clinical diagnosis of definite angina. The women with angina in our study were, on average, 64 years old; they had definite angina determined by two independent, standardized, physician-administered medical histories, which were subsequently reviewed and adjudicated by a panel of three physicians. Although the number of women with angina in our study who actually had coronary disease cannot be determined with certainty, estimation of prevalence and event rates by removal of half the women with angina would be inaccurate.

We wholeheartedly agree with Dr Horton that the prognosis in women with angina is not benign. We stated in our article that “women with angina have five times the risk for a subsequent coronary event (coronary insufficiency, myocardial infarction, or coronary death) when compared with women free of chest discomfort symptoms, a risk gradient just as high as that observed for men with angina.” The need is clear for further data on cardiovascular disease in women that is derived from a database that can confirm clinically suspect cases of coronary disease.

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References


Safe Current Limits for Electromedical Equipment and Hazards to Patients

As the industry co-chairman of the Electrical Safety Committee of AAMI (Association for the Advancement of Medical Instrumentation), I would like to assure your readers that the increased safe current limits in the 1993 ANSI (American National Standard Institute)/AAMI standard do not raise concerns for patient safety, as implied in the editorial in Circulation by Laks et al. The conclusions in the editorial use data in an article by Watson et al. and appear to stress a 57-μA value said to come from one of his experiments (the value in Watson’s article is 67 μA). On the other hand, it appears that the 67 μA said by Watson to trigger ventricular fibrillation comes from an assumption that the data obtained from the studies would be duplicated in any other human experiment using the same electrode. The method of calculation used by Watson was applied to data obtained by Starmer et al. Starmer’s current for “triggering ventricular fibrillation” was 154 μA with a somewhat smaller-diameter electrode, over twice as large as that obtained by Watson. (It should be noted that Watson used 13 patients in obtaining the 67-μA threshold, not 66, as stated in the editorial.) Both studies were on humans. The commentary on this difference in “trigger” values and other topics includes my analysis as well as information found in the rationale of ANSI/AAMI 1993.

Watson’s analysis for his Figure 5, the one used in the determination of the 67 μA, divides the data into 13 equal rankings, with the highest current being 100%. The resulting regression line is then extrapolated to 0%. The regression line for Watson is y (in percent) = 100 log (current) − 183, with a correlation coefficient of 0.96. For the seven patients of Starmer, using the technique of Watson, the regression line is y (in percent) = 261 log (current) − 571, with a correlation coefficient of 0.97. This calculates to a “threshold” current of 154 μA, 2.3 times larger than that found by Watson. Implicit in the ranking system of Watson is that the highest value found, as well as the other values, represent the entire population. Accordingly, it might be expected that the Starmer “threshold” would have been closer to Watson’s. This large difference suggests that the Watson and Starmer data form part of a bigger picture. Each experiment is really a sampling of the population at large.

By treating Watson’s and Starmer’s data as samples from the population at large, it is possible to obtain a distribution of current causing ventricular fibrillation and then determine the probabilities of ventricular fibrillation for given currents. The results are in Figure 1A in the rationale of ANSI/AAMI 1993. Watson and Starmer data were combined and fell into one distribution, indicating that the electrode diameter differences were not significant. The number of patients used was small, as with Watson, but it is possible to make valid determinations with small samples, although the errors are greater than for large samples. For 50 μA, the increased value for patient-applied risk current, the probability of causing ventricular fibrillation is near 2.5%. Multiple independent faults must occur before current can reach the heart. The combined probability of occurrence of these multiple faults multiplied by the .025 probability of inducing ventricular fibrillation for a 50-μA current results in a very low probability of injury to the patient. It must be recognized that there is no absolute safety. There is some risk to every undertaking. We may not cross the street safely. We might not safely reach our destination when traveling by car, boat, train, or plane.

Data on the occurrence of the more likely fault, open grounds, was not available when developing the earlier electrical safety standard. Some has been collected. From a hospital in Maryland, the probability of open grounds in power receptacles and beds was found to be 0.8% and 1.9%, respectively. From data collected by a service organization, the probability of an open instrument ground was found to be 0.3%.

Although the new enclosure leakage current of 300 μA is said to cause a “strong sensation” (Reference 4, cited in the editorial), there may be discomfort but not a hazard. Another reference, also cited in ANSI/AAMI 1993, found that 300 μA is not likely to cause a “startle” reaction. The probability of 300 μA reaching the patient is extremely low because an open ground, probability from 0.3% to 1.9%, must be present as well as some path to the patient from the equipment. This combination of independent probabilities is extremely low. Should 300 μA reach the surface of the patient, the probability of a hazard is remote. For the new value of patient-applied risk current (50 μA) to reach the heart, there must be an open ground, line voltage has to appear on the patient, and a failure in the isolation of the input circuit needs to be present. The multiplication of these three independent probabilities results in an extremely low probability. Further, should the 50 μA reach the heart, there is no certainty that ventricular fibrillation will occur. According to the previously mentioned distribution, the probability of 50 μA causing ventricular fibrillation is in the order of 2.5%.

The authors of the editorial have said that the absence of reported electrocutions due to leakage current is not surprising because it is difficult to recognize and reconstruct the sequence of events that may have taken place. There also may be another reason why there have been no reports. In the 18 to 19 years since the advent of the first AAMI standard and the appearance of the international standard with its higher limits, there have been no reports of incidents from what must be millions of patient connections. Although it may be difficult to reconstruct what might have taken place, it is also possible to conjecture that at least one event might have been reported in Europe, where millions of patient connections have been made to equipment with the higher 500-μA
enclosure limit. For almost 20 years, the patient-applied risk current limit in Europe has been at the higher 50–μA limit.

Increasing the enclosure leakage current to 300 μA from its former value of 100 μA will make it less difficult to gain immunity from electromagnetic interference (EMI) because more control can be exercised by filtering the input line power. Achieving an adequate level of immunity has been very difficult with the former limit of 100 μA. Silberberg of the Food and Drug Administration has documented several instances of hazardous events, including death, due to equipment being susceptible to electromagnetic interference. The increase in leakage current limits does not alter patient safety and offers an opportunity to address documented patient safety problems resulting from EMI.

Gathering new data is desirable, as the authors advocate, but it is not likely to happen. A United Kingdom proposal for a large-scale study did not garner support because of cost and a general feeling that leakage current is no longer a significant problem. The proposal was made known to user, manufacturer, and government representatives active in AAMI and IEC (International Electrotechnical Commission) standards bodies involved with leakage current. Underwriters Laboratories and the National Fire Protection Association have also adopted the 1993 ANSI/AAMI limits. It must be remembered that the ANSI/AAMI 1993 standard was approved by a consensus process that involves medical device users and manufacturers. Although the new limits are more in harmony with the international standards, some on the AAMI Electrical Safety Committee have long advocated increasing the current limits because, for the reasons already given, such increases do not compromise patient safety and make it less difficult to address another documented potential hazard, disruption and failure of equipment due to EMI.

Your readers should not have any concerns about the new limits.

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References

Reply
We wish to thank Mr Levin for bringing to our attention these two errors in our references to the data of Watson. However, our conclusions are not affected by the differences in the numbers quoted in the editorial compared with the numbers of experiments conducted by Watson et al.1 Our conclusions may, in fact, be strengthened in that ventricular electrode studies were performed on only 14 or 15 patients in Watson’s experiments.

The Watson et al study1 of human ventricular fibrillation (VF) experiments quoted in the editorial and by Levin forms an important basis for establishing current limits through the heart. A total of 56 individuals 3 to 62 years old were studied by Watson. Fourteen of these individuals, all with cardiac disease, had one electrode positioned in the apex of the right ventricle. In one of these patients, 67 μA was enough to cause VF. VF was also induced with a current of approximately 15 μA in one additional patient, but this patient was excluded from the study because of "atrial fibrillation and grossly abnormal ventricular complexes ... and multiple ectopic beats noted long before current was applied." Whalen et al2 performed experiments in both humans and dogs. In the human studies on six patients, the lowest current that produced VF was 180 μA. Of 20 dogs in the animal experiments, the lowest current that produced VF was 20 μA. The authors commented that patients "with complete heart block may well have a lower threshold because of decreased coronary blood flow and instability of the conducting system.” The 1972 AHA recommendation3 of a 10–μA limit was adopted (before the publication of the Watson study) because it is half the lowest value of 20 μA in the Whalen study reported to have produced fibrillation in dogs with line frequency current. In fact, it is two thirds of the 15 μA in Watson’s study that caused VF in 1 of 15 patients with an endocardial electrode. Despite Watson’s exclusion of this patient from his data set, this type of patient with an apparently unstable conducting system must be considered. If the analysis by Levin included this patient, the probability of inducing VF with 50 μA would be considerably greater than 2.5%. We agree with Levin that should 50 μA reach the heart, there is no certainty that VF will occur. With an open ground or an input circuit failure as a single fault, the 50-μA allowable current now specified in the US standard does indeed pose a risk that we believe is too high.

Of importance, if Watson’s experiments are to be the basis for applying a threshold to millions of patients, then 15 patients can hardly constitute an adequate “clinical trial.” Hence, statistical analysis of these data and the consequent probability calculations are moot. The fact that 15 μA was sufficient to produce VF in one case with abnormal electrical activity is, we believe, significant.

Levin argues that immunity from electromagnetic interference will become more difficult if the enclosure leakage current is limited to 100 μA under single-fault conditions. This is not a persuasive argument. In the first place, engineering design techniques must be sophisticated enough to achieve a high level of noise immunity while limiting enclosure leakage currents to 100 μA under no fault conditions. There is no urgent requirement to maintain the same level of noise immunity under a single-fault condition. The requirement is only to continue to limit leakage current to 100 μA. Second, with an equipment design that had basically high noise immunity, usually the level of noise interference is more sensitive to recording techniques, such as electrode to skin contact and orientation of patient leads, than to the increasing level of immunity of the equipment to electromagnetic interference.

How could one discover an adverse effect of leakage on patients? At the levels discussed, autopsy will not reveal the cause. Could one perhaps find evidence in the antemortem ECG (assuming one were suspicious enough to look for it in the first place)? Could one separate that evidence from artifact, noise, and the natural onset of VF in the course of the patient’s disease? These are questions we asked ourselves when considering Levin’s conjecture that in 20 years of the European standards for leakage, one might expect at least one event to be reported. However, without a formal required international reporting system, the absence of a case of death due to electrical current does not permit us to speculate as to its incidence.

As Levin remarks, there is no absolute safety for walking across the street, traveling by car, boat, train, or plane, and for electro-medical equipment. However, from the published studies, an increase in the level of permitted current leakage will raise the hazard. The magnitude of this hazard cannot be predicted from the currently available data with any confidence.

Levin’s recommendation to relax electrical safety standards is unsupported by credible data. Such a conclusion appears to have been developed by heuristic rather than scientific logic as a matter of convenience.
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M Levin

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