Over a decade of clinical experience with the implantable cardioverter-defibrillator has documented its clinical efficacy in the prevention of sudden cardiac death.\(^1-4\) Success of this therapy, however, has been associated with a small but significant mortality and morbidity risk.\(^5,6\) Contributing to this risk has been the need for entering the thoracic cavity in order to place patch leads for delivering cardioverting defibrillating shocks. Postoperative pulmonary complications including atelectasis, pneumonia, pleural effusion, and pneumothorax have been reported in up to 10% of patients.\(^5,6\) Although a subcostal approach for patch lead placement appears to reduce some of the perioperative morbidity, the procedure is technically more difficult, precludes easy lead repositioning, may be impossible to perform in the setting of previous cardiac surgery, and is still associated with some perioperative pulmonary morbidity. Early experience using a single endovascular nonthoracotomy lead system was associated with major technical problems related to failure of long-term lead integrity.\(^7\) Nevertheless, feasibility of the procedure with respect to reducing overall surgical risk and demonstrating adequacy of defibrillation threshold was documented. Now, several years later, it appears that the reliability of nonthoracotomy lead systems has become a reality. The work by Bardy and colleagues\(^8\) confirms the optimistic preliminary reports that have documented the short-term efficacy of the current investigational nonthoracotomy lead systems. Clearly, Bardy and colleagues\(^8\) in this issue of Circulation demonstrate that adequate defibrillation thresholds can be achieved in most patients with a nonthoracotomy lead system. Reduced postimplant pulmonary complications and long-term device efficacy for terminating spontaneous ventricular arrhythmias have been established.\(^8\)

### Multilead Systems: Are There Too Many Options?

Of note, the report by Bardy and colleagues also demonstrates the potential complexity of a multilead defibrillation lead system and the need for continued investigation of this area. Altering the described lead positions, polarity, and energy-pulsing methods provides over 20 different combinations when a three-lead system is used and the capability of different energy-pulsing techniques is present. The report by Bardy and colleagues does not present any systematic comparison of the different combinations of energy-delivering leads and pulsing techniques — only a method that represents “recent experience derived from 2 years of cumulative efforts at streamlining transvenous implant techniques.”

Unfortunately, the investigators never make it clear in their report at what point in their study the recommended methodology was used systematically in their patients. Thus, it is impossible to accurately judge the efficacy of their recommended technique. It is also of interest to note that in nine of the last 20 patients in their study, dual simultaneous pathways for energy delivery were used as the final pulsing method. These results differ from previous work published by the authors and supported by our own experience, which indicates that the sequential shocks are associated with a lower defibrillation threshold.\(^9,10\) It is obvious that much investigation is still required to define the optimum multilead configuration and energy-pulsing method. The variability in the observed results suggest that there might be a number of yet unidentified factors that can make a specific lead placement, polarity, and/or energy-pulsing techniques much more predictably effective and defibrillation testing results much more reproducible in an individual patient. Recommendations regarding implantation methodology should be established based on rigorous comparisons of different techniques and not on anecdotal observations. Because of patient safety concerns, such rigorous testing of all lead configurations, positions, and energy-pulsing techniques cannot be made at one institution. Carefully designed multicenter investigation is recommended.

The ideal nonthoracotomy implantable defibrillator lead system must not only be effective but must be simple to evaluate and to implant. Until reliable algorithms for multilead testing are documented based on rigorously designed investigation, we are left with a suggested algorithm that requires extensive implantation testing to achieve 95% implant success rate. The absence of well-established guidelines for lead placement and configuration remains a major limitation of all nonthoracotomy defibrillation systems currently being evaluated, including that described by Bardy and colleagues. Undoubtedly, simpler lead system designs coupled to more effective energy waveforms, such as biphasic shocks, ultimately may be the preferred approach.\(^11\)
New Complications With a New Lead System

One other note of caution should be made. With a new lead system comes new problems and complications that need to be recognized. The overall rate of lead-related complications reported by Bardy and colleagues was 16%. Complications included coronary sinus and right ventricular lead dislodgment, subclavian vein thrombosis, hematoma formation at patch lead site, and subcutaneous patch cable fracture. In our own experience with the same lead system in over 50 patients at two implant centers, lead dislodgment has been rare. However, additional unique lead-related complications have occurred. A single patient experienced an acute cardiac compression syndrome caused by right ventricular free wall perforation at the time of right ventricular lead placement. A second patient with a prior anterior myocardial infarction experienced a septal perforation and ventricular septal defect formation that became clinically apparent several months after lead placement. Undoubtedly, many of the problems described represent an obligate learning period related to the use of a unique lead system. The optimum techniques for placing, securing, and tunneling these leads to avoid migration, disruption, and unnecessary bleeding or other complications continue to be defined during the clinical investigation of these lead systems.

The nonthoracotomy implantable defibrillation lead system has passed from infancy into its adolescence. Its value as an effective lead system for defibrillation has been confirmed. However, attention should continue to focus on identifying potential complications associated with the lead system. Refinement and improvement in techniques to help maximize patient safety and ease of implantation are still needed. The demonstrated safety and efficacy of these "less invasive" lead systems will undoubtedly encourage the use of device therapy not only in patients with documented sustained ventricular arrhythmias but also in patients at high risk demonstrated on clinical grounds who are at significant risk for developing ventricular arrhythmias. Optimization of such an important lifesaving therapy is essential.

References


KEY WORDS • Editorial Comments • cardioverter-defibrillators • leads
Nonthoracotomy defibrillator lead systems. A welcomed addition but still a lot to learn.

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