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Use of automated external defibrillators for children: an update. An advisory statement from the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation

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1. ILCOR recommendations

On the basis of the published evidence to date, the Pediatric Advanced Life Support (PALS) Task Force of the International Liaison Committee on Resuscitation (ILCOR) has made the following recommendation (October 2002):

- Automated external defibrillators (AEDs) may be used for children 1–8 years of age who have no signs of circulation. Ideally, the device should deliver a pediatric dose. The arrhythmia detection algorithm used in the device should demonstrate high specificity for pediatric shockable rhythms, i.e. it will not recommend delivery of a shock for nonshockable rhythms (Class IIb).

In addition:

- Currently, there is insufficient evidence to support a recommendation for or against the use of AEDs in children < 1 year of age.
- For a lone rescuer responding to a child without signs of circulation, the task force continues to recommend provision of 1 min of CPR before any other action, such as activating the emergency medical services (EMS) system or attaching the AED.

- Defibrillation is recommended for documented ventricular fibrillation (VF)/pulseless ventricular tachycardia (VT) (Class I).

2. Introduction

This statement expands and clarifies the 2000 ILCOR recommendations about the potential use of AEDs in children. The need for this update has become critical. A growing number of AEDs for adults are being placed in public access settings, and the use of AEDs by non-traditional responders is increasing. The likelihood for use of AEDs in smaller (< 25 kg), younger (< 8 years of age) patients is now a reality. This statement provides the rationale for development of AEDs, outlines questions about the efficacy and safety of AEDs used in smaller, younger children, and summarizes recent efforts to justify the use of existing or modified AEDs in smaller, younger children.

2.1. Rationale for AED use

The primary determinant of survival from VF cardiac arrest is the time interval from collapse until defibrillation. Out-of-hospital defibrillation within the first 3 min of witnessed adult VF arrest results in survival rates > 50%. But the success of resuscitative efforts decreases dramatically with the passage of time. For every 1-min delay in defibrillation, the survival rate may decrease by 7–10%, although this number is influenced by the presence and quality of bystander CPR. After > 12 min of VF, the survival rate of adults is < 5% [1].

Therefore, ILCOR encourages the placement of simple AEDs for use by first responders in public settings. In some settings, AED use has substantially improved the rate of survival from VF in adults [2,3]. The AED is the only defibrillator available for use by first-responding EMS personnel, and it is now consid-

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ered the standard of care by first responders. ILCOR has become a strong advocate for greater use of public access defibrillation, calling for and supporting widespread availability of AEDs. Trained responders have effectively used AEDs in many public settings, including casinos, airport terminals, and airplanes [4–6].

2.2. *The conundrum of pediatric VF and AEDs for use in adults*

All commercially available AEDs use algorithmic rhythm analysis programs derived from in vitro rhythm libraries of adult shockable and nonshockable rhythms. AED developers use an empiric, iterative process to create and adjust filters, measurements, and decision rules. This process enables the AED to “decide” to recommend a shock for the highest possible percentage of shockable rhythms (maximum sensitivity) and to avoid shocking the highest possible percentage of nonshockable rhythms (maximum specificity).

All currently available AEDs are programmed to deliver adult-dose shocks with energies ranging from 150 to 360 Joules (J) when adult pad/cables are used. These adult doses of energy were selected to be safe and effective for adult victims only. At the time of publication of the *ILCOR Guidelines 2000*, no devices were designed for use in children < 8 years of age, and none was approved or cleared by the US Food and Drug Administration (FDA) for use in children. Moreover, there were no data regarding the safety and efficacy of either (1) an AED diagnostic rhythm analysis program to differentiate shockable from nonshockable rhythms in children or (2) an appropriate defibrillation dose or dosing sequence for children < 8 years of age. Therefore, the class of recommendation for use of AEDs in children < 8 years of age was necessarily indeterminate [7].

As a result, children with VF in the prehospital setting have been “orphans” with respect to this effective technology. This issue was highlighted as one of the most pressing problems for pediatric cardiac arrest victims at ILCOR’S 1999 Emergency Cardiovascular Care Evidence Evaluation Conference and the 1998 AHA conference “Ventricular Fibrillation: A Pediatric Problem” [8].

2.3. *Basis for pediatric defibrillation dosage*

In the mid 1970s, various authoritative sources recommended initial shock doses of 200 J for all children and 60–100 J for all infants in VF [9,10]. Use of the same defibrillation dose in both children and adults seemed potentially dangerous despite clinical experience that indicated the effectiveness of such doses. These concerns were supported by only limited animal data, some of which suggested that histopathological myo-

cardial damage may begin to occur with doses as low as > 10 J/kg [11–14]. In addition, further animal data suggested that doses of 0.5–10 J/kg were generally adequate for defibrillation in a variety of species [11].

Gutgesell and colleagues [15] conducted the largest clinical study of an effective defibrillation dose for children. They evaluated the efficacy of defibrillation attempts at energy doses of 2 J/kg retrospectively. The authors reviewed 71 transthoracic defibrillation attempts in 27 children whose ages ranged from 3 days to 15 years and who weighed from 2.1 to 50 kg. The authors reported that 91% of shocks within 10 J of the standard 2 J/kg dose successfully terminated VF.

The task force recommendation of 2 J/kg is derived entirely from this study, although it included only 27 children with short duration VF and the definition of success was electrical defibrillation with no reference to postshock clinical outcomes, such as a sustained stable perfusing rhythm. Although decades of clinical use confirm that 2 J/kg is effective, no research to date has confirmed it as the most effective dose.

2.4. *Incidence of VF in children*

VF is an uncommon cause of out-of-hospital pediatric cardiac arrest in infants (< 1 year of age), but its occurrence increases with growing age. Two studies reported VF as the initial rhythm in 19–24% of out-of-hospital pediatric cardiac arrests if sudden infant death syndrome (SIDS) deaths were excluded [16,17]. In studies that included SIDS victims, however, the frequency dropped to 6–10% [18–20]. The rationale for exclusion of SIDS patients is that SIDS is not amenable to treatment, so patients with SIDS should not be included in studies that may influence potential treatment strategies for cardiac arrest. A recent report, however, documented VF in a 3-month-old infant with SIDS who was subsequently diagnosed with prolonged QT syndrome [21].

Recent data suggest that VF is not a rare rhythm in pediatric arrest. This is encouraging because VF is the arrest arrhythmia associated with improved survival rate in most studies of children [16,17,22,23]. For example, Mogayzel and colleagues [16] reported that 5 of 29 children (17%) who presented with VF in a prehospital setting survived with good neurological outcome versus only 2 of 128 (2%) who presented with asystole/pulseless electrical activity ($P < 0.01$).

In-hospital studies of pediatric CPR also indicate that VF is not a rare rhythm among children in cardiac arrest. Two recent comprehensive studies report the incidence of VF as the initial rhythm and the incidence of VF at some time during the arrest. Suominen et al. [24] reported initial VF in 11% of children in cardiac arrest and VF in 20% of children some time during the arrest. In a much larger study [25], cardiac arrest data

submitted to the National Registry of CardioPulmonary Resuscitation reveal initial VF/VT in 12% of children and VF/VT at some time during 25% of the pediatric arrests.

2.5. Factors that affect effectiveness of transthoracic shocks

The success of defibrillation depends on delivery of sufficient current flow (A) for a sufficient length of time to depolarize a critical mass of myocardium. In the 1970s, animal studies established that inadequate current through the myocardium led to unsuccessful defibrillation, whereas too much current resulted in post-resuscitation myocardial damage [11,14]. These studies further established that the density of current through the myocardium⁴ determined the balance between effectiveness of the shock and myocardial damage.

The basic principles of electrical cardiac defibrillation have been reviewed [26]. For any given waveform, current flow increases with higher shock energy (J) and decreases with higher impedance or resistance (Ω). Several factors increase impedance along the path between defibrillator paddles or electrode pads and decrease current through the myocardium. These factors include a paddle or electrode pad that is too small, large lung volumes, and lack of conducting gel between the skin and defibrillator paddles or electrode pads.

Factors that decrease impedance and thus increase current through the myocardium include the use of electrical conducting gel and increased paddle pressure (reduces impedance by improving skin/electrode contact and squeezing air from the lungs). Impedance may also be reduced by repeated shocks (partly due to increased flow of blood after each shock), although the degree of this reduction is unclear [27]. Increased paddle or electrode pad size does reduce impedance, and therefore, increases total current flow. But this does not necessarily increase the amount of current delivered to the myocardium (current density), because if the paddles or electrode pads are larger than the cross section of the heart, much of the current bypasses its target—the myocardium—through extramyocardial pathways.

Studies of transthoracic impedance in animals, children, and adults suggest nonlinear relationships among size, weight, and thoracic impedance [28–31]. Additional acceptable evidence is needed to resolve these contemporary inconsistencies. The theme of the evidence suggests that children have higher thoracic

impedance than would be expected on the basis of weight alone. This suggests that the present dose of 2 J/kg may need an upward adjustment in smaller patients, or, equally valid, the chance of myocardial damage from any particular dose is less than previously feared.

Another important factor influencing shock effectiveness is the shock waveform. In recent years, biphasic waveforms have been introduced into external defibrillators and have been shown in clinical studies to have advantages over conventional monophasic waveforms. With biphasic waveforms, a smaller shock will defibrillate effectively yet larger energies are well tolerated, so that a single energy delivery may be applicable across a wider age or size range [32–34].

2.6. Why adult AEDs may not be appropriate for use in children

Young children are much smaller than adults, and therefore, require a much lower energy setting for delivery of the same defibrillation dose (J/kg) used in an adult. AEDs designed for use in adults have energy levels (or a single energy level) capable of delivering a substantially higher dose (J/kg) to young children. Another concern is that infants and small children with sinus tachycardia or supraventricular tachycardia can have a very high heart rate that might be misinterpreted as “shockable” rhythms by an AED with a diagnostic program developed for analyzing adult arrhythmias.

2.7. Current recommendations in pediatric guidelines for use of AEDs

The 2000 *International Guidelines* recommend use of AEDs for rhythm identification in children ≥ 8 years of age (Class IIb). Attempted defibrillation of VF/pulseless VT detected by an AED may be considered in these older children (Class Indeterminate). Attempted defibrillation of children less than approximately 8 years of age is not recommended, however [6].

The average 8-year-old child weighs 25 kg. The current recommended initial dose of 150–200 J would provide 6–8 J/kg for the average 8-year-old. If the initial shock fails to eliminate VF, some AEDs are programmed to provide escalating doses to a maximum dosage of up to 360 J. Thus, second and subsequent doses deliver 150–360 J, resulting in a shock of 1–4 J/kg in an adult who weighs 80–125 kg and 6–15 J/kg in an 8-year-old child who weighs 25 kg.

2.8. Criteria for changing the recommendations for use of AEDs in children

First, it is necessary to determine whether the rhythm analysis system of a particular AED is safe and effective

⁴ Current density (A/cm²) in the myocardium is the total amount of current flow that passes through an area defined by a plane perpendicular to the path of the current and the myocardium that intersects with that plane.

for children. This means that the rhythm analysis system must be evaluated to determine its capability to safely differentiate between shockable and nonshockable rhythms in children. Every effort must be made to confirm that the AED is safe when attached to and used in a child who does not have a shockable rhythm and who could be harmed by an inappropriate shock. Second, it is necessary to demonstrate that each AED delivers shocks that effectively defibrillate a child's heart and at the same time avoids any myocardial damage.

3. Clinical data

One case report describes the successful use of a biphasic AED for adults in a 3-year-old child (level of evidence [LOE] = 5) [35]. The child was successfully defibrillated with a single shock of 150 J (9 J/kg). Postresuscitation serum creatine kinase (216 IU/l) and troponin I (0.4 ng/ml) concentrations were normal. A postresuscitation echocardiogram showed no change in ventricular function compared with previous examinations.

3.1. Rhythm analysis

A recently published report [36] suggests that the rhythm analysis program of one AED system generally satisfies the sensitivity criterion of the AHA AED performance goals (i.e. the device shocks a shockable rhythm) for VF, one of the two shockable rhythms. The same system also satisfies the AHA specificity criterion (i.e. the device will not shock a nonshockable rhythm) for the nonshockable rhythms: sinus rhythm, supraventricular arrhythmias, ventricular ectopic beats, idioventricular rhythms, and asystole (this study contains LOE = 3 and 4) [36,37]. The sensitivity for VF was 96%, which satisfies the AHA recommendation of > 90%. The sensitivity for identification of rapid VT was 71%, which is below the AHA criterion of > 75% sensitivity to shock rapid VT. The study reported 100% specificity for shockable rhythms (i.e. the device never recommended a shock for a nonshockable rhythm). Most of the ECG rhythms (and all of the nonshockable rhythms) in that study were prospectively acquired (in-hospital) using a modified AED. About 12%, however, were retrospectively collected (from in-hospital and out-of-hospital sources) and digitized from paper strips, then subjected to analysis by the AED's rhythm recognition algorithm. Those ECG test signals, therefore, lacked the fidelity of the ECGs acquired directly by an AED. Nevertheless, these initial findings are encouraging.

Another study prospectively examined the accuracy of a rhythm analysis programme with an AED by another manufacturer. In this study the AED pads were used to

directly record all of the ECG signals that were subsequently analyzed by an AED (LOE = 3) [38], which more realistically simulated the signal that would be analyzed by an AED in clinical use. Sensitivity for shockable VF was 94%. Sensitivity for shockable rapid VT was 60%, once again falling below the AHA criterion for rapid VT. Overall specificity was > 99% (i.e. the device correctly recommended no shock for 99% of the nonshockable rhythms analyzed) among a wide variety of sinus rhythms, sinus tachycardias, and supraventricular arrhythmias. In addition, this study investigated the effects of pad position on ECG rhythm analysis and found no significant differences in specificity between pads placed in the sternal–apical position and those placed in the anterior–posterior position.

On the basis of these two published studies, it seems that AED algorithms developed for detection of adult arrhythmias can provide highly specific and reasonably sensitive rhythm analysis in infants and children, especially given the relative rarity of rapid VT in this patient population [39]. *Because AED manufacturers use different arrhythmia detection algorithms, however, each manufacturer's algorithm should be tested against a pediatric arrhythmia database to demonstrate its efficacy in this population.*

3.2. Delivered energy

One recent development addresses concern about the level of energy delivered to a child by an AED designed for use in adults. Several AED manufacturers have designed new pediatric pad/cable systems for use with AEDs designed for use in adults to reduce the energy delivered to patients under 8 years of age [40]. These modifications essentially raise impedance of the pad/cable system and also divert some of the delivered current away from the patient so that the adult energy dose delivered by the AED is reduced to about 50–75 J. The rationale was that with biphasic waveforms, the lower energy dose would be adequate for defibrillation yet reduce the possibility of myocardial damage to pediatric hearts. No changes were made in the AED rhythm analysis programme, which continues to use algorithms for defibrillation in adults.

The FDA has ruled that AEDs, with these pediatric pad/cable systems, are composed of components that are “substantially equivalent” to components previously cleared by the FDA. Thus, several AED manufacturers have been cleared by the FDA to advertise, distribute, and sell to physicians (or physicians' agents) this new system, which accommodates both adult pad/cable pads for use in patients ≥ 8 years of age and pediatric pad/cable systems that reduce the delivered energies for use in patients < 8 years of age.

The FDA clearance was based on the agency's conclusion that the new device is “substantially equivalent”

lent” to currently marketed devices. Because directly relevant clinical data are not yet available, the agency likely drew this conclusion by extrapolations from animal data and information similar to that included in this statement. FDA-cleared devices are subject to post-market clinical surveillance for the purpose of accumulating further clinical data on device safety or efficacy. The ILCOR PALS Task Force is not responsible for determining whether a device should or should not be marketed, nor are its classes of recommendation meant to be a quantitative measure of clinical efficacy. Rather, these recommendations reflect the quality of published data in support of a therapy.

4. ILCOR recommendations

ILCOR recently examined (October 2002) the literature regarding the use of AEDs in children. Its consensus was

- AEDs may be used for children 1–8 years of age with no signs of circulation. Ideally the device should deliver a pediatric dose. The arrhythmia detection algorithm used in the device should demonstrate high specificity for pediatric shockable rhythms, i.e. the device will not recommend a shock for nonshockable rhythms (Class IIb).
- Currently the evidence is insufficient to support a recommendation for or against the use of AEDs in children < 1 year of age.
- For a lone rescuer responding to a child without signs of circulation, provision of 1 min of CPR is still recommended before any other action such as activating EMS or attaching the AED.
- Defibrillation is recommended for documented VF/pulseless VT (Class I).

4.1. Limitations

One important limitation that arose during task force deliberations on this topic was the lack of data on *clinical use* of newly developed pediatric pad/cable systems that reduce the energy delivered by AEDs designed for use in the adult. This was especially problematic when discussing the risks and benefits of use of AEDs in very young infants. Relevant points of discussion included the following:

- 1) The experimental data in the Atkinson study [38] examining sensitivity and specificity included infants, but the sample size diminished with decreasing age, and thus there is less confidence in the data from that study analyzing sensitivity/specificity in the youngest patients.

- 2) Very small infants might receive doses demonstrated to cause myocardial damage in animal studies.
- 3) The incidence of shockable rhythms as a clinical cause of unresponsiveness in young infants is lower than in older children.

The last two points suggest that the number needed to harm and the number needed to treat would move in unfavorable directions with decreasing age, and thus there is consensus in the task force that the recommendations for very young infants be more conservative. The task force recognized that there were insufficient clinical data to determine the best appropriate lower age (the age at which the number needed to harm exceeds number needed to treat). Therefore, a pragmatic decision was made to limit the recommendation to children 1–8 years of age because many resuscitation councils use 1 year as the transition from infant to child CPR. Linking the recommendation to 1 year of age will facilitate training and retention.

Until clinical data from pediatric AED use becomes available, the task force recommends that institutions that care for children at risk for arrhythmias and cardiac arrest (e.g. in-hospital settings) routinely should continue to use defibrillators capable of energy adjustment for weight-based doses.

Because there is insufficient evidence to determine the best placement of AED pads (i.e. anterior/posterior vs. sternal/apical), the task force has not recommended a preferred position for pad placement.

5. Conclusion

The AED is becoming widely available and may be the first device available for defibrillation in the prehospital setting. Current evidence suggests that AEDs are capable of appropriate sensitivity and specificity for pediatric arrhythmias and are both safe and effective for defibrillation of children 1–8 years of age. Ideally pediatric pad/cables should be used, whenever available, to deliver a child dose. Each specific AED model must be tested against a library of pediatric arrhythmias to document its efficacy in detection of shockable and nonshockable rhythms. The task force strongly encourages industry to continue to develop pediatric rhythm diagnostic programs and investigate appropriate pediatric AED energy doses. The task force applauds efforts in this area and will conduct a comprehensive review of new data as they become available.

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