# Automatic Implantable Cardioverter/Defibrillator: An Overview

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## Introduction

Sudden cardiac death is one of the leading modes of death in the United States [1,2]. The majority of these episodes are due to malignant ventricular tachy arrythmias. Primary prevention of these arrhythmias by the elimination of risk factors associated with heart disease is not yet at hand [3]. Depending upon the availability of rescue services 25-37% of the victims of out of hospital sudden cardiac death are resuscitated and discharged home [4]. Unfortunately the recurrence rate of malignant arrhythmias in survivors of cardiac arrest is high and is reported 28-47% in 2 years [4,5]. Electrophysiological studies have demonstrated that a significant percentage of these arrhythmias are resistant to conventional and investigational anti-arrhythmic drugs [6,7,8]. Antitachycardia pacing devices had been used in an attempt to terminate ventricular tachycardias in patients with severely impaired left ventricular function, but were found to be inappropriate because these did not terminate the tachycardia on every occasion [9] or were responsible for tachycardia acceleration [10, 11]. Though in one study [12] an intelligent pacemaker (orthocor) implanted in carefully selected patients with ventricular and supraventricular tachycardias, despite some shortcomings, proved quite successful in recognising and terminating these dysrhythmias. Catheter ablation of ventricular tachycardia foci is still experimental and far less successful [1,3]. Direct surgical ablation of arrhythmias is possible in patients with the appropriate substrate (a discrete scar or LV aneurysm) and monomorphic ventricular tachycardia, allowing for endocardial mapping. The success rate with this procedure is reported to be 80%, but substantial morbidity and mortality exists with this extensive procedure [14].

Fig. No 1

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The "Automatic Implantable Cardioverter Defibrillator" (AICD) is a device capable of automatically recognising and promptly terminating lethal ventricular tachyarrhythmias. It has been shown to result in a dramatic reduction in arrhythmic mortality in a population at high risk from recurrent cardiac arrest [15,1,6 17]. The currently available AICD is a result of an evolutionary development process begun by Mirowski and colleagues over one and a half decades ago [18,19,20]. On 4th February 1980 the first implant in human was performed at John Hopkins Hospital, Baltimore [21].

## How Do These Devices Work?

Initially this automatic implantable defibrillator was designed for automatic conversion of ventricular fibrillation (including sinusoidal ventricular tachycardia) only. Detection of ventricular fibrillation was undertaken by an algorithm known as "the probability density function (PDF) [19]. In probability density function, the filtered signal of an intracardiac electrogram is analysed to measure the time which the input signal had spent near the base line, called zero peak. During sinus rhythm, the electrocardiogram signal spends most of the time close to the base line, thus the zero peak is highest. While on the other hand during ventricular fibrillation and other very severe tachy arrhythmias, these isoelectric segments almost disappear, leading to the absence of probability density zero peak for the filtered electrocardiogram signal. Using this algorithm one could discriminate between sinus rhythm and ventricular fibrillation (Fig. 1, 2). As a practical consequence ventricular tachycardia with less than 240-220
beats per minute were subject to rejection by the probability density function sensing circuitory.

However, it became apparent that most survivors of cardiac arrest initially had hypotensive ventricular

Fig. 1

tachycardia with rates less than 240 beats per minute [6, 22]. Ventricular fibrillation was only observed at a later stage, if at all. Therefore, extensive design modifications were undertaken and was accomplished in part through the development of a reliable rate detector system using a bipolar ventricular lead, which also served for R wave synchronisation of the delivered shock.

Rate of rate change is also utilised for detection of malignant arrhythmias. On exercise individuals increase their heart rates in a linear fashion (a physiologi-

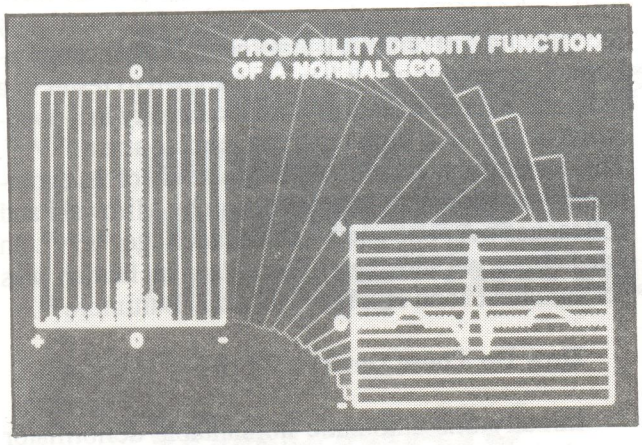


Fig. No. 1

cal response) whereas the onset of a pathological tachycardia increases the rate suddenly. The anti-tachycardia/defibrillator devices are currently being designed to recognise this.

## AICD Characteristics

The AICD was originally manufactured by INTEC Systems, but recently acquired by Cardiac Pacemaker Inc., St. Paul, MN, USA. The unit weighs 292 grams and contains lithium batteries capable of charging 2 capacitators to approximately 700 volts in 7-9 seconds. The device requires 5-15 seconds to diagnose the malignant arrhythmia and an additional 5-15 seconds to top up the capacitators. The recognition of serious ventricular arrhythmia results in the delivery of a truncated exponential pulse of 25 joules, 10-30 seconds following onset of arrhythmia (Fig 3). Should the initial shock not convert the arrhythmia a second shock of 30 joules will be given after another 10-30 sec. A third and fourth shock will be delivered if thearrhythmia persists. The unit will give no further shock unless it recognises a rhythm other than VT or VF for 30 sec. Successful defibrillation after this time period may be associated with significant cerebral impairment.

The pulse generator can be de-activated and re-activated externally with the proper use of a magnet. Using a magnet and detector device (AIDCHECK-B) the number of delivered pulses and the charging time

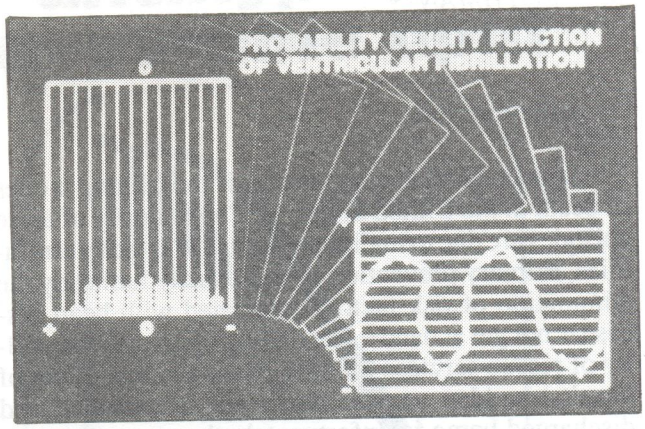


Fig. No. 2

of capacitators can be measured. From this data one can decide about elective replacement of the device. Expected life of batteries is 3 years or a total of 100 discharges. It is very expensive technology; approximately £10,000 per device, compared to a permanent pacemaker for approximately £ 500, the leads may cost another £2,000. However, considering the survival figures, this is a fairly inexpensive form of therapy, when compared with other health care costs. For example, in acute myocardial infarction it is considered clinically efficacious to treat with angioplasty and thrombolysis which costs approximately $7-10,000 per year of additional life achieved.

## Lead Systems

Two pairs of electrodes form part of the implantable defibrillator system (Fig. 3).

One pair of transcardiac electrodes is used both for defibrillation and acquisition of signals for probabilitydensity function determination. Two basic lead configurations are used for this:

1. Spring-Patch, consisting of a transvenous superior vena caval spring electrode as anode and an apical or lateral left ventricular patch electrode as the cathode, and,

therapy. The patients with spontaneous recurrences of sustained ventricular tachyarrhythmias despite anti-arrhythmic theraphy are appropriate candidates for the device regardless of whether their arrhythmias are inducible or not at electrophysiological study [26].

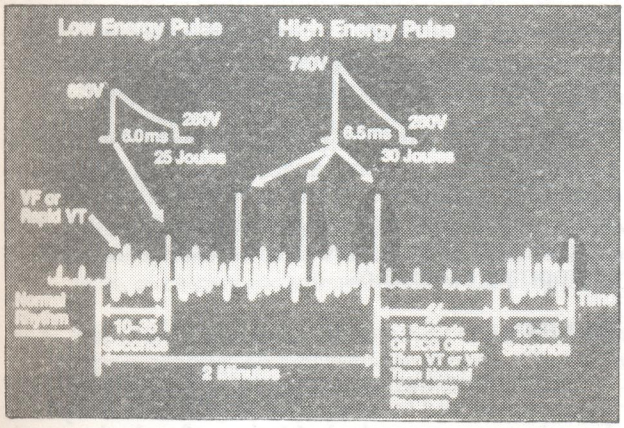


Fig. No. 3

Patients undergoing attempted surgical ablation of ventricular arrhythmias should also be considered for implantation of the AICD or at least the defibrilating lead system[27].

Implantation Techniques

Implantation techniques vary depending upon which lead system is selected, history of previous cardiac operation and whether some other cardiac surgical procedure is also being carried out at the time of implant. Two pioneer groups in this procedure, i.e., the John Hopkins group and the Stanford group, have differences in surgical approaches which largely reflect the personal experiences and preferences of the implanting surgical teams.

If a spring-patch e lectrode system is to be implanted, the superior vena caval spring electrode may be introduced via an internal jugular vein [21,28] innominate or thymic vein [28]. However, a subcutaneous approach through the subclavian vein is now the favoured approach [20, 24, 28]. The superior vena caval electrode is positioned with its tip at the superior vena cava/right atrial junction [28]. Some investigators have modified the spring electrode positioning with the tip located more towards the mid right atrium with approximately half the electrode above the superior vena cavaright atrial junction and approximately half below the junction [28]. The proximal portion of the spring electrode is routed intra-pleurally [16,28,29] or subcutaneously [29] into the left para-umbilical area where the subcutaneous generator pouch is formed.

Implant of the apical patch electrode was initially accomplished through a left anterior thoracotomy or through median sternotomy, the apical patch being placed extrapericardially [28]. Later in 1981 the John Hopkins group described the subxiphoid approach which obviated the need for a major thoracic operation for single patch placement [30]. The apical patch with this approach is placed intrapericardially. Candidates for this approach include patients who have not had a previous cardiac operation and in whom a concomitant open heart procedure is not indicated. Anterior thoracoto-my procedure is favoured for patients who have had previous cardiac operations and by Stanford group even for patients without previous cardiac surgical procedure[20, 29, 31]. The median sternotomy approach is reserved for patients undergoing concomitant cardiac surgical procedure[30]. When using the patch-patch electrode system, the placement of two patch electrodes is possible with subxiphoid approach, but with some difficulty[32]. However, it can be accomplished somewhat more easily with subcostal approach [33]. Left anterior thoracotomy provides an excellent exposure and maximises the options for patches and myocardial screw in electrode placements, particularly in patients with large, severely scarred ventricles[32].

Sensing leads may be placed in the right ventricle-transvenously through the subclavian vein[16] or internal jugular vein [28] (bipolar transvenous endocardial lead) or screwed in directly into the left ventricular myocardium[33] (two unipolar screw in leads). It is probably desirable to avoid introducing the endocardial lead through the same vessel as the spring lead, since subclavian thrombosis has been described in these circumstances [34]. Implant of the left ventricular screw in leads avoids the need for intraoperative fluoroscopy, generally results in larger ventricular signals than a right ventricular endocardial lead and obviates the need of tunnelling of the transvenous lead from the subclavian area to internal pulse generator pocket.

**Special Consideration**

All potential candidates for AICD implant must undergo a complete pre-operative cardiac evaluation including cardiac catheterisation with coronary angiography, exercise stress testing, electrophysiological study and serial drug testing[27]. AICD model selection is determined by analysis of the results of this cardiac evaluation.

An extensive intra-operative electrophysiological procedure is also needed to measure defibrillation

threshold and gives opportunity to assess for arrhythmia acceleration following cardioversion which is reported to occur following 10-30% of shocksdes pite local R wave synchronisation and regardless of energy level delivery[29]. Possibility of ventricular tachycardia acceleration by shocks confirms the absolute requirements for back-up defibrillation capability of any automatic cardioverter. Winkle et al has emphasised that since the AICD pulse generator stores only enough energy for approximately 100 shocks and further, since the shocks are not pleasant, patients must be selected who would not receive a large number of shocks in a short time[31]. Concomitant drug therapy may reduce the frequency of recurrent episodes to a level that can be reasonably managed by the device. On the other hand, implantation of AICD permits avoidance of potentially toxic anti-arrythmic therapy in about a third of patients who would otherwise require such therapy [16]. Amiodarone therapy is independently associated with significant increase in defibrillation threshold [23] so if a patient with an implanted defibrillator is commenced on Amiodarone therapy, repeat testing is mandatory to ensure that the device is still capable of achieving defibrillation.

Unwanted shocks may occur. The currently available AICD has notelemetry or memory function to permit documentation of patients rhythm at the time of shock. Although shocks that occur in the absence of symptoms are not always spurious, inappropriate shocks have been reported to occur with sinus tachycardia, atrial fibrillation and paroxysmal supra-ventricular tachycardia[31]. When shocks occur without symptoms of recurrent arrhythmia, investigations should include assessment of maximal heart rate with exercise (to ensure that sinus tachycardia is not recognised as ventricular tachycardia, especially with AID B). Cardiac rhythm should be assessed by continuous Holter monitoring to determine whether asymptomatic ventricular tachycardia is present. If these evaluations fail to reveal a cause, then the sensing system should be evaluated for lead fracture[35].

Patients with permanent pacemakers implanted deserve special mention. Pacemaker spikes of sufficient amplitude can result in both over and undercounting of the true ventricular rate[16]. The key to the majority of pacemaker-AICD interactions is the selection of a bipolar pacemaker electrode system and bipolar rate counting lead system with close interelectrode spacing alongwith orientation of bipolar pairs relative to one another. Devices with demand (VVI) pacing capabilities represent a welcome solution to this problem of device interaction.

Pacemaker failure to capture following internal defibrillation from an AICD may become a more prominent problem especially with the devices which have both pacing and defibrillating capabilities[36].

Further work will need to guarantee that back-up pacemaker system per se will be able to pace effectively post discharge. Pacemaker failure to caputre after an automatic defibrillator shock is suggested to be due to temporary increase in pacing thresho[37].

AICD implantation is associated with multiple physical, social and psychological alterations[38]. Therefore intensive education by medical and nursing staff in addition to intensive psychological counselling is needed to enable the patient and family to cope effectively with an implanted device of this nature.

Clearly for AICD implantation the patient must be a candidate for general anaesthesia and surgery required for installation of the device. Additionally, patients with markedly reduced life expectancy from concomitant illness (such as cancer) would not be appropriate candidates.

**Results**

Automatic implantable cardioverter/defibrillator is not considered to be a substitute for anti-arrhythmic drug therapy or surgical ablation of arrhythmogenic foci scine prevention of an arrhythmia is clearly preferred to the termination. However once it has occurred the device acts promptly. It can identify and correct potentially lethal ventricular tachyarrhythmias, leading to a substantial increase in one year survival in properly selected high risk patients. In one study there was an estimated 52% decrease in the total mortality rate in the year after implantation of the device[15]. In another study life table analysis revealed 12-month survival rate for sudden death in patients with this device who have had drug refractory ventricualr tachyarrhythmias to be 98.2%, proving the point that in their experience, survival with the implantation of AICD exceeded that with other forms of therapy[16]

Reid et al 17 has compared the mortality in patients receiving the first generation (AID) and 2nd generation (AICD) implantable devices. The mortality due to sudden cardiac death at one year in the original AID group was 10.6% while in AICD group it was 2%. These results showed improved survival in both the AID and AICD groups but even better results with AICD.

**Recent Developments**

A new generation of cardioverters (Telectronics Guardian 4201Cardioverters) was first implanted in February 1987 at Westmeal Hospital, NSW, Australia. It was fully programmable and incorporates bradycardia back-up via a standard VVI Telectronic pacemaker built in the defibrillator [39].

Development of a less invasive AICD system is a step closer to reality. A less invasive non-thoracotomy AICD system developed by CPI is under clinical evaluations[40]. In this system a tripolar intracardiac

defibrillating catheter was placed in the right ventricular apex and was used for sensing and shock delivery. The distal right ventricular electrode worked as the common cathode. The proximal superior vena caval/ right atrial electrode and the subcutaneous patch were cross connected with a y connector as dual anodes. Single 10 joule bidirectional shock was delivered during ventricular fibrillation which lead to successful defibrillation. Post-operative electrophysiological studies continued to demonstrate successful defibrillation of ventricular fibrillation with this electrode system.

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