Clinical Information

EDUCATIONAL SERIES

Biphasic trial: A randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest

Stiell IG, Walker RG, Nesbitt LP, et al. *Circulation* 2007; 115:1511-1517.

Purpose

Preliminary randomized study to compare two common biphasic shock energy regimens for defibrillation during out-of-hospital (OOH) cardiac arrest.

Methods

- Multi-center randomized controlled trial of 221 OOH cardiac arrest patients who received > 1 biphasic automated external defibrillator (AED) shocks.
- Study sites were in three large Canadian cities.
- LIFEPAK® 500 AEDs with ADAPTIV™ biphasic energy were used in the study.
- AEDs were randomly programmed to provide fixed lower energy (150-150-150 J) or escalating higher energy (200-300-360 J) protocols.
- Study was triple blinded---neither the patient, healthcare providers, nor researchers knew what shock protocol was being delivered.
- Primary endpoint of the study was electrical conversion of ventricular fibrillation (VF), defined as the termination of VF and the establishment of organized rhythm within 60 seconds, evaluated in those patients receiving at least two AED shocks (multishock patients).
- The primary endpoint focused on the multishock patients because the two energy regimens are quite similar for the first shock (150 J vs. 200 J), and only diverge substantially due to the "fixed" or "escalating" shock pattern for the second and subsequent shocks (150 J vs. 300/360 J).
- A secondary electrical outcome was termination of VF for at least five seconds after the shock.
- Clinical outcome data, such as return of spontaneous circulation and survival, and adverse effect data, including ECG changes for ischemia, cardiac enzymes, and left ventricular ejection fraction, were collected.
- Advanced life support (ALS) providers responded using both biphasic and monophasic manual defibrillators, but they were not involved in this study. The study only focused on the shocks delivered during the basic life support (BLS) AED interval.

Results

- Patients in the fixed lower energy group (n=114) and in the escalating higher energy group (n=107) were similar for most demographic and clinical characteristics.
- About half (48%) of the patients enrolled required more than one shock from the AED, most often due to refibrillation after successful defibrillation (rather than being due to the first shock failing to defibrillate).
- In the primary analysis of multishock patients (patients receiving more than one AED shock), conversion rates to an organized rhythm were significantly higher for shocks delivered according to the escalating higher energy protocol compared to the fixed lower energy protocol (36.6% versus 24.7%;P=0.035).
- VF termination rates also were significantly higher for shocks delivered according to the escalating higher energy protocol compared to the fixed lower energy protocol (82.5% versus 71.2%;P=0.027).
- For the first shock delivered to each patient, there were no significant differences in rates of VF termination or conversion to an organized rhythm between the first shock doses of 150 J and 200 J.
- There were no differences in survival outcomes or adverse events, although the study was not designed or powered to evaluate such outcomes. There was a nonsignificant trend toward more patients with left ventricular ejection fraction (LVEF) of less than 35% in the group treated with fixed lower-energy shocks (24.3% versus 10.5%; P=0.12).

Conclusions

This study demonstrates higher rates of VF termination and conversion to an organized rhythm with the higher-energy escalating shock regimen (200-300-360 J) in patients who had persistent or recurrent VF and needed multiple shocks. In addition, no adverse effects from the escalating shock protocol were observed.

Discussion

This study has several implications in light of the 2005 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care. The AHA and International

(ILCOR) Guidelines recommend resumption of CPR immediately after each shock and limiting interruptions of CPR. The difference in VF termination rates between the two energy regimens will influence this new protocol in two significant ways. First, a significantly larger percentage of patients would be left in VF after each shock and for the entire duration of the ensuing CPR interval when a fixed lower energy protocol is used. Also, the higher VF termination rate of the escalating higher energy regimen means fewer failed shocks, and thus decreased interruptions of CPR needed for additional shocks to reattempt defibrillation after a failed shock.

With respect to the clinical outcome data collected, there were two main limitations of the study. First, the study only involved shocks delivered from first responder AEDs, and did not include defibrillation performed by subsequent ALS responders. The period of AED use (median of approximately 4 minutes) was only a small portion of the overall prehospital care interval (median of approximately 32 minutes). Since ALS defibrillation energy protocols were not randomized or controlled, and included a mix of monophasic and biphasic shocks, the clinical outcomes and adverse effect data can not be considered reflective of just the initial AED defibrillation care. A second limitation was the small sample size of 221 patients. Only 106 of these patients received two shocks or more from the AED. The escalating or fixed aspect of a protocol only comes into effect when two or more shocks are delivered. This limited size of the multishock group would not allow enough power to meaningfully evaluate clinical outcomes such as survival, even if the study design limitation were not present.

One hypothesis that might be tested in future studies is whether even higher first shock energies (e.g. 360 J) might be beneficial in some settings. This question has yet to be clinically studied.

Physio-Control Discussion Points

Biphasic shocks are widely perceived to provide consistently high VF termination rates, even when lower energies are employed. However, a wide range of VF termination rates have been reported for biphasic shocks; while some studies found defibrillation rates above 90%, several recent clinical manuscripts report much lower (<70%) VF termination rates when lower biphasic energies are used for first (100 J – 150 J) and subsequent (150 J – 200 J) shocks. These reports indicate that use of lower energy biphasic shock regimens can leave significant room for improvement in defibrillation performance.

This study is the first randomized comparison of different, commonly used energy regimens for defibrillation during cardiac arrest resuscitation. It found that compared to a fixed lower energy shock regimen, an escalating higher energy regimen provided higher rates of VF termination and conversion to an organized rhythm in those patients who received multiple AED shocks. No adverse effects of the higher energy shocks were observed. It also confirms Physio-Control biphasic shocks can provide high 1st shock VF termination rates at either 150 or 200 J.

The results of this study have implications with respect to the 2005 International Guidelines for Emergency Cardiac Care. The new guidelines provide fewer opportunities for defibrillation, so the stakes are higher for each defibrillation attempt. Each shock is immediately followed by two minutes of CPR, so every failed shock leaves the patient in VF for at least two additional minutes before there is another opportunity for defibrillation. Also, every failed shock necessitates an additional defibrillation attempt, which adds to the interruptions in CPR. Fewer failed shocks mean decreased interruptions in CPR, helping to achieve the Guidelines objective of minimizing interruptions in CPR.

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