Low-Energy Endocardial Defibrillation Using an Axillary or a Pectoral Thoracic Electrode Location

Sanjeev Saksena, MD; Paul DeGroot, MS; Ryszard B. Krol, MD; Ramesh Raju, MD; Philip Mathew, MS; Rahul Mehra, PhD

Background. A significant proportion of patients receiving endocardial defibrillation lead systems must accept either high defibrillation thresholds (DFTs) with lower safety margins or lead implantation by thoracotomy. We examined the feasibility of achieving universal application of endocardial leads and lower defibrillation energy requirements by optimizing the lead system location in conjunction with biphasic shocks.

Methods and Results. Two defibrillation catheter electrodes were positioned in the right ventricle and superior vena cava. Thoracic patch electrodes were placed at three sites (apical, pectoral, and axillary). Fifteen-joule, 10-J, and 5-J bidirectional simultaneous biphasic shocks were delivered across three different triple electrode configurations (right ventricle, superior vena cava, and patch) after inducing ventricular fibrillation (VF), and DFT was determined. All patients in whom VF was reproducibly inducible (14 patients) could be reproducibly defibrillated at 15 J at one or more patch electrode locations. Fifteen-joule shocks were effective at three thoracic electrode locations in 12 patients and at two electrode locations in 6 patients. The lowest mean single-shock DFT was 8.1±3.8 J. In 4 patients, ventricular flutter was reproducibly induced and reverted at 15 J in all patients. Mean DFT for the axillary location was 8.3±3.5 J and was significantly lower than apical (12.8±5.6 J, \(P=.008\)) and pectoral (11.6±4.1 J, \(P<.04\)) patch locations. The probability of success was significantly higher at 10 J with axillary location (78% of patients, \(P<.03\) compared with both other sites) and at 15 J (\(P<.05\) compared with the apical location). Low-energy endocardial defibrillation (≤10 J) was feasible in 10 of 14 tested patients at more than 1 thoracic electrode location at 10 J, whereas only 1 of 7 successful patients could be reverted at more than 1 electrode location at 5 J (\(P<.02\)).

Conclusions. The use of axillary or pectoral patch lead location can allow endocardial defibrillation with biphasic shocks at energies ≤15 J in this lead configuration. Virtually universal application of endocardial defibrillation lead systems can be predicted from these data. Reduction in maximum pulse generator output to ≤25 J using these two thoracic electrode locations with bidirectional shocks can be feasible and maintain an adequate safety margin and permit thoracic pulse generator implantation. Lowering endocardial defibrillation energy <10 J requires increasing specificity of thoracic electrode location. (Circulation. 1993;88:2655-2660.)

Key Words: defibrillation • endocardial • implantable cardioverter-defibrillators • cardiac arrest

Implantation of cardioverter-defibrillators without thoracotomy for placement of defibrillation leads has been widely performed using a triple electrode system.1-3 This lead system usually uses catheter electrodes in the right ventricle, right atrium, or superior vena cava in conjunction with a thoracic patch lead. In recent clinical trials using implantable cardioverter-defibrillators (ICD) with monophasic shock capability, an estimated 65% to 70% of patients could be defibrillated with safety margins of ≥10 J with respect to maximum device output.4,5 A significant proportion (approximately 30%) of patients had to accept either lower safety margins or thoracotomy lead implantation. Currently used ICD pulse generators have energy outputs of 30 to 40 J. ICD pulse generator volumes range up to 140 mL, requiring abdominal device location. Long lead conductors requiring tunneling procedures are needed for this site, and lead conductor fracture has been reported.6 Universal nonthoracotomy implants and pectoral device implants have long been considered important refinements for ICD systems. We have recently reported increased defibrillation efficacy with simultaneous biphasic shock waveforms applied through endocardial leads.7 We examined use of this shock waveform in conjunction with three different thoracic patch lead locations to achieve universal application and low-energy defibrillation using a prospective, randomized study design. This could reduce generator shock output requirements and size for potential pectoral implant.
Study Population

Patients enrolled in this study fulfilled the following selection criteria: (1) history of either spontaneous ventricular tachycardia, ventricular fibrillation (VF), out-of-hospital cardiac arrest, or unexplained syncope and were undergoing clinically indicated electrophysiological evaluation, (2) presence of inducible sustained ventricular tachycardia or VF at electrophysiological study, & and (3) written informed consent for insertion of the investigational endocardial defibrillation lead system and the study protocol.

Device Description

The endocardial defibrillation lead system used two intravascular catheter electrodes and one cutaneous thoracic patch electrode to achieve a triple electrode configuration permitting dual current pathways. The ventricular tripolar electrode had a 10.5F lead body with a distal pace/sense active fixation screw-in electrode and a ring electrode. Twenty millimeters proximal to these electrodes was a 5-cm-long coil defibrillation electrode with a surface area of 4.19 cm². This lead permitted bipolar pacing and sensing using the distal and proximal electrode, while defibrillation shocks used the proximal coil electrode alone. The atrial lead is a 6F tripolar lead with a distal coil defibrillation electrode 5 cm in length with a surface area of 2.83 cm². Proximal to the defibrillation electrode are two ring electrodes for sensing. The cutaneous patch electrode (Dorax Corp, Skokie, Ill.) had an electrode surface area of 50 cm².

Shocks were generated using a Medtronic model 2394 external cardioverter-defibrillator. This device has been described in detail previously. It is capable of generating a single monophasic shock or two successive shocks. In the latter mode, the second shock can have the same polarity as the first shock (sequential monophasic shocks) or the reverse polarity to the first shock, i.e., a biphasic shock. The only shock waveform used in this study was a biphasic waveform generated in this manner. The two shock pulses were of equal duration and separated by an interpulse interval of 0.2 millisecond. The duration of each pulse was determined by the time taken by the pulse to decay from the leading edge voltage of the pulse to 35% of this value, giving a 65% tilt. The leading edge voltage of the second reversed polarity pulse was also specified. The individual leading edge voltages for the first and second pulses at the stored energy levels corresponding to 15 J, 9.6 J, and 5 J, respectively, were 500/140 V, 400/100 V, and 290/80 V. This voltage range was selected based on prior data on simultaneous biphasic shock efficacy in humans and extent of testing compatible with patient welfare and clinically relevant device refinement. The total capacitance used was 120 µF.

A triple electrode configuration was used and included a right ventricular common electrode paired with electrodes in the superior vena cava/right atrium (pathway 1) or left thorax (pathway 2). Biphasic shocks delivered through this electrode system achieved simultaneous pulsing in dual current pathways. Delivered voltage and current in each pathway were monitored using a three-channel storage oscilloscope. Delivered voltage and current were photographically recorded.

Using initial voltage and current data, actual input impedance for each pathway was calculated.

Lead Configurations

Subcutaneous thoracic electrode location was simulated using an adhesive cutaneous patch electrode. We have previously shown excellent concordance of this temporary lead with respect to monophasic shock efficacy and impedance with subcutaneous implantable patch electrodes that are in current clinical practice. This concordance has been noted for apical, pectoral, and axillary patch locations in our prior studies. The lead locations used in this study were (1) apical: patch center located in the fifth left intercostal space in midclavicular line, (2) axillary: patch center located in the fourth intercostal space in midaxillary line, and (3) pectoral: patch center in the second intercostal space in the midclavicular line. The patch electrode was connected to the anodal terminal of the external cardioverter-defibrillator using a Y-connector.

Study Design

The three electrode locations were tested in a predetermined randomized order using a computer-generated randomization schedule. VF was induced using 60-Hz alternating current through the bipolar intracardiac electrodes. The first defibrillation energy level had an initial leading edge shock voltage of 500 V, with an estimated stored energy level of 15 J. If the first shock was successful, a similar process was repeated for each of the other two randomized lead positions at the same energy level. For an unsuccessful shock, a rescue shock was delivered either through the same electrode system at higher voltage or using a transthoracic defibrillation system. If the 15-J energy level was successful at any of the patch locations, stepwise reduction to the 10-J storage energy level (initial shock leading edge voltage, 400 V; actual calculated stored energy, 9.6 J) was undertaken. The patch location(s) showing efficacy at 15 J were randomly tested at 9.6 J. If the 9.6-J energy level was successful at any patch location, testing of the 5-J energy level (initial shock leading edge voltage, 290 V) was undertaken. The protocol was terminated if all three lead positions were noted to be ineffective for VF reversion at one or more voltage levels or if the patient’s clinical status precluded further testing. In the latter instance, only the lowest effective energy was recorded. Alternatively, if success was still present at 5 J, the shock was deemed effective at ≤5 J, and the lower voltages were not tested for that patch position. Rescue shocks were not used in determining efficacy at a patch location in the 5- to 15-J energy range.

Definitions and Statistical Analysis

The definitions used in this study were as follows: lowest effective delivered energy was the lowest shock energy demonstrated to be successful in defibrillation without lower values being tested and shown to be unsuccessful, and DFT was the lowest energy that successfully reverted VF and required demonstration of failure at lower voltages. If successful at 5 J, this was accepted as a single-shock DFT. If unsuccessful at 15 J, a conservative estimate of success at 20 J was used or demonstrated in the patients. These failures at 15 J occurred in 4 patients at the apical location only.
Outcomes of Shocks at Each Energy Level

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S indicates success and F, failure.

*20 J estimated; 120 J successful; †ventricular flutter induced; ‡not performed.

Statistical comparisons were made using nonparametric correlation and regression analytic procedures for percentage efficacy at each energy level and mean DFT at each thoracic patch electrode location. The paired t test was used for comparisons between two groups. Bonferroni's correction was applied when the significance of differences in all three groups were simultaneously analyzed. Multivariate analysis was performed using correlation and discriminant analyses to determine prediction of DFT or lowest effective energy using a commercial software statistical program (STATGRAPHICS, STSC Corp, Rockville, Md). Parameters entered in model were clinical and demographic factors, tachycardia characteristics, and drug therapy.

Results

Patient Population

Eighteen patients (16 men and 2 women; mean age, 67±8 years) were enrolled. Fifteen patients had coronary artery disease, and 1 patient had dilated cardiomyopathy. Their mean left ventricular ejection fraction was 30±14%. Nine patients were on antiarrhythmic drug therapy at the time of DFT testing and 9 patients were on no drug therapy. Drugs used were type 1 agents in 5 patients (procainamide, quinidine, mexiletine), type 2 in 2 patients, type 3 in 1 patient (amiodarone), and type 4 in 1 patient.

Arrhythmia Characteristics

One hundred twelve episodes of VF (mean, 6.2 per patient) and 14 episodes of ventricular flutter (mean, 1 per patient) were induced in this study.6 VF could be reproducibly induced in 14 patients, whereas only ventricular flutter could be induced with alternating current in 4 patients. In 1 of these 4 patients, VF was also inducible but not reproducible. The flutter cycle length ranged from 190 to 330 milliseconds. Two episodes of slow ventricular tachycardia with cycle lengths of 370 and 400 milliseconds were also induced and not used in the analysis. A total of 163 shocks were delivered (mean, 9.1 per patient). The duration of testing procedures typically ranged from 1½ to 2 hours.

Defibrillation Testing

The lowest effective energy for VF or ventricular flutter could be elicited in 13 patients at the apex and in all patients at the pectoral or axillary thoracic electrode location. DFT could be obtained or estimated at 20 J at the apical position in 12 patients, axillary position in 12 patients, and pectoral position in 12 patients. The lowest mean DFT for the best patch electrode location in 15 patients in whom it could be obtained was 8.1±3.8 J. The Table shows the outcome of shocks at each energy level in each patient and Fig 1 shows DFT data obtained from VF patients at each electrode site. In 4 patients, apical DFT is indicated as estimated at 20 J due to failure of 15-J shocks. In 2 patients, 30- and 35-J shocks were successful. The mean DFT at the apical location was 12.8±5.6 J, which was significantly higher than the axillary location at 8.3±3.5 J (P=.008; with Bonferroni correction, P=.024). The apical DFT may be actually slightly underestimated due to the assumption of a 20-J DFT in 4 patients. The mean DFT at the pectoral site was 11.6±4.1 J (P=.038 compared with axillary location; with Bonferrooni correction, P=.11).
Fig 1. Comparison of single-shock endocardial defibrillation thresholds for simultaneous biphasic shocks for three thoracic patch electrode locations when used in conjunction with a right ventricular and superior vena caval electrode to deliver bidirectional shocks. Values are mean±1 SD, shown with vertical bars. Open asterisks indicate 4 patients in whom 15-J shocks failed to revert ventricular fibrillation, and defibrillation threshold (DFT) was conservatively estimated at 20 J.

Fig 2 shows the lowest effective energy determined at each site corrected to 1 J. The mean energy was 12.1±4.3 J at the apex, 8.8±3.6 J at the axilla, and 12.1±3.7 J at the pectoral region. Mean energy was significantly higher at the apical site (P=.017) and the pectoral site (P=.015) compared with the axilla. Multivariate discriminant or correlation analysis did not correlate age, sex, or left ventricular ejection fraction with either DFT or lowest effective energy at any site.

**Shock Characteristics**

Delivered shock current and resistance in individual pathways and total lead system could be obtained and analyzed in 13 of 18 patients. The mean resistance in the total lead system and in the individual pathways were comparable for all three electrode locations (Fig 3). Regardless of electrode location, the right atrial–right ventricular pathway had a significantly lower resistance than the thoracic patch–right ventricular path (P<.01). Mean current in the total system and in individual pathways did not differ in the three electrode locations. Delivered shock mean pulse widths for the first shock phase were 6.7±0.8 milliseconds with the apical electrode, 7.0±0.8 milliseconds with the axillary electrode, and 7.1±0.8 milliseconds with the pectoral electrode (P>.2). For the second shock phase, mean pulse width was 6.6±0.9 milliseconds with the apical electrode, 6.9±0.9 milliseconds with the axillary electrode, and 6.9±0.8 milliseconds with the pectoral electrode.

**Defibrillation Reliability**

The probability of repeated reliable defibrillation or cardioversion at a particular energy level was also analyzed from these data, eliminating electrode location as a variable. In 12 of the 18 patients in this study, three successive reversion of induced VF or ventricular flutter could be demonstrated at a 15-J or lower energy level. In the 6 remaining patients, two attempts at 15 J were successful. At the 9.6-J level, 4 patients tested demonstrated three consecutive successes. Six patients at the 9.6-J level and 1 patient at the 5-J level also had two successful reversion of VF or ventricular flutter. The remaining 2 patients at the 9.6-J level and 2 patients at the 5-J level were not tested for reproducibility. A 15 J or lower, DFT could be obtained for at least one and often more lead configurations in all patients using single-shock DFT data from each patch location. Twelve patients had successful reversion at 15 J at all three locations, whereas the remaining 6 patients demonstrated successful reversion at two electrode locations. At the 9.6-J level, 4 patients had successful reversion at all three electrode locations, 6 patients at two locations, and 2 patients at only one location. At the 5-J level, 1 patient had successful reversion at two
thoracic electrode locations, whereas the remaining 5 patients could only be reverted at one location. Low-energy endocardial defibrillation (≤10 J) was feasible in 10 of 14 patients tested at more than one thoracic electrode location, whereas only 1 of 7 patients could be reverted at more than one location at 5 J. The likelihood of more than one thoracic electrode location being effective was higher at 9.6 J than at 5 J (P=.013).

**Probability of Success Analysis**

The percent efficacy for defibrillation and cardioversion for biphasic shocks regardless of patch location is shown in Fig 4. When stratified by patch location in the figure, a significantly greater efficacy at 9.6 J at the axillary location is seen compared with the other two sites. At 15 J, the axillary location remains significantly superior to the apical location. It must be emphasized that individual shock efficacy can vary at each energy level for each thoracic patch location.

**Discussion**

Widespread clinical experience has now been obtained with endocardial lead systems for ICDs. The bulk of this experience is with devices with monophasic shock capability. There has been a marked reduction in perioperative mortality with improved total survival during the first 3 years of follow-up. Sudden death protection has been maintained as compared with epicardial lead systems. These clinical data have also confirmed several earlier observations. These include the need for extensive preoperative or intraoperative lead system testing for lead positioning and satisfactory monophasic DFTs. Despite extensive testing, in a recent multicenter experience, approximately 28% of patients did not meet an implant criterion of three conversions in four attempts at 18 J using monophasic shocks. In addition to limiting universal use of this lead system, this precluded any serious possibility of reducing maximum pulse generator output below 30 J due to lack of a satisfactory safety margin. Early efforts to achieve higher implant rates with nonthoracotomy approaches included use of patch mapping, change in lead polarity, or location. Biphasic shocks have been reported to enhance efficacy of transthoracic defibrillation but have more limited advantages in epicardial defibrillation. We have recently reported significantly increased efficacy and reduced defibrillation energy requirements with endocardial lead systems with simultaneous biphasic shocks. Similar advantages with cardioversion of ventricular flutter and tachycardia were also observed with endocardial leads. In this study, we conducted a controlled experiment to determine if the use of two beneficial approaches, ie, simultaneous biphasic shocks and optimal patch electrode location, could address the concerns seen in monophasic ICD system trials with endocardial leads. In addition to high-implant DFTs and inability to implant universally, complications such as infection and lead dislodgment have bedeviled current experience. Long procedure times with extensive testing and use of locations such as the coronary sinus, which are prone to lead dislodgment, have contributed to these results. Finally, the long lead tunneling procedure from the thoracic venous entry site(s) to the abdominal generator pocket is an aggravating factor for infection and lead complications.

The results of this study provide an encouraging and pivotal experience to address these issues. The data clearly predict high endocardial defibrillation efficacy at 15 J with biphasic shocks using an axillary or a pectoral electrode location. Defibrillation probability curves indicate that the axillary location is superior at 9.6 J, but pectoral and axillary locations achieve near parity at 15 J. Electrode location becomes more critical at ≤10 J with only one or two locations permitting this low DFT. Five-joule values for DFT were more likely to have one specific electrode site than 9.6-J values. Furthermore, the DFT of the apical site could actually have been higher, with 20-J estimates used by us in 4 patients being conservative values. While recognizing that the sample size is moderate, these data clearly merit further study in a larger multicenter study. However, earliest series of endocardial defibrillation lead efficacy were of similar size.

A 10-J safety margin would be available in the vast majority of patients with a 25-J maximum output device. This would clearly be helpful in reducing device size and pectoral implant of a smaller unit. Still lower outputs (20 J) may be considered for more than 70% of the patients in this study. Current 30- to 35-J monophasic devices have occasionally been implanted pectorally in obese patients or in a submammary location in women. Erosion and device migration with large subcutaneous thoracic devices are significant concerns in most patients and would require submuscular implantation. This is a more extensive surgical procedure. A smaller device with lower output would be more suitable for subcutaneous thoracic implant. To achieve a DFT ≤9.6 J requires a pectoral or an axillary electrode location in most patients. Pectoral implant by eliminating tunneling procedures would clearly reduce the surgical field and procedure and lower the risk of infection. The use of a triple lead system that excludes the coronary sinus or other locations such as the right ventricular outflow tract in this study also has some promise for improving lead dislodgment risk. Atrial and ventricular endocardial leads have been long evaluated for stability and

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**Fig 4.** Percent efficacy of defibrillation shocks at individual energy levels as stratified by thoracic electrode location. Note the near universal efficacy at 15 J at more than one location. However, at 9.6 J, axillary locations have significantly higher efficacy for defibrillation than pectoral or apical locations.
performance and should be less prone to dislodgment than the previously mentioned locations (1% in pacemaker recipients). The thoracic electrode may be a patch or even the generator casing if implanted in a pectoral or an axillary site. Thus, this approach could help address issues related to the long-term performance for endocardial defibrillation leads. These data also suggest that an axillary electrode location is more likely to provide lower DFTs than pectoral or apical sites. Five-joule or 9.6-J energy requirements were more consistently obtained at the former location, which should therefore always be tested before abandoning nonthoracotomy implant or low-output pulse generators.

The reliability of endocardial defibrillation in this study design merits comment. The methodology of a single-shock DFT in acute clinical studies in endocardial defibrillation has been used widely. However, using criteria for chronic implant requiring repetitive demonstration of efficacy, all patients in this study could demonstrate reproducibility at 15 J and the vast majority at 9.6 J. This is further supported by effective cardioversion of ventricular flutter at similar or lower energy levels. We have recently reported that the energy requirements for defibrillation in ventricular flutter and VF are quite similar for sequential monophasic, simultaneous monophasic, and biphasic shock waveforms with endocardial leads.

The use of cutaneous patch electrodes to replicate apical, axillary, or pectoral subcutaneous patch leads for defibrillation merits examination. Prior studies from our laboratory have indicated reproducible efficacy with the temporary and permanent lead systems for monophasic shocks. However, this remains to be demonstrated for biphasic shocks.

Conclusions

The use of simultaneous biphasic shocks with a pectoral or an axillary electrode location in a triple endocardial lead system should permit near-universal implantation of this nonthoracotomy lead system, assuming that cutaneous electrodes mimic implanted patch leads for biphasic shock waveforms. DFTs of 15 J or lower can be anticipated. A marked reduction in the extent of lead system testing and a standardization of lead configuration to the locations used in this study can be anticipated. A 25-J generator is feasible for chronic implant with this lead system with an adequate safety margin. Further lower generator outputs would require increasing electrode specificity, usually to an axillary location. Thoracic implantation of the ICD generator could become more applicable with a smaller generator. Pectoral or axillary implant of such a generator electrode could obviate the need for a patch lead. Reduction in extensive testing and tunneling at such implants can address many of the current difficulties with endocardial defibrillation leads. This should further increase acceptance of these systems by patients and their physicians as well as simplify their clinical use.

References

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