

Rebuttal to:

“The Case for Escalating Protocol and Energy Reserve in External Biphasic Defibrillators”

(by Dr. Josephson for Medtronic Physio-Control)

The Issue

Claim

“Is a single energy level adequate for all biphasic shocks, or is it prudent to increase the energy of each shock subsequent to a failed shock? What should the maximum energy level be?”

Response

The answer is, it depends. External biphasic waveform technologies are all designed differently and each is, therefore, associated with a different energy protocol.

The need for product-specific energy protocols is confirmed by ECRI, a non-profit organization whose mandate is to objectively evaluate biomedical equipment: “...a waveform designed for low-energy defibrillation may result in an overdose if applied at high energies, while another waveform designed for high energy may not defibrillate at lower energies.”¹

Background

Claim

“Defibrillation is dependent on the amount of electrical current...that flows through the heart...”The duration and shape of current flow (demonstrated graphically as the waveform shape) “also influence efficacy to a lesser degree.”

Response

Essentially true. It is current that delivers energy to the patient. Consequently, peak current and waveform shape are both critical to defibrillation success.

Claim

“...energy serves as a good overall measure of defibrillation effectiveness for it reflects, among other things, the current amplitude, duration and shape of the current flow.”

Response

Nonsense. Energy is energy, and doesn't reflect anything about the peak current, duration or shape of the waveform. If you place your fingers across the terminals of a 9V battery for 6 minutes, you will receive a 360 Joule (J) shock, but it won't do a thing to your heart!

The same energy can be achieved with a high current, short duration waveform as with a low current, long duration waveform. In fact, the SMART Biphasic waveform (Philips Medical Systems) delivers about the same current using 150 J as the Adaptiv waveform (Medtronic Physio-Control) at 300 J, and the Philips waveform at 200 J delivers the same current as the Physio waveform at 360 Joules. Further, the shape of the Philips and Physio waveforms, while not identical, are similar.

Claim

“...the amount of current flow is known to be the primary factor influencing defibrillation success...current required to defibrillate can differ considerably...”

Response

True. Indeed, it is current flow, not energy, which is critical to defibrillation success and, yes, current flow can differ considerably based on patient impedance.

Conventional monophasic waveform technology, constrained by electronics components available at the time it was developed (1960s), was unable to control peak current and waveform shape in response to the untoward effects of patient impedance. For some patients, peak currents were also dangerously high. Modern day electronics, by contrast, can measure and compensate for impedance, thus controlling the way in which current is delivered to the patient for optimum advantage and safety.

Claim

“These person-to-person variations make determination of optimal defibrillation energy a challenge. It may not be reasonable to expect that a single energy setting will provide defibrillation current suitable for every patient.”

Response

The claim that a fixed energy approach will not provide adequate current for every patient is unfounded and, not surprisingly, is not supported with a citation from the author. Energy is no longer the primary variable to be manipulated to achieve defibrillation success. The way in which energy is delivered to the patient—using sophisticated impedance compensating technology which delivers the energy as appropriately calibrated current and personalized waveform shapes—is, instead, the variable of greatest influence on success.

There is extensive and persuasive evidence that the Philips fixed 150 J biphasic truncated exponential (BTE) waveform is superior to the accepted gold standard monophasic waveform, even in cases of long duration, ischemic sudden cardiac arrest (SCA).^{2,3} Despite call-to-shock times averaging ^{8,9} minutes (actual down time is longer, about 12 minutes), the Philips BTE waveform is associated with superior efficacy on both first shock (96%) and all shock (100%) measures, improved return of spontaneous circulation (ROSC), and better neurological outcomes in survivors.³

Clinical Considerations

The Patient

Claim

“The surest way to increase current flow in a high impedance patient is to select a higher energy shock.”

Response

With modern electronics, it is no longer necessary to increase energy to achieve effective current flow. The patented Philips SMART Biphasic waveform design delivers more current with less energy, thereby minimizing dysfunction

Responder Technique

Claim

Dr. Josephson implies that extra energy will somehow compensate for improper pad placement and skin preparation, and suggests that first responders and lay rescuers will be less capable of proper pad placement than physicians.

Response

Neither claim is supported by a citation, again for good reason. We know of no evidence that higher energies will correct the failures of responder technique, and no specific study to show pad placement performance of first responders relative to physicians.

There is evidence, however, that the appropriateness of first responder pad placement is closely aligned with the design of the automated external defibrillator (AED) they are tasked to use. In fact, there is evidence that first responders had difficulty placing pads appropriately using a Physio-Control AED, in comparison to use of a Philips AED.⁴ In another study,⁵ untrained 6th graders using the Philips AED were able to use the device appropriately, relative to trained Emergency Medical Technicians.

The Origin and Duration of Ventricular Fibrillation

Claim

“...defibrillation shock-strength requirements are significantly higher [for ischemia-induced VF] than for termination of electrically-induced VF.”

Response

The studies cited by the author employ animal models. Philips has far more published, peer-reviewed manuscripts than any other external defibrillator manufacturer. Among the Philips manuscripts are ten “real world” studies demonstrating SMART Biphasic waveform performance in human populations experiencing long-duration VF from a variety of causes, including ischemic heart disease.^{2,3,6,7,8,9,10,11,12,13} These studies demonstrate that the fixed energy, 150 J Philips waveform performs far better than monophasic waveforms.

Claim

“While defibrillation may be possible with a series of fixed, low-energy shocks, multiple shocks increase the time to defibrillation.”

Response

Again, Dr. Josephson has offered conjecture without citations. He implies that the fixed, low-energy defibrillation approach is likely to require multiple shocks relative to other defibrillation therapies, yet there is no evidence to support the claim.

Why design a device that requires escalation when it is now possible to achieve defibrillation on the first dose using a carefully calibrated fixed low-energy waveform design? As noted above, the Philips SMART Biphasic waveform is proven to be effective on the first dose, and achieves currents on the first dose at 150 J similar to those delivered by the Physio waveform at 300 Joules.

Drug Interactions

Claim

“...several studies [the author only references one citation] have demonstrated that amiodarone can significantly increase defibrillation shock strength requirements. Limited low-energy shocks may not be as effective for terminating VF in individuals taking this antiarrhythmic.”

Response

Dr. Josephson again provides opinion without confirming references. The potential for antiarrhythmic drugs to affect biphasic shock defibrillation efficacy is unknown, but defibrillation thresholds are approximately 30% to 45% lower for biphasic waveforms compared to monophasic. This suggests that antiarrhythmics are likely to have fewer adverse effects with biphasic waveforms than monophasic waveforms.¹⁴

Historical Considerations

Claim

“There is good rationale for the escalating [energy] approach. While a non-escalated second shock will, on average, deliver slightly more current than the first shock due solely to a small decrease in impedance, escalating the second shock dose will provide a substantial increase in current... When a shock fails due to inadequate current, an increase in energy increases current and improves the chances that the next shock will succeed.”

Response

While there was some logic to an escalating energy approach with monophasic waveform technology, it is no longer necessary with Philips biphasic technology. Escalating energy became a clinical practice standard, without study evidence to support it, because monophasic waveforms performed poorly with high impedance patients. Escalating energy provided a mechanism to increase the current with monophasic waveforms, thus increasing the probability of success to counter this inherently inefficient technology. With modern BTE waveform technology, however, the probability of defibrillation is very high over a wide range of delivered current, without the need for either high- or escalating energy.¹⁵

The American Heart Association (AHA) concurs, stating: “Any given energy has a constant probability to achieve defibrillation. Repeated shocks, even at the same energy level, add to the probability of successful defibrillation.”¹⁶

AHA/International Guidelines

Claim

“The American Heart Association/International Guidelines 2000 acknowledge the value of the escalating-shock-energy concept and continue to recommend escalating protocols for monophasic shocks...the guidelines state only that biphasic shocks of 200J or less are safe and effective; they do not offer recommendations for optimal shock energies or shock protocols for biphasic defibrillators.”

Response

Essentially true, however the points are open to interpretation. Guidelines 2000 offers a variety of statements, some which seem to support escalating energy (with monophasic waveforms), and some, as noted above, which support repeat shocks at a constant energy.

Regarding biphasic waveforms, it is noted in the Guidelines that optimal energies are unknown; similarly, the Guidelines “cannot make a definitive recommendation for first and subsequent nonescalating biphasic defibrillation attempts.”¹⁶ We agree. Biphasic waveform designs are no longer standardized and neither are the energy protocols, making it impossible to create one, standard optimal energy for all devices. In addition, before the AHA can make a definitive recommendation, they require both in- and out-of-hospital data.¹⁷ To date, only Philips has published out-of-hospital long duration VF human studies to demonstrate biphasic waveform performance for this challenging patient population, and the protocol used is 150 J, non-escalating.

Amidst the varied qualifying language in the Guidelines are the evidence-based recommendations—only for biphasic waveforms ≤ 200J. Both a general recommendation for biphasic waveforms ≤ 200 J, and another classification specifically for the type of fixed low-energy biphasic waveform found in the Philips device I 6 have a Class IIa recommendation, defined as having “good to very good evidence”, a “standard of care”, “intervention of choice” therapy.

Finally, regarding promises of compelling data and the possibilities of future favorable AHA Guidelines for escalating, high-energy waveform designs: It is impossible to accurately predict futures. Today, the AHA requires both in-hospital and out-of-hospital, long duration VF studies in humans to achieve a recommendation. To date, only Philips has published evidence of waveform performance with the challenging long duration VF patients.

New Clinical Data

Claim

“A recent study of atrial fibrillation (AF) treatment in the electrophysiology laboratory illustrates the benefit of escalating energy for biphasic shocks.”

Response

The claim of escalating energy superiority is unfounded. The study cited by Dr. Josephson reflects performance of the Philips SMART Biphasic waveform.¹⁸ Since each biphasic waveform technology is designed differently, data from this study is not necessarily relevant to biphasic waveforms designed for escalating energy. Furthermore, the study was not designed to compare an escalating protocol to a non-escalating protocol, thus it is not appropriate to claim that escalation is more beneficial than a fixed energy protocol.

Evidence from Animal Studies

Claim

Dr. Josephson cites a swine study that he claims demonstrates improved performance of high-energy devices with higher impedance pigs.

Response

This claim is based on an abstract in a small number of swine. A manuscript based on the abstract has just been published.¹⁹ Both studies are based on an inaccurate experimental animal model in which resistors are placed between the animal and defibrillator in a manner inconsistent with the way impedance actually occurs in either the animal or human chest.²⁰ This experimental approach artificially favors improved performance with higher energies and is a meaningless finding in the real world. The animal data are contradicted by multiple studies using the Philips low-energy waveform in humans,^{2,3,6,7,8,9,10,11,12,13} which show comparable performance to the Physio waveform across a wide range of patient impedances. In fact, in one study in which performance relative to impedance was specifically noted,⁷ there was a trend towards slightly better performance on high impedance patients using the Philips SMART Biphasic waveform.

An Electrophysiologist's Perspective

Claim

Dr. Josephson claims value in escalating energy based on anecdotal experience, then proposes that this electrophysiology laboratory (EP lab) experience is "relevant" to the long duration, ischemic SCA patient population.

Response

Of course it is possible to have failed cardioversions and defibrillations, regardless of the energy protocol. As noted earlier, simply repeating a shock increases the probability of success, potentially favoring the second device in a two-device protocol. Furthermore, there are a myriad of factors related to defibrillation and cardioversion success, and energy is only one factor. Only a well-designed, randomized trial can answer this question and it doesn't exist. Therefore, as the AHA notes, "Any claim of superiority at this time is unsupported."¹⁶

Finally, Dr. Josephson's opinion that his anecdotal EP lab experience is relevant to anything but the EP lab patient population is meaningless conjecture. A short duration rhythm, quickly treated with shocks and drugs in a controlled setting is associated with a higher probability of treatment success than is typically possible in out-of-hospital delayed clinical practice settings.

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