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AHA Scientific Statement

Low-Energy Biphasic Waveform Defibrillation: Evidence-Based Review Applied to Emergency Cardiovascular Care Guidelines

A Statement for Healthcare Professionals From the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation

Writing Group and Panel of Expert Reviewers; Richard O. Cummins, MD[1]; Mary Fran Hazinski, RN, Cochairs[1]; Richard E. Kerber, MD[1]; Peter Kudenchuk, MD[1]; Lance Becker, MD; Graham Nichol, MD; Barbara Malanga, BSEE; Tom P. Aufderheide, MD[1]; Edward M. Stapleton, EMT-P[1]; Karl Kern, MD[1]; Joseph P. Ornato, MD; Arthur Sanders, MD[1]; Terence Valenzuela, MD[1]; ; Mickey Eisenberg, MD[1]

Key Words: AHA Medical/Scientific Statements • defibrillation • sudden death • cardiopulmonary resuscitation

Disclosure Statement

Researchers have only recently conducted out-of-hospital human studies that document outcomes of transthoracic defibrillation using a low-energy biphasic waveform shock. The American Heart Association Committee on Emergency Cardiovascular Care (ECC) and its subcommittees included prepublication reports of these studies in this review of transthoracic biphasic waveform defibrillation. The writing group and a panel of invited experts have diligently attempted to assess the quality of the studies reviewed here by using a formal evidence-based template, which is summarized in this statement.

The experts most familiar with defibrillation technology and assessment are often recipients of research support from manufacturers of automated external defibrillators (AEDs). Several of the authors and expert reviewers of this report have signed disclosure statements acknowledging training or research support from one or more AED manufacturers. However, in every case, support was administered through the academic institutions employing those individuals. No one has disclosed receiving personal salary support or consultant's fees from any AED manufacturer, nor has anyone disclosed that they are or were a shareholder, paid advisor, or member of an advisory board of an AED manufacturer. The same is true of ECC Committee members with one exception, an employee of an AED manufacturer who abstained from discussions of the reviewed material and this statement.

The final statement was reviewed and approved by the AHA Science Advisory and Coordinating Committee, 2 ECC science advisors, and 2 AHA vice presidents. These reviewers were familiar with the comments and recommendations of the expert reviewers and their disclosure statements. It was the opinion of the final reviewers that statements by the writing group and reviewers were objective, balanced, and based on known scientific facts and did not appear influenced by the disclosed possible conflicts of interest.

Purpose

This report addresses important clinical questions regarding newly developed AEDs that deliver impedance-compensating, fixed, low-energy biphasic waveform shocks.† Clinicians and responsible medical directors have phrased these questions in the context of the 1992 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care.[1] The guidelines did not address defibrillation waveforms because AEDs using biphasic waveforms were not commercially available until 1996 (1 biphasic AED, which is no longer available, existed before the 1976 Food and Drug Administration [FDA] amendment).

The ECC Committee and subcommittees recognize generic questions that should be addressed as new information, therapy, or

technology becomes available. What criteria are required to initiate a review of new technologies or interventions? How is such a review conducted? Will this evidence-based process apply to all future discussions of the guidelines? This report addresses immediate clinical questions regarding biphasic waveform defibrillators and describes the process to apply to new guideline questions in the future.

Review Triggers

New interventions, devices, or approaches can trigger a review by the ECC Committee when all or most of the following criteria are met:

- *The intervention raises important questions related to specific AHA ECC guidelines.* In the matter of lower-energy biphasic waveform shocks, the AHA guidelines recommend 200 J for the first defibrillation shock and progressive energy levels (300 J to 360 J) for subsequent shocks. The biphasic defibrillator currently delivers only 150-J shocks.
- *The intervention has generated controversy and questions among resuscitation experts or in the AHA training network, or the evidence for the intervention is so compelling as to warrant an immediate consideration of a change in clinical guidelines.* In this case, AHA instructors and affiliates have inquired about the role of a nonprogressive, low-energy defibrillator when they teach the AHA guidelines or make recommendations about AED purchases.
- *The intervention is (or is not) supported with data that fit into the ECC levels of evidence template.* For this report, several peer-reviewed publications fit into the ECC levels of evidence categories. In addition, the ECC Committee asked the 5 US manufacturers of AEDs for prepublication reports on clinical studies and postmarket surveillance data related to attempted resuscitation of humans in out-of-hospital cardiac arrest with biphasic defibrillators. Two manufacturers, including the company that manufactures the only commercially available biphasic AED, submitted information for review.
- *The intervention raises guideline issues of such a nature that only the AHA can provide a proper response.* The FDA has cleared the biphasic waveform defibrillator for commercial sale, yet its clinical use has been perceived or represented as a violation of specific AHA guidelines.

Review Process

The ECC Committee and subcommittees are dedicated to developing evidence-based guidelines and have prepared a new document on

developing such guidelines in emergency cardiovascular care.[2] This document presents in detail the ECC evidence-based review process. The clinical questions regarding biphasic defibrillation offered the first opportunity to use this process. Fig 1 displays the AHA template for evidence-based review of ECC guidelines. A brief summary of these steps applied to the clinical question of biphasic defibrillation follows.

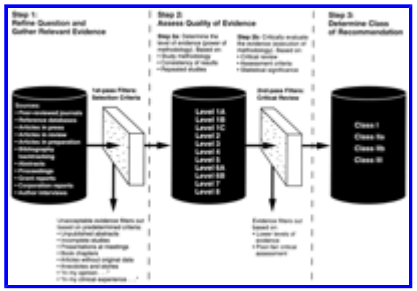

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Figure 1. AHA template for evidence-based evaluations of emergency cardiovascular care guideline recommendations.

Step 1: Refine the Question and Gather Relevant Evidence

Reviewers must gather evidence in the context of a specific, refined clinical question. The questions regarding biphasic defibrillators, which are discussed below, are specifically related to the use of these devices in humans in the out-of-hospital setting. Numerous studies of biphasic waveform defibrillation have been published, including

- Cellular models[3]
- Computer models[4]
- Isolated organ models[5]
- Large animal studies[6] [7] [8] [9]
- Animal studies of internal biphasic defibrillation[10] [11] [12]
- Animal studies of transthoracic biphasic defibrillation[9]
- Human studies of internal biphasic defibrillation in electrophysiological study (EPS) laboratories[13] [14]
- Human studies of transthoracic biphasic defibrillation in EPS laboratories or operating rooms during threshold testing for implantable defibrillators[15] [16] [17]

At the time this review began, results of studies of out-of-hospital biphasic defibrillation had not been published in peer-reviewed journals. For this statement, a panel of 14 expert reviewers examined 3 manuscripts in the prepublication stage that reported data on out-of-hospital biphasic defibrillation.[18] [19] [20] During preparation of this statement for publication, however, 2 of the 3 articles were published.

Several disadvantages are associated with any review of manuscripts or abstracts in preparation, review, prepublication, or press. Such reviews lack reactions and critique from the broad range of readers who review and comment on published articles. When possible, the ECC Committee will base all future guideline revisions on the results of published studies. However, circumstances may arise when prepublished materials are acceptable for review, as in this case. As a precedent, the ECC Committee reviewed data before publication when revising the 1992 guidelines on high-dose epinephrine.[21]

Step 2: Assess the Quality of Evidence

Step 2a: Determine the Level of Evidence (Power of Methodology)

This step requires identification of methods used in the research projects. Some study designs and methods are intrinsically more powerful than others. The ECC Committee uses 8 levels of evidence, which are listed and defined in Table 1.

View this table: **Table 1.** AHA Emergency Cardiovascular Care Levels of Evidence
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Step 2b: Critically Evaluate the Evidence (Execution of Methodology)

In this step the study is critiqued, and reviewers determine how well the researchers executed their design: "This was a randomized, controlled trial, but was it a *good* randomized, controlled trial?"

Step 3: Determine the Class of Recommendation

To determine the final class of recommendation, experts must integrate a heterogeneous collection of research, which is sorted by level of evidence and quality of execution. This is not an explicit step. Valid methods are lacking to weigh and sum multiple studies in which different methods were used and executed with varying degrees of success. In the final analysis, guideline developers as well as expert reviewers must make a form of global subjective judgment that integrates the evidence review with personal experience and existing expertise. Table 2 summarizes and defines the 1998 classes of recommendation used to qualify the ECC guidelines. Note that the ECC Committee and subcommittees have revised the language describing these classes of recommendations since publication of

the 1992 guidelines.[1] Previously the 4-point scale used the terms *definitely useful, probably useful, possibly useful,* and *harmful.* The improved scale defines the strength of evidence as *excellent, very good, fair to good,* and *harmful.*

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Table 2. 1998 Classes of Recommendations for Therapeutic Interventions in Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

The AHA Commitment to Early Defibrillation and the Chain of Survival

Since 1986,[22] the AHA has firmly supported the concept of a strong Chain of Survival,[23] with early defibrillation as the most important link.[24] This support has been expressed through

- Publication of position statements on the Chain of Survival,[23] early defibrillation,[25] and public access defibrillation[26]
- Appointment of an expert panel which concluded that future-generation AEDs are the key to improving out-of-hospital resuscitation[27]
- Development of a curriculum for training people to use AEDs[28]
- Inclusion of AED training in all advanced cardiac life support (ACLS) courses[29]
- Establishment of the Task Force on Public Access Defibrillation, which called for new innovations in AED technology[26]
- Sponsorship of 2 international conferences on public access defibrillation[30] [31] and support of a legislative advocacy campaign for the public[32] [33]
- Publication of task force reports on public access defibrillation[34] [35] [36]

Public Access Defibrillation: A Stimulus to New Technology

The AHA Task Force on Automatic External Defibrillation included a wide range of representatives from the scientific and clinical community. The task force promulgated the concept of public access defibrillation as an innovative means of achieving early defibrillation for adults in sudden out-of-hospital cardiac arrest.[26] *Public access defibrillation* means *witness defibrillation*: defibrillation shocks delivered by the person—most often a layperson—who witnesses the collapse. This concept represents the

development of ideas generated by the Task Force on the Future of CPR,[27] which affirmed that "the future of CPR lies with the future of defibrillation."

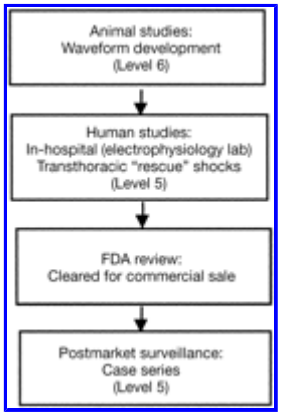
Public access defibrillation can succeed only if lay rescuers and nontraditional responders are trained and equipped to use AEDs. However, widespread dissemination of AED training and equipment requires devices that are small, light, modestly priced, durable, low-maintenance, almost intuitively obvious to operate, and capable of being stored for long periods without recharging.[30]

The goal of developing AEDs for public access has driven manufacturers to investigate design improvements, battery enhancements, and alternative waveforms. Alternative waveforms include multiple types of biphasic and monophasic waveforms as well as impedance-compensating or voltage-adjusting waveforms.[30] More effective waveforms mean decreased defibrillator energy requirements because equal effectiveness can be achieved at lower energy levels. A decrease in energy requirements confers advantages in size, weight, and cost. The Second Public Access Defibrillation Conference in 1997 provided a forum for a number of scientific reports and abstracts on alternative waveforms.[31] [36]

In 1995 the AED Task Force formed a subcommittee on AED safety and efficacy that included representatives from the FDA and AED manufacturers.[34] The group was charged with making recommendations for specifying arrhythmia analysis and algorithm performance and incorporating new defibrillator waveforms. The task force stated that alternative waveforms for transthoracic defibrillation "should be provisionally approved for use in AEDs" if they are "convincingly demonstrated to be equivalent or superior to standard waveforms in the electrophysiology laboratory... . Performance of waveforms incorporated into AEDs should be monitored as part of a postmarket surveillance program... . "[34]

The steps recommended by the AED Task Force are outlined schematically in Fig 2 along with a level-of-evidence notation as defined in Table 1.

Figure 2. Recommended steps to validate alternative defibrillation waveforms. Each of these steps was followed by the manufacturer of the AED reviewed in this report. FDA indicates Food and Drug Administration. From the AHA Task Force on Automated External Defibrillation, Subcommittee on AED Safety and Efficacy.[34]



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Monophasic Versus Biphasic Waveform Defibrillation

Defibrillation waveforms are a complex intervention. Monophasic waveforms vary in the speed with which the waveform returns to the zero voltage point—either gradually (damped sinusoidal) or instantaneously (truncated exponential). Biphasic waveforms deliver current that first flows in a positive direction for a specified duration. In the second phase the device reverses the direction of current so that it flows in a negative direction. Many features of defibrillation waveforms can be changed and shaped by researchers and manufacturers to develop new waveforms.[37] [38] [39] [40]

Over the past 2 decades, biphasic waveform defibrillation has attracted clinical and commercial attention in a variety of research models and settings.[3] [4] [5] [6] [7] [8] [9] [10] [11] [12] [13] [14] [15] [16] [17] In these studies biphasic shocks appear to achieve the same defibrillation success rates (most often defined as termination of ventricular fibrillation [VF] for at least 3 to 5 seconds) as monophasic waveforms but at significantly lower energy levels.[36] Defibrillator manufacturers can use lower-energy waveforms to achieve a number of technical advantages. Lower-energy devices can be smaller, lighter, less expensive, and less demanding of batteries, with fewer maintenance requirements. These technical advantages help fulfill the AED design features needed for public access defibrillation.[27] [30]

Researchers and manufacturers of implantable cardioverter-defibrillators (ICDs) have noted the advantages of biphasic waveforms for

more than a decade.[10] [11] [12] Human studies in EPS laboratories[13] [14] have confirmed the advantages of intracardiac and transvenous biphasic defibrillation noted in animals. By the early 1990s all implantable defibrillator manufacturers had switched to biphasic waveforms. Monophasic shocks are no longer used in newly implanted ICDs.

Commercially Available Biphasic Waveform AEDs

The first biphasic AED cleared by the FDA for commercial sale (ForeRunner(TM), HeartStream Corporation) became available in September 1996. The device adjusts the amount and duration of current delivered based on impedance measurements performed twice during every shock. Some research has confirmed the value of impedance-based adjustments to current and voltage.[41] [42] The manufacturer states that this unique combination of features—biphasic waveform shocks combined with impedance adjustment or compensation—provides equivalent defibrillation success at lower energy levels than those of monophasic shocks and eliminates the need to increase the energy for persistent VF.

The evidence regarding the efficacy and effectiveness of the biphasic AED has accumulated in the rationally sound sequence of animal studies,[9] pilot human feasibility studies,[15] and a prospective, randomized, controlled trial.[16] These data, which were gathered under controlled and rigorous conditions, fit the category of "efficacy" data (see footnote, Table 2).

After the device was cleared by the FDA for commercial sale, researchers and clinicians collected out-of-hospital data that fit Level 4 evidence (nonrandomized observational study with some historical control group)[20] and Level 5 evidence (case series).[18] Fig 3 illustrates the sequence of direct evidence related to biphasic waveform defibrillation.

Figure 3. Sequence of research and levels of evidence related to biphasic waveform defibrillation. EPS indicates electrophysiological study, and FDA, Food and Drug Administration.

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Human Studies: Biphasic Waveform Defibrillation for In-Hospital Transthoracic Rescue Shocks

The *efficacy* of different waveforms for human ventricular fibrillation (VF) has been measured by success at transthoracic "rescue" defibrillations delivered in EPS laboratories. Cardiologists delivered these transthoracic shocks during threshold determinations for ICDs. In this situation, VF is induced by an electric stimulus and allowed to persist for only 20 to 30 seconds before the rescue shock. Defibrillation success is defined as the termination of VF for 5 to 30 seconds, depending on the researchers. A successful postshock rhythm can therefore be any non-VF electrical activity, including asystole.

Three in-hospital studies are summarized in Table 3.[15] [16] [17] This data demonstrates that

- Low-energy biphasic shocks at 115 J to 130 J from an AED using impedance compensation achieve the same defibrillation rate as 200-J monophasic shocks (86% to 89% defibrillation rates).[15] [16] However, there is some evidence that 115-J to 130-J biphasic shocks may not be as successful as 360-J monophasic shocks, which achieved 96% success in 83 patients.[16] Reviewers debated the appropriateness of the authors' statistical approach, specifically with regard to multiple testing, and whether to test for *equivalency* or *superiority*. The authors combined the 115-J shocks with the 130-J shocks to form a single group to compare with the 360-J group; success for this combined "lower-energy" group was statistically equivalent to success for the 360-J group. If

compared separately, however, the 360-J shocks were more successful than either of the lower-energy biphasic shocks.[16] It should be noted that the single commercially available biphasic AED provides an energy level of 150 J rather than the 115-J or 130-J shocks used in these studies.[15] [16] This increased energy level may produce a defibrillation rate even higher than the 86% to 89% reported here.

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Table 3. In-Hospital and Out-of-Hospital Clinical Evidence on Alternative Waveform and Energy Level Defibrillation

- Low-energy (171-J) biphasic waveform shocks using the Gurvich waveform (damped sinusoidal waveforms with a substantial negative undershoot; in effect a biphasic waveform) achieve a better rate of conversion out of VF (100% defibrillation rate, 25/25) than higher-energy (215 J) Edmark damped sinusoidal monophasic waveforms (79% defibrillation rate, 22/28).[17]

Refine the Question: Biphasic Waveform Defibrillation for Out-of-Hospital Cardiac Arrest

The first biphasic AED is being marketed for use in the clinical setting of adult out-of-hospital sudden cardiac arrest. Intuitively the same high level of success associated with transthoracic shocks in EPS laboratories should occur with transthoracic shocks delivered in out-of-hospital VF arrest. The out-of-hospital scenario, however, is unquestionably different from the EPS laboratory. Out-of-hospital VF is most often due to myocardial ischemia, frequently in the absence of cardiopulmonary resuscitation (CPR), within a hypoxic and acidotic substrate.

Furthermore, the transthoracic "rescue" shock in the out-of-hospital scenario arrives late, minutes rather than seconds after onset of VF. Clinical evidence suggests that VF of long duration is much harder to defibrillate than VF of short duration.[46] Some research has compared the efficacy rates of defibrillation in short- versus long-duration VF using monophasic and biphasic transthoracic shocks. Biphasic shocks perform better in both animals[5] and humans.[47] In the recent human study, the biphasic shock defibrillation rate for long-duration VF was 82% (55/67), which was significantly higher than the monophasic shock defibrillation rate of 66% (108/164).[47]

Therefore, for humans in out-of-hospital cardiac arrest from VF, the clinical questions can best be refined as follows:

Are 150-J first defibrillation shocks using an impedance-compensated biphasic waveform clinically equivalent to 200-J first defibrillation shocks using a monophasic waveform? (First shock: 150 J biphasic versus 200 J monophasic.)

For people in refractory or recurrent VF (following an initial biphasic shock of 150 J), are subsequent impedance-compensated biphasic shocks of 150 J clinically equivalent to monophasic defibrillation shocks delivered in a progressive energy sequence of 300 J to 360 J? (First 3 shocks: 150 J-150 J-150 J biphasic versus 200 J-300 J-360 J monophasic.)

Attempts to answer these clinical questions have led to a sobering observation: research has not clearly established an expected success rate for out-of-hospital monophasic defibrillation using either truncated exponential or damped sinusoidal waveforms. Some measure of the success of defibrillation can be derived by reviewing published out-of-hospital research. In some studies, reviewers can relate defibrillation outcome to the type and energy of waveform. However, noncomparability of patients and inconsistent nomenclature for "success" render detailed comparisons difficult if not invalid.

The problem of imprecise nomenclature and noncomparability of out-of-hospital patients has challenged researchers for years. To resolve this situation, the AHA and other international resuscitation organizations conducted 4 Utstein Style symposia to address (1) out-of-hospital cardiac arrest,[48] (2) in-hospital arrest,[49] (3) pediatric resuscitation,[50] and (4) laboratory-based resuscitation research.[51] Fully 12 years ago 2 expert reviewers of this statement published an article titled "What Is a `Save'? Outcome Measures in Clinical Evaluations of Automatic External Defibrillators."[52] This same question applies to the current problem of selecting outcome measures for comparison of alternative defibrillation waveforms and energy levels.

Biphasic waveform defibrillators became clinically available so recently that no published report of out-of-hospital experience existed at the time of this review: 2 reports were in press, and a third had been submitted for publication.[18] [19] [20] Table 3 summarizes results from 2 of the 3 articles.[19] [20] The third article discusses the work of Roger D. White and colleagues in Rochester, Minn.[18] Although Dr. White's article is the first report on out-of-hospital use of a low-energy biphasic defibrillator, the 10 patients described are also discussed in the 2 later reports that review a larger experience. Table 3 also summarizes 3 other studies (1 unpublished) that provide comparative data on alternative waveforms and energy levels in the out-of-hospital setting.[43] [44] [45]

There are important limitations in the data in Table 3. This table is not a meta-analysis based on a comprehensive literature review using prescribed criteria to determine study eligibility. Therefore, any pooling of data or detailed cross-study comparisons would be invalid. These studies simply provide a broad-stroke framework for the question, "Do these various waveforms appear to have clinical equivalence?"

Another important limitation of this review must be understood: *The definitions of defibrillation and resuscitation success are inconsistent.* Table 4 lists the variations in definition that occurred or were mentioned.[15] [16] [19] [20] [43] [44] [45]

View this table: **Table 4.** Variations in Shock "Success" or Outcome Nomenclature and Definitions
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To a large extent, these variations reflect the realities of data collection in the prehospital setting. Resuscitations are dynamic events with multiple rescuers and interventions and intermediate outcomes. Defibrillation has several outcomes: persistent VF or conversion to a perfusing rhythm, asystole, or pulseless electrical activity. Furthermore, patients who have had defibrillation may later refibrillate and require more shocks. Shock delivery and outcome occur in combination with many other interventions, such as CPR and the arrival of ACLS personnel who provide endotracheal intubation and intravenous medications. Clinical treatment data are difficult to correlate with data recorded by the event documentation components of the AED. Claims that one definition of "shock success" is more meaningful or commonly accepted than another are insupportable.

The Need for an Energy Reserve: Persistent Low-Energy Biphasic Shocks Versus Progressive-Energy Monophasic Shocks

It could be argued that the outcome "all shocks success," "≤3 shocks success," or "return of an organized rhythm" for the 2 monophasic waveforms reflects progressive shock energies delivered to VF patients during resuscitation. These patients averaged 3 to 4 shocks during resuscitation. The standard protocols call for an increase in energy levels after the first shock. A rough comparison becomes available when the outcomes for multiple monophasic shocks are compared with outcomes for multiple biphasic shocks. Such a comparison provides a simple test of the sequence *150 J-150 J-150 J biphasic shocks* versus *200 J-300 J-360 J monophasic shocks.* If there is a clinical disadvantage for persistent low-energy biphasic shocks compared with progressive-energy monophasic shocks, the disadvantage should appear in these data.

Table 5, however, demonstrates that the "all shocks or ≤3 shocks success" rate was higher for the biphasic AED than for the monophasic damped sinusoidal AED and truncated exponential AED:

- 80% (N=44) for the biphasic AED[19]

  View this table: **Table 5.** Outcomes of Out-of-Hospital Defibrillation With AEDs Using Three Different Waveforms
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- 58% (N=108) for the monophasic damped sinusoidal AED[43]
- 35% (N=130) for the monophasic truncated exponential AED[43]

The return of either organized electrical activity or a pulse at the time of transport was also higher for the biphasic waveform: 77% of 44 patients had organized rhythm at transport, and 57% of 34 had a pulse. This compares with 48% of 85 patients treated with the monophasic truncated exponential AED, who had a return of organized electrical activity at the time of transport to the hospital.[45] Although statistical comparisons are inappropriate here, the trend toward better outcome rates for low-energy biphasic shocks is reassuring and should reduce concerns that withholding progressive energy shocks does harm or is a disservice to patients.

Limitations of Data and Reviewers' Critique

"Doing Versus Studying": Moving From the Laboratory to the Field

The numerous preliminary laboratory,[3 4 5 53] animal,[6 7 8] and pilot human studies[13 14 15 40] provided compelling support for performing multicenter studies in EPS laboratories. Subsequently the 2 multicenter studies of transthoracic biphasic rescue shocks delivered in the EPS laboratory provided definitive Level 1 evidence to confirm the efficacy of biphasic shocks in very short–duration, witnessed VF arrest induced by an electric stimulus.[16 17]

No clear conclusions could be reached on the precise implications of these data for patients during out-of-hospital VF arrest. Out-of-hospital VF is induced by ischemia and occurs most often in hypoxic, acidotic hearts with chronic, fixed coronary artery disease. Treatment of VF with an AED occurs in the late shock-refractory stages of the arrest. The marked differences in the mechanism of VF induction and its duration prevent direct comparison between in-hospital and out-of-hospital patients. Some reviewers considered these data sufficient evidence to support endorsement of out-of-hospital biphasic defibrillation. For others, however, these data only provided support for studying out-of-hospital biphasic defibrillation.

Small Numbers of Patients

At the start of this review, only 3 articles in the prepublication stage addressed the question of biphasic waveform defibrillation for out-of-hospital cardiac arrest.[18 19 20] Data from all 3 studies was considered only Level 4 or Level 5 evidence because of the simple case-series design and the small numbers of VF patients treated with the biphasic defibrillator: 10 patients were listed in the original report from Rochester,[18] 18 in the Gliner paper[20] (including the 10 from the White paper), and 44 in the Poole paper[19] (including the 18 from the Gliner paper). As of October 1, 1997, only 44 VF patients provided the total clinical out-of-hospital experience with biphasic

defibrillation. Two of the 14 reviewers considered these numbers unacceptably small and the data insufficient evidence on which to base any statement.

Unavailable and Nontraditional Outcomes

The success of defibrillation waveforms should be reported in terms of the most widely accepted definition of resuscitation success—survival-to–hospital discharge.[48] This primary outcome, however, was not available in the case series reported by Poole et al[19] because of the intrinsic limitations of postmarket surveillance data. In most cases, researchers had only intermediate outcome information downloaded from the AED event-documentation PCMCIA card. Although clinical data were supplied for some patients, often outcome determination ended when the patients were transported to the emergency department. Neither the Gliner nor the Poole study provided the recommended outcome of survival-to–hospital discharge. In the White study, only 1 of 10 patients survived to hospital discharge.

The intermediate outcome of defibrillation success, defined simply as removal or termination of VF for >5 seconds, was considered unsatisfactory, especially when asystole and pulseless electrical activity were classified as "success." Although it is preferable to report the effects of biphasic defibrillation based on the return of spontaneous circulation, hospital admission rates, and survival rates for this evidence-based guideline review, this information was not available in the Level 4 and Level 5 data supplied in these reports.

Inadequate Data for Comparisons

The 3 unpublished studies supplied few of the variables in patients, emergency medical services, treatment, and outcome recommended in the Utstein guidelines for reporting outcome of out-of-hospital cardiac arrest.[48] For example, the variables related to witnessed arrest, bystander CPR, and collapse-to–treatment intervals are largely lacking. The more comprehensive articles with respect to clinical variables (the original articles by White[18] and Gliner[20]) report on only 10 and 18 patients, respectively.

The redundancy of case reporting noted above prevented meaningful combinations of the 3 articles. In the absence of the recommended clinical variables, evaluations of defibrillation success, however defined, become extremely difficult. The problem of noncomparability arose in the Poole manuscript in the authors' efforts to construct at least a "historical" control group derived from previously published studies. Although the reviewers recognized the conscientious effort to provide some type of control comparison, most reviewers considered this compilation inadequate and invalid.

Lack of Definitive Level 1 Evidence

For this report, evidence existed only at *Level 4* (historically controlled, retrospective cohort studies) and *Level 5* (a case series with a historical control group assembled from published articles). There is no definitive Level 1 evidence regarding performance of low-energy biphasic defibrillators in the out-of-hospital setting. No randomized, controlled prospective clinical trial discusses either of the

2 clinical questions: 150 J biphasic versus 200 J monophasic for first shock success or a sequence of 150 J-150 J-150 J biphasic shocks versus 200 J-300 J-360 J monophasic shocks for persistent shock-refractory VF.

Lack of Comparative Data Regarding *Monophasic* Waveform Success

There are simply no out-of-hospital prospective studies of defibrillation waveforms, either monophasic or biphasic. Consequently it becomes impossible to define an expected performance level for a new alternative waveform such as a low-energy, impedance-compensated biphasic shock. Because clinical outcomes, such as survival-to–hospital discharge, are multifactorial in nature, the incremental value of a single intervention, such as a different defibrillation waveform, cannot be determined. 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.

FDA Clearance for Commercial Sale Versus AHA Class of Recommendation

More than 1 year after the FDA cleared the first biphasic defibrillator for commercial sale, the AHA ECC Committee has determined a class of recommendation for the device. For medical devices, the FDA must determine whether a device is *safe* and effective when used as intended. *Safety* means that the probable benefits of a device to health outweigh any probable risks when used in the manner for which it was intended and when accompanied by adequate warnings and directions for use. "Effectiveness," from the FDA perspective, means that in a significant portion of the target population the use of a device for its intended purpose will provide clinically significant benefit. The device is not required to work for every patient.

The safety and efficacy data that led to FDA clearance of the biphasic defibrillator came largely from laboratory animal projects and human EPS data on transthoracic rescue shocks.[16] For several reviewers, FDA clearance of a device proposed under the 510-K regulations should have led to prospective, randomized clinical trials (as outlined in Fig 3) rather than commercial distribution. The manufacturer of this biphasic AED followed the sequence noted in Fig 3, including FDA review and postmarketing studies.

Some questions have arisen over whether there is a need for AHA ECC recommendations when the FDA has cleared a device for commercial sale. There must be no confusion or misunderstanding on this point: the FDA evaluation and clearance process and the ECC evidence-based guideline recommendations are at this time separate, independent processes. Manufacturers of ECC-related products, medical devices, or pharmaceutical agents must not assume that FDA clearance for commercial sale automatically conveys a high-level recommendation by the AHA ECC Committee.

Lack of Energy Reserve: Possibility of Harm?

Although 150-J impedance-based biphasic AEDs may perform effectively for a large percentage of out-of-hospital VF arrest patients,

an unidentified proportion of patients will still need a higher energy shock. This energy reserve is lacking in the current biphasic device. In the 44 VF patients reported thus far, the all-shocks defibrillation success rate was 80% in 1 study[19] and 91% in the other.[20] It would be a misinterpretation, however, to argue that the remaining patients simply needed higher energy levels. Multiple high-energy shocks could easily result in more harm than good. A current perspective, as yet unproved, is that multiple low-energy shocks may be superior to a few high-energy shocks.

ECC providers who select a device that lacks the reserve to provide higher-energy shocks are in a sense depriving an unknown proportion of VF patients of this reserve. Although higher-energy shocks may improve outcomes in these situations, this is unlikely, given the long time intervals and physiological deterioration that occur in out-of-hospital cardiac arrest. The small amount of clinical data on the expected success rate of any type of defibrillation waveform makes it impossible to estimate the size or even the validity of this energy reserve problem. The comparative results from the first 44 instances of clinical use of the low-energy biphasic AED appear positive; if such success continues, this concern will be eliminated.

Summary: Applying the Evidence-Based Template to Evaluation of Biphasic Defibrillation

The AHA ECC Committee and the International Liaison Committee on Resuscitation (ILCOR)[54] will revise the AHA guidelines for CPR and ECC in the year 2000. The commitment to evidence-based guidelines requires an explicit template for guideline review and revision.

Review Triggers

Low-energy, biphasic waveform defibrillation met the stated criteria for guideline review:

- It raises questions related to specific AHA ECC guidelines.
- It has generated numerous clinical questions among members and observers of the AHA training network.
- It can be examined using a body of published and prepublication studies.
- When clinicians and trainees perceive that the use of nonprogressive, low-energy defibrillators may violate AHA ECC guidelines, the ECC Committee is presented with a question it must address.

Step 1: Refine the Question and Gather Relevant Evidence

The clinical questions are related to initial shocks delivered at 150 J (rather than the traditional 200 J) and all subsequent shocks delivered at 150 J (rather than the traditional progressive energy shocks of 300 J to 360 J). The refined guideline questions were

phrased in terms of out-of-hospital human cardiac arrest, a situation for which results of published studies were not available. Therefore, the process of gathering evidence included not only bibliography reviews and database searches but also a request for any unpublished or prepublication research data related to out-of-hospital VF cardiac arrest in humans treated with biphasic waveform defibrillators. Two articles scheduled for publication and one in preparation were identified[18] [19] [20] as well as an unpublished case series originally presented at a conference as an abstract and poster.[45]

Step 2a: Determine the Level of Evidence

Step 2b: Critically Evaluate the Evidence

Table 3 summarizes 3 studies from an in-hospital setting: a moderate-sized multicenter *Level 1B* study with 47 patients,[17] a moderate-sized *Level 1B* study with 30 patients,[15] and a large multicenter *Level 1B* study with 294 patients.[16] These studies, in the rigorously controlled setting of in-hospital EPS laboratories with witnessed, stimulus-induced VF of short duration, were considered to be of high quality, exact execution, and powerful design.

In the out-of-hospital setting, however, the level and quality of evidence drops precipitously due to the intrinsic difficulties of conducting controlled prospective studies in this setting.[55] Table 3 summarizes a Level 5 case series reporting on the first 44 VF patients treated with the biphasic AED[18] and a Level 4 series reporting on 18 patients treated with the biphasic AED.[20] Lacking a contemporaneous control group, instead the authors constructed a control group by examining published studies of monophasic defibrillation. For purposes of comparison, 3 of these "control group" studies are summarized in Table 3.[43] [44] [45] The quality of these data was considered modest.

Step 3: Determine the Class of Recommendation

Evidence-based guidelines should display a close match between the level and quality of evidence and the final class of recommendation. Table 2 describes Classes I, IIa, and IIb as *acceptable*, differing in the strength of the supporting evidence. A number of "mismatch" factors may come into play in the integration of evidence into a final class of recommendation,[2] including cost, practicality, ease of teaching and learning, and comparisons with "standard" practices that have arisen from common-sense extrapolations rather than compelling evidence.

Another mismatch factor that played a role in this review was the decision-making principles of expert reviewers and the differing weights they gave the same scientific evidence. For some reviewers, experience with ICDs and the numerous studies on biphasic defibrillation conducted in animal and EPS laboratories provided compelling support for a Class I recommendation. For other experts, the same evidence only provided justification for a prospective, randomized clinical trial.

Conclusions

The AHA ECC Committee and subcommittees reviewed this statement and have endorsed the following conclusions:

1. Positive evidence supports a statement that initial low-energy (150-J), nonprogressive (150 J-150 J-150 J), impedance-adjusted biphasic waveform shocks for patients in out-of-hospital VF arrest are *safe, acceptable, and clinically effective.*
    - The human out-of-hospital studies that currently exist, however, are only fair-to-good observational studies (Level 4) and case series (Level 5); definitive Level 1 evidence is not yet available.
    - This is consistent with a *Class IIb recommendation*: acceptable and useful; fair-to-good evidence provides support.
    - Low-energy, nonprogressive biphasic waveform defibrillators may be used for both out-of-hospital and in-hospital VF arrest, including persistent or recurrent VF that does not respond to the initial low-energy shock.
2. This Class IIb recommendation for the currently available biphasic defibrillator does *not* imply a higher class of recommendation for existing monophasic defibrillators. Researchers have not yet published prospective, randomized trials that directly compare different defibrillation waveforms at different energy levels in human out-of-hospital cardiac arrest. Potential clinical advantages of one defibrillator waveform over another, such as reduced myocardial injury[56] or increased effectiveness of antiarrhythmics,[57] await proper clinical trials.
3. This class of recommendation may be refined or revised when additional human clinical data become available. This statement does not necessarily extend to future biphasic defibrillators that might use significantly different waveforms. Manufacturers of these future defibrillators will need to gather independent evidence to receive an AHA classification.
4. The standard of care for both out-of-hospital and in-hospital VF arrest is defibrillation delivered early and effectively in the setting of a strong Chain of Survival. Any benefit of one waveform over another (as yet unproved) is unlikely to equal the magnitude of benefit that comes from significantly decreasing the interval from collapse to defibrillation.[58]
5. This statement of acceptable and useful performance should not obscure promising clinical advantages in the defibrillation safety factor[59] and potential technical advantages of biphasic waveform defibrillators in terms of size, weight, manufacturing cost, and battery demands.

Recently other manufacturers began marketing smaller, lightweight, less expensive monophasic defibrillators that require only low

maintenance, have long shelf and battery life, and allow for administration of progressive energy (200 J-300 J-360 J) shocks. These include LifePak 500(TM) (Physio-Control Corporation), Laerdal 911(TM) (Laerdal Manufacturing Company), and First Save(TM) (SurvivaLink Company). These general characteristics should translate into increased availability of AEDs in the community and reduced time to defibrillation for the cardiac arrest victim.

Future Research

AHA guidelines and recommendations for different defibrillation waveforms delivered at different energy levels have not yet been formulated. Prospective, randomized clinical trials must be conducted to confirm any advantage of one waveform over another. Some studies are in progress and will be carefully evaluated at the AHA Guidelines 2000 International Conference.

The AHA commends defibrillator manufacturers who are engaged in intensive efforts to develop better, more effective devices for use in a variety of clinical and community settings. Their efforts, coupled with those of scientists who evaluate the devices, will further the AHA mission to reduce disability and death from cardiovascular diseases and stroke.

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Footnotes

"Low-Energy Biphasic Waveform Defibrillation: Evidence-Based Review Applied to Emergency Cardiovascular Care Guidelines" was approved by the American Heart Association Science Advisory and Coordinating Committee in February 1998.

A single reprint is available by calling 800-242-8721 (US only) or writing the American Heart Association, Public Information, 7272 Greenville Avenue, Dallas, TX 75231-4596. Ask for reprint No. 71-0138. To purchase additional reprints: up to 999 copies, call 800-611-6083 (US only) or fax 413-665-2671; 1000 or more copies, call 214-706-1466, fax 214-691-6342, or E-mail pubauth@amhrt.org. To make photocopies for personal or educational use, call the Copyright Clearance Center, 508-750-8400.

[1] These reviewers have indicated a relationship involving previous or current research support that may be perceived as a conflict of

interest.

[2] As of December 1997, only 1 FDA-cleared defibrillator uses biphasic waveform defibrillation shocks. Unless otherwise stated, the term *biphasic defibrillator*, as used in this statement, refers only to ForeRunner(TM) (HeartStream Corporation), an impedance-compensated, fixed 150-J, biphasic waveform AED.

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