ELECTROMAGNETIC INTERFERENCE IN IMPLANTABLE CARDIAC PACEMAKER AND CARDIOVERTER DEFIBRILLATOR

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Abstract: Japan seems to be the most sensitive society to electromagnetic interference (EMI) in an implantable cardiac pacemaker (pacemaker) or an implantable cardioverter defibrillator (ICD). There are announcements requesting shut off the power of a mobile phone to prevent interference to cardiac pacemakers in commuter trains. In this sense, a pacemaker is believed to be a device that is the most susceptible to EMI in Japan.

In this article, mechanisms of electromagnetic interference how external fields affect an implantable cardiac pacemaker or an implantable cardioverter defibrillator, methods to evaluate electromagnetic environment and some examples of electromagnetic interference are described.

Keywords: implantable cardiac pacemaker, implantable cardioverter defibrillator, Electromagnetic interference, conducting current, magnetic field, high voltage electric field, Irnich's human body model.

1. Introduction

From some reason, Japan becomes to be the most sensitive society to electromagnetic interference in a pacemaker or an ICD. There are announcements requesting shutting off the power of a mobile phone to prevent interference to pacemakers in commuter trains. In this sense, a pacemaker is believed to be a device that is the most susceptible to EMI in Japan. But, this is not true. There are some other medical equipments that are affected by a mobile phone several meters apart, even though a wall of a hospital room. However, it is also true that the most possible problem in pacemaker patient's daily life will be EMI.

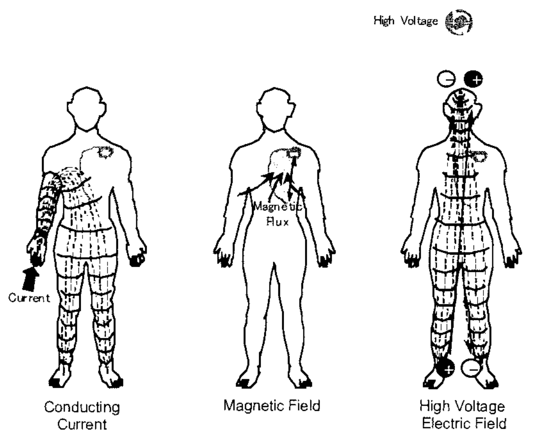

Figure 1. Mechanisms of electromagnetic interference

2. Mechanisms of Electromagnetic Interference in Pacemaker/ICD Patients

There are three factors that will cause EMI in an pacemaker/ICD patient as shown in Figure 1. One is alternating current that conducts through patient's body, the second is an alternating magnetic field and the third is an alternating high voltage electric field.

The conducting alternating current generates voltage along with its flow paths and it may generate 1mV noise in a unipolar pacemaker when the current is 43 μA at 50Hz.

A unipolar electrode of a pacemaker forms a one-turn coil in conjunction with patient's body tissue. Therefore, if alternating magnetic field is radiated to the coil, it will generate voltage. The intensity of the voltage is proportional to a loop area of the coil and frequency of the alternation of the flux. When the loop area is 573 cm^2 (the maximum area a pacemaker lead can form), 20 μT at 50Hz may generate a 1mV noise in a unipolar pacemaker. However, intensity of the noise depends on curvature of the magnetic flux and if it becomes larger, the noise becomes less.

The high voltage alternating electric field will induce alternating current in a human body, and the field above 5kV/m may affect a unipolar pacemaker with 1mV sensitivity.

Usually a bipolar pacemaker or ICD is less susceptible to EMI than a unipolar one by 6 to 10 times.

3. Assessment Methods of Electromagnetic Environment of Pacemaker/ICD Patients

Figure 2 shows an ECG strip recorded during evaluation of the conducting alternating current's effect by a method developed by the author. In this method,

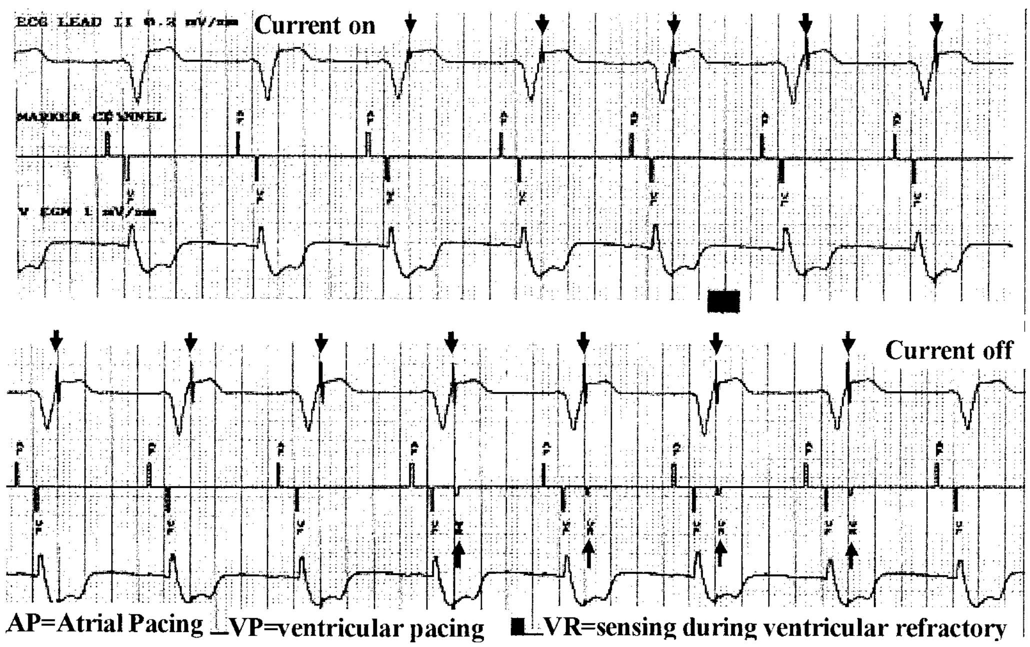

Figure 2. An ECG record of a method in which actual current pulses are injected to a patient during refractory periods of a pacemaker being triggered by QRS complexes.

current pulses are actually injected to a patient's body during the refractory period of a pacemaker in the patient trigged by patient's QRS complexes. When the pacemaker senses the current it issues a marker of "Refractory Sense". Thus it allows evaluating actual intensity of noise that affects an implanted pacemaker at a specific sensitivity without disturbing patient's cardiac rhythm at all. Figure 3 shows a result of this evaluation.

This method was modified to evaluate an effect of an alternating magnetic field, using a Helmholtz coil to radiate magnetic flux to patient also (Data unpublished yet).

In order to evaluate actual electromagnetic environment of a site, Irnich [1] proposed a human body model shown in Figure 4. This model is useful for evaluation of patient's actual environment especially for magnetic field.

In this model a ventricular electrode lead is placed in shape of a hemi-circle to form the maximum loop area with given length.

We use this model with some modifications. One of

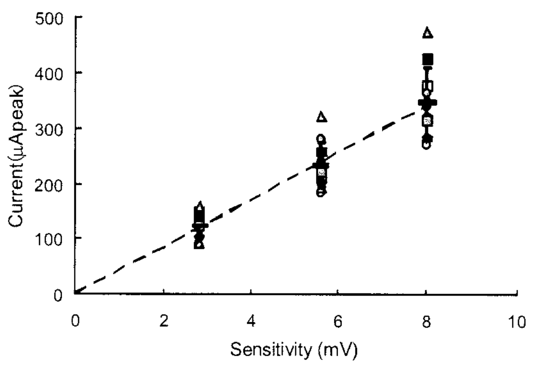

Figure 3. A result of the evaluation by the method of Figure 2.

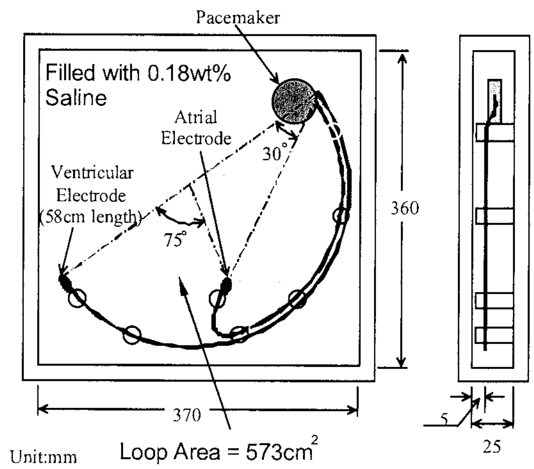

Figure 4. Irnich's human body model.

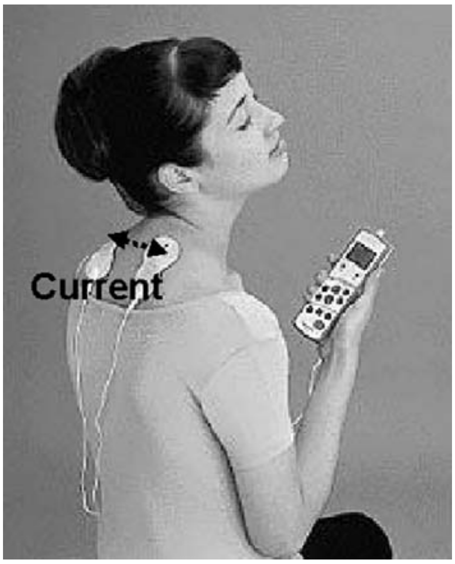

Figure 5. Transcutaneous electrical stimulator for muscle massage.

the modifications is the length of the ventricular lead. In our model, a 58cm lead that is the most popular in Japan is used, so that the loop area becomes 573 cm^2. And another modification is that we placed electrodes at a wall of the model to enable to induce simulated EGM signals to both ventricular and atrial pacemaker electrodes simultaneously without cross leakage between them. These electrodes also pick up pacemaker's output pulses with amplitude proportional to pacemaker's output for both atrial and ventricular outputs isolated.

According to our research, loop areas observed in 86 patients ranged in 119 to 366 cm^2, and average was 199 cm^2. Therefore, the area of 573 cm^2 seems too large. Actually this causes debates when discuss safety of the environments.

Usually we judge the environment under the worst condition, i.e. with the highest sensitivity, the shortest blanking and refractory periods, and in unipolar configuration of the device. Even we use the same device with implanted to the patient to evaluate the environment, and even we do not observe any interfere in the pacemaker with the worst condition settings, we can not know its margin if we use the same area with clinical situation. However, we can secure the safety margin of more than 1.6 times if we use the loop area of 573 cm^2.

4. Examples of Electromagnetic Interference

Usually an example of conducting current is leakage current from an electric appliance. Therefore, it is important to instruct patients to use it with appropriate grounding if required. However there are also other instruments that intently apply electric current to a human body such like a transcutaneous electrical stimulator for purposes of muscle massage or training (Figure 5). There are actual cases that the current caused unexpected inhibition of pacemaker output or unnecessary delivery of a shock from ICD.

The most popular sources of the magnetic flux are an inductive heater, an inductive heating rice cooker and an electric article surveillance (EAS) system.

Usually, an inductive heater (Figure 6) is turned off when cooking is over or a pan is removed. However, an inductive heating rice cooker continues generating

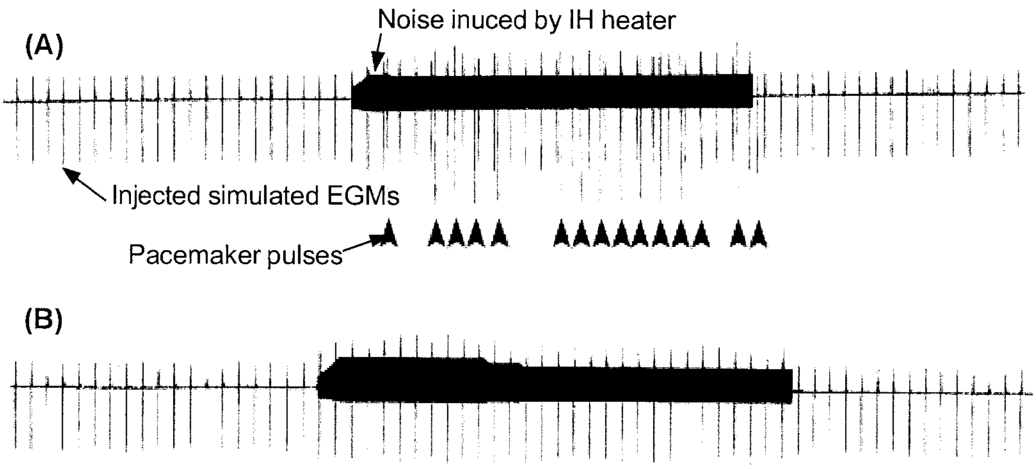

Figure 6. Effect of an inductive heater. If the heater close to a unipolar pacemaker is turned on, the pacemaker is reverted to asynchronous mode (A). If the pacemaker is bipolar, no effect is observed (B)

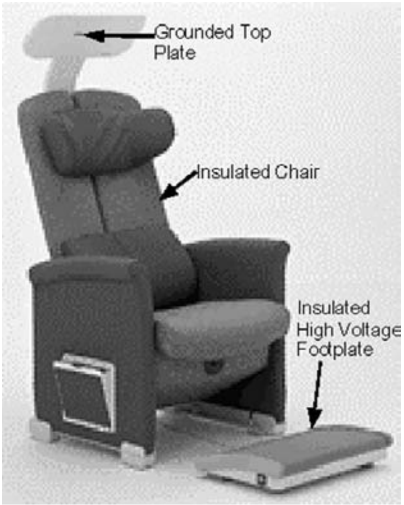

Figure 7. High voltage therapeutic chair.

magnetic flux intermittently even after cooking in order to keep the rice warm. So this causes some problems. The users tend to come close to the cooker while it is in warm keeping operation, because it is not too hot to let them be cautious.

A high power feeding line in a power plant, an electric welder and an inductive furnace are also the sources of alternating magnetic field that require a precise evaluation in occupational environment.

An example of a possible high voltage electric field is a high voltage power line. However, the Ministry of Economy, Trade and Industry Japan regulates the electric field beneath a high voltage power line to be less than 3kV/m. Therefore it would not cause any trouble to a pacemaker/ICD patient, in general. In contrast to this, electric feeder lines for trains especially in a rail yard are of concern. For example, the feeder line for the bullet train in Japan runs at about 5 meters height from the ground and the voltage is 25kV.

The equipment that should be regarded as contraindication for a pacemaker/ICD patient is a high voltage therapeutic chair that applies voltage greater than 5kV to human body (Figure 7). According to our research, the induced current in a human body is proportional to the voltage applied to the footplate and 21μA/kV, so that even the lowest voltage of 5kV of the equipment must not be applied to a pacemaker/ICD patient.

5. Conclusions (Guidelines for patients)

As previously described, Japan seems to be the most sensitive society to EMI in a pacemaker/ICD patient. So that there have been many petitions relating to the matters from citizens to the national diet and the government needed to respond to them and there have been several researches by the government.

The author have cooperated with these governmental activities as a member of the Electromagnetic Interference Investigation Committee of the Japanese Society of Pacing and Electrophysiology. As outcomes of those researches, guidelines below are established.

1. For a mobile phone: "Keep a mobile phone 22cm apart from a pacemaker or an ICD".
   The difference from 15 cm guideline in the USA dues that Japan has a 1500 MHz band for mobile phone.
2. For an inductive heater or an inductive heating rice cooker: Keep more than 50 cm between IH Heater/Rice Cooker and body.
3. For an electric article surveillance: Walk through the center of the gate, facing the front, do not stop inside, do not turn the body to the gate.

References

[1] Irnich, W. "Interference in pacemakers". PACE Vol. 7, pp1021-1048, 1984.