Electrophysiological Laboratory, Electrophysiologist-Implanted, Nonthoracotomy-Implantable Cardioverter/Defibrillators

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BackgroundImplantable cardioverter/defibrillators (ICDs) have conventionally been implanted in the operating room by surgeons. However, technological developments have reduced size and increased simplicity, bringing the procedure into the realm of the electrophysiologist. The purpose of this study was to evaluate the safety and efficacy of implantation of the entire ICD system by electrophysiologists in an electrophysiology laboratory.

Methods and ResultsBetween July 1993 and February 1994, 23 patients (21 men; age, 64±11 years) underwent transvenous ICD implantation by electrophysiologists working alone, entirely in the electrophysiology laboratory. Indications for ICD were sudden death in 10 patients, uncontrolled life-threatening ventricular tachycardia in 12, and syncope with cardiomyopathy and familial sudden death in 1. Seventeen patients had coronary artery disease and a past history of acute myocardial infarction. Four patients had idiopathic dilated cardiomyopathy, 1 had coronary ectasia and poor left ventricular function, and another had poor left ventricular function related to valvular dysfunction. The mean left ventricular ejection fraction was 34±10% (range, 20% to 50%). General anesthesia was administered in 22 cases, and deep sedation was used in 1 elderly patient. After positioning of transvenous leads and subcutaneous patch/array lead positioning, defibrillation testing was performed. After transvenous and subcutaneous lead tunneling, all generators were placed subcutaneously in an abdominal pocket. The mean total time in the electrophysiology laboratory was 254±68 minutes (range, 150 to 375 minutes), with 104±42 minutes for anesthetic and other preparation, 159±45 minutes for implantation, and 8.7±5 minutes (range, 3 to 25 minutes) of fluoroscopy required for positioning of transvenous and subcutaneous lead systems. Implant times showed a significant improvement when the first 10 cases (188±44 minutes) were compared with the last 10 in the series (124±44 minutes, P<.01). The mean defibrillation threshold was 17±5 J (range, 5 to 25 J). There were 5 complications (22%): 1 patch-site hematoma, 1 pneumothorax related to subclavian venous puncture, 1 pulmonary embolism, and 2 patients requiring overnight ventilation after hemodynamic deterioration following defibrillation testing. There were no deaths, and there were no infections. The mean time to hospital discharge after the implant was 5.1±3.5 days. After 11.6±9 weeks of follow-up, all devices were functioning satisfactorily, all patients had successfully defibrillated at postimplant predischarge checkup with 29±5 J, and there had been no late complications.

ConclusionsThis is the first report to show that nonthoracotomy ICD implantation may be successfully carried out by electrophysiologists working alone in the electrophysiology laboratory, with a high rate of success and few complications, even in high-risk patients. This high rate of success and safety probably relates to the availability of high-quality fluoroscopy and familiarity with electrophysiology laboratory equipment and personnel. (Circulation. 1994;99:2503-2508.)

Key Words • defibrillation • electrophysiology

The field of implantable devices for treating disorders of cardiac rhythm is rapidly changing. One of the most significant recent advances is the availability of nonthoracotomy (NTL)—implantable cardioverter/defibrillators (ICDs). Two lead systems are now commercially available in the United States, the CPI Endotak tripolar transvenous lead system and the Medtronic Transvene lead system. With increasing use of these systems, which do not require access to the chest cavity and have frequently been implanted with an additional subcutaneous patch lead, the need for physicians trained in thoracotomy is reduced. Physicians with exceptional experience with cardiac pacemaker implantation and a period of additional supervised training in subcutaneous tunneling techniques and abdominal generator implantation can undertake the procedure, provided that laboratory facilities are available. The purpose of this study was to evaluate the procedure time, success, and complication rate of NTL ICD implantation by electrophysiologists in an electrophysiology (EP) laboratory.

Methods

PatientsNTL ICD systems were implanted in 23 patients (see Table 1). All patients underwent thorough electrophysiological evaluation, including baseline electrophysiological study with programmed ventricular stimulation. Seventeen patients had doc-
Table 1. Characteristics of Patients Admitted to Study

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age, y</th>
<th>Diagnosis</th>
<th>LVEF, %</th>
<th>CHF</th>
<th>Event/Arrhythmia</th>
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<tr>
<td>1</td>
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<td>74</td>
<td>DCM</td>
<td>30</td>
<td>Y</td>
<td>VF</td>
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<tr>
<td>2</td>
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<td>CAD/MI</td>
<td>33</td>
<td>N</td>
<td>VT</td>
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<tr>
<td>3</td>
<td>M</td>
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<td>VT and VF</td>
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<tr>
<td>4</td>
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<td>81</td>
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<td>Y</td>
<td>Syncope, VT</td>
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<tr>
<td>5</td>
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<td>45</td>
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<td>VT/ventricular flutter</td>
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<tr>
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<td>VF</td>
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<td>N</td>
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LVEF indicates left ventricular ejection fraction; CHF, history of congestive cardiac failure; Event, type of clinical event precipitating hospital admission; DCM, dilated cardiomyopathy; VF, ventricular fibrillation; CAD/MI, coronary artery disease and prior myocardial infarction; and VT, ventricular tachycardia.

umented coronary artery disease with previous remote myocardial infarction. Among this subgroup, 9 patients had suffered an episode of sudden cardiac death that was not related to a further acute myocardial infarction, and 7 patients initially presented with hemodynamically unstable and subsequently medically refractory ventricular tachycardia. One patient had recurrent ventricular tachycardia that had been controlled by amiodarone but had had to discontinue the drug because of pulmonary toxicity.

Four patients had an idiopathic dilated cardiomyopathy, and one patient had poor left ventricular function as a consequence of mitral valve disease and had sustained a ventricular fibrillation/cardiac arrest. One patient had experienced syncope and had globally impaired left ventricular function and a family history of dilated cardiomyopathy and sudden death. Seven of 20 patients had a history of cardiac failure; the mean left ventricular ejection fraction was 34 ± 10%.

Procedures

All patients underwent baseline electrophysiological study. The details of the study are fully described elsewhere.1 In brief, the aim of the study was to exclude supraventricular causes of sudden death and conduction tissue disease and to deliver programmed ventricular stimulation with triple extrastimuli at two sites at two drive cycle lengths. The hemodynamic significance (ie, sustained >30 seconds, associated with systolic blood pressure <80 mm Hg and syncope or presyncope, requiring overdrive pacing or DC cardioversion, or associated with deteriorating patient condition) of induced ventricular arrhythmias and the effect of overdrive pacing were also assessed. The latter was performed with a view to choosing the appropriate type of ICD (with or without the availability of antitachycardia pacing) in the event that ventricular tachycardia was still inducible and still hemodynamically significant after a trial of medical therapy.

All patients had a cardiiological evaluation as part of their management, which included coronary arteriography and assessment of left ventricular function by contrast ventriculography, nuclear ventriculography, or two-dimensional echocardiography. Patients then gave informed consent to be enrolled in clinical studies (approved by the Committee on Human Research of the University of California, San Francisco) of NTL ICDs where appropriate, whereas other patients received market-approved NTL ICD systems.

For NTL ICD implantation, patients underwent general anesthesia in the EP laboratory unless it was felt that general anesthesia was unduly risky, in which case anesthesiologist-supervised deep sedation and local anesthesia were used instead. Patients were transported to the EP laboratory after an overnight fast, and general anesthesia was induced. Staffing of the laboratory included one anesthesiologist, two electrophysiologists, two electrophysiology nurse/technicians, and one device program coordinator. Kefsol (1 g IV) was given with induction of anesthesia. A cannula was introduced into the right or left radial artery for continuous monitoring of arterial blood pressure, and the urinary bladder was catheterized. In 17 patients, a quadripolar temporary electrode catheter was passed from the right femoral vein to the right ventricular apex for use in delivering AC for induction of ventricular fibrillation.
and also for use in backup intracardiac defibrillation (between the proximal two electrode poles and a large-surface-area posterior cutaneous patch), if needed. The entire torso from the chin to the pubis and from the right posterior axillary line to the left posterior axillary line laterally was thoroughly scrubbed with iodine/soap for 3 minutes, dried, and prepared with povidone-iodine solution, and the sterile field was delineated with linen and paper towels.

A 3-cm incision was made in the left or right subclavicular region, a small subcutaneous pocket fashioned, and a subclavian venous puncture made. A J guide wire was used to guide the passage of a 14F split-sheath introducer, and the transvenous lead was passed into the right atrium or to the innominate vein/superior vena cava. By use of fluoroscopic posteroanterior and oblique projections, the transvenous electrode was passed into the right ventricle and positioned at the right ventricular apex. When an Intermedics Res-Q or Medtronic Transvene system was implanted, an active fixation right ventricular electrode was used. When the CPI Endotak lead was used, fixation to the right ventricular endocardium was passive. Endocardial ECGs were recorded and analyzed for amplitude and the presence and size of injury current, and sensing and pacing characteristics were determined. When a single-pass (CPI Endotak) lead was used and the clinical trial protocol allowed it, the defibrillation threshold (DFT) was assessed by use of the lead alone. When a subcutaneous patch, or array, was required, an incision was made in the left axillary region just below and lateral to the left nipple, or the infraclavicular incision was expanded and the patch lead positioned via this incision. A flat subcutaneous plane was fashioned, with care taken to avoid accidental injury to the long thoracic nerve for axillary patch implants. A tunneling tool was used to position the three portions of the subcutaneous array around the postero lateral chest. The DFT was then assessed.

Before DFT testing, a low-energy (0.5-J) shock was administered during sinus rhythm to evaluate system integrity and measure lead impedance. Ventricular fibrillation was then induced. The lead systems were always first tested for ventricular defibrillation at an energy of approximately 20 J delivered manually by the implant testing device. If defibrillation was successful, ventricular fibrillation was reinduced, and delivered energies at approximately 5-J decrements were tested. If defibrillation failed, a rescue shock of 40 J was delivered by the implant test device or the device to be implanted (Intermedics Res-Q). At the next induction after an initial failed attempt, a 5-J increment in energy was made. No device was implanted with a defibrillation configuration yielding less than a 10-J safety margin below maximum device energy output for two defibrillation attempts. If a 10-J defibrillation safety margin failed to be achieved, a different lead/patch/array configuration was tried, and defibrillation testing was repeated.

After evaluation of DFT, a subcutaneous abdominal pocket was fashioned to the left or right of the midline, approximately midway between the level of the umbilicus and the costal margin. The lead or leads were then tunneled subcutaneously from the infraclavicular and axillary regions downward to the abdominal pocket, where they were connected to the pulse generator. Ventricular fibrillation was then reinduced, detected, and defibrillated once more, automatically, with the device implanted in the abdominal pocket. After a successful automatic test, the lead system shock impedance was checked telemetrically. The wounds were then irrigated with gentamicin in 0.9% saline solution, the deep tissues were closed with interrupted 2/0 Dexon sutures and subcuticular 4/0 Maxon, or simple adhesive strips were used to simulate the skin.

Patients were managed in the coronary care unit for 24 hours, then transferred to monitored beds on the cardiology ward. If there were no contraindications after 24 to 48 hours, they returned to the EP laboratory for predischarge device testing. Ventricular fibrillation was induced by rapid overdrive pacing or AC, with the device blinded during induction if necessary, and the integrity of the system and ability to defibrillate were again determined. If the predischarge check was successful and there were no complications, patients were allowed to go home the following day.

Numerical values are given as mean±SD. A Student’s t test was used to compare implant times of the earliest 10 versus the most recent 10 EP laboratory NTL ICD implants.

**Results**

Ventricular fibrillation could be induced in 19 patients by programmed ventricular stimulation. Four patients with a history of sudden cardiac death had easily inducible ventricular fibrillation, and 15 patients had inducible sustained monomorphic ventricular tachycardia (14 patients) or ventricular flutter (1 patient). Four patients were noninducible. Thirteen of 14 patients with ventricular tachycardia required emergent treatment by ventricular overdrive pacing or DC countershock. All these patients had a trial of medical therapy with amiodarone (10 patients) or sotalol (4 patients) and a further electrophysiological study after an appropriate in-hospital loading period. All patients had inducible hemodynamically significant ventricular tachycardia at the repeat electrophysiological study. One patient who had recurrent ventricular tachycardia and had discontinued amiodarone for reasons of pulmonary toxicity had reproducibly pace-terminable ventricular tachycardia, and it was decided to implant a tiered-therapy NTL ICD providing antitachycardia pacing with back-up cardioversion/defibrillation.

NTL ICDs were implanted in all 23 cases attempted. Thirteen patients received devices under clinical trial, and 10 received market-released devices. General anesthesia was administered in the EP laboratory in 22 cases, and deep sedation was used in one elderly patient. The mean total time in the EP laboratory was 254±68 minutes (range, 150 to 375 minutes), with 104±42 minutes for anesthetic and other preparation, 159±45 minutes for device implantation, and 8.7±5 minutes (3 to 25 minutes) of fluoroscopy required for positioning of transvenous and subcutaneous lead systems. Implant times showed a significant improvement when the first 10 cases (188±44 minutes) were compared with the last 10 in the series (124±44 minutes, P<.01). The mean DFT was 17±5 J (5 to 25 J). Seven patients received a CPI Ventak (6 Ventak PRX, 1 Ventak P, 1 Ventak P2) with the CPI Endotak lead and a subcutaneous patch (1 patient) or array (4 patients). Six patients received an Intermedics Res-Q with a bipolar active fixation lead and subcutaneous patch. Seven patients received a Ventritex Cadence with a CPI Endotak lead. Three patients received a Medtronic PCD, one with a CPI Endotak lead and subcutaneous array, one with a tripolar active fixation electrode and two subcutaneous patches (placed in the left axilla and left infraclavicular region), and one with a tripolar right ventricular lead and superior vena cava coil. Twenty-four patients had transvenous leads inserted on the left side and 2 on the right. Both right-sided leads required placement of a left axillary subcutaneous patch, such that the endocardial lead was tunneled to an abdominal generator pocket to the right of the midline, with tunneling of the subcutaneous patch lead down below the costal margin, then across the midline, to the right-sided generator pocket. Details of patient num-
bers, lead configurations, number of fibrillation/defibrillation episodes required, shock waveform, and defibrillation thresholds are given in Table 2. The mean DFT was 17±5 J. Eight patients with a tripolar lead (CPI Endotak) had a satisfactory DFT (15±4 J) with the lead alone or in conjunction with devices with a biphasic shock waveform (Ventritex Cadence or CPI Ventak P2). The remainder, who required a subcutaneous lead system (patch, 9 patients; array, 5 patients), had a mean DFT of 17.5±6 J.

There were five complications. One patient developed an axillary patch-site hematoma the day after device implantation. This was managed conservatively and resolved over the next few days without sequelae. One patient with Marfan’s syndrome developed a left pneumothorax, which became apparent on the night of the procedure, related to attempted left subclavian venous puncture. Left antecubital venography during the case showed that the left subclavian vein was absent and the left cephalic vein had an abnormal and tortuous course into the left common jugular venous trunk. The right subclavian vein was safely cannulated after contrast venography had confirmed its presence and location. In this case, the Endotak lead was positioned at the right ventricular apex and tunneled to a right-of-midline abdominal pocket, and a subcutaneous patch electrode was placed in the left axilla and tunneled downward and across the midline to the abdominal pocket. One patient, who had been on bed rest for 6 days before CPI Ventak PRx/Endotak lead/patch implantation, developed an acute minor pulmonary embolism 12 hours later. Intravenous heparin led to moderate bruising in and around the pulse generator pocket. This was managed conservatively with no sequelae.

Two patients with severely impaired left ventricular function (left ventricular ejection fraction of <20%), related to coronary artery disease, decompensated after defibrillation testing, with hypotension and hypoxia and an acute elevation of pulmonary capillary wedge pressure. Both patients required intensive therapy with vaso dilators, diuretics, and intravenous inotropic agents; they remained intubated, received continuing positive-pressure ventilation overnight, and were successfully extubated the following day. These patients were subsequently discharged on postoperative day 6 and were in New York Heart Association functional class II at follow-up at 4 and 25 weeks.

In all patients, the NTL ICD system satisfactorily defibrillated ventricular fibrillation at the predischarge device check with 29±5 J. The mean time to hospital discharge after the implant was 5.1±3.6 days. After 12.4±9 weeks of follow-up, all devices were functioning satisfactorily, and there had been no late complications. Ten patients received antitachycardia pacing therapy for ventricular tachycardia, which was successful in 7. Three patients received high-voltage shocks, which appear to have been appropriate in all cases, on the basis of therapy history data available from telemetry of the device and symptoms before device discharge.

**Discussion**

This report demonstrates that a successful program of NTL cardioverter/defibrillator implants can be initiated in an EP laboratory by electrophysiologists alone with a high level of success and minimal complications, provided that adequate facilities and expertise are available.

At present, the size of the ICD capacitors and batteries required to charge them repeatedly places miniaturization constraints on ICD generators. In the United States, smaller ICDs have a limited availability. Even with these smaller devices, which have been
implanted in larger numbers in Europe, however, a substantial proportion (≈40%) still need to be placed in the abdomen by use of tunneling techniques. Although a large series of pectoral “unipolar” NTL ICD systems has been tested in the United States before a conventional implant, there are as yet no data on these new devices chronically implanted. Reports do exist of patients receiving “conventional” sized (110 to 150 cm²) devices in the pectoral region, but usually the patient has been uncommonly large, rather than the device being comfortably small. In another US series of pectoral implants, a complex submuscular approach was needed to prevent generator migration, and two incisions were still required for implantation, one below the clavicle and a second under the breast. The time to market release of unequivocally pectoral NTL ICD systems in the United States is likely to be measured in years. Therefore, for the present, the complexity of NTL ICD implant procedures is greater than that required for pacemaker implantation, although the skills acquired from a considerable pacing experience are useful in NTL ICD implantation. In our center, all electrophysiologists involved in ICD and pacemaker implantation underwent additional supervised training with an experienced cardiac surgeon in the operating room to acquire knowledge of the tunneling technique and the superficial abdominal surgery required before the implant program was relocated to an EP laboratory without surgical assistance. The continuing large size of defibrillators relative to modern cardiac pacemakers makes it unlikely that implant procedures will become very much simpler in the near future and argues for an advanced level of experience for implanters.

To safely and efficiently coordinate and perform NTL ICD implants in an EP laboratory, a certain minimum staffing requirement was found to be necessary. Initially, nursing staff from the cardiothoracic operating room provided EP laboratory nursing staff with in-service supervision for the first three cases performed. Thereafter, two laboratory nursing staff were always scheduled to be available to assist with preparation and performance of the procedure. A clinical nurse–pacemaker specialist was also allocated time to coordinate scheduling of cases, consent for clinical studies, measurement of implant parameters, and completion of database records. The medical staffing included an attending anesthesiologist and two attending electrophysiologists.

The mean time of 254±45 minutes required for NTL ICD implantation made sharing facilities with a busy interventional EP laboratory impractical. A second fully equipped laboratory was necessary to use for this purpose and also for pacemaker implants, all predischARGE and follow-up device checks, and some EP studies. This had the advantage of ensuring an adequate volume of work with the ability to maintain a clean environment, which might not have been possible in a shared laboratory performing a wide variety of procedures. When angiographic and coronary interventional procedures might be performed in the same facility, the considerable time required for NTL ICD implant may be a potential cause of scheduling conflicts.

The complication rate in this series was 22%. There was no mortality, and there were no infections. In four of five cases, the complication could be related to general risks rather than the location of implantation or implant personnel. These were a pneumothorax with a subclavian venous puncture, the risk of pulmonary embolism during prolonged bed rest in hospital in the setting of cardiac failure, and hemodynamic deterioration related to DFT testing in high-risk patients with very poor left ventricular function. One complication (4%) could potentially be related specifically to electrophysiologist NTL ICD implantation. This was a hematoma at the site of axillary patch implantation, for which conservative management led to a satisfactory outcome. The incidence of patch-site hematoma was similar to that in another larger series of NTL ICD implants (4 of 84 patients, or 5%). In that series, however, all 80 of 84 patients successfully implanted (95%) required subcutaneous patch placement. Furthermore, the overall complication rate was higher, with 18 of 84 patients (21%) having complications directly related to the implant procedure. One significant complication commonly reported in NTL ICD implants is transvenous lead displacement, which may range from 0% to 10%. This was not encountered in our early experience. We attribute our lack of lead displacements to the availability of state-of-the-art radiographic equipment. This has to be contrasted with conditions in the operating room, where fluoroscopy is frequently portable and unsophisticated and electrophysiology staff make only rare appearances.

The rate of complications compares favorably with other reported series and with the results of epicardial ICD implants. One series of epicardial ICD implants reported an ICD operative mortality of 3.1% for patients also undergoing concomitant cardiac surgery and 4% for thoracotomy ICD implant alone. We and others observed no early mortality associated with implantation despite attempting the procedure in relatively high-risk patients, a number of whom had a history of cardiac failure and poor left ventricular function. Despite the small numbers in this series, the lack of early mortality so far and the low morbidity directly attributable to the NTL ICD implant has been reassuring, and we attribute it to the availability of high-quality equipment and familiarity of implanting electrophysiologists with laboratory surroundings and personnel. The reasons for a lower mortality with NTL versus epicardial ICD implantation cannot be clarified without randomized data to exclude differences in patient populations. However, one observation made by Bardy and confirmed in this series is the lack of a clustering of ventricular arrhythmia episodes around the time of operation, which has been reported elsewhere. It is possible that damage to epicardial sympathetic nerves with epicardial defibrillation may result in inhomogeneity of sympathetic innervation, dispersion of refractoriness, and proarrhythmia, as recently demonstrated in laboratory animals.

The combined considerations of NTL ICD hardware complexity; electrophysiologist, nursing, and support staff training; and time required for implantation suggest that a level of certification and capitalization are needed for a successful NTL ICD implant program. We anticipate that new NTL ICD programs will be expected to meet nationally agreed-upon professional guidelines for training and facilities, updated to meet the challenge of new technologies.
References

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