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

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By the time this commentary is published, the revised electrical safety standards for the United States will be adopted, with electric current limits relaxed so drastically as to raise serious concerns for the safety of patients connected to electromedical equipment. Compared with safe current limits that have been in existence for more than 20 years, the revised 1993 standards will raise by 2.5 to 5 times the allowable current through patient-connected leads and by 3 times the permissible leakage from the chassis of any medical device. These new limits have come about not because of the existence of new data regarding electric current levels and ventricular fibrillation but primarily as a result of the reinterpretation of data that have been available for many years. The biomedical clinical and research community should be especially vigilant and concerned about electrical safety if they use electromedical equipment conforming to these new standards.

In 1967, 1972, and 1975, the American Heart Association (AHA) Committee on Electrocardiography published recommendations for ECG instruments that included limits for AC leakage from powerline sources and isolation from ground of accessible metallic parts of the equipment.1 These recommendations called for a limit of 10 μA with assumption of a worst-case situation in mind, namely, connection of the equipment via a conductor connected directly to the heart. This limit was justified by being one half of the lowest value reported to have produced ventricular fibrillation (VF) in normal animals with powerline AC.2 The AHA committee noted that such small currents can produce very high current density at the electrode/myocardial interface. A major concern was that a single fault has a reasonable likelihood of occurring. The recommendations therefore required that the 10 μA not be exceeded under specified single-fault conditions (single fault implies one electric failure that may compromise the upper safe current limit for which the equipment has been designed, eg, a short circuit from primary to secondary winding of the power transformer or a short circuit from the powerline to the input circuitry of the ECG amplifier).

The Association for the Advancement of Medical Instrumentation (AAMI) developed the American National Standard in 1978.3 This standard differed from the 1975 AHA recommendations in two respects: First, it distinguished between current flowing into versus current flowing out of the patient, in reference to current flow through a conductor connected to the patient. This standard adopted the 10-μA limit for current flowing from the equipment to the patient but allowed 20 μA as an acceptable limit for current flowing from the patient to the equipment. Second, this standard treated chassis leakage current as a separate issue; it specified that leakage from chassis to ground could not exceed 100 μA under either no-fault or single-fault conditions.

More recently, the International Electrotechnical Commission (IEC) developed an international standard that adopted 50 μA as the limit on current through a patient-connected conductor and 500 μA as the limit for chassis leakage under single-fault conditions.4 Subsequently, the AAMI Committee on Electrical Safety hotly debated these issues, and a majority voted to alter the 1978 standard to bring it closer to the IEC values; hence, the revised limits have correspondingly become 50 and 300 μA.5 A minority, including two of the undersigned, voted against these revised limits. In December 1993, the American National Standards Institute approved as American National Standard the revision that contains these higher current limits.

The need for limitation of leakage current for equipment chassis is emphasized by the Canadian Bureau of Radiation and Medical Devices. They collected data showing that a current of 100 μA at line frequency can definitely be perceived by human volunteers, 300 μA causes a “strong sensation,” and 400 μA causes an “uncomfortable reaction,” with the volunteers attempting to remove the electrodes.6 The raising of this limit to 500 μA in the IEC standard apparently ignores these data.

The AHA Committee on Electrocardiography in 1975 based its recommendations not only on studies that were available at that time but also on practical engineering considerations. Watson et al7 in 1973 reported

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probably the best study of the relation between electric currents and the triggering of VF in humans. They used endocardial electrodes in 66 patients on cardiopulmonary bypass and demonstrated that 57 μA would trigger VF with a 99% confidence. In one case with abnormal electrical activity of the heart, a mere 15 μA was sufficient to induce VF. Watson et al concluded: “… we believe that there is no safe limit of 60 Hz electrical current that may be applied to the heart in every case,” and further, “… in hearts exhibiting abnormal ventricle activity, it would seem impossible at this stage to predict a safe current level. There indeed may not be one.”

In 1993, Watson’s study still appears to be applicable. No relevant studies have been published since that time. The Watson study points out a major problem, to wit, that studies done in healthy animal hearts cannot be used to predict results in human hearts that may be afflicted with abnormalities of electrophysiology. The relaxed limits in the revised American National Standard are not the result of new, improved studies of the relation between electric current levels and the risk of VF but rather stem from a reinterpretation of existing data, such as those cited above. A logical way to proceed would be to update Watson’s study with data from many laboratories doing electrophysiological studies in academic medical centers around the country; indeed, obtaining such data should be absolutely mandatory before a revision of the electric current limits is considered.

It is significant to note that in 1993, manufacturers of electomedical equipment continue to meet the 1975 AHA safety recommendations and the 1978 ANSI standard. During this period, no report has been published of VF caused by AC current leakage. During this period, there has been no report either in the literature or from the FDA of an instance of VF or other harmful effect due to alternating current leaking from diagnostic apparatus into the body and/or into the heart. This is not surprising. A major problem exists in reconstructing equipment and connection conditions after an incident occurs. Unless one designs a study with the specific goal of assessing the effects of current flow through the body or through the myocardium, it is unlikely that an association will be found. In the absence of a precise nationwide system for evaluating the incidence of adverse effects of unintentional electric current, the apparently benign nature of even the modest currents allowed by the AHA and ANSI (1978) cannot be ensured.

In the absence of such a reporting system and lacking new scientifically based data to supersede the old, we strongly urge manufacturers of electomedical equipment to continue to design their systems so as to meet the 1975 AHA committee recommendations and the 1978 ANSI standard. Although we understand the desirability for standards of individual countries to be in harmony with a single international standard, that alone cannot justify a relaxation of limits that may be hazardous to some patients. In the absence of credible data, the increases in risk current permitted by the new standard constitute unconsented-to human experiments to determine the safe range of such currents. There is a clear need for clinical studies (ethically approved) to provide robust information to resolve this issue. We strongly urge clinical investigators and members of industry to collaborate in gathering the appropriate data and designing a reporting system to establish a new realistic basis for safe current limits.

References

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