Causes, Effects, Measures to Reduce MRI Interactions in Patients with Pacemakers and Proposed Design of High Dielectric Jacket for the Head and Thorax

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Abstract. The use of Magnetic Resonance imaging in this fast advancing technological era cannot be under estimated. It has been estimated that about 1 person in 1000 in the Western world has received a pacemaker worldwide \cite{1} and each year up to 8 million MRI scans are performed in Europe \cite{2}. It has become the choice in many applications due to its merits. They include detection of blood-brain-barrier disruption, identification of atherosclerotic plaque morphological, detection of occult hip fractures, fast imaging and high contrast resolution to name a few. Despite these overwhelming advantages, (MRI) has been contraindicated in patients with pacemakers (PM) or implantable cardioverter-defibrillators (ICDs). Due to these interactions, patients with these devices are often denied access this advantageous system. This paper considers some of the causes, adverse effects and provides solution to aid patient who need MRI imaging.

Introduction

It is known in recent years that MR imaging is required to obtain more high quality images and to shorten the imaging time. In order to satisfy these demands, MRI system involving the transmission of more high frequency and high power of EM wave pulses is applied. Actually, risks for both patients and operators are still present though technology has advanced greatly. A simple example is to observe how the presence of a magnetic field precludes the access to the MR room to all people with pacemakers, cardiac clips and all metallic prosthesis implanted inside their bodies. Many articles have been already published concerning the adverse effects patients are exposed to, when they undergo MRI scanning which is obitiquous in the diagnosis of many diseases. This paper considers the causes, effects as well as solutions and proposes a new design of using HDM in the torso of the human body.

Works Done by Other Authors

Soo Jung Kim at el studied safety issues in the MR environments and said it poses unique risks to patients and employees. They explained some causes of MRI contradictions and they suggested that it affects physical movement and mis-regulation of active devices. However they did not provide detailed solutions and the use of HDM pad \cite{3}. Again Jalal B. Andre and at el also studied safety issues relating to MRI and suggested that artifacts produced in MRI causes a lot of Revenue loss to healthcare providers and could be controlled or improved if patients are more relaxed and are less likely to move during an MRI scan, then motion artifacts could be reduced. Additionally they elaborated that anxiety reactions, including increased heart rate and blood pressure, have been reported in up to 30\% of patients undergoing MRI scans. Specifically, entering the bore of an MRI scanner can be associated with anxiety reactions, with patients reporting feelings of abandonment or disorientation. This emotional discomfort can increase the likelihood that a patient will move while in the scanner bore, resulting in motion artifacts which may blur image interpretation \cite{4}. Again Earl Zastrow and at el. Studied that Patients with active implantable medical devices (AIMDs) are
generally excluded from magnetic resonance imaging (MRI) diagnostics because the interaction of
the AIMD with MRI-induced radiofrequency (RF) electromagnetic fields (EMFs) can lead to
hazardous localized heating in surrounding tissues. In their work, two safety numerical
implementation of Tiers 3 and 4 methods were demonstrated. While tier 4 method provided the
most accurate representation of the RF-AIMD interactions in complex media, but was
computationally intensive to implement, and for comprehensive evaluation, the simulation sample
size must be considerably increased. Tier 3 evaluation is practically feasible but other solutions
were not discussed [5]. Again Y. Cruypenincka and at el studied that despite major advances in
pacemakers, it should be borne in mind that these medical devices still contain ferromagnetic
material and remain a relative contraindication for MRI and proposed that in all cases, MRI in a
patient with a pacemaker must be closely supervised by cardiology specialists and the imaging
should only be performed in hospitals that have implemented efficient interdepartmental protocols
and collaboration procedures [1]. The potential risks for the patient are variable, depending on how
much the patient relies on his/her pacemaker. Although the risks are different, both dependent and
non-dependent patients are subject to potentially dangerous incidents, and non-dependent patients
are not apparently at less risk than dependent patients [6]. ST Jude medicals also studied how a
patient can know and safely undergo an MRI with pacemaker and proposed that a patient with an
MRI conditional system should receive a special patient card that identifies him as having an MRI
conditional system and must carry this card with him at all times to let the healthcare professionals
caring for the patient, as well as the MRI technologist or radiologist, know that he has an MRI
conditional system [2]. Edward T. Martin at el. Studied some guidelines that should be followed to
reduce the chance of an adverse pacemaker/MRI interaction: they included obtaining informed
consent of the patient, have emergency equipment and ACLS-trained personnel readily available,
interrogate the pulse generator immediately before and after MRI, disable the minute ventilation
feature, maintain voice contact throughout the procedure and continuously monitor heart rhythm
and rate but a possible limitation of this study was that the effects of MRI-related heating were not
concentrated on and no proposal was done on HDM pads [7]. The following explain the various
causes solutions and modeling of the HDJ for the torso of the human body.

Magnetic field Interactions at 3-Tesla; there are a number of factors that contribute to these
interactions. First the static magnetic field generated by MRI systems is non-uniform and rapidly
increases when moving towards the bore of the scanner. In so doing the movement inside the MRI
scanner bore is equivalent to an exposure to a time-varying magnetic field at very low frequency
[8]. In this manner there is an induced voltage at the pacemaker (PM) input during the movement of
the PM implant inside the static magnetic field generated by the MRI scanner.

Electromagnetic Induction Heating; According to Faradays law of electromagnetic induction,
change in the flux of the magnetic field through a fixed circuit produces an electromotive force
(EMF) which lasts as long as the flux is changing. The magnitude of this induced EMF is
proportional to the rate of change of flux with time. Corresponding currents are induced by the
changing magnetic field and result in heating of the conducting specimen. In the case of a
pacemaker it could result in heating of the conducting leads [9].

Radio frequency field; It has been established that patients who are assisted medically with
cardiac pacemakers are at risk of experiencing hazardous effect such as heating when taking an
MRI scan especially at the poles (tip) of the pacemakers. This is because the scanner of the MRI
produces a strong radio frequency field and the aforementioned area of these Pacemakers has the
ability to pick up the RF energy from MRI exposure and deposit the RF energy causing heating at
such points [10].

Electric field interactions; Studies have shown that the electric field established by the MRI coil
also interacts with pacemakers and cardioverter defibrillators. This goes a long way for such
patients to experience difficulty in the pacing of these devices. In some instances it even leads to the
reprogramming of the pacemaker. A typical study was done by considering an equivalent model of
the surface coil in a new environment with a heterogeneous model body, in order to evaluate
possible electromagnetic field of the MRI coil on a pacemaker system. The equivalent model was
the torso without the pacemaker and afterwards, a pacemaker was introduced to the thorax region. It was observed that the electric and magnetic field crossing the pacemaker as it got closer to the RF coil, caused some spikes of voltage in the area. Not only was that but there also spikes of magnetic effect. The peaks of the spike were known to cause temperature increase in the tissues around that region which may damage the device [11]. The figure 1 shows the increase in the electric and magnetic spikes.

![Figure 1](https://via.placeholder.com/150)

Figure 1. The blue shows the absence of pacemaker while the red when a pacemaker was fixed.

**Specific energy absorption rate (SAR);** The SAR level is one component that changes the temperature of patient’s body during the MRI examination. This is a quantity to measure ‘warming’ effect of RF electromagnetic fields in the frequency range 100 kHz – 10 GHz. Again the electromagnetic effects in the bore of MRI scanner are the same as that in a microwave oven. There are excitations of radio frequency pulses that are generated by RF transmitting coils during the scan execution. These pulses increase the radiation level that can result in heating patient’s body. If there is a temperature rise of more than 1–2 °C, it may cause adverse health affects such as heat stroke and heat exhaustion [12].

**MR gradient-induced device vibration;** It has been established that there exist eddy currents which give rise to a net magnetic force that attempts to align with the field of the MRI scanner which causes torque, vibration and induced current. This gradient-induced eddy current will flow in the pacemaker internal battery circuitry. This can result in decrease in the battery voltage and incorrect pacing of the device after the scanning process [13].

**MEASURES TO MITIGATE THESE INTERACTIONS** - At this juncture, some considerations will be explained in order to mitigate these problems. These include

**Determination of the induced electric and magnetic fields;** this can be done through electromagnetic simulations of the tier 2 and 4 approach. The Tiers 2 to 4 requires using numerical human body models to identify the electric and magnetic field magnitudes used in the in vitro phantom test procedure. This provides general requirements for determining the distribution of the excitation or of the field induced in the body that induces currents on the AIMD under test. In this approach excitation is derived for experimental assessment of the maximum local power deposition caused by the pacemaker (PM)[13].

**Device heating;** this can be assessed by exposing the PM device to the specified gradient field and measuring the resulting temperature rise. It may be necessary to immerse the device in a gelled solution using a suitable phantom to simulate transfer of heat away from the device which is absorbed by tissues when the device is implanted. Additionally the use of laboratory coil, amplifier and function generator can simulate clinical gradient field exposure [13]. These types of equipment have the merit of being able to easily generate arbitrary pulse sequences. The use of this type of apparatus may be applied to Tier 1 and to Tier 2.

**Use of radio frequency traps;** this is another method to abate the interaction of radio frequency. This is achieved by the use of frequency traps circuit that includes an operative radio frequency circuit and a trap. The radio circuit is usually tuned to a magnetic resonance to receive magnetic
resonance from a spatial region of concern. Additionally, the trap radio frequency circuit is tuned to block selected frequencies and disposed with the operative radio frequency circuit. The trap circuit is normally a linear transmission line that has a first end at which the operative radio frequency circuit and the trap radio frequency circuit are coupled at the same point[14]. Again it has a second end at which the transmission line terminate with its impedance.

**Application of virtual humans to estimate radio frequency**: to mitigate the associated risks, pacemaker manufacturers, MRI manufacturers and regulatory scientists, have developed an international technical specification to assess MRI conditional safety of AIMDs. The MRI conditional safety of a device is then assessed in a laboratory by generating conservative estimates of each field component. Virtual humans are used for evaluating several hazards. [15].

**Conditional Pacemaker (CPM)**; this is also another method to alleviate the interactions on the pacemaker patients. One of such CPM is the Biotronik ProMRI Pacemaker System which has been tested on patients in 1.5T MRI scanner. This device was placed in MRI pacing modes prior to the scan and restored to non-MRI mode after the scan. Interrogation was performed pre and post-MRI, and 1 month post-MRI follow up[10]. It was realized that 203 patients underwent MRI scan. Furthermore it was noted that 199 patients fully completed MRI scan and 1 month post-MRI follow up was done. At the end of the study only one patient was reported to have an adverse event and was adjudicated as possibly related to both the MRI and implanted system. [16]. Another type is the Medtronic's RevoMRI system which has also been tested on patience and found to be of no negative effect.

**Application of high dielectric material in the head and thorax**: It has been a happy time for many pacemaker patients when the invention of medtronic pacemaker was approved but the other side is that looking at the number of patients that depends on PM worldwide, it is almost impossible for every patient to have access to it. This will require a new surgery on all of them which comes with a cost. Additionally the cost of the device and other regulations regarding the use of these devices. This paper suggests that it is about time researchers focused on this new paradigm by considering the use of High Dielectric materials (HDR) to reduce the adverse effect of the MRI on Patience with PMs. A research conducted by the United State used an HDR pad on the human head and through test in a birdcage coil and computer simulations, obtained results that shows a significant improvement in the signal to noise ratio and tremendous reduction in SAR absorption.[17]. Again the radio frequency field was reduce more than 70% indicating less current require to maintain the RF power. In terms of cost, it is minimal. These HDM comes in the form of solids, liquids, ceramics, deuterium, water based gell etc. Again Eugenio Mattei et al studied the use of HDR in the thorax region of PM patient. Two different patient imaging positions inside the coil (i.e., head & thorax) were studied. In both cases, the use of HDM allowed reducing the induced power (i.e., 57% reduction with head landmark, 68% with thorax landmark), while maintaining the same magnitude of $B_1 \, \text{RMS}$ of the coil. Additionally, when the HDM pads were placed at the head landmark, there was a significant decrease in the local-induced power at the tip of the implant path (58%). Conversely, there was only a 9% decrease when pads were placed at the thorax landmark [18]. In a similar manner, this paper proposes design of HDM Pad in the form of a jacket for the thorax and in various sizes similar to the different sizes of humans. These will be worn by persons who will undergo MRI scan. These involve the children, adults with different sizes. Also in the design of these jackets for the thorax, different parameters such as the geometry, the amount of dielectric material, dimensions, mechanical and electrical properties of these new pad (jackets) must be carefully investigated. The jacket may be in the form of a wearable and removable as and when the PM patient is about to take the MRI, when this design is made practicable, there must be the presence of qualified personnel who will demonstrate to patience as to how they will wear and remove them to ensure safety of patients and durability of the pads.

**Modeling torso jacket**: The torso of an adult male in this paper is modeled as an elliptic cylinder with long –axis of length 265mm, with a short axis length 195mm and a height of 590mm according to Chinese adult male [19] as shown in figure 2. With these measurements the HDM jacket could be molded to fit an adults and other sizes be made. The head also could be modeled as
geometry of a semi-sphere and concentric cylinder with radius 80mm and the neck abstracted as a HDM modeled cone. Figure 2 shows the modeling the HDM jacket for the torso and it shows the skull, muscle and the central base (disc).

Figure 2. The modeling the HDM jacket for the torso.

Conclusion

It is evident that MRI is a technology which is used worldwide in many diagnoses of diseases through scanning. However the pronouncement of adverse interactions with pacemaker patients cannot be overlooked, but these adverse effects could be dealt with if the aforementioned measures are applied. A new area which will help deal with these contradictions will be the use of HDM or pads.

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