Revisiting the Question
Will Relaxing Safe Current Limits for Electromedical Equipment Increase Hazards to Patients?

Michael M. Laks, MD; Robert Arzbaecher, PhD; David Geselowitz, PhD; James J. Bailey, MD; Alan Berson, PhD

This editorial is a follow-up to a 1994 editorial by the same authors with the same title. The 1994 editorial emphasized that revised national standards, which relaxed the maximum allowable current that may be delivered to patients by electromedical equipment, presented unnecessary hazards to patients with indwelling catheters, and it described the need to obtain more scientifically based data to resolve the issues. Recently published data obtained from patients undergoing testing of implanted defibrillators provide the first direct and dramatic evidence that current levels as low as 32 μA can cause hemodynamic collapse simulating ventricular tachycardia before ventricular fibrillation (VF) occurs. These currents cannot be felt, and their presence cannot be identified on ECG waveforms. Consequently, both the standards of the United States and the recommendations of the American Heart Association (AHA) now need to be reconsidered. We believe that the maximum allowable current under single-fault conditions must be similarly reduced as the maximum allowable level of risk current must be changed back to the 1972 AHA recommendations of 10 μA, under single-fault conditions, regardless of the source or pathway of the current. The national standard of the United States, which now allows up to 50 μA in patient-connected leads and 300 μA of leakage current under single-fault conditions must be similarly changed. Current through the myocardium exceeding 10 μA places subjects at unnecessary risk. Furthermore, ventricular tachycardia with hypotension must be added as a new diagnostic and testing end point for electrical safety.

Background
The following history of the changing standards and various ways in which alternating current can get to the heart to produce cardiovascular collapse and/or VF is presented to emphasize that the lack of human data has been a barrier in developing a valid recommendation for electrical safety standards.

The AHA interest in allowable risk currents dates from 1967, when the Committee on Electrocardiography published recommendations covering many areas in electrocardiographic recording and display. That report included the need to protect human subjects from currents >50 μA and predates any national standard for allowable risk current. The committee recognized that these low levels of current were of concern only when indwelling catheters exist. However, these risk current limits were intended to apply to ECG instruments generally. The concern then was that any ECG instrument might be used to connect directly to an indwelling conducting lead or catheter, in which case a low resistance path to the heart could be established. The 50-μA limit was judged by committee members to be realistic given the technology of the times.

In 1972, the same Committee published a report specifically related to risk currents, in which 10 μA was recommended as the maximum allowable current that may flow through the subject. The authors of that report recognized that the current could reach the heart through different pathways and that, regardless of the pathway, the same allowable level should be observed. Thus, the wording in that report was crafted to include current that may be delivered to the patient through patient-connected conductors or through chassis leakage current. The Committee reaffirmed these recommendations in a 1975 report. The reduction of the limit from 50 to 10 μA reflected known animal and human data, as well as the advances in capabilities for designing the appropriate circuitry.

Leakage current is a term used by engineers to refer to current flowing from the chassis or case of an instrument to the ground. Unintended current into the subject through patient-connected leads is the most obvious and direct way in which safety may be compromised. However, a second way of delivering unintended current to the subject may result with too-high chassis leakage current. If the potential existing on the chassis is different from the ground potential, current can flow between the chassis and the ground. If a person simultaneously contacts the chassis and ground, current will flow through the person. Consider further the possibility of a patient with an indwelling catheter contacting the chassis while the catheter is connected to the ground, perhaps through another instrument. A chassis potential only slightly different from the ground potential would allow current to flow into the patient through the catheter, and this current is likely to flow through the heart. A few tenths of a volt difference...
between chassis and ground potentials could result in relatively large current flow. From the patient’s viewpoint, it makes no difference whether the source of this current is from chassis leakage or from current flow through any of the patient-connected leads.

A national standard on risk currents was released by the Association for Advancement of Medical Instrumentation in 1985, in which the allowable current levels were only in partial agreement with the AHA recommendations.11 The standard dealt separately with leakage current limits, allowing 100 μA for both no-fault and single-fault conditions. The latest revision of this standard was released in 1993, and it relaxed the requirements further.5 The standard now limits current through patient-connected leads to 10 μA under no-fault conditions and to 50-μA under single-fault conditions. For chassis leakage current, the standard allows 100 μA under no-fault conditions and 300 μA under single-fault conditions.

In 1996, the AHA Committee on Electrocardiography endorsed a report that revised the 1975 AHA recommendations and that differed importantly from the national standard.12 The 10-μA limit for current through patient-connected leads was reaffirmed for both no-fault and single-fault conditions. However, a separate requirement was introduced for leakage current that limited it to 100 μA under both no-fault and single-fault conditions. The authors of that report were divided about allowing leakage current to be 100 rather than 10 μA, as in the 1975 recommendations, but reluctantly concluded that not enough evidence existed for requiring apparatus to meet a smaller leakage current limit.†

New Data

The cohort of 40 individuals studied by Swerdlow et al2 is the first of its kind in which data were obtained from patients under light anesthesia with propofol in whom implanted defibrillators were being tested. Of particular importance, cardiovascular collapse with severe hypotension was associated with an ECG appearance of ventricular tachycardia that was produced by a 60-Hz current as low as 32 μA. The mechanism for this is not yet clear, but this observation emphasizes that alternating current may produce severe systemic hypotension associated with an ECG indistinguishable from ventricular tachycardia, before ECG evidence of VF.

In this study, a 60-Hz current was introduced between 2 electrodes; these electrodes were either both located in the right ventricular cavity (bipolar) or one was located in the ventricular cavity and the other on the body surface (unipolar). In 40 patients, the investigators observed that hemodynamic collapse occurred below the VF threshold; they further observed that a 50-μA current for 5 seconds caused hemodynamic collapse in 12% (unipolar case) or 22% (bipolar case) of these patients.

The authors also noted that unipolar conditions of current introduction closely simulated the situation for leakage current, in which undesirable current flows through the heart if the patient is in direct or indirect contact with the conducting surface of the ECG. Of clinical importance, these currents do not reveal any pacemaker-like waveforms on the ECG and are not felt. The patient’s survival depends on rapid interruption of this circuit, such as removing all connections to the patient. This poses a dilemma because it is necessary to monitor a patient during VF. Electrical cardioversion and antiarrhythmic drugs would be used to no avail.

The new findings by Swerdlow et al make it imperative that the Association for Advancement of Medical Instrumentation revise the national standard as quickly as possible, because the allowable levels for both leakage and patient-connected lead currents are much too high, bordering on dangerous. Now that new human data are available, no justification exists for any delay in modifying the national standard of the United States to be consistent with the scientific data. The result of low levels of alternating current is a severe drop in blood pressure that, if continued, will produce death.

As in many areas related to safety, engineers and scientists prudently design instruments based on the available scientific evidence, taking into account the practicality of achieving a specification and with a reasonable safety factor. The level of 10 μA is a compromise that we believe takes these factors into proper consideration. Manufacturers of electrocardiographs have shown their ability to be creative in the past in meeting the 10-μA limit for their instruments, and there is little doubt they can do so again.

Recommendations

The relaxation of safe current limits that began with the 1993 national standard increases hazards to patients. The following are proposed to reduce these hazards:

1. The standard for allowable current, regardless of its pathway to the heart, must be reduced to a level that is compatible with the scientific data. The AHA recommendation from 1972 and 1975 for a maximum allowable value of 10 μA is hereby reaffirmed.

2. Systemic hypotension associated with an ECG that is similar to those showing ventricular tachycardia must be made a new end point in electrical safety monitoring.

3. All healthcare workers must be educated regarding the possibility that hemodynamic cardiovascular collapse can be produced by a 60-Hz current <50 μA that is not visible on the ECG and that is not felt.

4. Although the findings of Swerdlow et al2 form a solid basis for the 10-μA current limit, we strongly urge clinical investigators and members of industry to collaborate in obtaining further appropriate data and designing a reporting system to establish an even better basis for safe current limits.
References


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