Clinical Trial Abbreviated Summary

External Cardioversion of Atrial Fibrillation[1]

Overview

The performance of the biphasic truncated exponential (BTE) waveform from Physio-Control 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). The primary dataset consisted of 72 enrolled patients confirmed to have been in AF.

Subjects were randomized to receive biphasic or monophasic shocks from LIFEPAK® 12 defibrillator/monitors. Progressive shocks of 70, 100, 200 and 360J of the assigned waveform, and a 360J crossover shock of the other waveform, were delivered if AF persisted. 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 reported significantly less post-procedure pain with the biphasic protocol.

Objectives

Primary Objective:

Compare the cumulative efficacy of biphasic and monophasic shocks of 200J or less for cardioversion of atrial fibrillation.

Secondary Objectives:

1. Provide an estimation of the dose response relationship for the two waveforms that would allow clinicians to make well-informed selections of energy doses for cardioversion with biphasic shocks.
2. Comparing the pain experienced by patients following treatment with monophasic and biphasic shocks.

Results

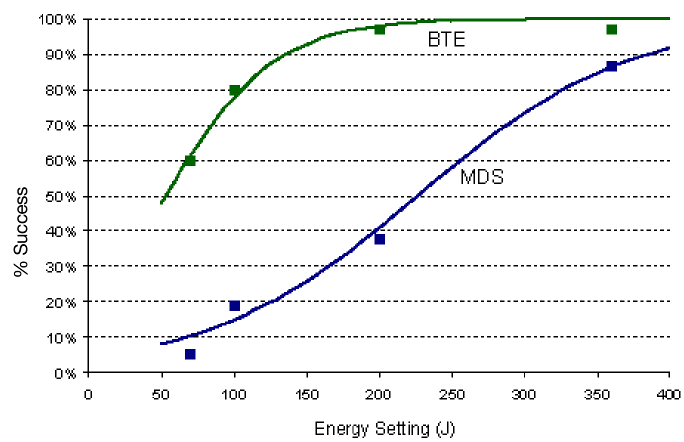

Figure 1. Cumulative shock success for cardioversion of atrial fibrillation with monophasic (MDS) and biphasic (BTE) shocks: observed success rates (n) plotted with estimated dose response curves.

Cumulative percentages of successes for cardioversion of AF with shocks of 200J or less, the primary endpoint of the study, was significantly higher in the biphasic group than the monophasic group ($p<0.0001$). Cumulative success rates are presented in Figure 1. The observed cumulative percentage of successes at 360J was also higher for biphasic shocks than for monophasic shocks, but did not attain statistical significance.

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 ± 120J, $p<0.0001$), fewer shocks (1.7 vs. 3.5 shocks, $p < 0.0001$) and less cumulative energy (146 ± 116 vs. 546 ± 265J, $p<0.0001$). 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, $p<0.0001$).

Conclusions

The data demonstrate the biphasic waveform from Physio-Control is clinically superior to the conventional monophasic damped sine waveform for cardioversion of atrial fibrillation. 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 an emerging standard in cardiac defibrillators. The study summarized here, in addition to a small pilot study of cardioversion of atrial fibrillation with Physio-Control biphasic truncated exponential shocks[1], provide 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 (e.g., use 200J biphasic instead of 200J monophasic).
- 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 (e.g., use 100J biphasic instead of 300J monophasic).
- To optimize for low initial and cumulative energy using a step-up protocol, select 70J 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.

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.

References

1 Koster RW, Dorian P, Chapman FW, et al. A randomized trial comparing monophasic and biphasic waveform shocks for external cardioversion of atrial fibrillation. *American Heart Journal*. 2004;147(5);e20.

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