Clinical Trial Abbreviated Summary

Intra-operative Ventricular Defibrillation[1]

Overview

The defibrillation efficacy of the biphasic truncated exponential (BTE) waveform from Physio-Control 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 were treated with one or more study shocks. Seven patients were removed from the data set either because the pre-shock rhythms were not VF (n=3) or for protocol violations (n=4).

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 20J 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

Primary Objective: Compare the cumulative efficacy of BTE shocks to MDS shocks at 5J or less.

Secondary Objective: 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. Cumulative defibrillation success at 5J or less, the primary endpoint of the study, was significantly higher in the BTE group than in the MDS group (p=0.011). Cumulative success rates are presented in Figure 1.

Compared to the MDS group, the BTE group required, on average, fewer shocks (2.5 vs. 3.5: p=0.002), less threshold energy (6.8J vs. 11.0J: p=0.003) and less cumulative energy (12.6J vs. 23.4J: p=0.002). There was no significant difference between success rates for BTE versus MDS crossover shocks.

Conclusions

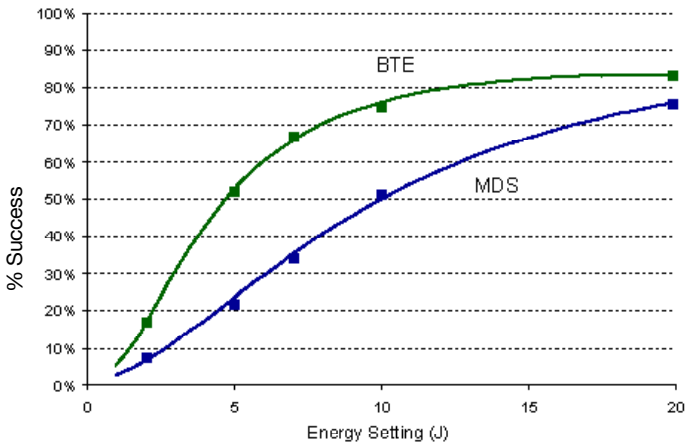

Figure 1. Cumulative shock success for direct defibrillation with monophasic (MDS) and biphasic (BTE) shocks: observed success rates (n) plotted with estimated dose response curves. Two subjects randomized to the BTE group were unable to be included in the cumulative success rates due to protocol violations after the 5J shock.

The data demonstrate the biphasic waveform from Physio-Control 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 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.

Intra-operative Ventricular Defibrillation

Guidance for Selection of Shock Energy

Biphasic waveform technology is an emerging standard in cardiac defibrillators. Defibrillation efficacy and dose recommendations have not been previously reported for open chest, direct defibrillation. The results of this study 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 5J for the first shock and use small incremental increases in energy if further shocks are needed.
- To optimize for more rapid defibrillation and fewer shocks, select the same BTE energy level used previously with MDS (e.g., 20J BTE instead of 20J 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 (e.g., 10J BTE instead of 20J 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.[2]

References

1 Schwartz B, et al. Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery. *Anesth*. 2003;98:1063-1069.

2 Zhang Y, et al. Open chest defibrillation: biphasic versus monophasic waveform shocks. *J Am Coll Cardiol*. 2001;37(2 suppl A):320A.

For further information, please contact your local Physio-Control representative or visit our website at www.physio-control.com

Physio-Control, Inc.
11811 Willows Road NE
P. O. Box 97006
Redmond, WA 98073-9706 USA
Tel 425 867 4000
Toll-Free (USA Only) 800 442 1142
Fax 425 867 4146
www.physio-control.com

GDR 3304792_A