An American view

Use of the implantable defibrillator

Ten years ago implantable cardioverter-defibrillators (ICDs) were cumbersome, required thoracotomy for placement of the epicardial patches, used only high energy shocks for treatment, and had short battery lives. Current devices are smaller and have lead systems that do not require thoracotomy. They also have facilities for antitachycardia pacing, low energy cardioversion, high energy defibrillation, backup bradycardia pacing, and documentation of the treated arrhythmias—and the batteries last longer. These improvements have added to the appeal of this treatment, and in the United States it is forecast that about 30 000 ICDs will be implanted in 1995.

Do ICDs prolong life?
Large series have shown that the recurrent sudden death rate in patients treated with the ICD is approximately 2% at one year and less than 5% at five years. Because there are no well controlled randomised studies we cannot be certain of the current risk of recurrent sudden death in patients without ICDs. In observational studies in the 1970s the risk of sudden death in those who had survived cardiac arrest was 30% at one year and 45% at two years. Considerable changes in medical management over the past two decades should have reduced the risk of recurrent cardiac arrest. There are no controlled studies that compare a management strategy that includes optimal treatment for ischaemic heart disease and congestive heart failure with the newer antiarrhythmic drugs with similar management with the addition of the defibrillator.

Noneetheless, recent reports suggest that the ICD has considerably reduced mortality in patients with life-threatening ventricular arrhythmias. Powell et al reported 331 survivors of out-of-hospital cardiac arrest who had intensive treatment for their ischaemic heart disease and heart failure together with electrophysiologically guided antiarrhythmic drug treatment to prevent recurrence of arrhythmia. Those who did not respond to antiarrhythmic drugs were treated with an ICD. In patients with a left ventricular ejection fraction <40% the five year probability of not dying of cardiac arrest was 70% with the ICD and 45% without it. For patients with left ventricular ejection fraction >40% the five year probability of survival was 95% with an ICD and 87% without it. Overall survival with the ICD should increase further because operative mortality has decreased from 5% to less than 1% with the use of non-thoracotomy lead systems and biphasic shock waveforms. New devices with bradycardia pacing will also help improve survival because bradycardia accounts for up to 20% of documented cardiac arrests.

In patients with class III and IV heart failure survival is poor at five years (about 50%) despite ICD therapy. The device does not prevent death from underlying heart disease or other organ failure in such patients. Important prospective randomised trials of ICD treatment that are in progress will determine the exact role of the ICD in patients with life-threatening ventricular arrhythmias.

Do ICDs improve quality of life?
Information on the impact of the ICD on quality of life and re-employment is limited. Kallklofsch et al reported that 62% of patients who had been employed before ICD implantation were able to return to work after the procedure. We have assessed quality of life in 54 patients receiving a first generation ICD. Patients were followed up for a mean of 3-6 years after implantation and although they felt less well than a healthy control group, in general, they were satisfied, with 78% reporting that their health was improved or unchanged. Quality of life measures are expected to be lower in patients with earlier ICDs than with current devices. The earlier devices treated tachycardia with shock therapy and shocks greater than 0.5 J are uncomfortable in most patients.

Newer devices with antitachycardia pacing can terminate 80-90% of episodes of ventricular tachycardia using therapy that is well tolerated or imperceptible by the patient. This should improve their quality of life by decreasing the anxiety associated with the painful shock especially in patients with frequent episodes of tachycardia.

Are ICDs cost effective?
The cost of ICD treatment causes concern. Increasing use of the device will place a financial burden on the healthcare system. Kottke et al reported that if published criteria are followed each year about 22 000 people will become candidates for first-time implantation of the ICD in the United States. This would reduce annual all-cause cardiac mortality in the United States by only 1-5% because recurrent sudden death does not account for many cardiac deaths. None the less, individual patients will benefit.

Kuppermann et al reported that with the older technology the ICD cost about $17 000 per life-year saved and that the cost fell to $7400 per life-year saved with the newer devices that lasted longer and did not require a thoracotomy. Larsen et al estimated that life expectancy with an ICD was 50% greater than with amiodarone and 250% greater than with conventional treatment. They estimated that if ICD has to be replaced every 36 months, the treatment costs (in 1989 dollars) for a 55 year old patient would be $21 800 extra for each year of life saved by an ICD compared with each year of life saved by amiodarone treatment.

By using a new, smaller defibrillator designed for pectoral implantation with endocardial leads we have reduced physician and hospital charges by 38% compared with a larger device requiring abdominal implantation of the generator and a non-thoracotomy lead system. Prospective randomised trials that are underway should establish the cost effectiveness of ICD treatment.

Currently, though ICD treatment is expensive it is no more expensive than other medical treatments in terms of cost per year of life saved.

Indications
The indications for ICD treatment are expanding (table) as operative mortality decreases and technology...
Indications for the ICD

I One or more documented episodes of haemodynamically significant ventricular tachycardia (VT) or ventricular fibrillation (VF)

and

Remediable causes of arrhythmia are excluded (that is, acute myocardial infarction, myocardial ischaemia, electrolyte imbalance, drug toxicity)

and

Documented failure or intolerance of antiarrhythmic drug treatment

or

Inability of electrophysiological testing to predict efficacy of therapy:

(a) Patients with non-inducible arrhythmias during electrophysiological study

or

(b) Patients in whom arrhythmia induced at electrophysiological study is not reliable for assessment of response to serial drug testing (VF or polymorphic VT).

II Continued inducibility of VT or VF despite surgery (that is, endocardial resection, coronary artery bypass) or catheter ablation.

III Patients with structural heart disease (that is, hypertrophic cardiomyopathy, familial dilated cardiomyopathy, long QT syndrome) and a strong family history of sudden cardiac death, even in the absence of symptoms caused by arrhythmia or inducible VT or VF during electrophysiological testing.

IV Recurrent syncope of undetermined cause in a patient with VT induced at electrophysiological study in whom no effective or no tolerated drug can be identified by serial drug treatment.

Future directions

Improving technology will increase the appeal of ICD therapy. Devices designed for pectoral implantation with endocardial leads and biphasic waveforms increase the ease of implantation and shorten hospital stay. Such devices have a reduced battery life which must be improved.

The prophylactic use of the ICD is currently the subject of three important prospective randomised trials (MADIT (multicenter automatic defibrillator implantation trial), MUSTT (multicenter unsustained tachycardia trial), CABG PATCH (coronary artery bypass graft-patch trial)). Such trials are essential because if the use of ICD technology is extended to prophylactic prevention of arrhythmia the use of ICDs and medical costs will increase markedly. Before prophylaxis is regarded as an indication these trials will need to show that the ICD is effective not only for reducing the incidence of sudden death in symptom free patients but also for prolonging survival at an acceptable cost per year of life saved.

Patients with life-threatening ventricular arrhythmias may develop ischaemia, infarction, ventricular dilatation during heart failure, electrolyte and acid base disturbance, hypoxia, or proarrhythmia associated with medications that alter the threshold for onset of a serious arrhythmia and render a previously effective antiarrhythmic drug ineffective. Arrhythmias associated with changes in the substrate can still be treated effectively by the ICD.

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