CLINICAL EXPERIENCE IN PATIENTS WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

HISAKO TSUJI, M.D.,* DAVID M. SHAHIAN, M.D.
AND FERDINAND J. VENDITTI, JR., M.D.*

Forty patients (36 men and 4 women) with life-threatening arrhythmia received an implantable cardioverter defibrillator (ICD). Mean age was 63 years (range, 46 to 80 years). All patients had structural heart disease, with coronary artery disease in 32 patients, idiopathic cardiomyopathy in 7 patients, and hypertensive heart disease in 1 patient. Mean left ventricular ejection fraction was 29 ±13%. The clinical arrhythmia was out-of-hospital cardiac arrest in 14 patients (35%), symptomatic sustained ventricular tachycardia in 21 patients (53%), and episodes of syncope without documented spontaneous ventricular arrhythmia but ventricular tachycardia that was easily provoked at the time of electrophysiologic testing in 5 patients (13%). Sustained ventricular tachycardia was induced in 37 patients (93%) at basic electrophysiologic testing. The average number of drug failures was 2.9 ±1.4 per patient. One patient (2.5%) died perioperatively because of intractable ventricular tachycardia and ventricular fibrillation. During a median follow-up period of 5.5 months (range 2-21 months) 2 sudden deaths occurred. No patient had a serious complication during the follow-up period. Ten patients (25%) received antiarrhythmic drugs to suppress spontaneous ventricular tachycardia. Appropriate shock treatment was received by 18 patients (45%), and inappropriate shock treatment was received by 2 patients (5%). Several issues regarding use of the ICD must be considered, but the device seems to be useful, and it is associated with an acceptable rate of complications and good long-term success at the present time.

The implantable cardioverter defibrillator (ICD) has been implanted in more than 12,000 patients in the United States and Europe (Cardiac Pacemakers, Inc., U.S.A., St. Paul, MN, Personal communication, 1990). Because patients with an ICD have a low incidence of sudden death, the device is important in therapy of patients with life-threatening ventricular arrhythmia!–5 Although the ICD (Ventak, Cardiac Pacemakers, Inc., St.Paul, MN, U.S.A.) is still being developed, it is improving rapidly and will be the treatment of choice in Japan for patients with ventricular arrhythmia. We report our clinical observations and experience with the Ventak ICD and discuss the complications, problems, and limitations of current models.

Key words:
Cardiac arrest
Defibrillation
Sudden cardiac death
Ventricular fibrillation
Ventricular tachycardia

(Received November 20, 1990; accepted December 26, 1990)
Section of Cardiology* and Department of Thoracic and Cardiovascular Surgery, Lahey Clinic Medical Center, Burlington, Massachusetts, U.S.A., and the Division of Thoracic and Cardiovascular Surgery, New England Deaconess Hospital, Boston, Massachusetts, U.S.A.
*Present address: The Second Department of Internal Medicine, Kansai Medical University, 1 Fumizono-cho, Moriguchi City, Osaka, Japan.
Mailing address: Hisako Tsuji, M.D., CCU, Kansai Medical University, 1 Fumizono-cho, Moriguchi City, Osaka 570, Japan

Japanese Circulation Journal Vol. 55, July 1991 669
TABLE I  CLINICAL CHARACTERISTICS OF 40 PATIENTS RECEIVING THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (range)</td>
<td>63±8 (46 to 80)</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>36/4</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>40</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>32</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td></td>
</tr>
<tr>
<td>Dilated</td>
<td>6</td>
</tr>
<tr>
<td>Hypertrophic</td>
<td>1</td>
</tr>
<tr>
<td>Hypertensive heart disease</td>
<td>1</td>
</tr>
<tr>
<td>Mean left ventricular ejection fraction</td>
<td>29±13%</td>
</tr>
</tbody>
</table>

METHODS

From September 1988 through April 1990, the ICD was implanted in 40 patients at the Lahey Clinic Medical Center, Burlington, Massachusetts, U.S.A., and the New England Deaconess Hospital, Boston, Massachusetts, U.S.A. Conditions considered indications for implantation were at least one cardiac arrest caused by ventricular tachycardia or ventricular fibrillation not associated with acute myocardial infarction, hypotensive sustained ventricular tachycardia, or an episode of syncope with inducible sustained hypotensive ventricular tachycardia at electrophysiologic study despite conventional therapy with antiarrhythmic drugs. Before March 1989, the Ventak model 1510 or 1520 was implanted in 6 patients. After February 1990, 3 patients received the Ventak model 1600 under protocol with informed written consent. The Ventak model 1550 was implanted in the remaining patients.

An electrophysiology study was performed on all patients to obtain baseline information. Sustained ventricular tachycardia was defined as tachycardia lasting longer than 30 seconds or requiring termination before that time because of hemodynamic collapse. Diagnostic coronary angiography, determination of left ventricular function by left ventriculography, echocardiography or gated blood pool scan, and catheterization (Swan-Ganz, American Edwards Laboratories, Santa Ana, CA, U.S.A.) for monitoring during operation were performed in all patients. Ten patients who had an ejection fraction of less than 15% or documented myocardial ischemia or both were supported by intracoronary balloon pumping during and after operation.

Median sternotomy was performed for patients who had concomitant cardiac surgery. Most other patients had a left anterior thoracotomy approach. When performed, concomitant coronary artery bypass grafting or aneurysmectomy or both preceded implantation of the ICD system. In most patients, one set of epicardial screw-in leads was implanted for rate sensing, and two-patch leads were sutured to the outside of the parietal pericardium for morphology sensing and defibrillation. The superior vena cava lead or bipolar endocardial lead, when necessary, was implanted transvenously through the left subclavian vein at the time of implantation of the device. The amplitude of electrogram and duration of the rate-sensing leads and the defibrillating leads were recorded. At least 5 mV of R wave amplitude was required in the rate-sensing leads. Two patients had a prolonged cardiopulmonary bypass time during the primary cardiac operation; therefore, testing for defibrillation threshold and implantation of the device were performed during a second procedure.

Ventricular fibrillation was induced by bursts of rapid pacing through the rate-sensing leads, and after 10 seconds, defibrillation was attempted by the external cardioverter defibrillator. Defibrillation threshold was defined as the energy level at which a 50% or higher rate of successful conversion occurred. The defibrillation threshold was acceptable when it was 20 J or less. When the defibrillation threshold was unacceptable, the polarity of the defibrillator patches was changed or the patches were repositioned or both, and the defibrillation threshold was determined again. Unacceptably high defibrillation threshold occurred in 8 patients. The device was implanted at the time of the operation in 5 of these patients based on the clinical circumstances. Two of the remaining patients had an acceptable defibrillation threshold 2 weeks after the first operation and had a second operation for implantation of the device. The device was implanted in 1 patient without further evaluation of defibrillation threshold. In patients with a satisfactory defibrillation threshold, the implanted leads were attached to the

left in the active mode after this study, and patients were usually discharged the next day.

After discharge from the hospital, patients underwent follow-up study every 2 months for the first year and monthly thereafter. At each visit, a physical examination was conducted, and charge time to evaluate battery status and the number of shocks delivered by the device were recorded. Appropriate discharges were defined as those preceded by symptoms. Sudden death was defined as death occurring within 1h after the onset of symptoms.

All data are presented as mean values ± SD unless otherwise specified. Kaplan-Meier analysis was performed on an IBM PS/2 Model 50 personal computer with an 80287 coprocessor using BMDPIL statistical software.

RESULTS

Characteristics of the patients are summarized in Table 1, and distribution of ejection fraction is shown in Fig. 1. Indications for electrophysiologic testing were out-of-hospital cardiac arrest in 14 patients (35%), symptomatic sustained ventricular tachycardia in 21 patients (53%), and syncope without documented ventricular arrhythmia in 5 patients (13%). Sustained ventricular tachycardia was induced in 37 patients. Ventricular
fibrillation was induced in 1 patient. Two patients did not have inducible ventricular arrhythmias but had had a cardiac arrest. The average number of drug failures was 2.9 ± 1.4 per patient.

One patient received a spring-patch lead system, and all other patients received defibrillating leads that were two-patch systems. After June 1989, a large-patch to large-patch configuration was used for most patients. Two epicardial active-fixation rate sensing leads were used in 38 patients, and 2 patients received bipolar endocardial leads. Concomitant coronary artery bypass surgery was performed in 8 patients, and in 1 of these patients simultaneous aneurysmectomy was performed. Six patients had a permanent pacemaker. Double counting was demonstrated in 1 patient as a result of the pacing artifact and was resolved by decreasing the pacing amplitude to 4 V. Double counting also occurred in 1 patient with large T waves. This problem was corrected by moving the sensing leads, resulting in a 90° change in the leads vector. The defibrillation threshold averaged 16.8 ± 9.2 J.

pockets were subfascial.

One patient (2.5%) died 3 days after operation because of intractable ventricular tachycardia and fibrillation. This patient had a history of coronary artery bypass grafting of five vessels. Coronary angiography before operation showed that one graft was occluded, and a new 50% stenosis had developed in the left main coronary artery. Ejection fraction was 7% by gated blood pool scan.

Of 39 patients who survived operation, 37 patients underwent testing of the ICD before discharge. Morphology sensing (PDF= probability density function) was used in 17 patients, and the average cut-off rate was 174±10 bpm (range 155-190 bpm). Ten patients (25%) received antiarrhythmic drugs, including amiodarone (Cordarone) in 2 patients, to suppress spontaneous ventricular tachycardia.

During a median follow-up period of 5.5 months (range 2 to 21 months), two sudden deaths occurred (Fig. 2). Ejection fractions were 15% and 19%, respectively. One death occurred during Holter monitoring; ventricular tachycardia degenerated into ventricular fibrillation, which was not terminated after five sequential shocks. This patient had previously had two episodes of ventricular tachycardia that were successfully terminated. The other patient had recurrent slow ventricular tachycardia below the cut-off rate of the ICD, which caused heart failure and multiple hospital admissions. He received an antitachycardia pacemaker (Intertach, Intermedics Inc., Angleton, Texas 77515, U.S.A.) but died suddenly 2 months after implantation of the pacemaker. The antitachycardia pacemaker recorded two episodes of successfully converted slow ventricular tachycardia and one more rapid episode of ventricular tachycardia. The ICD discharged once during the patient's terminal event.

Appropriate shocks were received by 18 patients, and 2 of these patients also had inappropriate shocks. Both patients who died during the follow-up period had received appropriate shocks. Five of 8 patients who had a high defibrillating threshold at the first operation received successful appropriate shocks. Twenty-two patients have not received shocks.

Inflammation of the pocket was suspected in 2 patients. In 1 patient, inflammation subsided after treatment with an oral antibiotic and in the other patient after treatment with an anti-inflammatory agent. No documented infections or pocket erosions have occurred.

DISCUSSION

Patients whose condition is not responsive to antiarrhythmic drugs during programmed electrical stimulation have been reported\textsuperscript{9,10} to have a 34% to 50% 1-year sudden death rate. Most patients who receive the ICD are in this population. Winkle et al\textsuperscript{2} reported a 0.9% 1-year sudden death rate in patients treated with an ICD. The sudden death rate in the present study is higher than that reported by Winkle et al\textsuperscript{2} but is acceptable considering the natural history of these patients\textsuperscript{11–14}.

Perioperative mortality associated with implantation of the ICD as reported is significantly lower than that associated with subendocardial resection procedures\textsuperscript{15–20} Our study population, many of whom had severely depressed left ventricular function, demonstrated a low operative risk. The only perioperative death occurred in the patient whose 7% ejection fraction was the lowest in our series. The ICD can be used in patients with severe left ventricular dysfunction with appropriate precautions.

Postoperatively, no patient has experienced serious complications resulting from implantation of the ICD. This finding is consistent with the low incidence of serious complications reported in previous studies\textsuperscript{1–5,7} The reported infection rates range from 2% to 4%\textsuperscript{1,2} None of our patients have had an infection related to implantation of the ICD.

Despite the efficacy of the ICD in preventing sudden cardiac death and its growing use in this population of patients\textsuperscript{21} several issues and limitations remain. Improvement in the total cardiac mortality is accounted for by the impressive reduction in the sudden death rate. Effectiveness of the ICD is determined by this reduction in sudden cardiac death. However, if the ICD decreases the number of sudden deaths but does not change the total cardiac mortality (resulting from progressive congestive heart failure), long-term efficacy may not remain as impressive.
Mortality data should be evaluated cautiously because none of the available data are from controlled studies. The population of patients with an ICD includes patients with various types of heart disease, each of which is associated with a different prognosis. For example, patients with out-of-hospital cardiac arrest do not have as poor a prognosis when ventricular tachycardia is not inducible, especially when left ventricular function is preserved, compared with patients with decreased ejection fraction and inducible ventricular tachycardia. Also, the prognosis of patients who have syncope without documented ventricular arrhythmia but with inducible ventricular tachycardia is not clear.

A preliminary study suggested that patients who do not receive an appropriate shock during follow-up have an excellent prognosis and contribute greatly to the favorable outcome of patients with an ICD. Consistent with this finding, both patients who died during our follow-up period had appropriate shocks, and no patient without an appropriate shock died.

Other relatively minor issues must be considered. On occasion, unacceptable defibrillation threshold cannot be avoided, and the approach to patients with this problem depends on the physician. Larger defibrillation surface area and biphasic discharge have been demonstrated to decrease defibrillation threshold. Newer patches and devices may provide a considerable reduction in energy requirement.

Devices made before the Ventak model 1600 could not avoid false discharges for nonsustained ventricular tachycardia. Non-sustained ventricular tachycardia would activate older devices, which are “committed” after a brief period of tachycardia. This problem could be avoided by a device that becomes “committed” just before discharge. A “second look” feature would permit this action, and such a system is under development. Alternatively, programmable devices that allow longer detection times before becoming “committed” are in clinical trials (Ventak model 1600, Cardiac Pacemakers Inc., St. Paul, MN, U.S.A.).

In the Ventak model 1600, the level of the first shock can be programmed from 0.1 J to 30 J with a variable delay (2.5 seconds to 10 seconds). Charging time depends on the energy level programmed; e.g., it takes 6 seconds to 7 seconds to charge capacitors to 30 J but only 0.3 seconds to charge to 1 J (Fig. 3). Usually, a low level of energy is required for conversion of ventricular tachycardia. Use of this approach, i.e., low energy conversion level, should help prevent early depletion of the battery. We used the Ventak model 1600 in 3 patients who had sustained ventricular tachycardia; patients required 0.1 J, 0.5 J, and 2.0 J, respectively, for conversion of ventricular tachycardia during four consecutive trials.

Because the ICD does not prevent the occurrence of ventricular tachycardia or fibrillation, some patients will experience syncope before the arrhythmia is successfully converted. Syncope during therapy is an unavoidable problem in some patients with this type of “rescue” therapy. Curative surgery obviously has merit when this problem is a consideration.

Although the ICD is not perfect, many patients in Japan are good candidates for this therapy. However, the ICD should be used only when the limitations and problems that can occur are fully understood by the physician who implants this device.

REFERENCES

5. GABRY MD, BRODMAN R, JOHNSTON D, FRAME R, KIM SG, WASPE LE, FISHER JD, FURMAN S: Automatic implantable cardioverter-defibrillator: Patient survival, battery longevity


