Implantable Cardioverter Defibrillators [1, 2]

Background

Sudden cardiac death is a common problem, and increasing numbers of patients are surviving a first episode of a life threatening ventricular arrhythmia. Patients who survive either ventricular fibrillation or sustained ventricular tachycardia have a high risk of further episodes, which may be fatal. Until recently antiarrhythmic drugs have been the standard treatment for patients with malignant ventricular arrhythmias, but despite using the best appropriate medical treatment, arrhythmia recurrence rates are still 40-50% at five years.

There is now growing evidence to support the wider use of implantable cardioverter-defibrillators (ICDs) as primary treatment in certain patients with serious ventricular arrhythmias. These devices were developed in the 1970s, with the first human implant in 1980. Original devices had a single therapy option of defibrillation only; the generator was implanted in the abdomen, and thoracotomy was required. With advances in technology the units have become smaller (current ICDs are little bigger than a pacemaker) and can be implanted pectorally. Furthermore, anti-tachycardia pacing, low energy synchronised cardioversion, and high-energy defibrillation shocks can be given via a single transvenous lead.

Implantation and follow-up

Nowadays, ICD implantation is technically straightforward and only slightly more complicated than pacemaker implantation. Strict attention to asepsis is necessary, and prophylactic antibiotics are generally used. In the past, ICD implants were performed under general anaesthetic; however, many centres now implant these devices using a combination of local anaesthesia and intravenous sedation. Most patients can be discharged home 24-48 hours after implantation following post-implantation device function checks. Patients are usually followed up 4-6 weeks post-implant, then at 3-6 monthly intervals. At each follow up visit, the device and its memory are interrogated and standard pacing and sensing tests are performed. Details of any stored arrhythmic events are downloaded and printed, and correlated with symptoms. If indicated, appropriate programming changes can be made or the patient's medication can be altered.

Complications of ICDs

ICD nowadays are much simpler to implant than five years ago and the complication rate is decreasing. Nevertheless all complications, which apply to pacemakers, can occur with the ICD of cardiac pacing (e.g. infection, lead fracture, etc.) and some of these complications may require revision or even replacement of the system, which can be a major undertaking. Additional problems may occur, the most common being inappropriate shocks. Such complications can usually be treated or circumvented either by additional medication or by further programming of the device.

Clinical trials of ICDs

ICDs are effective at treating ventricular arrhythmias but until recently there has not been clear evidence that they reduce mortality. Recently, the results of large randomised controlled trials of ICD treatment have been published.

These include the AVID, CIDS and CASH studies, which compared ICD therapy with medication in patients who had sustained VT or VF. They showed a superior beneficial outcome with ICD. In the three studies, 934 patients were treated with an ICD and 932 with amiodarone. In over 2000 patient years of follow up in each group, there were 200 deaths in patients treated with an ICD and 255 deaths in patients treated with amiodarone. This equates to a 28% reduction in mortality in the ICD group ($p = 0.0006$). Importantly, the meta-analysis showed that patients who presented with ventricular tachycardia had as much to gain from an ICD as those whose index arrhythmia was ventricular fibrillation.

Several studies have also assessed the efficacy of ICD treatment for "primary prevention" in patients at high risk for sudden death who have not yet had a clinical event. The MADIT study studied high-risk survivors of myocardial infarction with impaired left ventricular function and non-sustained ventricular tachycardia on ECG monitoring. Patients recruited to this trial had to have an inducible sustained ventricular arrhythmia at electrophysiological study, which could not be suppressed by medication. These patients were randomly allocated to treatment with an ICD or an antiarrhythmic drug (amiodarone in 80% of the cases). The trial was terminated in 1996 after demonstrating a 54% reduction in mortality with defibrillator therapy compared to antiarrhythmic drug treatment.

More recently, the MUSTT study recruited patients similar to the MADIT study. Patients were randomly allocated to a "control" group, who received no specific treatment, and an electrophysiologically guided treatment group, who received antiarrhythmic drugs, if the tachycardia could be suppressed by drugs, or an ICD if drugs were ineffective at electrophysiological study. The five year mortality in this study was 48% in those not treated with antiarrhythmic medication; patients on antiarrhythmic drugs fared marginally worse, but those treated with an ICD had a five year mortality rate of 24% ($p < 0.001$). These results show that patients with prior myocardial infarction, impaired left ventricular function, and non-sustained ventricular tachycardia can be stratified by electrophysiological study. Patients with inducible sustained ventricular arrhythmias are highly likely to benefit from prophylactic ICD implantation, even though they have not yet had a major spontaneous arrhythmic event.

ICDs have also been shown to be beneficial in terms of preventing sudden cardiac death and/or terminating potentially fatal ventricular arrhythmias among patients with hypertrophic cardiomyopathy (HCM). HCM is the commonest cause of non-traumatic sudden death in individuals below the age of 35 years and among athletes. ICD therapy is also the treatment of choice in high-risk patients with other forms of cardiomyopathy such as dilated cardiomyopathy or arrhythmogenic right ventricular cardiomyopathy.

There are several other ongoing trials, which are comparing the efficacy of ICD therapy with other treatments in high-risk patients with heart failure or with poor left ventricular function post-myocardial infarction.

Quality of life with ICDs

An ICD is not a cure. Patients are still considered to be at risk of an arrhythmia, which might cause unconsciousness or cardiac arrest, if only for a few seconds before treatment is delivered. Inevitably many patients face

significant lifestyle restrictions, and a minority of patients have psychological problems. Although the implant procedure is similar to pacemaker implantation, follow up of patients with ICDs tends to be more complex. Many of the patients have coronary artery disease and poor left ventricular function, and are likely to require ongoing medical treatment.

Although some patients may develop an adverse psychological reaction to ICD implantation, it is important to be aware that these patients often improve with the passage of time as they become accustomed to having the device and adapt to their physical limitations. There is no doubt, however, that many patients tolerate defibrillation shocks very poorly, particularly if they experience multiple shocks. For this reason, antiarrhythmic drugs may have a role in reducing the incidence of arrhythmias in patients with ICDs.

The issue of fitness to drive in patients with ICDs is a contentious one. Up until five years ago, patients with ICDs in the UK faced a lifetime ban from driving. Since then the regulations in the UK have been relaxed. Currently, ICD recipients may be allowed to drive provided that the device has been implanted for at least 6 months and has not delivered therapy for 6 months, and if previous shocks have not been accompanied by incapacity. Patients must stop driving for one month if the device is revised, or if any change is made in antiarrhythmic treatment. Patients who have an ICD implanted for "primary prevention" need only refrain from driving for one month, unless they subsequently receive shocks from the device. Licences are subject to annual review. Patients with ICDs are permanently disqualified from driving lorries and buses.

Indications for ICDs

In the UK, the National Institute for Clinical Excellence (NICE) has recently published guidance on the use of ICDs. The institute has stated that ICDs should be routinely considered for both primary and secondary prevention of life threatening arrhythmias. Their guidance is summarised below.

Secondary prevention

For patients who present, in the absence of a treatable cause, with:

- Cardiac arrest caused by either VT or VF
- Spontaneous sustained VT causing syncope or significant haemodynamic compromise
- Sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (< 35%) but are no worse than NYHA functional class III heart failure

Primary prevention

For patients with:

A history of previous myocardial infarction and *all* of the following:

- non-sustained VT on Holter monitoring
- inducible VT on electrophysiological testing
- left ventricular dysfunction with an ejection fraction < 35% and no worse than NYHA functional class III heart failure

A familial cardiac condition with a high risk of sudden death, including:

- long QT syndrome
- hypertrophic cardiomyopathy
- Brugada syndrome
- arrhythmogenic right ventricular dysplasia
- dilated cardiomyopathy

Patient groups in whom an ICD is usually *not* indicated

- Syncope of undetermined aetiology, VT/VF not inducible
- Incessant VT
- VT amenable to surgical or catheter ablation
- VT/VF due to transient or reversible cause
- Significant psychiatric illness that might be aggravated by device implant or may preclude systematic follow up
- Terminal illness with life expectancy < 6 months
- Patients with impaired left ventricular function undergoing coronary artery bypass graft surgery, without spontaneous or inducible VT
- Patients with NYHA functional class IV heart failure who are not candidates for heart transplantation

Conclusions

Although the rate of ICD implantation has doubled over the past three years, the implant rate in the UK is still little more than half that for western Europe, and less than 10% of the rate in the USA. It is now clear from several randomised controlled trials that, in selected high-risk patients, ICDs are more effective than drugs in prolonging life. When faced with such a patient, physicians should now consider an ICD as first line treatment.

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[1] The following medical information has been kindly provided by CRY and is available for download in the website: http://www.c-r-y.org.uk.

[2] The medical information contained in this website is provided for information only. It is not intended to replace a consultation with an appropriately qualified medical practitioner and should not be used for the diagnosis, treatment or management of a heart abnormality. If you would like more information or are concerned that you might be affected by any of the conditions described in this website you should seek professional medical help and/or consult your doctor.