Resuscitation (2008) **76**, 168—174

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CLINICAL PAPER

Sensitivity and specificity of an automated external defibrillator algorithm designed for pediatric patients☆

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Received 24 April 2007; received in revised form 13 June 2007; accepted 25 June 2007

KEYWORDS
Automated external defibrillator (AED);
Arrhythmias;
Cardiac arrest;
Cardiac resuscitation;
Electric counter-shock/instrumentation

Summary
Objective: Electrocardiographic (ECG) rhythm analysis algorithms for cardiac rhythm analysis in automated external defibrillators (AEDs) have been tested against pediatric patient rhythms (patients ≤8 years old) using adult ECG algorithm criteria. However these adult algorithms may fail to detect non-shockable pediatric tachycardias because they do not account for the difference in the rates of normal sinus rhythm and typical tachyarrhythmias in childhood.
Methods: This study was designed to define shockable and non-shockable rhythm detection criteria specific to pediatric patients to create a pediatric rhythm database of annotated rhythms, to develop a pediatric-based AED rhythm analysis algorithm, and to test the algorithm's accuracy. Pediatric rhythm detection criteria were defined for coarse ventricular fibrillation, rapid ventricular tachycardia, and non-shockable rhythms, including pediatric supraventricular tachycardia. Pediatric rhythms were collected as sustained, classifiable, rhythms ≥9 s in length, and were annotated by pediatric electrophysiologists as clinically shockable or non-shockable based on pediatric criteria. Rhythms were placed into a pediatric rhythm database; each rhythm was converted to digitally accessible, public-domain, MIT rhythm data format. The database was used to evaluate a pediatric-based AED rhythm analysis algorithm.

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at 10.1016/j.resuscitation.2007.06.032.

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doi:10.1016/j.resuscitation.2007.06.032

Results: Electrocardiographic rhythms from 198 children were recorded. There were 120 shockable rhythms from 49 patients (sensitivity; coarse ventricular fibrillation: 42 rhythms, 100%; rapid ventricular tachycardia: 78 rhythms, 94%), for combined sensitivity of 96.0% (115/120). There were 585 non-shockable rhythms from 155 patients (specificity normal sinus: 208 rhythms, 100%; asystole: 29 rhythms, 100%; supraventricular tachycardia: 161 rhythms, 99%; other arrhythmias: 187 rhythms, 100%), for combined specificity of 99.7% (583/585). Overall accuracy for shockable and non-shockable rhythms was 99.0% (702/709).
Conclusions: New pediatric rhythm detection criteria were defined and analysis based on these criteria demonstrated both high sensitivity (coarse ventricular fibrillation, rapid ventricular tachycardia) and high specificity (non-shockable rhythms, including supraventricular tachycardia). A pediatric-based AED can detect shockable rhythms correctly, making it safe and exceptionally effective for children.

Introduction

Automated external defibrillators (AEDs) are available in increasing numbers and are recommended for use by first responders, emergency medical personnel, hospital personnel and the trained lay public.[1,2] They are replacing manual defibrillators in some emergency medical settings such as hospitals and urgent care clinics.[3] The need to modify the equipment to permit safe use during pediatric cardiac arrest has been supported by an increased awareness of ventricular arrhythmias in children during both out-of-hospital and in-hospital arrest.[4–7] Safe use in children has required attenuation of the energy dose and validation that the rhythm algorithm has high sensitivity and specificity for pediatric rhythms.[8]

Electrocardiographic (ECG) rhythm analysis algorithms from two AEDs have been evaluated using pediatric patient rhythms (patients $\leq$8 years old).[9,10] The tested algorithms were originally designed using adult ECG detection criteria. The specificity and sensitivity for these two manufacturers was high for both non-shockable rhythms and ventricular fibrillation. However both were below the American Heart Association's recommendation for specificity for ventricular tachycardia.[11] Algorithms using adult thresholds for detection of shockable pediatric tachycardia have resulted in decreased accuracy. Adult algorithms may fail to identify non-shockable pediatric tachycardias correctly because they do not account for the difference in the wide spectrum of normal heart rates, QRS morphologies and tachyarrhythmias seen in children. Additionally, the rhythms were collected using the proprietary software of the individual manufacturers, limiting usefulness for testing other manufacturers' algorithms. A pediatric rhythm database that can be used to test future algorithms has not been developed.

The objectives of this study were to define shockable and non-shockable rhythm detection criteria specific for pediatric patients, to develop a pediatric-based AED rhythm algorithm for use in ZOLL AEDs, and determine the accuracy of this algorithm. This pediatric rhythm database of annotated rhythms could be used to test future device algorithms.

Methods

Definition of pediatric rhythms

Pediatric rhythm detection criteria were defined for coarse ventricular fibrillation, rapid ventricular tachycardia, and non-shockable rhythms, including pediatric supraventricular tachycardia. Definitions of rhythms were established by consensus five pediatric electrophysiologists (DA, WS, AB, IL, MD) and are presented in Table 1.

Rhythm collection and annotation

Pediatric rhythms were collected retrospectively from the electrophysiologic catheterization libraries at the participating institutions. Rhythms were obtained and recorded during intracardiac evaluation and testing of children <8 years with clinical arrhythmias. Rhythms were recorded with standard ECG electrodes. Acquisition software included the EP MEDSystem™, Prucka Cardiolab 400™ and Draeger™. Lead II was the preferred lead but if Lead II was not available, V5 was chosen. Electronically acquired and stored rhythms $\geq$9 s in length were converted to digitally accessible, public-domain, MIT rhythm data format with sampling rate of 250 samples/s and 12 bit resolution where the scaling was 4.9 μV/bit.

The rhythms were printed and distributed to three pediatric electrophysiologists (DA, WS, AB) who were blinded to institutional source and original interpretation of the rhythm. The cardiologists assumed that the patient was $\leq$8 years of age and was unresponsive. The rhythms were annotated by the cardiologists as clinically shockable, non-shockable, or intermediate based on the previously agreed pediatric criteria. Specific rhythm diagnoses were assigned to the strips based on interpretations from the three pediatric electrophysiologists. Disagreements were resolved by consensus.

Performance statistics for both the pediatric and adult algorithms were generated by running the ZOLL Advisory Algorithm against the rhythm strips, then comparing the results against the cardiologist assigned rhythm diagnosis. The sensitivity and specificity of the rhythms was calcu-

Table 1 Pediatric rhythm definitions

Shockable rhythm definitions	
Ventricular fibrillation	Uncoordinated ventricular depolarizations. Minimum of five complexes with an average >0.2 mVpp during a 3 s window
Rapid ventricular tachycardia	Absence of *P* waves. Rate >200 beats per minute (bpm) (R—R interval ≤300 ms). QRS complex width >160 ms. Includes monomorphic or polymorphic ventricular tachycardia, and ventricular flutter. Minimal (or no) isoelectric activity
Non-shockable rhythm definitions	
Normal sinus rhythm	Complexes are sinus in origin. Does not satisfy the criteria of supraventricular arrhythmias
Supraventricular tachycardia (ABN)	Complexes show supraventricular origin. Rate >180 bpm. QRS duration <120 ms. R—R interval variability <20%
Supraventricular and ventricular rhythms (ABN)	Supraventricular arrhythmias that do not qualify as NSR or supraventricular tachycardia with or without AV block and bundle-branch block. Includes atrial fibrillation, atrial flutter, junctional and sinus rhythm, arrhythmias with premature atrial junctional, or ventricular complexes. Complex width <160 ms
Idioventricular rhythms (ABN)	Ventricular complexes only, no supraventricular complexes. Monomorphic or polymorphic. Rate <100 bpm. At least one complex >0.3 mVpp
Asystole	Absence of consistent electrical activity of at least 0.1 mVpp amplitude
Intermediate rhythm definitions	
Fine ventricular fibrillation	Uncoordinated ventricular depolarizations with a minimum of five complexes with an average >0.1 mVpp and <0.2 mVpp
Intermediate ventricular rhythms	QRS duration >160 ms. Absence of *P* waves, or AV dissociation if *P* waves present, ventricular complexes only. Rate <200 bpm and >100 bpm (the idioventricular rate). Includes monomorphic and polymorphic ventricular tachycardia

Abbreviations: mVpp, millivolts peak to peak; ABN, abnormal rhythms.

lated and compared to the recommendations developed by the American Heart Association for arrhythmia algorithm analysis.[11]

Results

Electrocardiographic rhythms from 198 children were recorded. Thirty-one subjects were ≤1 year of age. Non-shockable rhythms were recorded from 155 patients and shockable rhythms were recorded from 49 patients: some patients had both non-shockable and shockable rhythms. A total of 749 separate, 9 s rhythm strips were analyzed and classified. There were 585 non-shockable rhythms of which 208 were normal sinus rhythm (heart rate range 53—184 beats per minute, mean 110 bpm), 348 were abnormal rhythms and 29 were asystole. Abnormal rhythms included all supraventricular arrhythmias, premature ventricular complexes and idioventricular rhythms. Within the abnormal rhythms, there were 161 tracings of supraventricular tachycardia with heart rate range of 151—302 bpm. There were 44 tracings classified as intermediate rhythms, and are not classified as either shockable or non-shockable. These were ventricular tachycardias that did not satisfy the shockable criteria. One hundred and twenty rhythms were shockable ventricular tachycardia or fibrillation.

The sensitivity and specificity for each category of shockable or non-shockable rhythms are shown in Tables 2 and 3. There were 120 shockable rhythms from 49 patients for combined sensitivity of 96.7% (115/120); there were 585 non-shockable rhythms from 155 patients for combined specificity of 99.5% (583/585); overall accuracy for shockable and non-shockable rhythms was 99.0% (702/709). The 90% one-sided lower confidence limits of the pediatric algo-

Table 2 Sensitivity of pediatric and adult algorithms for shockable rhythms

Rhythm classification	*n*	Sensitivity		One-sided confidence intervals	AHA performance goal
Ventricular fibrillation	42	Pediatric	100%	93.1%	>90%
		Adult	97.6%	89.2%	
Rapid ventricular tachycardia	78	Pediatric	94.9%	88.7%	>75%
		Adult	98.7%	94.1%	

Table 3 Specificity of pediatric and adult algorithm for non-shockable rhythms

Rhythm classification	n	Specificity		One-sided confidence intervals	AHA performance goal
Normal sinus rhythm	208	Pediatric	100%	98.6%	>99%
		Adult	99.0%	97%	
Supraventricular rhythms	348	Pediatric	99.6%	99.14%	>95%
		Adult	87.1%	83.7%	
Asystole	29	Pediatric	100%	90.19%	100%
		Adult	100%	90.2%	
Fine ventricular fibrillation	0	NA		NA	Report only
Other ventricular tachycardia	44	Pediatric	84.1%	72.19%	Report only
		Adult	54.6%	41.1%	

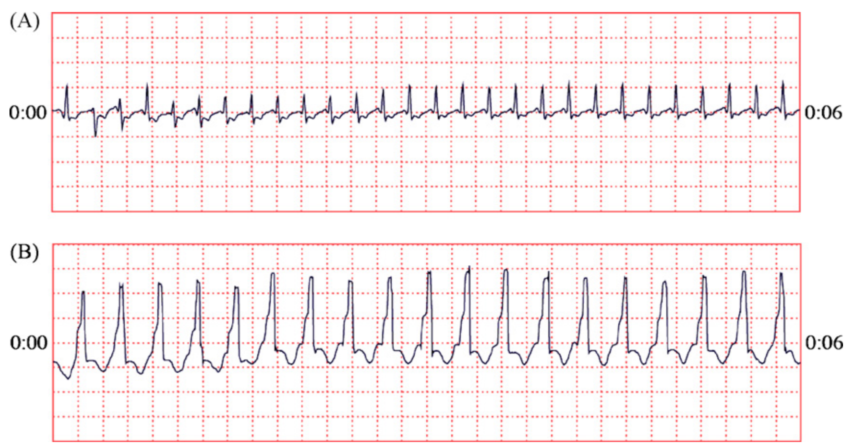

Figure 1 Non-shockable pediatric rhythms with significantly different rate characteristics compared to adult rhythms. Panel A shows supraventricular tachycardia with a heart rate of 300 bpm. Panel B shows ventricular tachycardia with a heart rate of 190 bpm.

rithm exceeded the goals recommended by the AHA in every category: the sample sizes, sensitivity, and specificity. The adult algorithm had high specificity and sensitivity but did not perform as well as the pediatric algorithm and was below the AHA standards for coarse ventricular fibrillation and asystole.

Figures 1 and 2 show representative tracings of rhythm disorders with characteristics different from comparable adult rhythms. Supraventricular tachycardia rates are frequently >250 bpm, however, they are non-shockable rhythms.

There were 14 tracings in which the physician diagnosis differed from the AED advisory. Four tracings were classi-

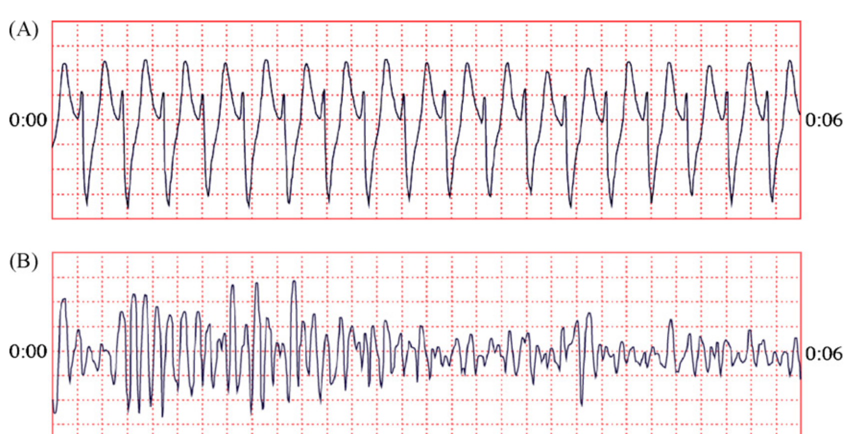

Figure 2 Typical shockable pediatric rhythms; shockable rates continue to remain higher than comparable adult rhythms. Panel A shows ventricular tachycardia and Panel B ventricular fibrillation.

fied by the electrophysiologists as ventricular tachycardia and shockable, but the QRS duration was just below the algorithm's criteria for a shockable rhythm. Three tracings were annotated as abnormal and non-shockable but were wide complex tachycardias with rates just inside the shockable criteria. The final seven tracings were classified as non-shockable ventricular tachycardia by the electrophysiologists due to the 200 beat per minute rate limitation. The AED algorithm determined the heart rate to lie on the 200 bpm rate boundary and therefore advised these seven tracings as shockable.

Discussion

Ventricular tachycardia and fibrillation are uncommon rhythms as a cause of pediatric cardiac arrest. However, their presence has been increasingly recognized in both in-hospital and out-of-hospital cardiac arrest.[4–6] The use of AEDs in children has increased since their original development. Equipment modifications have been developed to promote safe and accurate use.[9,10,12–14] AED use is now recommended for use in children <8 years.[8,15] Providers are strongly encouraged to use the pediatric modifications and to confirm that the algorithm accurately identifies pediatric rhythms.[8] To date, the algorithms from two other manufacturers have been demonstrated to have accurate sensitivity and specificity for pediatric rhythms.[9,10] Our study now provides the data for a specific pediatric algorithm which performs better than the adult algorithm.

Need for pediatric validation

The need for pediatric validation is based on the recognized higher heart rates, differing frequencies of rhythm abnormalities and differences of the QRS complexes with age. Children have higher heart rates compared to adults and this difference is greatest in the youngest children. Supraventricular tachycardia occurs commonly in children and the heart rates often exceed 250 bpm. Normal values for QRS duration are <0.09 ms in children <12 years of age.[16] Thus an algorithm based solely on rate could misidentify supraventricular tachycardia as a shockable rhythm and under identify ventricular tachycardia in which the QRS width is less than the adult values. Differences in both rate and conduction of ventricular fibrillation between children and adults have been identified.[9]

Our data demonstrate that an adult algorithm may not perform as well as one specifically designed to identify pediatric rhythms. Although the adult algorithm had both high sensitivity and specificity, the values were slightly below the AHA recommended values. In particular, the lower sensitivity of abnormal non-shockable rhythms might promote an inappropriate shock in a child with a supraventricular rhythm. This pediatric algorithm is present in all the ZOLL AEDs shipped by ZOLL since the April 2004. The earlier models can be upgraded to contain the pediatric algorithm. The pediatric algorithm is automatically used if the pediatric pads are attached. If the adult pads are used for a child, the device will operate in the adult mode with non-attenuated dosing. Even though the risk of an inappropriate shock is low, it is preferable to use the pediatric pads in a child <8 years, as recommended by the AHA.

Need for pediatric defibrillation

Although pediatric defibrillation is an uncommon event during pediatric cardiac arrest, accounting for 10–20% in both in hospital and out-of-hospital cardiac arrests,[4,6] survival and neurological outcome appears to be better if ventricular fibrillation is quickly recognized and treated. AEDs can identify and treat a shockable rhythm quickly. This may be particularly important in pediatric arrest for both experienced and inexperienced providers who frequently are unaware that ventricular fibrillation does indeed occur in young patients. If an AED is applied to all patients routinely in cardiac arrest, then identification of ventricular fibrillation is not dependent on a provider making a clinical judgment about the likelihood of ventricular fibrillation.

Recognition and detection of ventricular fibrillation may be associated with the frequency with which bystander CPR is performed,[4–6,17,18] in that locations which report high rates of bystander CPR also report higher frequencies of ventricular fibrillation and successful resuscitation. Even though most children suffer a cardiac arrest in the home and with family members in attendance, the frequency of CPR is no higher in children than in adults in public settings. As pediatric equipment is placed in locations where children are located, it is incumbent upon the healthcare providers to teach both CPR and use of the AED.

Differences between physician interpretation and shock advisory

The differences in interpretation between the physician diagnosis and the algorithm advisory were all at the decision boundaries of the algorithm. Skilled physician annotators can see that the waveform is ventricular tachycardia from subtle characteristics in the signal, e.g., lack of *P* waves and morphology shape. The algorithm typically cannot measure these characteristics and must make decisions based on the more obvious and/or quantitatively measurable characteristics. Also, the machine must make a shock decision in real-time. There were a number of records where the annotators had to discuss what would be the correct annotation based on repeated looks at the waveform. After much discussion and multiple views of the record, a consensus was achieved. The AED must make the same decision in 6–9 s. The current state of real-time signal processing cannot embed this level of knowledge into the system. During algorithm development, the thresholds are set based on clinical data to achieve a careful balance between the sensitivity and specificity of the system. Thus, it is expected that there will be an error rate. The error rate within the pediatric algorithm is well within accepted rates.

Limitations

Accuracy of the rhythm identification algorithm has been performed from in-hospital settings with patients in the intensive care units or the cardiac catheterization laboratory.[9,10] Most arrest rhythms were obtained from patients with short duration ventricular fibrillation or from digitized tracings. We also used tracings recorded with standard ECG electrodes rather than defibrillation pads. Thus artifacts that may exist in out-of-hospital cardiac arrest related to the recording characteristics of the pads were not present. Although ECG electrode placement is standardized, which may not be the situation with emergency application of defibrillation pads, pad position does not appear to affect the algorithm accuracy.[10] Additionally, recordings from ECG electrodes has been used previously to validate pediatric arrest rhythms.[9]

Tracings with fine ventricular fibrillation were not present in the rhythm strips that were analyzed. Fine ventricular fibrillation typically results from prolonged ventricular fibrillation, which will not occur in the catheterization laboratory. This has been a shortcoming of the pediatric studies where the tracings are obtained from hospitalized patients.[9,10] No specificity/sensitivity standards were established by the AHA recommendations for evaluating algorithm accuracy.[11]

Field assessment of rhythm identification during out-of-hospital cardiac arrest has been verified only in a small case series.[12,13,19] Although a prospective trial would be ideal, the difficulties of obtaining these data are significant. A prospective trial to assess cardiac arrest rhythms in children <8 years during cardiac catheterization or electrophysiological study is not feasible as the estimate to acquire sufficient tracings is >10 years.[20]

Summary

New pediatric rhythm detection criteria were defined, and analysis based on these criteria demonstrated both high sensitivity (coarse ventricular fibrillation, rapid ventricular tachycardia) and high specificity (non-shockable rhythms, including supraventricular tachycardia). A pediatric-based AED can detect shockable rhythms correctly, making it safe and exceptionally effective for children.

Acknowledgements

This work was supported by ZOLL Medical Corporation, which provided salary support (DLA) and assistance and reimbursement for acquisition of the EKG tracings to the other investigators.

Dr. Dianne Atkins—current research support: ZOLL Medical Corporation (support for the work reported in this manuscript); previous (within last 5 years): Phillips Medical Systems Inc., research support, consulting fees, Medtronic Inc., consulting fees. Dr. William Scott—research support: ZOLL Medical Corporation (support for the work reported in this manuscript). Dr. Andrew Blaufox—research support: ZOLL Medical Corporation (support for the work reported in this manuscript). Dr. Ian Law—current research support: ZOLL Medical Corporation: educational grants: Boston Scientific Inc., Medtronic Inc.: previous proctoring support and speaker fees: Medtronic Inc. Dr. Macdonald Dick—research support: ZOLL Medical Corporation (Support for the work reported in this manuscript). Dr. Frederick Geheb—employee ZOLL Medical Corporation. Jamil Sobh—employee ZOLL Medical Corporation. James E. Brewer—employee ZOLL Medical Corporation.

References

1. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. NEJM 2002;347: 1242—7.
2. White RD, Vukov LF, Bugliosi TF. Early defibrillation by police: initial experience with the measurement of critical time intervals and patient outcome. Ann Emerg Med 1994;23:1009—13.
3. Hanefeld C, Lichte C, Mentges-Schroter I, Sirtl C, Mugge A. Hospital-wide first-responder automated external defibrillator programme: 1 year experience. Resuscitation 2005;66(2):167—70.
4. Mogayzel C, Quan L, Graves JR, Tiedeman D, Fahrenbruch C, Herndon P. Out-of-hospital ventricular fibrillation in children and adolescents: causes and outcome. Ann Emerg Med 1995;25:484—91.
5. Hickey RW, Cohen DM, Strausbaugh S, Dietrich AM. Pediatric patients requiring CPR in the prehospital setting. Ann Emerg Med 1995;25:495—501.
6. Nadkarni VM, Larkin GL, Peberdy MA, et al. National registry of cardiopulmonary resuscitation. I First documented rhythm and clinical outcome from in-hospital cardiac arrest among children and adults. JAMA 2006;295(1):50—7.
7. Tibballs J, Kinney S. A prospective study of outcome of in-patient paediatric cardiopulmonary arrest. Resuscitation 2006;71(3):310—8.
8. Samson RA, Berg RA, Bingham R, et al. 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. Circulation 2003;107:3250—5.
9. Cecchin FC, Perry JC, Berul CI, et al. Is AED arrhythmia detection accurate for children? sensitivity and specificity of an AED algorithm in 696 pediatric arrhythmias. Circulation 2001;103:2483—8.
10. Atkinson E, Mikysa B, Conway JA, et al. Specificity and sensitivity of automated external defibrillators rhythm analysis in infants and young children. Ann Emerg Med 2003;42:185—96.
11. Kerber RE, Becker LB, Bourland JD, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. Circulation 1997;95:1677—82.
12. Atkins DL, Jorgenson DB. Attenuated pediatric electrode pads for automated external defibrillator use in children. Resuscitation 2005;66:31—7.
13. Gurnett CA, Atkins DL. Successful use of a biphasic waveform automated external defibrillator in a high-risk child. Am J Cardiol 2000;86:1051—3.
14. Jorgenson D, Morgan C, Snyder D, et al. Energy attenuator for pediatric application of an automated external defibrillator. Crit Care Med 2002;30(4 Suppl.):S145—7.
15. ECC Committee, Task Forces of the American Heart Association. 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation 2005; 112 (24 Suppl):13.
16. Garson Jr A. The electrocardiogram in infants and children. A systematic approach. Philadelphia: Lea and Febiger; 1983.
17. Sirbaugh PE, Pepe PE, Shook JE, et al. A prospective, population-based study of the demographics, epidemiology, management, and outcome of out-of-hospital pediatric cardiopulmonary arrest. Ann Emerg Med 1999;33:174—84.

18. Donoghue AJ, Nadkarni V, Berg RA, et al. Out-of-hospital pediatric cardiac arrest: an epidemiologic review and assessment of current knowledge. Ann Emerg Med 2005;46(6):512—22.
19. Atkins DL, Hartley LL, York DK. Accurate recognition and effective treatment of ventricular fibrillation by automated external defibrillators in adolescents. Pediatrics 1998;101: 393—7.
20. Knilans TK, Atkins DL, Berg RA, Nadkarni V, Bean J. Feasibility of a study to assess efficacy of defibrillation in children. Circulation 2002;106:II-403.