ORIGINAL ARTICLE

Advanced Cardiac Life Support in Out-of-Hospital Cardiac Arrest

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ABSTRACT

BACKGROUND

The Ontario Prehospital Advanced Life Support (OPALS) Study tested the incremental effect on the rate of survival after out-of-hospital cardiac arrest of adding a program of advanced life support to a program of rapid defibrillation.

METHODS

This multicenter, controlled clinical trial was conducted in 17 cities before and after advanced-life-support programs were instituted and enrolled 5638 patients who had had cardiac arrest outside the hospital. Of those patients, 1391 were enrolled during the rapid-defibrillation phase and 4247 during the subsequent advanced-life-support phase. Paramedics were trained in standard advanced life support, which includes endotracheal intubation and the administration of intravenous drugs.

RESULTS

From the rapid-defibrillation phase to the advanced-life-support phase, the rate of admission to a hospital increased significantly (10.9 percent vs. 14.6 percent, $P<0.001$), but the rate of survival to hospital discharge did not (5.0 percent vs. 5.1 percent, $P=0.83$). The multivariate odds ratio for survival after advanced life support was 1.1 (95 percent confidence interval, 0.8 to 1.5); after an arrest witnessed by a bystander, 4.4 (95 percent confidence interval, 3.1 to 6.4); after cardiopulmonary resuscitation administered by a bystander, 3.7 (95 percent confidence interval, 2.5 to 5.4); and after rapid defibrillation, 3.4 (95 percent confidence interval, 1.4 to 8.4). There was no improvement in the rate of survival with the use of advanced life support in any subgroup.

CONCLUSIONS

The addition of advanced-life-support interventions did not improve the rate of survival after out-of-hospital cardiac arrest in a previously optimized emergency-medical-services system of rapid defibrillation. In order to save lives, health care planners should make cardiopulmonary resuscitation by citizens and rapid-defibrillation responses a priority for the resources of emergency-medical-services systems.

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Sudden cardiac arrest occurring outside the hospital is an important public health problem. Almost half a million deaths per year in the United States are attributed to sudden cardiac arrest, and 47 percent of those deaths occur outside hospitals.[1] Most communities have overall survival rates of less than 5 percent for cardiac arrests occurring outside the hospital. There is no evidence that these rates are increasing, despite extensive use of advanced treatments and technology.[2,3] The American Heart Association's four-step "chain of survival" concept has been promoted as a means of optimizing community responses.[4] Better survival has been associated with the first three links in the chain: early access to emergency medical care, early cardiopulmonary resuscitation (CPR), and early defibrillation.[5,6] Early advanced care (advanced cardiac life support), the fourth link, is often considered of benefit in that it provides advanced airway management (endotracheal intubation) and intravenous drug therapy.[7-10] The incremental benefit of advanced life support has not been established for out-of-hospital cardiac arrest.[11]

High-quality controlled clinical trials of prehospital advanced life support in cardiac arrest are difficult to conduct and are rare. Several observational studies failed to find a difference in survival rates with the use of advanced cardiac care, but their conclusions cannot be generalized to other settings.[12-14]

In Ontario, a jurisdiction of 12 million people, the provincial government has demanded evidence to support budgetary requests to maintain and improve emergency medical services. The Ontario Ministry of Health and Long-Term Care funded the Ontario Prehospital Advanced Life Support (OPALS) Study, a large, multicenter, controlled clinical trial conducted in a prehospital setting. The three-phase study involved specific prehospital programs in multiple Ontario cities to determine the incremental benefit to survival and morbidity for four major groups of critically ill and injured patients. The first phase showed that, in patients who had had out-of-hospital cardiac arrest, the following factors were independently associated with survival: CPR administered by bystanders and CPR administered by first responders.[5] In the second phase, optimization of existing rapid-defibrillation programs, by the more efficient dispatch of ambulances and the use of automated external defibrillators by firefighters, demonstrated a 33 percent relative increase in survival to hospital discharge.[6] Nevertheless, overall survival remained low as compared with other published rates of survival of up to 20 percent,[15] and the expectation is that advanced-life-support programs would lead to greater improvements in survival.

The objective of the current study, the OPALS Study for out-of-hospital cardiac arrest, is to assess the incremental benefit with respect to survival and morbidity that results from the implementation of full prehospital advanced-life-support programs in the context of an existing emergency-medical-services system of rapid defibrillation.

METHODS

DESIGN

We performed a "before–after" controlled trial (before and after advanced-life-support programs were instituted), with the unit of study being all eligible patients with cardiac arrest seen during two distinct phases: the rapid-defibrillation phase (12 months), which introduced optimized rapid defibrillation,[6] and the advanced-life-support phase (36 months), which assessed full advanced-life-support programs.[16] Data were pooled across communities and the data-collection phases within each community were separated by intervening and overlapping run-in periods to allow for training and system optimization.

SETTING

Eleven base hospitals throughout Ontario participated in the OPALS Study and provided medical direction for emergency medical services for the 17 urban study communities. The aggregate population was 2.5 million people, with the populations of particular cities ranging from 20,000 to 750,000. One community had a population of less than 30,000, six had populations of 30,000 to 99,999, five had populations of 100,000 to 199,999, four had populations of 200,000 to 500,000, and one had a population of more than 500,000. Each community was served by its own Central Ambulance Communications Center, which provided the study with electronic dispatch information. Prehospital care was documented with the use of the standard Ontario Ambulance Call Report form. At the outset of the advanced-life-support phase, each community had met and maintained the criteria for the phase II rapid-defibrillation program: the time from receipt of the dispatch call to arrival of a first responder

with a defibrillator at the scene was eight minutes or less for at least 90 percent of cases.

POPULATION

The study population comprised all persons 16 years of age or older who had out-of-hospital cardiac arrest and for whom resuscitation was attempted. We used the Utstein-style guidelines for reporting the data about the cardiac arrests.[17] Excluded were children younger than 16 years of age, persons who were dead, patients with trauma, and others with disorders that clearly had a noncardiac cause. The study received full approval by the Ottawa Hospital Research Ethics Board, and the requirement for informed consent was waived.

INTERVENTION

The study intervention consisted of an advanced-life-support program whereby paramedics were trained to perform endotracheal intubation, to insert intravenous lines, and to administer intravenous medications. These paramedics had previously graduated from a 10-month community college program, had training in the use of automated external defibrillators, and had several years of experience. For the study, the paramedics completed the Canadian Medical Association Level III Emergency Medical Technician training program, which involved 6 weeks of didactic instruction, 6 weeks of clinical instruction, and 12 weeks of preceptorship training in the field. To qualify for the advanced-life-support phase of the OPALS Study, each community had to meet four criteria: emergency medical services had to achieve a rapid-defibrillation response interval of 8 minutes or less in 90 percent of patients with cardiac arrest, advanced-life-support paramedics had to respond to 95 percent of patients, paramedics had to arrive at the scene within 11 minutes for 80 percent of patients, and paramedics had to successfully perform an endotracheal intubation in 90 percent of patients. These criteria were monitored regularly, and the three communities that failed to meet the standards were excluded.

OUTCOME MEASURES

The primary outcome measure was survival to hospital discharge, defined as the patient's leaving the hospital alive. Secondary survival measures, collected according to the Utstein style, included the return of spontaneous circulation and admission to the hospital. The survivors' cerebral-performance category was assessed at discharge, with level 1 indicating excellent cerebral performance, level 4 coma, and level 5 brain death or death.[18] Health-related quality of life was measured at one year by the Ontario Health Utility Index, Mark III.[19,20]

STATISTICAL ANALYSIS

The primary hypothesis of improved survival rates from the rapid-defibrillation and advanced-life-support phases was tested with chi-square analysis. All reported P values are two-tailed. Ninety-five percent confidence intervals were calculated for the absolute difference in survival rates between phases. The minimal sample size for comparing survival was estimated to be 1200 patients for the rapid-defibrillation phase and 3600 for the advanced-life-support phase, on the basis of a two-sided alpha level of 0.05, a beta error of 0.20, a baseline survival rate of 5.0 percent, a 1:3 ratio of rapid-defibrillation patients to advanced-life-support patients, and power to detect a 40 percent change in survival (an increase in absolute survival from 5.0 percent to 7.0 percent). Stepwise logistic-regression analysis was performed to control for the following possible confounding variables: community, ambulance service, age, sex, whether cardiac arrest was witnessed, initial cardiac rhythm, initiation of CPR by a bystander or by a firefighter or police officer, and time intervals (from receipt of a call to arrival at the scene, from arrival at the scene to arrival at the patient's side, from arrival at the patient's side to departure from the scene, from departure from the scene to arrival at the hospital). Survival was also displayed graphically over time, and the resultant interrupted time-series analysis was used to evaluate the intervention. Differences between phases for other data were analyzed with the Wilcoxon rank-sum test, the chi-square test, Fisher's exact test, or Student's t-test, as appropriate.

RESULTS

Three of 20 participating communities were unable to meet the study criteria for inclusion in the advanced-life-support program and were excluded, leaving 17 communities in the final analysis. Two communities were unable to maintain the program standards for the entire 36-month period, and data from these sites were truncated early. Data from the rapid-defibrillation phase were truncated proportionately. Four other communities entered the ad-

Table 1. Baseline Characteristics of the 5638 Study Patients in the 12-Month Rapid-Defibrillation and the 36-Month Advanced-Life-Support Phases.*

Characteristic	Rapid-Defibrillation Phase (N=1391)	Advanced-Life-Support Phase (N=4247)
Mean (±SD) age — yr	68.9±14.4	69.3±14.6
Male sex — no. (%)	936 (67.3)	2823 (66.5)
Population of community — no. (%)		
<30,000	22 (1.6)	55 (1.3)
30,000–99,999	318 (22.9)	846 (19.9)
100,000–199,999	304 (21.8)	946 (22.3)
200,000–500,000	473 (34.0)	1572 (37.0)
>500,000	274 (19.7)	828 (19.5)
Arrest witnessed by bystander — no. (%)	649 (46.7)	1737 (40.9)
Arrest witnessed by EMS personnel — no. (%)	119 (8.6)	411 (9.7)
Initial cardiac rhythm — no./total no. (%)		
Ventricular fibrillation or tachycardia	480/1357 (34.5)	1339/4094 (31.5)
Pulseless electrical activity	350/1357 (25.8)	1036/4094 (25.3)
Asystole	527/1357 (38.8)	1719/4094 (42.0)
CPR by bystander — no. (%)	220 (15.8)	612 (14.4)
CPR by first responder — no. (%)	470 (33.8)	1679 (39.5)
Responses — no./total no. (%)		
Defibrillator to scene in ≤8 min	1161/1258 (92.3)	3576/3817 (93.7)
First responder preceded EMS to scene	401/1214 (33.0)	1454/3655 (39.8)
Advanced-life-support provider on scene	—	3981/4247 (93.7)
Advanced-life-support provider on scene in ≤11 min	—	3114/3601 (86.5)
Defibrillation shock — no. (%)		
Delivered by first responder	149 (10.7)	523 (12.3)
Delivered by EMS	414 (29.8)	1217 (28.7)
Endotracheal intubation — no. (%)		
Attempted	—	3848 (90.6)
Successful if attempted	—	3605 (93.7)
Intravenous-line insertion — no. (%)		
Attempted	—	3767 (88.7)
Successful if attempted	—	3354 (89.0)
Intravenous medications administered — no. (%)†		
Epinephrine	—	3583 (95.8)
Atropine	—	3267 (87.3)
Lidocaine	—	882 (23.6)
Dopamine	—	105 (2.8)
Bicarbonate	—	92 (2.5)
Fluid bolus	—	1588 (42.4)

vanced-life-support phase late and provided less than 36 months worth of data. Consequently, they too had their rapid-defibrillation phase data truncated proportionately.

The OPALS Study enrolled 5638 patients: 1391 consecutive patients in the 12-month rapid-defibrillation phase (from July 1, 1994, to February 28, 1998) and 4247 in the advanced-life-support phase (from February 1, 1998, to June 30, 2002). In each community, the two phases were separated by a run-

Table 1. (Continued.)

Characteristic	Rapid-Defibrillation Phase (N=1391)	Advanced-Life-Support Phase (N=4247)
Interval — min‡		
From call receipt to crew notification		
Median	0.7	0.6
Interquartile range	0.5–1.1	0.4–0.9
From crew notification to vehicle arrival at scene		
Median	4.2	4.2
Interquartile range	3.1–5.3	3.2–5.4
From crew notification to fire-department vehicle at scene		
Median	4.6	4.5
Interquartile range	3.5–6.0	3.5–5.8
From crew notification to ambulance (basic life support) at scene		
Median	5.2	6.4
Interquartile range	4.0–6.9	4.6–8.7
From crew notification to ambulance (advanced life support) at scene		
Median	—	6.3
Interquartile range	—	4.7–8.3
From vehicle arrival to patient's side		
Median	1.0	0.9
Interquartile range	0.5–2.0	0.5–1.7
From patient's side to first analysis§		
Median	1.7	1.6
Interquartile range	1.0–2.5	0.9–2.5
From first analysis to shock delivered¶		
Median	0.2	0.3
Interquartile range	0.2–0.3	0.2–0.4
From patient's side to departure from scene		
Median	9.0	22.2
Interquartile range	7.1–11.3	16.8–28.3
From departure from scene to arrival at hospital		
Median	4.0	4.8
Interquartile range	2.7–5.6	3.1–6.5

* Dashes denote not applicable, and EMS emergency medical services.
† Intravenous medications were administered to 3742 patients in the advanced-life-support phase.
‡ Arrests witnessed by EMS personnel were excluded.
§ The median time was recorded for 816 patients in the rapid-defibrillation phase and for 2053 in the advanced-life-support phase.
¶ The median time was recorded for 386 patients in the rapid-defibrillation phase and for 1033 in the advanced-life-support phase.

in period of 6 to 36 months. In general, patients in the two phases had similar characteristics (Table 1). The responses to patients with cardiac arrest were similar in the two phases, except that the advanced-life-support phase had higher proportions of CPR administered by firefighters and police officers and defibrillation delivered by first responders, and lower proportions of CPR by bystanders.

The primary outcome, the rate of survival to hospital discharge, did not improve significantly from

the rapid-defibrillation phase to the advanced-life-support phase (5.0 percent to 5.1 percent, P=0.83) (Table 2). There were, however, improvements in the secondary outcomes, which were the rates of a return of spontaneous circulation (12.9 percent to 18.0 percent, P<0.001) and admission to the hospital (10.9 percent to 14.6 percent, P<0.001). The proportion of survivors with a cerebral-performance category of 1 (out of 5) was unchanged (78.3 percent vs. 66.8 percent, P=0.73). The median score on the Health Utility Index, Mark III, for one-year survivors was also unchanged between phases.

Logistic-regression analysis showed that the odds ratio for survival in the advanced-life-support phase, as compared with the rapid-defibrillation phase, was 1.1 (95 percent confidence interval, 0.8 to 1.5) (Fig. 1). In contrast, the first three links in the chain of survival had odds ratios as follows: early access (cardiac arrest witnessed by a bystander), 4.4 (95 percent confidence interval, 3.1 to 6.4); early CPR (CPR administered by a bystander), 3.7 (95 percent confidence interval, 2.5 to 5.4); and early defibrillation (automated external defibrillator used within eight minutes after cardiac arrest), 3.4 (95 percent confidence interval, 1.4 to 8.4).

Figure 2 shows the results of the time-series analysis during a consecutive 100-month period with each community's start date in the advanced-life-support phase synchronized and the run-in periods included. The change in survival after the onset of the advanced-life-support phase had a P value of 0.83. We evaluated a number of clinically important subgroups, and none had better survival in the advanced-life-support phase (Table 3).

DISCUSSION

This controlled clinical trial was designed to assess the incremental value of prehospital advanced-life-support interventions. The study had the power and design to discriminate between the effects that rapid defibrillation and advanced life support have on rates of survival to hospital discharge, links that have together been described as definitive care.[21] The results of the OPALS Study did not show any incremental benefit of introducing a full advanced-life-support program to an emergency-medical-services system of optimized rapid defibrillation. Despite the large sample, controlled design, and multiple approaches to the analysis, we were not able to identify any evidence of a benefit of advanced life support for any subgroup of patients. The results did confirm, however, the separate value of each of the first three links in the chain of survival: early access, early CPR, and early defibrillation.[6] Cardiac arrest witnessed by a bystander, CPR by a bystander, and use of a defibrillator in eight minutes or less were each strongly associated with improved survival. We believe that public health and emergency-medical-services managers should recognize and address the two key modifiable links in their communities — namely, CPR by bystanders and rapid defibrillation.

These results are consistent with previous case

Table 2. Survival and Functional Outcomes of Patients from the Two Study Phases.*

Outcome	Rapid-Defibrillation Phase (N=1391)	Advanced-Life-Support Phase (N=4247)	Absolute Increase (95% CI)	P Value
	no. (%)		*percentage points*	
Return of spontaneous circulation	180 (12.9)	766 (18.0)	5.1 (3.0 to 7.2)	<0.001
Admission to hospital	152 (10.9)	621 (14.6)	3.7 (1.7 to 5.7)	<0.001
Survival to hospital discharge	69 (5.0)	217 (5.1)	0.1 (–1.2 to 1.5)	0.83
Survivors' cerebral performance category, level 1†	54 (78.3)	145 (66.8)	—	0.73
	score			
Survivors' Health Utility Index, Mark III, at one year			—	0.67
Median	0.84	0.79		
Interquartile range	0.49–0.97	0.43–0.91		

* CI denotes confidence interval, and dashes denote not applicable.
† There were 69 survivors in the rapid-defibrillation phase, and 217 in the advanced-life-support phase.

series that demonstrated poor survival after out-of-hospital cardiac arrest, despite the benefit of advanced-life-support interventions. The rate of survival was as low as 1.3 percent in Chicago and 1.4 percent in New York City.[22,23] Two meta-analyses showed no benefits of advanced life support for emergency-medical-services systems.[3,24] A number of reports have attributed improved survival after cardiac arrest to the provision of prehospital advanced life support.[2,4] These reports, however, generally did not adjust for the second and third links — that is, early CPR and early defibrillation.

Other investigations of the effectiveness of advanced life support have been limited by small samples and nonexperimental designs.[12-14] Our study was characterized by a large sample and a controlled clinical design implemented in 17 communities across a broad geographic area. We believe that these findings can be generalized to most communities with populations of less than 1 million. Training of paramedics was delivered at a single institution with a standardized national curriculum and clinical training period. All trainees were experienced emergency medical technicians and had the benefit of a 6-to-36-month run-in period in which to perfect their advanced-life-support skills. Quality assurance was vigorously monitored, and communities that did not meet the four performance criteria were excluded.

The optimal response interval for advanced life support is less well understood than is the optimal response time for defibrillation.[25-28] In our study, advanced-life-support providers met our arbitrary standard of arriving on the scene within 11 minutes 87 percent of the time. They also performed intubation with a high degree of success. In addition, rapid response with a defibrillator was maintained throughout both study phases.

An important potential limitation is that the study was designed as a before–after controlled trial rather than as a randomized trial. Nevertheless, we do not believe that this undermines the validity of the findings. Randomization by patient was not possible, because the paramedics considered it unethical to randomly withhold potentially lifesaving procedures from patients.

The primary outcome measure was survival to hospital discharge and was not subject to ascertainment bias. Selection bias was minimized by the population-based approach, in which all patients in each community were included for defined enrollment periods. We are not aware of any important new therapies or any general societal increase in survival rates for out-of-hospital cardiac arrest during the study period. Nevertheless, multiple statistical approaches were taken to assure the validity and robustness of our outcome assessments. Multivariate logistic-regression analyses that included cardiac arrests witnessed by emergency-medical-services personnel, initial rhythm, and interaction terms were performed, and the results did not change. A poten-

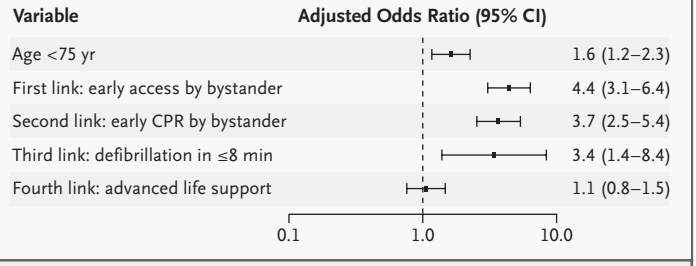

Figure 1. Odds Ratios for Survival to Hospital Discharge Associated with Selected Factors.

The goodness of fit for the model was 6.4 (P=0.60) and was assessed with the Hosmer–Lemeshow test. A reasonable fit can be assumed, since the result was not significant. The area under the receiver-operating-characteristic curve was 0.77, which indicates the validity of the model (a value of 1.0 represents 100 percent specificity and sensitivity). Odds ratios, determined after logistic-regression analysis, are for factors associated with survival to hospital discharge. CI denotes confidence interval.

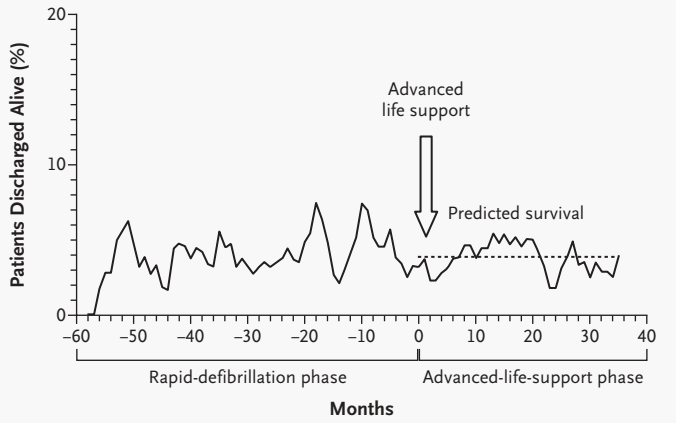

Figure 2. Actual versus Predicted Interrupted-Time-Series Model for Survival to Discharge for 100 Consecutive Months, from the Rapid-Defibrillation Phase to the Advanced-Life-Support Phase.

The solid line represents actual survival, and the dotted line represents predicted survival based on the rapid-defibrillation phase.

Table 3. Survival of Clinically Important Subgroups.

Variable	Total No. of Patients		Percent Discharged Alive		P Value
	Rapid-Defibrillation Phase (N=1391)	Advanced-Life-Support Phase (N=4247)	Rapid-Defibrillation Phase (N=69)	Advanced-Life-Support Phase (N=217)	
Population of community					
<30,000	22	55	0	7.3	0.19
30,000–99,999	318	846	5.0	7.1	0.20
100,000–199,999	304	946	3.9	5.2	0.39
200,000–500,000	473	1572	5.3	4.7	0.61
>500,000	274	828	5.8	3.6	0.11
Arrest witnessed by bystander	649	1737	7.1	6.8	0.80
Arrest witnessed by emergency medical services	119	411	13.4	16.6	0.41
CPR					
By bystander	220	612	11.4	10.3	0.66
By first responder	470	1679	3.4	2.3	0.19
Response in ≤8 min	1161	3576	4.3	4.0	0.71
Initial cardiac rhythm					
Ventricular fibrillation or pulseless ventricular tachycardia	480	1339	12.9	13.2	0.87
Pulseless electrical activity	350	1036	1.4	2.4	0.27
Asystole	527	1719	0.2	0.8	0.15
Ventricular fibrillation witnessed	338	895	15.1	15.5	0.85
By bystander	306	809	13.7	12.4	0.54
By emergency medical services	32	86	28.1	45.3	0.09

tial but unlikely threat to the validity of our findings was the minor differences in the study populations before and after advanced-life-support programs were instituted. A concern could have been whether first responders or emergency-medical-services attendants delayed CPR in order to defibrillate or perform advanced-life-support procedures. We found no evidence that this occurred in our communities.

Intermediate survival outcomes (return of spontaneous circulation and admission to a hospital) improved in the advanced-life-support phase. Skeptics could argue that the only outcome of the advanced-life-support program was an increase in the burden for hospitals and critical care units. Alternatively, optimists could argue that better postresuscitation care could ultimately lead to better survival rates. The recent interest in hypothermia therapy may help achieve this survival promise. We believe, however, that survival to discharge and neurologic performance are by far the most important outcomes for a clinical trial of cardiac arrest. We believe that decision makers for communities and national organizations should invest far more time and resources in optimizing the first three links in the chain of survival — that is, the early identification of cardiac arrest, CPR by a bystander, and rapid-defibrillation programs.

The introduction of advanced-life-support programs should not compromise investment in early access, early CPR, and early defibrillation. Although our studies show the very powerful effect that the second link — CPR by a bystander — has on survival rates, with odds ratios consistently greater than 3, there has been no increase in the frequency at which CPR has been administered by bystanders during the past 10 years. Public and media awareness of the value of CPR is far less than the awareness of more "high-tech" initiatives such as public-access defibrillation programs, despite the fact that the latter have the potential to benefit less than 10 percent of patients with cardiac arrest.[29-32] We must also ensure that responders do not delay or overlook CPR

while they focus on defibrillation or advanced-life-support measures.

The third link, which can be described as a community-wide system to optimize the defibrillation response, also has an odds ratio exceeding 3. Inexpensive initiatives include improving the dispatch of ambulances and instituting programs to teach first responders (firefighters and police officers) to use automated external defibrillators.

Our study does not address the value of advanced-life-support programs in urban communities that have high rates of CPR by bystanders or very rapid advanced-life-support responders. Some cities have had higher overall survival rates with advanced-life-support systems than the rates in our study, but those cities typically have a high rate of CPR by bystanders. Also unknown is the benefit of advanced life support in rural communities, where transport times to a hospital are longer.[33]

The OPALS Study showed that the systematic introduction of full advanced-life-support programs to an emergency-medical-services system that had previously optimized its rapid-defibrillation program did not decrease mortality or morbidity associated with cardiac arrest. In out-of-hospital cardiac arrest, the second and third links in the chain of survival are far more important than the fourth link. In order to save lives, and to do so efficiently, public health planners should make CPR by bystanders and a rapid defibrillation response major priorities for the allocation of resources.

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