Reconsideration of EMI Phenomenon in Active Implantable Medical Devices in the Age of MR Conditional Devices

Takeshi Toyoshima
CRDM Business Unit
USCI Holdings, Inc.
Tokyo, Japan
ttoyoshima@nifty.com

Abstract—Until recently, the presence of an AIMD has been considered a contraindication to MRI because of the potential adverse effects of MRI on AIMDs. However, all of AIMD manufacturers have released “MR Conditional” devices recently. These devices have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Therefore, it is quite important to understand what kind of clinical phenomena would take place if an accidental scan of a conventional device was performed. If the MRI scanning of a patient with non MR compatible AIMD is needed from special medical requirement, intensive monitoring of heart activity during the scanning and repetitive threshold measurements after the scanning will be essential.

Keywords—AIMD; MRI; static magnet field; magnet field gradient; rf pulses

I. INTRODUCTION

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to produce an image that is dependent on the distribution of proton in the human body. It creates cross sectional images of the body and is superior in imaging soft body tissues with clear contrast without using ionizing radiation. However, the magnetic field and radio waves used in MRI are both unordinary strong and repeatedly pulsed, so that they interact with an active implantable medical device (AIMD), such as a cardiac pacemaker, an implantable cardioverter defibrillator (ICD) or cardiac resynchronization devices. Therefore, until recently, the presence of an AIMD has been considered a contraindication to MRI because of the potential adverse effects of MRI on AIMDs. Earlier reports about those adverse effects documented serious complications, both electrical and clinical, and there were even some reports of patient’s death.

However, all of AIMD manufacturers have released “MR Conditional” devices recently [1]. These devices have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Thus, nowadays, there exist two kinds of AIMDs, one is contraindicated to MRI and the other is MR Conditional. This mixed existence may increase the risk of accidental MRI scan of a conventional and contraindicated AIMD. Therefore, it is quite important to understand what kind of clinical phenomena would take place if such an accidental scan was performed.

II. FACTORS THAT CAUSE INTERACTIONS BETWEEN AIMD AND MRI SCANNER

A. Factors in MRI scanner

Static magnetic field:
Most MRI scanner use a superconducting magnet to generate and maintain a strong static magnetic field. The magnets in use today in MRI are in the 1.5 to 3.0 Tesla range.

Magnetic field gradient:
MRI scanners also use magnetic field gradients, which vary linearly over space, to select a specific cross sectional slice to be imaged. The orientation of the image is controlled by varying the static magnetic field using gradient coils to generate additional magnetic fields. As these coils are repeatedly and rapidly switched on and off they create the characteristic repetitive noises of an MRI scanner.

Radio frequency pulses:
MRI scanners radiate radio frequency (RF) pulses to manipulate protons’ behavior to detect their reaction to magnetic resonance sequence. Power of radiated RF is limited so that the specific absorption rate (SAR) will not exceed the maximum limit defined in national and international regulations and standards. The maximum limit is 4 W/kg in most countries. The RF pulses are also radiated repeatedly.

B. Factors in AIMD

Magnetic switch:
In an AIMD, a magnetic switch is incorporated. Usually, this is a reed switch and used to temporarily change operation mode of the AIMD for the purpose of examination by placing a magnet close to it.

Over voltage protection diode:
When a patient with an AIMD is applied an external defibrillator or electrocautery, it may cause damage of electronic components in an AIMD due to overvoltage applied via its metal parts, i.e. electrodes and its case. Therefore, the
AIMD is incorporated in zener diodes between its each metal part so that the voltage between them would not exceed about twelve volts even when the excessive voltage is applied to the patient’s body.

This is a kind of protective means for the electronic circuitry in the AIMD. The zener diode acts as a current shunt when applied voltage is higher than the zener voltage to keep the voltage across the diode close to the zener voltage. This means that unintended current flows though the diode from AIMD’s case to the tip electrode when the protection takes place. Moreover, because of its nonlinear function, it will detect the envelope of a high frequency signal (envelope detection).

Electrode and lead:
An AIMD uses electrodes to stimulate, and to detect electrogram of, the heart. The electrode is attached at one end of an electrical lead to connect to the AIMD. This lead is usually around 60 cm long.

In the human body, this lead forms a one-turn coil in conjunction with body tissue between the tip electrode and the AIMD’s case. If this coil is exposed to a time-varying magnetic field, it will generate electricity.

The lead may serve as a radio receiving antenna. The type of antenna the lead forms is, most likely, a loop antenna. And inside human body is water rich environment, so the wavelength of a radio wave is decreased to about one ninths due to the specific permittivity of the water.

Sensing amplifier:
An AIMD monitors the heart activity by detecting electrograms via its electrodes. The amplitude of the electrogram is usually 0.2 to 10 mV, therefore amplifies are incorporated in the AIMD to control digital circuits to generate stimuli to the heart. If electromagnetic noises are induced to the patient body or the electrode lead, the operation of these amplifiers may be interfered (electromagnetic interference; EMI).

III. POSSIBLE INTERACTIONS
An intense static magnetic field of the MRI scanner is always present even when the scanner is not scanning and it exerts forces on ferromagnetic and other magnetic materials near the field. These forces can draw unrestrained objects, making them airborne, into the scanner’s magnet bore. This phenomenon is known as the projectile effect and can result in catastrophic consequences for individuals near the scanner, or sometimes for the patient in the bore.

Therefore, if an AICD contains components made of ferromagnetic material, most likely a battery case, it may be subjected to magnetic force and torque in the MRI scanner. In addition, if the reed switch in the AICD is placed in a strong static magnetic field, it may stay in the closed position due to magnetization of the reeds even after it is removed from the magnetic field (sticky reed switch).

When the gradient coils generate the additional magnetic field to produce the magnetic field gradient, the one-turn coil formed by the AIMD’s lead generates electricity. This works to generate electrical noises for the AIMD. If its amplitude is small and the over voltage protection diodes do not work, it stays as mere electrical noises for the AIMD. However, if the amplitude is large enough to make the protection diodes work, unintended current flows out from the electrode.

Usually, the biological effects of electrical current are thermal and stimulating effects. For frequencies of the current below about 100 kHz, an established effect is the stimulation of excitable tissue, and for higher frequencies, thermal effect predominate.

In the above case, since the time interval of the magnetic field generation is around hundreds of milliseconds, so that the possible effect will be stimulation of the heart, and may cause arrhythmic rapid stimulation.

The frequency of rf pulses is 64 MHz when the static magnetic field of the scanner is 1.5 Tesla. Its wavelength in the air is 4.7 m. However, inside human body, the wavelength is decreased to 52 cm. In addition to this, the peak power of radiated rf pulses reaches thousands of wattage even the SAR is limited to 2 W/kg, because the duty ratio of the rf pulse is less than 0.01 and the mass of scanned region is of the order of tens kilograms. Therefore, the lead of around 60 cm length acts as a tuned loop antenna, and being placed close to the transmitting coils, it may receive significant power to adversary affect the heart. The surface area of modern pacing electrode is less than 10 sq. mm. If an rf current is induce to the lead by its antenna effect, the current flows out from such a small area and it may cause heat injury of the heart tissue around the electrode. Moreover, if the envelope of the rf pulse is detected by the protection diodes, detected lower frequency components will produce stimulating effect to the heart. And this may also cause arrhythmic rapid stimulation of the heart.

IV. DISCUSSIONS ON THE INTERACTIONS
A. Static magnetic field Interactions
It is reported that the magnetic force and acceleration value exerted by MRI scanner is much lower than that of the gravity of the earth for modern pacemakers released after 1990s [2]. However, magnetic force is higher for ICDs as compared to the pacemakers. But some ICDs showed lower force as those of pacemakers. This means that there is a way to reduce the magnetic force exerted to ICDs. Usually this is to reduce ferromagnetic material as much as possible. In all of the MR conditional AIMDs, a similar way must have been adopted.

The issue of “sticky reed switch” can be solved by employing a semiconductor magnetic switch. And most of modern AIMD can be programmed to ignore the status of the magnetic switch not to change operation mode when magnetic field is applied.

B. Magnetic field gradient interaction
The maximum slew rate of the magnetic fields generated by the gradient coils is limited to 200 T/m/s for the MR compatible AIMD’s safe operation. And spacing between gradient coils is usually 50 cm. So that the actual maximum slew rate is 100 T/s. And if the loop area of the one-turn coil is
assumed as 573 sq. cm, that is the maximum area that the lead with 60-cm-length can form. The generated voltage in the coil will be 5.7 V. This voltage is lower than zener voltage of the protection diodes, so this would not cause to stimulate the heart. However, it will act as a noise to the sensing amplifier.

C. RF pulse interaction

According to intense study by Mattei[3] on MRI induced heating of 30 commercial pacemaker and ICD leads, the highest temperature rise observed was 15 degrees C and this was observed in a lead 50 cm long. And the lengths of leads that showed temperature rise more than 10 degrees C were within a range of 46 to 63 cm out of the whole range of 46 to 103 cm. However, there were leads which showed temperature rise of 2.1 and 2.4 degree C with the length of 52 and 65 cm respectively.

This means that the lead heating depends on many factors such like active or passive fixation, unipolar or bipolar, length and diameter of the lead, surface area of electrode, pitch of helically wound lead and so on. Thus its amount of the lead heating is largely variable. However, if the manufacturer could understand the effect of each factor, it will be able to control the situation.

The heating at the tissue contacting with the AIMD’s electrode may cause degeneration of surrounding tissue and it leads to elevation of stimulation threshold.

There were a couple of reports documented the unintended heart stimulation at the timing of rf pulse radiation [4, 5]. These reports were all animal studies, and the first clinical case was reported by Fontaine [6]. These may be evidences about stimulation of the heart by the detected envelope of the rf pulses.

To avoid both of the thermal and stimulating effects of rf pulses, it is important to decrease efficacy of the lead as an antenna. Structural change or adding an inductance to the lead will work for this purpose.

The sensing amplifier in the AIMD is also induced strong electrical noises in the MRI environment, and it is quite difficult to detect electrograms of the heart. Therefore, MR conditional devices are incorporated in the special operation mode for MRI scanning. It that mode, the AIMD does not monitor heart activity, instead it asynchronously stimulates the heart for a pacemaker dependent patient, or does not generate any stimulus for the patient who has regular heart beats.

V. CONCLUSIONS

Among the possible factors that adversary interact between a MRI scanner and an AMID, the physical force, acceleration and torque are seemed not to be safety risks in the modern pacemakers. Most of modern ICDs still pose problems, but a few device are almost same as pacemakers. This may be suggesting that there is a way to eliminate the problem. In addition to this, generation of magnetic field gradient also would not be of problem even under the worst case as long as its slew rate is kept below the required maximum limit.

The rf pulses are the most problematic one. The interaction strength seems specific to combination of the AIMD and the lead. Even the length of leads are the same, their temperature rise are not same. And, although some manufacturers released specially designed leads, there exist some leads among the conventional ones that is approved as MR conditional.

Of course, the lead labeled as MR conditional must be safe. But, if the MRI scanning of a patient with non MR compatible AIMD is needed from special medical requirement, intensive monitoring of heart activity during the scanning and repetitive threshold measurements after the scanning will be essential.

REFERENCES