The Effect of Paramedic Rapid Sequence Intubation on Outcome in Patients with Severe Traumatic Brain Injury

Daniel P. Davis, MD, David B. Hoyt, MD, Mel Ochs, MD, Dale Fortlage, BA, Troy Holbrook, PhD, Lawrence K. Marshall, MD, and Peter Rosen, MD

Objective: To evaluate the effect of paramedic rapid sequence intubation (RSI) on outcome in patients with severe traumatic brain injury.

Methods: Adult major trauma victims were prospectively enrolled over two years using the following inclusion criteria: Glasgow Coma Scale (GCS) 3–8, suspected head injury by mechanism or physical examination, transport time > 10," and inability to intubate without RSI. Midazolam and succinylcholine were administered before laryngoscopy; rocuronium was given after tube placement was confirmed using physical examination, capnometry, syringe aspiration, and pulse oximetry. The Combitube was used as a salvage airway device. For this analysis, trial patients were excluded for absence of a head injury (Head/Neck AIS score < 2), failure to fulfill major trauma outcome study criteria, unsuccessful intubation or Combitube insertion, or death in the field or in the resuscitation suite within 30" of arrival. Each study patient was hand matched to three nonintubated historical controls from our trauma registry using the following parameters: age, sex, mechanism of injury, trauma center, and AIS score for each body system. Controls were excluded for Head/Neck AIS defined by a c-spine injury or death in the field or in the resuscitation suite within 30" of arrival. χ^2, odds ratios, and logistic regression were used to investigate the impact of RSI on the primary outcome measures of mortality and incidence of a "good outcome," defined as discharge to home, rehabilitation, psychiatric facility, jail, or signing out against medical advice.

Results: A total of 209 trial patients were hand matched to 627 controls. The groups were similar with regard to all matching parameters, admission vital signs, frequency of specific head injury diagnoses, and incidence of invasive procedures. Mortality was significantly increased in the trial cohort versus controls for all patients (33.0% versus 24.2%, $p < 0.05$) and in those with Head/Neck AIS scores of 3 or greater (41.1% versus 30.3%, $p < 0.05$). The incidence of a "good outcome" was lower in the trial cohort versus controls (45.5% versus 57.9%, $p < 0.01$). Factors that may have contributed to the increase in mortality include transient hypoxia, inadvertent hyperventilation, and longer scene times associated with the RSI procedure.

Conclusion: Paramedic RSI protocols to facilitate intubation of head-injured patients were associated with an increase in mortality and decrease in good outcomes versus matched historical controls.

Key Words: Brain injury, Head trauma, Intubation, Paramedics, RSI outcome.

J Trauma. 2003;54:444–453.

Prehospital hypoxia and hypotension have been associated with increased mortality in patients with severe traumatic brain injury.[1–4] Aggressive prehospital airway protocols including rapid sequence intubation (RSI) by aeromedical crews and specially trained paramedics have been instituted in many systems to improve intubation success.[5–16] Multiple reports have demonstrated an increase in intubation success rates and minimal reported complications with prehospital RSI.[13,17–19] Our own experience with paramedic RSI includes successful airway management in 99% of patients, including 84% with orotracheal intubation (OTI) and 15% with Combitube (The Kendall Company, Mansfield, MA, U.S.A.) insertion (CTI) and no unrecognized esophageal intubations. As a result, airway management success rates for severely head-injured patients in our prehospital system increased from 39% in the pre-trial period to 86% during the trial.[20,21]

Despite improvements in prehospital intubation success with aggressive airway protocols, there have been relatively few attempts to document the effect on outcome. In a retrospective cohort analysis, Winchell and Hoyt reported a 10-percent absolute survival benefit from paramedic intubation without the use of neuromuscular blocking agents.[8] Garner et al. documented improved survival in trauma patients treated by aeromedical physicians versus patients transported by ground paramedics; however, there was not an independent benefit from intubation, with the improvements in survival likely a result of early blood administration.[22] The goal of this analysis was to explore the impact of paramedic RSI on outcome in severely head-injured patients.

Submitted for publication October 13, 2002.

Accepted for publication December 5, 2002.

From the Department of Emergency Medicine (D.D., P.R.), Department of Surgery, Division of Trauma, Department of Surgery (D.H., D.F., T.H.), and Division of Neurosurgery (L.M.), UC San Diego, and San Diego County Emergency Medical Services (M.O.), San Diego, California, U.S.A.

Presented at the 61st Annual Meeting of the American Association for the Surgery of Trauma, September 26–28, 2002, Orlando, Florida.

Support for this project was received from the Society for Academic Emergency Medicine.

Address for correspondence: Daniel Davis, MD, UCSD Emergency Medicine, 200 West Arbor Drive, #8676, San Diego, California, U.S.A. 92103-8676

DOI: 10.1097/01.TA.0000053396.02126.CD

PATIENTS AND METHODS

Design

Subjects were prospectively enrolled and hand-matched to historical nonintubated controls from the same prehospital

Table 1 Rapid Sequence Intubation Medication Protocols Used During the Trial

Medication	Small 80–140 lbs. (35–63 kg)	Average 141–225 lbs. (63–100 kg)	Large >225 lbs. (>100 kg)
Midazolam	2 mg	2.5 mg	3.0 mg
Succinylcholine	4 ml (80 mg)	6 ml (120 mg)	8 ml (160 mg)
Rocuronium	4 ml (40 mg)	6 ml (60 mg)	8 ml (80 mg)
Morphine	2 mg every 10 min for "stress response" (SBP >140 mmHg, HR >100 BPM)		

SBP, systolic blood pressure; HR, heart rate; BPM, beats per minute.

system. The enrollment period for this analysis was from November 1998 through November 2000. Waiver of consent was granted by the California State EMS Authority and from the Investigational Review Board for each participating institution.

Setting and prehospital system

San Diego County has a population of almost 3 million with an area of 4,261 square miles. Advanced life support is provided by 12 different agencies, with all but one agency participating in the trial. There are approximately 110,000–120,000 emergency transports each year of which about 30% are trauma related. Responses for major trauma victims are two-tiered, with a minimum of two paramedics dispatched to each call. In addition, aeromedical crews consisting of a flight nurse and either a specially trained flight paramedic or Emergency Medicine resident respond from two bases at the request of ground crews. Five designated adult trauma centers receive all major trauma victims. For this trial, paramedics attended an 8-hour training course to learn the RSI procedure and medications and Glasgow Coma Scale (GCS) scoring and to review ventilation procedures and CTI techniques.

Subjects

The target population for this study was adult major trauma victims with severe head injuries. Inclusion criteria were as follows: 1) apparent age 18 years or older; 2) major trauma victim per county protocols; 3) suspected head injury by mechanism or physical examination findings; 4) GCS score 3–8; and 5) estimated time for transport to the resuscitation suite 10 minutes or greater. Paramedics first attempted intubation without RSI medications. Patients were enrolled in the trial if intubation attempts were unsuccessful or in the presence of a clenched jaw or airway reflexes inhibiting laryngoscope blade insertion. Patients were excluded for inability to achieve intravenous (IV) access or if cardiopulmonary resuscitation (CPR) were required before administration of RSI medications.

Interventions

Trial patients were monitored with three-lead ECG and pulse oximetry and were pre-oxygenated for a minimum of 60 seconds using a non-rebreather mask. If oxygen saturation remained below 95%, then bag-valve-mask (BVM) ventilations were instituted before medication administration. Midazolam was administered for sedation if SBP was 120 mm Hg or greater; succinylcholine was used to achieve neuromuscular blockade. Once tube position was confirmed, rocuronium was administered to maintain paralysis during transport. Additional midazolam was administered after 30 minutes if SBP remained 120 mm Hg or greater. Morphine sulfate was given for a "stress response," defined as a SBP greater than 140 mm Hg and a heart rate greater than 100 BPM. A simplified, weight-based dosing system was used (Table 1).

Paramedics then attempted endotracheal (ET) intubation; after a maximum of three unsuccessful ET intubation attempts, CTI was mandated. The anterior cervical collar was loosened and manual in-line stabilization held during all intubation attempts; the Sellick maneuver was performed upon administration of medications. Tube position was confirmed using direct visualization, bilateral breath sounds and absent gastric air sounds, qualitative capnometry, syringe aspiration, and pulse oximetry. If all intubation attempts were unsuccessful, further laryngoscopy attempts were abandoned and BVM ventilation performed until spontaneous respirations resumed. Paramedics were taught standard ventilation parameters of 12 breaths per minute and a tidal volume of 800 cc; practice with a stopwatch and spirometer was incorporated into the training session. During the second year of the trial, one agency instituted the use of continuous end-tidal CO2 (ETCO2) monitoring; paramedics from this agency were instructed to adjust ventilation parameters to target an ETCO2 value of 30–35 mm Hg and avoid values of less than 25 mm Hg.

Data collection

Prehospital data are entered into an electronic database of all EMS patients transported in San Diego County. In addition, a field worksheet served as both a protocol guide and a data collection tool for RSI trial patients. One of the principal investigators was contacted immediately following delivery of each RSI patient for a 15-minute telephone debriefing to confirm proper GCS score calculation based on reported physical examination findings and obtain additional data regarding prehospital course. Finally, data for each trauma patient meeting major trauma outcome study criteria are entered into a county trauma registry; hospital admission summaries, including head injury diagnosis and invasive procedures, are available for most registry patients. Abstracted data were entered into an Excel (Microsoft, Redmond, WA, U.S.A.) database for further analysis.

Matched Controls

The primary objective for this analysis was to determine the effect of prehospital RSI on outcome in severely head-injured patients. Exclusion criteria for this analysis included: 1) inability to be intubated (OTI or CTI) by prehospital personnel following administration of RSI mediations; 2) absence of a head injury (Head/Neck AIS less than 2); 3) Head/Neck AIS defined by a neck injury; 4) failure to fulfill MTOS criteria; and 5) death in the field or resuscitation suite within 30 minutes of arrival. Each of the remaining study patients was hand matched to three nonintubated historical controls from the county trauma registry using the following criteria: age, sex, mechanism of injury, trauma center, ISS, Head/Neck AIS score, Face AIS score, Chest AIS score, Abdomen AIS score, Extremities AIS score, and Skin AIS score. The two individuals responsible for matching were blinded to outcome. Controls were excluded for death in the field or within 30 minutes of arrival in the resuscitation suite and if the Head/Neck AIS score were defined by a cervical spine injury rather than a head injury. Although the registry includes patients from the past 10 years, preference was given to selecting patients from the preceding 5 years.

Data Analysis

Patients were pooled into a trial cohort and a control cohort for analysis. The primary outcome measures were mortality, defined as death before hospital discharge, and incidence of a "good outcome," which included discharge to home, rehabilitation, psychiatric facility, jail, or signing out against medical advice. In our trauma system, discharge to rehabilitation requires anticipation of some degree of functional recovery and is not used for patients expected to require long-term support. In addition, a small group of trial patients underwent primary management by aeromedical crews, with RSI medications administered by the flight paramedic and the intubation performed by the flight nurse. Separate analyses were performed after exclusion of these patients and their matched controls and for patients with more severe head injuries (Head/Neck AIS of 3 or greater).

Trial patients and controls were also compared with regard to each of the matching parameters: presenting vital signs, scene times, arterial blood gas (ABG) values, and serum ethanol. Available admission summaries were used to determine the incidence of head injury diagnoses (contusion/intraparenchymal hemorrhage, subdural hematoma, epidural hematoma, cerebral edema, subarachnoid hemorrhage, and skull fracture) and the incidence of invasive procedures (craniotomy, laparotomy, and thoracotomy). Finally, the mortality impact of hyperventilation, multiple intubation attempts, OTI versus CTI, and location of the RSI procedure (on scene versus en route) were explored using actual versus predicted mortality, calculated for each trial patient using the mean survival for the three matched controls. The median arrival pCO2 value was used as a threshold to defined hyperventilation.

Statistical analysis

The primary outcome measures of mortality and a "good outcome" as defined above were analyzed using χ^2, with the association between outcome and RSI status quantified using the odds ratio. In addition, logistic regression was used to investigate the association between mortality and RSI status, controlling for age, sex, Head/Neck AIS, Chest AIS, Abdomen AIS, scene time, and admission SBP. Rank sum and *t*-testing were used when appropriate to compare RSI patients and controls with regard to matching and clinical parameters. Descriptive statistics were used to explore the impact of hyperventilation, multiple intubation attempts, CTI versus OTI, and location of RSI on outcome. Statistical significance was attributed to a *p*-value less than 0.05. Statistical calculations were performed using SAS/STAT (SAS Institute Inc., Cary, NC, U.S.A.).

RESULTS

During the 2-year study period, 250 patients were enrolled in the trial. Two patients were intubated before paramedic contact but received midazolam and rocuronium en route to the trauma center; another patient was taken to a nontrauma center and was excluded from further analysis. In addition, four patients did not receive succinylcholine per the study protocol. One began vomiting after receiving midazolam and did not receive succinylcholine, while a second patient mistakenly received a tenth dose of succinylcholine and never achieved relaxation. In the other two cases, paramedics arrived at the trauma center before administering succinylcholine and elected not to continue the procedure. All four patients underwent successful intubation in the trauma resuscitation suite. Of the remaining 243 patients, 242 (99%) underwent successful airway management, including 212 (87%) OTI patients and 30 (12%) CTI patients.

Of the 242 patients undergoing successful airway management, 10 were excluded for a Head/Neck AIS score less than 2, and 16 were excluded for not fulfilling MTOS criteria. One of these had a myocardial infarction while driving and hit a parked car at low speed, but was unresponsive due to a dysrhythmia. Another patient sustained an arterial gas embolism while scuba diving, and four others were ultimately determined to have nontraumatic intracranial hemorrhage. In addition, three patients were declared dead in the field and four died in the resuscitation suite within 30 minutes of arrival; all seven had severe multi-system traumatic injuries and were felt to be nonsalvageable (Table 2).

The remaining 209 patients were hand-matched to 627 controls from the county trauma registry. Matching parameters are displayed in Table 3 with no significant differences observed between the two groups. Scene time, arrival vital

Table 2 Trial Patients Excluded from This Analysis Using Criteria Determined a Priori

Reason for Exclusion	No. of Patients
Protocol violation	5
No succinylcholine given	4
Inappropriate succinylcholine dose	1
Did not meet MTOS criteria	16
Discharge <24 hours	10
Cerebrovascular accident	4
Myocardial infarction with dysrhythmia	1
Arterial gas embolism while scuba diving	1
Trauma victim with Head/Neck AIS score of 0 or 1	10
Death in resuscitation suite <30 minutes after arrival	4
Death in field	3
Intubated prior to paramedic contact	1
Taken to nontrauma center	1
Failure to intubate	1

MTOS, major trauma outcome study; AIS, abbreviated injury score.

signs and ABG values, and serum ethanol are displayed in Table 4. Of note, scene times were longer, arrival pO2 values higher, and arrival pCO2 values lower in the RSI cohort. In addition, the incidence of inadvertent severe hyperventilation, defined as an arrival pCO2 value of 25 mm Hg or less was significantly higher in the RSI cohort versus controls. Admission summaries were available for a total of 561 control patients (83%) and 173 RSI patients (83%). Head injury diagnoses and the incidence of invasive procedures were similar between the two cohorts (Table 5).

With regard to the primary outcome measures, there was a statistically significant increase in mortality and decrease in "good outcomes" in the RSI cohort versus controls; this was also true for patients with Head/Neck AIS scores of 3 or greater and after exclusion of six aeromedical patients and their matched controls (Table 6). There were no statistically significant differences between the groups with regard to the number of days in the ICU or total hospital length of stay. Logistic regression revealed a statistically significant effect on mortality for RSI status (trial patient versus control) controlling for all other variables modeled (Table 7). The hospital day of death was similar between the two groups, with a bimodal distribution of deaths on hospital days 1 or 2 and on hospital days 4 and 5 (Fig. 1).

Using the predicted mortality defined above, we explored the effect of inadvertent hyperventilation on outcome using the median arrival pCO2 value of 33 mm Hg as a threshold. Hyperventilated RSI patients (pCO2 less than the median value of 33 mm Hg) appeared to have an increased mortality when compared with nonhyperventilated RSI patients; the groups were similar with regard to other parameters (Table 8). A similar increase in mortality was observed for patients undergoing a single (versus multiple) intubation attempt, CTI patients, and those intubated en route (Tables 9–11).

Table 3 Age, Sex, Mechanism of Injury, Abbreviated Injury Scores, and ISS for the RSI Cohort ($n = 209$) Versus Pooled Matched Controls ($n = 627$)

Parameter	Controls (%)	RSI (%)	*p* Value
Demographics			
Age (years)	36.8	37.1	0.629
Male sex	81	81	0.918
Mechanism of injury			
Motor vehicle accident	39	39	0.935
Fall	23	23	0.924
Assault	8	8	0.884
Bike accident	5	5	0.858
Motorcycle accident	5	5	0.852
Peds vs. auto	10	10	0.894
Gunshot wound	5	5	0.852
Found down	3	3	0.811
Other	2	2	0.771
Abbreviated injury scores			
Head/Neck (mean)	3.92	3.91	0.930
2	20	20	0.881
3	14	15	0.777
4	19	20	0.880
5	45	44	0.779
6	1	1	1.000
Face (mean)	0.56	0.62	0.519
0	72	69	0.451
1–2	22	25	0.417
3+	6	6	0.864
Chest (mean)	1.01	1.24	0.155
0	69	63	0.137
1–3	20	22	0.552
4–6	12	15	0.206
Abdomen (mean)	0.58	0.67	0.473
0	80	77	0.325
1–3	15	17	0.509
4–6	12	15	0.206
Extremities (mean)	0.98	0.92	0.692
0	61	62	0.870
1–2	18	20	0.605
3+	21	18	0.157
Skin (mean)	0.96	0.96	0.917
0	18	23	0.157
1+	82	77	0.157
ISS (mean)	26.3	27.6	0.222

RSI, rapid sequence intubation; ISS, injury severity score.

DISCUSSION

Despite multiple studies documenting the adverse effects of hypoxia on outcome in patients with severe traumatic brain injury, there is a paucity of evidence to suggest that an aggressive approach to airway management leads to improvements in mortality. Here we document a mortality increase in patients undergoing paramedic RSI when compared with matched historical controls from the same prehospital system. This increase was most profound in patients with higher Head/Neck AIS scores, with mortality of 41.1% in the RSI cohort versus 30.3% in controls. In addition, there was a corresponding decrease in "good outcomes" for the RSI cohort, defined as discharge to home, rehabilitation, psychiatric facility, jail, or signing out against medical advice.

Table 4 Scene Time, Arrival SBP, Arterial Blood Gas Values, and Serum Ethanol for RSI Patients (n = 209) Versus Pooled Matched Controls (n = 627)

	Controls	RSI	*p* Value
Minutes on scene (mean)	16.4	22.8	<0.0001
Systolic blood pressure			
Mean (mmHg)	138.4	138.6	0.907
SBP ≤90 mmHg (%)	6.4	6.8	1.000
ABG data			
pH (mean)	7.36	7.36	0.850
pO2 (mean in mmHg)	216	315	<0.0001
pCO2 (mean in mmHg)	38.3	34.9	<0.0001
Base excess (mean)	−3.4	−4.3	0.002
Inadvertent hyperventilation (%)	8.0	15.4	0.014
Mean serum ethanol (mg/dl)	101	111	0.656

RSI, rapid sequence intubation; SBP, systolic blood pressure; ABG, arterial blood gas.

The critical challenge in interpreting these results is to determine whether the mortality increase in the RSI cohort is an unanticipated consequence of the procedure itself or instead represents some inequity between the trial patients and their matched controls. The two cohorts appeared to be equivalent on all parameters we measured, including age, sex, AIS values for each body system, ISS, arrival SBP, head injury diagnoses, and incidence of invasive procedures. Absent from our matching criteria, however, was GCS score, which can be predictive of outcome in head-injured patients. Before the trial, field GCS was not consistently calculated and when obtained reflected arrival GCS rather than immediately upon arrival. Admission GCS values were available for the control cohort but were recorded as a value of 3 or omitted from most trial patients, as they were paralyzed and intubated. We felt that the use of individual body system AIS scores provided more consistent and accurate matching. In addition, the head injury diagnoses and incidence of invasive procedures were similar between the two groups.

Table 5 Incidence of Head Injury Diagnoses and Invasive Procedures from Review of Available Admission Summaries for Controls (n = 521) and RSI Patients (n = 173)

Outcome measure	Controls (%)	RSI (%)	*p* Value
Head injury diagnoses			
Contusion/intraparenchymal hematoma	53.6	53.8	0.967
Subdural hematoma	40.1	42.8	0.598
Epidural hematoma	27.6	25.4	0.641
Skull fracture	38.2	34.7	0.461
Subarachnoid hemorrhage	38.2	46.2	0.075
Cerebral edema	24.8	27.7	0.497
Invasive procedures			
Craniotomy	22.6	17.9	0.228
Laparotomy	8.8	11.0	0.489
Thoracotomy	2.3	4.0	0.343

RSI, rapid sequence intubation.

Table 6 Primary Outcome Measures for the RSI Cohort (n = 209) Versus Controls (n = 627)

Outcome measure	Controls (%)	RSI (%)	Odds ratio
Mortality			
All patients	24.2	33.0	1.6 (1.1–2.2)*
Head/neck AIS 3 or greater	30.3	41.1	1.6 (1.1–2.3)*
Non-aeromedical	24.3	33.0	1.6 (1.1–2.2)*
Good outcome¶			
All patients	57.9	45.5	1.6 (1.2–2.3)†
Head/neck AIS 3 or greater	49.3	37.5	1.6 (1.1–2.3)†
Non-aeromedical	58.3	45.8	1.7 (1.2–2.3)‡
Total days in ICU	6.0	7.1	NS
Total days in hospital	14.5	12.2	NS

* $p < 0.05$
† $p < 0.01$
‡ $p < 0.001$
¶ Odds ratios calculated with "good outcome" as the reference variable.

RSI, rapid sequence intubation; AIS, abbreviated injury scale; ICU, intensive care unit; NS, non-significant.

We excluded patients intubated in the field without RSI medications from both the trial and control cohorts. If a higher percentage of these patients existed before the trial, this would create a selection bias toward more neurologically intact patients in the pool of patients from which we selected the controls. Our previous analysis reveals the opposite to be true, however, with a higher percentage of patients intubated without RSI medications during the trial.[21] This would have selected more neurologically intact patients for inclusion in the trial, although the impact is likely small. We also considered whether the RSI procedure and early intubation merely prolonged life for a few hours in patients who otherwise might have died in the field or the resuscitation suite and been excluded from analysis. Figure 1 demonstrates that the hospital day of death was similar between the two cohorts, with no increase in deaths on hospital days 1 and 2 observed in the RSI cohort.

If the differences in outcome represent a true negative effect of paramedic RSI, then it is imperative that factors potentially responsible for the increase in mortality be thoroughly investigated. One possibility concerns the incidence of inadvertent hyperventilation, which was significantly higher in the RSI group. This phenomenon has been docu-

Table 7 Logistic Regression Model Investigating the Impact of RSI and Head/Neck AIS on Mortality for All Patients Together (n = 836)

Parameter	Adjusted OR*	*p* Value
RSI	1.6	0.03
Head/Neck AIS	73.0	<0.0001

* Adjusted for age, sex, Chest AIS, Abdomen AIS, admission SBP, and scene time.

RSI, rapid sequence intubation; AIS, abbreviated injury scale; OR, odds ratio.

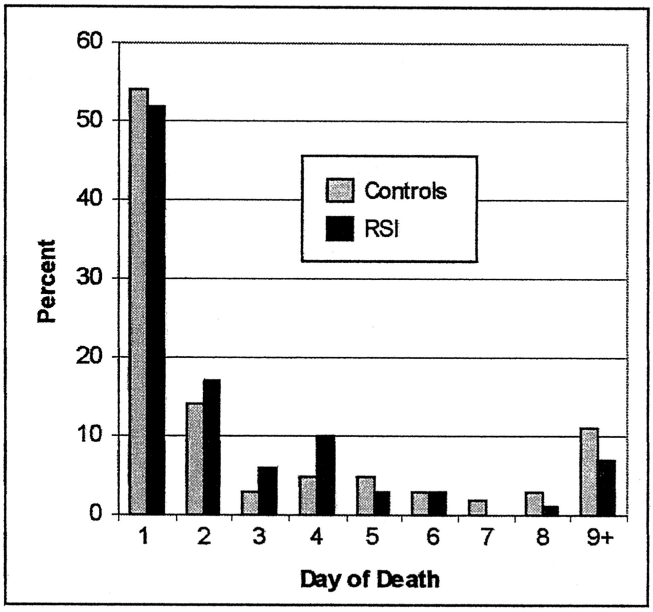

Fig. 1. *Hospital day of death for RSI patients (n = 209) controls (n = 627).*

mented previously with both paramedics and aeromedical crews, but the impact on outcome is unknown.[23] While hyperventilated and nonhyperventilated patients appeared to be equivalent on all parameters measured, the mortality was higher for RSI patients with lower arrival pCO2 values versus their predicted outcomes as compared with those with higher pCO2 values. The introduction of ETCO2 monitors may allow more accurate control of ventilation and avoid potential complications related to hyperventilation.

The introduction of ETCO2 monitors also allowed pulse oximetry data to be recorded and stored for later analysis. Using these data, we documented transient hypoxia in over half of patients undergoing ETCO2 monitoring, with many of these developing concurrent bradycardia.[24] This is substantially higher than the 15–20% incidence of hypoxia reported for trauma intubations performed in the resuscitation suite.[25] While the impact of transient hypoxemia on head injury is unknown, the concurrent hemodynamic instability we observed suggests a systemic effect that may be even more significant to the injured brain.

Patients with multiple intubation attempts appeared to do slightly better than those intubated on the first attempt. While this may seem counterintuitive, patients undergoing multiple attempts at intubation may have been monitored more closely, with paramedics quickly abandoning an attempt at

Table 8 Effect of Hyperventilation on Outcome Using the Median Arrival pCO2 Value of 33 mmHg as Threshold

	RSI patients with pCO2 <33 mmHg (n = 100)	RSI patients with pCO2 ≥33 mmHg (n = 101)
Mortality		
RSI cohort (%)	39.0	25.7
Predicted (%)	27.3	23.1
Years of age (mean)	38.2	35.4
Sex (% male)	79.0	83.2
Abbreviated Injury Scores (mean)		
Head/Neck	3.98	3.80
Face	0.55	0.72
Chest	0.91	1.55
Abdomen	0.66	0.70
Extremities	0.77	1.13
Skin	0.99	0.94
ISS (mean)	26.6	28.5
Mean arrival SBP (mean)	134.0	142.6

RSI, rapid sequence intubation; ISS, injury severity score; SBP, systolic blood pressure.

Table 9 Effect of Multiple Intubation Attempts on Outcome

	RSI patients with single intubation attempt (n = 123)	RSI patients with multiple intubation attempts (n = 86)
Mortality		
RSI cohort (%)	37.4	26.7
Predicted (%)	23.6	25.2
Years of age (mean)	36.1	38.5
Sex (% male)	80.5	80.2
Abbreviated Injury Scores (mean)		
Head/Neck	3.86	3.99
Face	0.56	0.70
Chest	1.17	1.35
Abdomen	0.72	0.58
Extremities	0.86	1.01
Skin	0.95	0.97
ISS (mean)	27.7	27.5
Mean arrival SBP (mean)	133.0	146.4

RSI, rapid sequence intubation; ISS, injury severity score; SBP, systolic blood pressure.

Table 10 Effect of CTI Versus OTI on Outcome

	RSI patients with Combitube insertion (n = 28)	RSI patients with orotracheal intubation (n = 181)
Mortality		
RSI cohort (%)	39.3	32.0
Predicted (%)	26.2	23.9
Years of age (mean)	39.0	36.9
Sex (% male)	89.0	79.0
Abbreviated Injury Scores (mean)		
Head/Neck	4.14	3.89
Face	1.00	0.57
Chest	1.46	1.20
Abdomen	0.82	0.64
Extremities	0.96	0.91
Skin	0.93	0.96
ISS (mean)	29.6	27.3
Mean arrival SBP (mean)	136.4	137.3

CTI, Combitube insertion; OTI, orotracheal intubation; RSI, rapid sequence intubation; ISS, injury severity score; SBP, systolic blood pressure.

Table 11 Effect of Performing RSI on Scene Versus En Route on Outcome

	Patients undergoing RSI on scene (n = 140)	Patients undergoing RSI en route (n = 69)
Mortality		
RSI cohort (%)	31.4	36.2
Predicted (%)	25.7	21.3
Years of age (mean)	36.4	38.6
Sex (% male)	80.7	79.7
Abbreviated Injury Scores (mean)		
Head/Neck	3.99	3.77
Face	0.66	0.52
Chest	1.32	1.09
Abdomen	0.72	0.55
Extremities	0.94	0.90
Skin	0.95	0.97
ISS (mean)	28.6	25.7
Mean arrival SBP (mean)	140.5	134.4

RSI, rapid sequence intubation; ISS, injury severity score; SBP, systolic blood pressure.

the first sign of desaturation or hemodynamic instability. This is difficult to extract from these data, and further analysis of the ETCO2 recordings may lead to a better understanding of this phenomenon. Patients undergoing CTI appeared to have slightly poorer outcomes; however, these patients appeared to have more severe injuries. Nevertheless, the effect of CTI on hemodynamics, cerebral perfusion, and ICP has not been documented.

Another factor that may play a role in outcome is the delay in transport associated with RSI, especially when the procedure was performed on scene rather than en route. The impact of this delay is unclear, especially since the incidence of significant chest or abdominal trauma that might lead to hemorrhagic shock was relatively low. Nevertheless, rapid transport to a designated trauma center has been demonstrated to improve outcome, and the impact of additional prehospital delays cannot be discounted. We observed slightly worse outcomes in patients undergoing RSI en route. The initial SBP was lower in this group, possibly explaining the decision to transport sooner and potentially accounting for some of the increase in mortality. There may also have been additional challenges and complications with the RSI procedure performed in the back of a moving ambulance.

It is important to note the relatively high number of trial patients (n = 67) ultimately determined to have either a minor concussion or no head injury. A small number of these had significant nontraumatic disease that might also have benefited from aggressive airway management, including hemorrhagic stroke and cardiac dysrhythmia; however, most of these had normal neurologic examinations upon arrival at the trauma center. Fortunately, none had complications related to the RSI procedure or early intubation, but their existence underscores the need to consider the impact of RSI protocols on patient selection. Ultimately, additional variables, such as hypoxia or the absence of airway reflexes, may need to be incorporated into the decision regarding the use of RSI. It is also interesting to note that the mean arrival pO2 value for nonintubated controls was 216 mm Hg, which is well into the therapeutic range.

It is important to consider the limitations of this analysis in interpreting these results. While the RSI and control cohorts appeared to be identically matched, there may have been other parameters we did not consider that could account for the increase in mortality in the RSI cohort. Ultimately, a randomized trial is warranted to further investigate the impact of prehospital RSI on outcome in head-injured patients. Based on these data, the San Diego Paramedic RSI Trial was suspended until an avoidable cause for the increase in mortality could be determined.

Several important factors were identified that warrant further attention in other prehospital systems considering paramedic RSI. The high incidence of inadvertent hyperventilation and transient hypoxia and their potentially detrimental effect on outcome suggest that the procedure should be performed only after intensive training and with use of sophisticated monitoring devices. In addition, the use of GCS alone as indication for RSI may be too limited, and other factors, such as loss of airway reflexes or hypoxia despite supplemental oxygen, deserve further investigation as indictors of the need for invasive airway management. Finally, the experience of the paramedics performing RSI should be considered. The paramedics in our prehospital system have significant experience with advanced airway skills; however, performing RSI every one or two years may lead to a decay in familiarity with the RSI procedure. Ultimately, a small group of specially trained paramedics with significant airway experience and ongoing training may be safer and more efficient in applying RSI to the prehospital environment.

CONCLUSIONS

Paramedic RSI improves intubation success rates but is associated with an increase in mortality and decrease in "good outcomes" when compared with hand-matched controls. These differences may reflect inherent inequities between the two groups, although they appeared similar on all parameters we measured. Alternatively, the increase in mortality may be related to inadvertent hyperventilation, transient hypoxic episodes, and prolonged scene times associated with the RSI procedure.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the contributions made by the San Diego County Base Hospital and Trauma Departments, American Medical Response, San Diego Medical Services Enterprise, Mercy Air, county flight nurses, the RSI Educational Task Force and trainers, paramedic provider agency coordinators, Palomar and Southwestern Colleges, the County of San Diego Division of EMS bio-statistical team, the California EMS Authority, and especially the paramedics throughout San Diego County whose enthusiastic support made the study possible. The authors particularly note David Bailey, RN, Ginger Ochs, RN, Gina Anderson, RN, Kelly Forman, RN, and Mark Angeloni, RN, for their training contributions.

REFERENCES

1. Chesnut RM, Marshall LF, Klauber MR, et al. The role of secondary brain injury in determining outcome from severe head injury. *J Trauma.* 1993;34:216–222.
2. Pigula FA, Wald SL, Shackford SR, Vane DW. The effect of hypotension and hypoxia on children with severe head injuries. *J Pediatr Surg.* 1993;28:310–316.
3. Stocchetti N, Furlan A, Volta F. Hypoxemia and arterial hypotension at the accident scene in head injury. *J Trauma.* 1996;40:764–767.
4. Kokoska ER, Smith GS, Pittman T, Weber TR. Early hypotension worsens neurological outcome in pediatric patients with moderately severe head trauma. *J Pediatr Surg.* 1998;33:333–338.
5. Smith JP, Bodai BI. The urban paramedic's scope of practice. *JAMA.* 1985;253:544–548.
6. Aprahamian C, Darin JC, Thompson BM, Mateer JR, Tucker JF. Traumatic cardiac arrest: Scope of paramedic services. *Ann Emerg Med.* 1985;14:583–586.
7. Hatley T, Ma OJ, Weaver N, Strong D. Flight paramedic scope of practice: Current level and breadth. *J Emerg Med.* 1998;16:731–735.
8. Winchell RJ, Hoyt DB. Endotracheal intubation in the field improves survival in patients with severe head injury. *Trauma Research and Education Foundation of San Diego Archives of Surgery*. 1997; 132:592–597.
9. McDonald CC, Bailey B. Out-of-hospital use of neuromuscular-blocking agents in the United States. *Prehosp Emerg Care.* 1998; 2:29–32.
10. Karch SB, Lewis T, Young S, Hales D, Ho CH. Field intubation of trauma patients: Complications, indications, and outcomes. *Am J Emerg Med.* 1996;14:617–619.
11. Doran JV, Tortella BJ, Drivet WJ, Lavery RF. Factors influencing successful intubation in the prehospital setting. *Prehospital and Disaster Medicine.* 1995;10(4):259–64.
12. Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. *Ann Emerg Med.* 2001;37:32–37.
13. Sing RF, Reilly PM, Rotondo MF, Lynch MJ, McCans JP, Schwab CW. Out-of-hospital rapid-sequence induction for intubation of the pediatric patient. *Acad Emerg Med.* 1996;3:41–45.
14. Syverud SA, Borron SW, Storer DL, et al. Prehospital use of neuromuscular blocking agents in a helicopter ambulance program. *Ann Emerg Med.* 1988;17:236–242.
15. Vilke GM, Hoyt DB, Epperson M, Fortlage D, Hutton KC, Rosen P. Intubation techniques in the helicopter. *J Emerg Med.* 1994;12:217–224.
16. Falcone RE, Herron H, Dean B, Werman H. Emergency scene endotracheal intubation before and after the introduction of a rapid sequence induction protocol. *Air Med J.* 1996;15:163–167.
17. Wayne MA, Friedland E. Prehospital use of succinylcholine: A 20-year review. *Prehosp Emerg Care.* 1999;3:107–109.
18. Pace SA, Fuller FP. Out-of-hospital succinylcholine-assisted endotracheal intubation by paramedics. *Ann Emerg Med.* 2000; 35:568–572.
19. Hedges JR, Dronen SC, Feero S, Hawkins S, Syverud SA, Shultz B. Succinylcholine-assisted intubations in prehospital care. *Ann Emerg Med.* 1988;17:469–472.
20. Ochs M, Davis DP, Hoyt DB, Bailey D, Marshall LM, Rosen P. Paramedic-performed rapid sequence intubation of severely head-injured patients. *Ann Emerg Med.* 2002;40:159–167.
21. Davis DP, Ochs M, Hoyt DB, Marshall LM, Rosen P. Standing Orders for Paramedic Rapid Sequence Intubation Improves Prehospital Intubation Success in Severe Head-injured Patients. *J Trauma.* (in press).
22. Garner A, Crooks J, Lee A, Bishop R. Efficacy of prehospital critical care teams for severe blunt head injury in the Australian setting. *Injury.* 2001;32:455–460.
23. Thomas SH, Orf J, Wedel SK, Conn AK. Hyperventilation in traumatic brain injury patients: Inconsistency between consensus guidelines and clinical practice. *J Trauma.* 2002;52:47–53.
24. Doney M, Dunford J, Ochs M. Transient hypoxemia during rapid sequence intubation by paramedics for closed head injury [abstract]. *Prehosp Emerg Care.* 2002;6:148–149.
25. Omert L, Yeaney W, Mizikowski S, Protetch J. Role of the emergency medicine physician in airway management of the trauma patient. *J Trauma.* 2001;51:1065–8.

DISCUSSION

Dr. David H. Livingston (Newark, New Jersey): This excellently written study covers an important topic—does allowing field paramedics to perform RSI in the field improve outcome with patients with traumatic brain injury? There is really little to offer these patients other than removing mass lesions and avoiding hypotension and hypoxia and probably hypercapnia. Thus, it would seem logical that intubating them in the field would be beneficial. However, despite really a very nice, elegant study and an analysis that tortured the data until it would confess, the authors could not show a benefit of RSI in patients with RSI who did worse no matter how they cut the data.

As this argument is currently played out in my own home state of New Jersey and elsewhere, I can assure the audience that I used this data to try to quash paramedic RSI in my own state.

The authors began to articulate some of the issues here—unrecognized hypoxia during the intubation and over aggressive ventilation that resulted in some of the respiratory parameters. Clearly, this study also shows that the time in the field was increased in patients undergoing RSI. In the argument between the scoop and run and stay and play, scoop and run once again wins out.

Lastly, the study again demonstrates the concept: just because you can do something, maybe you shouldn't. During my fellowship, Dr. Richardson kept referring to this as if the only tool you have is a hammer, and everything begins to look like a nail. Thus, if we give the paramedics the ability to intubate, they will want to intubate again and again.

Who do you think really was benefiting from this procedure if there was anybody benefiting from it in the field?

In our own estimation, looking at 1,200 RSIs in our emergency department, maybe 10 to 15 or 20 percent of patients, max, would benefit; thus, a lot of people would be intubated in the field, and you'd wonder whether they should.

How much did this whole program cost? If you were going to go forward to do this, how do you keep the paramedics recurrently training, especially if they are only doing one or two a year, and how much does this cost in an ongoing program?

Lastly, given your data, I have a big question. Are you going to pull this from the paramedics in the field? Clearly, your data at a 3:1 cohort match looks pretty good that patients are doing worse.

Dr. Daniel P. Davis (San Diego, California): The principal investigators met 2 days after the data was analyzed, and they decided to suspend the trial until we could determine whether the increase in mortality was a true effect of RSI or whether there was some error in the way that we had done the matching. In continuing to analyze the data for the subsequent 6 months, we could not come up with anything to suggest that these 2 groups were inappropriately matched. Thus, we have not reinitiated the trial, and within the past month, the California State EMS Board voted to discontinue the trial.

We have discussed performing a different trial in the future that might utilize a select group of medics who undergo more specific training. That introduces the question about the cost of training. For this trial, all medics who went through the training course were eligible to perform RSI regardless of how many intubations they had accumulated. Over 500 medics went through an 8-hour training course for which they were compensated. Instructors were also paid, and course materials, including home study aids, were supplied to the medics. In addition, there were administrative costs, not to mention the cost of medication and equipment. I'm sure you can imagine that it's a fairly substantial endeavor. Of note, specific refresher courses were not required, bringing up the issue of a decay in skills with time.

We are looking at the number of medication and protocol violations and have noticed that they appear to increase as a function of time following the initial training module. Anecdotally, medics have told me that they feel less comfortable with the procedure several years out from the training course, especially if they hadn't been involved with an RSI in the interim. The data collection sheet also served as a cheat sheet for the medics, helping guide them through the procedure, but anybody who has performed RSI knows that it's infinitely more complex than something that can be performed from a cookbook.

As far as who benefits from the procedure, we have not yet identified a particular RSI subgroup that does better than their matched controls. This analysis pooled all RSI patients and all controls, breaking the line between each patient and his or her matched controls. Future analyses may retain this link to investigate the role of certain parameters in determining outcome and defining patients who may benefit from RSI. I think there were many patients who were doing just fine on their own and did not require RSI, opposed to patients who were hypoxic despite supplemental oxygen or bag valve mass ventilation and likely benefitted from intubation.

Dr. Richard J. Mullins (Portland, Oregon): I think the authors have carefully examined the value of rapid sequence intubation and demonstrated that, with it, patients had improved survival in the prehospital phase in the later time period.

If you improve airway management in patients with brain injury, one consequence should be that more patients will survive to be admitted to your trauma center, but some will still expire because of their lethal brain injury. Vital statistics records regarding patients who die of unintended injury generally show that 60 to 80 percent of blunt trauma patients expire at the scene.

My question relates to your measure of survival. Would not 6-month survival be a better indicator in brain-injured patients of whether you benefited patients with your process of rapid sequence intubation?

Dr. Daniel P. Davis (San Diego, California): Originally, one arm of this study was intended to use the Glasgow Outcome Scale to determine long-term outcome, however it quickly became apparent that the only patients that we could find consistently were the dead ones, and the lack of follow-up became the fatal flaw for that part of the study. We were limited to using data available from the trauma registry, which meant that once a patient left the hospital, they were lost to follow up.

Dr. James W. Davis (Fresno, California): I, too, commend the authors on this study, however I'm wondering if the outcomes aren't even worse than were suggested. Should the failure to intubate be part of an intent to treat analysis? In other words, you can make an airway a whole lot worse by attempting to instrument it, and then, if you don't get that airway, those patients may, indeed, do worse. Further, you excluded all your early deaths and your scene deaths. Did any of those patients have an unrecognized or a missed intubation or an esophageal intubation?

Dr. Daniel P. Davis (San Diego, California): Those are excellent questions, and I think that those questions would have even more relevance if we had demonstrated a benefit with RSI. If we had performed an intent to treat analysis, we most likely would have observed even greater mortality in the RSI group.

Of the 7 deaths that occurred in the field or within 30 minutes of arrival, all had severe multi-system injuries that were deemed to be nonsurvivable. It was not thought to be the RSI procedure itself that lead to the death. Conversely, there were patients who did not have significant injuries but in whom the medics had difficulty establishing an airway, with hypoxic injury noted on CT scans, although none resulted in death.

Dr. Arthur L. Trask (Vienna, Virginia): The scenario that you described is a reverse of what we have done in Fairfax, Virginia, where there is only a select group, probably 10 or fewer, that are allowed to do RSI. They are all related to the helicopter services in that area. Our statistics are totally the opposite of what yours are, and that is that we don't do RSI if they're less than 10 minutes from the hospital, or if they can be there with the scoop and run technique. However, in those areas where we can't get there because of the traffic and so on, the helicopter comes in, picks them up, and does RSI. The mortality statistics in those patients were significantly different, 30 percent improved mortality in our RSI group. The training of 10 people is a lot different than the training of 600, and that's why we have kept it to that size group.

Dr. Daniel P. Davis (San Diego, California): I agree. I think that the future of prehospital RSI is going to require more intensive training for a select group of people, be they air medical teams or a small group of specially trained medics who may or may not work in every prehospital system.

Our enrollment criteria required that the transport time be an estimated 10 minutes or longer; thus "scoop and haul" was still the standard when closer to the trauma center.

Dr. Randal M. Chesnut (Portland, Oregon): This is a very nice study, and this methodology becomes quite definitely Class II when it reaches peer-reviewed publication. The question will then be when it generates a lot of discussion, to whom will this be not generalizable? In other words, San Diego is sort of a specific situation—the history of the trauma system, the set up of short transport times, etc. In what communities would this not be applicable? What does it take as a baseline to consider applying such an RSI protocol?

Dr. Daniel P. Davis (closing): In any city that was considering adding RSI to the scope of practice for all medics, I think this is going to give them significant pause. If the situation is such that a "strike team" of specially trained medics can be stationed at several locations in a particular city and quickly reach the scene to perform RSI, it may still be worth considering.

In southern California, where the cities are 50 to 100 or more miles wide, it's not feasible to have specially trained teams of medics who will require 30 to 45 minutes to get to any particular scene. In this scenario, air medical teams are the only viable option to perform RSI.

As far as paramedic RSI is concerned, i think it must be special trained "strike teams" stationed at various points in a city where they could easily get to any scene in a timely fashion. Even in such an idealized scenario, there is not enough evidence that early intubation improves outcome in traumatic brain injury.