Is Arrhythmia Detection by Automatic External Defibrillator Accurate for Children?
Sensitivity and Specificity of an Automatic External Defibrillator Algorithm in 696 Pediatric Arrhythmias

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Background—Use of automatic external defibrillators (AEDs) in children aged <8 years is not recommended. The purpose of this study was to develop an ECG database of shockable and nonshockable rhythms from a broad age range of pediatric patients and to test the accuracy of the Agilent Heartstream FR2 Patient Analysis System for sensitivity and specificity.

Methods and Results—Children aged ≤12 years who either developed arrhythmias or were at risk for developing arrhythmias were studied. Two sources were used for the database: children whose rhythms were recorded prospectively via a modified AED and children who had arrhythmias captured on paper and digitized for subsequent analysis. The rhythms were divided into 5-second strips, classified by 3 reviewers, and then assessed by the AED analysis algorithm. A total of 696 five-second rhythm strips from 191 children (81 female and 110 male) aged 1 day to 12 years (median 3.0 years) were analyzed. There was 100% specificity for nonshockable rhythms. Sensitivity for ventricular fibrillation was 96%.

Conclusions—There was excellent AED rhythm analysis sensitivity and specificity in all age groups for ventricular fibrillation and nonshockable rhythms. The high specificity and sensitivity indicate that there is a very low risk of an inappropriate shock and that the AED correctly identifies shockable rhythms, making the algorithm both safe and effective for children. (Circulation. 2001;103:2483-2488.)

Key Words: defibrillation ■ pediatrics ■ arrhythmia

Automatic external defibrillators (AEDs) have been available to the adult population for >20 years.1 Recent technology has allowed AEDs to be widely disseminated, improving treatment and decreasing the time to defibrillation. Currently AED use is not recommended for children aged <8 years.2 Restriction of the use of AEDs means that pediatric patients do not receive a level of care equivalent to that of adults. After a cardiac arrest, a child must wait for the arrival of advanced life support and treatment with a manual defibrillator. This increases the crucial time to shock delivery, which has been shown to be the major determinant of resuscitation.3–5 Although ventricular fibrillation (VF) has been reported to occur in only 19% of pediatric cardiac arrests, the percent survival and neurological outcome is better in survivors of VF arrest compared with victims of asystolic arrest.3

The algorithms in use with current AEDs were derived by using rhythm databases recorded from adults. Children differ from adults as to the types and characteristics of shockable and nonshockable rhythms. The lower incidence of VF indicates that they are more likely to have nonshockable rhythms than are adults. The characteristics of these nonshockable rhythms will be different because children have faster sinus and supraventricular tachycardia rates than do adults. Theoretical concerns about the capacity of the AED to detect VF in pediatric patients exist because of the smaller cardiac mass in children. Although AEDs have not been fully tested in children, the available data suggest excellent specificity.6,7

The purpose of the present study was to create a database of recordings of shockable and nonshockable rhythms from children. This database was used to test an AED patient analysis system for accuracy in determining a shock decision for pediatric rhythms.

Methods

Study Design
Two sources of ECG recordings were used to create the database for children aged ≤12 years. First, we performed a prospective clinical
TABLE 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Median Age, y (Range)</th>
<th>Median Weight, kg</th>
<th>Sex (Male/Female), n/n</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1 y (74 patients)</td>
<td>0.3 (2.1–10.1)</td>
<td>5.2</td>
<td>47/27</td>
</tr>
<tr>
<td>&gt;1 to ≤8 y (62 patients)</td>
<td>3.5 (6.0–38.0)</td>
<td>16.0</td>
<td>30/32</td>
</tr>
<tr>
<td>≥8 to ≤12 y (55 patients)</td>
<td>10.0 (22.0–70.7)</td>
<td>35.0</td>
<td>33/22</td>
</tr>
<tr>
<td>Total (191 patients)</td>
<td>3.0</td>
<td>13.9</td>
<td>110/81</td>
</tr>
</tbody>
</table>

study in which rhythms were recorded via a modified AED in children at risk of arrhythmias. Second, prerecorded ECG strips of infrequently observed shockable arrhythmias were digitized for subsequent analysis.

Recorded Rhythms
Children at risk for developing arrhythmias were enrolled prospectively at 4 pediatric care centers (Children’s Hospital and Medical Center, Seattle, Wash; Children’s Hospital of Iowa, Iowa City; Children’s Hospital, Boston, Mass; and Children’s Hospital and Health Center, San Diego, Calif). Institutional review board approval was obtained from each institution in addition to informed consent and consent from each study participant and parent. Rhythms were recorded in the following settings: electrophysiology laboratory, intensive care unit, and cardiac surgical operating room.

An AED (ForeRunner, Agilent Heartstream) was modified to function as a 30-minute loop recorder with a wide bandwidth (0.2 to 80 Hz) ECG recording system identical to a fully functioning AED and similar to a standard 12-lead ECG. The defibrillation capability of the device was disabled. Defibrillation pads were used to record the rhythms. Pad size depended on the child’s chest size and clinical setting; either the standard 100-cm² adult size (DP1, Agilent Heartstream) or a smaller 43-cm² pediatric version (M3717A, modified to connect to a ForeRunner, Agilent Heartstream) was used. Pad position was determined by the clinical setting, with the preferred pad position being anterior-anterior. The other pad position was anterior-posterior, and some patients required a more side-to-side configuration. In some instances, monitoring electrodes were used if it was not possible to apply defibrillation pads. Some of the recorded supraventricular and ventricular tachycardia (VT) rhythms were paced rhythms, and the pacing artifact was filtered for the reviewers. Paced rhythms were 5% of the total, and 59% of these were in the unspecified VT group.

Digitized Rhythms
VF and VT paper recordings were acquired retrospectively from 11 centers via solicitation through letters mailed to a registry of pediatric electrophysiologists. Recordings came from both in-hospital and out-of-hospital sources and were converted into a digital format by scanning, image manipulation, and data processing.

Rhythm Strip Classification
AED algorithm performance was evaluated for both sensitivity and specificity. Sensitivity refers to the ability of the device to detect shockable rhythms. Specificity refers to the ability of the device to detect nonshockable rhythms.

The American Heart Association (AHA) 1997 recommendations for classification and performance goals were used. This is intended for the assessment of AEDs developed for adults. No AED standards are available for children. Rhythm groups are organized in 3 broad categories that are based on the likely benefit of defibrillation for that rhythm group: (1) Shockable rhythms are lethal rhythms unless a shock is delivered very quickly. (2) Intermediate rhythms are those for which the benefits of immediate electric countershock are limited or uncertain. No performance goals have been established for this category. (3) The final category is nonshockable rhythms, which are benign (or normal) rhythms that must not be shocked, especially in children who have a pulse, because no benefit will follow and deterioration in rhythm may result. To maximize safety in the event of misapplication of the device/electrodes, asystole is included in this group. The following definitions refer to a 5-second ECG strip.

Shockable Rhythms
For VF, complexes show only ventricular origin and rapidly changing morphology. The amplitude is ≥200 μVpp for ≥5 of the complexes, and there are ≥12 complexes ≥100 μVpp (peak to peak).

Rapid VT involves polymorphic VT and ventricular flutter with rates ≥250 bpm.

Intermediate Rhythms
For intermediate VT, complexes show only ventricular origin but do not satisfy the criteria for rapid VT.

Low rate/amplitude VF includes low-rate or low-amplitude VF or electrical activity of unknown etiology. The rhythm does not satisfy criteria for asystole, VF, or idioventricular classes.

Nonshockable Rhythms
For sinus rhythm, complexes show an atrial origin and do not qualify for supraventricular arrhythmia (SVA) class.

For SVA, complexes show a supraventricular origin with or without atrioventricular block and bundle-branch block. This includes atrial flutter and AF, sinus arrhythmia with or without premature atrial contractions, junctional rhythms, and supraventricular tachycardia.

Ventricular ectopic beats are defined as single or multiple ventricular ectopic beats mixed with or without supraventricular ectopic beats.

For idioventricular rhythms, complexes are only of ventricular origin, with or without uniform morphology. The rate is <100 bpm, with at least 1 complex of ≥100 μVpp.

Asystole is defined as a maximum of 1 complex >100 μVpp and all complexes <200 μVpp.

Classification Process
The recordings were divided into 5-second segments, classified by 3 pediatric electrophysiologists (F.C., J.C.P., D.L.A.) and by the AED analysis algorithm. The reviewers used the following assumptions: (1) The patient is “unresponsive.” (2) The age of the patient is unknown. (3) The patient may or may not have a pulse. (4) The AED

TABLE 2. Recorded and Digitized Data Sensitivity of Shockable Rhythms

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Recorded Rhythms, n</th>
<th>Sensitivity, %</th>
<th>Digitized Rhythms, n</th>
<th>Sensitivity, %</th>
<th>Recorded Rhythms, n</th>
<th>Sensitivity, %</th>
<th>Digitized Rhythms, n</th>
<th>Sensitivity, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1 y (19 patients)</td>
<td>30</td>
<td>93</td>
<td>8</td>
<td>100</td>
<td>2</td>
<td>100</td>
<td>4</td>
<td>50</td>
</tr>
<tr>
<td>&gt;1 to ≤8 y (28 patients)</td>
<td>5</td>
<td>100</td>
<td>10</td>
<td>90</td>
<td>9</td>
<td>33</td>
<td>15</td>
<td>93</td>
</tr>
<tr>
<td>≥8 to ≤12 y (25 patients)</td>
<td>11</td>
<td>100</td>
<td>9</td>
<td>100</td>
<td>21</td>
<td>62</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Total (72 patients)</td>
<td>46</td>
<td>96</td>
<td>27</td>
<td>96</td>
<td>32</td>
<td>56</td>
<td>26</td>
<td>88</td>
</tr>
</tbody>
</table>

n indicates number of rhythms recorded.
cannot deliver a synchronized shock. Each reviewer independently reviewed the segments, identified the rhythm class, and made a shock or no-shock recommendation. The recommendations of the 3 reviewers were compiled, and disagreements were resolved for rhythms that were not unanimously placed into a defined category. The results reported in the present study reflect the final consensus of the reviewers after discussion of the merit of each potential recommendation.

The AED patient analysis system characterizes the ECG in terms of 4 rhythmic characteristics: the rate of ECG complex occurrence, morphological stability of the ECG complexes, evidence of rapidly conducted electrical signals, and signal amplitude. These characteristics are respectively referred to as rate, stability, conduction, and amplitude. Stability and conduction are measured on a scale of 0 to 1. Higher conduction and stability scores indicate more rapid conduction and less variability in the morphology of the ECG complexes. To optimize the robustness of the analytical system, redundant assessments of the ECG measurements are performed with the use of both temporal and transform-based analyses. Amplitude measurement is used only for identifying asystole. Rate, stability, and conduction measures are assessed concurrently to make a shock/no-shock determination. Each measure exerts an influence over the decision, but none is independently capable of triggering a shock recommendation. This synergistic use of the rhythm characteristics ensures that a high rate rhythm will not cause a shock recommendation. This synergistic use of the rhythm characteristics that a lower VF rate will receive a shock recommendation if evidence of supraventricular origin is present and that a lower VF rate will receive a shock recommendation if it demonstrates poor stability and conduction properties.

### Statistical Analysis

Data are expressed as median (range) or mean±SD. With consensus from a panel of 3 electrophysiologists as the gold standard, the sensitivity and specificity of the algorithm for detecting shockable rhythms were calculated. Comparisons were made by the Student’s test and x² test. A value of $P<0.05$ was considered significant.

### Results

#### Patient Characteristics

**Recorded Rhythms**

One hundred thirty-eight children were studied at 4 centers over 11 months; 4 children were excluded because of incorrectly recorded data with irretrievable ECG recordings. The largest group (44%) were those aged <1 year. The reviewers classified a total of 614 rhythm strips. Heart disease was present in 73% of the children, of whom 63% had congenital heart disease and 10% had cardiomyopathy.

**Digitized Rhythms**

Data were digitized from 57 children, and reviewers classified a total of 82 rhythm strips.

**All Rhythms**

The children were divided into 3 groups according to age: ≤1 year, >1 year to <8 years, and ≥8 years to ≤12 years. The characteristics for the children are displayed in Table 1. A total of 696 rhythms were classified by the reviewers and were subjected to algorithm analysis. There were 463 nonshockable, 131 shockable, and 102 intermediate rhythms. Nonshockable rhythms constituted 67% of the total. Table 2 summarizes the shockable rhythms, and Table 3 summarizes the nonshockable rhythms. Sinus rhythm was the most frequent nonshockable rhythm, at 37%. VF (n=73) was the most common shockable rhythm, at 56%. The largest percentage of VF, 52%, was recorded in those aged <1 year. The low-amplitude VF and shockable unspecified VT had the lowest percentages, 5% and <1%, respectively.

### Table 3: Recorded Data Specificity of Nonshockable Rhythms

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sinus Rhythm</th>
<th>SVA</th>
<th>VEB</th>
<th>Idioventricular</th>
<th>Asystole</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1 y (59 patients)</td>
<td>83</td>
<td>100</td>
<td>50</td>
<td>100</td>
<td>17</td>
</tr>
<tr>
<td>&gt;1 to &lt;8 y (40 patients)</td>
<td>52</td>
<td>100</td>
<td>43</td>
<td>100</td>
<td>27</td>
</tr>
<tr>
<td>≥8 to ≤12 y (47 patients)</td>
<td>38</td>
<td>100</td>
<td>23</td>
<td>100</td>
<td>34</td>
</tr>
<tr>
<td>Total (146 patients)</td>
<td>173</td>
<td>100</td>
<td>116</td>
<td>100</td>
<td>95</td>
</tr>
</tbody>
</table>

VEB indicates ventricular ectopic beats.

### Table 4: Pooled Rhythm Sensitivity and Specificity and LCL

<table>
<thead>
<tr>
<th>Rhythm</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
<th>AHA Goal, %</th>
<th>90% 1-Sided LCL, %</th>
<th>AHA LCL Goal, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF (38 patients)</td>
<td>96</td>
<td>...</td>
<td>&gt;90</td>
<td>91</td>
<td>87</td>
</tr>
<tr>
<td>Rapid VT (49 patients)</td>
<td>71</td>
<td>...</td>
<td>&gt;75</td>
<td>62</td>
<td>67</td>
</tr>
<tr>
<td>Sinus rhythm (103 patients)</td>
<td>...</td>
<td>100</td>
<td>&gt;99</td>
<td>99</td>
<td>97</td>
</tr>
<tr>
<td>SVA (69 patients)</td>
<td>...</td>
<td>100</td>
<td>&gt;95</td>
<td>98</td>
<td>88</td>
</tr>
<tr>
<td>VEB (52 patients)</td>
<td>...</td>
<td>100</td>
<td>&gt;95</td>
<td>98</td>
<td>88</td>
</tr>
<tr>
<td>Idioventricular (27 patients)</td>
<td>...</td>
<td>100</td>
<td>&gt;95</td>
<td>94</td>
<td>88</td>
</tr>
<tr>
<td>Asystole (28 patients)</td>
<td>...</td>
<td>100</td>
<td>&gt;95</td>
<td>94</td>
<td>92</td>
</tr>
</tbody>
</table>

LCL indicates lower confidence limits.
Sensitivity and Specificity of Rhythms

The sensitivity and specificity of the AED analysis algorithm for the 3 age groups are shown in Tables 2 and 3. The overall sensitivity, specificity, 90% one-sided lower confidence limits, and AHA performance goals for each rhythm classification are displayed in Table 4. Specificity for nonshockable rhythms was 100%. Sensitivity for the shockable rhythms was highest for VF, at 96%. The overall accuracy was 97%. The AED analysis algorithm exceeded the AHA performance goals for each rhythm classification except for rapid VT. Intermediate rhythms (for which the benefits of defibrillation are limited or uncertain and there are no performance goals) had a sensitivity of 45% and specificity of 97%. There was no significant difference in sensitivity or specificity between the 3 age groups.

The sensitivity results for the rapid VT group were further explored by examining the AED algorithm classification parameters: stability, conduction, and rate. The mean conduction scores for the 41 shock and 17 no-shock designations were $0.55 \pm 0.12$ and $0.91 \pm 0.06$, respectively ($P<0.001$). The stability scores were $0.48 \pm 0.28$ and $0.94 \pm 0.03$, respectively ($P<0.001$). The rates were $288 \pm 74$ and $261 \pm 28$, respectively ($P=0.16$). Figure 1 illustrates 2 rhythms that were classified as rapid VT by the reviewers. Figure 1A shows a high conduction and stability score (0.94 and 0.96, respectively) and was given a no-shock designation by the analysis algorithm. Figure 1B shows a low conduction and stability score (0.52 and 0.18, respectively) and was given a shock designation.

**Adult Versus Pediatric Rhythm Characteristics**

The pediatric ECG database was compared with a previously collected database of adult rhythms. The rhythm characteristics (rate, stability, and conduction), as determined by the algorithm, were compared between the databases. Figure 2 demonstrates the rhythm characteristics for the shockable rhythm groups, VF and rapid VT. The pediatric VF (n=73) had a mean rate of $323 \pm 95$ bpm. This was significantly higher than the adult VF (n=300) rate of $289 \pm 71$ bpm ($P<0.001$). Similarly, VT rates were significantly higher for pediatric subjects (n=58, $281 \pm 65$ bpm) than for adult subjects (n=100, $221 \pm 59$ bpm) ($P<0.001$). Conduction scores were higher ($P<0.001$) for the pediatric database in both shockable rhythm groups. Stability scores were not statistically different between the 2 databases.

The pediatric nonshockable rhythm groups, ie, sinus rhythm, SVA, and ventricular ectopic beats, were also compared with the adult database. These groups had the following overall mean rates for the pediatric (n=384) and adult (n=500) databases: $129 \pm 57$ and $87 \pm 46$ bpm, respectively ($P<0.001$). The average rate for these rhythm groups in the

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pediatric database was fastest in the youngest age group, at 136 bpm, and slowest for the oldest age group, at 107 bpm. Of these 384 nonshockable rhythms, the rate was >180 bpm in 70 (18.2%) rhythms, with a maximum of 300 bpm. In the comparable adult database, there were 500 rhythms. The maximal rate was 250 bpm, and 7% were >180 bpm. Figure 3 shows the distribution of the rates of the nonshockable rhythms in these groups.

Discussion
This is the first published study to record and analyze shockable and nonshockable rhythms from a pediatric population. We have successfully created a large rhythm database from a broad age range of children to test an AED detection algorithm. The largest group was aged <1 year, and from this group, we analyzed 38 recordings of VF. The AED analysis algorithm exceeded the AHA performance goals for each rhythm classification except for rapid VT. Sensitivity for VF was excellent at 96%. Specificity for all nonshockable rhythms was excellent at 100%. Although the performance goal for rapid VT was not achieved, a conservative approach for this rhythm category for pediatric patients is appropriate because of the higher uncertainty of association of wide QRS supraventricular tachycardias with pediatric cardiac arrest. Furthermore, nonperfusing rapid VT is likely to rapidly degenerate into VF, for which there is a higher sensitivity. In regard to the intermediate rhythm group, for which the benefits of defibrillation are limited or uncertain, the AED algorithm was appropriately conservative. The 90% one-sided lower confidence limit goals set by the AHA were also satisfied in every category, with the exception of the rapid VT group. This indicates that the pooled sample sizes and sensitivity and specificity values were within acceptable goals of the AHA.

Prior Studies
There are minimal data evaluating arrhythmia analysis or AED use in pediatric patients. Hazinski et al8 presented data demonstrating high sensitivity and specificity in 21 hospitalized infants and children aged <8 years. Atkins et al7 reported a sensitivity of 88% and specificity of 100% when AEDs were used in older children during out-of-hospital cardiac arrest and resuscitation. Atkins et al further reported that there were 3 of 25 instances in which VF was initially not recognized, but the second analysis was correct, and shocks were delivered. In addition, 43% survival was observed in patients who received an electric countershock as opposed to 11% survival in those who had a nonshockable life-threatening rhythm, such as asystole. This emphasizes the importance of early recognition of VF followed by defibrillation in the young.

In adults, studies using prerecorded and field-tested databases9–16 have reported sensitivity for VF (81% to 100%) similar to that obtained in the present study. Most studies have not separated VT into a separate category, but in the study that did, there was sensitivity of 65% for sustained VT recorded in the electrophysiology laboratory.16 To set standards for specifying and reporting the performance of the arrhythmia analysis algorithm, the AHA published recommendations in 1995.5 The present study is the first to incorporate those recommendations regarding the performance of the arrhythmia analysis algorithm into AED testing for pediatric patients.

Pediatric Database Creation and Algorithm Development
Development of a pediatric database for algorithm testing is essential to ensure adequate safety and efficacy of AEDs in a pediatric population. Our rhythm database collected from children was clearly different from the adult database. Children had higher heart rates for shockable VF and rapid VT. Importantly, the nonshockable rhythm group contained rhythms with faster maximal and overall rates. The maximal rate in the pediatric supraventricular tachycardia group was 300 versus 250 bpm in the adult database. Garson et al17 reported that the overall mean rate of pediatric supraventricular tachycardia was 240 bpm, and for infants aged <4 months, it was 268 bpm.

The pediatric population had higher conduction scores for the VF and rapid VT group than did the adult population. This is consistent with large 12-lead ECG recording studies in
normal children. Heart rate decreases and QRS duration increases during childhood. The lower sensitivity found in the rapid VT group can potentially be explained by these differences between adults and children. The AED algorithm assigned no-shock designations to the most stable and well-conducting episodes of rapid VT, as seen in Figure 1. These rhythms are rare in children and may not be clinically relevant in pediatric victims of cardiac arrest.

The present data illustrate the importance of using multiple parameters in a rhythm-detection algorithm for shock designation in children. The analysis algorithm of the Agilent Heartstream FR2 AED uses the 4 rhythm characteristics (rate, conduction, stability, and amplitude) as covariables in determining whether a particular rhythm is shockable. The large number of nonshockable pediatric rhythms with rates >180 bpm indicates that simplistic algorithms with shock criteria merely based on rate would be unsafe if used in children. The ability of the algorithm to evaluate conduction and stability in addition to rate reduces the potential for inappropriate shock recommendations for rhythms that are simply faster. This emphasizes the importance of testing each AED manufacturer’s algorithm in a distinct pediatric database. That database should contain multiple age groups, especially infants aged <1 year. Shockable and nonshockable rhythms should be represented in each age group. Those nonshockable rhythms should include rhythms with rates >250 bpm, with at least 10% having rates >180 bpm.

Study Limitations

The major limitation of the present study is the lack of wide-bandwidth recordings of spontaneous or out-of-hospital VF. However, obtaining wide-bandwidth recordings of spontaneous shockable ventricular arrhythmias from children is extremely difficult. These events occur so infrequently that thousands of hours of recording are required to capture a single event. Each of the surgical patients, a high-risk group for ventricular arrhythmias, had recording continued for 12 hours after surgery. However, no shockable rhythms were recorded in the postoperative period.

Field testing is essential ultimately for assessing performance of the AED arrhythmia algorithm. Weaver et al demonstrated that an algorithm derived from a prerecorded rhythm database performed poorly in field testing. Despite the fact that the algorithm used in the present study has been field-tested in adults and did very well, a postmarket surveillance study is required to assess its performance in children. The present study examined the performance of the arrhythmia analysis system and did not address the issue of appropriate energy dosage for children.

Conclusions

A pediatric database of shockable and nonshockable rhythms that was significantly different from an adult database was created. This pediatric database was used to test the Agilent Heartstream FR2 AED analysis algorithm. Excellent sensitivity and specificity in all age groups for VF and nonshockable rhythms were demonstrated. The high sensitivity to VF and the high specificity to nonshockable rhythms indicate that the analysis algorithm is both safe and effective for pediatric rhythms. Importantly, the analysis algorithm is unlikely to inappropriately shock a pediatric rhythm. These results indicate that the use of 1 algorithm for both adults and children is feasible.

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