Implantation by Electrophysiologists of 100 Consecutive Cardioverter Defibrillators With Nonthoracotomy Lead Systems

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Background Traditional lead systems for implantable cardioverter defibrillators (ICDs) require a thoracotomy for placement. Nonthoracotomy lead systems are available and are usually implanted by an electrophysiologist and a surgeon. The purpose of this study was to prospectively evaluate the safety and efficacy of ICD implantation with a nonthoracotomy lead system by electrophysiologists.

Methods and Results A consecutive series of 100 patients (mean age, 61 ± 13 years; ±SD) underwent ICD implantation with a nonthoracotomy lead system while intubated and under general anesthesia. Seventy-seven patients had coronary artery disease, 15 had idiopathic cardiomyopathy, 6 had miscellaneous heart disease, and 2 had structurally normal hearts. The mean ejection fraction was 0.29 ± 0.13. Sixty-eight patients had suffered a cardiac arrest, and 32 had had ventricular tachycardia or syncope. All patients except 9 underwent electrophysiological testing and had failed 1 ± 1 drug trials before ICD implantation. Three types of nonthoracotomy lead systems were used. The nonthoracotomy lead with an ICD was successfully implanted in 96 patients (96%). Of the unsuccessful implants, 1 patient did not have venous access, the passive fixation lead in 1 would not remain lodged, 1 had elevated defibrillation thresholds, and 1 developed a hemopneumothorax while venous access was being obtained. The mean defibrillation threshold was 17 ± 6 J. The mean procedure duration was 161 ± 57 minutes. When a subcutaneous patch was used (n = 58), the procedure duration was 189 ± 5 minutes, and when a subcutaneous patch was not required (n = 40), the procedure lasted 123 ± 37 minutes (P < .0001). Patients remained in the hospital 4.5 ± 4.1 days after implantation, with no procedure-related deaths. Acute complications occurred in 10 patients; 2 had lead dislodgments, 1 with previous abdominal surgery had his abdominal cavity entered (without other complications) while the ICD pocket was being made, 1 had postoperative heart failure, 1 developed a large hematoma when anticoagulation therapy was initiated, 3 required reintubation because of excessive anesthesia, 1 developed superficial cellulitis, and 1 developed a hemopneumothorax secondary to a lacerated subclavian vein. During 6 ± 3 months of follow-up, 2 patients developed lead fractures.

Conclusions (1) Electrophysiologists can implant an ICD with a nonthoracotomy lead system safely and with a high success rate; (2) use of a subcutaneous patch correlates with longer procedure durations; and (3) special precautions should be taken in patients with previous abdominal surgery.

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Key Words • defibrillation • ventricular tachycardia • ventricular fibrillation

Current therapeutic options for treatment of lethal ventricular arrhythmias include antiarrhythmia drug therapy, surgical resection, transcatheter ablation, and implantable cardioverter defibrillators (ICDs). Conventional lead systems for use with an ICD require a thoracotomy to place epicardial defibrillation patches. The risks of this operation have been significant, with perioperative mortality up to 8%. Nonthoracotomy lead systems are available and practical, and a large patient series recently reported the safety and efficacy of this new type of lead system. A team of electrophysiologists and surgeons is used at many centers for implanting an ICD with a nonthoracotomy lead system; the transvenous portion is usually implanted by an electrophysiologist, and a cardiovascular surgeon implants the subcutaneous lead, if needed, and performs the remainder of the implant procedure (Cardiac Pacemakers, Inc, unpublished data). Therefore, the purpose of this study was to prospectively evaluate the safety and efficacy of an electrophysiologist performing the entire ICD implantation with a nonthoracotomy lead system.

Methods

Patient Population The patient population consisted of 100 consecutive patients undergoing implantation of an ICD with a nonthoracotomy lead system between October 1992 and September 1993. The mean age of the patients was 61 ± 13 years; there were 80 men and 20 women. Ischemic cardiomyopathy was present in 77 patients, idiopathic dilated cardiomyopathy in 15, other forms of cardiomyopathy in 6, and structurally normal hearts in 2. Of these patients, 68 presented with cardiac arrest, and 32 presented with sustained ventricular tachycardia or syncope. The mean left ventricular ejection fraction was 0.29 ± 0.13, and 21 patients had an ejection fraction < 0.20. Electrophysiological testing was performed in 91 patients; 58 had inducible ventricular tachycardia, and 33 did not. The patients failed 1 ± 1 antiarrhythmic medications before ICD implantation.
None of the patients were thought to need concomitant coronary artery bypass graft surgery.

**Surgical Approach and Electrode Position**

The device and lead systems were implanted in the clinical electrophysiology laboratory until June 7, 1993 (n=62). After that, the implantations were performed in an operating room (n=38). The patient was anesthetized and intubated. The entire surgical procedure of ICD implantation with a nonthoracotomy lead system was performed by two electrophysiologists. A 3-cm incision was made 2 cm inferior to the clavicle along the lateral half of this bone after the patient was prepared and draped. Electrocautery was used to dissect to the pectoralis major. Access to the subclavian vein was obtained by venipuncture, and the transvenous lead was advanced through a sheath to the right ventricular apex. One of the nonthoracotomy lead systems (Medtronic Inc) required a second transvenous lead, which was advanced to the heart in the same manner and was positioned either in the right atrium, the superior vena cava, or the coronary sinus.

A subcutaneous patch was sometimes a requisite component of the nonthoracotomy lead system (Intermedics Inc) and sometimes was required because the defibrillation threshold mandated its use (Medtronic, Cardiac Pacemakers). When a subcutaneous defibrillation patch was required, it was positioned in one of two ways: either inferior to the clavicle in the high left anterolateral thorax or in the low left lateral thorax overlying the left ventricular apex. After defibrillation testing demonstrated an acceptable defibrillation threshold, the abdominal incision was made lateral and superior to the umbilicus, and the pocket was created anterior to the rectus sheath. A tunneler was then advanced subcutaneously from the abdominal pocket to the lead, which was attached to the tunneler and subsequently pulled down to the abdominal pocket and attached to the ICD. The duration of the entire procedure was defined to be from the initial incision until all wounds were closed.

**Lead Systems and Defibrillators**

Nonthoracotomy lead systems from Cardiac Pacemakers, Inc, Medtronic, Inc, and Intermedics, Inc were used. The Cardiac Pacemakers lead system (Endotak C) consists of a right ventricular endocardial lead that has two shocking coils and a porous passive fixation tip. When needed, a subcutaneous patch (model 0063) was used. This lead system was used in conjunction with the AICD model 1550, 1555, or 1600. This device delivers only monophasic shocks.

The Medtronic nonthoracotomy lead system consists of two transvenous leads and a subcutaneous patch (model 6999) if needed. One of the transvenous leads was positioned in the right ventricle (model 6966) via an active fixation lead, and the second transvenous lead (model 6963) was positioned either at the junction of the high right atrium with the superior vena cava, exclusively in one of these two structures, or in the coronary sinus. This lead system defibrillates between the right ventricular lead and the superior vena cava/coronary sinus lead or in combination with the subcutaneous patch if it was required to obtain an adequate defibrillation threshold. This lead system was used in conjunction with the PCD defibrillator, which is multi-programmable and offers VVI and anti-tachycardia pacing, low-energy cardioversion, and high-energy shock therapies (34 J) with a monophasic waveform.

The third system was manufactured by Intermedics, Inc. This lead system has a requisite subcutaneous patch and a single intravascular electrode that is positioned in the right ventricle via a screw in the tip. This manufacturer’s ICD (RES-Q) has features similar to the Medtronic PCD, except it delivers the shocks with a biphasic waveform.

**Defibrillation Threshold Testing**

An adequate defibrillation threshold was defined as being at least 10 J less than the maximum output of the ICD. After the endocardial lead or leads were appropriately positioned, the defibrillation threshold was determined. Ventricular fibrillation was induced with alternating current, and 10 seconds later a 20-J shock was delivered. If this converted the patient to sinus rhythm, an additional successful conversion at the same energy or less was required to demonstrate an adequate defibrillation threshold. A subcutaneous patch was used when the “lead alone” defibrillation threshold was >20 J. Multiple patch positions were attempted, as described above, until an adequate defibrillation threshold was demonstrated.

**Postoperative Care**

After implantation of the ICD, patients were extubated in the operating room. Routinely, the patient remained in the operating room recovery area 2 hours and then returned to a telemetered bed in a cardiac step-down unit. Patients with operative or anesthesia-related complications and patients who came to the operating room from an Intensive Care Unit bed returned to an Intensive Care Unit bed after the procedure.

Routine postoperative care included 48 hours of intravenous vancomycin, in addition to a single dose administered before surgery. All patients then received an oral, first-generation cephalosporin for 5 additional days. Two days after the implant, the patient was brought to the electrophysiology laboratory for a predischarge ICD evaluation. This study was designed to evaluate the efficacy of the device and lead system as therapy for ventricular fibrillation and for ventricular tachycardia when indicated. The discharge parameters of the device were programmed at this time. Patients were discharged from the hospital after this evaluation.

**Follow-up and Complications**

All complications related to the implantation of the ICD were tabulated and tracked. Intraoperative and postoperative complications and complications during follow-up were also monitored. All patients returned to the electrophysiology laboratory 1 to 4 months after device implantation for reevaluation of the efficacy of the device and lead system for therapy of ventricular fibrillation and/or ventricular tachycardia.

**Data Analysis**

Continuous variables are expressed as mean ±1 SD and were compared by Student’s t test for unpaired variables. Multiple continuous variables were compared by ANOVA, and nominal variables were compared by χ² analysis. Analyses of variables related to device manufacturers were compared by ANOVA with repeated measures, and the individual comparisons were then made with an unpaired t test. Regression analysis was used to compare two continuous variables. Statistical significance required a probability value <.05.

**Results**

**Major Findings**

The ICD was successfully implanted in 96 of 100 patients. The manufacturers of the devices were Cardiac Pacemakers in 58 patients, Medtronic in 26 patients, and Intermedics in 14 patients. Subcutaneous patches were required in 58 patients. The mean procedure duration was 161±57 minutes, the mean defibrillation threshold was 17±6 J, and patients remained in hospital for 4.5±4.1 days after implantation. There were 10 acute complications associated with device implantation. There were no procedure-related deaths.
Failed Implants

In four patients, an ICD with a nonthoracotomy lead system could not be successfully implanted. In one of these patients, access to a subclavian vein could not be achieved; the left subclavian vein could not be used because a catheter for hemodialysis was in that location and the right subclavian vein was occluded at the junction with the superior vena cava. This patient received an ICD with an epicardial lead system via a thoracotomy. In a patient with an ejection fraction of 0.15, the procedure was unsuccessful because of a high defibrillation threshold. This patient subsequently required a lead system that included two epicardial patches and an endocardial lead from the nonthoracotomy lead system to achieve an adequate defibrillation threshold. A third patient had a hypertrophic cardiomyopathy and had few ventricular trabeculations. Despite two separate attempts at placing the tined endocardial lead (Cardiac Pacemakers), a stable lead position could not be achieved. This patient subsequently received a conventional epicardial lead system. The fourth patient developed a laceration of the subclavian vein when intravenous access was obtained. The patient required a thoracotomy to treat a hemopneumothorax and was subsequently treated with amiodarone.

An additional three patients who had inadequate defibrillation thresholds at the time of the initial implant either had just completed a 10-day course of amiodarone (1800 mg/d orally) or had been on amiodarone chronically (400 mg/d). In these patients, the wound was closed with the lead system in the patient, and amiodarone therapy was discontinued. One week later, defibrillation threshold testing was repeated, and the results were acceptable in all of these patients.

Defibrillation Thresholds

The mean defibrillation threshold was 17±6 J, and 58 patients required a subcutaneous patch to obtain an adequate defibrillation threshold. Only 14 patients received an ICD with a biphasic waveform, whereas the majority (n=86) received an ICD with a monophasic waveform. The defibrillation threshold was not associated with ejection fraction, age, sex, heart disease, or presentation with cardiac arrest.

Procedure Duration

The average procedure duration was 161±57 minutes. Several characteristics were associated with longer procedures. Implant procedures that required subcutaneous patches required 189±53 minutes, whereas procedures that did not require patches lasted 123±37 minutes (P<.001). Procedure duration was significantly related to the number of leads required (P<.0001) when one, two, or three leads were used at implant. Procedure times were 119±34 minutes, 175±53 minutes, and 211±44 minutes, respectively.

The system manufactured by Medtronic required three leads in 23 of 26 implants. The Cardiac Pacemakers system required a subcutaneous patch less often (20 of 58 implants; P<.001). The procedure duration with the Cardiac Pacemakers system (136±43 minutes) was significantly shorter than with either the Intermedics system (171±50 minutes; P=.01) or the Medronic system (216±52 minutes; P≤.0001); the procedure duration with the latter was longer than with the Intermedics system (P=.02).

Procedure-Related Complications

Procedure-related complications occurred in 10 patients. There were no operative deaths. The most serious complication occurred in a 67-year-old woman who developed a lacerated subclavian vein while intravascular access was being attempted. This patient required a thoracotomy for management of a hemopneumothorax, and she was treated with amiodarone. Anesthesia-related complications occurred in 3 patients who developed hypercapnea and hypoxia soon after extubation and required temporary reintubation. Another patient developed congestive heart failure immediately after surgery and required reintubation and intensive therapy for 24 hours. Acute lead dislodgments occurred in 2 patients, including 1 patient in whom the procedure was unsuccessful. In the other patient, the lead in the coronary sinus dislodged. The lead was successfully repositioned, and the defibrillation threshold was again demonstrated to be acceptable. Both lead dislodgments occurred within the first 30 implants. The peritoneal cavity was entered in 1 patient who had had previous surgery for an abdominal aneurysm repair. As a result of this surgery, the patient had surgical absence of the medial aspect of his rectus sheath and rectus muscle. A 2-cm incision of the peritoneum was closed without complications. A large hematoma developed in 1 patient 3 days after his implantation when heparin therapy was initiated. He was transfused with 3 U of packed red blood cells and required surgical evacuation of the hematoma. There was 1 postoperative infection. This patient developed superficial cellulitis 2 days after his implantation, despite receiving intravenous vancomycin for 48 hours. He was treated with intravenous piperacillin and gentamicin for 3 days and then oral Augmentin therapy for 2 weeks.

Long-term Follow-up and Complications

These 100 patients were followed for 6±3 months. During this time, only 1 patient died, the cause being complications of coronary artery bypass graft surgery. Two patients developed lead fractures 4 and 5 months after implantation that were attributable to lead injury from the first rib. Of the patients with successful implantations, all except 2 returned for the outpatient follow-up electrophysiology study. In 1 patient, ventricular fibrillation could not be converted to sinus rhythm with a 30-J shock. This patient had a defibrillation threshold of 25 J with a patch at his initial implant. An epicardial patch was placed through a left lateral thoracotomy and was used in conjunction with the venous lead to obtain a defibrillation threshold of 10 J.

Discussion

This study demonstrates that nonthoracotomy lead systems can be implanted by electrophysiologists with a high success rate (96%) and with an acceptable incidence of complications. The success rate in this study compares favorably with the 71% to 95% success rate observed when this procedure is performed by a team of electrophysiologists and surgeons.17,18 These results are not unexpected, since the investigators are highly trained at pacemaker implantation, and the skills re-
quired for ICD implantation with a nonthoracotomy lead system are similar.

Defibrillation Thresholds

The defibrillation thresholds in this study were similar to those observed with epicardial lead systems and nonthoracotomy lead systems. An adequate defibrillation threshold was achieved in 96 of 100 patients. Of note, the approach to defibrillation threshold testing has been aimed primarily at determining clinical efficacy, whereas formal defibrillation thresholds were obtained in only a small number of patients. Therefore, factors affecting defibrillation thresholds may not be possible to determine from these data.

Acute defibrillation thresholds were not acceptable for ICD implant in three patients who had recently discontinued oral amiodarone. However, repeat defibrillation threshold testing 1 week later was adequate for implantation in all patients, suggesting that amiodarone may adversely affect defibrillation thresholds.

Procedure Duration

Implantation of an ICD with a nonthoracotomy lead system can usually be accomplished in approximately 2.5 hours. The use of each additional lead prolongs the procedure approximately 50 minutes. Implantation of the Cardiac Pacemakers lead system was associated with shorter procedure durations than either the Intermedics or Medtronic systems. This is probably a result of this manufacturer’s simpler lead system design.

Complications

The complications that occurred in this series are similar to those reported in two previous reports of ICDs with nonthoracotomy lead systems implanted by a cardiologist and a surgeon.

In the current series, despite 21 patients with ejection fractions <0.20, the ejection fraction was not inversely proportional to the development of complications. The device was successfully implanted in these 21 patients.

Making the ICD pocket in a patient with a history of an abdominal aortic aneurysm repair was complicated by entry into the peritoneal cavity. This patient, as a result of his abdominal surgery, did not have a rectus muscle or rectus sheath. Therefore, particular care is required when making the pocket in patients with previous abdominal surgery; the dissection to the rectus sheath should be started from the lateral aspect of the incision and extended medially. The most serious complication related to the development of a hemopneumothorax, which occurred while intravascular access to the subclavian vein was being obtained. This is a recognized, though quite uncommon, complication of direct subclavian venipuncture. Some authors suggest that the cephalic vein approach is safer and as efficacious.

Follow-up

During the follow-up period of 6±3 months, 94 patients returned for a 2-month postimplantation electrophysiology study to demonstrate device efficacy. In 1 patient, ventricular fibrillation was not converted to sinus rhythm by a 30- or 34-J shock. This demonstrates the importance of evaluating the defibrillation efficacy after hospital discharge.

Lead fractures were unusual in this series. The two lead fractures were with the Medtronic lead system and were attributable to lead injury from the first rib. All endocardial leads in this series were implanted via the subclavian vein. However, for the Medtronic system, the cephalic vein approach may be preferable, at least for the large ventricular lead.

Clinical Implications

These results demonstrate that electrophysiologists can implant ICDs with a nonthoracotomy lead system effectively and with an acceptable complication rate provided that they have extensive experience at implanting pacemakers. Implantation of the entire ICD system by the electrophysiologist may provide the patient with better continuity of care, easier procedure scheduling, and perhaps a shorter duration of hospitalization and lower costs.

References


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