

CARDIAC PACING

Long-Term Outcome With the Automatic Implantable Cardioverter-Defibrillator

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The automatic implantable cardioverter-defibrillator was implanted in 270 patients because of life-threatening arrhythmias over a 7 year period. There was a history of sustained ventricular tachycardia or fibrillation, or both, in 96% of these patients, 80% had one or more prior cardiac arrests and 78% had coronary artery disease as their underlying diagnosis. The average ejection fraction was 34%, and 96% of these patients had had an average of 3.4 antiarrhythmic drug failures per patient before defibrillator implantation. There were four perioperative deaths and eight patients had generator infection or generator erosion, or both, during the perioperative period or during long-term follow-up. Concomitant antiarrhythmic drug therapy was given to 69% of patients.

Shocks from the device were given to 58% of patients,

and 20% received "problematic" shocks. The device was removed from 16 patients during long-term follow-up for a variety of reasons. There were 7 sudden cardiac deaths and 30 nonsudden cardiac deaths, 18 of which were secondary to congestive heart failure. The actuarial incidence of sudden death, total cardiac death and total mortality from all causes was 1%, 7% and 8%, respectively, at 1 year, and 4%, 24% and 26% at 5 years.

The automatic implantable cardioverter-defibrillator nearly eliminates sudden death over a long-term follow-up period in a high risk group of patients. It has an acceptable rate of complications or problems, or both, and most late deaths in these patients are nonsudden and of cardiovascular origin.

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Patients who have survived out of hospital cardiac arrest or who have recurrent sustained ventricular tachycardia have a high long-term total and sudden death mortality rate when their arrhythmias cannot be controlled with antiarrhythmic drug therapy (1,2). Previous reports (3-6) have shown a remarkably low short-term sudden death mortality rate in patients receiving the automatic implantable cardioverter-defibrillator (AICD). Although most centers have reported an acceptable rate of complications, others have emphasized certain problems with the device (7). There is undoubtedly a "learning curve" that exists for the implantation of these devices, with fewer complications and problems occurring as a center gains additional experience.

In the near future, there will be tremendous changes in the types of devices being implanted, the lead configurations

and defibrillating waveforms used and, over the next few years, in patient selection. Devices will soon include features such as backup bradycardia pacing, antitachycardia pacing and low energy cardioverting capabilities (8-10). Lead configurations will include three epicardial patch lead systems, transvenous catheters (11) and transvenous catheters coupled with subcutaneous patches (12). In addition to the standard monophasic truncated exponential waveform now utilized, devices with sequential pulses (13,14) and biphasic pulses (15-17) will become available. These newer devices may be better suited than the current device to treat patients with more frequent episodes of arrhythmia recurrence, and the indications for implantation may therefore broaden. There have been no significant changes in patient selection criteria for the currently available defibrillator from the inception of the program in 1980. Although there have been improvements in the device and implant techniques, they have been relatively minor compared with changes that will likely occur during the next few years. Therefore, it seems an appropriate time to report our long-term experience with the automatic implantable cardioverter-defibril-

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lator. In the present study, we report our seven year experience with regard to clinical observations, complications, modifications of implantation techniques over time and long-term survival.

Methods

Study patients. This study describes our experience with 273 consecutive patients undergoing surgery for implantation of the automatic implantable cardioverter-defibrillator between March 2, 1981 and March 2, 1988. This experience represents the personal experience of one of the authors (R.W.), and includes 88 implantations at Stanford University Medical Center, Stanford and 185 at Sequoia Hospital, Redwood City, California. Our early experience after the first 70 implantations was reported in detail in 1985 (3). All patients undergoing initial implantation at our centers are included even if they were subsequently followed up at other implanting centers. Patients undergoing initial implantation elsewhere and followed up by our center are not included in this analysis. All patients signed written informed consent before device implantation, and implantation protocols were approved by the Human Subjects Committee of Stanford Medical Center and the Institutional Review Board of Sequoia Hospital for all implantations done before Food and Drug Administration approval of the device.

Patient selection and preoperative evaluation. Patients were offered the automatic implantable cardioverter-defibrillator as a therapeutic alternative if they had at least one cardiac arrest caused by ventricular tachycardia or ventricular fibrillation, or both, or had recurrent episodes of sustained life-threatening ventricular tachycardia. Patients were excluded from implantation if their cardiac arrest was due to acute myocardial infarction, antiarrhythmic or other drug toxicity or severe electrolyte abnormalities. A small number of patients had either syncopal episodes that were unmonitored or known to be due to nonsustained ventricular tachycardia with sustained hypotensive ventricular tachycardia inducible at electrophysiologic study, or had a familial sudden death syndrome with inducible sustained ventricular tachycardia at electrophysiologic study.

Except for unusual circumstances, all patients underwent complete cardiac evaluation, including right and left heart catheterization, coronary and left ventricular angiography, a complete baseline intracardiac electrophysiologic study and an extensive period of in-hospital telemetry monitoring. Patients with inducible sustained ventricular tachyarrhythmia underwent serial electrophysiologic studies in an effort to find an antiarrhythmic drug that would prevent arrhythmia induction. Patients whose arrhythmia could not be induced while they were receiving antiarrhythmic medication were not offered a defibrillator implant. Patients with a single out of hospital cardiac arrest whose arrhythmia was not inducible at baseline electrophysiologic study were offered a

defibrillator implant as a therapeutic option if they had poor ventricular function and repetitive forms on noninvasive monitoring, or if they had the long QT syndrome or primary ventricular fibrillation. When an implantable defibrillator was contemplated for a patient, the patient and his or her family underwent extensive preoperative education, including provision of audiovisual and written materials, extensive sessions with specially trained nurses as well as ample time to discuss the therapy with one or more physicians (18).

All patients with episodes of nonsustained ventricular or supraventricular tachycardia that could trigger the committed device had these arrhythmias controlled with antiarrhythmic drugs. Patients with extremely frequent episodes of sustained ventricular tachycardia had these episodes controlled with antiarrhythmic medication or were excluded from device implantation, as were most patients whose rate of ventricular tachycardia was <140 beats/min. After early 1985, most patients with significant organic heart disease were routinely treated with digoxin to slow episodes of atrial fibrillation, even if they had never had this arrhythmia. Treadmill exercise tests were routinely performed early in our experience to evaluate peak sinus rate, but they were not performed routinely after 1984. Review of previous spontaneously occurring ventricular tachyarrhythmias, in-hospital monitoring data and the arrhythmias induced at electrophysiologic study was utilized to select the cutoff rate of the implanted device. Whenever possible, antiarrhythmic therapy was discontinued shortly before defibrillator implantation to avoid myocardial depression during surgery.

Device and lead selection. Devices implanted before July 1982 (Patients 1 to 5) were the original automatic implantable defibrillator (AID) models, which sensed only sinusoidal ventricular tachycardia or fibrillation. From July 1982 until October 1986, the automatic implantable cardioverter-defibrillator (AICD) was used, after which time the Ventak model 1520 was utilized. All devices were manufactured by Intec Systems or Cardiac Pacemakers, Inc. Ninety-nine percent of all devices used were rate only/high energy models. The first four patients received spring and patch leads made of silver tinsel. All other cardioverting-defibrillating leads were made with drawn braided strands of conducting material. For Patients 1 to 13, only spring-patch lead configurations were utilized. For Patients 14 to 109, spring-patch lead systems were the standard configuration but, if unacceptable defibrillation thresholds were obtained, two patch lead systems were utilized. After Patient 109, nearly all patients received large patch-large patch configurations. Epicardial screw-in leads manufactured by Medtronic Corp., Daig Corp. or Cardiac Pacemakers, Inc. were used in most patients. Transvenous endocardial sensing leads were utilized only when patients had unacceptable R wave amplitudes at several ventricular sites or when the sensing leads needed late revision because of insulation or conductor

malfunction, or both, of previously implanted epicardial leads.

Surgical technique. Except for the first two patients who underwent median sternotomy, all patients undergoing only automatic implantable cardioverter-defibrillator implantation had this done by a limited left thoracotomy performed for patch lead and epicardial sensing lead placement. After September 1984, a double lumen endotracheal tube was utilized to deflate the left lung transiently to facilitate posterior patch placement. When one patch lead was used in conjunction with the superior vena cava spring, it was the cathode and was positioned near the apex of the heart. When two patch leads were used, the cathode was positioned on the posterolateral left ventricular wall and the anode over the anterior right ventricular walls. When superior vena cava spring leads or transvenous endocardial leads were utilized, they were inserted percutaneously through the left subclavian vein. The distal ends of all leads were tunneled below the costal margin to the deep subcutaneous space in the mid left abdomen and connected to the generator, which was placed in a deep subcutaneous pocket. Patients undergoing patch implantation by means of a median sternotomy had the left cathodal patch placed near the inferoapical left ventricle and the right patch placed along the right atrial border.

All patients with significant (>70%) coronary artery lesions supplying viable myocardium had the lesions bypassed or (less frequently) treated with percutaneous transluminal angioplasty. Most patients undergoing other major cardiac procedures in addition to defibrillator implantation had a two stage operation, with the patch leads implanted initially at the time of their primary cardiac surgical procedure and the generator placed after recovery from surgery. All patients undergoing endocardial resection had patch leads left in place pending the outcome of postoperative electrophysiologic studies. In these patients, an automatic implantable cardioverter-defibrillator generator was placed if ventricular tachycardia occurred spontaneously or remained inducible after endocardial resection. Patch leads were sutured to the outside of the parietal pericardium. Only when defibrillation thresholds were unacceptable were the patches placed inside the pericardium or was the polarity of the shocking leads reversed.

Most patients undergoing generator changes for depleted batteries were admitted on the morning of the generator change and discharged the next day. Prophylactic cephalosporin antibiotic agents were given to patients before early 1985. Since then, all nonallergic patients undergoing either new system implantation or generator changes underwent preoperative povidone iodine (Betadine) showers and received prophylactic antibiotics using both a cephalosporin and vancomycin.

Intraoperative testing. After Patient 14, extensive defibrillation threshold testing (19) was performed routinely for new implants and generator changes utilizing the Intec/CPI

external cardioverting defibrillator (ECD) box or the Ventri-tex HVS-02 testing device. Ventricular fibrillation was induced in all patients, utilizing either alternating (AC) current or bursts of rapid pacing with a cycle length of 10 to 20 ms. Testing of cardioversion thresholds was not routinely carried out at the time of device implantation. Patients undergoing a two stage procedure who had a prolonged cardiopulmonary bypass time during their primary cardiac operation had only limited initial testing to be certain that 15 J was effective, with extensive defibrillation threshold evaluation at the time of generator implantation. In order for a "defibrillation threshold" to be acceptable, 25 J was required to reliably provide a "clean defibrillation" on essentially every test. It was also desired to have 20 J be nearly uniformly effective, and 15 J was expected to be effective approximately half the time. Lower energies were routinely tested, with 25 J rescue shocks being given for ineffective low energy defibrillations.

If the defibrillation threshold was considered unacceptable and the patient had a spring-patch lead system, it was upgraded to a two patch system. For patch-patch lead systems, an unacceptable defibrillation threshold led to further attempts at lead repositioning, placement of the patches inside the pericardium or reversal of defibrillating lead polarity. If these maneuvers failed to result in an acceptable defibrillation threshold, the device was not implanted, the leads were left in place and the patient returned to the operating room approximately 7 to 10 days later when the leads had a chance to approach "chronic" thresholds. If the defibrillation threshold remained unacceptable, a decision was made regarding the advisability of device implantation, or the patient was considered for a reoperation to try a different patch placement. When a satisfactory defibrillation threshold was obtained with the external testing equipment, the permanently implanted leads were attached to the AICD generator and the arrhythmia was induced one or more additional times to be certain that the device to be implanted would effectively terminate the arrhythmia with a single shock.

Pacemaker evaluations. Only bipolar pacemakers were utilized in conjunction with the automatic implantable cardioverter-defibrillator. Care was taken to avoid double counting of atrial and ventricular pacing stimuli or a ventricular pacing stimulus and its evoked local potential if this occurred >150 ms beyond the pacing spike. All implanted pacemakers were chosen to have maximal programmability of pacemaker output. Testing was performed to avoid this potential double counting by evaluating the pacemaker when programmed to its maximal output, and the defibrillator in the electrophysiologic test mode. In addition, the pacemaker was generally programmed to values of heart rate less than half the automatic implantable cardioverter-defibrillator rate cutoff so that if double counting did occur, the defibrillator would not be triggered. To be certain that the pacemaker did not cause undersensing of a sustained ventricular tachy-

arrhythmia by causing the automatic gain control circuits of the defibrillator to "lock-in" on the pacing spike and ignore the underlying ventricular tachyarrhythmia, arrhythmia episodes were induced with the pacemaker programmed to maximal output in an asynchronous pacing mode. Finally, pacemakers were ultimately programmed to the lowest voltage output consistent with a reasonable margin of safety for atrial or ventricular capture, or both.

Postoperative care. All newly implanted automatic implantable cardioverter-defibrillators were kept inactive during the early postoperative period. Antiarrhythmic medications, if indicated, were restarted in the postoperative period. Encainide was not given to any patient receiving an automatic implantable cardioverter-defibrillator because of the possibility of increasing defibrillation thresholds (20). Patients undergoing therapy with other type IC drugs always underwent generator testing while taking the drug being used. Patients undergoing a staged procedure had no further testing of the device. Patients with an initial complete system implant had follow-up electrophysiologic studies at approximately 5 to 7 days postoperatively. The clinical arrhythmia was induced at this study on the antiarrhythmic medication to be given on a long-term basis. The device was left in the active mode after this study. A 24 h ambulatory electrocardiographic (ECG) recording was obtained during the first 24 h after all newly implanted devices were placed in the active mode. Patients were generally discharged the day after device activation unless other medical conditions required them to stay in the hospital. Operative deaths were defined as those occurring within 30 days of the initial implantation or during the initial hospitalization if it was >30 days and the death was thought to be a direct complication of the surgery.

Long-term follow-up. Two hundred twenty-three of the 273 patients were followed up primarily by us in conjunction with each patient's personal cardiologist. The remaining 50 patients were followed up primarily at other implanting centers. Follow-up evaluation was by direct communication with the patient or patient's physician, or both, mailed questionnaires or data obtained from the Cardiac Pacemaker Inc. computer data base. Patients were seen every 2 months for the first 14 months after each new generator was placed and 1 month thereafter. At each visit a physical examination, charge time to evaluate battery status and the number of shocks delivered by the device were recorded. Patients were generally not reevaluated extensively for single defibrillator shocks; they were hospitalized promptly when a barrage of defibrillator shocks developed. For intermittent but frequent discharge of devices, continuous 24 h ambulatory ECG recordings were obtained until 1984. After that time, generous use was made of transtelephonic devices with a memory loop to determine the cause of frequent discharges. Once the cause of the defibrillator shocks was confirmed, drug therapy was modified to prevent these discharges.

Throughout the study, aggressive therapy was given for

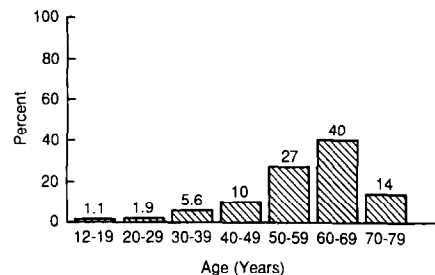


Figure 1. Distribution of ages of 270 patients receiving an automatic implantable cardioverter-defibrillator. The average age was 58.2 ± 11.8 years.

underlying congestive heart failure and, since 1986, the oral inotrope vasodilator enoximone has been utilized for patients, followed up primarily by us, who failed to respond to diuretic drugs and vasodilators. Patients with uncontrolled heart failure who were otherwise appropriate candidates were referred for cardiac transplantation.

For the purposes of this study, sudden cardiac death was defined as witnessed instantaneous death. All unwitnessed out of hospital deaths were considered to be sudden. All patients whose deaths were classified as due to congestive heart failure were under observation in a medical facility at the time of death and died after a progressive course of worsening heart failure unresponsive to maximal medical therapy. Deaths were considered as arrhythmic but nonsudden when they occurred in-hospital as a result of uncontrolled ventricular tachyarrhythmias.

Statistical analysis. All data are presented as mean values \pm SD unless otherwise specified. Life table analysis of survival was evaluated by the Kaplan-Meier method.

Results

Patient characteristics. The average age of the patients undergoing defibrillator implantation was 58.2 ± 11.9 years (range 12 to 77) (Fig. 1). Two hundred seventeen of the 270 patients were male and 53 were female. The underlying heart disease is summarized in Table 1. Ejection fraction, available for 200 patients (73%), had a median value of $34 \pm 15\%$ (Fig. 2). The primary underlying cardiac arrhythmia is summarized in Table 2. Fifty-three patients (20%) had not expe-

Table 1. Underlying Cardiac Disease in 270 Patients

Coronary artery disease	211 (78.2%)
Dilated cardiomyopathy	22 (8.1%)
Valvular	13 (4.8%)
Primary electrical	7 (2.6%)
Long QT syndrome	6 (2.2%)
Hypertrophic cardiomyopathy	3 (1.1%)
Other (hypertension 2, Marfan's syndrome 2, right ventricular dysplasia 2, congenital 1, myasthenia gravis 1)	8 (3.0%)

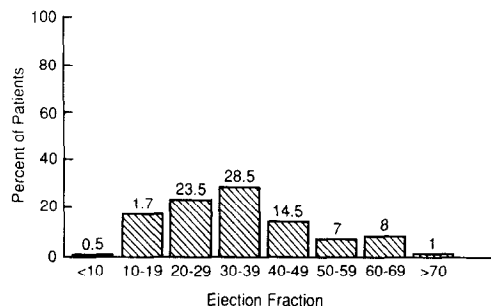


Figure 2. Distribution of ejection fractions of 200 patients receiving an automatic implantable cardioverter-defibrillator. Ejection fraction averaged 34%: it was <40% in 70% of patients.

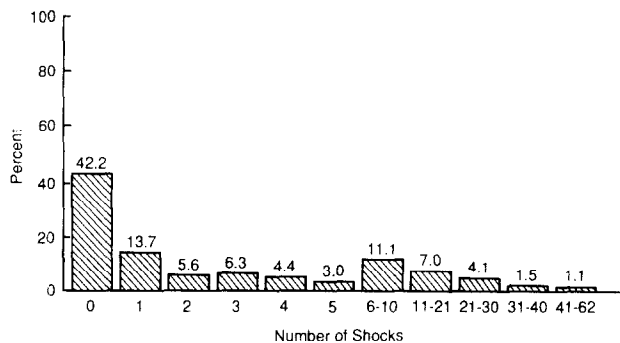


Figure 3. Number of device shocks per patient. The average number was 4.8 per patient.

rienced prior cardiac arrest, 136 (50%) had had a single cardiac arrest and 81 (30%) had had more than one cardiac arrest (average = 1.5 cardiac arrests per patient). At baseline electrophysiologic study, 231 patients (86%) had sustained ventricular tachyarrhythmias reliably induced. Ten patients (4%) had ventricular tachyarrhythmias induced, but induction was not reliable enough for serial drug testing; in 27 patients (10%), tachyarrhythmias were not inducible, and 2 patients (1%) had no baseline electrophysiologic study. Eighty-six patients (32%) had undergone previous cardiac surgery, including coronary artery bypass grafting alone in 53 patients, prosthetic valve replacement in 7 patients, bypass surgery plus valve replacement in 10 patients, aneurysm resection with bypass grafting in 12 patients and other procedures in 4 patients. Two hundred sixty-nine patients (96%) had had at least one antiarrhythmic drug failure clinically or at electrophysiologic study, and the average number of drug failures for the entire group was 3.4 ± 1.8 per patient.

Operative procedure. Two hundred seventy patients received an automatic implantable cardioverter-defibrillator generator; three patients did not undergo generator implantation despite operation for lead placement because of elevated defibrillation thresholds (see later discussion). The

initial shocking lead configuration was large patch-large patch in 183 patients (68%), spring-small patch in 71 patients (26%), spring-large patch in 9 patients (3%), large patch-small patch in 5 patients (2%) and small patch-small patch in 2 patients (1%). The sensing lead configuration was epicardial screw-in leads in 242 patients (90%) and endocardial sensing leads in 27 patients (10%). One patient received only the AID device, which required no sensing leads. A total of 189 patients (70%) received the AICD generator as the only operation performed. Eighty-one patients (30%) underwent AICD system implantation as part of a concomitant cardiac surgical procedure. These procedures included coronary bypass surgery alone in 54 patients, endocardial resection alone in 8, valve replacement alone in 2, endocardial resection plus bypass surgery in 12, endocardial resection plus valve replacement in 2 and other operations in 3. Among the patients receiving the AICD in conjunction with additional cardiac surgery, the generator was implanted at the time of initial surgery in 21 patients and at a second procedure before hospital discharge in 60. Subsequent generator replacements were for the standard indications of battery depletion, excessive capacitor charge times or device malfunction. Only a single generator was implanted in 148 patients, two generators in 75, three generators in 36, four generators in 10 and five generators in 1 patient.

Concomitant pacemakers. A total of 29 patients (11%) had a bradycardia pacemaker used simultaneously with the AICD. These included 10 (VVI) pacemakers, 16 (DDD) pacemakers, 1 (AAI) pacemaker and 2 Intermedics InterTach antitachycardia pacemakers. One patient with the antitachycardia pacemaker has terminated a number of episodes of slow ventricular tachycardia with the antitachycardia device. The other patient had significant interactions between the InterTach and the AICD at the time of implantation, and the combination was a clinical failure.

Defibrillator shocks. A total of 156 patients (58%) received shocks from their AICD generator (Fig. 3). For most patients receiving occasional infrequent shocks, no effort

Table 2. Problematic Device Shocks in 270 Patients

Sinus tachycardia (one nonfatal arrest)	7
SVT including atrial fibrillation	13
NSVT	3
VT	7
NSVT/VT	7
Unknown	10
Misdirection (one nonfatal arrest)	3
Sensing lead fracture	2
Screw caps off	1
Generator malfunction	1
Pacemaker interaction	1
Total	55 (20.5%)

NSVT = nonsustained ventricular tachycardia; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

was made to determine whether the shocks were "appropriate" or "inappropriate" because our previous experience indicated this was difficult on clinical grounds. A total of 55 patients (20%), however, had episodes of problematic shocks; the causes for these are listed in Table 2. Once the cause for the problematic shocks was identified, all but five patients had them controlled by changes in drug therapy.

Lead problems. Eight (10%) of 80 patients receiving superior vena cava spring leads had a total of 12 episodes of complications. These included five instances of lead migration and seven instances of lead fracture. One sudden death occurred when a device failed to terminate ventricular tachycardia/fibrillation because of the migration of a spring lead. Eight patients (2%) experienced problems with 462 patch leads. One of these was a crinkled patch lead that resulted in late elevation of the defibrillation threshold and the lead was replaced. Several other patients have crinkled patches on chest X-ray study, but defibrillation thresholds remain acceptable. One patient had an insulation break near the header that was successfully repaired. Six patients had a lead conductor fracture in the abdomen. Repair was successful in two patients and required repeat thoracotomy with patch lead replacement in four patients. One of the patch lead fractures was detected when a patient had an out of hospital cardiac arrest that the device did not terminate and from which he was successfully resuscitated by paramedics. The other patch lead fractures were diagnosed at the time of elective generator replacement. Six patients (1%) experienced problems with 511 sensing leads. One patient had a bad signal whose precise cause was never determined. In two patients with insulation breaks, the leads were replaced with new endocardial lead systems. One patient had an epicardial screw-in lead accidentally cut at the time of generator change, and two patients received inappropriate shocks (the sensing lead was found to be loose in the header in one patient, and the screw caps had been inadvertently left off at the time of original generator implantation in the other).

Three of the four patients with the originally used silver tinsel leads had these changed. Two patients had spring leads and patches electively replaced because of a known history of a high incidence of lead fracture with this system. One patient had the spring lead electively replaced and subsequently had the patch lead replaced when it became infected.

System infections/erosions. Six patients had AICD system infection, one had erosion with subsequent infection and another had erosion without infection. For the six system-induced infections not due to erosion, three occurred at the time of new implantation, two at the time of generator change and one when a lead was repositioned. One of the seven infections was due to *Serratia* and was treated with generator removal and antibiotics, with the patch lead left intact. The remaining infections were due to *Staphylococcus aureus*, and one patient with this infection died from over-

whelming sepsis. In the remaining five patients, the entire AICD system was removed. Three of the five patients had the system reimplanted at a new surgical procedure after full recovery from the infection.

Operative complications. There were four postoperative deaths (1.5%). One of these occurred in a patient with amiodarone pulmonary toxicity preoperatively who developed adult respiratory distress syndrome postoperatively. A second was due to perforation of the superior vena cava at the time of pacemaker implantation, which was performed immediately after placement of an automatic defibrillator. A third death was related to amiodarone toxicity postoperatively; the fourth occurred in a patient who had intractable ventricular tachycardia postoperatively that required emergency endocardial resection on the fourth postoperative day and who subsequently died of overwhelming sepsis related to the endocardial resection. Other perioperative complications included an infected chest tube site in one patient, staphylococcal sepsis caused by a central venous pressure catheter in one patient and a pacemaker infection that required revision of the pacemaker generator in one patient. Four patients experienced a perioperative cerebrovascular accident, none of which resulted in permanent sequelae. There were two pocket hematomas related to anticoagulant therapy. Two patients were taken back to the operating room because of bleeding related to their patch leads.

Elevated defibrillation thresholds. A total of seven patients had an unacceptable defibrillation threshold at the time of implantation or at a 7 to 10 day follow-up assessment of defibrillation threshold, or both. Five (6%) of these patients were in our first group of 88 patients and only 2 (1%) were in the last group of 182 patients. In three of these patients, including one who underwent reoperation with a three patch configuration, the generator was never implanted because it was believed that it would be totally nonfunctional. In one patient, the device was removed before hospital discharge because it was found to accelerate ventricular tachycardia to fibrillation that it could not terminate. Two of these seven patients had good defibrillation thresholds achieved by reoperation. One (the first patient known to receive two patches) was reoperated on the day after the initial operation, and successful defibrillation thresholds were achieved with use of two patches; the other patient required mitral valve replacement 2 years after the original implantation, and underwent lead revision at the time of sternotomy, with excellent defibrillation thresholds. One patient whose ventricular fibrillation was terminated approximately 50% of the time with 25 J had the device left in place. Two patients had subsequent late elevation of previously acceptable defibrillation thresholds. One of these patients, with a spring-patch lead system, refused reoperation for revision to a patch-patch system and had the device removed after it failed to work for sustained ventricular tachycardia on several occasions. The other patient had a crinkled patch lead and

Table 3. Concomitant Drug Therapy in 270 Patients

	No. (%)
Antiarrhythmic drugs	
Amiodarone alone	61 (22.6)
Amiodarone plus a type I agent	10 (3.7)
Procainamide	22 (8.1)
Sotalol	22 (8.1)
Propafenone	18 (6.7)
Mexiletine plus a type I agent	13 (4.8)
Mexiletine alone	12 (4.4)
Quinidine	10 (3.7)
Tocainide	9 (3.3)
Flecainide	3 (1.1)
Lorcainide	3 (1.1)
Other	3 (1.1)
Total	186 (68.9)
AV node blocking drugs	
Digoxin alone	102 (37.8)
Digoxin plus a beta-blocker	11 (4.1)
Digoxin plus a calcium channel blocker	11 (4.1)
Beta-blocker alone	19 (7.0)
Calcium channel blocker alone	3 (7.1)
Calcium channel blocker plus a beta-blocker	1 (0.4)
Total	147 (54.5)

AV = atrioventricular.

underwent reoperation with revision of the crinkled patch lead with restoration of excellent defibrillation thresholds.

Concomitant drug therapy. One hundred eighty-six patients (69%) received one or more antiarrhythmic drugs to suppress nonsustained or sustained tachyarrhythmias that might cause frequent device discharges, and atrioventricular (AV) node blocking drugs were given to 147 patients (55%) (Table 3).

Long-term follow-up. There was a total of 40 deaths among the patients undergoing continuous treatment with the AICD. Seven of these deaths were sudden, including two in patients who were believed to have battery depletion (one on the basis of glass corrosion and one because of reaching generator end of life) and one patient who experienced sudden death and was not resuscitated by his defibrillator because of spring lead migration. Three of the 40 deaths were noncardiac as a result of pneumonia in one patient, a primary respiratory arrest in one patient and exsanguination from end stage lung cancer in one patient. The cause of death among the 30 patients with nonsudden cardiac death was slow progressive congestive heart failure in 18 patients, cerebrovascular accident in 3, clotted prosthetic valve in 1 patient, postoperative death in 4, infection after generator change in 1 patient, subsequent myocardial infarction in 1, subacute electromechanical dissociation in 1 and uncontrolled slow ventricular tachycardia in 1. Except for one patient who refused hospitalization despite severe end stage congestive heart failure and the patient with end stage lung cancer, all patients classified as having a nonsudden death

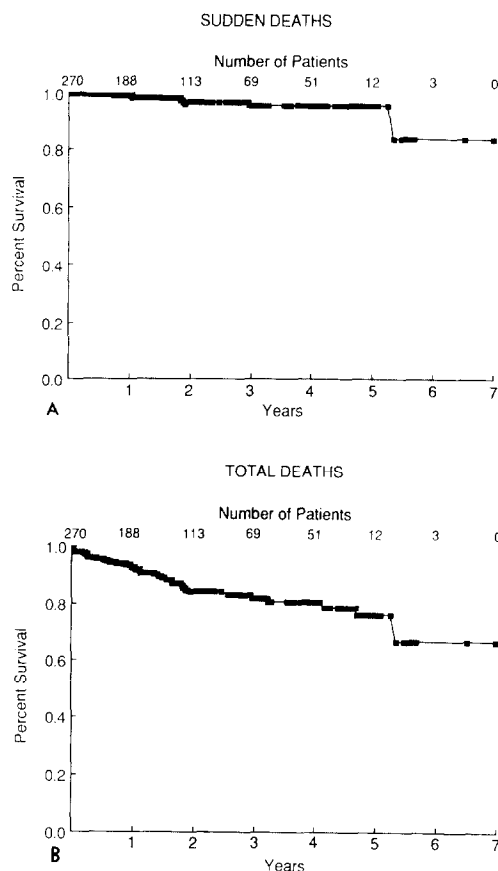


Figure 4. Survival of patients receiving an automatic implantable cardioverter-defibrillator. A, Actuarial survival rate with regard to sudden death. B, Total survival rate, including operative deaths (see Table 4).

died under direct medical observation, generally after a prolonged downhill hospital course.

Figure 4 shows the actuarial survival curves for these patients. Exact yearly survival data are listed in Table 4.

Six patients experienced nonfatal out of hospital cardiac arrest, and were not successfully resuscitated by their device. Two of these episodes were induced by the device in an outpatient medical setting; one occurred in the patient with a crinkled patch who was undergoing a treadmill exercise test when the device fired and precipitated a malignant ventricular arrhythmia that it could not terminate, and the other occurred during a magnet test with a misdirected initiating ventricular fibrillation that the device could not terminate because of a device malfunction. Both patients were successfully resuscitated by medical personnel in attendance. Of the four additional nonfatal out of hospital cardiac arrests, one was due to complete heart block and a second was a result of documented cardiac asystole. The device appropriately did not fire for either of the bradyarrhythmic arrests. A third episode occurred in the patient who subsequently was found to have a fractured patch lead. In this patient, the

Table 4. Kaplan-Meier Actuarial Mortality Rate in 270 Patients

	1 Year (n = 188)	2 Years (n = 113)	3 Years (n = 69)	4 Years (n = 51)	5 Years (n = 12)
Sudden death	0.9%	3.1%	4.4%	4.4%	4.4%
Cardiac (nonsudden)	6.2%	13.0%	13.9%	15.3%	20.3%
All cardiac	7.0%	15.6%	17.8%	19.1%	23.8%
Total	7.7%	16.3%	18.4%	19.7%	26.2%

device had attempted to terminate the arrhythmia with four shocks, but these were obviously unsuccessful. The fourth patient, who received a series of shocks that failed to abort the cardiac arrest, was successfully externally resuscitated by bystanders. The device functioned normally when it was subsequently tested at electrophysiologic study. The reason for its failure to abort the cardiac arrest is unknown.

Among the 270 patients receiving an AICD generator, 16 living patients were withdrawn from the series. Four of these patients had the device explanted because it proved to be ineffective; one of these had one of the original defibrillator units that could not sense ventricular tachycardia, one had ventricular tachycardia that accelerated to ventricular fibrillation that could not be terminated, one had a high defibrillation threshold at implantation and one had late elevation of the defibrillation threshold. Three patients asked to have the device removed because they thought it was no longer needed, three underwent subsequent cardiac transplantation and three did not have the device replaced after it became infected; in three other patients it was removed because their personal physician believed it was no longer needed. One patient withdrawn alive from this series was lost to follow-up study. Three of the 19 patients who never had the device placed because of high defibrillation thresholds or were withdrawn from the series alive experienced subsequent sudden cardiac death.

Discussion

Improvements during the past 7 years. This report describes our 7 year experience with the automatic implantable cardioverter-defibrillator (AICD). It considerably expands on the number of patients (70) we had previously reported on (3) and gives a much longer-term follow-up assessment. Over the past 7 years, our indications for implantation of this device, the patients in whom it has been used, the number of antiarrhythmic drug failures and the use of other therapies have not changed remarkably. However, several changes have occurred with regard to implantation technique and follow-up of these patients, and our experience contains an ongoing "learning curve." Very early in our experience, it became apparent that the devices needed to sense ventricular tachycardia as well as fibrillation, and the original automatic implantable defibrillator (AID) generator was modified to include cardioverting capabilities. The high incidence of

silver tinsel lead fractures led to the development of sturdier leads with a much lower failure rate. Failure to defibrillate with the implanted device led to the utilization of extensive defibrillation threshold testing (19) and two large patch leads rather than the original spring-patch lead configuration for delivering the defibrillating shocks (21). We have incorporated into our operative routines more extensive antibiotic prophylaxis to protect against *Staphylococcus aureus*. Because of the occurrence of rather unpleasant AICD shocks for nonsustained ventricular tachyarrhythmias and supra-ventricular tachycardia, we have made generous use of antiarrhythmic drugs and AV node blocking drugs to prevent these shocks. Finally, improved therapy for congestive heart failure has become possible through the use of the angiotensin-converting enzyme inhibitors and the oral inotrope enoximone. Finally, the skills of the investigators have improved remarkably in the management of patients with end stage congestive heart failure.

Follow-up mortality and complications. The present study demonstrates that the extremely low 1 and 2 year sudden death rates previously reported (3,4,6) in patients receiving the automatic implantable cardioverter-defibrillator continue to be maintained for as long as 5 years. During the longer follow-up period, the largest number of deaths are nonsudden and of cardiovascular origin, with more than half of these a result of progressive congestive heart failure. The longer follow-up period and larger number of patients have uncovered relatively few problems and complications not previously appreciated, but have served to provide a better assessment of their frequency of occurrence.

Device improvements. The knowledge obtained during the past 7 years has already resulted in some device improvements. This experience also provides data on which to base recommendations for improvements needed in future devices. The shocks given for nonsustained supraventricular and ventricular tachycardia could be eliminated if the device had programmable sensing times and was a noncommitted device that did not fire if an arrhythmia terminated before the defibrillating shocks had been delivered. Patient acceptance would probably be improved even further if the device provided antitachycardia pacing and programmability for shock output to reduce the discomfort from the shocks. The large number of generator changes required because of short battery life would be substantially reduced with greater battery longevity. The >10% incidence of need for a sepa-

rate concomitant backup bradycardia pacemaker as well as the two documented bradyarrhythmic aborted cardiac arrests indicate that backup bradycardia pacing would be a desirable feature in these devices. The ability to reliably distinguish supraventricular from ventricular tachycardia would also reduce the number of unnecessary shocks. Despite the limitations of the present device, its remarkable success in preventing sudden death supports its widespread use in high risk patients.

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