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Editorial

Life at a price: the implantable defibrillator

Electrical reversion of ventricular fibrillation has a long and fascinating history. Kouwenhoven, Zoll, Lown, and Pantridge through their contribution to defibrillator development have saved countless lives, but they did not foresee the automatic implantable defibrillator. For years, Michel Mirowski battled against problems, some technical others political, to develop a reliable automatic implantable defibrillator.[1] Its initial acceptance into clinical practice in the United States was uncharacteristically cautious. Doubts were raised about reliability, longevity, and implantability (the unit weighs up to 250 g with a volume of 145 ml). Rumours were broadcast of runaway defibrillators, bystander shocks, swimming pool hazards, and resistance to external defibrillation. Ten years after the first human implantation, the success of the new generation implantable defibrillators is silencing the critics. Over 10 000 units have been implanted world wide, most in the United States, for a broad and at times remarkable range of indications.

The crucial breakthrough in the development of an implantable defibrillator came from establishing that the epicardial energy requirements for defibrillation of the human heart are an order of magnitude less than those for transthoracic defibrillation. None the less, substantial problems had to be overcome to miniaturise a unit capable of delivering scores of 20–35 J shocks. Improved battery and capacitor technology has given a margin of safety but it remains a vital part of the implantation that the epicardial electrode patches through which the shocks are delivered are sited in areas with the lowest possible energy requirements for reliable defibrillation. Modification of electrode characteristics, electrode numbers, shock numbers, and the energy envelope will allow further reductions in energy requirements for defibrillation. Low energy shocks have important advantages. They use less battery power and thereby increase device longevity; they use smaller batteries and capacitors, which reduces the size of the device; and low energy shocks are better tolerated by patients. The electrical benefits of delivering shocks through epicardial patches are offset by the clinical disadvantages of the thoracotomy, albeit limited, needed for their placement. Transvenous defibrillating electrodes are proving an effective alternative to epicardial patches and they reduce the procedure for defibrillator implantation to little more than that required for a permanent pacemaker.

Reliable automatic activation of an implanted defibrillator is both an absolute clinical necessity and a major technical challenge. Failure to detect a ventricular tachycardia may prove fatal whereas inappropriate delivery of a shock during normal rhythm will cause patient distress and could provoke lethal arrhythmias. Arrhythmia sensing usually depends upon the absolute heart rate or the pattern of heart rate change or both. Positive identification of ventricular fibrillation is an ideal that has been attempted with "probability density function" analysis of electrograms.[2] It is based on the principle that during ventricular fibrillation there are no periods of electrical stability corresponding to the isoelectric line in other cardiac arrhythmias. Unfortunately, local electrograms during ventricular fibrillation may not show the disorganised electrical pattern that characterises the surface electrocardiogram. Further, the myocardium sensed may be subject to entry block and therefore will not reflect the rhythm in the rest of the myocardium. Detection of ventricular tachycardia is even more demanding because its rate may overlap with rates seen during sinus tachycardia or atrial fibrillation.[3] Current systems are not perfect, and inappropriate shock delivery (false positive arrhythmia detection) by implantable defibrillators has been reported in up to 14% of patients.[4] Failure to recognise a ventricular tachycardia (false negative) is less common.[3,4]

Implantable cardioverter defibrillators, antiarrhythmic drugs, and surgery all have a role in the management of life threatening ventricular tachycardia. The relative merits of each need to be examined.

Drugs

Drugs used for the control of life threatening ventricular tachycardias are chosen empirically because there are no reliable criteria that predict the profile of responsiveness of a particular ventricular tachycardia. Once selected, the efficacy of treatment should be tested by programmed electrical stimulation.[5] Multiform ventricular tachycardia and ventricular fibrillation pose difficulties. Their control by antiarrhythmic treatment is less certain than for sustained uniform ventricular tachycardia and there is still debate regarding the value of electrophysiological testing because multiform ventricular tachycardia and ventricular fibrillation may be non-specific responses to vigorous stimulation and thus may be indistinguishable from the native event. Medical treatment (electrophysiologically tested) is successful in only 40% of patients with life threatening ventricular tachycardias. For them, continued long term treatment is associated with a 90–95% survival rate and freedom from arrhythmia at one year.[6,7] Those who do not respond and those given empirical antiarrhythmic treatment without electrophysiological confirmation of efficacy, fare much less well (30–50% one year survival and freedom from recurrence). The results of electrophysiological testing of amiodarone may be difficult to interpret but even untested treatment with this agent offers a $\geqslant 80\%$ one year survival and freedom from arrhythmia recurrence.[8] Left ventricular depression and arrhythmogenesis are important unwanted effects of antiarrhythmic drugs that may seriously restrict their use. Other unwanted effects are usually tolerable if the agent prevents life threatening recurrences of arrhythmia.

Operation

Surgical management of ventricular tachycardia has many attractions; it offers the prospect of a cure, allows other corrective surgery (coronary artery bypass grafting etc), and is relatively inexpensive. But operative risks, the specialised nature of the mapping procedures, and problems of postoperative myocardial function are major detractions. Because ventricular fibrillation affects most if not all of the ventricle and does not originate from a circumscribed focus (as does ventricular tachycardia), prospects for surgical treatment of this arrhythmia seemed bleak. New mapping strategies and the development of surgical procedures that raise ventricular fibrillation thresholds may yet extend the usefulness of surgery to this arrhythmia.[9] Ventricular fibrillation caused by ischaemia should be managed by revascularisation—a strategy that is particularly applicable to patients resuscitated from out-of-hospital ventricular fibrillation who have coronary artery disease but have not suffered an acute myocardial infarction. The results of map directed antiarrhythmic operations are varied and patient selection is important to outcome. Operative mortality ranges from 7% to 27%[10] but nearly all survivors (94%) are alive a year later.[9]

Implantable defibrillators

Implantation of a cardioverter defibrillator carries a small risk (1–2% mortality) and even very sick patients, particularly those with severe left ventricular depression, tolerate the procedure well.[3 4 11] Recent efficacy figures indicate a 1% one year and an 8% five year sudden death rate.[4] Manufacturers of the devices not unnaturally tend to quote such statistics but overall mortality figures in the same study (that is, total mortality) are 4% at one year and 26% at five years.[4] In the United States and in parts of Europe, defibrillators are being implanted on a scale beyond belief. A past history of a life threatening ventricular tachycardia or the inability to exclude the risk of such an event in the future may be sufficient to identify candidates for these devices. But many ventricular tachycardias are single unique events that are unlikely to be repeated—for example, when they occur in acute phase infarction. Covering a risk, however small, and offering protection at all costs has a humanitarian appeal but in the United Kingdom these are unrealistic health strategies. Unnecessary implantation is a profligate use of resources and creates falsely optimistic survival figures because patients not at risk of arrhythmic death are counted as defibrillator recipients. Appropriate device discharge is the best endorsement of implantation. Reports that only 58% of patients have received a shock in some series[4] must raise concerns about patient selection. Implantable defibrillators are not without their problems—extrusion, infection, lead problems, arrhythmogenesis (most series report patients in whom new arrhythmias develop or in whom the index arrhythmia becomes more troublesome after implantation), and psychiatric disturbance.[3 4 11 12]

Outlook

What of the future? Implantable cardioverter defibrillator technology will advance. Back up bradycardia pacing, automatic cardioversion/defibrillation selection, antitachycardia pacing, and miniaturisation will be available—but at a price. Competition eventually will drive down costs although the substantial development investment must be recouped in some way. "Hype" and fashion will encourage us to buy the latest technology, which may over-provide for clinical need. Antiarrhythmic surgery will stagnate until the differences between cure and palliation are better appreciated. New antiarrhythmic drugs will appear but they will be better versions of currently available compounds rather than agents with dramatically new features likely to increase the number of patients who respond.

What of the present? The evidence is that automatic implantable defibrillators work. The reality is that their implantation is easy and demands neither great skill nor complex equipment. Defibrillators are already available but they have yet to make an impact in the United Kingdom. The problem is not apathy but rather price. Each unit costs £9000–£13 000, which must be met from current NHS resources, from insurance companies, or from patients themselves. If we are to achieve optimal cost benefit patients must be carefully selected. Yet there are no guidelines for practice in the United Kingdom. Regulatory and professional bodies—the Department of Health, the British Cardiac Society, and the British Pacing and Electrophysiology Group—are aware of the problems and have begun to act; but their initiative seems neither powerful nor rapid. The clinical and budgetary issues are already on our doorstep.

Medicines, surgery, the implantable defibrillator—which is best? The question is unanswerable though some reports suggest the contrary. There have been no randomised studies of these three management strategies and perhaps there never will be. Electrophysiologically tested and proven antiarrhythmic drug treatment that is tolerated by the patient is the best management for the present. This option is badly implemented largely because electrophysiological services are not as well developed as they ought to be. This is unpardonable. Electrophysiological testing for such patients requires only a single temporary right ventricular pacing catheter linked to a simple inexpensive stimulator. The end point—arrhythmia or no arrhythmia—can be determined from a standard electrocardiographic monitor. This management shortcoming can be corrected easily but the real problem is the 60% of patients for whom medical treatment is ineffective or not tolerated. For this population, a randomised study of surgery versus the implantable defibrillator has scientific appeal; yet these options are so radically different. Surgery has a high operative risk but is relatively inexpensive and offers a cure. The defibrillator carries a low implantation risk, is expensive, and offers palliation. The mortality for each treatment is broadly similar. Seen in this light the issue could be decided on the basis of cost or on the basis of the quality of life. In practice, surgery and the implantable defibrillator should not be seen as competitive solutions for the same problem. The optimal application of each must be defined. Yet surprisingly this aspect has been almost completely neglected. Perhaps this is because few centres have embraced both strategies with equal fervour. We must accept that each has a role and identify the arrhythmias and patients to which each is best suited. That done, we can define good clinical practice and can estimate the cost of optimal care. This research can and should be done in the United Kingdom. Interested and worried clinicians are beginning to address the issue but their activities need funding and coordination. The implantable defibrillator will not be the last expensive technical development in cardiology and the United Kingdom needs a reliable, sensitive, rapid, and informed mechanism for evaluating this and similar expensive treatments.

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