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JOURNAL OF PACING AND CLINICAL ELECTROPHYSIOLOGY, Volume 25, No. 8, August 2002

Measurement of Body Surface Energy Leakage of Defibrillation Shock by an Implantable Cardioverter Defibrillator

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From the *Department of Internal Medicine, Kitasato University School of Medicine, Sagamihara, †Tachy Business Group and ‡Research and Development, Medtronic Japan Co., Ltd, Tokyo, Japan, and the ‡First Department of Internal Medicine, Niigata University School of Medicine, Niigata, Japan

NIWANO, S., ET AL.: Measurement of Body Surface Energy Leakage of Defibrillation Shock by an Implantable Cardioverter Defibrillator. *Leakage of electrical current from the body surface during a defibrillation shock delivery by an ICD device was evaluated in 27 patients with life-threatening ventricular tachyarrhythmias. All patients underwent the implantation of the Medtronic Jewel Plus ICD system, and the defibrillation shocks were delivered between the active can implanted in the left subclavicular region and the endocardial lead placed in the right ventricle. At the time of measurement of the effect of electrical energy delivery for defibrillation, the shocks were delivered in a biphasic form at the energy level of 20 or 30 J. During each delivery of the defibrillation shock, the electrical current to the body surface was measured through large skin electrodes (6.2 cm^2) that were pasted at the following positions: (1) parallel position: the electrodes were placed at the left shoulder and the right low-chest, and the direction of the electrode vector was parallel to the direction of the defibrillation energy flow, and (2) cross position: the electrodes were placed at the right shoulder and the left low-chest, and the vector of the electrodes was roughly perpendicular to the direction of the energy flow. The energy leakages were measured in 80 defibrillation shocks. The peak leakage current during the shock delivery at energy of 30 J was 48 ± 26 mA at the parallel position and 19 ± 15 mA at the cross position (P = 0.0002). The energy leakage at a 30-J shock was 7.4 ± 7.2 mJ at the parallel position and 1.4 ± 2.3 mJ at the cross position (P = 0.0002). The actual maximum energy leakage was 105 mA, 29 mJ, and 106 V that appeared at the parallel position. The body surface leakage of the defibrillation energy of the ICD device was evaluated. The power of the energy leakage strongly depended on the angle between the alignment of the recording electrodes and the direction of the energy flow. The highest current leakage to the body surface reached a considerable level, but the energy leakage was small because of the short duration of the defibrillation shock. (PACE 2002; 25:1212–1218)*

defibrillation, electrical stimulation, electrical shock, tachyarrhythmias, antitachycardia device

Introduction

It has been reported that the prognosis of patients with life-threatening ventricular arrhythmias has been dramatically improved by implantation of an implantable cardioverter defibrillator (ICD).[1–8] Recently, antiarrhythmics versus implantable defibrillator (AVID) studies have demonstrated that the lifesaving effect of the ICD was superior to that of administration of amiodarone in patients with old myocardial infarction and life-threatening ventricular tachyarrhythmias.[9–12] The population of patients who will undergo ICD implantation is expected to increase in the future,[3,9–12] therefore, the likelihood of a person having physical contact with ICD patients during the delivery of a defibrillation shock may also increase. What will really happen to a person who touches a patient with an ICD implantation during a defibrillation shock delivery? Although the energy leakage or electrical current of the defibrillation shock from a patient's body surface would be expected to be small because of a con-

Supported in part by a grant from the Foundation for Total Health Promotion, Tokyo, Japan.

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Received June 5, 2001; revised August 29, 2001; accepted September 13, 2001.

siderably high impedance between the dry skins of the two people,[13,14] a worst case situation can be expected (e.g., a patient holding a naked baby with wet arms in a bathtub). Although, the evaluation of the energy leakage of the defibrillation shock to the body surface seems to be quite important,[15–21] there has been no systematic study of this point. The authors' previous report showed that the body surface energy leakage during a defibrillation shock was up to 124 mA and 47 mJ in a canine body and seemed to be safe for others who may come in physical contact with them during defibrillation.[22] In the present study, the body surface energy leakage during defibrillation shock was measured in human subjects to determine the possible amount of energy that can flow from the patient to another person during therapy delivery.

Methods

Patients

The study included 27 patients (20 men, 7 women) with sustained ventricular tachyarrhythmia who underwent implantation of and ICD system.[23,24] All patients had at least one episode of syncope caused by ventricular tachyarrhythmia and 12 of 27 had a history of aborted sudden cardiac death. The mean age was 61 ± 14 years (range 23–73 years). The type of ventricular tachyarrhythmia was sustained ventricular tachycardia (n = 15) sustained polymorphic ventricular tachycardia (including torsades de pointes) (n = 6) and ventricular fibrillation (n = 6) patients. With regard to underlying structural heart disease, 13 patients had ischemic heart disease, 3 had arrhythmogenic right ventricular dysplasia, 3 had hypertrophic cardiomyopathy, 3 had dilated cardiomyopathy, and 1 patient had familiar long QT syndrome. No structural heart disease was present in the remaining four patients. The mean left ventricular ejection fraction was 0.41 ± 0.19 (range 0.21–0.68). At the time of evaluation of the body surface energy leakage, 13 of 27 patients were treated with antiarrhythmic drugs (i.e., amiodarone in 9 patients, procainamide in 2, atenolol in 1, carvedilol in 1, and the remaining 14 patients did not take any antiarrhythmic drug therapy.

Implantation and Setting of the Defibrillation System

In the present study, a Medtronic Jewel Plus ICD system (Medtronic Inc., Minneapolis, MN, USA) was implanted in all patients.[25,26] In all patients, the ICD generator (Micro Jewel II, Model 7223Cx, Medtronic) was implanted subcutaneously in the high left chest (subclavicular) region in accordance with the standard implantation procedure (i.e., between the skin and the left major pectoral muscle). An endocardial lead with a 6-cm coil at the tip (Models 6936, 6932 or 6943, Medtronic) was inserted through the right cephalic vein and positioned against the right ventricular apex. The setting of the parameters of the defibrillation device was performed with the ICD programmer (9790 programmer, Medtronic). To evaluate the appropriateness of the placement of the lead system, two consecutive successful defibrillations of induced ventricular fibrillation with a 20-J shock were confirmed. All shocks were delivered from the implanted ICD device and were biphasic with a duration of 10–18 ms for both phases. For the initial phase of each shock, the endocardial electrode placed in the right ventricle served as the cathode and the active can as the anode. For the latter phase of each shock, the cathode and the anode were reversed.[25–28]

Body Surface Electrode Placement for Measurement

For measurements of the energy leakage during the defibrillation shock deliveries, two pairs of large-sized skin electrodes (6.2 cm^2) were placed at the following positions (Fig. 1) after removing skin hair and oil that mimics relatively good skin contact[22]: (1) parallel recording position: two skin electrodes were pasted at the left shoulder and the right low chest, and so the direction of electrodes vector was parallel to the direction of the electrical current flow of defibrillation shock; and (2) cross recording position: two skin electrodes were pasted at the right shoulder and the left low chest, and so the vector of the electrode was crossed by the direction of the defibrillation energy flow.[22]

Measurement of the Whole Body Impedance

To determine the out-circuit resistance for the measurement of the energy leakage, the whole body impedance (Z) of each patient was measured as a "shock receiver."[22] The pair of electrodes at each recording position was connected to a customized pacing system analyzer (PSA) (Model 5311B Medtronic), and the electrical current (I) was measured during pacing with a rectangular pulse at a duration of 18 ms to mimic the defibrillation shock at 10 V (Fig. 2A).[22] Then the impedance was calculated as the following formula.

$$Z = V/I$$

In accordance with the measurement of the circuit resistance of each electrode pair, the out-circuit resistance was set at 1,000 Ω (Fig. 2B).[29,30]

Recording of the Energy Leakage of the Defibrillation Shocks

The energy leakage was measured at the parallel and cross positions simultaneously. Note that

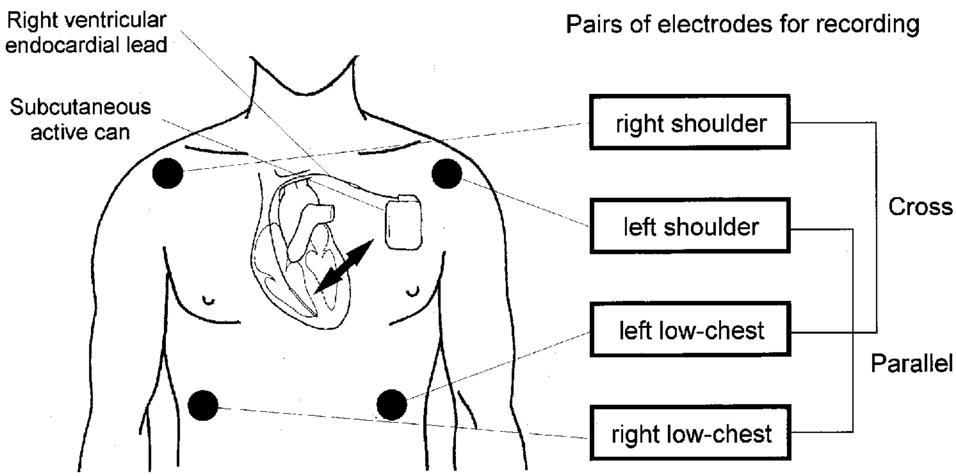

Figure 1. *The position of the skin electrodes for the measurement. Four large-sized skin electrodes (6.2 cm²)* were pasted at the shoulders and low chest on both sides. The electrodes on the left shoulder and the right low chest were used for the parallel recording position and the electrodes on the right shoulder and the left low chest were used for the cross recording position. The recording sites were designed to have the direction of electrodes vector parallel and perpendicular to the direction of the electrical current flow of defibrillation shock.

all recordings were performed during delivery of defibrillation shock in a standard procedure to confirm the effect of defibrillation for induced ventricular fibrillation.[25–28] The out-circuit resistance was set at 1,000 Ω in accordance with the result of the measurement of the whole body impedance as the "shock receiver" that mimics the worst case (i.e., lowest impedance). The electrical current during a defibrillation shock was recorded by an ammeter connected in the out-circuit for each pair of electrodes (Fig. 2B). The change in voltage across the resistor during a shock delivery was amplified and converted to digital signals by a waveform recorder (Memory HiCorder Model 8853, Hioki Co., Ltd., Nagano, Japan or Omniace Model RT3216J, NEC Co., Ltd., Tokyo, Japan) and the data were retrieved on a chart by a thermal recorder embedded on each of them. The energy appeared across the resistor was calculated by a formula shown in Figure 3.

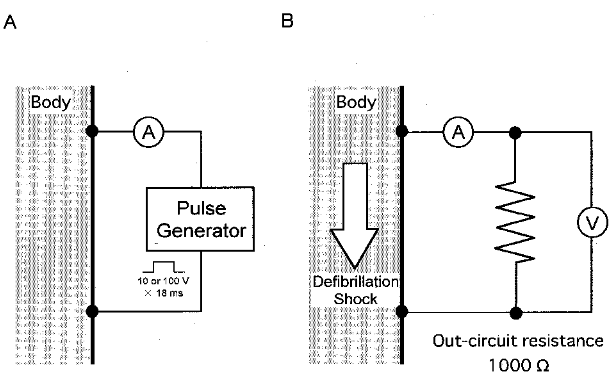

Figure 2. *The recording system of the whole body impedance and the body surface leakage energy. Panel A shows the system to measure the whole body impedance during a 10-V stimulation with 18-ms width. Panel B shows the system to record the electrical current and the change in voltage during a defibrillation shock. Out-circuit resistance was set at 1,000 Ω.*

$$E = \int \frac{V^2}{R}\, dt \approx \frac{(S/T)^2}{R} \cdot T \qquad S/T = \text{mean voltage}$$

The area of two phases during a shock was calculated by the recorder. The total energy leakage was determined as the sum of the energies calculated for two phases during each shock.[22] Even by thinking about the internal resistance of the patient and the recorder itself on the basis of Thevenin's theorem, the error of the values recorded in this system should be small because the internal resistance of the recorder was considerably higher than that of the recording circuit.

Statistical Analysis

Data are expressed as mean ± S.D.. Basic comparative statistics were performed with one-way ANOVA test or paired *t*-test. A P value < 0.05 was considered statistically significant.

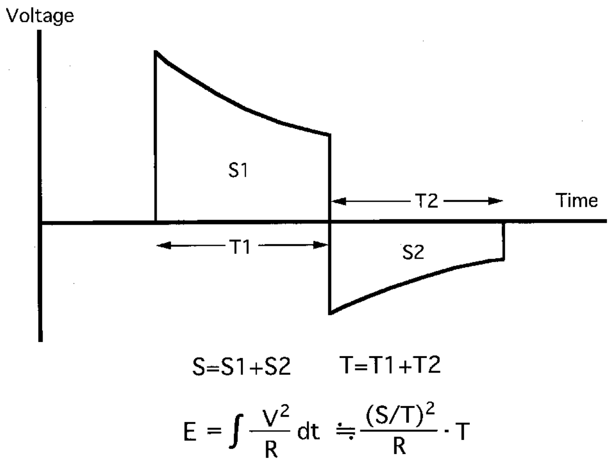

Figure 3. *Calculation of energy leakage from the recording of changes in voltage during a defibrillation shock. Because the energy is calculated as the integration of the product of the voltage and the current, the actual energy leakage was approximately calculated from the area of the curve of the voltage changes in the formula shown in this figure. The areas (S_1 and S_2) were automatically calculated by the recorder. E = energy; V = voltage; R = resistance; T = time; S = area.*

Results

The Whole Body Impedance Through the Skin Electrodes

The whole body impedance measured during the delivery of 10 V pacing was 4584 ± 2356 Ω (range 812–9,462 Ω) in the parallel position and 4,966 ± 2,101 Ω (range 820–9,777 Ω) in the cross position. There was no statistical difference between the two recording positions. Note that the lowest data of the whole body impedance was < 1,000 Ω (i.e., the out-circuit resistance used in the present study as the worst case).

Energy Leakage Recording During Defibrillation Shocks

Figure 4 shows a representative example of the recording traces of the electrical current and the change in voltage that appeared at the parallel recording position during a defibrillation shock delivery. These are the actual recording traces during a shock at an energy of 20 J in a patient with idiopathic ventricular fibrillation. The peak current was observed at the very beginning of the defibrillation shock and was 36.2 mA. The mean current during the shock was 14.7 mA when it was calculated as the absolute value. Similarly, the peak of change in voltage was 34.7 V. The total duration of this defibrillation shock was 16.8 ms. Then the energy leakage for this recording position was calculated as 3.0 mJ through the formula explained in Figure 3.

Body Surface Energy Leakage During Defibrillation Shock Delivery

The energy leakages were measured in 80 defibrillation shocks in 27 patients. Table I summarizes the body surface current leakage and energy during defibrillation shock delivery in all patients and Figure 5 shows in a graph the peak current and the leakage energy. The defibrillation shocks

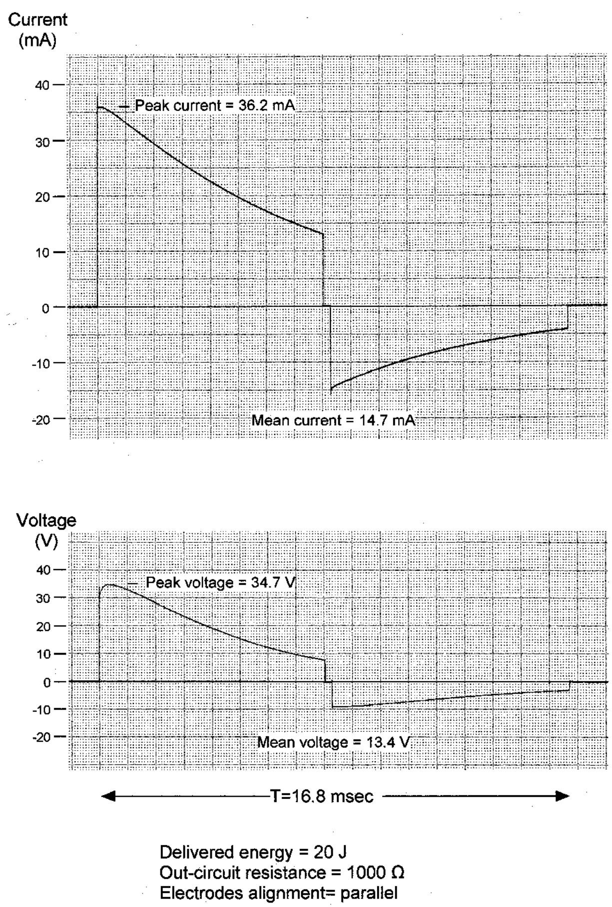

Figure 4. *The recording traces of the electrical current and the change in the voltage during a defibrillation shock delivery. This figure shows the actual recording traces of the electrical current (upper panel) and the voltage change (lower panel) during a defibrillation shock at an energy of 20 J in a patient with idiopathic ventricular fibrillation. The electrode alignments of the recording position was parallel to the direction of the defibrillation shock. The mean of the change in voltage was 13.4 V when it was calculated as the absolute value. The energy leakage for this recording position was calculated as 3.0 mJ through the formula explained in Figure 3.*

Table I.

Summary of Energy Leakage Data During Defibrillation Shock

Electrode Alignment	Delivered Energy (J)	Peak Voltage (V)	Mean Voltage (V)	Peak Current (mA)	Mean Current (mA)	Energy Leakage (mJ)
Parallel	20 (n = 63)	33.7 ± 17.5 (3.1 ~ 82.1)	13.5 ± 7.1 (1.3 ~ 32.8)	33.2 ± 17.8 (3.1 ~ 82.4)	13.4 ± 6.9 (1.3 ~ 33.2)	3.7 ± 3.5 (0.03 ~ 16.8)
	30 (n = 17)	48.4 ± 25.6 (6.2 ~ 106.2)	19.3 ± 10.2 (2.5 ~ 42.5)	48.6 ± 26.2 (6.3 ~ 105.3)	19.4 ± 10.6 (2.5 ~ 42.7)	7.4 ± 7.2 (0.09 ~ 28.5)
Cross	20 (n = 63)	9.2 ± 9.1 (0.3 ~ 40.1)	3.7 ± 3.7 (0.12 ~ 16.0)	9.2 ± 8.9 (0.3 ~ 9.2)	3.8 ± 3.6 (0.11 ~ 16.2)	0.4 ± 0.9 (0.002 ~ 4.4)
	30 (n = 17)	18.5 ± 14.6 (2.2 ~ 60.2)	7.4 ± 5.8 (0.9 ~ 24.1)	18.3 ± 14.3 (2.2 ~ 60.4)	7.1 ± 5.6 (0.9 ~ 24.3)	1.4 ± 2.3 (0.011 ~ 9.2)

Data were shown as mean ± SD. Numbers in parentheses show the ranges of actual data.

were delivered in 20 J for 63 times and in 30 J for 17 times. All three electric parameters were higher in the parallel recording position than in the cross position. They were also higher with 30-J defibrillation shock than with 20 J. Among all subjects, the highest energy leakage was observed at the parallel recording position during 30-J shock. The peak change in voltage was 106.2 V at that time. The peak current leakage was 105.3 mA and the energy leakage was calculated as 28.5 mJ.

Discussion

Because the opportunities for physical contact with a patient during the delivery of an ICD shock are increasing[1–12] it is important to identify the possible risk in a worst case scenario caused

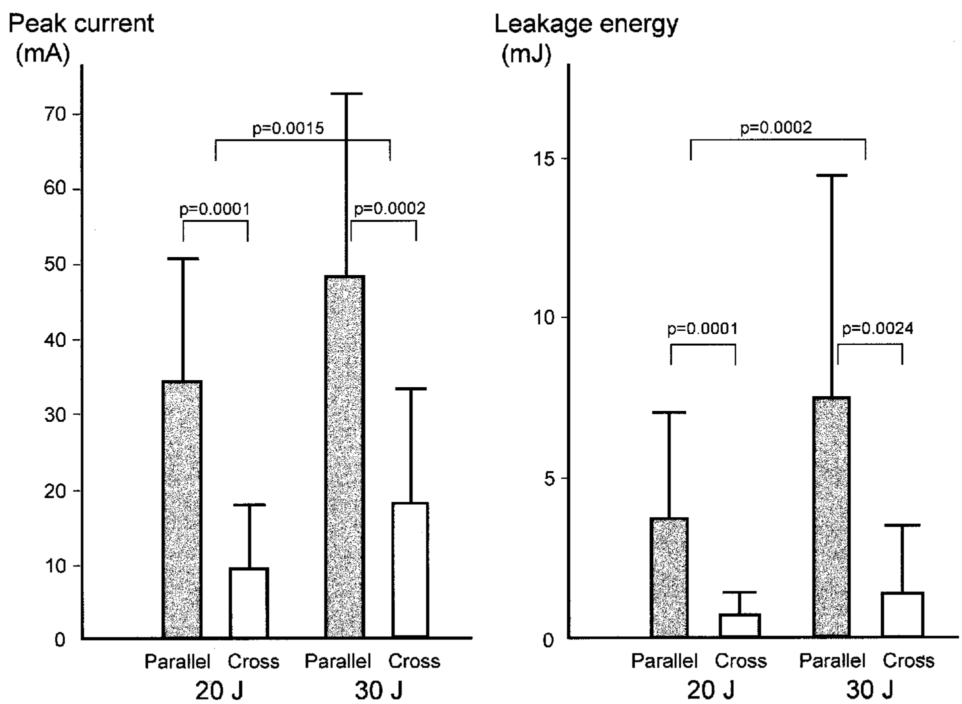

Figure 5. *The peak electrical current and the energy leakage during the defibrillation shocks with 20 or 30 J. The vertical axis indicates the peak electrical current (left panel) and the leakage energy (right panel) appeared during the defibrillation shocks. The parallel position showed higher current and energy leakage than the cross position. The current leakage and energy also depended on the delivered energy.*

by body surface leakage of the defibrillation energy to another person who is touching the patient while the shock is delivered.[13,14] We have recently reported the evaluation of body surface leakage of the defibrillation energy from an implanted ICD system in canine bodies and found that the highest energy leakage was up to 1.18 A and 47 mJ, although this kind of relatively small energy might cause some electrical injury in specific situation.[22] The present study is the first systematic evaluation of the body surface energy leakage during defibrillation shock deliveries by an ICD device in a human body, and it shows unique and interesting results. First, the whole body impedance of the patient as a "shock receiver" could be $< 1000\ \Omega$, although it depended on the contact between the electrode and patient's skin. Second, the angle of energy flow to the electrode alignment was considered one of the important factors to determine the power of the energy and the shock energy. Third, the mean energy leakage that appeared in the parallel recording position (Fig. 1) was 48.4 ± 25.6 V in peak change in voltage, 48.6 ± 26.2 mA in peak current, and 7.4 ± 7.2 mJ in energy leakage with the delivered energy of 30 J. The highest energy leakage observed in the present study was 106.2 V, 26.2 mA, and 28.5 mJ, respectively.

In the authors' previous report regarding the body surface leakage of defibrillation energy, the highest energy leakage was observed during the defibrillation shock delivery at the highest delivered energy (34 J) and at the recording position with the lowest impedance.[22] The impedance of the electrodes in the recording position could be $< 100\ \Omega$ when the electrodes were directly contacting the subcutaneous tissue but averaged to $2{,}622 \pm 2{,}095\ \Omega$ (range 460–6,966 Ω) when the electrodes were contacting shaved skin in canine bodies even with large-sized (6.2 cm^2) electrodes. The impedance data measured in the present study in human bodies were $4{,}584 \pm 2{,}356\ \Omega$ in parallel recording position and $4{,}966 \pm 2{,}101\ \Omega$ in the cross recording position. They were higher than those observed at body surface recording positions in canine bodies probably because of the larger size of human bodies. This indicates that the energy leakage of a defibrillation shock in human bodies should be lower than in the canine bodies evaluated in the previous study. However, it is important to recognize that the lowest impedance of the electrodes of the recording positions in the present study was 820 Ω, and it was smaller than the average impedance in the canine study. In addition, the size of the electrode used in the present study was just a representative system, so that one should consider the possibility of larger energy with a larger and better contact in actual case.

The worst case scenario in the present study (i.e., the highest energy leakage appearing at a body surface recording position) was observed at the parallel recording position with the defibrillation energy of 30 J. The peak electrical current and change in voltage reached to considerable level to cause macroshock or tetany[15–21] when someone continuously touches the voltage source, but the energy leakage was small because the duration of the shock was short. The voltage of a static shock is much higher than the usual situations of electrocution with home electricity, but the energy of a static shock is small and practically does not harm the human body as much. Therefore, the electrification of a patient's body surface by an ICD defibrillation may not be harmful to a person who touches the patient during the shock delivery.

Study Limitations

There are several important limitations in the present study. First, the number of subjects studied was limited. The impedance between the recording electrodes in the present study varied in a large range. It probably depends on the physical size of individual patients and the contact condition between the skin surface and the electrode interface. The degree of possibly lowest impedance of the surface positions should be evaluated in a larger number of patients. Second, the size and the position of skin electrodes were limited, so it is questionable that this study protocol has mimicked various conditions of skin contacts between a patient (i.e., a shock source and a shock receiver). Third, the actual influence on the person touching the patient by the energy leakage of the electrical shock was not evaluated. Probably, it can be determined by delivering an actual electrical shock with the pattern similar to the energy leakage to the experimental subjects. Fourth, the body surface energy leakage was evaluated in only Japanese people (i.e., relatively small-sized bodies) so that a similar evaluation will be necessary in a larger number of patients including the people with relatively large-sized bodies. Finally, only one shock configuration (i.e., right ventricular coil and can) has been tested in the present study, but the other shock configurations, like dual coil leads with active cans, should be studied in future.

Conclusions

The body surface energy leakage from defibrillation shocks by an ICD device was systematically evaluated in humans. (1) The power of the energy leakage depended on the energy delivered during the defibrillation shock. (2) The direction of alignment of the recording electrodes was another important factor to determine the power of the energy leakage. (3) The highest body surface leakage energy observed in the present study was 105.3 mA in peak current, 106.2 V in peak change in voltage, and 28.5 mJ in leakage energy. The highest leakage current to the body surface reached a considerable level, but the energy leakage was quite small because of the short duration of the defibrillation shock.

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