Does High-Power Computed Tomography Scanning Equipment Affect the Operation of Pacemakers?

Satoshi Yamaji, MD; Shinobu Imai, MD; Fumio Saito, MD; Hiroshi Yagi, MD; Toshio Kushiro, MD; Takahisa Uchiyama, MD

Background  Computed tomography (CT) is widely used in clinical practice, but there has not been a detailed report of its effect on the functioning of pacemakers.

Methods and Results  During CT, ECGs were recorded in 11 patients with pacemakers and the electromagnetic field in the CT room was also measured. The effect of CT on a pacemaker was also investigated in a human body model with and without shielding by rubber or lead. Transient malfunctions of pacemakers during CT occurred in 6 of 11 patients. The model showed that malfunctioning of the pacemaker was induced by CT scanning and this was prevented by lead but not by rubber. The alternating electrical field was 150 V/m on the CT scanning line, which was lower than the level influencing pacemaker functions. The alternating magnetic field was 15 μT on the CT scanning line, which was also lower than the level influencing pacemaker functions.

Conclusions  Malfunctions of the pacemaker during CT may be caused by diagnostic radiant rays and although they are transient, the possibility of lethal arrhythmia cannot be ignored. (Circ J 2006; 70: 190–197)

Key Words: Asynchronous pacing; Computed tomography; Electromagnetic interference; Over-sensing; Pacemaker

Malfunctioning of a pacemaker because of electromagnetic interference (EMI) was reported after development of the demand pacemaker. Clinically, a variety of medical appliances that produce electromagnetic or radiofrequency waves are now used for diagnostic or therapeutic purposes, and precautions or restrictions on their use have been enforced to protect patients with an implanted pacemaker from possible hazards. Computed tomography (CT) is widely used in clinical practice, but a detailed report has not been published of the effects of CT scanning on the operation of pacemakers. Although it is commonly believed that CT scanning does not affect the functioning of pacemakers, we have previously reported a transient malfunction of the pacemaker probably caused by over-sensing.

The present study was undertaken to examine the influence of multislice spiral CT on pacemakers in patients and experimental models of the human body.

Methods

ECG Monitoring During Chest CT Scanning in Pacemaker-Implanted Patients

In 11 patients with implanted demand-type pacemaker, chest CT scanning using a multislice spiral CT system (4-detector row, SOMATOM Volume Zoom, Siemens, Germany) was performed for further evaluation of abnormal shadows that had been observed on chest X-ray.

Measurement of Alternating Electric and Magnetic Fields in the CT Room and on CT Scan Lines

This experiment was conducted to examine whether the CT procedure produces electromagnetic fields in the CT room and induces EMI with pacemakers. Alternations of the electric and magnetic fields on the CT scanning line, and at points 1 m distant from the CT scanning line within the CT room, were measured during CT scanning using an electric-field measuring device (FD-1, Combinova, Sweden) and a magnetic-field measuring device (Model 5080, F.W. Bell, Orlando, FL, USA). The measurements were repeated 3 times, and the maximum values were adopted.

Effects of CT Scanning on Pacemaker Function in Human Body Models

The pacemakers, Thera SR8960i and Kappa SR701 (Medtronic, Minneapolis, MN, USA), combined with a 5024M lead (Medtronic) were mounted in Irnich’s human body model (Fig 1) and subjected to CT scanning. The bench model (Fig 2) was constructed for this study to clarify the conditions induced by CT scanning that might influence pacemaker function.

Measuring Systems  The Irnich’s body model was filled with 0.18 w-% saline, and the electroconductivity of the model was set at a value equivalent to that of the human body. Pick-up electrodes to receive pacing pulses from the pacemaker were attached to the pacemaker lead. Specific electrodes to input the sensing signals (known as cenelic patterns) produced by the pseudo-beat generator were also arranged on the model. The model was connected to the pseudo-beat generator and recorder via a 20-m cable that...
Fig 1. Schematic of Irnich’s human body model. Pick-up electrodes to receive pacing pulses from the pacemaker and specific electrodes as input of simulated signals are arranged on the lead. Simulated signals are produced from the pseudo-beat generator, which is battery-driven. The signals from the pacemaker are connected via a differential amplifier to the recorder driven by an alternating current from a commercial power source.

Fig 2. Schematic of the bench model. A 510-Ω load resistance is placed between the tip and the ring of the pacemaker lead. At both ends, a differential simulated signals output unit is attached via a 240 kΩ attenuation resistance. Simulated signals are produced from the pseudo-beat generator. The signals collected from the pacemaker are perceived by the differential amplifier and fed through the isolation amplifier into the recorder driven by alternating current from a commercial power source.
load resistance was placed between the tip and the ring of the pacemaker lead. A cable for differential output of the simulated signals was attached via a 240 kΩ attenuation resistance to both ends of the load resistance. The simulated signals from the pseudo-beat generator assumed the form of a cenic pattern with a 100 ms period. The cable was a 20-m shielded cable, similar to the one used in the Irnich’s model. The pseudo-beat generator was battery-driven to avoid generating alternating current noise.

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Setting of the Pacemaker and CT Output In the studies using Irnich’s human body model, the pacemaker was set to AAI mode, the sensitivity setting was 0.5 mV, the rate setting was 60 pulses/min, and the sensing polarity was unipolar. The CT output was 140 kV and 150 mAs (collimation 2.5 mm, feed/rotation 10 mm, gantry rotation time 500 ms).

During CT scanning of the human body model, if non-standard movement of the pacemaker was observed, further experiments using the bench model were conducted by changing the sensing polarity (bipolar, unipolar) and sensing sensitivity (0.5, 1.0, 2.8, 4.0 mV). The CT output was 140 kV and 300 mAs, or 140 kV and 100 mAs (collimation 2.5 mm, feed/rotation 10 mm, gantry rotation time 500 ms).

Determination of Malfunction Caused by CT Scanning The pacemaker mounted on the model was tested under 2 conditions in order to simulate the presence or absence of the patient’s own pulse.

Inhibition Test The pacemaker, without signal input from the pseudo-beat generator and with the stimulus pulse output at a setting rate of 60 beats/min, was CT scanned.

If pulse inhibition, or prolongation of the pulse interval, even for a single pulse, occurred during scanning, and if the same phenomenon occurred during repeat scanning, the malfunction was taken to be caused by CT.

Asynchronous Test CT scanning was performed when the pacemaker sensed the pulse at 60 beats/min from the pseudo-beat generator and inhibited the stimulus pulse output. If asynchronous pacing occurred even once, or transferred to the asynchronous mode, and if the same phenomenon occurred during repeat scanning, the malfunction was taken to be caused by CT.

During CT scanning, in order to identify the site from which the effect arose, scanning was performed in 2 directions, the long and short axis of the pacemaker generator, and the affected site was confirmed from the images scanned.

Identification of the CT Scanning Parameter Influencing the Pacemaker If the pacemaker was affected by CT scanning then, to refine the factor, the pacemaker was mounted on the Irnich’s human body model under the following conditions, and the inhibition test and asynchronous test were again conducted.

(1) To exclude effects of conduction current or alternating current, the pacemaker and lead were CT scanned while insulated with rubber.

(2) To exclude direct effects of irradiation on pacemaker function, the pacemaker was shielded by lead during CT scanning.

It could not be ruled out that the noises that were entered into the connecting cable, oscilloscope, or recorder in the experimental circuit would be mistaken for interference. The pacemaker and the lead, not mounted on the model, were therefore CT scanned at a setting rate of 60 pulses/min and programmed to detect a high rate episode (≥80 pulses/min).

Results Effects of CT Scanning on Pacemaker Function in Patients Table 1 shows the patients’ backgrounds and ECG patterns observed during CT imaging. Transient nonstandard movement of the pacemaker occurred in 6 of the 11 patients. In the telemetric data analyzed after CT scanning, neither modification nor resetting of the program occurred. Two patients in whom there was nonstandard movement during CT scanning are described.

Case 1 A 65-year-old man had undergone permanent pacemaker (Kappa KDR701, Medtronic) insertion for sick sinus syndrome. He was scheduled for a CT scan of the chest for more detailed evaluation of a mass lesion found in the right upper zone on chest X-ray. The CT was conducted at 150 kV and 150 mAs (collimation 2.5 mm, feed/rotation 17.5 mm, gantry rotation time 500 ms).

Before the CT, the ECG showed full-beat atrial pacing and ventricular sensing pattern, with an atrial pacing inter-

### Table 1 Characteristics of the Patients With an Implanted Pacemaker

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age (years)</th>
<th>Pacemaker mode</th>
<th>ECG pattern before CT</th>
<th>Malfunction during CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>80</td>
<td>VVI</td>
<td>VP</td>
<td>Over-sensing</td>
</tr>
<tr>
<td>2</td>
<td>77</td>
<td>VVI</td>
<td>VP</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>78</td>
<td>VVI</td>
<td>VP</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>56</td>
<td>VVI</td>
<td>Own beats + VP</td>
<td>None</td>
</tr>
<tr>
<td>5</td>
<td>87</td>
<td>VDD</td>
<td>ASVP</td>
<td>Over-sensing</td>
</tr>
<tr>
<td>6</td>
<td>72</td>
<td>VDD</td>
<td>ASVP</td>
<td>Over-sensing</td>
</tr>
<tr>
<td>7</td>
<td>66</td>
<td>VDD</td>
<td>ASVP</td>
<td>Over-sensing</td>
</tr>
<tr>
<td>8</td>
<td>77</td>
<td>DDD</td>
<td>Own beats</td>
<td>None</td>
</tr>
<tr>
<td>9</td>
<td>65</td>
<td>DDD</td>
<td>APVS</td>
<td>Over-sensing</td>
</tr>
<tr>
<td>10</td>
<td>74</td>
<td>DDD</td>
<td>APVP</td>
<td>None</td>
</tr>
<tr>
<td>11</td>
<td>77</td>
<td>DDD</td>
<td>APVP</td>
<td>Over-sensing</td>
</tr>
</tbody>
</table>

CT, computed tomography; VP, ventricular pacing; ASVP, atrial sensing-ventricular pacing; APVS, atrial pacing-ventricular pacing.

was shielded against noise. They were driven by the input/output differential method. The pseudo-beat generator was battery-driven to avoid generation of alternating current noise.

In the bench model, 510-Ω load resistance was placed between the tip and the ring of the pacemaker lead. A cable for differential output of the simulated signals was attached via a 240 kΩ attenuation resistance to both ends of the load resistance. The simulated signals from the pseudo-beat generator assumed the form of a cenic pattern with a 100 ms period. The cable was a 20-m shielded cable, similar to the one used in the Irnich’s model. The pseudo-beat generator was battery-driven to avoid generating alternating current noise.

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Effect of CT on Pacemakers

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val of 857 ms. During CT scanning through the pacemaker generator, the atrial pacing interval increased to 1,200 ms, returning to 857 ms after the scanning line had passed the generator (Fig 3). Changes in pacemaker activity were observed only during scanning through the pacemaker generator, and no effect was seen during scanning through the lead.

Case 2  An 87-year-old man had undergone permanent pacemaker (Kappa KVDD701, Medtronic) insertion for complete atrioventricular block. During hospitalization he underwent CT for detailed evaluation of a mass observed in the right pulmonary hilum on chest X-ray. The CT was conducted at 150 kV and 150 mAs (collimation 2.5 mm, feed/rotation 17.5 mm, gantry rotation time 500 ms).

Before CT scanning, the pacemaker was running to an atrial sensing-ventricular pacing pattern regulated by the patient’s own PP interval of 1,200 ms. During CT scanning through the pacemaker generator, ventricular pacing appeared approximately 40 ms earlier than in the previous AS-VP pattern. Ventricular pacing occurs 500 ms later.

Fig 3. Case 1. Before computed tomography (CT) scanning, the ECG shows full-beat atrial pacing (AP) and ventricular sensing (VS) pattern, with an atrial pacing interval of 857 ms. During CT scanning through the pacemaker generator, the atrial pacing interval increases to 1,200 ms, returning to 857 ms after the scanning line had passed the generator.

Fig 4. Case 2. Before computed tomography (CT) scanning, the pacemaker has to an atrial sensing-ventricular pacing (AS-VP) pattern regulated by the patient’s own PP interval of 1,200 ms. During CT scanning through the pacemaker generator, ventricular pacing appears approximately 40 ms earlier than in the previous AS-VP pattern. Ventricular pacing occurs 500 ms later.
Alternating Electric and Magnetic Fields in the Vicinity of the CT Scanning Line and in the CT Room

During scanning the alternating electric field parameters were 150 V/m on the CT scanning line and 80 V/m in the CT room, and the values for the magnetic fields were 15 T on the CT scanning line and 300 nT in the CT room.

Effects of CT Scanning on Pacemaker Function

Interference by CT Scanning In the inhibition test, pacing was inhibited for approximately 4 s during scanning above the pacemaker (Fig 5). In the asynchronous test, 2 asynchronous pacing spikes appeared from the pacemaker generator during CT scanning above the pacemaker (Fig 6).

Both phenomena were reproducible only when the upper part of the pacemaker was scanned, and there was no difference between types of pacemaker. These phenomena subsided rapidly after the CT scan lines passed through the pacemaker, without causing any modification or re-setting of the program.

Conditions and Site of the CT Scanning Table 2 shows the conditions in which effects caused by CT scanning appeared on the bench model. Identical results were obtained for the 2 types of pacemaker.

The transient inhibition of pacing observed during CT scanning in the inhibition test depended on the sensing sensitivity of the pacemaker, not on the sensing polarity.

Table 2 Relationship Between Pacemaker Malfunction and Settings of CT and Pacemaker

<table>
<thead>
<tr>
<th>Sensing polarity</th>
<th>Inhibition test</th>
<th>Asynchronous test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (mV)</td>
<td>CT output</td>
<td>CT output</td>
</tr>
<tr>
<td></td>
<td>140kV/300mAs</td>
<td>140kV/100mAs</td>
</tr>
<tr>
<td>0.5</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>1.0</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>2.8</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>4.0</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

CT, computed tomography; I, pacing inhibition; A, asynchronous pacing; ×, no malfunction.
The transient asynchronous pacing observed during CT scanning in asynchronous testing also depended on the sensing sensitivity, and showed no relation to the sensing polarity.

Examination using CT output revealed that higher output tended to affect the pacemaker.

Fig 7 is a transparent image of the site at which all malfunctions occurred reproducibly in the tests, and no effect was observed during scanning through the lead.

Identification of Factors Affecting Pacemaker Function
In both the inhibition test and the asynchronous test, pacemaker malfunctioning was not prevented by insulation with rubber but was prevented completely by lead shielding. Insulation with rubber did not alter any of the malfunctions that appeared in either test.

Telemetric data from the pacemaker not mounted on the model were analyzed after the CT scanning and high rate episodes were observed during the scanning process (Fig 8).

Discussion
With the development of electromagnetic devices, such as mobile phones, electromagnetic cookers and antitheft devices, EMI of the operation of implanted pacemakers and defibrillators has become a serious problem, and a number of reports addressing this issue have been published.\(^2,3,11\) The effect of medical appliances, such as magnetic resonance imaging or an electrosurgical knife, on an implanted pacemaker presents a similar problem.\(^4–6\) High-dose irradiation equipment can interfere with pacemaker function, which necessitates re-programming, and may even permanently damage the pacemaker.\(^12–16\) According to the existing American Association of Physicists in Medicine Task Group 34 Guidelines,\(^17,18\) the total irradiation exposure level of a pacemaker in patients receiving radiotherapy should not exceed 2.0 Gy. It has also been recommended that there be no direct irradiation of the pacemaker. However, the effect of CT equipment on the functioning of pacemakers has not yet been clarified, and guidelines are not available for patients undergoing diagnostic testing with equipment that emits radiation (CT devices etc). We conducted experiments to clarify the effects of electric and magnetic fields and radiation used in CT scanning.

Our main results are that transient malfunctions of pacemakers during CT scanning occurred in 6 of 11 patients. Experimental studies using a model showed that malfunctioning of pacemakers induced by CT scanning was prevented by lead shielding but not by rubber.

Conducting currents, and alternating magnetic and electric fields are generally known to cause EMI of pacemakers.\(^1,8\) We found that the maximum alternation of electric fields on the CT scanning line was 150 V/m. Butrous et al reported that a current of about 10 \(\mu\)A was induced per 1 kV/m at a frequency of 50 Hz, and that pacemakers implanted in patients were affected by alternating electric fields of over 5 kV/m, which is 33-fold more than the maximum in the present study. Furthermore, in the present study rubber insulation, which completely intercepts the influence of alternating electric fields and conducting currents, could not prevent pacemaker malfunctioning induced by CT scanning, so we therefore believe that the observed pacemaker malfunctions were not caused by alternation of the electric fields or the conduction currents.

The maximum alternation of the magnetic field on the CT scan lines in the present study was 15 \(\mu\)T. Irnich reported that a unipolar pacemaker and a lead may form a semicircle with an area of up to 570 cm\(^2\), and if an environmental magnetic field is approximately 20 \(\mu\)T at 50 Hz, the induced voltage according to Faraday’s law is 1 mV peak to peak.\(^8,9\) However, Irnich looked at the unipolar electrode pacemaker, and a bipolar electrode pacemaker should not be affected by alternating magnetic fields that are approximately 6–10 times larger.\(^1\) For a bipolar electrode, the...
region between the ring and the tip of the lead may be affected. However, in our experiment there was no difference between bipolar and unipolar electrodes. Furthermore, the effect was observed reproducibly during scanning of the same site in the upper part of the generator. We therefore believe that the alternating magnetic fields do not significantly affect the pacemaker.

The X-rays used for CT scanning are also electromagnetic waves (wave length: 0.01–10 nm) with high penetrability, but which can be cut off by lead shielding. To examine the effect of irradiation on pacemaker function, the pacemakers were shielded by lead and mounted on Irnich’s human body model during CT scanning. In this setting, direct exposure to the X-ray was prevented by the lead, but conducting current can affect the pacemaker through saline. With this shielding the pacemaker malfunctions ceased, indicating that the irradiation used in CT scanning, which was previously thought to have little influence, affects the function of pacemakers. Analysis of the telemetric data recorded during the scanning revealed that these pacemaker malfunctions were recorded as high-rate episodes, which rules out interference with the measuring system, and demonstrates that the malfunctions were an effect of irradiation of the pacemaker itself.

Pacemaker malfunctions associated with irradiation have been reported in patients receiving radiotherapy, and the explanation has been that high-dose irradiation produces unnecessary electric currents within the semi-conductor circuit (C-MOS type) used in the present generation of pacemakers, sealing electrons within the insulator and causing malfunctions. Adamec et al reported that once the stimulus pulse width or the preset rate was altered during radiotherapy, the resulting failure lasted for periods varying from less than 1 h to more than 24 h. It is known that C-MOS type semiconductor elements are damaged when exposed to 6–10 Gy radiation.

Recently, the radiation dose rate during CT scanning has become higher to shorten the scanning time and improve the quality of the image. Furthermore, multislice CT requires higher radiation doses rate than single spiral CT and thus affects more of the C-MOS semi-conductor circuit. In addition, the size of the pacemaker transistor is getting smaller by high integration degree and a power-saving function is required to maintain many pacemaker functions, with the consequence that the electrical circuit has become more sensitive to minute electrical currents caused by the photoelectric effect.

The sensing circuit, called a hybrid integrated circuit, was located in the upper part (Fig 7) of the generator used in this study, which is the amplifying part. We therefore believe that the phenomenon occurred because radiation directly entering the sensing circuit was amplified by the pacemaker.

The effect of cell phones and other wireless communication devices has also been studied in detail. Changes in pacemaker function occurring as a result of EMI include inhibition of stimulus pulses, over-sensing, and asynchronous pacing because of an anti-EMI mechanism.

The inhibition of pacing that occurred for several seconds in our inhibition test may have been caused by over-sensing, in view of the noise from the radiation entering the sensing circuit of the generator during CT scanning. The phenomenon observed in the asynchronous test may have occurred as follows. If the noises enter during simulated signal sensing, the pacemaker corrects the stimulus cycle and enters a refractory period, during which noises exceeding the sensing sensitivity enter for a certain time, activating the EMI preventive mode and causing a change to asynchronous pacing. A smaller effect was observed in the asynchronous test than in the inhibition test because, in the former, if even a single shot of noise entered it was falsely recognized as the heart’s own beat and pacing inhibition may occur. In contrast, in the asynchronous test, even if noise is entered, the pacemaker enters the refractory period, and time is needed for the EMI preventive mode to be activated, during which, if the scanning line passes through it, the effect may not occur.

In Case 1, inhibition of pacing probably occurred as a result of over-sensing, as described above, on the atrial or ventricular side or both.

In Case 2, ventricular pacing of the fourth beat (Fig 2) appeared about 40 ms earlier than in the other atrial sensing-ventricular pacing. It was therefore considered that noise induced by radiation, and not the p-wave, was over-sensed in the atrial side; ventricular pacing followed this sensing. Furthermore, subsequent ventricular pacing at the upper rate may have been caused by over-sensing of the atrial side, in view of the continuing irradiation.

These phenomena were transient because the CT scanning was completed within a few seconds. However, the lowest sensitivity of the pacemaker affected during the CT scanning in the present study was 2.8 mV, which is the sensitivity level usually used for ventricular sensing, and is not an exceptional value.

The output of CT can clearly affects pacemakers under the conditions used for chest imaging. Recently, because of its typical high output and resolution CT has been used to image the coronary arteries. In dynamic CT, scanning is repeated at the same site, so the pacemaker could be irradiated for much longer. In fact, Medtronic Company released a warning about pacemaker implanted patients undergoing dynamic CT. Moreover, the pacemaker indication now encompasses biventricular pacing, and compact thin-type pacemakers, or pacemakers with high performance, high function, and complicated circuits, have been developed, and the sensing circuit has also become complex. Thus the increasing indications for CT and the increasing complexity of pacemakers worsen the problem.

The present study shows that pacemaker malfunction genuinely occurs in clinical cases, and was reproducible in our experimental studies using human body models.

The pacemaker malfunctions observed were transient because CT scanning passed rapidly through the crucial part of the pacemaker and none of the patients showed clinical symptoms. However, under certain conditions asynchronous pacing may generate a spike on the T wave of the patient’s own pulses and induce ventricular tachycardia or ventricular fibrillation.

Study Limitations

There were 5 cases that did not show pacemaker malfunctions during CT scanning, and the pacemakers used in our experimental studies were both made by the Medtronic Company. Further studies using pacemakers from other manufacturers, with different design parameters, are necessary.

Conclusion

EMI may occur in the pacemaker during CT scanning.
The malfunctions are transient, but we cannot rule out the possibility of lethal arrhythmia. During CT scanning of the implantation site, medical staff, including medical doctor, nurse, and radiological technologist, need to be aware of this phenomenon and ECG monitoring is recommended. Further studies to examine the effect of CT scanning on the function of all types of pacemaker are needed.

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We thank Mr Hiroshi Fujimoto and Mr Katsumi Yokomizo (Education Department, Medtronic, Inc) for their cooperation during this study.

References