Defibrillation of Ventricular Fibrillation and Ventricular Tachycardia

Background

Physio-Control conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200 J and 130 J BTE shocks to 200 J MDS shocks\(^1\) was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks (95UCLD=2%). The difference in success rates of 200 J MDS minus 200 J BTE shocks was -10% (exact 95% confidence interval from -27% to 4%). The 130 J BTE shocks were not demonstrated equivalent to 200 J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200 J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

<table>
<thead>
<tr>
<th>SHOCK</th>
<th>VENTRICULAR FIBRILLATION 1ST SHOCK SUCCESS</th>
<th>EXACT 95% CONFIDENCE INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 J MDS</td>
<td>61/68 (90%)</td>
<td>80–96%</td>
</tr>
<tr>
<td>200 J BTE</td>
<td>39/39 (100%)</td>
<td>91–100%</td>
</tr>
<tr>
<td>130 J BTE</td>
<td>39/47 (83%)</td>
<td>69–92%</td>
</tr>
</tbody>
</table>

**Ventricular Tachycardia**

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

<table>
<thead>
<tr>
<th>SHOCK</th>
<th>VENTRICULAR TACHYCARDIA 1ST SHOCK SUCCESS</th>
<th>EXACT 95% CONFIDENCE INTERVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 J MDS</td>
<td>26/28 (93%)</td>
<td>77–99%</td>
</tr>
<tr>
<td>200 J BTE</td>
<td>22/23 (96%)</td>
<td>78–100%</td>
</tr>
<tr>
<td>130 J BTE</td>
<td>20/21 (95%)</td>
<td>76–100%</td>
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</table>

**Conclusions**

In this double-blinded study, the efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130 J biphasic and 200 J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200 J monophasic shocks, 200 J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.
External Cardioversion of Atrial Fibrillation

Overview

The performance of the Physio-Control biphasic truncated exponential (BTE) waveform was compared to the conventional monophasic damped sine (MDS) waveform in an international, multi-center, prospective, randomized clinical study of adult patients undergoing elective cardioversion of atrial fibrillation (AF). A total of 80 patients were enrolled in the study and were treated with one or more study shocks. The primary dataset consisted of 72 enrolled patients confirmed to have been in AF. Data from seven patients with atrial flutter were analyzed separately. One patient who did not satisfy all protocol criteria was excluded from analysis.

Subjects were randomized to receive biphasic or monophasic shocks from LIFEPAK 12 defibrillator/monitors. Progressive shocks of 70, 100, 200 and 360 J of the assigned waveform, and a 360 J crossover shock of the other waveform, were delivered if AF persisted. Shocks were delivered using EDGE System™ QUIK-COMBO® Pacing/Defibrillation/ECG electrodes applied in the standard anterior-lateral position. Successful cardioversion was defined as the confirmed removal of AF after delivery of a shock, as determined by ECG over-read by two cardiologists with no knowledge of the shock waveform. Patients rated skin pain on a scale from 0 to 8 after the procedure.

This study showed that these biphasic shocks provide higher efficacy for cardioversion of atrial fibrillation, requiring fewer shocks, 65% less current and 65% less energy to cardiovert atrial fibrillation. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain.

Objectives

The primary objective of the study was to compare the cumulative efficacy of biphasic and monophasic shocks of 200 J or less for cardioversion of atrial fibrillation. A triangular sequential design was used to test for a statistically significant difference between groups of patients treated with these two waveforms.

Secondary objectives included 1) providing an estimation of the dose response relationship for the two waveforms which would allow clinicians to make well-informed selections of energy doses for cardioversion with biphasic shocks and 2) comparing the pain experienced by patients following treatment with monophasic and biphasic shocks.

Results

Seventy-two of the patients enrolled were in atrial fibrillation and 7 were in atrial flutter. On average, patients had been in atrial fibrillation for 88 days, were 66 years old, weighed 81 kg and had 72 ohms of transthoracic impedance. Sixty-three percent were male and 46% had been previously cardioverted. There were no significant differences between the groups of patients treated with monophasic and biphasic shocks, either in these baseline characteristics or in left atrial dimension, cardiac medications, or diagnosis.

The cumulative success rates for cardioversion of atrial fibrillation are presented in Table 1 and Figure 1. These data provide a reasonable estimate of the expected probability of cardioversion success for a single shock at any given energy level within the range studied. Energy and peak current delivered for all shocks at each energy setting are presented in Table 2.
Cumulative percentages of successes for cardioversion of AF with shocks of 200 J or less, the primary endpoint of the study, was significantly higher in the biphasic group than in the monophasic group (p<0.0001). The observed cumulative percentage of successes at 360 J was also higher for biphasic shocks than for monophasic shocks, but did not attain statistical significance.

Table 1  Cumulative Success Rates and Crossover Results for Cardioversion of AF

<table>
<thead>
<tr>
<th>ENERGY SETTING</th>
<th>70 J</th>
<th>100 J</th>
<th>200 J</th>
<th>360 J</th>
<th>360 J CROSSOVER SUCCESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDS: n = 37</td>
<td>5.4%</td>
<td>19%</td>
<td>38%</td>
<td>86%</td>
<td>4 of 5 pts succeeded with 360 J BTE shock</td>
</tr>
<tr>
<td>BTE: n = 35</td>
<td>60%</td>
<td>80%</td>
<td>97%</td>
<td>97%</td>
<td>0 of 1 pts succeeded with 360 J MDS shock</td>
</tr>
</tbody>
</table>

Table 2  Energy Settings, Delivered Energy, and Peak Current for Shocks Delivered to Patients in AF

<table>
<thead>
<tr>
<th>ENERGY SETTING</th>
<th>NUMBER OF PATIENTS</th>
<th>DELIVERED ENERGY</th>
<th>PEAK CURRENT, AMPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monophasic shocks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70 J</td>
<td>37</td>
<td>73 ±3</td>
<td>21.0 ±3.5</td>
</tr>
<tr>
<td>100 J</td>
<td>35</td>
<td>105 ±4</td>
<td>24.6 ±4.3</td>
</tr>
<tr>
<td>200 J</td>
<td>30</td>
<td>209 ±7</td>
<td>34.6 ±5.9</td>
</tr>
<tr>
<td>360 J</td>
<td>23</td>
<td>376 ±13</td>
<td>46.8 ±8</td>
</tr>
<tr>
<td>360 J crossover shocks</td>
<td>1</td>
<td>380</td>
<td>44.7</td>
</tr>
<tr>
<td>Biphasic shocks*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70 J</td>
<td>35</td>
<td>71 ±0</td>
<td>11.9 ±2.5</td>
</tr>
<tr>
<td>100 J</td>
<td>14</td>
<td>102 ±0</td>
<td>14.9 ±3.5</td>
</tr>
<tr>
<td>200 J</td>
<td>7</td>
<td>203 ±1</td>
<td>20.6 ±3.5</td>
</tr>
<tr>
<td>360 J</td>
<td>1</td>
<td>362</td>
<td>28.5</td>
</tr>
<tr>
<td>360 J crossover shocks</td>
<td>5</td>
<td>361 ±6</td>
<td>32.4 ±8.5</td>
</tr>
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</table>

*Peak current and delivered energy are not available for two of the patients treated with biphasic shocks.
Compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current (14.0 ± 4.3 vs. 39.5 ± 11.2 A, p<0.0001), less energy (97 ± 47 vs. 278 ± 120 J, p<0.0001), fewer shocks (1.7 vs. 3.5 shocks, p < 0.0001) and less cumulative energy (146 ± 116 vs. 546 ± 265 J, p<0.0001). Patients treated with the biphasic protocol, as compared to those treated with the monophasic protocol, reported significantly less post-procedure pain just after (0.4 ± 0.9 vs. 2.5 ± 2.2, p<0.0001) and 24 hours after the procedure (0.2 ± 0.4 vs. 1.6 ± 2.0, p<0.0001).

All patients with atrial flutter were cardioverted with the first shock (70 J), whether that shock was monophasic (n=4) or biphasic (n=3).

Anterior-lateral electrode placement was used for treatment of most (96%) of the patients studied. Reports in the literature differ on whether anterior-posterior electrode placement provides better shock efficacy than anterior-lateral placement. If there is a benefit to anterior-posterior electrode placement, it may be possible to obtain modestly higher cardioversion success rates with both waveforms than those observed in this study. However, placement is not likely to affect the observed relationship between the efficacies of monophasic and biphasic waveforms.

**Conclusions**

The data demonstrate the Physio-Control biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for cardioversion of atrial fibrillation. Specifically, compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current, less energy, fewer shocks, and less cumulative energy. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain just after and 24 hours after the procedure. This may be due to fewer required shocks, less cumulative energy, less delivered peak current, or other characteristics of this biphasic waveform.
Guidance for Selection of Shock Energy

Biphasic waveform technology is a standard in cardiac defibrillators. The study summarized here\(^1\) provides the best information available on which to base energy selections for cardioversion with this waveform.

For cardioversion of atrial fibrillation, the results of this study provide specific guidance for three possible strategies in selection of shock energy levels.

- To optimize for more rapid cardioversion and fewer shocks, select the same biphasic energy levels used previously with monophasic defibrillators (for example, use 200 J biphasic instead of 200 J monophasic). This can be expected to increase the success rate yet decrease the peak current of the first and subsequent shocks.
- To maintain shock efficacy equivalent to that previously observed with monophasic shocks, select a biphasic energy level of about one-third the energy previously used for monophasic shocks (for example, use 100 J biphasic instead of 300 J monophasic).
- To optimize for low initial and cumulative energy using a step-up protocol, select 70 J for the first shock and use small increases in energy if further shocks are needed.

Each of these strategies should provide effective cardioversion therapy while substantially reducing the amount of peak current to which the heart is exposed.

For cardioversion of atrial arrhythmias other than atrial fibrillation, the data available to guide the selection of energy settings is very limited. It is likely that biphasic doses below 50 J will provide high success rates when treating atrial flutter and paroxysmal supraventricular tachycardia. However, until more clinical data becomes available, it may be advisable to use the same energy settings for biphasic shocks as are customarily used for monophasic shocks.

Arrhythmias may persist for a variety of reasons unrelated to the type of waveform used for cardioversion. In persistent cases, clinicians continue to have the option to either increase shock intensity or switch to an alternate electrode placement.

Intra-operative Ventricular Defibrillation

Overview

The defibrillation efficacy of the Physio-Control biphasic truncated exponential (BTE) waveform was compared to the standard monophasic damped sine waveform (MDS) in a prospective, randomized multi-center study of patients undergoing intra-operative, direct defibrillation for ventricular fibrillation (VF). A total of 251 adult patients were enrolled in the study; 98 of these developed VF that was treated with one or more study shocks. Seven patients who did not satisfy all protocol criteria were excluded from analysis.

Subjects were randomized to receive BTE or MDS shocks from LIFEPAK 12 defibrillator/monitors. Those who developed VF after removal of the aortic clamp received progressively stronger shocks of 2, 5, 7, 10 and 20 joules (J) using 2-inch paddles until defibrillation occurred. A 20 J crossover shock of the alternate waveform was given if VF persisted.

This study showed that these biphasic shocks have higher defibrillation efficacy, requiring fewer shocks, less threshold energy, and less cumulative energy than monophasic damped sine shocks.

Objectives

The primary objective of the study was to compare the cumulative efficacy of BTE shocks to MDS shocks at 5 J or less. A triangular sequential design was used to test for a difference between waveform groups.

The secondary objective was to provide an estimation of the dose response relationship for the two waveforms that would allow physicians to make well-informed selections of energy doses for intra-operative defibrillation with biphasic shocks.

Results

Thirty-five male and 15 female subjects were randomized to the BTE group; 34 and 7 to the MDS group. Mean age was 66 and 68 years, respectively. There were no significant differences between BTE and MDS treatment groups for cardiac etiology, arrhythmia history, current cardiac medications, American Society of Anesthesiology (ASA) risk class, left ventricular wall thickness, cardiopulmonary bypass time, core temperature, or blood chemistry values at the time of aortic clamp removal.

Cumulative defibrillation success at 5 J or less, the primary endpoint of the study, was significantly higher in the BTE group than in the MDS group (p=0.011). Two of the 91 patients included in this primary endpoint analysis could not be included in more comprehensive analyses due to protocol variances that occurred in the shock sequence after the 5 J shock. Thus, the cumulative success rates for intra-operative defibrillation in the remaining 89 patients are presented in Table 3 and Figure 2. These data provide a reasonable estimate of the expected probability of defibrillation success for a single shock at any given energy level within the range studied.

Compared to the MDS group, the BTE group required, on average, fewer shocks (2.5 vs. 3.5: p=0.002), less threshold energy (6.8 J vs. 11.0 J: p=0.003) and less cumulative energy (12.6 J vs. 23.4 J: p=0.002). There was no significant difference between success rates for BTE versus MDS crossover shocks.
Figure 2  Cumulative Shock Success for Intra-operative Defibrillation with Monophasic (MDS) and Biphasic (BTE) Shocks: Observed Rates (n) Plotted with Estimated Dose Response Curves

Conclusions

The data demonstrate the Physio-Control biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for intra-operative internal defibrillation of VF. Specifically, these biphasic shocks have higher defibrillation efficacy, while requiring fewer shocks, less threshold energy, and less cumulative energy than monophasic damped sine shocks. There were no unsafe outcomes or adverse effects from the use of the biphasic waveform.

Guidance for Selection of Shock Energy

Biphasic waveform technology is a standard in cardiac defibrillators. The results of this study\(^1\) provide specific guidance for three possible strategies in developing a dosing regimen.

- To optimize for lower initial and cumulative energy using a step-up protocol, select 5 J for the first shock and use small incremental increases in energy if further shocks are needed. In this study, biphasic shocks of 5 J were successful in approximately half of the patients.

\(^{1}\)B. Schwarz et al., Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery. *Anesthesiology*. 2003;98(5):1063-1069.
• To optimize for more rapid defibrillation and fewer shocks, select the same BTE energy level used previously with MDS (for example, 20 J BTE instead of 20 J MDS), which can be expected to increase the success rate, yet decrease by approximately 30% the peak current of the first and subsequent shocks.

• To maintain an equivalent degree of efficacy as previously observed with MDS shocks, a BTE energy level one-half of that previously used for MDS shocks (for example, 10 J BTE instead of 20 J MDS) would be an appropriate choice.

Each of these strategies should provide effective defibrillation therapy while substantially reducing the amount of peak current to which the heart is exposed.

Fibrillation may persist for a variety of reasons unrelated to the type of waveform used for defibrillation. In cases where fibrillation is persistent, physicians continue to have the option to either increase shock intensity or switch to a larger paddle size. Larger paddle size is known to decrease energy requirements for successful defibrillation.¹
