

The OPALS Major Trauma Study: impact of advanced life-support on survival and morbidity

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ABSTRACT

Background: To date, the benefit of prehospital advanced life-support programs on trauma-related mortality and morbidity has not been established

Methods: The Ontario Prehospital Advanced Life Support (OPALS) Major Trauma Study was a before–after systemwide controlled clinical trial conducted in 17 cities. We enrolled adult patients who had experienced major trauma in a basic life-support phase and a subsequent advanced life-support phase (during which paramedics were able to perform endotracheal intubation and administer fluids and drugs intravenously). The primary outcome was survival to hospital discharge.

Results: Among the 2867 patients enrolled in the basic life-support ($n = 1373$) and advanced life-support ($n = 1494$) phases, characteristics were similar, including mean age (44.8 v. 47.5 years), frequency of blunt injury (92.0% v. 91.4%), median injury severity score (24 v. 22) and percentage of patients with Glasgow Coma Scale score less than 9 (27.2% v. 22.1%). Survival did not differ overall (81.1% among patients in the advanced life-support phase v. 81.8% among those in the basic life-support phase; $p = 0.65$). Among patients with Glasgow Coma Scale score less than 9, survival was lower among those in the advanced life-support phase (50.9% v. 60.0%; $p = 0.02$). The adjusted odds of death for the advanced life-support v. basic life-support phases were nonsignificant (1.2, 95% confidence interval 0.9–1.7; $p = 0.16$).

Interpretation: The OPALS Major Trauma Study showed that systemwide implementation of full advanced life-support programs did not decrease mortality or morbidity for major trauma patients. We also found that during the advanced life-support phase, mortality was greater among patients with Glasgow Coma Scale scores less than 9. We believe that emergency medical services should carefully re-evaluate the indications for and application of prehospital advanced life-support measures for patients who have experienced major trauma.

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Each year in the United States, an estimated 500 000 adult patients are transported to hospital after experiencing major trauma.^{1,2} Major trauma can be described as life- or limb-threatening injury due to blunt force, penetrating injury or burn injury. Considering both frequency and associated mortality, major trauma is the second most important condition for children and the fourth most important condition for adults treated by emergency medical service providers.² About 20% of these patients die, and many survivors are left with permanent disability.

Throughout most urban areas of the United States and Canada, paramedics provide prehospital advanced life-support to many of these critically injured patients. Advanced life-support protocols include advanced airway management (endotracheal intubation) and intravenous fluid therapy. In contrast, basic life-support providers administer oxygen, ventilate with a bag valve mask, and provide immobilization and dressings. The relative effectiveness of community-based advanced life-support programs for major trauma patients has not been clearly established, and there have been calls for larger and more rigorously designed studies.^{3–5}

Endotracheal intubation in the field has not been proven to reduce mortality and morbidity among severely injured patients, and there are concerns that performing this difficult task under trying conditions may cause harm.^{6,7} The value of prehospital intravenous resuscitation has also been questioned.^{8,9} In addition, there are concerns that the on-scene time spent providing advanced life-support measures may ac-

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tually delay life-saving expeditious transfer to the hospital and the operating room.¹⁰ To date, no large controlled clinical trials have been conducted to evaluate the impact of prehospital advanced life-support programs on trauma-related mortality and morbidity.³

As part of the Ontario Prehospital Advanced Life Support (OPALS) studies, we recently demonstrated that advanced life-support programs had no impact on the outcomes of patients who had experienced cardiac arrest, but they did lead

to significant improvement in survival among patients with respiratory distress.^{11,12} The primary objective of the current study, the OPALS Major Trauma Study, was to assess any change in survival that might result from the systemwide introduction of prehospital advanced life-support programs in multiple cities with existing basic life-support programs provided through emergency medical services. We also evaluated the impact of advanced life-support on morbidity and processes of care.

Table 1: Characteristics of the 2867* study patients obtained from prehospital and on-scene records (part 1)

Characteristic	Phase of study; no. (%) of patients†		p value
	Basic life-support phase n = 1373	Advanced life-support phase n = 1494	
Age, yr	n = 1373	n = 1494	
Mean (SD)	44.8 (20.9)	47.5 (21.8)	0.001
Min-max	16-97	16-98	
Sex, no. (%) male	n = 1373	n = 1494	
	1002 (73.0)	1065 (71.3)	0.33
Community population	n = 1373	n = 1494	0.02
< 100 000 (n = 6)	164 (11.9)	147 (9.8)	0.07
100 000-200 000 (n = 5)	251 (18.3)	233 (15.6)	0.06
> 200 000 (n = 6)	958 (69.8)	1114 (74.6)	0.004
Case severity	n = 1005	n = 1255	0.87
Minor	35 (3.5)	40 (3.2)	0.70
Moderate	214 (21.3)	277 (22.1)	0.66
Severe	374 (37.2)	486 (38.7)	0.46
Severe or life-threatening	366 (36.4)	433 (34.5)	0.34
Vital signs absent	16 (1.6)	19 (1.5)	0.88
Physiologic measures, mean (SD)			
Diastolic blood pressure, mm Hg	n = 280	n = 669	
	79.4 (17.2)	80.3 (38.0)	0.71
Systolic blood pressure, mm Hg	n = 710	n = 1094	
	116.1 (45.3)	127.2 (39.9)	0.001
Respiratory rate, breaths/min	n = 1014	n = 1256	
	20.5 (8.4)	19.1 (6.7)	0.001
Systolic blood pressure at scene	n = 681	n = 1077	0.001
< 100 mm Hg	187 (26.3)	178 (16.3)	0.001
≥ 100 mm Hg	523 (73.7)	916 (83.7)	0.001
Glasgow Coma Scale score‡	n = 1340	n = 1450	0.003
Severe (< 9)	365 (27.2)	320 (22.1)	0.002
Moderate (9-12)	133 (9.9)	132 (9.1)	0.46
Minor (13-15)	842 (62.8)	998 (68.8)	0.001
Median (interquartile range)	14 (7-15)	14 (10-15)	0.008
Revised trauma score‡	n = 1227	n = 1341	0.001
0 to < 2	56 (4.6)	36 (2.7)	0.01
2 to < 4	64 (5.2)	42 (3.1)	0.008
4 to < 6	191 (15.6)	193 (14.4)	0.41
6 to 7.84	916 (74.7)	1070 (79.8)	0.002
Median (interquartile range)	7.84 (5.97-7.84)	7.84 (6.9-7.84)	0.001

Methods

Design

We conducted a systemwide before–after controlled clinical trial, the unit of study being individual eligible patients with major trauma seen during 2 distinct phases: the basic life-support phase (36 months) and the advanced life-support phase (36 months).¹³ Patient data were pooled across multiple study cities, but the start date for each phase differed, as each community re-

quired different periods to train paramedics to the advanced-life-support standard. The data-collection phases for each city were separated by intervening run-in periods to allow for training and system optimization. Detailed methods for the major trauma portion of the OPALS Study were published previously.¹³

Setting

We conducted the study in 17 cities within the province of Ontario, Canada, with medical oversight for emergency medical

Table 1: Characteristics of the 2867* study patients obtained from prehospital and on-scene records (part 2)

Characteristic	Phase of study; no. (%) of patients†		p value
	Basic life-support phase n = 1373	Advanced life-support phase n = 1494	
Nature of injury	n = 1371	n = 1494	0.94
Blunt	1262 (92.0)	1366 (91.4)	0.55
Penetrating	80 (5.8)	89 (6.0)	0.89
Burn	29 (2.1)	39 (2.6)	0.38
Extrication required	n = 1329	n = 1472	
	234 (17.6)	303 (20.6)	0.05
Time intervals, min, median (interquartile range)	n = 1373	n = 1494	
Call received to crew notified	0.9 (0.5-1.4)	0.8 (0.5-1.6)	0.84
Crew notified to vehicle stops – basic life-support	6.0 (4.1-8.7)	6.9 (4.2-10.2)	0.001
Crew notified to vehicle stops – advanced life-support	–	6.5 (4.5-8.8)	0.10
Crew notified to vehicle stops – first	6.0 (4.0-8.7)	6.6 (4.5-9.1)	0.001
Vehicle stops to patient side	2.0 (1.0-2.0)	2.0 (2.0-2.0)	0.001
Patient side to depart scene	13.0 (9.0-18.5)	14.8 (10.6-20.6)	0.001
Depart scene to arrive hospital	6.1 (3.9-10.4)	7.2 (4.4-10.8)	0.001
Total time on scene	15.0 (10.0-20.5)	16.8 (12.6-22.6)	0.001
Total time, notified to arrive hospital	29.7 (23.0-40.1)	34.2 (26.5-43.9)	0.001
Prehospital interventions by emergency medical service	n = 1373	n = 1494	
Advanced life-support on scene	35 (2.5)	1082 (72.4)	0.001
Ventilation	137 (10.0)	180 (12.0)	0.10
Immobilization	n = 1353	n = 1491	
	993 (73.4)	1120 (75.1)	0.29
Intubation	n = 1373	n = 1494	
All	–	102 (6.8)	–
Oral	–	68 (4.6)	–
Nasal	–	34 (2.3)	–
Intravenous line inserted	–	n = 1236	
	–	779 (63.0)	–
Intravenous fluid bolus	–	n = 1236	
	–	144 (11.7)	–
Intravenous morphine	–	n = 1236	
	–	35 (2.8)	–

Note: SD = standard deviation.

*Some analyses are based on fewer observations than the total n for each phase because of missing data (indicated by n values in columns 2 and 3).

†Unless stated otherwise.

‡Glasgow Coma Scale and revised trauma scores reflect the first available record, either prehospital or hospital.

services provided by 11 provincial base-hospital programs. The total population was 2.5 million, with the population of individual cities varying from 20 000 to 750 000. Two large cities in the jurisdiction, Toronto and Hamilton, were not included because they both had pre-existing advanced life-support response systems. Each of the participating centres was served by a provincial Central Ambulance Communications Centre, which provided electronic and synchronized dispatch information. The paramedics documented prehospital care on a standardized provincial ambulance call report form. During the basic life-support phase, each community provided a tiered response: firefighters first, followed by primary care paramedics who were trained to provide all basic life-support measures.

Population

The study population consisted of all patients 16 years of age or older who had been injured by any mechanism, whose injury severity score was more than 12, who had been transported by land ambulance and who had been treated at one of the 13 lead trauma hospitals in Ontario. Patients could have been transferred from a primary hospital or taken directly from the scene to the trauma hospital. Hospital and outcome data were available from the Ontario Trauma Registry Comprehensive Data Set.¹⁴ We abstracted prehospital information from ambulance call reports and the database of the provincial dispatch centre. Excluded were patients younger than 16 years, those whose injury had occurred more than 8 hours before the call to emergency medical services and those who were pronounced dead at the scene. 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 400 paramedics were trained to perform endotracheal intubation, insert intravenous lines and administer medications and fluids intravenously. The Ontario Ministry of Health and Long-Term Care funded this advanced life-support program and has estimated that the total cost of training and operational upgrades was \$15.8 million. All of these paramedics had previously completed a 10-month community college program and had several years of experience. For the study, the paramedics completed training to meet the Canadian Medical Association's Emergency Medical Technician Level III standards; this training involved 6 weeks of didactic instruction, 6 weeks of clinical instruction and a 12-week preceptorship (training in the field). To qualify for the advanced life-support phase of the OPALS Study, each community had to meet the following criteria for cardiac arrest patients: paramedics responded to 95% of cases, paramedics arrived at the scene within 11 minutes for 80% of cases, and paramedics successfully performed endotracheal intubation for 90% of cases. Of the original 20 communities considered for this study, 3 did not meet these standards and were excluded.

Outcome measures

The primary outcome, survival to hospital discharge, was defined as the patient leaving the hospital alive or being trans-

ferred to a long-term care facility; we obtained these data from hospital records. In addition, we measured disease-specific quality of life with the 7-level functional independence measure for survivors.¹⁵

Data analysis

The sample size available for analyzing the primary outcome (survival to hospital discharge) was determined from the number of available cases in the study communities before ($n = 1373$) and after ($n = 1494$) introduction of advanced life-support services. Given a set of 4 assumptions (2-sided $\alpha = 0.05$, $\beta = 0.20$, baseline survival = 81.9%, and 1:1.09 ratio of patients in the 2 study phases), we estimated that the minimum absolute difference in the primary outcome that was detectable between the study phases was 3.8% (85.7% advanced life-support v. 81.9% basic life-support). We tested the primary hypothesis of improvement in survival rates from the basic life-support phase to the advanced life-support phase by χ^2 analysis techniques. All p values are 2-tailed.

We captured data for the following potential confounders: demographic characteristics (age, sex, community); prehospital variables (case severity, systolic and diastolic blood pressure, respiratory rate, Glasgow Coma Scale score, revised trauma score,¹⁶ nature of injury, requirement for extrication, the response-time intervals "crew notified to vehicle stops," "vehicle stops to patient side," "patient side to depart scene" and "depart scene to arrive hospital emergency department"); measures of specific advanced life-support interventions (ventilation, oral and nasal intubation, intravenous administration of fluids, administration of morphine); and hospital variables from the records of the lead trauma hospital (Glasgow Coma Scale score, revised trauma score, injury severity score, abbreviated injury score by body region,¹⁷ external cause of injury code from the 9th revision of the International Classification of Diseases, direct admission or transfer from another primary or secondary hospital, intensive care). In cases during the second phase of the study where basic life-support and advanced life-support crews were both sent to the scene, the first response time or the shortest response interval was employed in analytical comparisons.

We assessed the match of injury severity between the OPALS Study patients and the reference group of the earlier Major Trauma Outcome Study by phase using the " M statistic," as described in trauma score and injury severity score methodology.^{18,19} The M statistic ranges from 0 to 1, with a value close to 1 indicating a good match and a value close to 0 indicating a disparity in the injury severity match. We expressed the clinical importance of the difference between the observed (OPALS) and expected (Major Trauma Outcome Study) number of survivors as the " W statistic," and we compared the mean increase or decrease in the number of survivors per 100 patients treated with norm expectations. We expressed the statistical significance of the difference in survival in the OPALS study population relative to the Major Trauma Outcome Study population with the " Z statistic." Absolute Z values exceeding 1.96 indicate a statistically significant difference in observed v. predicted survival rates.

We compared outcomes between phases for the following

Table 2: Characteristics of the 2867* study patients obtained from records of lead trauma hospital

Characteristic	Phase of study; no. (%) of patients†		p value
	Basic life-support phase n = 1373	Advanced life-support phase n = 1494	
Clinical measures			
Glasgow Coma Scale score‡	n = 1340	n = 1450	0.03
Severe (< 9)	344 (25.7)	328 (22.6)	0.06
Moderate (9-12)	110 (8.2)	96 (6.6)	0.11
Minor (13-15)	886 (66.1)	1026 (70.8)	0.008
Median (interquartile range)	14 (8-15)	15 (10-15)	0.03
Revised trauma score‡	n = 1227	n = 1341	0.02
0 to < 2	47 (3.8)	33 (2.5)	0.05
2 to < 4	57 (4.6)	38 (2.8)	0.02
4 to < 6	190 (15.5)	208 (15.5)	0.99
6 to 7.84	933 (76.0)	1062 (79.2)	0.06
Median (interquartile range)	7.84 (6.38-7.84)	7.84 (6.90-7.84)	0.001
Abbreviated injury score by body region, mean (SD)	n = 1373	n = 1494	
Head and neck	2.8 (2.2)	3.2 (2.5)	0.001
Face	0.3 (0.8)	0.4 (0.8)	0.41
Chest	2.1 (2.6)	2.1 (2.7)	0.70
Abdomen	0.8 (1.5)	0.9 (1.7)	0.20
Extremities and pelvic girdle	1.5 (1.9)	1.6 (2.1)	0.60
External	0.6 (0.9)	0.7 (1.0)	0.02
Injury severity score by category§	n = 1372	n = 1494	< 0.001
12-15	185 (13.5)	145 (9.7)	0.002
16-24	512 (37.3)	669 (44.8)	0.001
25-40	541 (39.4)	524 (35.1)	0.02
41-49	66 (4.8)	90 (6.0)	0.15
50-74	42 (3.1)	43 (2.9)	0.77
75	26 (1.9)	23 (1.5)	0.46
Median (interquartile range)	24 (17-29)	22 (17-27)	0.67
External cause of injury (ICD-9 code)§	n = 1328	n = 1494	0.001
Motor vehicle collision	697 (52.5)	675 (45.2)	0.001
Fall	334 (25.2)	440 (29.5)	0.01
Other road vehicle incident	29 (2.2)	30 (2.0)	0.75
Struck by or against object	21 (1.6)	38 (2.5)	0.08
Purposefully inflicted by other	103 (7.8)	144 (9.6)	0.08
Self-inflicted	62 (4.7)	53 (3.5)	0.13
Other or unknown	82 (6.2)	114 (7.6)	0.13
Care at lead trauma hospital	n = 1373	n = 1494	
Intubation	206 (15.1)	235 (15.9)	0.57
Admission			
Transferred from primary hospital	411 (29.9)	380 (25.4)	0.007
Directly to lead trauma hospital only	962 (70.1)	1114 (74.6)	0.007
Specialized care unit	767 (55.9)	1036 (69.3)	0.001
Duration of medical care, d, mean (SD)	n = 767	n = 1036	
Specialized (e.g., intensive) care	8.5 (11.0)	7.6 (10.5)	0.08
Total hospital stay	n = 1373	n = 1494	
	22.7 (35.8)	17.0 (21.8)	0.001

Note: ICD-9 = International Classification of Diseases, 9th revision.

*Some analyses are based on fewer observations than the total *n* for each phase because of missing data (indicated by *n* values in columns 2 and 3).

†Unless stated otherwise.

‡Glasgow Coma Scale and revised trauma scores reflect the lead hospital record or (if unavailable) the last prehospital or hospital record.

§Classified according to levels in the Multiple Trauma Outcome Study.¹⁹

a priori subgroups: community size, nature of injury, external cause of injury, injury severity, Glasgow Coma Scale score, systolic blood pressure, abbreviated injury score and patient age. We also developed a series of multiple logistic regression models to assess the effects of study interventions (study phase, advanced life-support on site, and specific advanced life-support interventions) on patient nonsurvival, while simultaneously controlling for confounders indicated by the trauma score and injury severity score methodology.

Results

A total of 2867 patients were enrolled during the basic life-support phase ($n = 1373$; total period July 1, 1992, to Feb. 28, 1998) and advanced life-support phase ($n = 1494$; total period Feb. 1, 1998, and June 30, 2002) for all cities. Patients in the 2 phases were similar for most characteristics obtained from the prehospital (Table 1) and trauma hospital (Table 2) records. Compared with patients in the basic life-support phase, those in the advanced life-support phase were slightly older and from larger communities, had higher mean systolic blood pressure and lower respiratory rates, and had less severe injuries as indicated by Glasgow Coma Scale scores and revised trauma scores. During the advanced life-support

phase, 6.8% of patients were intubated, which represents a success rate of 71.8% of cases in which intubation was attempted. In addition, intravenous access was established in 63.0% of patients, which represents a success rate of 90.3% for all attempts. Overall, 11.7% of the patients received intravenous fluid bolus therapy. According to hospital records (Table 2), patients in the advanced life-support phase had less severe injuries (as indicated by Glasgow Coma Scale score, revised trauma score, abbreviated injury scale and injury severity score), were more likely to have had a fall and less likely to have been involved in a motor vehicle collision, and were more likely to have been directly admitted to the lead trauma hospital compared with patients in the basic life-support phase.

There was no substantial difference in overall survival to hospital discharge by study phase (81.8% for the basic life-support phase v. 81.1% for the advanced life-support phase; $p = 0.65$) (Table 3). In addition, the proportion of early deaths, within 24 hours, did not differ. More patients in the advanced life-support phase than in the basic life-support phase were judged by the paramedics to have "improved en route to hospital" (5.3% v. 10.1%; $p < 0.001$). There were no differences in morbidity between the phases, as indicated by the Glasgow outcome scale and functional independence

Table 3: Survival and other clinical outcomes during the 2 study phases*

Outcome	Phase of study; no. (%) of patients†		p value	Absolute difference (95% CI)
	Basic life-support phase $n = 1373$	Advanced life-support phase $n = 1494$		
Primary	$n = 1373$	$n = 1494$		
Survival to hospital discharge	1123 (81.8)	1212 (81.1)	0.65	-0.7 (-3.6 to 2.2)
Death < 24 h	$n = 1330$	$n = 1439$		
	93 (7.0)	103 (7.2)	0.86	0.2 (-1.7 to 2.1)
Secondary				
Condition en route to hospital	$n = 1034$	$n = 1278$		
Improved	55 (5.3)	129 (10.1)	0.001	4.8 (2.6 to 7.0)
Worsened	841 (81.3)	1065 (83.3)	0.21	2.0 (-1.2 to 5.2)
No change	129 (12.5)	76 (5.9)	0.001	-6.5 (-9.0 to 4.1)
Vital signs absent	9 (0.9)	8 (0.6)	0.49	-0.2 (-1.0 to 0.5)
Glasgow outcome score at discharge	$n = 629$	$n = 598$		
Good recovery	271 (43.1)	234 (39.1)	0.16	-4.0 (-9.5 to 1.6)
Moderate disability	68 (10.8)	56 (9.4)	0.40	-1.5 (-4.9 to 2.0)
Severe disability	103 (16.4)	119 (19.9)	0.11	3.5 (-0.9 to 7.9)
Vegetative state	11 (1.7)	12 (2.0)	0.73	0.3 (-1.4 to 1.9)
Death	176 (28.0)	177 (29.6)	0.53	1.6 (-3.1 to 6.8)
Functional independence measure, mean (SD)	$n = 762$	$n = 990$		
At discharge	95.0 (28.6)	94.2 (28.2)	0.54	-0.8 (-3.5 to 1.9)
At 6 mo after discharge	$n = 455$	$n = 692$		
	115.3 (21.0)	116.2 (20.2)	0.47	0.9 (-1.6 to 3.3)

Note: CI = confidence interval.

*Some analyses are based on fewer observations than the total n for each phase because of missing data (indicated by n values in columns 2 and 3).

†Unless stated otherwise.

Table 4: Survival to hospital discharge (primary outcome) among clinically important subgroups

Subgroup characteristic	No. of patients <i>n</i> = 2867	Phase of study; % of patients discharged alive		<i>p</i> value
		Basic life-support phase (47.9% of total)	Advanced life-support phase (52.1% of total)	
Community by population size				0.68
< 100 000 (<i>n</i> = 6)	311	90.2	85.7	0.22
100 000-200 000 (<i>n</i> = 5)	484	74.5	78.1	0.35
> 200 000 (<i>n</i> = 6)	2072	82.3	81.1	0.52
Nature of injury				0.73
Blunt	2628	82.7	81.5	0.41
Penetrating	169	73.8	78.7	0.45
Burn	68	62.1	74.4	0.28
External cause of injury (selected)				NA
Motor vehicle collision	1372	84.8	84.6	0.92
Fall	774	78.4	73.4	0.11
Purposefully inflicted by other	247	87.4	87.5	0.98
Self-inflicted	115	67.7	66.0	0.85
Systolic blood pressure at scene, mm Hg				0.39
< 100	365	69.0	68.0	0.84
≥ 100	1439	87.6	85.7	0.32
Glasgow Coma Scale score				0.19
< 9	685	60.0	50.9	0.02
9-15	2105	90.5	90.1	0.83
Injury severity score				0.22
< 25	1511	95.8	94.3	0.18
≥ 25	1355	67.3	65.3	0.44
Patient age, yr				0.98
< 30	795	86.8	89.3	0.28
30-54	1104	87.2	87.1	0.97
≥ 55	965	70.5	68.8	0.57
Abbreviated injury score by body region				
Score 1-3				NA
Head and neck	670	94.4	92.0	0.22
Face	521	84.0	84.1	0.98
Chest	583	90.0	86.2	0.16
Abdomen	472	87.0	90.1	0.29
Extremities or pelvic girdle	1077	87.5	86.2	0.52
External	1270	85.2	83.6	0.42
Score 4-5				NA
Head and neck	752	72.8	72.5	0.91
Face	2	100.0	NA	NA
Chest	236	74.4	70.9	0.54
Abdomen	205	74.3	80.8	0.26
Extremities or pelvic girdle	66	66.7	83.3	0.12
External	58	60.7	76.7	0.19
Patient transport				0.69
Transferred from primary hospital	791	82.2	81.1	0.67
Direct from scene to lead trauma hospital	2076	81.6	81.1	0.79
Advanced life-support crew on scene*				
No	412	NA	86.4	0.001
Yes	1082	NA	79.1	

Note: NA = not applicable.

*Comparison of survival between patients with and without advanced life-support crew on scene, for the advanced life-support phase only.

Table 5: Exploratory univariable association of patient and emergency medical services factors with survival to hospital discharge for 2866* patients with major trauma

Characteristic	Survival; median (interquartile range)†		p value
	Survived n = 2334	Did not survive n = 532	
Patient	n = 2334	n = 532	
Age, yr, mean (SD)	43.8 (20.2)	56.6 (23.3)	< 0.001
Sex, no. (%) males	1656 (71.0)	349 (65.6)	0.08
Initial injury severity score	20 (16-26)	26 (25-41)	< 0.001
Glasgow Coma Scale score	n = 2282	n = 508	
Initial	15 (12-15)	6 (3-14)	< 0.001
Final	15 (13-15)	5.5 (3-14)	< 0.001
Revised trauma score	n = 2148	n = 420	
Initial	7.84 (6.90-7.84)	5.68 (3.29-7.84)	< 0.001
Final	7.84 (7.11-7.84)	5.56 (3.38-7.55)	< 0.001
Initial systolic blood pressure, mm Hg	n = 2326	n = 514	
	128 (110-146)	120 (71-158)	< 0.001
Emergency medical services	n = 2334	n = 532	
Time from receipt of call to patient side, min	9.3 (7.0-13.0)	8.8 (7.0-11.8)	0.008
Advanced life support phase of study, no. (%)	1212 (51.9)	282 (53.0)	0.67
Advanced life support at scene, no. (%)	876 (37.5)	233 (43.8)	0.008
Intubation in field, no. (%)	35 (1.5)	67 (12.6)	< 0.001
Intravenous fluid bolus administered in field, no. (%)	107 (4.6)	37 (7.0)	0.03

*Some analyses are based on fewer observations because of missing data (indicated by *n* values in columns 2 and 3).

†Unless stated otherwise.

measure at discharge and 6 months after discharge.

For most of the a priori subgroups examined, there was also no difference in survival to hospital discharge by study phase (Table 4). The exception were the 598 cases with an initial Glasgow Coma Scale score of less than 9, for whom survival was lower in the advanced life-support phase than in the basic life-support phase (60.1% v. 51.2%; $p = 0.03$). Within the advanced life-support phase, survival was lower for cases in which an advanced life-support crew attended the trauma scene than for those attended by basic life-support crews only (86.4% for basic life-support v. 79.1% for advanced life-support; $p < 0.001$). The trauma cases in both phases of this study were more severe than norms from the Major Trauma Outcome Study ($M = 0.67$ and 0.70 for basic and advanced life-support phases, respectively). The number of survivors in each phase of the OPALS Study was not substantially different from that predicted by Major Trauma Outcome Study norms ($Z = 0.72$ for basic life-support phase, $Z = -0.62$ for advanced life-support phase).

To better understand the factors influencing survival, we compared survivors with nonsurvivors (Table 5) and then conducted several logistic regression analyses to assess the effects of study interventions on patient mortality while controlling for potential confounding variables (Figure 1, Figure 2, Figure 3, Figure 4; Appendix 1, available online at www.cmaj.ca/cgi/content/full/178/9/1141/DC2). In all models,

poorer survival was associated with older age, higher injury severity score and lower revised trauma score (i.e., more severe). We found that the adjusted odds ratio (OR) for mortality between the advanced life-support and basic life-support phases was not significant when we used the revised trauma score obtained from the trauma hospital (adjusted OR 1.2, 95% confidence interval [CI] 0.9–1.7; Figure 1), but it was significant when we used the prehospital revised trauma score (adjusted OR 1.4, 95% CI 1.0–1.9; Figure 2). The presence of advanced life-support providers at the scene was associated with increased mortality (adjusted OR 1.5, 95% CI 1.1–2.0; Figure 3). In addition, intubation in the field was associated with increased mortality (adjusted OR 2.8, 95% CI 1.6–5.0; Figure 4), and intravenous fluid therapy was associated with no benefit (adjusted OR 0.8, 95% CI 0.4–1.4).

Interpretation

In this controlled clinical trial, we found that the systemwide implementation of prehospital advanced life-support did not decrease mortality or morbidity among major trauma victims. Despite the large sample, controlled design and multiple approaches to the analysis, we found no evidence of benefit in any clinically relevant subgroup of patients. To the contrary, the evidence suggested that patients with Glasgow Coma Scale scores less than 9 had worse survival during the ad-

vanced life-support phase than during the basic life-support phase. Our findings support those who believe that definitive trauma care is best provided in the operating room and that prehospital interventions may be associated with increased complications or may delay transfer to hospital.

Controlled clinical trials of critically injured patients are difficult to conduct, particularly in the out-of-hospital setting, and observers have called for better evidence from more rigorous studies.³⁻⁵ Previous evaluations of advanced life-support programs have generally had small numbers or have used observational methods.²⁰⁻²⁶ These studies generally found no support for prehospital advanced life-support

measures in major trauma. Although our study evaluated the package of interventions that is considered part of advanced life-support protocols, endotracheal intubation and intravenous fluid administration were the dominant elements of the protocols of care. We documented higher mortality among patients undergoing prehospital endotracheal intubation even after controlling for age, injury severity and physiologic measures. It seems intuitive that intubation would help some trauma patients in the field, but there is surprisingly little evidence to support aggressive airway management by paramedics. Multiple studies have found no benefit from paramedic intubation of patients with head injury.^{23,27-30}

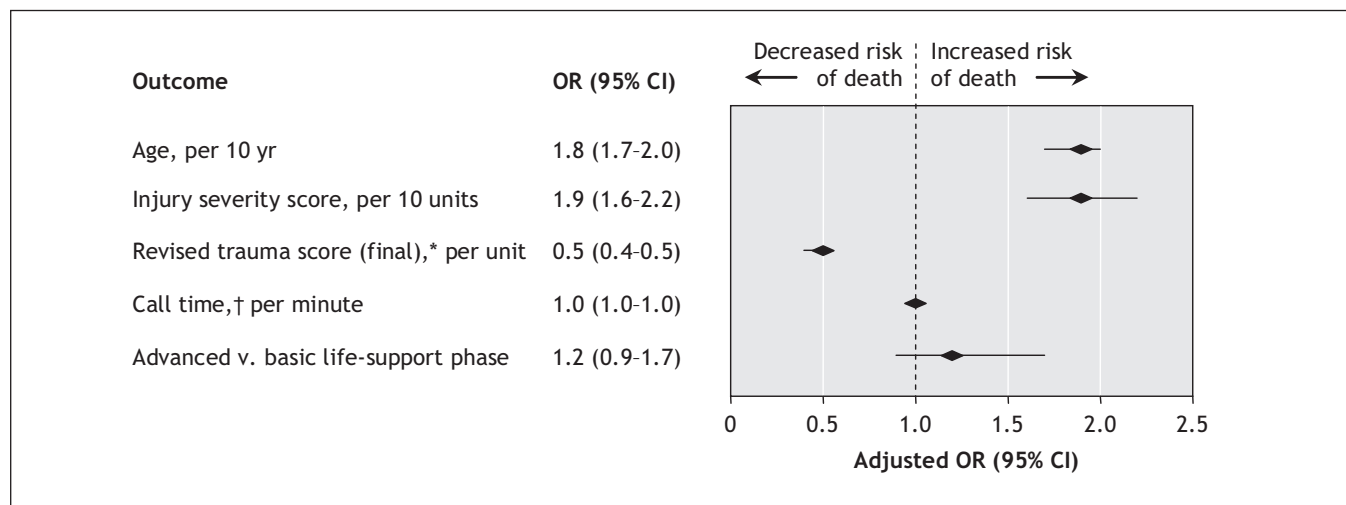


Figure 1: Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) evaluating factors associated with mortality at hospital discharge. Model incorporates study phase and final (hospital) revised trauma score as predictors of mortality. Goodness-of-fit: $p > 0.20$. *Final assessment of revised trauma score represents value from lead trauma hospital; if missing, the value from the scene was used. †Time from call received to arrival of crew at patient side.

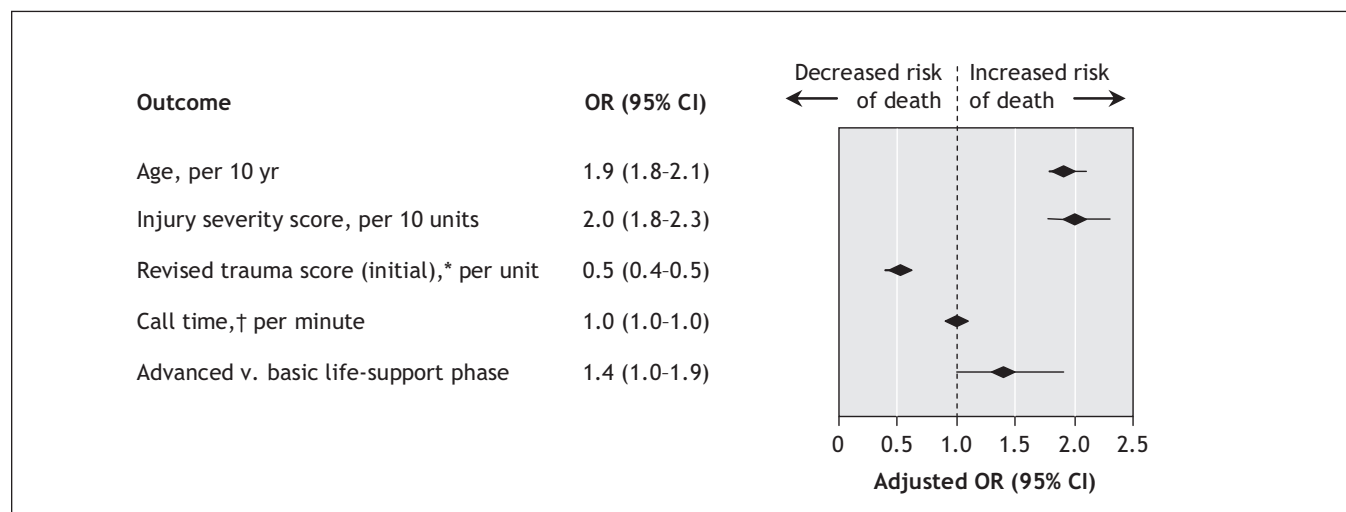


Figure 2: Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) evaluating factors associated with mortality at hospital discharge. Model incorporates study phase and initial (field) revised trauma score as predictors of mortality. Goodness-of-fit: $p > 0.20$. *Initial assessment of revised trauma score represents value from the scene; if missing, the value from the lead trauma hospital was used. †Time from call received to arrival of crew at patient side.

Other observational studies have suggested worse outcomes for patients with head injury who are intubated in the field.^{31,32} Rapid-sequence intubation techniques that employ neuromuscular blockade are particularly controversial, and expectations of benefit have not been confirmed by controlled studies.^{6,7,33-38} Three retrospective studies suggested that field intubation by ground or aeromedical paramedics was associated with better survival among patients with traumatic brain injury.³³⁻³⁵ These expectations of benefit have not been con-

firmed by controlled studies. In addition, ours was the first large-scale controlled study to evaluate intravenous fluid therapy in patients with blunt trauma and head injury, but no benefit was observed. Lack of effectiveness of intravenous fluid therapy has been previously demonstrated, especially for patients with penetrating trauma to the torso.^{8,9,39,40}

The strengths of our study include the large number of patients, the involvement of communities of differing size across a broad geographic area and a controlled design that

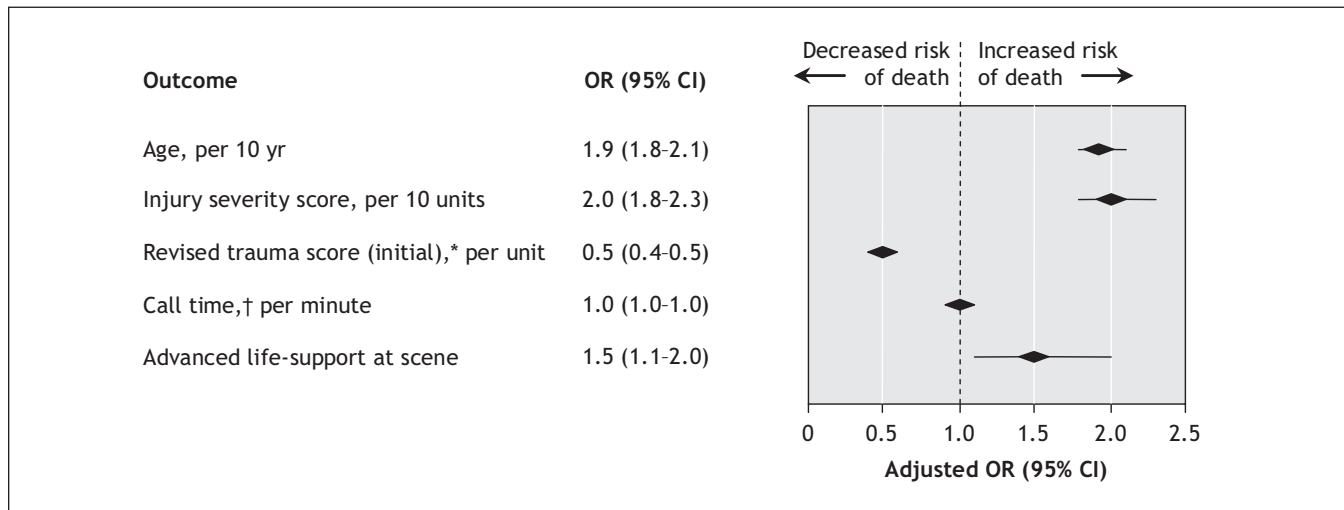


Figure 3: Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) evaluating factors associated with mortality at hospital discharge. Model incorporates advanced life-support provided at the scene as predictor of mortality. Goodness-of-fit: $p > 0.20$. *Initial assessment of revised trauma score represents value from the scene; if missing, the value from the lead trauma hospital was used. †Time from call received to arrival of crew at patient side.

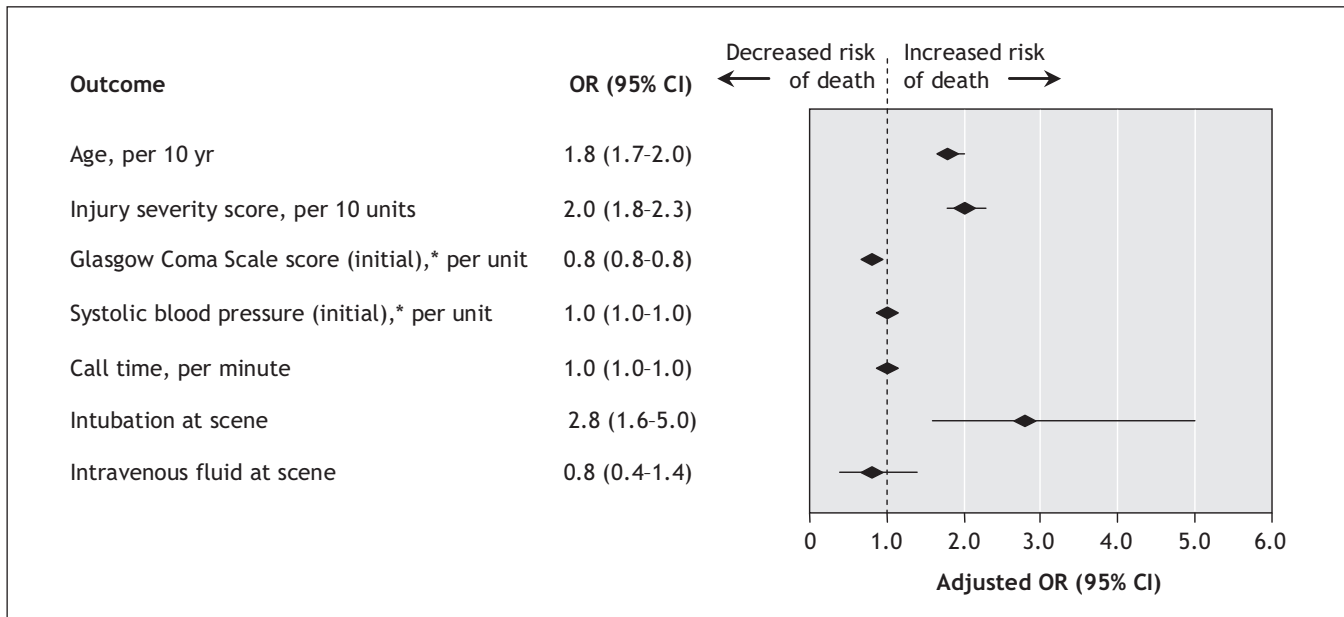


Figure 4: Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) evaluating factors associated with mortality at hospital discharge. Model incorporates advanced life-support interventions as predictors of mortality. Goodness-of-fit: $p > 0.20$. *Initial assessments of Glasgow Coma Scale score and systolic blood pressure represent values from the scene; if missing, the value from the lead trauma hospital was used. †Time from call received to arrival of crew at patient side.

included a complete population-based sample. Training of the paramedics involved 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 skills. The paramedics were skilful at performing procedures in these difficult cases; we previously demonstrated that, for patients who had experienced cardiac arrest, these same paramedics were able to successfully intubate in 93.7% of cases and to start an intravenous line in 89.0%.¹¹ The crews arrived at scene in a timely fashion (median 6.6 minutes).

An important potential limitation is that this study was designed as a before–after controlled trial, rather than as a randomized trial. However, 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 life-saving procedures from patients. Selection bias was minimized by the population-based approach, whereby all patients from the study communities who had been treated at the regional trauma centre were included. We are not aware of any important new therapies or any general societal increase in survival rates among patients experiencing major trauma during the study period. Nevertheless, multiple statistical approaches were taken to ensure the validity and robustness of our outcome measures.

The implications of this study are that community emergency medical services should carefully re-evaluate the use of advanced life-support measures for most trauma patients. Our data showed no benefit for any group of patients. Furthermore, we are concerned that the patients with head injury who had a Glasgow Coma Scale score of less than 9 appeared to have higher mortality during the advanced life-support phase than during the basic life-support phase. We note that, after controlling for age, injury severity and physiologic measures, intubation in the field had an odds ratio for mortality of 2.8. These data should lead to a re-evaluation of the indications for and application of advanced life-support measures in the field for trauma patients in urban areas. These findings cannot be extrapolated to either the care of trauma patients in rural settings or advanced life-support care for patients with nontraumatic conditions such as respiratory distress and chest pain. To prevent the deleterious effects of misplaced tubes, hypoxia and hypercapnea, prehospital intubation of trauma patients should always be accompanied by continuous pulse oximetry as well as end-tidal carbon dioxide monitoring and recording.

Conclusion

The implementation of full prehospital advanced life-support by trained paramedics was not associated with lower mortality rates relative to basic life-support measures for patients with major trauma. Furthermore, our evidence indicates that, for patients with suspected head injuries and a Glasgow Coma Scale score of less than 9, mortality was greater during the advanced life-support phase of the study than during the basic life-support phase. On the basis of these findings, we

suggest that emergency medical services should carefully re-evaluate the indications for and application of prehospital advanced life-support measures for patients with major trauma.

This article has been peer reviewed.

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Contributors: Ian Stiell and George Wells conceived the study, designed the trial and obtained research funding. Ian Stiell and Lisa Nesbitt supervised the conduct of the trial and data collection. Ian Stiell, Lisa Nesbitt, William Pickett, Douglas Munkley, Daniel Spaitte, Jane Banek, Brian Field, Lorraine Luinstra-Toohy, Justin Maloney, Joe Dreyer, Marion Lyver and Tony Campeau recruited the participating centres and managed the data, including quality control. Ian Stiell, Lisa Nesbitt, William Pickett and George Wells provided statistical advice on study design and analyzed the data. Ian Stiell drafted the manuscript, and all of the authors contributed substantially to its revision and approved the final version. Ian Stiell takes responsibility for the paper as a whole.

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