Preliminary Experience With a Hybrid Nonthoracotomy Defibrillating System That Includes a Biphasic Device: Comparison With a Standard Monophasic Device Using the Same Lead System

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Objectives. This study analyzed the advantage of combining a biphasic device with a transvenous system and compared the results with those obtained with a standard monophasic device.

Background. Available lead systems use monophasic pulses and may require lengthy intraoperative testing to achieve adequate defibrillation threshold in a conspicuous number of patients. The option of biphasic waveform may provide further benefits. However, clinical experience with a permanent implant is lacking.

Methods. Fifty-five patients underwent testing and received a permanent implant using the Endotak lead system associated with a CPI monophasic device. The remaining 36 patients received a permanent implant with the Endotak lead system connected to a biphasic device. In both groups a subcutaneous patch was combined when needed to obtain acceptable defibrillation thresholds.

Results. Biphasic pulses resulted in lower mean (±SD) defibrillation thresholds (monophasic 15 ± 4.7 J vs. biphasic 12 ± 5 J, p = 0.03) and a better implantation rate (100% biphasic vs. 89% monophasic, p = 0.07). Biphasic pulses allowed implantation with less ventricular fibrillation induction (7.4 ± 3.2 vs. 3.5 ± 1.8, p < 0.01) and a mean shorter procedure time (168 ± 39 vs. 111 ± 30 min, p < 0.01). With the biphasic waveform a greater proportion of patients met the implantation criteria with the lead system alone (83% vs. 45%, p < 0.01). When needed, the left prepectoral location of the patch electrode was always sufficient in patients receiving the biphasic device, whereas placement in the left subcapular position was required in 15 patients in the monophasic group. Implantation of the biphasic device was associated with a shorter mean hospital stay (3.8 ± 0.9 vs. 5.4 ± 2.2 days, p < 0.01).

Conclusions. Incorporation of a biphasic device in a transvenous implantable cardioverter-defibrillator uniformly increases the efficacy of the system and the ease of implantation.

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Implantable cardioverter-defibrillators have been widely used to prevent sudden cardiac death. Rapid development of defibrillator technology and its efficacy in aborting malignant ventricular arrhythmias have dramatically improved management and prognosis of patients with ventricular tachycardia or ventricular fibrillation and survivors of cardiac arrest (1-7). Recently, the use of lead systems that do not require thoracotomy has been advocated to minimize the postoperative morbidity and mortality associated with thoracotomy for placement of the defibrillating electrodes (8-16). Nonthoracotomy implantable lead systems have now passed from the initial stage of development, and their value as an effective method for defibrillation has been confirmed (8-18).

However, although recent developments in defibrillation pulsing methods and lead systems have led to lower energy requirements for successful defibrillation, as many as 10% to 30% of patients may still not have reliable defibrillation with this approach and may require thoracotomy (12-13,16-20). In addition, the complexity of the available multilead defibrillation systems may result in extensive intraoperative testing procedures, resulting in poor patient tolerance (12,17,20). Implantable cardioverter-defibrillator systems lack certain desirable features, and alternate approaches need to be explored. Experimental data in animal models and in humans suggest that the biphasic waveform provides an option for improving defibrillation efficacy (21-27). However, experience with permanent implantation of transvenous systems that include a biphasic device is limited. In this study we analyzed the advantage of implanting a nonthoracotomy defibrillation system connected to a cardioverter-defibrillator that delivers asymmetric biphasic shocks and compared the results with those achieved with a standard device able to deliver monophasic pulses.

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Methods

Patient group. After informed verbal and written consent for implantation of a transvenous defibrillator was obtained, 91 patients with a history of sudden cardiac death or ventricular tachycardia refractory to antiarrhythmic medications underwent defibrillator implantation. The patients were assigned to two different groups and were not randomized to receive either device; rather, they were assigned to receive one of them according to availability. The first group included 55 consecutive patients who underwent implantation and testing using a device capable of delivering monophasic shocks. The remaining 36 patients underwent implantation using a hybrid system consisting of the same defibrillating electrodes that were, however, connected to a device that allowed defibrillation with asymmetric biphasic pulses. The presenting arrhythmia was sustained monomorphic ventricular tachycardia in 48 patients, ventricular fibrillation in 29 and both ventricular tachycardia and ventricular fibrillation in the remaining 14. Coronary artery disease was present in 70 patients, all of whom had a history of previous myocardial infarction. Two patients had a history of valvular heart disease; 15 had dilated idiopathic cardiomyopathy; and the remaining four had primary ventricular fibrillation. All 91 patients underwent electrophysiologic study before defibrillator implantation. Before electrophysiologic study and defibrillator implantation, antiarrhythmic therapy was discontinued for at least five half-lives. All patients were considered candidates for an implantable cardioverter-defibrillator on the basis of clinical history and the presence of inducible, sustained monomorphic ventricular tachycardia not responding to antiarrhythmic medications.

Lead system. The transvenous lead system comprised a 12F tripolar endocardial catheter for rate and configuration sensing, as well as shock delivery. The proximal spring electrode had a surface area of 617 mm² and the distal spring electrode a surface area of 295 mm². A porous tip functioned as the rate-sensing cathode, and the right ventricular spring electrode served as both the shocking cathode and the rate-sensing anode. The proximal spring electrode was used as a cardioversion-defibrillation electrode only. The distal end of the endocardial lead had tines for passive fixation. To accommodate different intracardiac proportions, two endocardial leads (Endotak-C models 0062 and 0064) were used in our patients. The proximal electrode positions for models 0062 and 0064 are 13 and 16 cm, respectively, with the sensing tip to the distal end of the proximal electrode. A patch electrode (CPI model 0063) with a total surface area of 28 cm² was also available for implantation when bidirectional current pathways were chosen to provide better defibrillation efficacy. The patch electrode was placed in either the subcutaneous or submuscular left thoracic wall. Defibrillation thresholds were tested using either the coil/coil or the patch/coil configuration. The devices used for permanent implantation included the Ventak 1600, 1550 and 1555 (CPI) in the first 55 patients, and the Cadence model V-100 (Ventricex, Sunnyvale, CA) was implanted in the remaining 36 patients. All three CPI devices were able to deliver truncated exponential monophasic shocks, whereas the Ventricex device allowed defibrillation with the asymmetric biphasic waveform with a programmable pulse width and shock voltage. Although the biphasic waveform has an independently programmable positive and negative pulse width phase, the negative phase is never allowed to be programmed longer than the positive phase. According to the impedance, the pulse width of both positive and negative phases was chosen to maintain a constant waveform tilt ~65%. With both CPI and Ventricex devices, when bidirectional shocks were needed a 15-cm long AICD-Y connector (CPI model 0836) was used to connect the endocardial lead and patch electrodes to the device header.

Device implantation. All implantation procedures were performed with the patient under general anesthesia. The left subclavian vein was then cannulated through a 4-cm transverse left infraclavicular incision. Under fluoroscopic guidance, the tripolar endocardial catheter was passed into the right ventricular apex, with the proximal spring position at the junction of the high right atrium and superior vena cava. The endocardial lead sensing and pacing thresholds were then measured with a pacing system analyzer. Rate and configuration sensing lead electrograms were recorded during sinus rhythm, as well as during induced ventricular fibrillation. When the patch electrode was needed, it was initially placed in the pectoral left thoracic wall. If this position did not result in adequate improvement of the defibrillation threshold, the patient was placed in a 20° left lateral position, and a 10-cm transverse incision was made at the left fifth intercostal space crossing the midaxillary line. At that site the patch electrode was implanted in the submuscular plane deep to the latissimus dorsi and overlying the serratus anterior muscle.

Fibrillation-defibrillation protocol. Ventricular fibrillation was induced using 60-Hz alternating current applied through the rate-sensing electrode. The defibrillation threshold was then assessed. In the 35 patients undergoing implantation with the Ventritex device, initial attempts were made with ~18-J shocks delivered through an external defibrillator (HSV-02, Ventritex) that allowed defibrillation with biphasic pulses with a programmable pulse width and shock voltage. If the first shock was successful, the energy of subsequent fibrillation episodes was decremented by ~5 J until failure was obtained. If the 18-J shock was unsuccessful, further testing of higher energy using ~5-J increments was performed until successful defibrillation was achieved. No energy >35 J was tested. In patients undergoing implantation with monophasic CPI devices, defibrillation threshold determination was performed in the same manner. However, the first defibrillation shock was usually performed using ~20 J. In this cohort defibrillation testing was performed using an external defibrillator (CPI ECD model 2806). Defibrillation threshold was defined as the lowest energy of the
first shock that successfully terminated ventricular fibrillation. Ten seconds of stable ventricular fibrillation were allowed before attempting defibrillation. Before reinduction of ventricular fibrillation, electrocardiographic and hemodynamic changes were required to recover. All patients underwent initial testing using the coil/coil configuration. If this resulted in an inadequate defibrillation threshold, the subcutaneous patch was then used. With a few exceptions patients were considered to meet the implantation criteria when the defibrillation threshold was \(<25\) J with the Ventritex and CPI 1555 devices and \(<22\) J with the CPI 1600 and 1550 generators. After a lead configuration was chosen for permanent implantation, the leads were tunneled to the generator pocket created in the left anterior abdomen. The detection and termination of induced ventricular fibrillation by the implanted defibrillator were then tested. The pulse generator and leads were placed in the abdominal pocket, and the incisions were closed using reabsorbable sutures.

**Postimplantation and follow-up testing.** Before discharge from hospital, defibrillator testing was performed in all patients. This included induction of ventricular fibrillation and ventricular tachycardia. When available, tiered therapy was programmed according to individual patient characteristics. Implantable cardioverter-defibrillator evaluation was repeated 4 to 6 weeks postoperatively. Thereafter, patients were seen every 3 months or earlier if any shocks were delivered or if any complications occurred.

**Statistical analysis.** Results are expressed as mean value ± SD. The unpaired Student t test was used to compare numeric variables in the two patient groups. The chi-square test was used to compare defibrillation efficacy and other categoric variables between the two groups; \(p < 0.05\) was considered significant.

**Results**

Clinical characteristics and demographic data for both group of patients are summarized in Table 1. Between the two groups there was no difference in terms of age, gender, distribution, mean ejection fraction and type of underlying structural heart disease. Although slightly higher proportion of patients in the group receiving the biphasic device had sustained inducible monomorphic ventricular tachycardia, this did not prove statistically significant. In patients receiving the biphasic device, mean age was 64 ± 10 years (range 38 to 79), mean ejection fraction was 29 ± 10%, and 64% had inducible sustained monomorphic ventricular tachycardia at preimplantation electrophysiologic study. Previous antiarrhythmic drug therapy ranged from zero to 4 medications. Implantation thresholds. Of these, 10 patients had better defibrillation efficacy using a reverse polarity, namely, the superior vena cava coil as cathode and the right ventricular coil as anode. In the remaining six patients the patch electrode was used. With the same defibrillating lead system the biphasic device was successfully implanted in all 36 patients (100%) in whom it was attempted; successful implantation was possible only in 49 (89%) of 55 patients receiving the standard monophasic device (\(p = 0.07\)) (Table 2).

**Table 1. Demographic Data and Clinical Characteristics of the Two Groups of Patients Undergoing Implantation**

<table>
<thead>
<tr>
<th></th>
<th>Biphasic Device (n = 36)</th>
<th>Monophasic Device (n = 55)</th>
<th>(p) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>64 ± 10</td>
<td>62 ± 12</td>
<td>NS</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>25/11</td>
<td>37/18</td>
<td>NS</td>
</tr>
<tr>
<td>EF (%)</td>
<td>29 ± 10</td>
<td>28 ± 11</td>
<td>NS</td>
</tr>
<tr>
<td>VT-S (inducible) (%)</td>
<td>23 (64%)</td>
<td>30 (54%)</td>
<td>NS</td>
</tr>
<tr>
<td>IHD</td>
<td>29</td>
<td>41</td>
<td>NS</td>
</tr>
<tr>
<td>DC</td>
<td>6</td>
<td>9</td>
<td>NS</td>
</tr>
<tr>
<td>VHD</td>
<td>—</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>IVF</td>
<td>1</td>
<td>3</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data presented are mean value ± SD or number (%). DC = dilated cardiomyopathy; EF = ejection fraction; \(\alpha\) = female; IHD = ischemic heart disease; IVF = idiopathic ventricular fibrillation; \(\beta\) = male; VHD = valvular heart disease; VT-S (inducible) = inducible, sustained monomorphic ventricular tachycardia.

**Table 2. Implant Data Relative to Patients Who Received Permanent Implants With the Transvenous System in the Two Groups**

<table>
<thead>
<tr>
<th></th>
<th>Biphasic Device</th>
<th>Monophasic Device</th>
<th>(p) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success rate</td>
<td>36/36</td>
<td>49/55</td>
<td>0.07</td>
</tr>
<tr>
<td>Mean DFT (J)</td>
<td>(100%)</td>
<td>(89%)</td>
<td></td>
</tr>
<tr>
<td>VF induction (n)</td>
<td>12 ± 5</td>
<td>15 ± 4.7</td>
<td>0.03</td>
</tr>
<tr>
<td>Implantation time (min)</td>
<td>3.5 ± 1.8</td>
<td>7.4 ± 3.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hospital stay (d)</td>
<td>3.8 ± 0.8</td>
<td>5.4 ± 2.2</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Data presented are mean value ± SD or number (%). Hospital stay = mean hospital stay in patients receiving permanent implants; Mean DFT = mean defibrillation threshold; Success rate = permanent implantation with transvenous system; VF induction = mean ventricular fibrillation inductions required to determine successful configuration.
The mean total time in the operating room for implantation with the nonthoracotomy lead system was 168 ± 39 min; the implantation procedure could be terminated within a mean total time of 111 ± 30 min in patients undergoing implantation with a biphosphic device (p < 0.01).

Defibrillation threshold data. Among patients undergoing implantation with the nonthoracotomy lead system, the measured delivered energy defibrillation threshold obtained with the final lead configuration at implantation was significantly lower with the biphosphic than monophasic pulse (12 ± 5 J vs. 15 ± 4.7 J, p = 0.03). Similar results were obtained comparing the stored energy defibrillation threshold. Mean pulse width for the monophasic waveform was 6.6 ± 1.2 ms, whereas that including both positive and negative phases of the biphosphic 65% tilt waveform was 14.8 ± 1.6 ms. There was no significant difference in the lead system impedance with the two waveforms (biphosphic 46 ± 4.9 ohms vs. monophasic 44 ± 8 ohms, p = NS).

Although direct comparison between biphosphic and monophasic pulses in the same patient was not prospectively performed, in nine patients receiving the biphosphic device, monophasic shocks with leads alone were also tested. In seven of them, a biphosphic waveform resulted in higher defibrillation efficacy with respect to monophasic pulses. In the remaining two patients, similar defibrillation thresholds were obtained with both biphosphic and monophasic waveforms. In three additional patients undergoing permanent implantation with the biphosphic device using the negative right ventricular coil, positive superior vena cava coil, positive subcutaneous patch configuration, simultaneous bi-directional monophasic shocks did not achieve defibrillation with the highest energy tested at 35 J in two patients and provided a defibrillation threshold of 28 J in the third patient. In the same patients simultaneous biphosphic pulses achieved defibrillation thresholds of 18, 15 and 10 J, respectively.

The number of configurations tested in the biphosphic group ranged from one to four (mean 1.6 ± 0.8); in the other group undergoing testing with the monophasic device, one to eight (mean 3.6 ± 1.3, p < 0.01) different lead configurations were tested. Similarly, the mean number of ventricular fibrillation inductions required to determine the successful configuration for permanent implantation was significantly higher in the monophasic waveform group, at 7.4 ± 3.2 versus 3.5 ± 1.8 inductions in the biphosphic waveform group (p < 0.01). Six patients in the monophasic device group did not satisfy the implantation criteria and underwent permanent implantation using an epicardial defibrillation system placed through a left lateral thoracotomy. None of these patients was receiving amiodarone therapy at implantation. No ready explanation for the high defibrillation threshold energy could be found in any of these patients. Data relative to these patients were not included in the analysis of the monophasic group variables.

Postoperative course. All patients tolerated the implantation procedure without difficulty, and there were no perioperative complications or deaths in both groups. All 36 patients receiving the biphosphic device were awake and extubated in the operating room at the end of the operation. In addition, all of these patients were able to ambulate within 24 h, and none experienced prolonged discomfort because of the procedure. Mean hospital stay in this group was 3.8 ± 0.8 days. Similarly, in the other group the immediate postoperative course was relatively uneventful. However, in six patients who received more extensive testing during the intraoperative procedure, extubation was delayed, and a
24-h stay in the intensive care unit was required because of hemodynamic instability. Mean hospital stay in this group was 5.4 ± 2.2 days (p < 0.01). Three patients in the monophasic device group developed hematoma at the site of the subcutaneous patch. One of these patients received anticoagulation 24 h after the procedure because of a recent history of deep venous thrombosis. All three patients had the patch electrode located in the left posterior subscapular position. One of them required intervention. Usually, when the left posterior patch was used, patients required longer therapy with analgesic medications to relieve discomfort (3.6 ± 1.2 vs. 7 ± 3.2 days, p < 0.01). All 85 patients receiving a transvenous system underwent predischarge and 1-month cardioverter-defibrillator testing, including induction of ventricular fibrillation and ventricular tachycardia. In none of these patients was a significant increase in ventricular defibrillation threshold energy observed. In the group receiving the biphasic device, the longer follow-up period was 5 months; the mean follow-up among the 49 patients with the standard monophasic device was 24 ± 8.8 months. In the latter group, during the follow-up period, one patient experienced sudden death after receiving multiple firing from the device, and four additional patients died of congestive heart failure. No evidence of lead dislodgment occurred in all 85 patients.

Discussion

The use of the automatic implantable cardioverter-defibrillator in patients with sudden cardiac death or recurrent sustained monomorphic ventricular tachycardia has drastically changed our therapeutic approach to this patient population and has also improved the survival rate of this cohort. Despite its efficacy, initial experience with the epicardial defibrillating system has been associated with a perioperative mortality rate as high as 8% (10,15,28–31). Nonthoracotomy lead systems were proposed and introduced to minimize the overall surgical risk associated with defibrillator implantation and to maximize the overall benefit of this procedure (8–18). After several years of experience, the feasibility of different nonthoracotomy lead systems with respect to reducing overall perioperative risks and demonstrating adequacy of defibrillation threshold has been documented. However, although it appears that the reliability of a nonthoracotomy lead system has become a reality, several problems remain unsolved.

Previous data with monophasic systems. As suggested by previous investigations, even though testing of multiple combinations of lead systems and pulsing methods may ultimately provide an adequate safety margin for defibrillation in the majority of patients, this involves extensive testing using different pulsing techniques, various defibrillation lead combinations and changes of polarity (12,17–18,20,26). When a triple-lead defibrillating system is used, altering these variables may result in >20 different combinations to be tested (17,20). The complexity of such a system raises important concerns with regard to patient safety and has also made it difficult to establish guidelines for lead placement and to determine the relative efficacy of various lead configurations. From a practical standpoint, however, finding an acceptable configuration in an individual patient may be limited by the excessive amount of defibrillation testing required. Although certain pulsing methods and electrode positions will have a higher likelihood of success than others (20,32–33), there is currently no way to predict the optimal system in an individual subject without extensive testing. Finally, as suggested by several reports, the relative benefit achieved by testing the myriad of lead combinations or permutations possible is still not satisfactory, and in 10% to 30% of the patients, acceptable defibrillation efficacy is not achieved (12–14,16–20). Undoubtedly, there is a need for a more effective energy waveform. In addition, the ideal nonthoracotomy defibrillator lead system must also be simpler to evaluate and implant.

Benefits of a biphasic device. In our study the use of a hybrid system that combined the Endotak lead with a device able to deliver asymmetric biphasic pulses increased the rate of successful implantation and remarkably shortened the implantation procedure time, minimizing intraoperative testing. In fact, although in all 91 patients the defibrillation lead system initially tested was the same, the sole use of a biphasic pulse generator allowed an increase in defibrillation efficacy from 89% to 100%. In addition, in our experience a larger proportion of patients was able to receive permanent implantation with the lead alone when biphasic shocks were used. Moreover, when the subcutaneous patch was needed to achieve better defibrillation efficacy, placement of this electrode in the left posterior chest wall was necessary in none of the subjects, which spared the patient an additional surgical incision. However, in the group undergoing permanent implantation with a device that incorporates monophasic pulses only, placement of the patch electrode in the left posterior thoracic wall was required in a conspicuous number of patients.

Although we do not have long-term follow-up in the patients receiving permanent implantation with a biphasic device, all of these advantages can potentially reduce complications related to multiple testing and additional electrode placement and surgical procedures, such as infection, hematoma, lead-related malfunction and hemodynamic instability. This may account for the shorter average hospital stay required after implantation of the biphasic device. In our institution, we previously showed that implantation of the Endotak system required a significant lower time than did an alternative triple-lead defibrillating system (34). This probably reflected the lower number of leads to be implanted and a device with fewer alternative pulsing methods to test. Despite this, the larger total surface area available in the Endotak system provided defibrillation efficacy as high as that achieved with the triple-lead system. In the present study incorporation and testing of the biphasic waveform
appeared to reduce further the procedure time and the number of ventricular fibrillation trials required to determine the successful configuration for permanent implantation.

This study did not compare the defibrillation efficacy achieved with the biphasic waveform with that achieved by the monophasic waveform in individual patients. However, when testing of both waveforms was performed, it appeared that the biphasic shocks could enhance defibrillation efficacy in patients refractory to single and bidirectional monophasic shocks. Concern has been expressed that a limited safety margin in patients with a high defibrillation threshold at implantation might influence the subsequent sudden cardiac death rate in this cohort. Our experience clearly suggested that biphasic shocks not only increase defibrillation efficacy and abbreviate intraoperative testing, but they also provide a larger safety margin that might be of particular importance in patients requiring additional antithrombotic treatment.

Our results are similar to those reported by Sakse na et al. (26) using a triple-lead system. The slightly higher successful defibrillation rate reported in our study might be related to the larger surface area of the defibrillating system used in our patients. The reason for a better defibrillation efficacy with biphasic waveform cannot be explained on the basis of our study. In addition, different biphasic waveform shapes might further improve defibrillation efficacy, and this needs further investigation (35-37). However, as shown in our study, the use of biphasic shocks as the waveform of initial choice eliminates the need for a multitude of ventricular fibrillation inductions, obviating the need for a prolonged defibrillation threshold testing and implantation procedure. Furthermore, the lower defibrillation energy requirement obtained with the biphasic waveform ultimately might facilitate more widespread use of this technology and increase the proportion of patients who are candidates for permanent implantation with a transvenous defibrillation lead system. Despite such encouraging results, this improvised defibrillating system constitutes an off-label use of approved, commercially available hardware. This raises legitimate concerns with regard to the hypothetical higher potential for some component failure. In view of these concerns, it may be misleading to equate the feasibility of this approach with its long-term function.

Conclusions. Although longer follow-up is needed to establish the long-term stability and efficacy of this system, and although the use of a hybrid cardioverter-defibrillator is disputable, the biphasic waveform has the potential to expand the acceptability of the presently available transvenous defibrillation system, to minimize the complexity of the implantation procedure and to provide the appropriate minimal energy requirement for defibrillation in the majority of defibrillator recipients.

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References

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