Cardiovascular Collapse Caused by Electrocardiographically Silent 60-Hz Intracardiac Leakage Current

Implications for Electrical Safety

Charles D. Swerdlow, MD; Walter H. Olson, PhD; Mark E. O’Connor, BS; Donna M. Gallik, MD; Robert A. Malkin, PhD; Michael Laks, MD

Background—The national standard for safe 60-Hz intracardiac leakage current under a single-fault condition is 50 μA. This standard is intended to protect patients from alternating current (AC) at levels below the threshold for sensation, but the minimum unsafe level for AC in closed-chest humans is not known. To determine this value, we studied 40 patients at testing of implantable cardioverter-defibrillators using a programmable source of 60-Hz AC.

Methods and Results—We applied AC for 5-second test periods in increasing strengths until ventricular fibrillation (VF) was induced or 1 mA was reached. Two current paths were tested: bipolar, between tip and ring electrodes of a right ventricular pacing catheter, and unipolar, from tip to a remote electrode. We observed a characteristic sequence of 3 responses as AC was increased: (1) intermittent ventricular capture with QRS morphology identical to pacing through the electrodes (minimum value, 20 μA); (2) continuous capture at cycle length 282±88 ms (minimum value, 32 μA); and (3) VF persisting after AC termination (minimum value, 49 μA). Continuous capture caused loss of pulsatile arterial pressure and cardiovascular collapse (mean arterial pressure, 32±8 mm Hg) for the duration of AC with no ECG evidence of AC stimulation. Thus, the clinical picture was that of hypotensive ventricular tachycardia (VT). The continuous-capture threshold was ≤50 μA in 9 patients (22%) for bipolar AC and in 5 (12%) for unipolar AC. All patients showed continuous capture over a wide range for both bipolar AC (68±18 to 216±238 μA) and unipolar AC (84±27 to 278±226 μA).

Conclusions—Leakage current causes cardiovascular collapse at levels below the VF threshold. Stimulation by silent AC that is neither felt nor visible on the ECG presents as hypotensive VT. In patients with intracardiac electrodes, leakage current less than or equal to the present standard of 50 μA may cause VT or VF. The safety standard for leakage current lasting ≥5 seconds should be ≤20 μA. This standard should be based on the continuous-capture threshold. (Circulation. 1999;99:2559-2564.)

Key Words: electrical stimulation ■ fibrillation ■ tachyarrhythmias

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ower-line–operated electromedical equipment, connected to patients for monitoring or therapeutic purposes, may permit accidental flow (leakage) of weak alternating current (AC) through patients to ground. An intracardiac catheter may provide a low-resistance path to ground through the patient’s heart and thereby place the patient at risk for electrically induced ventricular tachycardia (VT) or ventricular fibrillation (VF).

In 1993, the American national standard for leakage current through the heart under a single-fault condition in mains-operated electrical equipment was increased from 10 to 50 μA,1 the value of the European standard since 1988.2 Both the 10-μA standard1,4 and the 50-μA standard2 were based on estimates of the risk of AC-induced VF. However, AC may cause cardiovascular collapse at levels that are below the VF threshold.5–9 This adverse response to AC was not considered in the selection of either safety standard. Furthermore, safe levels of AC have not been determined in closed-chest humans.

The 10-μA standard was adopted in 1967 to ensure patient safety during cardiac catheterization10 and pacemaker11 procedures. The annual number of invasive cardiac procedures in the United States has increased from <60 000 when the 10-μA standard was adopted to >3 million today. The potential number of adverse outcomes from leakage current has increased correspondingly.

Electromedical devices contain electrical isolation circuits and insulation to limit leakage current. Manufacturers continue to comply with the original 10-μA standard, but they may realize substantial cost savings by equipment designs.
that comply only with the newer 50-μA standard. However, the American Heart Association continues to recommend the 10-μA standard. We therefore determined the minimum unsafe levels for AC in closed-chest humans.

Methods

Patients

We studied 40 patients under propofol anesthesia at postoperative testing of transvenous implantable defibrillators. All patients gave written informed consent according to a protocol approved by the Human Subjects Committee of Cedars–Sinai Medical Center. Table 1 shows clinical characteristics of the study patients. At the time of study, all antiarrhythmic drugs had been discontinued for 5 half-lives, except for digoxin (3 patients) and β-blockers (7 patients). The 3 patients in whom atrial fibrillation was the indication for a dual-chamber implantable defibrillator had neither spontaneous nor inducible VT or VF.

Study Procedure

Radial arterial pressure was recorded continuously. We gave AC through a standard 6F temporary pacing catheter with a distal electrode area of 15 mm² and ring-electrode area of 7 mm² (Explorer, Boston Scientific). It was inserted via the right femoral vein and positioned with its tip near the right ventricular apex. AC was delivered from a battery-operated, custom-built, constant-current source (Medtronic model 2917 60-Hz fibrillator, IDE No. G970011) that permitted us to program the duration and strength of AC. We increased it step down in AC. There was a 15-second rest period after each application of AC that produced continuous capture and a 4-minute rest after each episode of sustained VT or VF.

Threshold Measurement

The initial programmed strength of AC was 40 μA. We increased it by 10-μA increments up to 200 μA, by 50 μA between 250 and 600 μA, and by 100 μA thereafter. A characteristic sequence of 3 responses occurred as AC was increased (Figure 1): (1) intermittent ventricular capture with QRS morphology identical to pacing through the electrodes; (2) continuous ventricular capture with the same QRS morphology; and (3) initial continuous capture progressing to sustained VT or VF that persisted after termination of AC. We defined continuous capture as a consecutive series of stimulated QRS complexes without intervening spontaneous QRS complexes with the same QRS morphology that could be interrupted with DC shock.

<table>
<thead>
<tr>
<th>TABLE 1. Clinical Characteristics of Study Patients (n=40)</th>
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<tbody>
<tr>
<td>Age, y, mean±SD</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Cardiac disease</td>
</tr>
<tr>
<td>Clinical arrhythmia</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Left ventricular ejection fraction, mean±SD*</td>
</tr>
</tbody>
</table>

*Left ventricular ejection fraction was measured by contrast angiography (n=34) or by radionuclide ventriculography (n=6).

![Figure 1. One patient's responses to increasing AC. Baseline rhythm is DDD pacing with varying degrees of ventricular fusion. ECG leads I, II, and right ventricular apical electrogram (RVA) are shown for 5-second applications of bipolar AC at 20, 40, and 120 μA and unipolar AC at 500 μA. On the RVA electrogram, amplitude modulation of the 60-Hz signal is artifact caused by the electrophysiological recording system. At 20 μA (top), intermittent capture results in predominantly negative QRS complexes in lead II. At 40 μA (second panel), continuous capture occurs during AC, resulting in ventricular cycle length of 200 ms. At 120 μA (third panel), continuous capture degenerates to VF. Bottom, Unipolar AC at 999 μA results in continuous capture at cycle length of 275 ms. Note that even at this level, AC artifact cannot be detected on surface ECG. In this patient, the range of continuous capture for bipolar AC is 40 to 110 μA versus 70 to >999 μA for unipolar AC.](image-url)
TABLE 2. Threshold Values (RMS) in μA for 60-Hz AC of 5-second Duration

<table>
<thead>
<tr>
<th>Threshold</th>
<th>Unipolar</th>
<th>Bipolar</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Group mean value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermittent-capture threshold</td>
<td>62±18</td>
<td>55±16</td>
<td>0.001</td>
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<tr>
<td>Continuous-capture threshold</td>
<td>84±27</td>
<td>68±18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sustained-VT/VF threshold</td>
<td>278±226*</td>
<td>216±238†</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group median value</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Intermittent-capture threshold</td>
<td>64</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Continuous-capture threshold</td>
<td>81</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>Sustained-VT/VF threshold</td>
<td>178*</td>
<td>121†</td>
<td></td>
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<tr>
<td>Lowest individual-patient value</td>
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<td></td>
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<tr>
<td>Intermittent-capture threshold</td>
<td>20</td>
<td>30</td>
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<tr>
<td>Continuous-capture threshold</td>
<td>32</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Sustained-VT/VF threshold</td>
<td>61</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Highest individual-patient value</td>
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<tr>
<td>Intermittent-capture threshold</td>
<td>99</td>
<td>89</td>
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<tr>
<td>Continuous-capture threshold</td>
<td>154</td>
<td>117</td>
<td></td>
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<tr>
<td>Sustained-VT/VF threshold</td>
<td>&gt;999</td>
<td>&gt;999</td>
<td></td>
</tr>
</tbody>
</table>

RMS indicates root-mean-square. *n=32; †n=34.

Study Protocols

In all patients, we applied AC for 5-second test intervals over 2 current paths in random order: bipolar, between tip and ring electrodes; and unipolar, from tip to an ECG patch electrode positioned on the skin near the left or right shoulder. In the first 20 patients, we tested reproducibility of the continuous-capture and VF thresholds. Unipolar and bipolar thresholds were determined twice. Randomization for the first and second trials was done independently. In the final 20 patients, we determined a strength-duration relationship for AC. In addition to determining thresholds for unipolar and bipolar AC of 5-second duration, we determined thresholds for bipolar AC synchronized to the QRS complex with durations of 0.5 and 1 second. The order of testing was determined randomly. We recorded only the capture threshold and sustained-VT/VF threshold for 0.5- and 1-second applications because intermittent and continuous capture could not be distinguished.

Statistical Analysis

We compared bipolar and unipolar thresholds for intermittent capture, continuous capture, and sustained VT/VF using paired t tests. We analyzed possible correlations between selected clinical variables and threshold values. We analyzed prior myocardial infarction, left ventricular ejection fraction, and heart failure class to test the hypothesis that thresholds are lower for patients who have more advanced heart disease. We performed correlations between thresholds and the clinical variables of body-surface area, age, and sex to test the null hypothesis.

To analyze reproducibility, we used the Lin concordance coefficient between first and second determinations of each threshold value in the first 20 patients. We used a previously described paired t test based on absolute differences normalized by median value to determine whether continuous-capture threshold or VF threshold was more reproducible.

Results

Table 2 shows that group mean values for intermittent-capture, continuous-capture, and sustained-VT/VF thresholds were lower for bipolar AC than for unipolar AC (P=0.001).
Relation of Pacing Threshold to Continuous-Capture Threshold

The pacing threshold for single 0.5-ms, constant-voltage pulses was not significantly different for unipolar pulses versus bipolar pulses (1.01±0.89 versus 0.96±0.38 mA; P=0.65), but these values were higher than the corresponding continuous-capture thresholds (P<0.001). The ratio of the pacing threshold for single 0.5-ms pulses to the continuous-capture threshold was 13±13 for unipolar AC and 15±7 for bipolar AC.

ECG Findings at Continuous Capture

At the bipolar continuous-capture threshold, AC interference could not be detected on any of the 3 monitors in any patient. At the unipolar continuous-capture threshold, AC interference ≥0.5 mV was recorded in 4 patients (10%) on the electrophysiological recording system in leads I, aVR, or aVL. Six other patients (15%) had subtle thickening of the baseline <0.5 mV. With the other 2 monitors, AC interference could not be detected for either unipolar or bipolar AC ≤500 mA. Thus, the typical ECG appearance of continuous capture was that of VT with morphology identical to pacing through the electrode catheter but no AC interference.

Sustained VT/VF

Sustained VT or VF was induced in 34 patients (85%) for bipolar AC and in 32 patients (80%) for unipolar AC. Figure 3B is a percentile plot of sustained-VT/VF thresholds. Table 2 shows minimum, mean, median, and maximum values. The end-point arrhythmia (VT or VF) was the same for bipolar and unipolar AC in all patients. It was VF in 25 patients and sustained monomorphic VT (cycle length, 274±51 ms) in 9. Both the group mean threshold and the lowest individual patient threshold were lower for bipolar AC than unipolar AC. The continuous-capture and VF thresholds were equal for 2 patients with bipolar AC and for 1 with unipolar AC.

Ranges of Intermittent and Continuous Capture

Intermittent capture occurred over a narrow range (14±13 μA for bipolar AC versus 22±21 μA for unipolar AC; P<0.02). Continuous capture occurred over a wider range than intermittent capture (P<0.001). In patients in whom sustained VT/VF was induced, the range of continuous capture was less for bipolar AC than for unipolar AC (146±236 versus 193±222 μA; P=0.001). In those patients in whom sustained VT/VF could not be induced, the difference between the maximum output of 999 μA and the continuous-capture threshold (bipolar, 60±7 μA [n=6]; unipolar, 77±18 μA [n=8]) provides a lower limit for this range.

Clinical Correlates of Threshold Values

None of the clinical variables evaluated correlated with the continuous-capture threshold or the VF threshold for unipolar or bipolar AC. The patient with the lowest continuous-capture threshold (32 μA) was a 60-year-old woman who had hypertensive cardiovascular disease, normal coronary arteries, and a left ventricular ejection fraction of 60%. The patient with the lowest VF threshold (49 μA) was a 72-year-old man who had valvular heart disease and an ejection fraction of 20%. There were too few patients without spontaneous or inducible ventricular arrhythmias to provide a meaningful analysis of this subgroup. Of these patients, the lowest continuous-capture thresholds occurred in a 73-year-old man who had coronary artery disease, paroxysmal atrial fibrillation, and a left ventricular ejection fraction of 58%. These values were 50 μA for bipolar AC and 60 μA for unipolar AC.

Reproducibility

Figure 4 shows reproducibility of the continuous-capture and sustained-VT/VF thresholds in the first 20 patients. The continuous-capture threshold was more reproducible than the sustained-VT/VF threshold for both unipolar AC (P<0.005) and bipolar AC (P<0.001).

Strength-Duration Relation

In the final 20 patients, there were no significant differences among the capture threshold for 0.5 second of AC (68±18 μA), the capture threshold for 1 second of AC (67±18 μA), and the continuous-capture threshold for 5 seconds of AC (66±17 μA). In contrast, we induced sustained VT/VF in none of the tested patients when we gave 0.5 second of AC to none of the tested patients when we gave 1 second of AC (50%), and in 16 patients when we gave 5 seconds of AC (80%) (P<0.001). In those 10 patients in whom the sustained-VT/VF threshold for 1 second of AC could be measured, the value was 474±255 versus 217±254 μA for 5 seconds (P<0.001). Figure 5 shows an example. The lowest VF threshold for 1 second of AC was 140 μA.

Discussion

The present study is the first report of the effects of AC applied directly to the heart in closed-chest humans. We found that continuous capture by AC causes cardiovascular collapse over a wide range of AC at levels that are below the VF threshold and in some patients, below the present national standard for a single-fault condition of 50 μA. At this 50
induction of VF in the vast majority of patients; (4) the continuous-capture threshold is independent of the duration of AC, whereas the VF threshold is strongly dependent on duration; and (5) the continuous-capture threshold is more reproducible and behaves more like a step function than the VF threshold.

Factors That Influence Thresholds

Electrode size and location have been reported to influence the VF threshold in animal studies. To hold these factors constant, we placed a temporary electrode near the right ventricular apex, the most common clinical location. However, some clinically used electrodes have smaller surface areas than the electrodes used in the present study. They would be expected to have correspondingly lower continuous-capture and VF thresholds.

Our study is the first to compare unipolar and bipolar thresholds for AC. We found that the group mean thresholds for continuous capture and VF were lower for bipolar AC than for unipolar AC. Bipolar AC may produce higher intramyocardial current density or cause unipolar stimulation from the ring electrode, which has a smaller surface area than the tip electrode. The common clinical path for leakage current is unipolar.

Our study is also the first to examine the strength-duration relationship for AC in humans. For AC durations between 0.5 and 5 seconds, we found that the VF threshold decreases but the capture threshold remains constant. The duration of leakage current may depend on the cause: short for a power-line surge, intermediate for current induced by electromagnetic interference from nearby equipment, or long for a broken ground wire.

Limitations

We determined the minimum unsafe value of AC, not the maximum safe value. We studied patients under propofol anesthesia; thresholds might differ in conscious patients. Most patients in this study had ventricular arrhythmias and structural heart disease. However, patients with cardiac disease are most likely to undergo invasive cardiac procedures and thus to be exposed to intracardiac AC.

Clinical Implications

The principal clinical implication of our study is that AC causes cardiovascular collapse in closed-chest humans at levels substantially below the VF threshold.

A second implication is that the physician cannot rely on the ECG to distinguish continuous capture by AC from spontaneous VT. American Heart Association guidelines require 60-Hz notch filters on ECG equipment to suppress AC interference, and our data show that intracardiac AC at 50 μA causes no such interference. Thus, the clinical presentation of continuous capture by AC ≤50 μA is electrocardiographically silent and indistinguishable from hypotensive VT. Transient continuous capture may be misdiagnosed as nonsustained VT. This spurious diagnosis may lead to unnecessary diagnostic procedures, including costly and invasive electrophysiological studies. Sustained flow of intracardiac leakage current could present as VT refractory to cardiover-
sion. In this situation, the patient’s survival depends on rapid interruption of the leakage-current circuit. However, a responsible physician would probably treat the patient unsuccessfully with the sequence of electrical cardioversions and antiarrhythmic drugs recommended for VT. In a patient with an intracardiac catheter, leakage current should be considered a new mechanism in the differential diagnosis of VT.

A third implication is that under certain circumstances, routine methods would fail to detect leakage-current–induced VF, resulting in sudden cardiac death. AC at 50 µA is below the threshold of cutaneous sensation and could thus be conducted through an unsuspecting device operator to an unsuspecting patient.

A fourth implication is that safety standards may consider the duration of AC and, by implication, its cause. Under transient conditions, such as power-line surges, the 50-µA standard may be safe.

A final implication is that the 50-µA standard is insufficient to protect patients with intracardiac electrodes from VT or VF caused by leakage current lasting ≥5 seconds. Our results indicate that the safety standard for AC lasting ≥5 seconds must be based on the continuous-capture threshold. In the present study, the maximum value that did not cause cardiovascular collapse in any patient was 20 µA.

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References
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