Who needs an implantable cardioverter defibrillator?

The implantable cardioverter defibrillator has been shown to be the optimal treatment for both primary and secondary prevention in patients with previous aborted sudden death and with life-threatening cardiac arrhythmias. This article reviews the latest evidence and guidelines supporting implantable cardioverter defibrillator use.

Cardiovascular disease is responsible for over 300 000 deaths each year in the UK with over 70 000 of those from sudden cardiac death (SCD). Only 2–30% of patients with cardiac arrest survive (de Vreede-Swageemakers et al, 1997), and a number of these will have further events which if untreated are usually fatal. Antiarrhythmic therapy is ineffective in improving mortality in high-risk patients. The implantable cardioverter defibrillator (ICD) was introduced into clinical medicine in 1980 (Mirowski et al, 1980) and can diagnose and treat life-threatening ventricular arrhythmias. ICD guidelines have recently been updated in line with recent trial evidence (National Institute for Health and Clinical Excellence (NICE), 2006).

This article reviews the trial evidence supporting the use of ICDs and discusses which patients should be considered for implantation. It will also cover practical aspects of ICD implantation and discuss current and future advances in ICD technology.

Evidence base for the ICD

A large body of evidence now exists to support the use of ICDs as first-line treatment for both primary and secondary prevention of life-threatening arrhythmias (*Table 1* and *2*).

Secondary prevention

No recent studies in secondary prevention of SCD have been performed. The Antiarrhythmics *vs* Implantable Defibrillators (AVID) study included 1016 patients resuscitated from an episode of near fatal ventricular fibrillation (VF) or with sustained ventricular tachycardia (VT) requiring cardioversion, or patients with ventricular tachycardia with syncope and a left ventricular ejection fraction (LVEF) <40% (The AVID Investigators, 1997). Patients were randomized to the ICD or class III antiarrhythmic therapy (primarily amiodarone). Overall survival was improved in the ICD group with reductions in mortality of 39%, 27% and 31% at 1, 2 and 3 years respectively.

The superiority of the ICD over amiodarone has been confirmed in two other secondary prevention trials: the Canadian Implantable Defibrillator Study (CIDS) and the Cardiac Arrest Study Hamburg (CASH) (Connolly et al, 2000b; Kuck et al, 2000). A meta-analysis of these three trials (Kuck et al, 2000) showed a 28% reduction in relative risk of death that was almost entirely the result of a 50% reduction of arrhythmic death. The greatest mortality benefit was seen in those with worse left ventricular function (LVEF <35%). ICDs significantly reduced deaths in these patients; patients lived 0.36 years longer on average. For every 10 patients treated with an ICD one death was averted in the first 3 years. ICD implantation is now considered first-line therapy in such patients.

Primary prevention

Several large-scale trials have suggested that a larger patient group may be candidates for primary prevention of SCD (Moss et al, 2002; Bristow et al, 2004; Bardy et al, 2005). The fact that only a minority of patients survive a cardiac arrest mandates that treatments should be offered to high-risk patients before they have suffered an event (primary prevention). Unsustained ventricular tachycardia in patients with previous myocardial infarction and left ventricular dysfunction is associated with a 2-year mortality rate of about 30% (Moss et al, 1996).

Several studies have examined the benefit of the ICD in this high-risk group and have shown the superiority of the ICD over medical treatment (Moss et al, 1996; Buxton et al, 1999; Moss et al, 2002; Bristow et al, 2004; Bardy et al, 2005). The earliest of these was the Multicenter Automatic Defibrillator Implantation Trial (MADIT) (Moss et al, 1996). This studied 196 patients with prior myocardial infarction and a LVEF <35% who had a documented episode of asymptomatic non-sustained ventricular tachycardia that was inducible at electrophysiological study. Patients were randomized to the ICD or conventional medical therapy. During an average follow up of 27 months, there was a significant mortality reduction in the ICD group from over 32% to 10%. The Multicenter Unsustained Tachycardia Trial (MUSST) studied 704 patients with coronary artery

Dr MWH Behan *is Specialist Registrar in Cardiology,* **Dr JS Gill** *is Consultant Cardiologist and* **Dr CA Rinaldi** *is Consultant Cardiologist in the Cardiothoracic Department at Guy's and St Thomas' NHS Trust, London SE1 7EH*

Correspondence to: Dr CA Rinaldi

disease and an LVEF <40% and inducible ventricular tachycardia. There was a significant mortality reduction at 2 years follow up from 33% in the group not receiving an ICD to 10% in the ICD treated group.

The MADIT 2 study examined 1232 patients with previous myocardial infarction and an LVEF <30% (Moss et al, 2002). Unlike MUSST and MADIT patients had no documented arrhythmia. Patients received either the ICD or conventional medical therapy. After 20 months of follow up there was a significant mortality benefit in favour of the ICD (31% reduction in the relative risk of death, absolute reduction of 6%). Importantly subgroup analysis revealed increased effectiveness of ICD therapy in patients who had an increased QRS duration.

The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators (Bardy et al, 2005) randomly assigned 2521 patients with New York Health Association (NYHA) class II/III symptoms and LVEF ≤35% to either optimized medical therapy (845) or amiodarone (845) or the ICD (829). Notably the trial consisted of both ischaemic and non-ischaemic dilated cardiomyopathy patients. The study showed that ICD therapy was associated with a 24% relative risk reduction and a 7% absolute risk reduction in all-cause mortality as compared with optimized medical therapy (P=0.007) whereas amiodarone had no favourable effect on survival compared to placebo.

The hypothesis that prophylactic cardiac resynchronization therapy (CRT) with (CRT-D) or without a defi-

Table 1. Evidence base for ICD use in primary prevention

Trial	Patient population	Primary endpoint	Trial design	Key finding
MADIT (Multicenter Automatic Defibrillator Implantation Trial) (Moss et al, 1996)	196 patients MI >3 weeks before entry NYHA I/II/III, LVEF<35% Asymptomatic NSVT, VT on EPS	Death from any cause	RCT ICD *vs* conventional medical therapy	ICD led to reduction in mortality
CABG-Patch (Coronary Artery Bypass Graft Patch Trial) (Bigger, 1997)	1055 patients Scheduled for CABG LVEF<35%	Death from any cause	RCT ICD *vs* control	No evidence of improved survival with prophylactic ICD
MUSST (Multicenter Unsustained Tachycardia Trial) (Buxton et al, 1999)	704 patients Ischaemic DCM LVEF <40% Inducible sustained tachyarrhythmia	Cardiac arrest or death from arrhythmia	RCT EPS guided therapy (drugs or ICD) *vs* no anti-arrhythmic therapy	EPS guided ICD but not drugs reduce risk of SCD in high-risk patients
CAT (Cardiomyopathy Trial) (Bansch et al, 2002)	104 patients Recent onset idiopathic DCM LVEF<30%	Death from any cause at 1 year	RCT ICD *vs* control	No survival benefit with ICD
MADIT II (Multicenter Automatic Defibrillator Implantation Trial II) (Moss et al, 2002)	1232 patients Previous MI LVEF<30%	Death from any cause	RCT ICD *vs* conventional medical therapy	ICD improves survival
AMIOVIRT (Amiodarone Versus Implantable Cardioverter-Defibrillator Trial) (Strickberger et al, 2003)	103 patients Non-ischaemic DCM LVEF<35% Asymptomatic NSVT	Death from any cause	RCT Amiodarone *vs* ICD	No difference between groups in mortality or quality of life
COMPANION (Comparison of Medical therapy, Pacing, and Defibrillation in Heart Failure Trial) (Bristow et al, 2004)	1520 patients Ischaemic/non-ischaemic DCM LVEF<35	Death or hospitalization for any cause	RCT Optimal medical therapy alone ± CRT ± CRT-D	CRT-D reduces mortality, CRT reduces risk of death or hospitalization
DEFINITE (Defibrillators in Non-Ischaemic Cardiomyopathy Treatment Evaluation trial) (Kadish et al, 2004)	458 patients Non-ischaemic DCM LVEF<36% NSVT or PVCs	Death from any cause	RCT Standard medical therapy alone or in combination with ICD	ICD reduces risk of SCD from arrhythmia
DINAMIT (Defibrillator in Acute MI Trial) (Dorian et al, 2004)	674 patients 6–40 days post MI, LVEF<35%	Death from any cause	RCT ICD *vs* optimal medical therapy	No difference between groups in death from any cause
SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) (Bardy et al, 2005)	2521 patients, NYHA II/III Ischaemic/non-ischaemic DCM, LVEF<35	Death from any cause	Conventional medical therapy ± amiodarone ± ICD	ICD reduces overall mortality, no effect by amiodarone

CABG = coronary artery bypass graft; CRT = cardiac resynchronization therapy; CRT-D = cardiac synchronization therapy with ICD; DCM = dilated cardiomyopathy; EPS = electrophysiological study; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction, MI = myocardial infarction; NYHA = New York Heart Association; NSVT = non-sustained ventricular tachycardia; PVC = premature ventricular complex; RCT = randomized controlled trial; SCD = sudden cardiac death; VF = ventricular fibrillation; VT = ventricular tachycardia

Table 2. Evidence base for ICD use in secondary prevention

Trial	Patient population	Primary endpoint	Trial design	Key finding
AVID (Antiarrhythmics Versus Implantable Defibrillators Trial, 1997)	1013 patients Resuscitated VF/VT VT + syncope + EF<40%	Death from any cause	RCT ICD *vs* class III antiarrhythmic drugs (mainly amiodarone)	Increased survival with ICD
CIDS (Canadian Implantable Defibrillator Study) (Connolly et al, 2000a)	659 patients with either VF, arrest requiring DCCV, VT + syncope or VT + LVEF<35%	Death from any cause	RCT ICD *vs* amiodarone	Non-significant reduction in all-cause mortality with ICD
CASH (Cardiac Arrest Study Hamburg) (Kuck et al, 2000)	288 patients Cardiac arrest from ventricular arrhythmia	Death from any cause	RCT ICD *vs* amiodarone or metoprolol	Non-significant reduction in all-cause mortality with ICD

DCCV = electrical cardioversion; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; NSVT = non-sustained ventricular tachycardia; RCT = randomized controlled trial; VT = ventricular tachycardia; VF = ventricular fibrillation

brillator would reduce the risk of death or hospitalization in patients with chronic heart failure and intraventricular conduction delays, was tested in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial (Bristow et al, 2004). A total of 1520 patients (NYHA class III/IV), with both ischaemic and non-ischaemic dilated cardiomyopathy and with QRS duration greater than 120 ms, were randomly assigned to optimal medical therapy alone or with either CRT or CRT-D. They found that the risk of death or hospitalization was reduced by 34% in the pacemaker group and 40% in the pacemaker and defibrillator group. The positive effect of CRT was confirmed in the Cardiac Resynchronisation-Heart Failure (CARE-HF) study (Cleland et al, 2005), which showed a significant decrease in mortality (36%) in NYHA class III/IV patients with evidence of ventricular dysynchrony findings who received a biventricular pacemaker. Interestingly in the CARE-HF patients who received CRT a third of the deaths were sudden and a back-up ICD may have prevented many of these.

Three studies have looked specifically at patients with non-ischaemic dilated dilated cardiomyopathy: the Cardiomyopathy Trial (CAT), Amiodarone *vs* Implantable Cardioverter Defibrillator Trial (AMIOVIRT) and the Defibrillators in Non-Ischaemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial (Bansch et al, 2002; Strickberger et al, 2003; Kadish et al, 2004). Both CAT and AMIOVIRT showed no significant difference between either the ICD compared to control or amiodarone respectively. DEFINITE did, however, show a significant reduction in the risk of sudden death with an ICD and medical therapy compared to medical therapy alone.

Two trials found no benefit of ICD in ischaemic patients: The CABG (Coronary artery bypass graft) Patch Study and The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) (Bigger, 1997; Dorian et al, 2004). The CABG Patch studied 900 patients undergoing CABG with impaired LVEF (<36%) and an abnormal signal averaged electrocardiogram and showed no benefit of the ICD. The DINAMIT evaluated patients immediately after myocardial infarction. Standard therapy alone, or in combination with an ICD, was compared in 674 patients who were between 6 and 40 days post myocardial infarction (with an LVEF ≤35%). There was no difference in all-cause mortality between the two groups (6.9% compared to 7.5% in the medical therapy and ICD groups respectively).

A meta-analysis of ten trials of primary prevention in patients with impaired left ventricular systolic function irrespective of aetiology concludes that ICD therapy significantly reduces mortality at intermediate term follow up (Nanthakumar et al, 2004). They also note that 90% of the pooled patients in their analysis come from the later trials (MADIT II, DEFINITE, COMPANION and SCD-HeFT) in which all patients were on optimized medical therapy for heart failure. Therefore the mortality benefit of ICDs is in addition to that derived from angiotensin-converting enzyme (ACE) inhibitors and beta-blockers. The authors did point out that ICD therapy does differ substantially from drug therapy, not least from the standpoint of initial cost.

Current indications for ICD implantation

NICE has recently published an update of its original guidelines for ICD implantation (NICE, 2006) (*Table 3*). They recommend that ICDs should be considered routinely for secondary prevention in cardiac arrest survivors as well as patients with ventricular tachycardia and syncope/haemodynamic compromise and those with ventricular tachycardia and an LVEF <35%. ICDs should be considered for primary prevention in patients with a history of previous myocardial infarction and either an LVEF <35% and non-sustained ventricular tachycardia on Holter monitoring, or which is inducible at electrophysiological study. The guidelines have incorporated a new subgroup of patients felt to be at high risk for primary prevention: those with LVEF <30% and a QRS interval of greater than 120 ms. ICDs are also indicated for certain (but not all) patients with high-risk familial conditions and those who have undergone surgical repair of congenital heart disease (*Table 2*).

ICD implantation and follow up

Initially ICD leads were epicardial requiring a thoracotomy but now leads are implanted transvenously in the same manner as a pacemaker. The 'shock' lead, which delivers the energy required for defibrillation, is placed via the subclavian or cephalic vein to the right ventricular cavity. This delivers the energy in a vector across the heart (Rinaldi et al, 2003). The generator or 'box' (approximately 40cc in volume) is implanted subcutaneously or submuscularly in the left pectoral area. Tests are then carried out to ensure adequate pacing values and then Ventricular fibrillation is induced to ensure that the device can successfully detect and treat the arrhythmia. In the authors' institution the majority of devices are implanted using local anaesthesia and patients stay in hospital for 1–2 days.

Current ICDs have a battery life of up to 9 years, but longevity is dependent on the number of shocks delivered and the amount of pacing. Patients are followed up regularly in a dedicated ICD clinic where the device can be interrogated and reprogrammed as required (routinely every 6 months). ICD patients are unable to drive for 6 months after implantation or after a shock is delivered. The ban is shorter for primary prevention devices (Jung et al, 2002; Rinaldi et al, 2003; Driver and Vehicle Licensing Agency, 2005). ICD implantation complications are similar to those of pacemaker implantation including pneumothorax, pericardial effusion or tamponade and infection. Patients are at risk of receiving inappropriate therapy during follow up, with up to 20% of patients receiving inappropriate shocks for rhythms that are not ventricular tachycardia or ventricular fibrillation usually as a result of atrial fibrillation (Rinaldi et al, 2004).

ICD technology: current and future advances

There have been significant technological advances since the introduction of the ICD. Initial devices were capable of delivering shock therapy, but the current generation of devices incorporate dual chamber pacing, enhanced arrhythmia detection algorithms and tiered therapy. Current ICDs are able to discriminate between a number of arrhythmias and may reduce the incidence of inappropriate shocks. A large proportion of ventricular arrhythmias can now be terminated by using anti-tachycardia pacing, which can prevent the need for shock delivery.

During their lifetime more than 50% of ICD patients may develop atrial fibrillation (Grimm et al, 1992). The implantable atrial defibrillators will deliver shock therapy to cardiovert atrial fibrillation. Similarly dual chamber defibrillators with the ability to specifically cardiovert atrial arrhythmias as well as ventricular arrhythmias are in use (Schmitt et al, 1998). The confirmed benefits of CRT in heart failure patients mean that this therapy should be incorporated with ICDs in appropriate patients (Cazeau et al, 2001; Bristow et al, 2004; Cleland et al, 2005). Devices that have sensors that are able to monitor the progression of heart failure are under development. Devices could potentially be developed to provide feedback management of heart failure by changing pacing rate, atrioventricular intervals, VV (intervals in biventricular devices), or other parameters (Kadish and Mehra, 2005).

Cost effectiveness of ICDs

Cost effectiveness remains a critical issue regarding defibrillator therapy (Hlatsky and Bigger, 2001). Current ICD systems cost around £20 000, but are subject to contractual agreements and company discounts. The incremental costs of the treatment are dependent on the number and length of hospital admissions. ICDs tend to reduce hospitalization for arrhythmic episodes but this could be offset by an increased incidence of admissions from heart failure (Moss et al, 2002).

For secondary prevention, data from the AVID trial suggest the cost per life year gained, using a 5-year model with ICD replacement where necessary, is £26 000–31 000. As the longevity of devices increases cost effectiveness should be more favourable. Increased sales volumes of ICDs are likely to lower their cost. The cost-effectiveness of ICD therapy varies by patient risk factor status with more favourable cost effectiveness in high-risk groups (Sheldon et al, 1997). Thus risk stratification will remain an important tool; the ideal ICD patient would be someone at high risk of death from cardiac arrhythmia but not from other causes. The impact of ICDs on the quality of life of patients is important. Data from the AVID trial suggest improved mental wellbeing in patients whose devices are rarely or never activated in comparison to patients whose devices are often activated (Bardy et al, 2005).

Table 3. The new National Institute for Health and Clinical Excellence guidelines

ICDs are recommended for patients in the following categories	
Secondary prevention*, that is for patients who present, in the absence of a treatable cause, with one of the following:	Having survived a cardiac arrest as a result of VT or VF
	Spontaneous sustained VT causing syncope or significant haemodynamic compromise
	Sustained VT (without syncope/cardiac arrest), with an ejection fraction $<35\%$ (no worse than NYHA class III functional classification of heart failure)
Primary prevention†, that is for patients who have:	A history of previous (more than 4 weeks) MI and:
	either LVEF $< 35\%$ and no worse than NYHA class III and inducible VT on electrophysiological testing and non-sustained VT on Holter monitoring or LVEF $< 30\%$ and no worse than NYHA class III and QRS duration ≥ 120 ms
	Familial conditions with a high risk of sudden death including: Long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia and following repair of congenital heart disease

ICD = implantable cardioverter defibrillator; MI = myocardial infarction; NYHA = New York Heart Association; VF = ventricular fibrillation; VT = ventricular tachycardia. *Secondary prevention of sudden cardiac death is defined as the prevention of an additional life-threatening event in survivors of sudden cardiac events or in patients with recurrent unstable rhythms; †Primary prevention of sudden cardiac death is defined as prevention of a first life-threatening event. From National Institute for Health and Clinical Excellence (2006)

Conclusions

The annual implant rate for ICDs in the UK is 50 per million compared to an implant rate of 400 per million in the USA and an average for Western Europe of 85 per million. The new NICE guidance would double the current implant rate to 100 per million in England and Wales. There is a firm evidence base as to which patients should receive ICD implantation, but there is a need to develop protocols for screening high-risk subjects and to ensure early referral of appropriate patients. There is a need to develop a rehabilitative approach to after-care including psychological preparation for living with an ICD, early discharge efficient, and comprehensive follow up, which will have important training and funding implications for the NHS. **BJHM**

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KEY POINTS

- Implantable cardioverter defibrillator therapy is effective in treating malignant ventricular arrhythmias.
- Implantable cardioverter defibrillators are considered first-line therapy for secondary prevention (cardiac arrest survivors, those with ventricular tachycardia and syncope, or with ventricular tachycardia and significant left ventricular dysfunction), and primary prevention (ischaemic heart disease and significant left ventricular dysfunction (left ventricular ejection fraction $<35\%$) with non-sustained ventricular tachycardia inducible at electrophysiological studies or left ventricular ejection fraction $<30\%$ and QRS >120 ms).
- Current devices are implanted transvenously without the need for general anaesthesia requiring a short hospital stay.
- Current devices are able to perform multiple functions and can pace terminate arrhythmias negating the need for shock therapy.
- New developments include ability to terminate atrial arrhythmias and biventricular pacing to achieve cardiac resynchronization.
- Cost effectiveness remains an important issue.
- Implant rate in the UK is rising dramatically with important issues of funding and training for the NHS.