Setting a standard in external defibrillation: Low energy biphasic waveforms

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Introduction

The progression from monophasic-waveform to biphasic-waveform external defibrillation is a case study of collaboration between industry, the Food and Drug Administration (FDA), and an organized physician body (in this case the American Heart Association [AHA]) to achieve a defined public-health goal. The goal in this case, according to the AHA Task Force on Public Access Defibrillation,1 was innovation in external defibrillation technology that would make shocks more efficacious, cause less myocardial dysfunction, and render defibrillation devices easier to administer by medical personnel and laypersons alike. The clinical context is the AHA’s “chain of survival” concept,2 in which early defibrillation of cardiac arrest victims has come to be recognized as the most important link.3 Since 1992, the AHA has looked to the development of future-generation external defibrillators as the key to improving out-of-hospital resuscitation.4

Advantages of the biphasic waveform

The intrinsically smaller energy-storage and energy-delivery requirements of the biphasic waveform represent an important advantage for defibrillation. These characteristics were first discovered for implantable cardioverter defibrillators (ICDs), devices for which a concentrated search for miniaturization took place as soon as their clinical utility became apparent.5 By the early 1990s, almost all ICDs employed biphasic waveforms.6 It was reasoned that if the biphasic waveform could reduce energy requirements for external defibrillation as it had for internal defibrillation, it could produce better clinical outcomes, capacity and battery size could be reduced, and the large, less reliable high-voltage mechanical switches could be replaced with smaller, more dependable solid-state switches. In addition, the wave-shaping inductor, used with one type of monophasic defibrillator, could be eliminated.7 It was also reasoned that smaller external defibrillation devices would enhance public-access defibrillation (PAD). A basic premise of PAD is the wide availability of devices that are small, light, modestly priced, durable, low maintenance, almost intuitively obvious to operate, and capable of being stored for long periods of time.8

We now have six years of experience with the first biphasic external defibrillator approved for market by the FDA — the low-energy Philips SMART Biphasic defibrillator. Since the September 1996 FDA clearance of this technology, ten research articles have been published in the peer-reviewed medical literature supporting its use for defibrillation in patients with long-downtime sudden cardiac arrest (SCA). These articles include the results of one multicenter, randomized, controlled trial (Optimized Response to Cardiac Arrest [ORCA])9 comparing the low-energy Philips SMART Biphasic defibrillator with high-energy monophasic external defibrillators for resuscitating victims of out-of-hospital SCA. Several of the articles feature results from prospective human case series.10-14

The body of peer-reviewed literature supporting the low-energy Philips SMART Biphasic defibrillator is more extensive, with higher levels of supporting evidence as defined by the AHA Committee on Emergency Cardiovascular Care,6 than that for any other recent innovation in external defibrillation. The design and sequence of the research conducted to support the low-energy Philips SMART Biphasic defibrillator was structured...
in accordance with recommendations of related AHA task forces and the consultation of individual members. I was one of several principal investigators of a multicenter, blinded, randomized, controlled trial comparing the Philips SMART Biphasic technology with monophasic external defibrillation in an electrophysiology (EP) laboratory setting during internal defibrillation with an ICD. Our results demonstrated that low-energy biphasic shocks defibrillated as well as high-energy monophasic shocks with fewer electrocardiographic (ECG) abnormalities.

Since FDA clearance of the low-energy Philips SMART Biphasic defibrillator, the research evidence supporting its use for adult ventricular fibrillation (VF) has received a class IIa recommendation from the International 2000 Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, as published in the AHA International Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (henceforth Guidelines 2000). This recommendation upgrades the class IIb recommendation accorded low-energy biphasic therapy by the AHA Committee on Emergency Cardiovascular Care in 1998. According to Guidelines 2000, the therapy used in the low-energy Philips SMART Biphasic defibrillator is “acceptable, safe, and useful” and is “considered [an] intervention of choice by [a] majority of experts” — the clinical interpretation of class IIa interventions.

As the emphasis in emergency medicine shifts from monophasic to biphasic external defibrillation, it is helpful to weigh some of the defibrillation choices made at different institutions and to recognize the successes achieved with biphasic external defibrillation. The cases presented later in this publication report the experience of four hospital-based cardiologists who use low-energy Philips SMART Biphasic defibrillators.

Two areas of confusion about biphasic external defibrillators are addressed in this essay: (1) the differences between the FDA-cleared biphasic external defibrillators, and (2) the differences between low-energy and high-energy protocol settings. The closing essay reviews published research supporting the low-energy Philips SMART Biphasic technology.

**Comparison of biphasic external defibrillators**

Which of the several FDA-cleared biphasic external defibrillators is most effective? To date, no published studies have compared the efficacy or safety of the different biphasic defibrillators for external defibrillation in humans either in the EP laboratory setting or in the out-of-hospital SCA setting. There is consequently no answer to this question based on peer-reviewed evidence.

In addition, the biphasic-waveform designs of each of the FDA-cleared biphasic external defibrillators differ in terms of waveform shape, energy requirements, and duration of energy delivery. To date, no published studies have compared the intrinsic efficacy or safety of these designs.

At this stage, then, each biphasic external defibrillator and each biphasic-waveform design must be evaluated individually — first on the merits of published clinical evidence to support it, then on the basis of characteristics like features of its use (simplicity, maintenance), safety, and cost.

**Energy levels for biphasic external defibrillation**

With biphasic external defibrillators, what energy protocols are most appropriate for adult and pediatric defibrillation and for cardioversion?

Defibrillation depends upon delivering the correct amount of energy to generate a sufficient current across the heart to terminate the arrhythmia while at the same time causing minimal electrical injury to the heart. A shock will not defibrillate if the energy level is too low, and functional and morphological damage may occur if the energy level is too high.

Determining an optimal energy protocol for all biphasic external defibrillators as a class is made impossible by individual hard-
ware and waveform differences among the devices. Some hardware-component designs in these devices are patented by the manufacturers and cannot be duplicated. The actual components, in turn, influence specific biphasic-waveform designs. In combination, hardware and biphasic-waveform designs bear upon the energy levels recommended by the manufacturers and studied in research.

It is thus not appropriate to use a single energy protocol for all biphasic waveforms, nor is it appropriate to use an escalating high-energy protocol — such as is used for monophasic waveforms (200 J, 300 J, and 360 J) — for low-energy biphasic designs.

Surprisingly, the electrical variable that correlates most highly with defibrillator efficacy for a given waveform type is not energy (as measured in joules) but delivered current. Current is the medical dose of this intervention, and it is determined by a defibrillator’s initial voltage and a patient’s impedance.

What distinguishes the low-energy Philips SMART Biphasic defibrillator from monophasic predecessors — and what appears to be its most ingenious engineering achievement — is its capacity for impedance compensation. Philips researchers discovered that it was possible to maintain the high efficacy of the biphasic waveform over a wide range of patient impedance (and electrical current) by adjusting the shape of the waveform. Based on an instantaneous assessment of the patient’s resistance to current, the Philips SMART Biphasic technology adjusts both the overall duration and shape of the waveform while it is being delivered (Figure 1).

If compensation can be made from shock to shock — for different patients, or even for the same patient (impedance decreases slightly with each successive shock) — the energy level need not change: Optimal

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**Figure 1.** The first phase of the Philips SMART Biphasic waveform (0-5 msecs) is a monophasic shock to the ventricle; the second phase (5-9 msecs) reverses the polarity of the waveform to remove the charge placed on myocardial cells in the first phase and lessen the odds of cell damage.

![Waveform schematic](image)

Before the waveform enters its second phase, the capacitor gauges the patient’s impedance — the transthoracic resistance to the flow of current from the shock — and adjusts the peak current and the duration of the shock. The three lines portray the compensation for patient impedance of 50, 75, and 125 ohms, respectively (typical impedance is 75-80 ohms). The resulting optimal level of power delivered is a uniform shock of 150 J.
current and waveform shape can be delivered with each shock using a constant 150-J energy dose.

Monophasic external defibrillators do not compensate for patient impedance from shock to shock by purposefully adjusting waveform characteristics. They also use an escalating high-energy protocol of 200 J, 300 J, and 360 J for terminating adult VF. In a 1998 evidence review, the AHA found this escalating high-energy protocol unsupported by research: “[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.”

In the context of this AHA finding, Guidelines 2000 issued a class Ila classification for biphasic waveforms in general at energy settings ≤200 J and for the Philips SMART Biphasic waveform in particular. Guidelines 2000 did not issue any classification for biphasic waveforms requiring energy settings >200 J.

**Advantages of the low-energy biphasic waveform**

The low-energy requirements of the Philips SMART Biphasic defibrillator also made possible an extremely important clinical benefit: the potential for reducing the postresuscitation myocardial dysfunction — whether injury or ischemia — associated with high-energy shocks. Postresuscitation myocardial dysfunction is implicated as a mechanism accounting for fatal outcomes after successful resuscitation in 70% of SCA victims within the first 72 hours. Biphasic waveforms have also been observed in animal studies to interfere less than monophasic waveforms with pharmacological resuscitation efforts using either lidocaine or amiodarone.

Two recent animal studies extend the association between myocardial dysfunction and high-energy shocks. In one study, Xie and colleagues demonstrated that depressed global myocardial function, as measured by decreases in the cardiac index and the rates of increase and decrease in left ventricular (LV) pressure, was related to the delivered magnitude of the defibrillation shock. In another animal study, Tang and colleagues directly compared the impact of the low-energy Philips SMART Biphasic shocks and high-energy monophasic shocks on postresuscitation myocardial function for swine after prolonged (4 or 7 minutes) untreated VF. Although the waveforms were equally effective at restoring spontaneous circulation after 4 minutes and after 7 minutes of untreated VF, there was significantly less impairment of myocardial function with low-energy biphasic defibrillation than with high-energy monophasic defibrillation (as measured by ejection fraction, LV stroke volume, and LV end-diastolic volume). These differences were magnified when the duration of VF increased from 4 minutes to 7 minutes, indicating that the lower energies associated with the biphasic waveform caused less damage to LV function.

**Conclusion**

The biphasic waveform conveys technologic benefits for external defibrillation. And because it is possible to use the biphasic waveform with lower-energy settings, it also conveys probable clinical benefits.

Energy settings for specific uses of each brand of biphasic external defibrillator should ideally balance a unit’s maximum medical efficacy against its own, even slight, potential for causing myocardial dysfunction. Moreover, these energy settings should be justified by research; they should not be merely empiric values selected by users.

For the low-energy Philips SMART Biphasic defibrillator, current research strongly supports an energy protocol of three successive 150-J shocks for terminating adult VF. This research incorporates not only studies of induced short-downtime VF in EP laboratory settings but also studies of long-downtime SCA in out-of-hospital settings. Altogether, there is proof today of the promise of the low-energy biphasic waveform as pioneered by Philips researchers and other investigators.
According to David Cooke, MD, Lutheran General Hospital deployed the Philips HeartStart XL for several definite reasons — ease-of-use characteristics, similarity to the operation of existing Cardemaster defibrillators, and advantages in service and maintenance. But Lutheran General Hospital also selected the low-energy Philips HeartStart XL because it wanted a single type of external defibrillator for a tiered Basic Life Support (BLS)/Advanced Cardiac Life Support (ACLS) response model. This tiered approach was pioneered by Kaye and colleagues to avoid the documented long delays (5 to 10 minutes) before first-attempt defibrillation that confound conventional in-hospital response teams.26,27

To improve in-hospital response times, Lutheran General Hospital implemented a BLS program to train nurses, attendants, and other staff to use the Philips HeartStart XL’s automated-external-defibrillator (AED) mode in cardiac emergencies before a “code blue” team arrives.

“There are simple physical limitations that slow response times for the code-blue team. We wanted to empower the non-ACLS-trained staff to take necessary action. Because the Philips HeartStart XL defibrillator replicates the clean and simplified design of the Philips AED, that should help alleviate confusion or uncertainty on the part of untrained users,” relates Dr. Cooke.

Even before he read confirming documentation in the scientific literature, Dr. Cooke says he observed first-hand the myocardial dysfunction resulting from the traditional use of escalating high-energy levels with monophasic defibrillators. Although it is sometimes difficult to distinguish this dysfunction from symptoms of underlying heart disease, in many cases the myocardial damage from high-energy monophasic waveforms was unmistakable.

“The first time you see this very advanced LV dysfunction, you might assume that the patient has severe heart disease,” Dr. Cooke explains. “Quite predictably, these patients go back to having normal LV function after a week to several months. But after two or three cases, you realize that the dysfunction you are witnessing is the result of a difficult resuscitation in which multiple shocks were needed.”

The use of escalating high-energy levels was the “primitive way” in which physicians responded to the perceived high impedance of their patients, says Dr. Cooke. That physician judgment is no longer necessary, as the low-energy Philips SMART Biphasic defibrillator automatically gauges and immediately compensates for patient impedance during waveform release.

The protocol for defibrillation of adult VF at Lutheran General Hospital is three shocks at 150 J. The Philips HeartStart XL defibrilla-
tor does provide a manual joule setting up to 200 J based on clinical evidence that this energy level may occasionally be needed for cardioversion of atrial fibrillation (AF). According to Dr. Cooke, individual physicians use different approaches for AF, but the general approach is to employ about 50% of the energy used for monophasic shocks. In his own experience with the Philips HeartStart XL defibrillator, cardioversion of AF is typically achieved with a first shock of 100 J.

Commentary by Richard M. Luceri, MD

The in-hospital early defibrillation program at Lutheran General Hospital entails the training of all potential early responders in defibrillation — not on AEDs, however, but on a more technical ACLS defibrillation device, the Philips HeartStart XL defibrillator.

Lutheran General Hospital believes that the ease of operation of the Philips HeartStartXL defibrillator approaches that of an AED, thus enabling use of an ACLS device by BLS responders. Any tiered response model of BLS and ACLS is an improvement over the traditional ACLS-only response model. Lutheran General Hospital chose to standardize the use of one product for training and ease of use instead of following a potentially more cost-effective approach of using a combination of manual and automated defibrillators. Clearly, Lutheran General has taken an important step toward improving system-wide response to resuscitation.

Atlanta VAMC Hospital, Atlanta
Samuel C. Dudley, Jr, MD, PhD

Samuel C. Dudley, Jr, MD, PhD, is chief of cardiology at Veteran’s Administration Medical Center in Atlanta, Georgia.

When the Veteran’s Administration Medical Center (VAMC) in Atlanta, Georgia, began replacing nearly half of its defibrillators in 1999, Samuel C. Dudley, Jr, MD, PhD, sought to reduce time to defibrillation by employing a single brand of easy-to-use biphasic devices. He found the answer in the low-energy Philips SMART Biphasic HeartStart FR2 AEDs.

Given the hospital’s relatively high proportion of very ill patients, Dr. Dudley knew that to improve cardiac arrest outcomes, VAMC staff needed to deliver shocks sooner. A key factor was to instill confidence in BLS-trained employees to defibrillate immediately rather than call for the ACLS-trained cardiac specialists — and add several critical minutes to response times. Dr. Dudley’s team sought an AED with simple functions that could be easily mastered by BLS-trained nonmedical as well as medical personnel.

“The monophasic AEDs we were using were large and cumbersome and intimidating to people who did not defibrillate frequently,” recounts Dr. Dudley. “We wanted to simplify the device and hopefully decrease the time to first shock. Standardization of equipment was important.”
VAMC and Philips Medical Systems jointly undertook a pilot program on three floors of the hospital to assess whether the newer generation of AEDs would improve survival to discharge after in-hospital cardiac arrest. In 2000, 79% of cardiac arrests occurred “after hours,” the majority of them taking place outside the emergency department and intensive care units. Before starting the program, says Dr. Dudley, the hospital had a 4% survival-to-discharge rate after cardiac arrest. Initial data indicated that the rate increased to 14% after deploying the Philips HeartStart FR2 AEDs.

Dr. Dudley’s belief that the biphasic waveform is at least as efficacious as the monophasic waveform and his appreciation of the impedance compensation function of low-energy Philips SMART HeartStart FR2 AEDs were prime considerations. He believes there is sufficient evidence — beginning with ICD research — that the biphasic waveform is superior to the monophasic waveform at depolarizing the heart, and he refers to a growing body of data showing that multiple shocks administered at escalating energy levels result in transient myocardial dysfunction without increasing defibrillation efficiency.

Choosing a biphasic AED that uses a single 150-J low-energy setting was straightforward and reduced the potential for confusion. “If we put a very complex device out there and worry about manual defibrillation and escalating energy doses, the situation becomes so worrisome that nobody wants to use it,” notes Dr. Dudley. “With the constant energy approach, this isn’t a concern.”

Another advantage of the low-energy Philips HeartStart FR2 AED, states Dr. Dudley, is its built-in capacity for self-diagnostics, so that only a visual check of a status indicator is necessary to document maintenance. With the previous monophasic defibrillators, documenting maintenance required a manual discharge sequence. The result was that documentation of daily checks of these devices was missing almost a third of the time.

In comparing the low-energy Philips HeartStart FR2 AED to competitor devices, Dr. Dudley and his colleagues concluded that, overall, the performance data favored the Philips SMART Biphasic waveform.

“Philips had a longer track record with external defibrillation,” explains Dr. Dudley, “better documented efficacy than the defibrillators of other companies, and a wide range of equipment options suitable to us, including the very small Philips HeartStart FR2 AEDs. Their approach was more rational, more scientific, and more focused on patient outcomes.”

The VAMC protocol for adult VF is three shocks at 150 J, with the option of escalating to 200 J if one is using the low-energy Philips HeartStart XL defibrillator — the ACLS model — which has a manual setting up to 200 J. For AF, Dr. Dudley says he usually cardioverts about 70% of cases with a first shock of 50 J. If unsuccessful on the first try, he escalates the energy level in 50-J increments.

Of the hospital’s 64 defibrillators, 30 are low-energy Philips models. The VAMC now has traditional ACLS defibrillators in hospital areas with the highest usage, like critical care, and the Philips HeartStart FR2 AEDs in areas such as outpatient services and off-site clinics, where staff are less familiar with the devices.

**Commentary by Richard M. Luceri, MD**

The experience at the Atlanta VAMC Hospital speaks to the technologic benefits of the Philips SMART Biphasic waveform, which allows external defibrillators to be more compact and easier to use.

The AHA has established the National Registry of Cardiopulmonary Resuscitation to assist participating hospitals — of which Atlanta VAMC is one — with systematic data collection of resuscitative efforts. The objective of the registry is to develop a well-defined database documenting resuscitation performance of hospitals over time.
n-hospital and emergency medical personnel who externally defibrillate children in cardiac arrest face the additional complications of not knowing the exact nature of the arrhythmia and potentially applying excessive energy through an inefficient waveform.

Frank Cecchin, MD, believes that the likelihood of applying an inappropriate shock can be substantially reduced by using a biphasic external defibrillator that delivers a low-energy waveform.

Dr. Cecchin tested the sensitivity and specificity of the low-energy Philips AED Patient Analysis System for assessing shockable and nonshockable rhythms in 191 pediatric patients age \(<12\) years (median age, 3 years) who either developed arrhythmias or were at risk for developing them. Dr. Cecchin and colleagues prospectively recorded the patients’ shockable and nonshockable rhythms by means of the Philips HeartStart FR2 AED, then obtained a second set of paper recordings of shockable arrhythmias and digitized them. Each rhythm tracing was then reviewed by three physicians, designated shockable or nonshockable, and analyzed against the AED algorithm.

“We found the AED results were very favorable. There was a 96% sensitivity for VF and a 100% specificity for the nonshockable rhythms,” he explains. “This indicates that the AED algorithm is safe and effective for children, with a very low risk for delivering an inappropriate shock.”

Dr. Cecchin’s manual Philips SMART Biphasic protocol for pediatric defibrillation is 2 J per kg of body weight for the initial shock then 4 J per kg for the second shock. Some children may require up to 10 J per kg of body weight.

“Many variables have to be taken into account with young patients. However, the limited data we have make it clear that a protocol that restores more rhythm faster is better than a repeat-shock protocol,” he explains. “If we stick with 2 J to 4 J per kg of body weight with biphasic shock, we’re going to be right on the mark.”

Dr. Cecchin’s guideline of 2 J to 4 J per kg of body weight applies to the low-energy Philips HeartStart XL defibrillator — the manual ACLS model. Based on the only published study on biphasic therapy in pediatric applications, Philips has also implemented a 50-J shock protocol for children <8 years using the low-energy Philips SMART Biphasic AEDs.

Two new features on the Philips AED are specifically designed to improve the ease-of-use of pediatric defibrillation. Smaller pads are easier to apply to patients who weigh <10 kg, according to Dr. Cecchin. Moreover, the pads attenuate the joule output to a maximum of 50 J rather than the standardized setting of 150 J.

Commentary by Richard M. Luceri, MD

The experience with AEDs for children is very limited, and their use for children <8 years is currently not recommended by the AHA because of the lack of data concerning sensitivity, specificity, safety, and efficacy. Yet half of all SCAs that children experience occur in children <1 year; most of these are associated with sudden infant death syndrome and respiratory disease. The study by Dr. Cecchin and colleagues confirming that an AED can detect with 100% specificity non-
External transthoracic electrical cardioversion using a monophasic waveform has been a highly effective method for terminating AF. That enviable track record can be improved even further, at lower energies and with less tissue dysfunction, by employing a biphasic waveform, according to David G. Benditt, MD.

Dr. Benditt believes the exclusive use of the biphasic waveform in ICDs during the past decade provides a sound model for applying it to external atrial defibrillation. The use of the low-energy Philips SMART Biphasic waveform has been particularly efficacious in cardioverting patients whose AF was otherwise refractory to repeated higher-energy monophasic shocks or who experienced early recurrence of AF after cardioversion.

As the Central Minnesota Heart Center began replacing its monophasic external defibrillators with the low-energy Philips HeartStart XL models, he says staff had the opportunity to use them side-by-side and observe firsthand the benefits of the Philips SMART Biphasic waveform. Dr. Benditt has found that a first biphasic shock of 150 J with the Philips HeartStart XL is usually sufficient to defibrillate patients in AF, at least temporarily. In an unpublished case series he conducted using the Philips Heartstart XL model, six of eight patients who had AF refractory to repeated monophasic shocks at 360 J were cardioverted with a first biphasic shock of 150 J, and two patients required a second biphasic shock of 200 J. Only three patients experienced recurrences, according to Dr. Benditt, and the other five patients were considered long-term successes.

“The results we compiled convinced us that we were deriving a better effect with low energy, using repeat shocks less frequently, and causing less skin damage,” says Dr. Benditt.

The Philips SMART Biphasic AED was the first to receive FDA clearance for pediatric defibrillation. Philips subsequently released the patent on their pediatric pads to enable other manufacturers to replicate them.

University of Minnesota, Minneapolis
David G. Benditt, MD

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Commentary by Richard M. Luceri, MD

In addition to Dr. Benditt’s use of biphasic external defibrillation in a small case series of patients with refractory AF, there are two studies on the Philips SMART Biphasic waveform in AF.

The most ambitious of these was presented by Page and colleagues from the University of Texas as an abstract at the 2000 meeting of the AHA. The study design was a blinded, multicenter trial, in which 205 patients were randomized to receive a protocol of 4 shocks to cardiovert AF with either a Philips SMART Biphasic waveform or a damped-sine monophasic waveform in this sequence: biphasic, 100 J, 150 J, 200 J, 200 J; monophasic, 100 J, 150 J, 200 J, 360 J. If the fourth shock did not succeed, the patient was crossed over to the maximum of the other waveform. The investigators found that cardioversion success rates were markedly higher with the biphasic waveform ($P < 0.0001$) than with the monophasic waveform at energy levels of <200 J. Moreover, confirming Dr. Benditt’s experience, they found that half the time when 360-J monophasic shocks were unsuccessful, a 200-J biphasic shock effectively converted AF.

Ricard and colleagues likewise randomized 57 patients to shock treatment with the Philips SMART Biphasic waveform or a damped-sine monophasic waveform. They found that at the same energy level of 150 J, the biphasic shocks were superior in restoring sinus rhythm ($P = 0.02$).
Part 3. Update on out-of-hospital clinical studies supporting biphasic external defibrillation for adult VF
Richard M. Luceri, MD

Introduction

Studies supporting biphasic external defibrillation for termination of adult VF in the out-of-hospital setting are currently confined to the low-energy Philips SMART Biphasic AED. The most ambitious of these studies, the ORCA trial, is a prospective randomized controlled trial comparing the low-energy Philips SMART Biphasic AED with high-energy monophasic AEDs in four European cities: Mainz, Germany; Hamburg, Germany; Brugge, Belgium; and Helsinki, Finland.9

There are also multiple out-of-hospital human case series reports about the low-energy Philips SMART Biphasic AED. In 1998, Gliner and colleagues reported on 100 consecutive cardiac-arrest uses of the low-energy Philips SMART Biphasic AED, drawing data from 34 sites.11 Two of these sites have since published their own case series data. One site, Rochester, Minnesota, the location of the Mayo Clinic, is a national leader in EMS development and research.14,34

In this update, I focus on the ORCA trial and on the experiences in Rochester, Minnesota. Each of these studies was published after the International 2000 Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care issued its Guidelines 2000.15 If this committee had possessed the results of the ORCA randomized controlled trial at the time of classifying its recommendations, its class IIa recommendation (“standard of care”) for the low-energy Philips SMART Biphasic defibrillator might have been higher. The minimum evidence for a class I recommendation — “class I interventions are always acceptable, proven safe, and definitely useful” — is achievement of positive outcomes in at least one randomized controlled trial.15

The European cities’ experience: the ORCA trial

This multicenter, prospective, randomized, controlled trial compared the low-energy Philips SMART Biphasic AED with two different types of high-energy monophasic AEDs: the Heartstart 3000 or Heartstart 911 (Laerdal Medical Corporation, Wappingers Falls, NY), which deliver a monophasic truncated exponential waveform, and the Heartstart 2000 (Laerdal Medical Corporation) and LifePak 200 (Physio-Control, Seattle, Wash.), which deliver a monophasic damped sine waveform.9 Two of the European cities (Mainz and Hamburg) employed as their first-level responders paramedics with 2000 hours of training; the other two (Brugge and Helsinki) employed emergency medical technicians.

Every quarter of the year during the course of the trial, a daily schedule of AED randomization was provided to EMS crews by the investigators, and these crews would then carry the appropriately tagged AED for the full day starting in the morning. The ORCA trial was therefore not blinded. The trial began at the first site, Mainz, in December 1996; it ended in each of the four cities in December 1998.

Defibrillation was defined as the termination of VF for >5 secs without regard to hemodynamic features.12 This definition of defibrillation, before any drugs or other ACLS interventions are instituted, is noted by Guidelines 2000 as one that yields “the most useful information about shock efficacy.” It is consistent with data from electrophysiologic mapping studies confirming the time course of termination of VF after shock delivery, and clinically it is an easily measured point in time after a shock.15
Electrocardiogram and shock data were obtained from the recording systems within the AEDs, and patient data were collected from incident and follow-up reports. The neurological status of patients discharged from the hospital was scored by the Glasgow-Pittsburgh Cerebral Performance Category (CPC) instrument, and the overall status of patients discharged from the hospital was scored by the Overall Performance Category (OPC) instrument. Use of each instrument was in accordance with AHA Task Force recommendations for presenting data from out-of-hospital arrests in the Utstein style.

During the study, 54 patients presented with VF to be shocked by the low-energy Philips SMART Biphasic AED, and 61 patients presented with VF to be shocked by one of the high-energy monophasic AEDs. There were no significant enrollment differences between these two groups of patients. There was also no significant difference between the two groups in the time from the emergency call to the first shock: 8.7 ± 3.2 minutes for the high-energy monophasic AEDs and 9.2 ± 2.9 minutes for the low-energy Philips SMART Biphasic AEDs. These call-to-shock times are longer than optimal, although realistic for urban areas (the smallest, Mainz, has a population of 190,000; the largest, Hamburg, has 1.7 million). Survival rates after VF cardiac arrest decrease by approximately 7% to 10% with every minute defibrillation is delayed. When defibrillation is delayed, survival rates decrease to approximately 50% at 5 minutes, 30% at 7 minutes, 10% at 9 to 11 minutes, and 2% to 5% beyond 12 minutes. A high-priority goal in Guidelines 2000 is shock delivery within 5 minutes of EMS call receipt.

The efficacy of the low-energy Philips SMART Biphasic AED was statistically superior on all parameters related to termination of VF (Figure 2). More patients were defibrillated with the initial biphasic shock than with the initial monophasic shock (96% vs 59%), more patients ultimately were defibrillated with the low-energy Philips SMART Biphasic AED (100% vs 84%), and more patients achieved return of spontaneous circulation (ROSC) (76% vs 54%).
There was also a statistically significant difference in neurological status at discharge, measured by the CPC instrument, favoring the low-energy Philips SMART Biphasic AED. Based on the OPC instrument, there was a trend favoring the Philips AED for discharge destination (Figure 3). However, there were no differences between the two treatments in terms of patient survival to hospital admission and to hospital discharge. The investigators report that this outcome is a consequence of the study not being designed to show differences in patient survival.

A limitation of this study was that 79% of the monophasic shocks came from high-energy monophasic AEDs that deployed a truncated exponential monophasic waveform. This waveform is believed to have a lower defibrillation efficacy rate than the damped-sine monophasic waveform, and monophasic defibrillators that deploy it appear to be less frequently used in the United States. Consequently, the investigators undertook a subset analysis to examine waveform effects and substantiated the efficacy benefits of the low-energy Philips SMART Biphasic AED over both of the monophasic therapies.

The Rochester, Minnesota, experience

Since December 1996, low-energy Philips SMART Biphasic AEDs have been employed in the Rochester, Minnesota EMS system, in which first-arriving personnel — police, firefighters, or paramedics — deliver initial shocks. This study updates outcomes using the Philips AED until June 2000.

Of 42 patients with VF treated with the low-energy Philips SMART Biphasic AED, 35 were bystander witnessed, and their outcomes were subsequently analyzed. For all 35 patients, VF was terminated with the first shock. Fourteen of the 35 patients (40%) achieved ROSC after defibrillation only. Each of the 14 patients survived to a neurologically intact discharge and fulfilled the criteria for an OPC classification of 1. The remaining 21 patients required epinephrine and other...
ACLS interventions. Of these, only two survived to neurologically intact discharge with OPC 1 status. Altogether, 28 of 35 (80%) patients regained sustained spontaneous circulation, and 16 of 35 (46%) survived to discharge.

According to these investigators, the results are similar to their data with high-energy monophasic defibrillators deploying the monophasic damped sine waveform. Among 70 patients defibrillated with monophasic AEDs, 23 (33%) achieved ROSC with shocks only. Overall, 54 of 70 (77%) patients achieved ROSC, and 32 of 70 patients (46%) survived to discharge home.

This study confirms that ROSC achieved by shocks only is a powerful determinant of survival. The median call-to-shock time for these patients was 5.0 minutes (range, 2.9 to 8.0 minutes). In contrast, the median call-to-shock time of nonsurvivors was 6.2 minute (range, 4.3 to 9.1 minutes).

**Conclusion**

The results of ORCA and the Rochester case series suggest that the low-energy Philips SMART Biphasic AED is superior to high-energy monophasic AEDs in shock efficacy for terminating adult VF and superior to or equal to high-energy monophasic AEDs in terms of postresuscitation patient outcomes. Further evaluation of biphasic defibrillator technology is still needed; the experience in Rochester, for example, should be updated regularly. However, today the evidence in support of the low-energy Philips SMART Biphasic defibrillator for long downtime adult SCA is strong proof that this intervention confirms its promise.
References


