Implantable defibrillators

Preventing sudden cardiac death

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Implantable cardioverter defibrillators (ICDs) are recommended for patients at risk of sudden cardiac death caused by cardiac arrhythmias such as ventricular fibrillation and tachycardia. Some ICDs also have ventricular pacing functions that can improve symptoms in patients with poor left ventricular systolic function.

Sudden cardiac death remains a significant public health issue. It is conservatively estimated that 1000 to 2000 Australians die suddenly each year and, of these, up to 10% are under the age of 35 years.[1,2] A common cause of sudden cardiac death is cardiac arrhythmia caused by either ventricular fibrillation or ventricular tachycardia, both of which are treatable with electrical countershock. This therapy needs to be delivered within seconds or minutes of the arrhythmia onset. As survival after out-of-hospital cardiac arrest is poor, implantable cardioverter defibrillators (ICDs) were developed in the 1970s to resuscitate patients at high risk of arrhythmic cardiac death.

All ICDs have a battery and capacitors able to deliver an intracardiac shock, together with a lead implanted directly into the right ventricle and a software-based detection algorithm to determine the onset of ventricular fibrillation or ventricular tachycardia. ICDs can detect the onset of a potentially fatal arrhythmia and immediately deliver the intracardiac shock. All ICDs also have a pacemaker function, as severe bradycardia may occur after delivery of an intracardiac shock. Some ICDs have additional leads with pacing support functions and are recommended in selected patients (see below).

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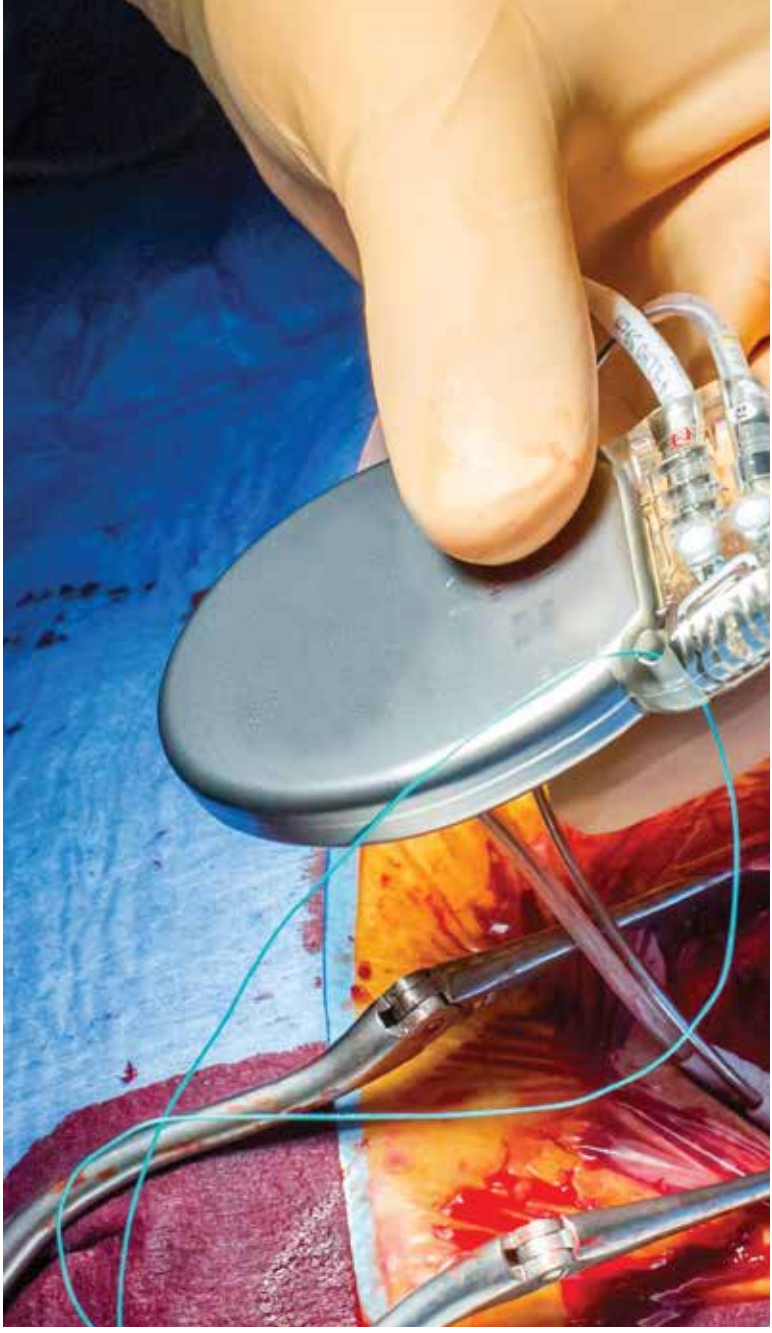


Indications for an ICD

Primary prevention

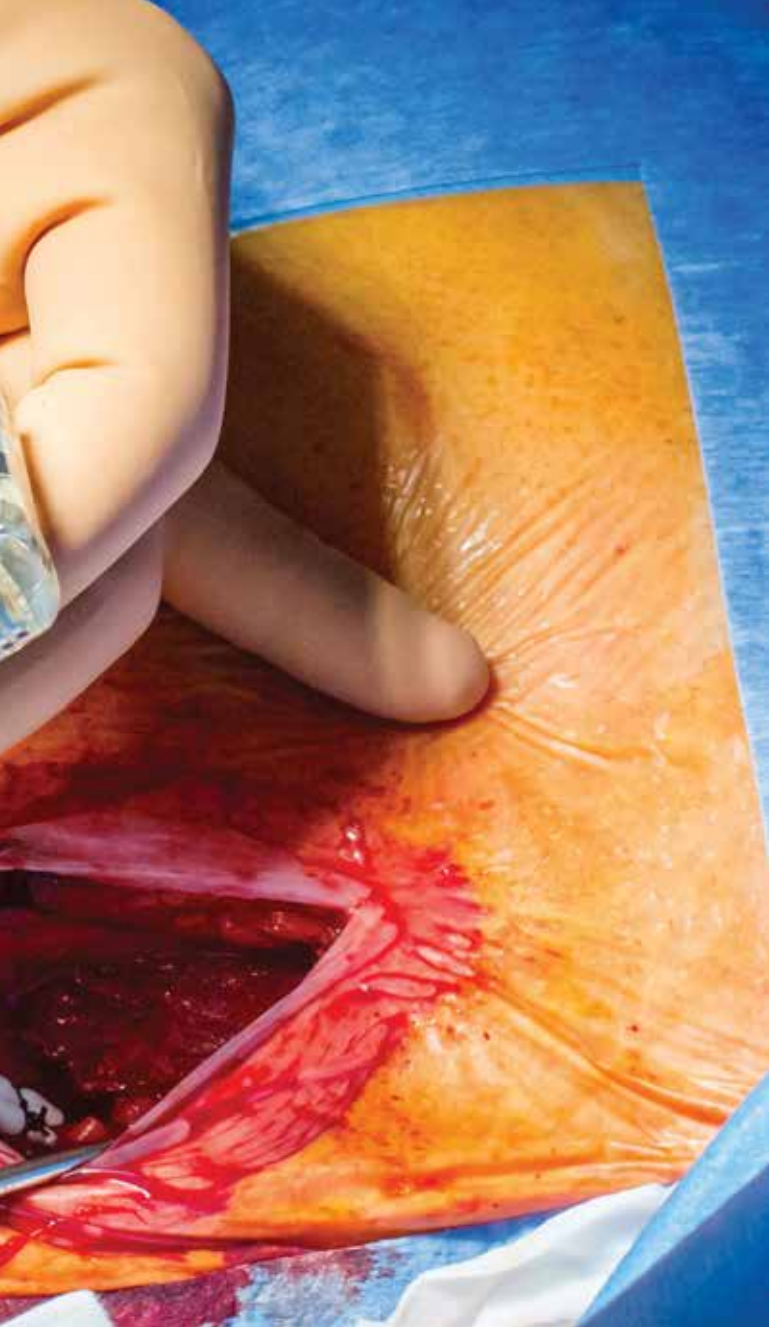
Although our ability to accurately predict sudden cardiac death is limited, clinical studies have identified a group of patients who are at higher risk and derive a mortality benefit from prophylactic ICD insertion.[3,4] Inserting a device before the patient has a cardiac arrest is referred to as primary prevention.

Impaired left ventricular systolic function, measured by left ventricular ejection fraction (LVEF), has been found to be a major predictor of sudden cardiac death.[5] Patients with poor LVEF (≤35%) are recommended to receive an ICD. These patients often have ischaemic heart disease or dilated cardiomyopathy.

Other indications for ICDs include genetic disorders such as:

- hypertrophic cardiomyopathy
- long QT and Brugada syndromes, where left ventricular function is usually preserved but there may be a high risk of fatal arrhythmia.

As our ability to predict which patients will develop a fatal



arrhythmia is limited, many ICDs must be implanted to save one life. Nevertheless, they are highly cost effective.

Secondary prevention

Patients resuscitated from a cardiac arrest who do not have an identifiable reversible cause (such as severe electrolyte disturbance or drug side effects) have an ongoing high mortality risk, even with surgical and medical management. These patients will benefit from an ICD. Similarly, patients with symptomatic ventricular tachycardia associated with syncope have high ongoing mortality, and ICDs have shown an important mortality benefit.[6]

Types of ICD

There are three types of ICD: single-, dual- and three-lead devices. All ICDs have a shock lead placed within the right ventricle; this can also deliver antitachycardia pacing and pacing to treat bradycardia after shock delivery. For some patients a single lead is adequate. Other patients benefit from the addition of a lead in the right atrium (dual-chamber or dual-lead ICD), particularly if they require pacing support (Figure 1).

A third specific group of patients benefits from a three-lead device that provides cardiac resynchronisation therapy (CRT) as well as defibrillation (referred to as a CRT-D device). These patients usually have heart failure (see below). The third lead is placed via the coronary sinus vein to pace the left ventricle. Simultaneous pacing of the right and left ventricles can improve the contractile function of the left ventricle. Three-lead systems thus have (Figures 2a and b):

- a lead in the right ventricle (to pace and deliver an intracardiac shock)
- a lead in the right atrium (if the patient is in sinus rhythm, to allow timing of ventricular pacing to coincide with maximal atrial contraction)
- a lead within the distal coronary sinus veins to pace the left ventricle.

Key points

- **Implantable cardioverter defibrillators (ICDs) are very successful at reducing sudden death in high-risk patients; all ICDs also have a pacemaker function.**
- **Patients with structural heart disease or poor left ventricular systolic function and syncope require urgent cardiological assessment.**
- **Patients with poor left ventricular function should be referred for prophylactic ICD assessment.**
- **Patients with an ICD require regular cardiological review.**
- **Patients with impaired left ventricular systolic function, symptomatic heart failure on optimal medical treatment and broad QRS complexes (≥120 ms) and left bundle branch block should be considered for cardiac resynchronisation therapy.**

Indications for cardiac resynchronisation therapy

Indications for CRT include:

- symptomatic shortness of breath (New York Heart Association [NYHA] classes II to IV dyspnoea) despite optimal medical treatment with diuretics, beta blockers, ACE inhibitors and spironolactone
- a broad QRS complex (≥120 ms or three small squares on an ECG recording)
- left bundle branch block morphology on ECG
- impaired left ventricular systolic function with LVEF ≤35%.

As patients who meet the criteria for CRT because of poor ventricular function also have a high risk of sudden death, they are often recommended to receive a CRT-D rather than just a CRT device. CRT-D devices both improve symptoms through their biventricular pacing effects and reduce sudden death through defibrillation.

CRT reduces both mortality and morbidity over and above medical treatment in patients with heart failure and is an adjunct to optimal therapy. However, heart failure symptoms do not improve

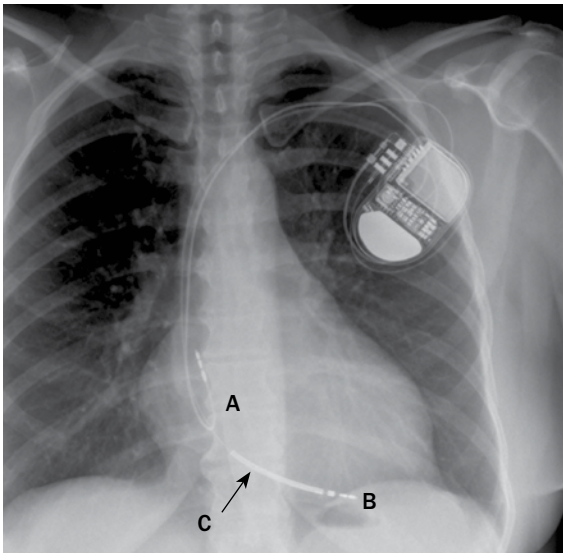


Figure 1. Chest x-ray showing an implanted dual-lead cardioverter defibrillator, with the generator in the left prepectoral area, a lead in the right atrium (A) and the pacing/shock lead at the right ventricular apex (B). The shock coil is highlighted (C).

in up to 30% of patients, referred to as non-responders. The reasons for nonresponse to CRT are complex and not fully understood. Despite much research it has proved difficult to accurately identify patients who will not benefit from CRT before device implantation. Nevertheless, CRT has been one of the major advances in heart failure management in the past 15 years for selected patients.

Mode of action of ICDs

An ICD contains a battery, a capacitor to deliver the shock and software to detect the onset of ventricular fibrillation or ventricular tachycardia. The lead positioned within the right ventricle constantly monitors the underlying heart rhythm. When ventricular fibrillation or tachycardia begins, the ICD determines onset and delivers pre-programmed therapies, usually set by the implanting physician and often individualised for the patient.

For example, for ventricular fibrillation a defibrillating shock is given (Figure 3). If the rhythm is slower then it may be possible to terminate the arrhythmia using pacing protocols, which are painless and often not felt by patients. The ICD detects a change in heart rate from sinus rhythm and applies a short sequence of antitachycardia pacing via the shock lead (Figure 4). Although antitachycardia pacing can successfully terminate many episodes of ventricular tachycardia, when it is not successful a shock is given.

Overall, ICDs are highly successful at terminating ventricular arrhythmias and are life saving.

Device implantation

ICDs are implanted in a similar manner to pacemakers. A lead is always positioned in the right ventricle, through which a shock can be delivered to the heart. This lead is larger than a pacing lead to accommodate a specialised coil from which the shock is delivered. The generator is implanted under the skin in the deltopectoral area, usually on the left side of the chest but sometimes on the right. Implantation takes 30 to 60 minutes for a single-lead device, longer for a two- or three-lead system. During implantation, the ICD can be tested under anaesthesia by inducing ventricular fibrillation and allowing the device to deliver an intracardiac shock. This assesses whether the ICD correctly senses ventricular fibrillation and delivers enough shock energy to convert the rhythm to sinus. Increasingly, this is not necessary as the devices are so reliable.

Complications of ICDs

Acute and chronic complications

Acute complications of ICD implantation are similar to those for cardiac pacemaker implantation. These include pneumothorax (1%), infection and lead problems, which include a small risk of the lead perforating the myocardium or displacing after implantation requiring lead re-positioning. However, a chronic complication of ICDs, unlike pacemakers, is inappropriate delivery of shocks for sinus tachycardia or atrial arrhythmias, most commonly atrial fibrillation. Despite sophisticated detection algorithms, ICDs can fail to differentiate ventricular arrhythmia from atrial arrhythmia with a rapid ventricular rate or sometimes from sinus tachycardia. This can be highly problematic as these shocks are painful and patients are often conscious at the time. Psychological problems are common, and counselling plays an important role.

Uncommonly, ICDs have suffered from manufacturing problems, and in the recent past premature lead failure has been a significant issue. Under normal circumstances, leads rarely fail. Batteries need replacement every five to eight years.

Many patients with an ICD also take concomitant antiarrhythmic therapy, which helps to reduce ICD usage.

Impact on activity and quality of life

ICDs can have a range of effects on patients' activities and quality of life, as follows.

- Psychological issues. Implantation of an ICD is a major decision. Having an ICD constantly reminds patients that they have a life-threatening condition and, although many are reassured by the technology, in some the device can induce severe anxiety. If this is the case then psychological counselling may be necessary.
- Driving. If the device has been implanted following a cardiac arrest or the patient has experienced sudden syncope then driving is suspended for six months. If a patient receives an appropriate shock for ventricular arrhythmia not associated with syncope then driving is suspended for four weeks. Drivers who have an ICD implanted are permanently disqualified from holding a commercial or passenger licence (see *Medical Standards for Licensing*).[7]
- Occupation. Patients should avoid occupations that expose them to high-density electric currents, such as electric arc welding.

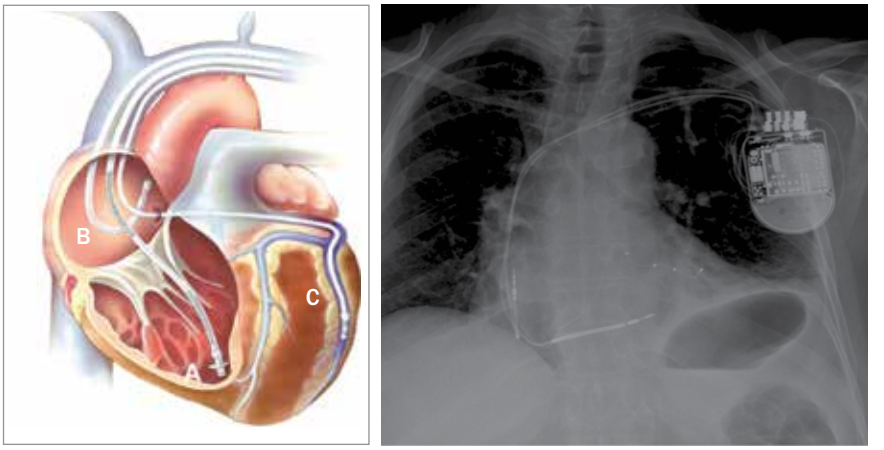
- Exercise. There is no specific exercise that should be avoided by patients with an ICD. Any limitations relate to the underlying cardiac pathology.
- Mobile telephones. Patients are recommended to use their mobile telephone in the ear on the opposite side of the body to the ICD as telephone signals can occasionally be sensed by the ICD.
- Microwave ovens. Patients can safely activate a microwave oven but should stand back at least one metre while the oven is active as microwave radiation close to the oven can interfere with the ICD.

Defibrillator removal

The presence of infection mandates removal of all parts of the ICD (i.e. leads and generator). Lead extraction carries a small but significant risk. Nowadays leads are removed percutaneously, which usually involves a laser-cutting device to extract the leads from the myocardium and carries an overall mortality of around 1 to 3%. All ICD generators must be removed after death if the patient is to be cremated because of the risk of the device exploding.

Monitoring of patients with ICDs

All patients with an ICD require regular clinical and device monitoring. The ICD can now be monitored remotely via mobile telephone or landline. A wealth of data can be obtained on a daily basis, including heart rhythm and rate, lead and battery integrity and occurrence of arrhythmia. In some cases, this monitoring allows treatment to be altered pre-emptively before the patient presents with a clinical problem.



Figures 2a and b. Positions of the three leads in a cardiac resynchronisation therapy – defibrillation system. a. A pacing/shock lead is positioned in the right ventricle (A), a second lead is positioned in the right atrium (B) and a third lead under the left ventricle via the coronary sinus vein (C). b. Chest x-ray showing the generator and lead positions.

Figure 2a © 2015 Medtronic. Used with permission of Medtronic Australasia Pty Ltd.

The role of the GP

GPs have a role in referring patients for consideration of ICD therapy. Patients with poor left ventricular function should be assessed for a prophylactic ICD. Those with structural heart disease or poor left ventricular systolic function and syncope require urgent cardiological assessment. Those with impaired left ventricular systolic function, symptomatic heart failure on optimal medical treatment and with broad QRS complexes (≥120 ms) and left bundle branch block should be considered for CRT.

All patients with an ICD require regular cardiological review. In addition, many patients with an ICD have advanced structural heart disease and require close follow up from their GP. A small percentage of patients have normal heart structure with a cardiac electrical fault alone (usually genetic) and require less follow up. Patients with severe left ventricular dysfunction are usually taking a number of medications and will need regular monitoring of renal function. Patients taking amiodarone require liver and thyroid function tests every four months and an annual chest x-ray.

Patients with an ICD who receive repeated shocks from the device require urgent referral to hospital or, if indicated, their supervising cardiologist. Patients with symptoms and signs of developing heart failure require prompt intervention and referral. Some patients may require psychological and social support, particularly when recurrent shocks have been an issue.

Risk factor modification such as smoking cessation, weight reduction for obesity and strict control of diabetes are strongly advised,

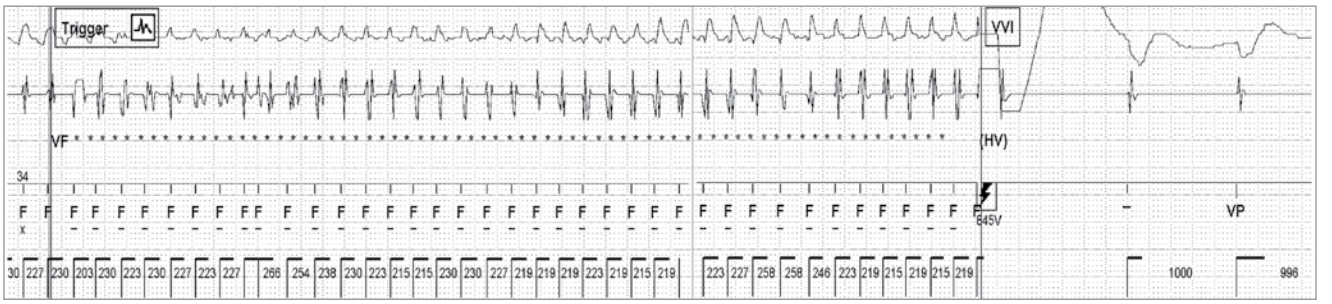


Figure 3. An internal electrogram downloaded from an implanted cardioverter defibrillator, showing an episode of ventricular fibrillation (VF) that was correctly detected. The defibrillator charged up over 8 to 10 seconds and then delivered a shock (HV, high voltage), which reverted the rhythm to ventricular pacing (VP). The numbers in the bottom line are the intervals between detected heart beats in milliseconds.

Websites with useful information about cardiac arrhythmias

- **Arrhythmia Alliance**
  www.heartrhythmcharity.org.uk
- **Arrhythmia Alliance Australia**
  www.aa-international.org/au
- **Heart Rhythm Society**
  www.hrsonline.org

as are identification and management of obstructive sleep apnoea.

Websites with useful information abut cardiac arrhythmias are listed in the Box.

Future trends

Subcutaneous ICDs have been developed that do not require an intracardiac lead (Figure 5). The generator is placed under the subcutaneous tissue over the left rib cage, with a shock lead under the skin. As there is no intracardiac lead, a pacing function for bradycardia is not possible. Initial studies have proven the benefit of these ICDs, and large-scale clinical trials are currently underway.[8]

Miniaturised CRT devices are currently under investigation to pace the left ventricle, either via the pericardium or placed directly into the left ventricular endocardium. In the future, it is likely that pacing and shocking the heart will not involve direct placement of a lead within the endocardium.

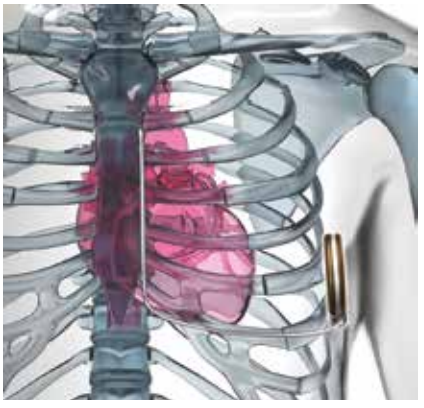


Figure 5. Position of a subcutaneous implantable cardioverter defibrillator. The generator is placed under the subcutaneous fat layer in the lateral chest wall, with a shock coil tunnelled under the skin over the sternum.

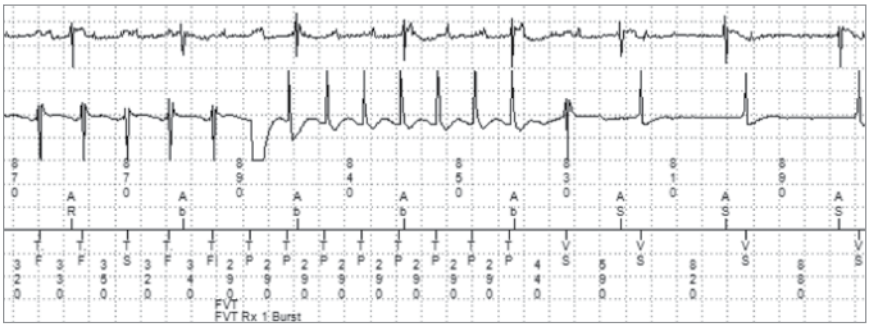


Figure 4. An internal electrogram downloaded from an implanted cardioverter defibrillator, showing stable ventricular tachycardia (left), which was terminated by a burst of rapid ventricular antitachycardia pacing (centre), after which the rhythm reverted to sinus rhythm (right). Antitachycardia pacing is painless and often not noticed by patients. The annotations below the ECG strip indicate the actions of the defibrillator: TF = tachycardia fast; TS = tachycardia sensed; FVT = fast ventricular tachycardia; TP = ventricular antitachycardia pacing; and VS = ventricular sensing, confirming the tachycardia was terminated. The numbers in the bottom row indicate the intervals between detected heart beats in milliseconds.

Conclusion

Sudden cardiac death remains a significant health issue worldwide. Clinical studies have confirmed that patients who have survived a cardiac arrest from a nonreversible cause and those with significant left ventricular impairment gain a mortality benefit from an ICD. These devices have proved life saving and are cost effective. Patients with symptomatic heart failure and broad QRS complexes also derive a long-term morbidity and mortality benefit from CRT. At-risk patients should be referred to an electrophysiologist for assessment. Technological advances will help increase the number of patients who will benefit from these devices. CT

References

1. Doolan A, Semsarin C, Langolis N. Med J Aust 2004; 180: 110-112.
2. Nichols M, Peterson K, Alston L, Allender S. Australian heart disease statistics 2014. Melbourne: National Heart Foundation of Australia, 2014. Available online at: http://www.heartfoundation.org.au/information-for-professionals/data-and-statistics/Pages/default.aspx (accessed September 2015).
3. Barold SS, Guglin M, Herweg B. Indications for implantable defibrillator therapy for the primary prevention of sudden death in patients with left ventricular dysfunction and narrow QRS. J Innov Cardiac Rhythm Manage 2012; 3: 1006-1009.
4. Moss AJ; MADIT-II. MADIT-II: substudies and their implications. Card Electrophysiol Rev 2003; 7: 430-433.
5. Russo A, Stainback R. Appropriate use criteria for implantable cardioverter defibrillators and cardiac resynchronisation therapy. Heart Rhythm 2013; 10: e11-e58.
6. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. N Engl J Med 1996; 335: 1933-1940.
7. Austroads, National Transport Commission Australia. Assessing fitness to drive for commercial and private vehicle drivers. Medical standards for licensing and clinical management guidelines: a resource for health professionals in Australia. 4th ed. Sydney: Austroads; 2012 (updated 2014). Available online at: https://www.onlinepublications.austroads.com.au/downloads/AP-G56-13 (accessed September 2015).
8. Weiss R, Knight BP, Gold M, et al. Safety and efficacy of a totally subcutaneous implantable cardioverter defibrillator. Circulation 2013; 128: 944-953.

Further reading

Bigger JT Jr, Whang W, Rottman JN, et al. Mechanisms of death in the CABG Patch trial: a randomized trial of implantable cardiac defibrillator prophylaxis in patients at high risk of death after coronary artery bypass graft surgery. Circulation 1999; 99: 1416-1421.

Kaye G, Furniss S, Lemery R. Fast facts: cardiac arrhythmias. 2nd ed. Oxford, UK: Health Press; 2013.

Moss AJ. MADIT-I and MADIT-II. J Cardiovasc Electrophysiol 2003; 14(9 Suppl): S96-S98.

Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002; 346: 877-883.

Nanthakumar K, Epstein AE, Kay GN, Plumb VJ, Lee DS. Prophylactic implantable cardioverter-defibrillator therapy in patients with left ventricular systolic dysfunction: a pooled analysis of 10 primary prevention trials. J Am Coll Cardiol 2004; 44: 2166-2172.

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