EFFICACY OF LOWER-ENERGY BIPHASIC SHOCKS FOR TRANSTHORACIC DEFIBRILLATION:

A FOLLOW-UP CLINICAL STUDY

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ABSTRACT

Objective. This clinical study prospectively evaluated the first-shock defibrillation efficacy of 150-joule impedance-compensated, 200-μF biphasic truncated exponential (BTE) shocks in patients with electrically-induced ventricular fibrillation (VF), and compared it with a historical control group treated with 200-J monophasic damped sine (MDS) shocks. **Methods.** Ventricular tachyarrhythmias were induced in patients undergoing electrophysiologic (EP) testing for ventricular arrhythmias or testing of an implantable cardioverter-defibrillator (ICD). A 150-J shock was delivered as the primary therapy to terminate induced arrhythmias in the EP group, and as a "rescue" shock when a single ICD shock failed to terminate the arrhythmias in the ICD group. **Results.** Ninety-six patients received study shocks. The preshock rhythm was classified as VF in 77 patients and as ventricular tachycardia (VT) in 19 patients. First-shock success rates for VF and VT were 75 out of 77 (97.4%) and 19 out of 19 (100%) for the 150-J BTE compared with the historical control rates of 61 out of 68 (89.7%) and 29 out of 31 (94%) for 200-J MDS. The first-shock success rate for VF treated with 150-J BTE was technically equivalent to that of 200-J MDS ($p = 0.001$). The transthoracic impedance did not vary between groups, yet the peak current delivered by the 150-J BTE shock was about 50% lower. **Conclusions.** This study demonstrated that 150-J shocks of this impedance-compensated, 200-μF BTE waveform provided very high efficacy for defibrillation of short duration, electrically-induced VF. These lower-energy biphasic shocks had a success rate equivalent to that of 200-J MDS shocks, and they provided this efficacy while exposing patients to much less current than the monophasic shocks. **Key words:** defibrillation; ventricular fibrillation; external defibrillation.

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Biphasic shocks typically require less energy than monophasic shocks to terminate ventricular fibrillation (VF), and they provide higher efficacy than monophasic shocks of the same energy.[1–4] Several biphasic external defibrillators are now commercially available, and each one has a unique waveform and an associated recommendation for dosage.[5] Defibrillation efficacy is affected by waveform characteristics, as well as by delivered dosage and patient characteristics. For this reason, the relationship between the delivered dose and defibrillation efficacy should be evaluated clinically for each unique waveform.

Multiple clinical studies in various settings have established the efficacy of 150-joule shocks of a 100-μF biphasic truncated exponential (BTE) waveform[1,6,7] and 200-J shocks of a 200-μF BTE waveform.[4,8] Data on defibrillation with 150-J shocks of the 200-μF BTE waveform are limited to the animal laboratory, in which these shocks had better efficacy than 200-J shocks of both monophasic damped sine (MDS) and monophasic truncated exponential (MTE) waveforms.[9]

This clinical study prospectively evaluated the first-shock defibrillation efficacy of 150-J shocks of an impedance-compensated, 200-μF BTE waveform in patients with short-duration electrically-induced VF, and compared it with a historical control group treated with 200-J MDS shocks. The primary objective of this study was to test whether the defibrillation success rate of a 150-J biphasic waveform is equivalent to that of the standard 200-J MDS waveform per the American Heart Association (AHA) definition.

METHODS

Patient Population

This study included patients at least 18 years of age undergoing electrophysiologic (EP) testing for known or suspected ventricular arrhythmias or testing of an implantable cardioverter-defibrillator (ICD). Patients were excluded if they had a right-side pectoral ICD, or an intrathoracic or subcutaneous patch or array ICD electrodes. To enable comparison with a historical control group, patients in this study were enrolled from the same hospital-based electrophysiology department that was the leading enrolling site for the historical study, and they were selected with the same criteria used for patient selection in that study.[4] Written, informed consent was obtained from all patients before their participation in the investigation, and the center had approval from its institutional human subjects review committee to conduct the study.

Experimental Protocol

Patients were studied in the sedated, postabsorptive state. Arrhythmias were induced via implanted or temporary right-ventricular electrodes (as part of a catheter EP study) by programmed stimulation, burst ventricular stimulation, or synchronized T-wave shock.

In patients studied during ICD testing, the ICD delivered the first shock after induction. A transthoracic defibrillation shock was subsequently applied to persisting arrhythmias. In the EP group, the study shock was delivered as the primary therapy to terminate the induced arrhythmia. The commercially available biphasic Lifepak 12 defibrillator/monitor (Medtronic Physio-Control, Redmond, WA) delivered the study shocks via disposable pacing/defibrillation/electrocardiogram (ECG) electrodes in the conventional anterior and left-lateral positions (EDGE System electrodes with Quik-Combo; Medtronic Physio-Control). The impedance-compensated BTE waveform, as described previously elsewhere, included adjustment of both pulse duration[4,10] and charge voltage in response to transthoracic impedance.[5,9] If the study shock was unsuccessful, rescue shocks were delivered first by the study device, and, if necessary, by a backup defibrillator or by internal shocks from the ICD.

Data Collection

Data collection was similar to that described in the historical control study.[4] Briefly, surface and intracardiac electrograms were recorded at least 10 seconds before and after the external shock. Preshock and postshock rhythms were read from the ECG-strip chart recordings by the principal investigator and overread by two independent cardiologists who were blinded to the waveform type and energy setting. If different classifications were assigned to the rhythm, the independent cardiologists conferred to finalize the classification. A shock was classified as successful if VF was resolved without further shocks. Postshock asystole or pulseless electrical activity was defined as a successful outcome of defibrillation shocks. Termination of VF within 10 seconds after the shock (type II conversions) was also considered a success outcome. Data monitors were responsible for data quality, adherence to the study protocol, and regulatory compliance at the study site. A data and safety monitoring board was not used in this study, although there was a procedure in place for reporting unexpected events.

Statistical Considerations

The sample size of this study was based on a test of equivalence of 150-J biphasic shocks to the 200-J MDS historical control group of the previous study. We used the recommended construct provided by the Association for the Advancement of Medical Instrumentation and an AHA task force to define statistical equivalence of one defibrillation waveform to another.[11,12] Per this definition, statistical equivalence is demonstrated if and only if the *upper* 95% confidence limit on the efficacy difference, $\pi_s - \pi_e$, is less than 0.10, where π_s denotes the proportion of first-shock successes with the standard therapy (200-J MDS) and π_e denotes the proportion of first-shock successes with the experimental therapy (150-J BTE). A p-value was obtained for that comparison using an unconditional test of non-inferiority.[13] A p-value of less than 0.05 supports the equivalence of the success rates for the two waveforms.

We determined the sample size using a statistical power of 0.85, an allowable probability of type I error (α) of 0.05, and an effect size (δ) of 0.10. We assumed a success rate of 92.8% for the 150-J BTE shocks (based on logistic interpolation between previously measured success rates at 130 J and 200 J)[4] and the success rate observed for 200-J MDS shocks in the historical control (89.7%). Consequently, the study needed to include at least 70 patients requiring shocks for VF.

Continuous data are reported as mean $\pm$ standard deviation (SD). We calculated 95% confidence intervals (CIs) on differences between binomial proportions using an unconditional exact statistical procedure.[13] A t-test was used for statistical testing of continuous variables.

RESULTS

Patient Characteristics

A total of 117 patients were enrolled. Twenty-one patients were excluded from the study for the following reasons: arrhythmia not inducible ($n = 10$), arrhythmia spontaneously converted ($n = 5$), or exclusion criteria not recognized at the time of the initial study (i.e., implanted ICD hardware) ($n = 6$). Ninety-six patients received a study shock of 150 J for electrically-induced ventricular arrhythmias. The preshock rhythm was classified as VF in 77 patients and ventricular tachycardia (VT) in 19 patients. Unless otherwise noted, the results presented include only data from the first transthoracic shock applied to the VF episode from 77 patients, referred to as the study group.

TABLE 1. Patient Clinical Characteristics

	Shock Waveform and Energy	
	150-J Biphasic	200-J Monophasic*
Number of patients	77	68
No. (%) undergoing electrophysiologic testing	46 (60%)	13 (19%)
No. (%) undergoing implantable cardioverter–defibrillator testing	31 (40%)	55 (81%)
Gender, males	59 (77%)	54 (79%)
	Mean ± SD	Mean ± SD
Age (years)	70 ± 10	69 ± 12
Height (cm)	176 ± 9	175 ± 9
Weight (kg)	84 ± 19	80 ± 16
Ventricular fibrillation duration (sec)	16 ± 5	19 ± 9

*Historical control.[4]

Study shocks for VF were delivered to 46 patients during the catheter electrophysiology study and to 31 patients undergoing ICD testing. The characteristics of the study group patients are detailed in Table 1. The VF persisted an average of 16 ± 5 seconds before the first transthoracic defibrillation shock, compared with an average of 19 ± 9 seconds for the historical control (Table 1). The mean left-ejection fraction in this study was 0.35 ± 0.14 in the 37 patients in whom it was measured versus 0.32 ± 0.14 in the 45 patients from the historical control study (p = NS, t-test).

The cardiac diagnoses present for this study versus the historical control group included coronary artery disease (CAD) in 53 (69%) versus 55 (81%) patients; hypertensive heart disease in 32 (42%) versus nine (13%) patients; syncope in 17 (22%) versus 16 (24%) patients; valvular disease in 12 (16%) versus five (7%) patients; cardiomyopathy (dilated or hypertrophic) in 15 (19%) versus 12 (18%) patients; and other diseases in five (6%) versus three (4%) patients. The percentages do not add up to 100% because a patient could have more than one diagnosis.

The patient arrhythmia history is detailed in Table 2. A difference from the control group was present for the documented VF category. All but nine patients were taking at least one cardiac medication (Table 3).

TABLE 2. Patient Arrhythmia History

	Shock Waveform and Energy	
	150-J Biphasic	200-J Monophasic*
Number of patients	77	68
Ventricular tachycardia (sustained and nonsustained)	70 (91%)	55 (81%)
Atrial fibrillation	22 (29%)	18 (26%)
Other	10 (13%)	7 (10%)
Documented ventricular fibrillation	7 (9%)	20 (29%)
Syncope without documented arrhythmia	7 (9%)	7 (10%)
Atrial flutter	5 (6%)	4 (6%)

*Historical control.[4]

TABLE 3. Patient Prestudy Cardiac Medication

	Shock Waveform and Energy	
	150-J Biphasic	200-J Monophasic*
Number of patients	77	68
None	9 (12%)	—
Class 1a	3 (4%)	5 (7%)
Class 1b	5 (6%)	1 (2%)
Class 1c	0 (0%)	2 (3%)
Class 2	40 (52%)	6 (9%)
Class 3	15 (19%)	15 (22%)
Class 4	10 (13%)	12 (18%)
Digoxin	21 (27%)	30 (44%)
Other	45 (58%)	39 (57%)

*Historical control.[4]

Characteristics and Outcome of Defibrillation Shocks

The first 150-J BTE shock was successful in 75 of the 77 patients (97.4%). A second 150-J BTE shock successfully defibrillated both of the patients who had remained in VF after the first 150-J BTE shock. By comparison, the first 200-J MDS shock was successful in 61 of the 68 patients in the historical control group (89.7%) (Table 4).

The 150-J BTE waveform first-shock success rate was statistically equivalent to the success rate of the 200-J MDS waveform historical control (p = 0.001). The upper 95% confidence limit on the efficacy difference, $\pi_s - \pi_e$, was −0.009, substantially less than the +0.10 limit required for formal equivalence.

The first 150-J study shock converted all 19 patients in the VT class (100%), whereas the historical control group had a first-shock success for VT of 29 out of 31 (94% CI on the difference: [−0.11, 0.22]). The study shocks in the VT group were applied in asynchronous mode. The first-shock success rate for the combined group of patients receiving 150-J BTE shocks with VF or VT was 94 out of 96 (97.9%) compared with the reported control for 200-J MDS shocks of 83 out of 93 (89%). In the combined group, the confidence interval on the difference in successful termination between the two therapies was −0.17, −0.02.

Impedance and impedance-derived measures, such as peak current and delivered-energy data, were available for only 71 of 77 patients because of procedural limitations (Table 4). The transthoracic impedance for the 150-J BTE group was not different from the 200-J MDS control group. The peak current delivered by the 150-J BTE shock was 47% lower than the peak current of the 200-J MDS shocks ($p < 0.001$, t-test).

The postshock rhythm following successful shocks is reported in Table 5. All patients who received a 150-J BTE shock survived VF testing. One patient experienced pulseless electrical activity, necessitating cardiopulmonary resuscitation (CPR) and administration of dopamine. This occurred after successful VF termination by the study shock; the patient was discharged as planned the next day without incident. The study author (SLH) reviewed this event and determined it to be an anticipated event during ICD testing, as outlined in the standard patient-consent form for this procedure.

DISCUSSION

This study demonstrated that 150-J shocks of this impedance-compensated, 200-μF BTE waveform provide very high efficacy for defibrillation of induced VF. The first-shock success rate of these lower-energy biphasic shocks is equivalent to the success rate of 200-J MDS shocks, and they provide this efficacy while exposing patients to only about one-half the peak current of the monophasic shocks.

The "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" provide a class IIa recommendation for defibrillation with biphasic shocks of 200 J or less.[14] They provide no definitive recommendation for dosing with biphasic waveforms, except to say that shocks of 200 J or less are considered safe and effective. Their emphasis remains on rapid defibrillation for improved resuscitation success. Although not evaluated with this study, charge times can be up to 2 seconds shorter with 150 J. Although this difference by itself is unlikely to produce a measurable difference in outcome, it could contribute to a desirable attempt to systematically shorten the hands-off interval preceding AED defibrillation in out-of-hospital cardiac arrest.[15]

Study Population

The comparison between the two shock waveforms and energies has been made assuming the two patient groups have the same characteristics. Although these groups were similar with respect to most variables, there were two factors that differed enough to warrant discussion. Both of these reflect medical practice changes that have occurred during the few years separating the studies. A majority of patients in the historical control group were studied during ICD testing, whereas a majority of the patients in this study were undergoing EP testing. This difference is attributable to a reduced need for restudy after implant, resulting in fewer opportunities to study patients undergoing ICD testing in the more recent study. However, we found no reports suggesting that defibrillation thresholds would be different between these procedures, and we found no difference in the percentage of successful defibrillation shocks between ICD and EP procedures for either the study group or the control group (97% vs. 98% and 90% vs. 92%, respectively).

TABLE 4. Ventricular Fibrillation First-shock Efficacy

	Shock Waveform and Energy	
	150-J Biphasic	200-J Monophasic*
Sample size	77	68
First-shock success, *n* (%)	75 (97.4%)	61 (89.7%)
95% confidence interval	90.9–99.7%	79.9–95.8%
Transthoracic impedance (Ω)	75 ± 15	77 ± 19
Peak current of shock (A)	18 ± 3	34 ± 6
Delivered energy (J)	151 ± 0.5	202 ± 8

*Historical control.[4]

TABLE 5. Postshock Rhythms Following Successful Shocks

	Shock Waveform and Energy	
	150-J Biphasic	200-J Monophasic*
Sample size	75	61
Normal sinus rhythm	35 (47%)	32 (53%)
Paced rhythm	20 (27%)	6 (10%)
Sinus bradycardia	15 (19%)	9 (15%)
Supraventricular tachycardia	3 (4%)	7 (12%)
Sinus tachycardia	2 (3%)	0 (0%)
Idioventricular	0 (0%)	3 (5%)
Other	0 (0%)	3 (5%)
Junctional rhythm	0 (0%)	1 (2%)

*Historical control.[4]

The other notable difference was that fewer patients in the recent study than in the historical control had histories of documented VF. This is a result of the expanded indications for ICD usage, such as described in reports of the Multicenter Automatic Defibrillator Implantation Trial (MADIT) studies.[16,17]

Performance of External Biphasic Shocks

In a previous clinical trial, we showed a statistically significant improvement in first-shock efficacy for short-duration VF using 200-J shocks of this biphasic waveform compared with 200-J MDS shocks.[4] The same study also tested 130-J biphasic shocks and found their efficacy (83% CI: 69%–92%) to be numerically lower but statistically not different from the efficacy of 200-J MDS shocks (90% CI: 80%–96%). Logistic regression using the outcomes from this previous clinical trial predicted a success rate of 92.8% for the 150-J biphasic. Although the observed success rate for 150-J shocks in this study (97.4%) was higher than predicted, the predicted efficacy falls well within the confidence interval of the observed success rate. Thus, the present study further elucidates the dose–efficacy relationship for this particular biphasic waveform, and supports the use of these 150-J shocks for the first attempt to externally defibrillate adults in VF.

The success rate we observed is comparable with success rates from several clinical studies of other biphasic waveforms conducted in a similar setting. Bardy et al. found that 130-J shocks of a 100-μF BTE waveform had a first-shock success rate of 144 out of 167 (86%) for defibrillating short-duration VF,[1] whereas the single 150-J shock of the 200-μF BTE waveform we tested defibrillated 75 of 77 (97%) patients with VF. With biphasic rectilinear waveform shocks delivering 129 J, Mittal et al. obtained a first-shock success rate of 97 out of 98 (99%) for a group of patients with short-duration VT or VF.[2] The shocks we studied delivered 151 J and succeeded on first shock in 94 out of 96 (98%) patients with VT or VF.

For out-of-hospital defibrillation of cardiac arrest patients, the success of 200-J biphasic shocks[8] corroborates our previous findings of successful defibrillation with 200-J shocks for short-duration VF.[4] An important difference between the outcomes of these studies using the same shock in different settings is the rate of postshock return of spontaneous circulation. It is clinically important not only to terminate VF, but also to obtain a perfusing rhythm following the shock. This outcome is believed to be a function of the state of the heart before the shock.[18,19] Although current therapies do not yet ensure a return to spontaneous circulation, the relative shock performance can be predicted by short-duration VF studies.

In out-of-hospital cardiac arrest, MDS and BTE shocks have both been found to have high rates of termination of VF, though the resulting rhythm is often asystole.[8,20] A recent study in out-of-hospital cardiac arrest, with the same waveforms we tested, found that the percentage of patients returning to an organized rhythm within 1 minute of shock delivery was statistically higher after a 200-J BTE shock (69%) than a 200-J MDS shock (45%).[8] It is speculated that the lower peak current of these BTE shocks may have facilitated the observed increase in recovery of organized rhythms. The 150-J BTE shocks we studied have similarly high rates of termination of VF, and deliver about 15% less peak current than 200-J shocks of the same BTE waveform. Whether these 150-J shocks will further facilitate the return of an organized rhythm and associated survival in out-of-hospital cardiac arrest patients should be investigated.

LIMITATIONS

The results of this study may not reflect the efficacy of 150-J shocks of other biphasic waveforms. Although several biphasic waveform defibrillators are currently on the market, each manufacturer uses a unique version of biphasic waveform. Each of these biphasic waveforms also uses some form of impedance compensation, in which the waveform characteristics are adjusted in response to transthoracic impedance. The different biphasic waveforms also deliver substantially different current doses; for example, in low-impedance conditions, a recent study found the peak current for 150-J shocks of 100-μF and 200-μF BTE waveforms to be 41.8 and 28.9 A, respectively.[9] The relationship between the delivered dose and defibrillation efficacy should be evaluated clinically for each unique waveform.

The subset of patients studied during ICD testing received a failed internal shock before the study shocks were administered. Because that subset made up 81% of the historical control but only 40% of the experimental group, if exposure to such a shock alters success of the study shock, it could have biased our results. However, there is evidence in the literature that a failed shock does not affect the efficacy of a subsequent shock.[21]

The high survival outcomes obtained from hospital defibrillation during implant or electrophysiology testing cannot be applied or extrapolated to out-of-hospital defibrillations, where factors other than waveform and shock strength may play a greater role in patient outcome. Although we cannot control the delay between a sudden cardiac event and the emergency medical response, it remains desirable to optimize shock parameters and delivery for prompt defibrillation when needed. Furthermore, it is possible that a higher energy setting would be needed in patients with prolonged, spontaneous VF, to obtain the high defibrillation success rate we observed for short-duration, electrically-induced VF. On the other hand, given the success obtained with 150-J shocks applied following a failed first shock from an ICD on patients undergoing ICD testing, it suggests that successive shocks may not require higher doses for short-duration VF.

CONCLUSION

We have demonstrated that the first-shock defibrillation success rate of 150-J shocks of a 200-μF BTE waveform is equivalent to the success rate of 200-J MDS shocks in patients with induced VF. The lower peak current and more rapid charge times associated with these lower energy shocks may have clinical benefit. The findings of this study support the use of these lower-current, lower-energy biphasic shocks as a first shock to defibrillate adults with VF.

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