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Discussion of Biphasic Waveform Energy Protocols

Philips Medical Systems

Introduction

Biphasic defibrillation waveform therapy offers unique advantages compared to the monophasic therapy used over the past 35 years. Biphasic waveform cardioversion and defibrillation therapy is increasingly becoming the standard of care. Of particular interest is the issue of energy protocols for cardioversion and defibrillation. Ultimately, a protocol is a matter of clinician discretion. This document is a summary of currently available information on SMART Biphasic waveform therapy, to assist in your decision-making process.

Much of the early research supporting low-energy biphasic waveforms is based on the internal cardioverter defibrillator (ICD) experience. The ICD was originally based on monophasic therapy, but by 1988 virtually all ICD manufacturers had transitioned to biphasic therapy. This transition occurred approximately 8 years prior to the use of a biphasic waveform in external defibrillators. More recently, a whole new body of research and experience has developed to guide the use of biphasic waveform therapy in transthoracic applications. As with ICDs, use of biphasic technology has allowed external defibrillators to be smaller, use more reliable solid-state technology, and provide superior performance with substantially lower energies. In addition, a well-designed external defibrillation waveform must compensate for inherent variations in patient resistance to current flow (impedance) and contend with challenging patient conditions, including long duration sudden cardiac arrest (SCA) and low amplitude ventricular fibrillation (VF).

Since the 1996 introduction of the first low-energy (150 Joules [J], non-escalating), impedance-compensating biphasic waveform in an AED, Philips Medical Systems has standardized on this "SMART Biphasic" truncated exponential waveform across its entire defibrillation line, offering up to 200 Joules in its adjustable-energy models. The patented SMART Biphasic waveform is designed to be effective at low energies, measuring impedance, then adjusting the waveform for each patient on each shock. The SMART Biphasic design has consistently demonstrated performance which is equivalent or superior to that shown with conventional monophasic waveforms, in a variety of in-hospital,[1,2] and out-of-hospital[3,4,5,6,7] patient settings. To date, the low-energy SMART Biphasic waveform has been the subject of 12 peer-reviewed, published manuscripts in humans, showing its efficacy in comparison to monophasic waveforms.

While the focus of this document is energy protocols, it is important to note that successful defibrillation involves a number of variables including energy level, waveform shape, and duration of delivery. Philips' SMART Biphasic waveform has been designed to optimize these attributes. Due to the differences among the manufacturers' waveforms, one standardized energy protocol may not be appropriate. The clinician should evaluate each defibrillation waveform and energy based on its unique design and the research available to demonstrate its performance.

Adult Defibrillation

Extensive research supports a non-escalating 150 J SMART Biphasic protocol recommendation in the treatment of ventricular fibrillation and ventricular tachycardia in adults. This protocol is consistent with the American Heart Association (AHA) recommendations for biphasic defibrillation ≤ 200 J.

Favorable results for low-energy biphasic defibrillation continue to mount. In 2000[8], the American Heart Association published their Class IIa recommendation (defined as a "standard of care", "considered intervention of choice by majority of experts," based on "good/very good evidence") for biphasic defibrillation ≤ 200 J.

Subsequently, the same authors detailed the deliberative process behind this decision. They indicated that the recommendation was for "biphasic waveform defibrillation with shocks less than 200 J", based on "evidence showing that a low-energy (150-J), impedance-compensating, biphasic truncated exponential (BTE) waveform is safe and as effective as or more effective than higher energy, escalating, monophasic waveform shock for termination of VF".[9]

In addition, the AHA noted the following about the data specifically supporting the SMART Biphasic waveform: "the growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low-energy biphasic truncated exponential waveform."[8] In the companion document, the authors explained "this specific biphasic waveform was evaluated because it was the only biphasic waveform for which out-of-hospital data on efficacy in termination of prolonged VF was available."[9]

In the Guidelines 2000 document,[8] the AHA also refuted the long-held belief that higher energies may be required for certain patients, stating: "There is no clear relation between body size and energy requirements for defibrillation in adults," and ". . . if energy and current are too high, myocardial damage may result." The AHA had previously noted, in a 1998 evidence review paper[10], the following about escalating energy: "A review of previous AHA guidelines for the energy sequence 200 J - 300 J - 360 J reveals that the evidence supporting this reputed 'gold standard' is largely speculative and based on common-sense extrapolations from animal data and human case series."

There is substantial evidence that the SMART Biphasic waveform is highly effective with a non-escalating 150 J - 150 J - 150 J protocol. As of this writing, SMART Biphasic first shock efficacy in humans has been reported in at least 13 peer-reviewed published articles, and ranges from a low of 87% to a high of 100%. Among the studies is one in which a 96% first-shock efficacy rate was achieved, despite an SCA population in which the average call-to-shock time was 8.9 minutes.[4] The biphasic rate was far greater than the 54% monophasic rate ($p < 0.0001$). In this same challenging patient population, the SMART Biphasic waveform was also associated with improved return of spontaneous circulation (76% vs. 54%; $p = 0.01$), and improved brain function in survivors ($p = 0.04$).[4] Biphasic efficacy was demonstrated to be superior to both monophasic truncated exponential ($p < 0.0001$) and monophasic damped sine ($p = 0.02$) controls.[6]

Cardioversion of Atrial Fibrillation

Data from three studies[11,12,13] indicate superior cardioversion performance with low-energy biphasic shocks, compared to monophasic shocks, in the treatment of atrial fibrillation. All three studies employed low-energy protocols in the treatment of AF, with consistent results. The data are compelling in demonstrating the advantage of low-energy biphasic therapy in comparison to high-energy monophasic.

Data from a multi-site randomized trial[11] employing the SMART Biphasic truncated exponential waveform demonstrate the benefits of low-energy biphasic waveforms for cardioversion. The study demonstrates that biphasic shocks of ≤ 200 J are as effective as monophasic shocks of up to 360 J. Data from the study indicate a 90% success rate utilizing a 100 J –150J - 200 J – 200 J biphasic protocol with a 60% first shock success rate. The actual energy settings used in practice are a matter of clinical discretion, which should consider the dysrhythmia to be treated and its refractoriness to conversion, among other factors.

In this study[11], the energy protocol studied ranged from 100 J to 200 J biphasic (100 J - 150 J - 200 J – 200 J), and 100 J to 360 J monophasic (100 J -150 J - 200 J - 360 J). Cumulative cardioversion rates were higher for biphasic shocks than for monophasic at the same energy levels, and were equivalent only when the monophasic energy was increased to 360 J.

In a separate SMART Biphasic study,[13] cardioversion of atrial fibrillation using a fixed 150 J protocol was compared to an escalating (150 J - 360 J) monophasic protocol. First shock cardioversion was higher for SMART Biphasic. Furthermore, the conversion rate using monophasic waveforms only approached that of SMART Biphasic when the monophasic energy was increased to 360 J.[13]

As an added note, Page, et al[11] demonstrated a significantly lower incidence of skin burns, defined as complaint of pain or blistering under the pads, with the SMART Biphasic waveform (17%) in comparison to monophasic (41%; $p < 0,0001$).

Ultimately, the initial energy chosen is a matter of clinical discretion, taking into account not only the research, but also patient factors. We are anecdotally aware of cardioversion success in treating AF using energies as low as 50 to 100 J. Among the patient factors to consider are not only pad location, but also the duration of the AF episode. A lower initial energy may be sufficient for AF of short duration (e.g., < 48 hours). Long duration AF (e.g., > 48 hours), on the other hand, may require a higher energy.[12,13,14,15,16] Obviously, a higher initial shock conversion rate may therefore minimize the total number of shocks and duration of anesthesia required. Non-ischemic cardioversion patients can generally tolerate somewhat higher energies than ischemic sudden cardiac arrest patients, in whom high defibrillation energies are associated with evidence of myocardial dysfunction.[2,17,18,19,20]

Intrathoracic (Open Chest) Defibrillation

There have been no formal studies on biphasic waveforms to support specific energy level recommendations for use in direct defibrillation of the heart. In fact, there are few such studies using monophasic waveforms in this application. Until an optimal energy protocol is established through further research, an empirical approach of initiating therapy with a low energy and escalating, as has been traditional with monophasic waveforms, is a reasonable expectation within clinical discretion. In clinical practice, it is not unusual to encounter monophasic energies ranging from 10 to 50 J for adult internal defibrillation using a direct epicardial approach. An appropriate initial biphasic energy dose can reasonably be expected to be as low as, or lower than, the traditional monophasic dose.

Early evidence by Bardy, et al[21] utilizing epicardial patch electrodes, showed successful ventricular fibrillation conversions using energies of approximately 20 J for monophasic, and 10 J for a biphasic waveform. A recent abstract and early anecdotal case reports, confirm that biphasic waveform shocks may have higher shock success rates than monophasic shocks, although the success may be dependent on electrode size. Specifically, Zhang, et al[22] demonstrated in swine that biphasic waveform shocks were more successful than monophasic shocks at lower energies (approximately 10 to 20 J), but only when small electrodes (16 cm2) were used; with large (44 cm2) electrodes, no difference was apparent.

Pediatric Defibrillation

The common monophasic energy protocol is 2 to 4 J/kg for children less than 8 years of age. The 2 to 4 J/kg standard was developed based on an early study by Gutgesell et al,[23] later confirmed by Mogayzel et al,[24] showing high (> 90%) efficacy in defibrillation of pediatric VF patients with this protocol. This protocol represents a monophasic *effectiveness* standard, not a safety limit, however. In other words, 2 to 4 J/kg is the proposed lower limit at which defibrillation is likely to be successful, but does not reflect the possible higher energy limits beyond which myocardial dysfunction or damage may occur. Gutgesell, et al[23] acknowledged that the damage threshold is much higher, but advocated a 2 J/kg initial-, and 4 J/kg subsequent-shock protocol, because it appeared to be successful in most cases and was easy to remember. At least one prominent pediatric cardiologist and defibrillation researcher has stated he would recommend, that as with monophasic, using 2 to 4 J/kg as a starting point for biphasic therapy[25].

We are aware of only one published study in which *any* biphasic therapy has been investigated for pediatric applications.[26] In this study, a 50 J SMART Biphasic waveform was applied to piglets, of varying weight categories designed to reflect pediatric populations. Ventricular fibrillation was induced and left untreated for 7 minutes. All animals were resuscitated with the SMART Biphasic waveform at 50 J, and there were no differences in myocardial dysfunction post-shock, compared to baseline.

Outside the context of pediatrics, there are numerous studies demonstrating that the low-energy SMART Biphasic waveform defibrillation may be as effective as, or superior to, high-energy monophasic waveform therapy,[1-6] and with less evidence of dysfunction.[2,17,18,19,20] It is therefore possible, although not demonstrated, that with a biphasic waveform, lower energies than currently practiced with monophasic devices may be effective for children.

Summary

Biphasic waveforms have long been shown to be more effective at lower energies than monophasic waveforms. In addition, multiple studies have demonstrated that high energies are linked to myocardial dysfunction. The AHA has provided a Class IIa recommendation for biphasic waveforms ≤ 200 J, as well as a Class IIa recommendation for the SMART Biphasic waveform. The AHA has provided no classification for higher energies.

Each biphasic waveform must be evaluated on the quality and breadth of research to demonstrate its performance in a given setting. The SMART Biphasic waveform has been extensively evaluated, with more peer-reviewed research to support its efficacy than any other waveform for external application. Particularly for adult defibrillation, this research indicates superior efficacy with a 150 J non-escalating energy protocol, consistent with the AHA Class IIa recommendation. For other defibrillation and cardioversion applications, the data are relatively incomplete for all biphasic waveforms. However, in general, low-energy biphasic waveforms are likely to perform as well, or better, than monophasic waveforms.

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