Implanted Standby Defibrillators

WHEN A PROBLEM gains wide social consciousness a diversity of practical and impractical solutions is engendered. This is now the case with the formidable problem of sudden death in patients with coronary heart disease.

Sudden death largely afflicts the ambulatory subject, prodromes are not distinctive, lead time is short, and death probably results from ventricular fibrillation (VF). Tragedy is magnified by the realization that the heart may have been only minimally impaired, that the arrhythmia could have been reversed, and, if reversed, a long and productive life would have been possible. Hospital experiences during this past decade have amply demonstrated that survival depends upon promptness in defibrillation. The time for effective action is limited to a few minutes. It seems unlikely, therefore, that medical intervention after the event will yield a substantial harvest of survivors. The inexorable logic of the problem coaxes a new direction, namely, identification and protection of the patient at high risk from sudden death. One intriguing approach is to prevent sudden death by the implantation in the body of a standby automatic defibrillator system. A completely implanted defibrillator can reverse VF in dogs. A special transducer-tipped catheter, sensing pulsatile pressure, is introduced through a peripheral vein into the right ventricle. Six seconds of asystole initiates automatic charging of a 16-µfarad capacitor to a preset limit of 2500 volts, which is completed 50 sec after cessation of the heart beat. If phasic right ventricular pressure returns, the discharge is inhibited; otherwise the charge is delivered through the right ventricular electrode. The circuit is completed by a second electrode positioned in the superior vena cava. As compared to delivery of the shock transthoracically, only a fraction of the energy is necessary for intracardiac defibrillation.

Though fraught with a multitude of technical difficulties, on first examination, this method bears the stamp of logic. The underdamped exponential waveform currently employed for external defibrillation and cardioversion is unsuitable for an internal system because of the weight required by the series inductor. A change in waveform is necessary...
so that an adequate charge can be generated with lightweight switching devices. Trapezoidal and truncated waveforms can be produced by these means which defibrillate the heart.6 However, there has been no systematic and thorough study of the possible immediate and delayed deleterious effects on the myocardium.

Sensing of the onset of VF presents a difficult problem. Unlike asystole which serves as a ready trigger for demand pacemakers, VF may present large depolarizations simulating the QRS complex. No doubt, this is why Mirowski et al.2 have selected a pressure sensor as a trigger for their device. Should such a sensing probe migrate into the pericardial sac or become encased in fibrous tissue or thrombus, unnecessary shocks would be delivered. Such random discharges could even precipitate VF. Many safety features and complex electronics will be required to circumvent these hazards.

Electrical discharge can damage the myocardium even when delivered transthoracically despite relatively uniform energy density within the heart.5 The more proximate the electrodes are to the heart and the smaller the area of contact, the higher is the electrical density in tissue adjacent to the electrodes, and the greater is the predisposition to myocardial injury. It requires about 5 w-sec to defibrillate dog's ventricle with large electrode paddles directly cradling the heart. Such shocks may provoke epicardial burns. The smaller the surface through which defibrillation is effected, the higher the energy required. It is therefore likely that energies in excess of 5 w-sec will be necessary to defibrillate the ischemic dog heart through an electrode catheter system. The energy for defibrillation is a function of heart weight. The human heart is far heavier than that of large dogs. It follows that even higher energies will be required for defibrillation in man. That the heart will be injured is certain; the only uncertainty is its extent. In preliminary studies, delivery of single or double truncated exponential discharges to dog's endocardium resulted in 2–10-mm areas of petechial hemorrhage of 1 mm in depth.7 These were still in evidence as small fibrous scars 6 weeks later.

An additional problem is the absence of a method for testing operational readiness and reliability of the implanted defibrillator. Experience with pacemakers has demonstrated the need for frequent evaluation of function. This is particularly important when a device is in the standby mode. In the case of an implanted defibrillator, proof of function would require several different tests. Verification of adequacy would include not only the triggering of the device exclusively by VF, but delivery of a charge sufficient to defibrillate. In the case of a cardiac pacemaker, slowing or transient asystole is a suitable test condition. What constitutes a suitable test in the case of a standby defibrillator? Even in this age of derring-do and erosion of ethical constraints, it is unlikely that VF will be induced deliberately to ascertain performance. Barring such a test, how can one be certain that the fixed charge will prove adequate? The catheter position and orientation no doubt will prove crucial. However, more important is the complex geometry and electrophysiologic properties of a particular heart which cannot be readily modeled. It is known that recurrent VF in the same patient on different occasions may require strikingly different defibrillation energies. How then is one to be guided in selecting a fixed charge? Experience teaches that a rigid solution to a biologic problem is usually no solution. If the patient with such an implanted device is found dead, numerous questions will loom including the gnawing doubt that electrocution may have been a factor.

Nevertheless, the above cited objections are by no means decisive. Great caution needs to be exercised in stating that a problem is insoluble. Technologic advance is so rapid that the man who says, "it cannot be done," is frequently interrupted by someone who has done it. The most crucial question, however, is not technical but clinical, namely, for whom is such a device intended? The promulgators of this method have stated: "It is too early to
determine exactly the indications and contra-
indications of the standby automatic defibril-
lator." Should not such a question be
answered before social energies are expended?
If no indications can be clearly defined, why
dissipate scarce health resources?

There is serious question whether an
indication can be spelled out for the use of an
implanted standby defibrillator. The patient
who survives an acute myocardial infarction
has about 3% risk of dying suddenly in the
ensuing year. Since there is currently no
precise method for identifying the susceptible
subject, obviously there is little justification in
burdening a large group in order to possibly
save the very few. Furthermore, there is no
evidence that the individual who has a single
bout of VF is likely to have recurrences. The
very rare patient who has frequent bouts of
VF is best treated in a coronary care unit and
is better served by an effective antiarrhythmic
program or surgical correction of inadequate
coronary flow or ventricular malfunction. In
fact, the implanted defibrillator system repre-
sents an imperfect solution in search of a
plausible and practical application.

In the absence of a clearly defined clinical
purpose, what then energizes such undertak-
ings by a number of groups? The rationale for
some current bioelectronic development is
best exemplified by Edmund Hillary's reasons
for climbing Mt. Everest, "Because it was
there." The same holds for some electronic
gadget manufacture: "It was developed be-
cause it was possible."

Bernard Lown
Paul Axelrod

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BERNARD LOWN and PAUL AXELROD

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