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80

Implantable Defibrillators

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Edwin G. Duffin
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The implantable cardioverter defibrillator (ICD) is a therapeutic device that can detect ventricular tachycardia or fibrillation and automatically deliver high-voltage (750 V) shocks that will restore normal sinus rhythm. Advanced versions also provide low-voltage (5–10 V) pacing stimuli for painless termination of ventricular tachycardia and for management of bradyarrhythmias. The proven efficacy of the automatic implantable defibrillator has placed it in the mainstream of therapies for the prevention of sudden arrhythmic cardiac death.

The implantable defibrillator has evolved significantly since first appearing in 1980. The newest devices can be implanted in the patient's pectoral region and use electrodes that can be inserted transvenously, eliminating the traumatic thoracotomy required for placement of the earlier epicardial electrode systems. Transvenous systems provide rapid, minimally invasive implants with high assurance of success and greater patient comfort. Advanced arrhythmia detection algorithms offer a high degree of sensitivity with reasonable specificity, and extensive monitoring is provided to document performance and to facilitate appropriate programming of arrhythmia detection and therapy parameters. Generator longevity can now exceed 4 years, and the cost of providing this therapy is declining.

80.1 Pulse Generators

The implantable defibrillator consists of a primary battery, high-voltage capacitor bank, and sensing and control circuitry housed in a hermetically sealed titanium case. Commercially available devices weigh between 197 and 237 grams and range in volume from 113 to 145 cm³. Clinical trials are in progress on devices with volumes ranging from 178 cm³ to 60 cm³ and weights between 275 and 104 grams. Further size reductions will be achieved with the introduction of improved capacitor and integrated circuit technologies and lead systems offering lower pacing and defibrillation thresholds. Progress should parallel that made with antibradycardia pacemakers that have evolved from 250-gram, nonprogrammable, VOO units with 600- μ J pacing outputs to 26-gram, multiprogrammable, DDDR units with dual 25- μ J outputs.

Implantable defibrillator circuitry must include an amplifier, to allow detection of the millivolt-range cardiac electrogram signals; noninvasively programmable processing and control functions, to evaluate

the sensed cardiac activity and to direct generation and delivery of the therapeutic energy; high-voltage switching capability; dc-dc conversion functions to step up the low battery voltages; random access memories, to store appropriate patient and device data; and radiofrequency telemetry systems, to allow communication to and from the implanted device. Monolithic integrated circuits on hybridized substrates have made it possible to accomplish these diverse functions in a commercially acceptable and highly reliable form.

Defibrillators must convert battery voltages of approximately 6.5 V to the 600–750 V needed to defibrillate the heart. Since the conversion process cannot directly supply this high voltage at current strengths needed for defibrillation, charge is accumulated in relatively large ($\approx 85\text{--}120\mu\text{F}$ effective capacitance) aluminum electrolytic capacitors that account for 20–30% of the volume of a typical defibrillator. These capacitors must be charged periodically to prevent their dielectric from deteriorating. If this is not done, the capacitors become electrically leaky, yielding excessively long charge times and delay of therapy. Early defibrillators required that the patient return to the clinic periodically to have the capacitors reformed, whereas newer devices do this automatically at preset or programmable times. Improved capacitor technology, perhaps ceramic or thin-film, will eventually offer higher storage densities, greater shape variability for denser component packaging, and freedom from the need to waste battery capacity performing periodic reforming charges. Packaging density has already improved from 0.03 J/cm^3 for devices such as the early cardioverter to 0.43 J/cm^3 with some investigational ICDs. Capacitors that allow conformal shaping could readily increase this density to more than 0.6 J/cm^3 .

Power sources used in defibrillators must have sufficient capacity to provide 50–400 full energy charges ($\approx 34\text{ J}$) and 3 to 5 years of bradycardia pacing and background circuit operation. They must have a very low internal resistance in order to supply the relatively high currents needed to charge the defibrillation capacitors in 5–15 s. This generally requires that the batteries have large surface area electrodes and use chemistries that exhibit higher rates of internal discharge than those seen with the lithium iodide batteries used in pacemakers. The most commonly used defibrillator battery chemistry is lithium silver vanadium oxide.

80.2 Electrode Systems (“Leads”)

Early implantable defibrillators utilized patch electrodes (typically a titanium mesh electrode) placed on the surface of the heart, requiring entry through the chest (Fig. 80.1). This procedure is associated with approximately 3–4% perioperative mortality, significant hospitalization time and complications, patient discomfort, and high costs. Although subcostal, subxiphoid, and thoracoscopic techniques can minimize the surgical procedure, the ultimate solution has been development of fully transvenous lead systems with acceptable defibrillation thresholds.

Currently available transvenous leads are constructed much like pacemaker leads, using polyurethane or silicone insulation and platinum-iridium electrode materials. Acceptable thresholds are obtained in 67–95% of patients, with mean defibrillation thresholds ranging from 10.9–18.1 J. These lead systems use a combination of two or more electrodes located in the right ventricular apex, the superior vena cava, the coronary sinus, and sometimes, a subcutaneous patch electrode is placed in the chest region. These leads offer advantages beyond the avoidance of major surgery. They are easier to remove should there be infections or a need for lead system revision. The pacing thresholds of current transvenous defibrillation electrodes are typically

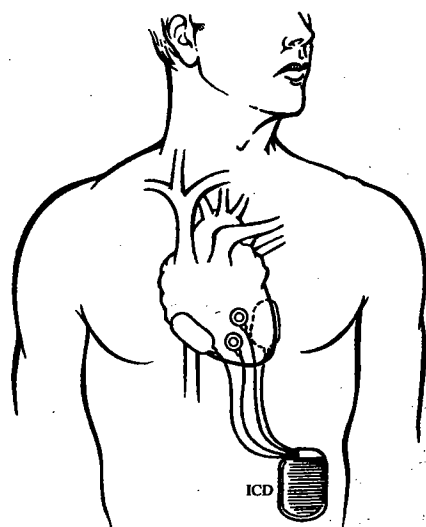


FIGURE 80.1 Epicardial ICD systems typically use two or three large defibrillating patch electrodes placed on the epicardium of the left and right ventricles and a pair of myocardial electrodes for detection and pacing. The generator is usually placed in the abdomen. (Copyright Medtronic, Inc. Used with permission.)

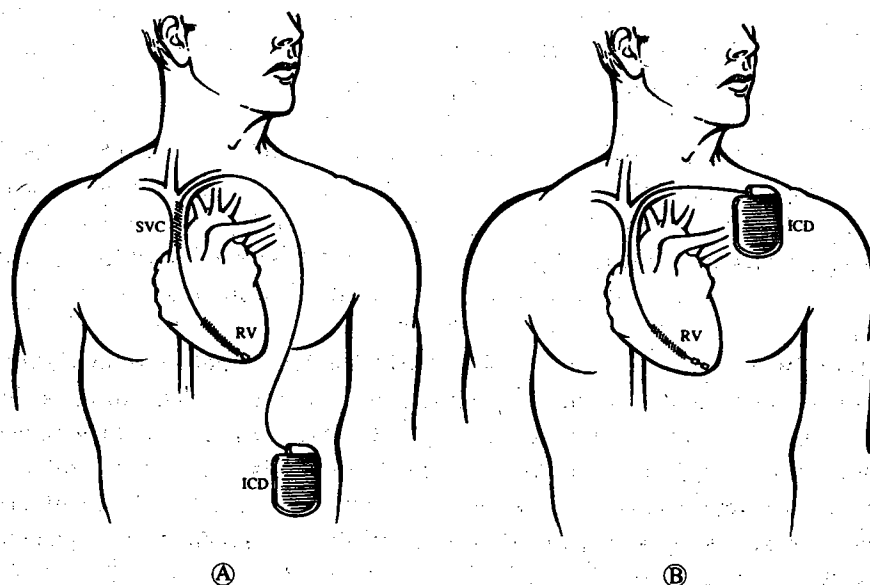


FIGURE 80.2 The latest transvenous fibrillation systems employ a single catheter placed in the right ventricular apex. In panel *a*, a single transvenous catheter provides defibrillation electrodes in the superior vena cava and in the right ventricle. This catheter provides a single pace/sense electrode which is used in conjunction with the right ventricular high-voltage defibrillation electrode for arrhythmia detection and antibradycardia/antitachycardia pacing (a configuration that is sometimes referred to as *integrated bipolar*). With pulse generators small enough to be placed in the pectoral region, defibrillation can be achieved by delivering energy between the generator housing and one high-voltage electrode in the right ventricle (analogous to unipolar pacing) as is shown in panel *b*. This catheter provided bipolar pace/sense electrodes for arrhythmia detection and antibradycardia/antitachycardia pacing. (Copyright Medtronic, Inc. Used with permission.)

0.96 ± 0.39 V, and the electrogram amplitudes are on the order of 16.4 ± 6.4 mV. The eventual application of steroid-eluting materials in the leads should provide increased pacing efficiency with transvenous lead systems, thereby reducing the current drain associated with pacing and extending pulse generator longevity.

Lead systems are being refined to simplify the implant procedures. One approach is the use of a single catheter having a single right ventricular low-voltage electrode for pacing and detection, and a pair of high-voltage defibrillation electrodes spaced for replacement in the right ventricle and in the superior vena cava (Fig. 80.2*a*). A more recent approach parallels that used for unipolar pacemakers. A single right-ventricular catheter having bipolar pace/sense electrodes and one right ventricular high-voltage electrode is used in conjunction with a defibrillator housing that serves as the second high-voltage electrode (Fig. 80.2*b*). Mean biphasic pulse defibrillation thresholds with the generator-electrode placed in the patient's left pectoral region are reported to be 9.8 ± 6.6 J ($n = 102$). This approach appears to be practicable only with generators suitable for pectoral placement, but such devices will become increasingly available.

80.3 Arrhythmia Detection

Most defibrillator detection algorithms rely primarily on heart rate to indicate the presence of a treatable rhythm. Additional refinements sometimes include simple morphology assessments, as with the probability density function, and analysis of rhythm stability and rate of change in rate.

The *probability density function* evaluates the percentage of time that the filtered ventricular electrogram spends in a window centered on the baseline. The rate-of-change-in-rate or *onset* evaluation discriminates sinus tachycardia from ventricular tachycardia on the basis of the typically gradual acceleration of sinus rhythms versus the relatively abrupt acceleration of many pathologic tachycardias. The *rate stability*

function is designed to bar detection of tachyarrhythmias as long as the variation in ventricular rate exceeds a physician-programmed tolerance, thereby reducing the likelihood of inappropriate therapy delivery in response to atrial fibrillation. This concept appears to be one of the more successful detection algorithm enhancements.

Because these additions to the detection algorithm reduce sensitivity, some defibrillator designs offer a supplementary detection mode that will trigger therapy in response to any elevated ventricular rate of prolonged duration. These *extended-high-rate* algorithms bypass all or portions of the normal detection screening, resulting in low specificity for rhythms with prolonged elevated rates such as exercise-induced sinus tachycardia. Consequently, use of such algorithms generally increases the incidence of inappropriate therapies.

Improvements in arrhythmia detection specificity are desirable, but they must not decrease the excellent sensitivity offered by current algorithms. The anticipated introduction of defibrillators incorporating dual-chamber pacemaker capability will certainly help in this quest, since it will then be possible to use atrial electrograms in the rhythm classification process. It would also be desirable to have a means of evaluating the patient's hemodynamic tolerance of the rhythm, so that the more comfortable pacing sequences could be used as long as the patient was not syncopeal yet branch quickly to a definitive shock should the patient begin to lose consciousness.

Although various enhanced detection processes have been proposed, many have not been tested clinically, in some cases because sufficient processing power was not available in implantable systems, and in some cases because sensor technology was not yet ready for chronic implantation. Advances in technology may eventually make some of these very elegant proposals practicable. Examples of proposed detection enhancements include extended analyses of cardiac event timing (PR and RR stability, AV interval variation, temporal distribution of atrial electrogram intervals and of ventricular electrogram intervals, timing differences and/or coherency of multiple ventricular electrograms, ventricular response to a provocative atrial extrastimuli), electrogram waveform analyses (paced depolarization integral, morphology analyses of right ventricular or atrial electrograms), analyses of hemodynamic parameters (right-ventricular pulsatile pressure, mean right atrial and mean right ventricular pressures, wedge coronary sinus pressure, static right ventricular pressure, right atrial pressure, right ventricular stroke volume, mixed venous oxygen saturation and mixed venous blood temperature, left ventricular impedance, intramyocardial pressure gradient, aortic and pulmonary artery flow), and detection of physical motion.

Because defibrillator designs are intentionally biased to overtreat in preference to the life-threatening consequences associated with failure to treat, there is some incidence of inappropriate therapy delivery. Unwarranted therapies are usually triggered by supraventricular tachyarrhythmias, especially atrial fibrillation, or sinus tachycardia associated with rates faster than the ventricular tachycardia detection rate threshold. Additional causes include nonsustained ventricular tachycardia, oversensing of *T* waves, double counting of *R* waves and pacing stimuli from brady pacemakers, and technical faults such as loose lead-generator connections or lead fractures.

Despite the bias for high detection sensitivity, undersensing does occur. It has been shown to result from inappropriate detection algorithm programming, such as an excessively high tachycardia detection rate; inappropriate amplifier gain characteristics; and electrode designs that place the sensing terminals too close to the high-voltage electrodes with a consequent reduction in electrogram amplitude following shocks. Undersensing can also result in the induction of tachycardia should the amplifier gain control algorithm result in undersensing of sinus rhythms.

80.4 Arrhythmia Therapy

Pioneering implantable defibrillators were capable only of defibrillation shocks. Subsequently, synchronized cardioversion capability was added. Antibradycardia pacing had to be provided by implantation of a standard pacemaker in addition to the defibrillator, and, if antitachycardia pacing was prescribed, it

was necessary to use an antitachycardia pacemaker. Several currently marketed implantable defibrillators offer integrated ventricular demand pacemaker function and tiered antiarrhythmia therapy (pacing/cardioversion/defibrillation). Various burst and ramp antitachycardia pacing algorithms are offered, and they all seem to offer comparably high success rates. These expanded therapeutic capabilities improve patient comfort by reducing the incidence of shocks in conscious patients, eliminate the problems and discomfort associated with implantation of multiple devices, and contribute to a greater degree of success, since the prescribed regimens can be carefully tailored to specific patient needs. Availability of devices with antitachy pacing capability significantly increases the acceptability of the implantable defibrillator for patients with ventricular tachycardia.

Human clinical trials have shown that biphasic defibrillation waveforms are more effective than monophasic waveforms, and newer devices now incorporate this characteristic. Speculative explanations for biphasic superiority include the large voltage change at the transition from the first to the second phase or hyperpolarization of tissue and reactivation of sodium channels during the initial phase, with resultant tissue conditioning that allows the second phase to more readily excite the myocardium.

Antitachycardia pacing and cardioversion are not uniformly successful. There is some incidence of ventricular arrhythmia acceleration with antitachycardia pacing and cardioversion, and it is also not unusual for cardioversion to induce atrial fibrillation that in turn triggers unwarranted therapies. An ideal therapeutic solution would be one capable of preventing the occurrence of tachycardia altogether. Prevention techniques have been investigated, among them the use of precisely timed subthreshold stimuli, simultaneous stimulation at multiple sites, and pacing with elevated energies at the site of the tachycardia, but none has yet proven practical.

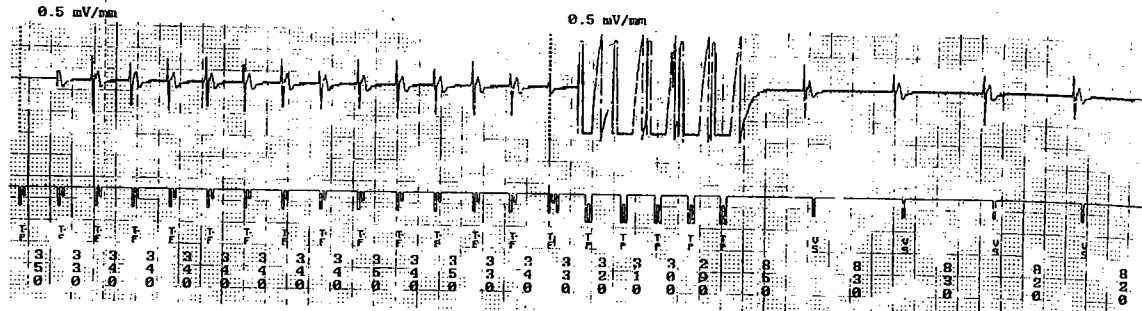
The rudimentary VVI antibradycardia pacing provided by current defibrillators lacks rate responsiveness and atrial pacing capability. Consequently, some defibrillator patients require implantation of a separate dual-chamber pacemaker for hemodynamic support. It is inevitable that future generations of defibrillators will offer dual-chamber pacing capabilities.

Atrial fibrillation, occurring either as a consequence of defibrillator operation or as a natural progression in many defibrillator patients, is a major therapeutic challenge. It is certainly possible to adapt implantable defibrillator technology to treat atrial fibrillation, but the challenge is to do so without causing the patient undue discomfort. Biphasic waveform defibrillation of acutely induced atrial fibrillation has been demonstrated in humans with an 80% success rate at 0.4 J using *epicardial* electrodes. Stand-alone atrial defibrillators are in development, and, if they are successful, it is likely that this capability would be integrated into the mainstream ventricular defibrillators as well. However, most conscious patients find shocks above 0.5 J to be very unpleasant, and it remains to be demonstrated that a clinically acceptable energy level will be efficacious when applied with transvenous electrode systems to spontaneously occurring atrial fibrillation. Moreover, a stand-alone atrial defibrillator either must deliver an atrial shock with complete assurance of appropriate synchronization to ventricular activity or must restrict the therapeutic energy delivery to atrial structures in order to prevent inadvertent induction of a malignant ventricular arrhythmia.

80.5 Implantable Monitoring

Until recently, defibrillator data recording capabilities were quite limited, making it difficult to verify the adequacy of arrhythmia detection and therapy settings. The latest devices record electrograms and diagnostic channel data showing device behavior during multiple tachyarrhythmia episodes. These devices also include counters (number of events detected, success and failure of each programmed therapy, and so on) that present a broad, though less specific, overview of device behavior (Fig. 80.3). Monitoring capability in some of the newest devices appears to be the equivalent of 32 Kbytes of random access memory, allowing electrogram waveform records of approximately 2-min duration, with some opportunity for later expansion by judicious selection of sampling rates and data compression techniques. Electrogram storage has proven useful for documenting false therapy delivery due to atrial fibrillation,

EPISODE DATA REPORT ----- Episode 1 of 1
 EPISODE TYPE: FVT
 TIME OF EPISODE: Oct 06, 1993 10:55:01 DURATION: 6 sec
 LAST THERAPY: FVT Rx 1, Successful
 AVERAGE CYCLE(ms): 340



MEDTRONIC 9760 PROGRAMMER 9858A001 Jul 22, 1992 10:08
 Copyright (c) Medtronic, Inc. 1992
 PCD 7219 Serial Number:
 COUNTER DATA REPORT Page 1 of 2

Date Interrogated: Jul 22, 1992 10:07:44
 Counters Last Cleared: Jul 22, 1992 00:16:29

TACHYCARDIA COUNTERS:	BRADYCARDIA PACING COUNTERS:	
VF: 4	TOTAL BRADY PULSES: 2572	
VTF: 0	RUNS OF >= 4 CONSECUTIVE PULSES: 6	
VT: 0		
UNSET CRITERION MET: 0	PREMATURE EVENTS COUNTERS:	
	ISOLATED PREMATURE EVENTS: 0	
	RUNS OF 2-4 PREMATURE BEATS: 0	

VF THERAPY	Rx1	Rx2	Rx3	Rx4
INITIATED:	4	1	0	0
SUCCESSFUL:	3	1	0	0
ABORTED:	0	0	0	0
INEFFECTIVE:	1	0	0	0
CONVERTED TO VT:	0	0	0	0
CONVERTED TO VTF:	0	0	0	0
UNDETERMINED:	0	0	0	0

MEDTRONIC 9760 PROGRAMMER 9858A001 Jul 22, 1992 10:08
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 PCD 7219 Serial Number:
 COUNTER DATA REPORT Page 2 of 2

VTF THERAPY	Rx1	Rx2	Rx3	Rx4
INITIATED:	0	0	0	0
REENTERED:	0	0	0	0
SUCCESSFUL:	0	0	0	0
ABORTED:	0	0	0	0
INEFFECTIVE:	0	0	0	0
CONVERTED TO VT:	0	0	0	0
CONVERTED TO VF:	0	0	0	0
UNDETERMINED:	0	0	0	0

VT THERAPY	Rx1	Rx2	Rx3	Rx4
INITIATED:	0	0	0	0
SUCCESSFUL:	0	0	0	0
ABORTED:	0	0	0	0
INEFFECTIVE:	0	0	0	0
CONVERTED TO VTF:	0	0	0	0
CONVERTED TO VF:	0	0	0	0
UNDETERMINED:	0	0	0	0

FIGURE 80.3 Typical data recorded by an implantable defibrillator include stored intracardiac electrograms with annotated markers indicating cardiac intervals, paced and sensed events, and device classification of events (TF = fast tachycardia; TP = antitachy pacing stimulus; VS = sensed nontachy ventricular event). In the example, five rapid pacing pulses convert a ventricular tachycardia with a cycle length of 340 ms into sinus rhythm with a cycle length of 830 ms. In the lower portion of the figure is an example of the summary data collected by the ICD, showing detailed counts of the performance of the various therapies (Rx) for ventricular tachycardia (VT), fast ventricular (VTF), and ventricular (VF). (Copyright Medtronic, Inc. Used with permission.)

lead fractures, and sinus tachycardia, determining the triggers of arrhythmias; documenting rhythm accelerations in response to therapies; and demonstrating appropriate device behavior when treating asymptomatic rhythms.

Electrograms provide useful information by themselves, yet they cannot indicate how the device interpreted cardiac activity. Increasingly, electrogram records are being supplemented with event markers that indicate how the device is responding on a beat-by-beat basis. These records can include measurements of the sensed and paced intervals, indication as to the specific detection zone an event falls in, indication of charge initiation, and other device performance data.

80.6 Follow-up

Defibrillator patients and their devices require careful follow-up. In one study of 241 ICD patients with epicardial lead systems, 53% of the patients experienced one or more complications during an average exposure of 24 months. These complications included infection requiring device removal in 5%, postoperative respiratory complications in 11%, postoperative bleeding and/or thrombosis in 4%, lead system migration or disruption in 8%, and documented inappropriate therapy delivery, most commonly due to atrial fibrillation, in 22%. A shorter study of eighty patients with transvenous defibrillator systems reported no postoperative pulmonary complications, transient nerve injury (1%), asymptomatic subclavian vein occlusion (2.5%), pericardial effusion (1%), subcutaneous patch pocket hematoma (5%), pulse

generator pocket infection (1%), lead fracture (1%), and lead system dislodgement (10%). During a mean follow-up period of 11 months, 7.5% of the patients in this series experienced inappropriate therapy delivery, half for atrial fibrillation and the rest for sinus tachycardia.

Although routine follow-up can be accomplished in the clinic, detection and analysis of transient events depends on the recording capabilities available in the devices or on the use of various external monitoring equipment.

80.7 Economics

The annual cost of ICD therapy is dropping as a consequence of better longevity and simpler implantation techniques. Early generators that lacked programmability, antibradycardia pacing capability, and event recording had 62% survival at 18 months and 2% at 30 months. Some recent programmable designs that include VVI pacing capability and considerable event storage exhibit 96.8% survival at 48 months. It has been estimated that an increase in generator longevity from 2–5 years would lower the cost per life-year saved by 55% in a hypothetical patient population with a 3-year sudden mortality of 28%. More efficient energy conversion circuits and finer line-width integrated circuit technology with smaller, more highly integrated circuits and reduced current drains will yield longer-lasting defibrillators while continuing the evolution to smaller volumes.

Cost of the implantation procedure is clearly declining as transvenous lead systems become commonplace. Total hospitalization duration, complication rates, and use of costly hospital operating rooms and intensive care facilities all are reduced, providing significant financial benefits. One study reported requiring half the intensive care unit time and a reduction in total hospitalization from 26 to 15 days when comparing transvenous to epicardial approaches. Another center reported a mean hospitalization stay of 6 days for patients receiving transvenous defibrillation systems.

Increasing sophistication of the implantable defibrillators paradoxically contributes to cost efficacy. Incorporation of single-chamber brady pacing capability eliminates the cost of a separate pacemaker and lead for those patients who need one. Eventually even dual-chamber pacing capability will be available. Programmable detection and therapy features obviate the need for device replacement that was required when fixed parameter devices proved to be inappropriately specified or too inflexible to adapt to a patient's physiologic changes.

Significant cost savings may be obtained by better patient selection criteria and processes, obviating the need for extensive hospitalization and costly electrophysiologic studies prior to device implantation in some patient groups. One frequently discussed issue is the prophylactic role that implantable defibrillators will or should play. Unless a means is found to build far less expensive devices that can be placed with minimal time and facilities, the life-saving yield for prophylactic defibrillators will have to be high if they are to be cost-effective. This remains an open issue.

80.8 Conclusion

The implantable defibrillator is now an established and powerful therapeutic tool. The transition to pectoral implants with biphasic waveforms and efficient yet simple transvenous lead systems is simplifying the implant procedure and drastically reducing the number of unpleasant VF inductions required to demonstrate adequate system performance. These advances are making the implantable defibrillator easier to use, less costly, and more acceptable to patients and their physicians.

Acknowledgment

Portions of this text are derived from Duffin EG, Barold SS. 1994. Implantable cardioverter-defibrillators: An overview and future directions, Chapter 28 of I Singer (ed), *Implantable Cardioverter-Defibrillator*, and are used with permission of Futura Publishing Company, Inc.

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