81	M	1.6	3	20	59	M	1.6	3

Table C5: Values for patient data (age, sex), time and SAR values for Imaging with fluid attenuated inversion recovery and long repetition time (TR) for coronal brain MRI using the Smart brain examination card.

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
FLAIR_LongTR Cor_PH									
1	30	M	0.4	5	11	43	M	0.4	5
2	28	M	0.4	5	12	66	M	0.4	5
3	80	M	0.4	5	13	47	M	0.4	5
4	1	M	0.4	5	14	64	F	0.4	5
5	47	F	0.4	5	15	48	F	0.4	5
6	30	M	0.4	5	16	52	F	0.4	5
7	23	F	0.4	5	17	7	F	0.4	5
8	81	F	0.4	5	18	27	M	0.4	5
9	45	M	0.4	5	19	39	M	0.4	5
10	81	M	0.4	5	20	59	M	0.4	5

2. Lumbar Spine MRI

Table C6: Values for patient data (age, sex), time and SAR values for Imaging with short repetition (TR), echo time (TE) fluid attenuated inversion recovery for lumbar spine MRI using the Routine examination card

Patient no.	Age	Sex	SAR(W/kg)	Time (min)	Patient no.	Age	Sex	SAR(W/kg)	Time (min)
T1W_FLAIR									
1	67	F	1.0	4	11	43	M	1.0	4
2	28	M	1.0	4	12	66	M	1.0	4
3	80	M	1.0	4	13	47	M	1.0	4
4	1	M	1.0	4	14	64	F	1.0	4
5	47	F	1.0	4	15	48	F	1.0	4
6	30	M	1.0	4	16	52	F	1.0	4
7	23	F	1.0	4	17	7	F	1.0	4
8	81	F	1.0	4	18	27	M	1.0	4
9	45	M	1.0	4	19	39	M	1.0	4
10	81	M	1.0	4	20	59	M	1.0	4

Table C7: Values for patient data (age, sex), time and SAR values for Imaging with short repetition (TR) and turbo spin echo (TSE) for axial lumbar spine MRI using the Routine examination card

Patient no.	Age	Sex	SAR(W/kg)	Time (min)	Patient no.	Age	Sex	SAR(W/kg)	Time (min)
T1W_TSE axial									
1	60	M	2.5	3	11	39	F	2.5	2
2	25	F	2.5	2	12	57	F	2.5	2
3	48	F	2.5	3	13	58	M	2.5	2
4	67	F	2.5	2	14	34	F	2.5	2
5	36	M	2.5	2	15	66	F	2.5	2
6	44	F	2.5	2	16	42	F	2.5	2
7	44	F	2.5	2	17	66	M	2.5	2
8	16	F	2.5	2	18	7	M	2.5	2
9	61	M	2.5	2	19	71	M	2.5	2
10	51	F	2.5	2	20	57	M	2.5	2

Table C8: Values for patient data (age, sex), time and SAR values for Imaging with short repetition (TR) and turbo spin echo (TSE) for sagittal lumbar spine MRI using the Routine examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T1W_TSE sag									
1	60	M	1.9	3	11	51	F	1.9	3
2	25	F	1.9	3	12	39	F	1.9	3
3	48	F	1.9	3	13	57	F	1.9	3
4	67	F	1.9	3	14	58	M	1.9	3
5	67	F	1.9	3	15	34	F	1.9	3
6	36	M	1.9	3	16	66	F	1.9	3
7	44	F	1.9	3	17	42	F	1.9	3
8	44	F	1.9	3	18	66	M	1.9	3
9	16	F	1.9	3	19	7	M	1.9	3
10	61	M	1.9	3	20	71	M	1.9	3

Table C9: Values for patient data (age, sex), time and SAR values for Imaging with long repetition (TR) and turbo spin echo (TSE) for sagittal lumbar spine MRI using the Routine examination card

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T2W_TSE sag									
1	25	F	1.9	2	11	51	F	1.9	2
2	48	F	1.9	1	12	39	F	1.9	2
3	67	F	1.9	2	13	57	F	1.9	2
4	48	M	1.9	2	14	58	M	1.9	2
5	67	F	1.9	2	15	34	F	1.9	2
6	36	M	1.9	2	16	66	F	1.9	2
7	44	F	1.9	2	17	42	F	1.9	2
8	44	F	1.9	2	18	66	M	1.9	2
9	16	F	1.9	2	19	7	M	1.9	2
10	61	M	1.9	2	20	71	M	1.9	2

Table C10: Values for patient data (age, sex), time and SAR values for Imaging with long repetition (TR) and turbo spin echo (TSE) for axial lumbar spine MRI using the Routine examination card.

Patient no.	Age	Sex	SAR (W/kg)	Time (min)	Patient no.	Age	Sex	SAR (W/kg)	Time (min)
T2W_TSE axial									
1	25	F	2.2	3	11	36	M	3.8	1
2	48	F	2.2	4	12	52	F	3.8	2
3	67	F	3.8	1	13	68	M	2.7	3
4	46	F	3.8	2	14	57	F	3.1	3
5	78	M	3.1	2	15	79	F	3.8	1
6	53	M	3.1	3	16	59	M	2.2	3
7	61	M	3.1	3	17	26	M	3.8	1
8	1	F	2.5	2	18	54	F	2.2	2
9	55	M	3.8	1	19	69	F	3.1	3
10	44	F	3.8	1	20	51	F	2.2	4

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