Improved Out-of-Hospital Cardiac Arrest Survival Through the Inexpensive Optimization of an Existing Defibrillation Program

OPALS Study Phase II

Ian G. Stiell, MD, MSc, FRCPC
George A. Wells, PhD
Brian J. Field, EMA III
Daniel W. Spaite, MD
Valerie J. De Maio, MSc
Roxanne Ward, RN
Douglas P. Munkley, MD, MCFP(EM)
Marion B. Lyver, MD, FRCPC, MCFP(EM)
Lorraine G. Luinstra, BScN, MHA
Tony Campeau, BSc
Justin Maloney, MD, FRCPC
Eugene Dagnone, MD, FRCPC
for the OPALS Study Group

Context Survival rates for out-of-hospital cardiac arrest are low; published survival rates in Ontario are only 2.5%. This study represents phase II of the Ontario Prehospital Advanced Life Support (OPALS) study, which is designed to systematically evaluate the effectiveness and efficiency of various prehospital interventions for patients with cardiac arrest, trauma, and critical illnesses.

Objective To assess the impact on out-of-hospital cardiac arrest survival of the implementation of a rapid defibrillation program in a large multicenter emergency medical services (EMS) system with existing basic life support and defibrillation (BLS-D) level of care.

Design Controlled clinical trial comparing survival for 36 months before (phase I) and 12 months after (phase II) system optimization.

Setting Nineteen urban and suburban Ontario communities (populations ranging from 16 000 to 750 000 [total, 2.7 million]).

Patients All patients who had out-of-hospital cardiac arrest in the study communities for whom resuscitation was attempted by emergency responders.

Interventions Study communities optimized their EMS systems to achieve the target response interval from when a call was received until a vehicle stopped with a defibrillator of 8 minutes or less for 90% of cardiac arrest cases. Working both locally and provincially, communities implemented multiple measures, including defibrillation by firefighters, base paging, tiered response agreements with fire departments, continuous quality improvement for response intervals, and province-wide revision and implementation of standard dispatch policies. All response times were obtained from a central dispatch system.

Main Outcome Measure Survival to hospital discharge.

Results The 4690 cardiac arrest patients studied in phase I and the 1641 in phase II were similar for all clinical and demographic characteristics, including age, sex, witnessed status, rhythm, and receipt of bystander cardiopulmonary resuscitation. The proportion of cases meeting the 8-minute response criterion improved (76.7% vs 92.5%; \( P < .001 \)) as did most median response intervals. Overall survival to hospital discharge for all rhythm groups combined improved from 3.9% to 5.2% \( (P = .03) \). The 33% relative increase in survival represents an additional 21 lives saved each year in the study communities (approximately 1 life per 120 000 residents). The charges were estimated to be US $46 900 per life saved for establishing the rapid defibrillation program and US $2400 per life saved annually for maintaining the program.

Conclusion An inexpensive, multifaceted system optimization approach to rapid defibrillation can lead to significant improvements in survival after cardiac arrest in a large BLS-D EMS system.
tion (CPR) by bystanders and first responders, (3) early defibrillation with automated external defibrillators, and (4) early ACLS (intubation and intravenous medications) provided by paramedics, physicians, or nurses at the scene. The relative importance or effectiveness of each of the 4 links in the chain of survival has not been clearly demonstrated. In particular, the effectiveness of emergency medical services (EMS) systems in which rapid defibrillation is provided by basic life support (BLS-D) rather than by advanced life support (ALS) providers remains unknown.

Survival rates for out-of-hospital cardiac arrest for the 11 million residents of the province of Ontario are very low, a published 2.5% overall survival rate. In Ontario, EMS response in most cities is provided by an ambulance-based BLS-D EMS system incorporating automated external defibrillators. Unfortunately, these systems provide what Cummins et al call “late defibrillation,” with mean response intervals of 7.8 minutes to arrival at the scene and 13.1 minutes to defibrillation.

The Ontario Ministry of Health, the agency responsible for emergency health services, has been reluctant to fund ACLS services without better evidence of effectiveness. In this era of health care fiscal restraint, with hospital closings and health care provider layoffs, the government has been unwilling to fund new expensive programs without better data.

Consequently, the Ontario Ministry of Health has funded the Ontario Prehospital Advanced Life Support (OPALS) study, which will be the largest prehospital study yet conducted. This study will involve more than 25 000 patients with cardiac arrest, trauma, or critical illnesses over an 8-year period (1994-2002) in 20 Ontario communities. Phase I of the OPALS study was designed to serve as a baseline for phases II and III as well as to evaluate which modular factors would be associated with improved cardiac arrest survival in a multicenter BLS-D EMS system. Phase III of the OPALS study will assess the impact of full ACLS measures, including endotracheal intubation and intravenous drug therapy.

The current report represents OPALS study phase II, which assessed the incremental benefit in cardiac arrest survival of implementing an inexpensive system optimization approach to rapid defibrillation (defined as arriving at the scene with a defibrillator within 8 minutes of receiving the call in 90% of cases) in an existing multicenter ambulance-based BLS-D EMS system.

**METHODS**

**Design**

Detailed methods for the cardiac arrest and trauma portions of the OPALS study have been previously described. The OPALS study incorporates a multiphase before-after controlled clinical trial design with the unit of study being all eligible patients with cardiac arrest seen during each of the 3 distinct phases. The study was designed at a series of 3 consensus conferences involving prehospital providers, EMS medical directors, ministry of health representatives, and research consultants. Phase I (36 months) represents the baseline status after the introduction of the ambulance automatic defibrillation programs. Phase II (12 months) assesses survival after the introduction of “rapid defibrillation” as defined below. Phase III (36 months) will assess survival after the introduction of “full ALS programs.”

Data will be pooled across the 20 study communities, but the start date for the phases will vary for each community as each will require different periods of time to prepare for phases II and III. Data collection phases within each community are separated by intervening and overlapping training and run-in periods.

**Setting**

Phase II was conducted in 19 Ontario urban or suburban communities, ranging in population from 16 000 to 750 000 (total, 2.7 million). All communities had EMS medical control provided by 1 of 11 provincial base hospital programs, had 911 telephone service, and had provided an ambulance-based automated external defibrillator program for at least 3 years. All ambulance officers in the EMS system were certified and had graduated from a 1-year community college program (or equivalent) supplemented by an 8-hour course on the use of an automated external defibrillator. All ambulance dispatch information was obtained from a central computerized Ambulance Response Information System, and all patient encounters were documented with a common ambulance call report used throughout the province.

At the outset of the study, none of the communities had defibrillation performed by firefighters, and none had ACLS providers. In most communities, firefighters responded to some calls to provide oxygen and CPR. One additional eligible community (population, 25 000) was not included in the analysis because it did not implement the study intervention, ie, did not meet the rapid response criteria.

**Population**

The study population included all patients with out-of-hospital cardiac arrest in the study communities and for whom resuscitation was attempted by emergency responders (TABLE 1). Excluded were patients who were younger than 16 years, who had trauma, or whose arrests were clearly of noncardiac etiology, including drug overdose, carbon monoxide poisoning, drowning, exsanguination, electrocution, asphyxia, hypoxia due to respiratory disease, cerebrovascular accident, and documented terminal illness. Case definitions followed the Utstein style guidelines for reporting cardiac arrest data.

The OPALS study had full research ethics committee approval; informed consent was deemed unnecessary because patients were not randomly allocated to receive different therapies.

**Intervention**

The study intervention, a rapid defibrillation program, was implemented
during a 6- to 24-month run-in period between phases I and II. Each study community optimized the local EMS system to achieve the target rapid defibrillation interval from call received by ambulance dispatch to arrival at scene by responder with defibrillator in 8 minutes or less for at least 90% of cases. This optimization process included (1) reduction of dispatch time intervals, (2) more efficient deployment of existing ambulances, and (3) firefighters performing defibrillation. Study communities were assisted by a provincial OPALS Study Implementation Advisory Committee, which suggested optimization strategies, redrafted province dispatch guidelines, developed standards, and provided consultation services for communities having difficulty achieving the target response interval. Locally, community optimization committees developed rapid defibrillation strategies. The most commonly used maneuvers included ambulance base paging, mobile deployment of ambulances, implementation of new provincial dispatch guidelines, tiered response agreements with fire departments, continuous quality improvement for response intervals, and introduction of defibrillation performed by firefighters. The local base hospital medical directors oversaw an 8- to 12-hour firefighter training program that made use of existing training networks. Ambulance and fire dispatch centers and the defibrillator clocks were all regularly synchronized.

Outcome
The primary outcome measure for the study was survival to hospital discharge, which was defined as the patient’s leaving the hospital alive and was verified by review of hospital records or an interview of the patient’s family physician. Other survival measures were collected according to the Utstein style, ie, return of spontaneous circulation and admission to a hospital. Only phase II patients were followed up at 1 year to determine survival, neurological function according to a 5-point scale of Cerebral Performance Category,13 and quality of life by means of the Health Utility Index.14 Study data were provided by each base hospital program and included ambulance call reports, initial rhythm records, dispatch reports from the central ambulance communications center for each base hospital region, and survival records. In addition, the base hospitals provided first-responder defibrillation documentation and fire department dispatch times for "arrival at scene."

Data Analysis
The minimum sample size for comparing the primary outcome was estimated to be 3600 for phase I and 1200 for phase II, based on these assumptions: (1) 2-sided a level of .05, (2) β error of .20, (3) baseline survival rate of 4.0%, (4) 3:1 ratio of phase I to phase II patients to minimize duration of phase II, and (5) adequate power to demonstrate a relative difference in survival of 50% from phase I to phase II (absolute survival from 4.0% to 6.0%). The primary hypothesis of improved survival rates from phase I to phase II was tested by χ² analysis techniques. All P values are 2-tailed; 95% confidence intervals (CIs) were calculated for the absolute and relative difference in survival rates. We attempted to capture all the indicators of changes in the system that could have affected survival (potential confounders): community, ambulance service, age, sex, witnessed status, initial rhythm, CPR initiated by bystander, CPR initiated by fire or police, and the response time intervals “call receipt—arrived scene,” “arrived scene—arrived patient’s side,” “patient’s side–depart scene,” and “depart scene–arrived hospital.” Stepwise logistic regression analysis was performed to control for the possible confounding effects of these indicators and to assess the effect of the study intervention on survival. The variable “call receipt—arrived scene in 8 minutes or less” was displayed descriptively in a graph per month over time. Interrupted time-series analysis procedures were used to evaluate the effect of the intervention on response interval. Run-in period data were included in the time-series analyses only. Differences between phases for other outcomes, patient characteristics, and treatment and system characteristics were tested with the Wilcoxon rank sum, χ², Fisher exact, or t test analyses, as appropriate. All changes are presented in US dollars.

RESULTS
A total of 4690 consecutive patients were enrolled between January 1, 1991, and December 31, 1995, during the 36-

<table>
<thead>
<tr>
<th>Table 1. Characteristics of the 6331 Study Patients*</th>
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<tbody>
<tr>
<td>Phase I (n = 4690)</td>
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<tr>
<td>Mean (SD) age, y</td>
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<tr>
<td>Male sex</td>
</tr>
<tr>
<td>Community by population size</td>
</tr>
<tr>
<td>&lt;30,000 (n = 4)</td>
</tr>
<tr>
<td>20,000-100,000 (n = 6)</td>
</tr>
<tr>
<td>100,000-200,000 (n = 4)</td>
</tr>
<tr>
<td>200,000-500,000 (n = 4)</td>
</tr>
<tr>
<td>&gt;500,000 (n = 1)</td>
</tr>
<tr>
<td>Bystander-witnessed arrest</td>
</tr>
<tr>
<td>EMS-witnessed arrest</td>
</tr>
<tr>
<td>Initial rhythm (n = 4492/1610)†</td>
</tr>
<tr>
<td>Ventricular fibrillation or tachycardia</td>
</tr>
<tr>
<td>Pulseless electrical activity</td>
</tr>
<tr>
<td>Asystole</td>
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*All data are presented as number (percentage) unless otherwise noted. EMS indicates emergency medical services.
†Numbers of patients in each phase for whom initial rhythm was recorded.
All aspects of survival were improved in phase II (TABLE 3). In particular, survival to hospital discharge, for all rhythm groups combined, showed a relative improvement of 33% (from 3.9% to 5.2%; \(P = .03\)). This is equivalent to an additional 21 lives saved each year in the 19 communities, or approximately 1 life per 120,000 residents. Similarly, phase II demonstrated improved rates of admission (from 7.2% to 9.6%) and return of spontaneous circulation (from 9.8% to 12.2%). Of 85 phase II survivors, 66 were still alive at 1 year (not assessed during phase I). The neurological status of survivors was good, with the best Cerebral Performance Category score (ie, level 1 on the 5-level scale) being achieved by 73.2% at discharge and 79.7% at 1 year. Similarly, the functional status of 1-year survivors was very good, with a median Health Utility Index score of 0.90 (interquartile range, 0.74-0.95), with 1.0 representing the maximum or perfect health. Most of the subgroups assessed showed a nonsignificant trend toward improved survival in phase II when compared with phase I (TABLE 4).

Logistic regression analysis controlled for potential confounding variables in this nonrandomized study design (FIGURE 2 and TABLE 5). Better
survival, as expected, was associated with younger age, bystander-witnessed status, and CPR initiated by bystanders or first responders. The study intervention, response with a defibrillator in 8 minutes or less, was also associated with significantly improved survival (odds ratio, 3.0; 95% CI, 1.8-5.1). The goodness of fit for this model was 7.7 (P = .46) and the area under the receiver operating characteristic curve was 0.77.

The initial charges for implementing the defibrillation program are estimated to total $980,000 ($850,000 to the communities for equipment; $65,000 to the base hospital programs for training firefighters; $65,000 to the Ministry of Health for the administrative costs of policy revisions). These initial charges are equivalent to $39,400 per 100,000 residents in the study communities and approximately $46,900 per life saved. The ongoing annual charges for continuing the program are estimated to total $50,000 ($18,500 for equipment maintenance and $31,500 for training firefighters; $65,000 to the base hospital programs). Hence, we believe that this study has demonstrated that the implementation of a rapid defibrillation program is effective and inexpensive in comparison with traditional services. The goodness of fit for this model was 7.7 (P = .46), and the area under the receiver operating characteristic curve was 0.77.


cOMMENT

Having included 6331 patients with cardiac arrest, this study represents the largest multicenter controlled clinical trial of prehospital resuscitation yet conducted. The OPALS study phase II has clearly shown the benefits in response interval and survival of a multifaceted system optimization approach to improving community defibrillation capability. The study communities used improved dispatch procedures, more efficient use of BLS-D ambulances, and firefighter defibrillation programs, all at relatively little cost. This led to a 1.4-minute mean reduction in the “call receipt to vehicle stops with defibrillator” response interval and a 21% relative increase (to 93%) in the proportion of cases reached in 8 minutes or less. More important, however, was a 33% relative increase in the survival to hospital discharge rate. In other words, during the 12-month intervention period, 21 additional lives were saved in the 19 study communities. The quality of life of these survivors, based on functional and global health criteria, was very good. We estimate that the crude start-up cost of establishing the rapid defibrillation programs was approximately $36,500 per 100,000 residents and that the annual cost would be small. Hence, we believe that this study has demonstrated that the implementation of a rapid defibrillation program is an effective and inexpensive approach to significantly improving out-of-hospital cardiac arrest survival.

How original are our findings? Several previous studies have addressed the effectiveness of defibrillation provided by BLS or first-responder personnel rather than paramedics. Five separate US communities found im-

Table 4. Survival of Clinically Important Subgroups

<table>
<thead>
<tr>
<th>Community by population size</th>
<th>Total Cases, No.</th>
<th>Discharged Alive, %</th>
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<tbody>
<tr>
<td>Phase I</td>
<td>Phase II</td>
<td>Phase I</td>
</tr>
<tr>
<td>&lt;30,000 (n = 4)</td>
<td>200</td>
<td>64</td>
</tr>
<tr>
<td>30,000-100,000 (n = 6)</td>
<td>994</td>
<td>332</td>
</tr>
<tr>
<td>100,000-200,000 (n = 4)</td>
<td>830</td>
<td>334</td>
</tr>
<tr>
<td>200,000-500,000 (n = 4)</td>
<td>1727</td>
<td>637</td>
</tr>
<tr>
<td>&gt;500,000 (n = 1)</td>
<td>939</td>
<td>274</td>
</tr>
<tr>
<td>Bystander-witnessed arrest</td>
<td>2072</td>
<td>741</td>
</tr>
<tr>
<td>EMS-witnessed arrest</td>
<td>295</td>
<td>132</td>
</tr>
</tbody>
</table>

Table 5. Results of Logistic Regression Analysis of Factors Contributing to Survival

<table>
<thead>
<tr>
<th>Intercept</th>
<th>Estimate</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-4.61</td>
<td>-0.18</td>
<td>0.8 (0.8-0.9)</td>
</tr>
<tr>
<td>Bystander-witnessed</td>
<td>1.35</td>
<td>3.9 (2.7-5.5)</td>
</tr>
<tr>
<td>Bystander CPR</td>
<td>1.30</td>
<td>3.7 (2.6-5.1)</td>
</tr>
<tr>
<td>Fire/police CPR</td>
<td>0.47</td>
<td>1.6 (1.1-2.3)</td>
</tr>
<tr>
<td>EMS response in ≤8 min</td>
<td>1.11</td>
<td>3.0 (1.8-5.1)</td>
</tr>
</tbody>
</table>

*EMS indicates emergency medical services; VF, ventricular fibrillation.

CPR indicates cardiopulmonary resuscitation.
proved survival (ranging from 5% to 19%) for patients with cardiac arrest by introducing BLS-D programs without ALS care. In contrast, an Ontario study in 5 communities recently found that introduction of a BLS-D program to an existing BLS system did not significantly improve survival rates (from 2.1% before to 2.9% after). This last study did not provide rapid defibrillation, and response intervals were much slower than achieved in our study. We believe that rapid defibrillation requires EMS systems to have a responder with a defibrillator dispatched and at the scene in 8 minutes or less for at least 90% of cases. An uncontrolled Scottish study assessed implementation of a BLS-D system but was limited by underreporting and loss of cases to follow-up. Stacwynski et al found that automated external defibrillator use was not beneficial in rural Kentucky areas with a population density of less than 100 people per square mile. Other studies have examined the benefits of adding a BLS-D tier to an existing ALS system, but none has previously addressed the addition of a first-responder program to an existing BLS-D ambulance system. Our study has answered the major EMS question, “What incremental benefit in cardiac arrest survival may be expected when system optimization initiatives, including first-responder firefighter defibrillator, are added to an existing BLS-D (ie, non-ALS) ambulance system?”

A strength of our study is that 19 different communities of varying populations were involved, thereby avoiding the problem of regional clustering discussed by Auble and colleagues. We believe that our findings should be generalizable to most North American and European communities with populations of less than 1 million. The study findings are based on a large sample size, a strong controlled study design, and rigorous data collection and analysis methods. The study interventions were overseen through a central advisory committee. Patient and dispatch data relied on centralized and standardized record keeping systems.

This study did not use a randomized design for several reasons. The study intervention represented a community-wide program involving the training of hundreds of providers and permanent changes to dispatch policies. Consequently, any attempt to randomize individual patients within a community or to use a crossover approach would not have been feasible. Randomization by community might have been feasible but would likely have been subject to more confounding than our chosen design due to inherent differences between communities. Nevertheless, we feel that the likelihood of selection bias was minimized by our population-based approach whereby all patients with out-of-hospital arrests in the study communities were included. The same inclusion and exclusion criteria were carefully applied to all cases throughout both phases. Possible confounding factors were controlled for by the logistic regression analysis.

Other potential limitations merit discussion. Measurements of interval to defibrillation were not considered reliable during the preintervention period and, consequently, we used the interval to “arrived on scene with defibrillator” as our main indicator of rapid response. Phase II measurements indicated, however, that estimates of the interval from vehicle stops to arrival at the patient’s side were relatively brief with a mean interval of 2.0 minutes (SD, 1.5 minutes). In addition, some secondary outcome measures (1-year measures of survival, Cerebral Performance Category status, and Health Utility Index scores) were not available for the preintervention period.

This study did not attempt to address the question of the incremental benefit of rapid defibrillation added to an existing ALS system. We did not attempt to conduct a formal cost-effectiveness analysis, relying instead on a crude estimate of program costs.

An indicator variable for the initial rhythm of ventricular fibrillation (VF) was not included in the logistic regression model owing to its association with several other variables offered to the model. This approach is similar to that of Cummins et al and Wilcox-Gok, who considered VF to be a dependent rather than an independent variable. We found that VF is collinear with other covariates in that the rate of VF can be predicted by the same variables that predict survival. Consequently, we believe that VF is a path variable, ie, it occurs along the causal pathway to survival. We believe this argument is sensible also on biological grounds. We found that the rate of VF in our study (37%) was lower than in some other reports and did not increase between phases. This may be accounted for by the relatively low rate of bystander-initiated CPR in our communities.

Several research questions remain to be answered from the groundwork laid to date by the OPALS study. First, we plan to systematically evaluate survival as a function of defibrillation response intervals. This will allow us to determine whether the optimal standards for a community are really “90% reached in 8 minutes” or whether the time frame should be shortened to 7 or 6 or fewer minutes. Second, we are currently conducting a formal health economic evaluation of our results to accurately determine the cost-effectiveness of rapid defibrillation programs. Third, phase III of the OPALS study will evaluate the incremental benefit for cardiac arrest survival of an ALS system added to an already optimized rapid defibrillation program.

What is the importance of this study? We believe that our findings are fully applicable to prehospital care in most other Western countries. This is an era when providers of health care services, whether government, health maintenance organization, or private insurance company, are reevaluating the costs and effectiveness of medical services for their constituents. In an age of evidence-based health care and severe fiscal restraint, it is natural that providers question the need of full ALS for out-of-hospital patients. Phase I of the OPALS study demonstrated the value of com-
community optimization of bystander and first-responder CPR. Phase II has clearly shown the effectiveness of an inexpensive program of rapid defibrillation. Phase III will assess the value of ALS care for patients with cardiac arrest, trauma, and respiratory distress.

We believe that our findings have important health policy implications for communities that wish to improve their response to cardiac arrest. Every effort should be made to optimize defibrillation response intervals by improving dispatch methods, better deploying existing EMS vehicles, and using first-responder defibrillation. The importance of CPR by bystanders or first-responding fire or police officers is further corroborated by our study.

In summary, the OPALS study represents the largest multicenter BLS-D study of out-of-hospital cardiac arrest yet conducted. A multifaceted but inexpensive community approach to optimizing defibrillation response leads to a significant improvement in cardiac arrest survival. The final phase of the study will address the value of full ALS programs.

Author Affiliations: Division of Emergency Medicine (Drs Stell and Maloney), Department of Medicine (Dr Wells), and Ottawa Civic Hospital Loeb Health Research Institute (Miss De Maio and Ward), University of Ottawa, Ottawa, Ontario; Sunnybrook Base Hospital Program, Toronto, Ontario (Mr Spite); Arizona Emergency Medicine Research Center, University of Arizona, Tucson (Dr Spalte); Niagara Regional Base Hospital Program, Niagara Falls (Dr Munleky and Ms Luiistra), Department of Emergency Medicine, Joseph Brant Memorial Hospital, Burlington (Dr Lyver), Ontario Ministry of Health, Toronto (Mr Campeau), and Division of Emergency Medicine, Queen's University, Kingston (Dr Dagno), Ontario. Dr Stell is a career scientist of the Medical Research Council of Canada, Ottawa, Ontario.

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REFERENCES