DEFI 2005

A Randomized Controlled Trial of the Effect of Automated External Defibrillator Cardiopulmonary Resuscitation Protocol on Outcome From Out-of-Hospital Cardiac Arrest

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Background—Using automated external defibrillators (AEDs) that implement the Guidelines 2000 resuscitation protocol constrains administration of cardiopulmonary resuscitation (CPR) to <50% of AED connection time. We tested a different AED protocol aimed at increasing the CPR administered to patients with out-of-hospital cardiac arrest.

Methods and Results—In a randomized controlled trial, patients with out-of-hospital cardiac arrest requiring defibrillation were treated with 1 of 2 AED protocols. In the control protocol, based on Guidelines 2000, sequences of up to 3 stacked countershocks were delivered, with rhythm analyses initially and after the first and second shocks. The study protocol featured 1 minute of CPR before the first shock, shorter CPR interruptions before and after each shock, and no stacked shocks. The primary end point was survival to hospital admission. Of 5107 out-of-hospital cardiac arrest patients connected to an AED, 1238 required defibrillation, and 845 were included in the final analysis. Study patients (n=421) had shorter preshock pauses (9 versus 19 seconds; P<0.001), had shorter postshock pauses (11 versus 33 seconds; P<0.001), and received more CPR (61% versus 48%; P<0.001) and fewer shocks (2.5 versus 2.9; P<0.001) than control patients (n=424). Similar proportions survived to hospital admission (43.2% versus 42.7%; P=0.87), survived to hospital discharge (13.3% versus 10.6%; P=0.19), achieved return of spontaneous circulation before physician arrival (47.0% versus 48.6%; P=0.65), and survived to 1 year (P=0.77).

Conclusions—Following prompts from AEDs programmed with a protocol similar to Guidelines 2005, firefighters shortened pauses in CPR and improved overall hands-on time, but survival to hospital admission of patients with ventricular fibrillation out-of-hospital cardiac arrest did not improve.

Clinical Trial Registration—http://www.clinicaltrials.gov. Unique identifier: NCT00139542.

Key Words: cardiopulmonary resuscitation ■ defibrillation, electric ■ heart arrest ■ resuscitation ■ survival

Out-of-hospital cardiac arrest (OHCA) remains a major public health issue in France, where >30,000 events occur each year.1 Comparable to other countries, France has an OHCA patient survival rate under 4%.2 Some locations have proven it possible to achieve much higher survival rates; therefore, improving patient outcome should remain a priority of emergency medical systems around the world.3,4

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Automated external defibrillators (AEDs) have enabled earlier defibrillation by less-trained responders, thereby improving outcomes for victims experiencing ventricular fibrillation (VF) in out-of-hospital settings.5 However, AEDs implementing the protocol described in the Guidelines 2000 for emergency cardiac care prompt for pauses in cardiopulmonary resuscitation (CPR) for rhythm analysis, shock delivery, and pulse checks. Observational cohort studies have shown that these pauses, compounded by human delay, limit the delivery of chest compressions to <50% of the time during the resuscitation attempt.6–10 Because chest compressions are the only means of providing forward blood flow during cardiac arrest, it is likely that these hands-off intervals are deleterious to outcome and that protocols designed to reduce hands-off time would be beneficial.
The trial enrolled all victims of OHCA with VF treated with an AED by BSPP BLS rescuers. Exclusions from data analysis were determined after randomization according to a specified record review process by 2 investigators blinded to the treatment group. Patients were excluded from analysis if they were aged <18 years or had arrested after trauma, if consent could not be obtained, if the ECG recorded by the AED showed no VF, or if multiple victims were treated at once by a single BLS team.

**Methods**

**Study Design and Setting**

To test the effect of AED protocol on patient outcome, we conducted a single-blinded, prospective, randomized controlled trial of patients treated by 1 of 2 different defibrillation/CPR protocols (http://www.clinicaltrials.gov; unique identifier NCT00139542).

The study was conducted in Paris and its suburbs, 124 communities with an area of 762 km². The emergency medical system is a 2-tiered response system: a basic life support (BLS) tier served by 200 teams of 3 to 5 professional rescuers deployed in 77 stations and an advanced cardiac life support (ACLS) tier served by 44 ambulance teams comprising an emergency physician, a nurse, and a driver. The AEDs are operated and BLS care is provided by firefighters of the Brigade de Sapeurs-Pompiers de Paris (BSPP), which has used AEDs since 1993. The ACLS ambulances are dispatched by either the Service d’Aide Médicale Urgente or BSPP on the basis of geographic territory.

The study protocol was approved by an ethics committee (Comité de protection des personnes, Ile de France SUD, Paris Cochin), a regulatory agency (Agence française de sécurité sanitaire des produits de santé), and a patient data protection commission (Commission Nationale de l’Informatique et des Libertés). The current French regulatory mandate required deferred informed consent by the family and by the surviving victims to allow the use of the collected data for analysis.

**Study Population**

The trial enrolled all victims of OHCA with VF treated with an AED by BSPP BLS rescuers. Exclusions from data analysis were determined after randomization according to a specified record review process by 2 investigators blinded to the treatment group. Patients were excluded from analysis if they were aged <18 years or had arrested after trauma, if consent could not be obtained, if the ECG recorded by the AED showed no VF, or if multiple victims were treated at once by a single BLS team.

**Intervention**

Each fire station was initially randomly assigned to 1 of 2 AED protocols, which subsequently alternated every 2 months. By study design, all patients were randomized to 1 of 2 BLS treatment arms without the option for an alternate treatment. All AEDs used in the trial were Biphasic LIFEPAK 500 AEDs with cpMAX technology and preconnected QUIK-COMBO electrodes (Physio-Control Inc, Redmond Wash), programmed to deliver shocks with escalating energy of 200, 200, and 300 J.

The protocols followed in the control and study groups differed in several ways (Figure 1). The control algorithm followed the 2000 Guidelines; countershocks were delivered in sequences of up to 3 consecutive stacked shocks, with rhythm analysis initially and after the first and second shocks. The prompted CPR period between each stack of shocks was 60 seconds, and every analysis of a nonshockable rhythm was followed by a pulse check. The study algorithm was designed before the November 2005 publication of the 2005 Guidelines. The study algorithm added CPR intervals and eliminated pulse checks and stacked shocks. At AED power on, patients in this group received 60 seconds of CPR unless the BSPP rescuers pushed a key on the AED, confirming that they had witnessed the arrest, thereby skipping the CPR interval. All subsequent shocks were immediately preceded by 30-second CPR intervals and followed by 60-second CPR intervals, resulting in 90-second CPR intervals between shocks.

Trial-specific training for all BLS-trained firefighters was initiated 3 months before the start of the study as part of the daily military training (1 h/d) and continued for the entire trial period. This training was aimed at raising awareness of the importance of CPR and at eliminating unnecessary pauses. For the ACLS teams, broad pretrial training was conducted with a reminder of good clinical practice and adherence to guideline recommendations for OHCA.

**Resuscitation Protocol**

On BLS arrival on the scene, 1 rescuer performed chest compressions with a Cardio-pump (Ambu, Denmark), another attached the AED, and a third maintained communication with dispatch. Randomization was determined by the configured protocol of the AED in use. Ventilation was provided with a bag valve mask. On ACLS arrival on the scene, the physician decided whether to terminate the resuscitation on the basis of down time or a Do Not Resuscitate order. Otherwise the patient was intubated, intravenous infusion was...
initiated, and treatment followed the current International Recom-

mendations for ACLS.15,16 At the end of the intervention, a BLS
crue and the physician consulted with the family to obtain
consent.

Eight months into the trial, on April 1, 2006, the protocol was
amended, changing the compression-to-ventilation (CV) ratio from
15:2 to 30:2 for all adults with OHCA in both groups in accordance
with the new Guidelines published in November 200516 (see Figure
I of the online-only Data Supplement). At the same time, each AED
was outfitted with a metronome (DM70, SEIKO, Japan) set to
100/min to guide the chest compression rate. The AED and metro-
nome were manually powered on at the same time. This was the only
protocol change introduced at this time; the programming of AED
algorithms was not altered in either group.

Data Collection

Trial data were collected in accordance with the Utstein style. On
return to the station, the firefighters transmitted the AED-recorded
electronic data (ECG, impedance, events, shocks, analyses) to a
BSPP server, and time stamps of the recorded data were corrected on
the basis of the current time on clocks of the AED and the central
dispatch center. The 12-month patient follow-up was performed by a
team of clinical research assistants.

Outcome

The primary end point was admission to the hospital with evidence
of a pulse; admission was defined as administrative registration into
a reanimation department. The secondary end point evaluating the
immediate effect of BLS treatment was return of spontaneous
circulation (ROSC) before physician arrival. ROSC was assessed by
carotid pulse check by firefighters instructed to consider any doubt as
absence of a pulse and immediately resume CPR. The occurrence of
ROSC at any time before physician arrival was considered a
successful ROSC. Other secondary end points were hospital dis-
charge and survival to 1 year. Safety end points were occurrences of
CPR-related hemothorax requiring thoracic drain and/or hemor-
rhagic lesions requiring transfusion. Adherence to protocol was
quantified by the ratio of CPR duration to AED connection time, along
with the durations of preshock and postshock CPR pauses.

Data Analysis

The first 9 minutes of AED files were reviewed; this interval
represents the mean duration of BLS treatment before ACLS
treatment. This review was performed after the event with the use of
CODE-STAT 7.0 Data Review Software with Advanced CPR
Analytics (Physio-Control, Inc) to identify the cardiac rhythm and
quantify all CPR intervals.17 Preshock or postshock pauses were
defined as the time interval between the shock and the last preceding
or first following chest compression.

The outcome analysis, done on an intention-to-treat basis, in-
cluded all patients who received at least 1 appropriate shock at any
time during AED connection and was not limited to patients
presenting in a shockable rhythm or meeting any CPR measure
criterion. The sample size of this trial (430 in each group) was
calculated, for detecting an 11% increase in the rate of hospital
admission from its historical rate of 34% to a new rate of 45%, to
provide a power of 85% and a type 1 error rate of 0.0294 (1
interim analysis).

To take into account observed correlation between fire stations,
we used a generalized estimating equation approach for statistical
analysis of correlated data. The variance explained by the fire station
effect was 2% of the overall variance (95% confidence interval [CI],
0.3% to 10.8%; P=0.08). This correlation effect was not deemed to
have introduced a randomization bias and was not retained in the
statistical analysis.

The effect of treatment group on each end point was evaluated by
a model adjusted strictly on CV ratio, followed by a multivariate
model taking into account the predictive factors for each end point.
The differences between groups were assessed with the Mann-
Whitney test for continuous data and χ² test for categorical data. A
logistic regression was performed for binary end points (hospital
admission, hospital discharge, ROSC) and a Cox model for 1-year
survival end point. The survival probability was estimated with the
use of the Kaplan-Meier estimator. The CV ratio was forced as a
treatment parameter in all analyses. All statistical calculations were
performed with the use of STATA/SE 8.2 (StataCorp LP, College
Station, Tex).

Results

During the study period of September 2005 through March
2008, a total of 5107 patients were connected to an AED;
5102 were in cardiac arrest, and 1238 were shocked by an AED (Figure 2). A total of 845 patients were included in the final analysis; 72% were initially in a shockable rhythm, 24% developed a shockable rhythm during BLS care, and 4% did not have an electronic AED record. There were 424 patients in the control and 421 patients in the study group. The developed a shockable rhythm during BLS care, and 4% did not have an electronic AED record. There were 424 patients in the control and 421 patients in the study group. The final analysis; 72% were initially in a shockable rhythm, 24% developed a shockable rhythm during BLS care, and 4% did not have an electronic AED record. There were 424 patients in the control and 421 patients in the study group. The proportion of patients receiving a mean chest compression rate between 95 and 105 compressions per minute significantly increased from 17% to 60% in the control group (P<0.001) and from 19% to 54% in the study group (P<0.001).

The epinephrine and antiarrhythmic agent treatments provided by the second-tier ACLS responders were not significantly different between the 2 groups. No safety concerns were observed during the trial.

Outcomes

The rate of hospital admission was not significantly different between the control and study groups (42.7% versus 43.2%) as calculated by the odds ratio, adjusted for CV ratio (0.98; 95% CI, 0.78 to 1.34; P=0.87) (Table 3). The multivariate odds ratio (0.97; 95% CI, 0.7 to 1.3; P=0.84) was adjusted for gender, age, presence of a bystander who initiated CPR, CV ratio, and location of the OHCA (Figure 3). The change in CV ratio from 15.2 to 30.2 had no impact on the hospital admission rate (P=0.77). ACLS interventions (epinephrine and antiarrhythmic administration) also did not affect this end point. No interactions were detected between any of the variables used in the multivariate analysis.

The second end point of ROSC before ACLS arrival also was not different between control and study groups (48.6% versus 47.0%) as calculated by the odds ratio adjusted for CV ratio (1.06; 95% CI, 0.72 to 1.23; P=0.65) (Table 3). The multivariate odds ratio (1.04; 95% CI, 0.75 to 1.28; P=0.74) was adjusted for presence of a bystander, location, CV ratio, and pathogenesis of cardiac arrest. The rate of survival to hospital discharge was not different between control and study groups for all included patients (10.6% versus 13.3%; P=0.19) or for the subset of patients with a shockable initial rhythm (14.6% versus 17.8%; P=0.10).

Of the 845 patients enrolled in the study, 85 patients were lost to follow-up at 1 year after OHCA (41 control and 44 study), 747 were confirmed dead, and 13 were confirmed alive. Compared with patients not lost to follow-up, those lost to follow-up had significant differences in characteristics.
associated with better survival; they were younger, more frequently arrested in public places rather than at home, more frequently received bystander CPR, more frequently arrested in the presence of firefighters, and experienced a shorter response time.

The calculated Kaplan-Meier 1-year probability of survival from OHCA VF was 7.6% in the control versus 10.6% in the study group (P=0.45) (Figure 4). The multivariate analysis with Cox model retained the following parameters as factors associated with decreased survival: age >75 years, OHCA occurring at home, response time >12 minutes, and >3 AED shocks. After adjustment, treatment group did not have a significant impact on the hazard ratio (1.03; 95% CI, 0.89 to 1.19; P=0.77) (Figure 5).

### Discussion

This randomized trial compared outcomes in patients with OHCA treated according to 2 AED algorithms, 1 implementing the Guidelines 2000 AED protocol \(^{15}\) (control) and the other implementing a protocol (study) very similar to Guidelines 2005. \(^{16}\) The study protocol significantly shortened both preshock and postshock pauses in CPR, reduced the number

### Table 3. Outcomes

<table>
<thead>
<tr>
<th></th>
<th>No. of Patients (%)</th>
<th>Odds Ratio (95% CI) and P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n=424)</td>
<td>Study (n=421)</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>181/424 (42.7)</td>
<td>182/421 (43.2)</td>
</tr>
<tr>
<td>ROSC before ACLS</td>
<td>206/424 (48.6)</td>
<td>198/421 (47.0)</td>
</tr>
<tr>
<td>Survival to hospital discharge</td>
<td>45/424 (10.6)</td>
<td>56/421 (13.3)</td>
</tr>
</tbody>
</table>

Figure 3. Factors associated with the rate of hospital admission in multivariable analysis (830 patients with complete data; 9 patients did not have age data, and 6 did not have response time data).
of countershocks administered, and significantly improved the CPR hands-on ratio. Nevertheless, there was no measurable improvement in the rates of hospital admission, hospital discharge, or ROSC before ACLS arrival or in the probability of survival to 1 year.

The limited evidence available before the writing of the 2005 Guidelines indicated that the sequencing of chest compressions and activities requiring interruptions of chest compressions can directly affect outcomes. This included studies in experimental models and 2 clinical studies that found a survival improvement when CPR was administered before the first shock. More recently, several clinical studies have evaluated outcomes before and after implementing new protocols like that described in the 2005 Guidelines. Three of these found improved outcome with the new protocol, and 2 were neutral. Altogether, the results of these studies are inconclusive. Furthermore, they all share the limitations associated with before-and-after study design.

Our study is the first randomized trial to test AED protocol changes consistent with the changes that the 2005 Guidelines recommend to reduce pauses in chest compressions. It demonstrates that, at least in the context of an emergency medical services system with typical nonoptimal response times, such protocol modifications do not directly translate into improvement in survival. This suggests that resuscitation outcomes are less sensitive to the CPR ratio than may have been expected at the writing of Guidelines 2005. Perhaps, like many other individual changes proposed over the years to improve resuscitation, increases in hands-on time alone...
cannot be expected to produce an improvement in outcome large enough to be measurable with a “reasonably sized” randomized controlled prehospital study. Although more extensive improvement in the hands-on ratio might provide improved outcome,\(^2\), achieving this during AED use will not be easy.

The hands-on ratio attained in our study group was substantially better than the ratio in our control group and is representative of the likely performance by AED users who have received extensive training.\(^2\),\(^8\),\(^24\) Although a better hands-on ratio can be achieved by ACLS-trained rescuers using manual defibrillators,\(^1\) several factors prevent easy improvement in ratio during AED use. The duration of pauses to switch rescuers during CPR or to perform pulse checks is directly related to rescuer behavior\(^4\) and can perhaps be shortened by additional targeted training. Other pauses are inherent in the present design of AEDs (eg, those for AED analysis of the cardiac rhythm and for safe delivery of defibrillation shocks).\(^8\),\(^25\) Future research aimed at developing the AED capability to analyze during CPR,\(^26\) finding ways to safely defibrillate during ongoing chest compressions, and optimizing the use of mechanical chest compression devices could reduce those pauses.

Training effects could reasonably explain the difference between the neutral results of our trial and the positive results of recent before-and-after studies.\(^1\),\(^11\),\(^12\),\(^14\) Our trial design ensured that firefighters in both concurrent treatment groups received intensive training; study-specific training was integrated into the daily military training 3 months before the trial began and continued until the end of the trial. We postulate that daily reinforcement of the importance of CPR improved CPR in both control and study groups. This hypothesis is supported by the results of a cohort study that obtained a significant improvement in CPR ratio from 42% to 51% (P=0.02) simply by retraining BLS rescuers using manual defibrillators,\(^1\) several factors prevent easy improvement in ratio during AED use. The duration of pauses to switch rescuers during CPR or to perform pulse checks is directly related to rescuer behavior\(^4\) and can perhaps be shortened by additional targeted training. Other pauses are inherent in the present design of AEDs (eg, those for AED analysis of the cardiac rhythm and for safe delivery of defibrillation shocks).\(^8\),\(^25\) Future research aimed at developing the AED capability to analyze during CPR,\(^26\) finding ways to safety defibrillate during ongoing chest compressions, and optimizing the use of mechanical chest compression devices could reduce those pauses.

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Despite the lack of agreement between results of the before-and-after studies of the multiple changes implemented in the 2005 Guidelines, expectations have remained high for improved outcome. However, our randomized controlled trial now provides more definitive evidence that this combination of Guidelines 2005 CPR protocol changes does not measurably improve outcome. Although the protocol changes accomplished the desired effect of increasing chest compressions, they may also cause other effects, such as earlier defibrillation and more time spent in VF, with as yet unknown consequences.\(^27\),\(^28\)
more sensitive to pauses in chest compressions than it was in our study.36 Our results also might not generalize to systems with shorter response times. Many of the patients in our trial probably received care during the metabolic phase of cardiac arrest.37 Consistent with this notion is the observation that, in both groups in our trial, we obtained relatively low rates of hospital discharge and long-term survival despite relatively high occurrences of ROSC and hospital admission. It may be that increasing the overall CPR would be more beneficial for patients with shorter response times, who receive care during the circulatory phase of cardiac arrest.

Conclusions

In this randomized controlled trial, BLS-trained firefighters following prompts from AEDs programmed with a new protocol akin to Guidelines 2005 were able to shorten pauses in chest compressions and improve their overall hands-on time during resuscitation of patients with VF OHCA. However, this improvement in CPR metrics did not translate into measurable differences in ROSC before ACLS arrival, survival to hospital admission or discharge, or 1-year survival.

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Disclosures

Dr Barville, Dr Chapman, and P. Lank are current employees of Physio-Control. The remaining authors report no conflicts.

References

The American Heart Association Guidelines 2005 for Emergency Cardiac Care made changes to the way that chest compressions, ventilations, and defibrillation countershocks are sequenced in an effort to resuscitate more patients in cardiac arrest. These changes, which were based on theoretical considerations, experimental studies, and few clinical studies, aimed to increase cardiopulmonary resuscitation (CPR) in hopes of improving patient outcomes. Although several published articles have reported on the effect of increasing CPR in cohort studies, none has the evidence level of a randomized controlled trial. The results of this 18-month, 845-patient, randomized controlled trial on out-of-hospital ventricular fibrillation cardiac arrest are of particular interest and potential impact on the next cycle of the evidence review process of the International Liaison Committee on Resuscitation, leading to the American Heart Association 2010 Guidelines. This randomized controlled trial demonstrated that, by following new automated external defibrillator prompts, basic life support–trained firefighters could shorten pauses in chest compressions and improve their overall CPR hands-on ratio from 48% to 61% during resuscitation of patients with ventricular fibrillation out-of-hospital cardiac arrest. However, this improvement in CPR metrics did not translate into measurable differences in rates of return of spontaneous circulation before advanced cardiac life support arrival, survival to hospital admission or discharge, or 1-year survival. The lack of benefit from increased CPR in this trial, combined with experience from this and other emergency medical systems, suggests that the survival rate may be further improved by efforts focused on other changes to community resuscitation such as increasing bystander CPR, shortening response times, or even providing more extensive and regular CPR training to rescuers.
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Figure 1-supp. Clinical trial timeline with important dates and patient enrollment.