PHILIPS

Philips SMART Biphasic Waveform

Scientific discussion

SMART Biphasic waveform energy protocols

Biphasic waveform defibrillation therapy offers unique advantages compared to the monophasic therapy used predominantly 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 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. More recently, a whole new body of research and experience has developed to guide the use of biphasic waveform therapy in transthoracic applications.

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 defibrillator line, offering up to 200 J in its adjustable-energy models. The patented SMART Biphasic waveform is designed to be effective at low energies, with the defibrillator first measuring patient impedance, then adjusting the waveform 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[1,2,3] and out-of-hospital[3,4,5,6,7] patient settings.

While the focus of this document is energy protocols, it is important to note that successful defibrillation and resuscitation involves a number of variables including energy level, waveform shape, duration of therapy delivery, and proper CPR. Philips' SMART Biphasic waveform has been designed to optimize the waveform's contribution. Due to the differences among the various 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.

HEARTSTART
DEFIBRILLATORS

Adult Defibrillation of VF and VT

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 with ≤200 J.

Favorable results for low-energy biphasic defibrillation continue to mount. In 2000, 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 with ≤200 J.[8]

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]

Furthermore, a study by Tang et al.,[31] of various biphasic waveforms concluded that low energy biphasic waveform such as Philips' SMART maximizes survival and minimizes post-resuscitation myocardial dysfunction in a swine model of prolonged (7 minute) cardiac arrest.

Based upon extensive clinical data, Philips recommends a defibrillation energy protocol of non-escalating 150 J shocks for VF and non-perfusing VT. Note that Philips' manual defibrillators offer the discretion of using energies up to 200 J, but that there is no solid evidence showing that escalation is beneficial for non-perfusing rhythms.

Data for elective synchronized cardioversion of VT with biphasic waveforms is limited. It is, therefore, reasonable to treat this arrhythmia with a titrated (escalating) dose, similar to AHA guidelines for monophasic synchronized cardioversion of VT with starting energy of 100 J, escalating to 150 and 200 J if needed.

Cardioversion of Atrial Fibrillation and Flutter

Data from four studies indicate superior cardioversion performance with low-energy biphasic shocks, compared to monophasic shocks, in the treatment of atrial fibrillation.[11,12,13,15] All four 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 therapy.

Data from a multi-site randomized trial employing the SMART Biphasic truncated exponential waveform demonstrate the benefits of low-energy biphasic waveforms for cardioversion.[11] 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, 150, 200, 200 J biphasic protocol with a 60% first shock success rate.

In this same study, 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.

Clinical experience with various four shock protocols (Page et al., 2002: 100, 150, 200, 200 J) and (Walsh et al., 2005: 70, 100, 150, 200J) have yielded high overall success rates (89-95%).[11,15] Success with lower energy shocks (70 and 100 J) in these protocols was limited to from 32% to 66%. Although the higher overall success rates may be attributable in part to the cumulative effect of multiple shocks, the results suggest that a higher initial energy (150 J) may be advisable particularly for a longer duration of AF.

As an added note, Page et al. 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%; $p < 0.0001$).[11]

Ultimately, the initial energy chosen is a matter of clinical discretion, which must take 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.[12,13,15,16,17]

For cardioversion of AF, Philips recommends 100, 150, 200, 200 J protocol or, depending on clinical factors, starting at 150 J and escalating to 200 J, 200 J as needed.

There are limited data for elective synchronized cardioversion of Atrial Flutter with biphasic waveforms. Other biphasic waveforms have shown reduction of energy of approximately 50% for treating Atrial Flutter versus Atrial Fibrillation.[14] Based upon these data Philips recommends a starting energy of 50 J, escalating to 70 J and 100 J if needed.

Intrathoracic (Open Chest) Defibrillation

There has been at least one formal study on biphasic waveforms to support specific energy level recommendations for use in direct defibrillation of the heart.[18] Schawrtz et al. showed that biphasic energies as low as 5 J optimize for lowest threshold and cumulative energy, whereas 10 or 20 J optimize for more rapid defibrillation and fewer shocks. There are few such studies using monophasic waveforms in this application. Additionally, based upon long lasting history of monophasic waveforms, 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, if not lower than, the traditional monophasic dose.

Early evidence by Bardy et al., utilizing epicardial patch electrodes, showed successful ventricular fibrillation conversions using energies of approximately 20 J for monophasic and 10 J for a biphasic waveform.[21] Recent publications and anecdotal case reports confirm that biphasic waveform shocks have higher shock success rates than monophasic shocks.

Philips recommends starting energy of 10 J for intrathoracic defibrillation for adults with successive escalation to 20, 30, and 50 J if needed.

Pediatric Defibrillation and Synchronized Cardioversion

The standard 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., later confirmed by Mogayzel et al., showing high (>90%) efficacy in defibrillation of pediatric VF patients with this protocol.[26,27] Gutgesell acknowledged that the myocardial 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 using 2 to 4 J/kg as a starting point for biphasic therapy.[28]

We are aware of only two published studies in which any biphasic therapy has been investigated for pediatric applications.[29,30] In the study by Tang et al., 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 sustained differences in myocardial dysfunction post-shock, compared to baseline. Berg et al. similarly concluded that a biphasic pediatric dose in the range of 50 J to 80 J is safe and effective.

Outside the context of pediatrics, there are numerous studies demonstrating that Philips' low-energy SMART Biphasic waveform is as effective as, or superior to, high-energy monophasic waveform therapy,[1-6] with less evidence of dysfunction.[2,20,21,22,23] 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.

Therefore, Philips recommends the following 3-shock protocol for pediatric defibrillation that is similar to current AHA guidelines: 1-2 J/Kg, 2-3 J/Kg and 3-4 J/Kg.

Information regarding pediatric synchronized cardioversion for treatment of tachyarrhythmias can be found in Pediatric Advance Life Support Provider Manual.[32] The recommended initial energy dose is 0.5 - 1 J/Kg and then increased to 1-2 J/Kg.

Summary

Biphasic waveforms have consistently 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 use of biphasic waveforms for defibrillation with ≤200 J. 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, at lower energies and with less dysfunction.

The following table outlines the above-mentioned protocol recommendations for Philips' SMART Biphasic waveform

Arrhythmia	Shock sequence	Reference
VF/non-perfusing VT	150, 150, 150 J	1,2,3,4,5,6,7,8,9
Perfusing VT	100, 150, 200 J	8
Atrial Fibrillation	100, 150, 200, 200 J or 150, 200, 200 J	11,12,13,15,16,17
Atrial Flutter	50, 100, 150 J	8,14
Intrathoracic defibrillation	10, 20, 30 J	18,21
Pediatric defibrillation	1-2 J/Kg, 2-3 J/Kg, 3-4 J/Kg	8,26,27,28,29,30
Pediatric synchronized cardioversion	0.5 - 1 J/Kg, 1-2 J/Kg	32

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Philips Medical Systems is part of Royal Philips Electronics
www.philips.com/heartstart
medical@philips.com

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085
+ 1 800 934 7372

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