ventricular dysfunction (left ventricular ejection fraction 17 ± 2%) and normal exercise tolerance (average exercise duration using the Sheffield protocol of 13.3 ± 6 minutes). During two-thirds maximal upright exercise in these patients, cardiac output increased from 5.5 ± 0.6 to 11.8 ± 1.2 L/min, stroke volume increased from 59 ± 6 to 90 ± 5 ml, heart rate increased from 80 ± 5 to 130 ± 11 beats/min, peripheral vascular resistance decreased from 1609 ± 207 to 783 ± 141 dyn/sec/cm², pulmonary arterial saturation decreased from 55 ± 5 to 36 ± 3% and oxygen consumption increased from 3.7 ± 3 to 15.6 ± 1.4 ml/kg/min. These direct measurements indicate that one need not invoke "internal inconsistencies" to account for our observation that patients with severely impaired left ventricular function can achieve normal levels of exercise. Various compensatory mechanisms permit some patients with severe left ventricular dysfunction to achieve normal levels of exercise.

(3) Despite the low left ventricular ejection fraction of the patients reported by Benge et al., can this really be called "severe left ventricular dysfunction"?

Considerable data suggest that left ventricular ejection fraction is a valid index of left ventricular performance. First, the left ventricular ejection fraction compares favorably with other indices of left ventricular performance such as \( V_{\text{max}} \), end-diastolic pressure, left ventricular contraction pattern and the velocity of contractile element shortening. Second, we have recently measured pulmonary wedge pressure during exercise in six patients similar to those reported by Benge (see above). Pulmonary wedge pressure increased from 15 ± 4 to 33 ± 3 mm Hg at two-thirds maximal supine exercise. Third, various studies have emphasized the prognostic significance of left ventricular ejection fraction in patients with coronary artery and valvular heart disease. In our view, patients with a left ventricular ejection fraction of less than 30% and a pulmonary wedge pressure during supine exercise of 33 mm Hg have severe left ventricular dysfunction.

(4) The radionuclide ejection fraction is a poor predictor of peak cardiac output.

We agree that radionuclide ejection fractions do not correlate with direct measurements of peak cardiac output or exercise capacity. This is the obvious point of the paper. Cardiac output is affected by variables other than left ventricular contractility, such as heart rate, end-diastolic volume and peripheral vascular resistance, so it is not surprising that some patients with severe left ventricular dysfunction can substantially increase their cardiac output during exercise.

In conclusion, our previous study and subsequent studies in our laboratory indicate that some patients with severe left ventricular dysfunction do have normal or near-normal exercise capacity. These studies underline the importance of assessing left ventricular function directly rather than relying on left ventricular function on the basis of the patient’s symptoms, exercise capacity or chest x-ray findings.

References

Electrical Safety Standards for Electrocardiographic Apparatus

To the Editor:

The authors of the recent editorial on electrical safety standards for electrocardiographic apparatus recommend that the American National Standards Institute (ANSI) Safe Current Limits for Electro-medical Apparatus (SCL) be changed to allow only 10 \( \mu \)A of leakage current to be available on the chassis or other exposed parts of electrocardiographic equipment under first-fault conditions. The ANSI standard allows up to 100 \( \mu \)A of leakage current. In supporting this argument the authors make several errors.

In the opening paragraph the authors state, "To our knowledge, practically all manufacturers of ECG equipment sold in the United States now follow the recommendations." This is not at all true in terms of chassis leakage current. The reference the authors cite to support this claim presents the chassis leakage data only in a very general manner. In this compilation of specifications of various types of electrocardiographic apparatus, only an average value of chassis leakage current is presented for all models as a group for each manufacturer. In addition, all types of such equipment are lumped together, including portable ECGs, central station recorders, oscillographic recorders and bedside modules.

The authors of this report clearly state in note 4 of their table that "The range in ‘leakage current’ specs is due to variation in testing procedures. In questioning manufacturers, be sure to find out exactly how his measurements were obtained!" Therefore, one cannot infer from this table that "practically all" current ECG apparatus meets AHA recommendations on chassis leakage current.

The most widely used models of ECG equipment do not meet the American Heart Association (AHA) specifications for chassis leakage current (Shepard M; Royal JO; Frost and Sullivan, Inc: personal communications). For example, the Burdick EK-5 and Hewlett Packard 1511 ECG machines, which are the most popular single-channel units, and the HP 1513, 1515, and 1517 and the Marquette 4000, which are the most popular three-channel units, do not meet the AHA specifications.

In the third paragraph the authors state: "However, the maximum leakage current allowable in ECG apparatus clearly must be lower than the minimal current needed to induce experimental fibrillation." This statement implies that leakage currents of more than 10 \( \mu \)A, which might be available from the chassis of electrocardiographic equipment meeting the ANSI standards instead of the AHA standards, could present a danger to the patient with direct intracardiac conductors. However, the authors do not present a discussion of the probabilities of this happening, nor do they present any evidence that the chassis leakage from an electromedical device meeting ANSI standards has ever produced ventricular fibrillation in clinical use. In fact, there have been no documented cases involving microshock fibrillation from an electromedical device with chassis leakage that met ANSI standards.

The authors also state, "Currents of this magnitude or less are considered safe even when applied directly to the heart, as occurs when ECG measurements are made with an intracardiac catheter or postoperatively with a wire conductor attached to the myocardium during surgery." This statement illustrates one of the major errors...
made when electrical safety is discussed without reference to the probability of any particular hazard. When ECG measurements are made directly from intracardiac conductors, 10 μA of current might flow directly to the heart. If the ECG machine is properly grounded, no current will flow. Leakage current is only a potential current that could flow if a fault were to occur. When deciding on appropriate levels of safety for any kind of apparatus, equal consideration must be given to the hazard, the probability of the hazard occurring, and the costs associated with preventing the hazard.

In the fifth paragraph the authors attempt to illustrate a scenario in which a chassis leakage of 100 μA from an ECG might be introduced into a patient in such a manner as to produce microshock fibrillation. They state, "For example, a grounded or imperfectly grounded pressure sensor connected by a saline column in a catheter to the right ventricle might provide a path for a dangerous 100-μA current from an ECG technician touched the paper transport mechanism of the ECG apparatus while touching the patient with the other hand." What they fail to point out is that the same ANSI standard that mandates isolated patient leads for direct connection to intracardiac conductors also mandates that pressure-measuring apparatus connected to an intracardiac catheter also be electrically isolated from power line ground and have less than 10 μA of leakage. For the hypothetical accident that the authors describe to happen, four simultaneous single-faults must occur: (1) the ground fails on the ECG machine; (2) the electrical isolation in the pressure transducer fails; (3) the electrical isolation in the pressure amplifier fails; and (4) the ECG technician fails to follow proper electrical safety procedures. The probability of all four faults occurring simultaneously is extremely small.

The authors also state, "Before the 1972 AHA recommendations dealing with electrical safety, at least four publications noted the occurrence of ventricular fibrillation in humans due to ECG apparatus." However, careful study of the references show that they have no applicability to a discussion of the merits of a 10-μA chassis leakage current standard vs a 100-μA standard.

Each of the incidents in these references they cited occurred because of what would today be considered gross violations of good electrical safety practice. All of the incidents would have been prevented by use of electromedical equipment meeting ANSI standards. In fact, the simple procedure of grounding each of the pieces of equipment would have been sufficient to prevent ventricular fibrillation. None of the incidents reported was solely involved with ECG apparatus and one incident had nothing to do with ECG apparatus.

An important factor in all of these incidents was that they all involved deliberate connection of electrical apparatus to intracardiac conductors. However, the hazard the authors are attempting to prevent by suggesting more stringent chassis leakage current standards involves an improbable accidental application of chassis leakage current directly to the heart. It is difficult to see how the incidents cited in the references relate to a discussion of chassis leakage current standards.

The authors state, "Although no cause-and-effect relationship can be proved, we are unaware of similar incidents after major American manufacturers of ECG apparatus adopted the AHA recommendations." The manufacturers adopted the ANSI standards regarding leakage currents and not the AHA standard so the proper conclusion is that the ANSI safe leakage current standard is more than adequate to protect electrically sensitive patients.

In their final paragraph, the authors say, "The ANSI standard in its present form will encourage the development of ECG apparatus distinctly less safe under normal and fault conditions than contemporary devices meeting AHA recommendations." Again, current ECG apparatus meets ANSI and not AHA standards and will in the future continue to meet them, so one cannot conclude that less safe ECG apparatus will be produced in the future.

The final paragraph also urges that the ANSI Safe Current Limit Standard not be applied to ECG and VCG apparatus. The authors fail to point out that the FDA has contracted the Association for the Advancement of Medical Instrumentation (AAMI) to develop standards for electrocardiographic apparatus under the medical device amendments. AHA has two members serving on the Committee, including the chairman of the AHA electrocardiography committee. Members of the Standards Committee have been informed that the ANSI standard for leakage current is a general one. If any particular device was thought to need a more stringent electrical safety specification, then the committee writing the standard for that device could have included such additions directly in the device standard.

In conclusion, the authors have not made a convincing argument for more stringent electrical safety specifications for ECG apparatus. There is no evidence to suggest that the great cost of meeting the AHA standard would result in any measureable benefit.

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References
5. Electrocardiographic Subcommittee of AAMI ECG Committee: Minutes of 6 Sept 1979 meeting
6. Electrocardiographic Subcommittee of AAMI ECG Committee: Minutes of 12 Nov 1979 meeting

The author replies:
To the Editor:
Mr. Rubinstein questions the recommendations of the AHA concerning safe levels of chassis leakage current in electrocardiographs. This is most curious because the AHA recommendations for electrical safety do not mention chassis leakage current.

The AHA recommendations do refer to the case of the instrument. Manufacturers could meet the 10-μA limit we recommend by either limiting the chassis current accordingly or insulating the case from the chassis.

Mr. Rubinstein takes no issue with the recommended limit of 10 μA for the patient connection (as opposed to the chassis). Hence, I assume he agrees that currents that might possibly be conducted directly to the heart should be limited to 10 μA. He argues for a 100-μA limit for chassis leakage current apparently because he feels that it is unlikely for the chassis leakage current to be conducted to the heart, and that reduction of chassis leakage current to 10 μA would result in great cost to the manufacturer, and hence the consumer.

The use of epicardial wires after open heart surgery is not uncommon, and the probability of an electrocardiograph in a hospital being connected to such a wire is far from negligible. Electrocardiographs are also used to position balloon flotation catheters in the heart chambers. In either situation the patient connection leakage current of the electrocardiograph would be delivered to the heart unless the impedance from patient to ground was very high. A large enough leakage current could cause ventricular fibrillation. There is good evidence that the danger of fibrillation is extremely small, even in sick hearts, if the current supplied to the heart does not exceed 10 μA.

Admittedly, the probability of the establishment of a current pathway allowing the leakage current from the case or exposed metal part of the electrocardiograph to be conducted to the heart is less than from a patient connection. Nonetheless, it is not extremely small. We then face the classic problem in standards development of a tradeoff between cost and benefit. Evidence at hand, however, is that manufacturers can meet the 10-μA level for chassis or case...
Electrical safety standards for electrocardiographic apparatus.
M L Rubinstein

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