

THE USE OF NEUROMUSCULAR BLOCKING AGENTS AND ADVANCED SEDATION BY FIELD EMT-PARAMEDICS FOR MORE EFFECTIVE AIRWAY MANAGEMENT IN ADULT TRAUMA PATIENTS WITH GLASGOW COMA SCORE OF 8 OR LESS

#### SUCCINYLCHOLINE

ROCURONIUM

MIDAZOLAM

Paramedic Scope of Practice Trial Study Final Report—Addendum

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#### **INTRODUCTION**

Paramedics from San Diego County EMS began a prospective trial using neuromuscular blocking agents as part of a rapid sequence intubation (RSI) protocol in August 1998. Following a one-day training module that included an original video to teach Glasgow Coma Scale (GCS) scoring, paramedics administered midazolam and succinylcholine to selected patients to facilitate endotracheal intubation. Inclusion criteria included: adult major trauma victim, suspected head injury, GCS 3-8, unable to be intubated without RSI, and transport time greater than 10 minutes. Following RSI medication administration, paramedics were allowed three laryngoscopy attempts; patients unable to be intubated underwent Combitube<sup>™</sup> insertion. Confirmation of tube position was made using direct observation, syringe aspiration, capnometry, and pulse oximetry. Once tube position was confirmed, rocuronium was administered to maintain paralysis during transport; morphine was used for a "stress response," defined by hypertension and tachycardia.

The first year's experience with these protocols was reviewed to determine the ability of paramedics to successfully follow these protocols. The overall incidence for successful airway management was greater than 99 percent, including over 84 percent endotracheally intubated and 15 percent undergoing Combitube<sup>™</sup> insertion. Perhaps more importantly, there were no unrecognized esophageal intubations and excellent oxygenation, and the standardized ventilation protocols were successful in maintaining a target pCO2 of 35 mmHg, as defined by neurosurgical guidelines. There were no reported complications, and the low incidence of post-procedure hypotension was attributable to critical injuries. Absent from our preliminary analysis was outcome data to determine the efficacy of these protocols in preventing secondary injury in patients sustaining severe head trauma. This supplement reports the initial analysis including hospital data obtained from the San Diego County Trauma Registry.

### **METHODS**

Inclusion criteria and interventions have been described in our previous report. In brief, adult major trauma victims with a mechanism of injury or physical exam consistent with potential head injury, a GCS score of 8 or less, and an estimated transport time greater than 10 minutes to one of five trauma centers were eligible for enrollment. Paramedics were instructed to attempt intubation without paralytics; however, inability to intubate or intact airway reflexes were indications to administer RSI medications. Midazolam and succinylcholine were used for RSI, rocuronium was used for continued paralysis during transport following intubation, and morphine was used for a "stress response" (hypertension and tachycardia). Paramedics were given three attempts at intubation, defined by laryngoscope blade insertion with or without attempts to pass an ET tube; if this was unsuccessful, Combitube<sup>™</sup> insertion was indicated. Tube placement was confirmed using physical exam, capnometry, syringe aspiration, and pulse oximetry.

For this supplement, trial patients were compared to historic controls taken from the San Diego County Trauma Registry. Three controls were hand matched for each trial patient using the following criteria: hospital of admission, age, gender, mechanism of injury, Head/Neck Abbreviated Injury Score (AIS), and other body region AIS values (Chest, Abdomen/Pelvis, Extremity, Face, Skin). Patients whose Head/Neck AIS was defined by a neck injury were eliminated to better match

head injured patients. Each trial patient and control was reviewed to assure that all inclusion criteria were met. All trial patients were pooled to form the treatment group, and all matched controls were pooled to form the control group for comparison. Exclusion criteria included: not transported to trauma center by paramedics, absence of head injury (Head/Neck AIS less than 2 or absence of ICD-9 Code defining a head injury), failure to intubate following RSI (study group) or successful prehospital intubation (control group), death within 30 minutes of trauma center arrival, or incomplete registry data.

Descriptive statistics were used to compare the two groups with regard to demographic data, AIS values, toxicology screen results, and vital signs. The primary outcome measure was survival to hospital discharge for all patients and for those with significant head injuries (defined by Head/Neck/AIS of 3 or greater). Secondary outcomes included length of stay, ICU days, arrival ABG data, advanced procedures (craniotomy, laparotomy, thoracotomy, ventriculostomy, ICP monitor insertion), incidence of complications such as pneumonia and ARDS, discharge location (home, rehabilitation, skilled nursing facility, other hospital, psychiatric facility, or jail). In addition, the number of controls requiring immediate intubation (in the resuscitation suite) was evaluated. Data were analyzed using multivariate analysis, chi-square, and t testing.

#### RESULTS

A total of 172 study patients were admitted to four of the five trauma centers from August 1998 through November 2000. Data from the remaining trauma center was unavailable for this preliminary analysis and is not included here. Two patients were unable to be intubated and two patients had incomplete data, requiring exclusion from the analysis. Thirteen additional patients were excluded due to an absence of head injury or death within 30 minutes (generally declared dead immediately upon arrival). The remaining 155 patients were included in the final analysis. A total of 465 historic controls were hand matched from the Trauma Registry and fulfilled all inclusion criteria. The two groups were similar with regard to demographic data, AIS values, admission vital signs, and toxicology screen results (see Table 1).

With regard to the primary outcome measure (survival to hospital discharge), there were no significant differences observed between the two groups. A greater number of controls were discharged home; however, this may reflect the impact of managed care with patients being transferred to plan hospitals, or an evolution in alternative health care facilities, over the past decade rather than a true difference in outcomes. Study patients had a lower duration of admission but a greater number of ICU days. Arterial blood gas data revealed a higher pO2 and a lower pCO2 among study patients. With regard to the pulmonary complications, there did not appear to be significant differences between the two groups; the differences in the incidence of ARDS, atelectasis, and pleural effusion reflect a change in the scoring system instituted since the trial began and likely do not reflect real differences. A higher percentage of controls required either craniotomy or invasive ICP monitoring; the incidence of thoracotomy and laparotomy were similar between the two groups. All of these results are displayed in Table 1.

### CONCLUSIONS

In this preliminary analysis, we were unable to demonstrate any differences in mortality between the study group and controls. One possibility is that early prehospital intubation using RSI does not contribute significantly to outcome in severely head-injured patients. Certainly, traumatic brain injury is a complex, multifactorial disease, and it is challenging at best to demonstrate a treatment effect of any one factor. The paramedics demonstrated great success in successfully intubating patients who otherwise would not have been intubated, as the incidence of intubations without neuromuscular blockade did not change before and after the trial. Oxygenation and ventilation were optimized, with supranormal pO2 values and successful achievement of our target pCO2 value (35 mmHg). Furthermore, almost half of the severely injured controls were intubated in the trauma suite, indicating the emergent need for invasive airway control. Conversely, many controls, especially those with Head/Neck AIS scores of 2 (indicating a "concussion" or brief loss of consciousness) did not require intubation, while the study patients to which they had been matched were intubated in the field. This did not appear to lead to an increase in complications or in total length of hospital stay, although the number of ICU days did increase slightly.

The second possibility is that the methodology used here made it difficult to demonstrate any real difference that exists between the two groups. While a randomized, controlled trial may be methodologically superior, previous attempts in other systems have led to inadequate power due to the relative paucity of severely head-injured patients or intergroup heterogeneity, generally due to inclusion criteria that were not stringent enough. The matching process used here was extremely rigorous and could only be done in a system such as ours where trauma care is standardized and a comprehensive database of patients exists. As Table 1 demonstrates, the patient groups were virtually identical, and the exclusive use of severely head-injured adult trauma patients resulted in a relatively homogeneous group. It is also possible that prehospital RSI had a detrimental effect on patient outcome, although this cannot be concluded from the data presented here. We could not demonstrate an increase in complications that would have led to a mortality difference; however, further analysis of data from the field and inclusion of additional patients may help illuminate this issue.

The final possibility is that a lack of statistical power led to our inability to demonstrate a mortality difference in either direction. Inclusion of additional patients, both from the fifth trauma center and through continued enrollment of trial patients, should improve this aspect of our study. In addition, continued enrollment of patients will strengthen our ability to perform subgroup analyses to determine the effect of early intubation on selected patient groups and injuries. Thus, it is our recommendation that patients continue to be enrolled to best evaluate the question of early prehospital intubation using RSI for head-injured patients.

## TABLE 1.

	N=155	N=465	
	<b>RSI GROUP</b>	CONTROLS	
<b>DEATHS</b>	45 - 29%	104 - 22%	p=.11 6
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AMA	3	14	
ECF	13	33	
Ноте	36	200	
Jail	2	6	
Other Hosp	22	52	
Psych	0	1	
Rehab	34	55	
DEATHS WITH H/N AIS > 2	45/123 = 37%	103/364 = 28%	p=.10 6
ICU_DAYS	7.79 / 0.75	5.88 / 0.44	0
LOS	12.61 / 1.27	15.10 / 1.77	
ISS	26.96 / 1.11	25.59 / 0.65	
H_AIS	3.82 / 0.09	3.83 / 0.05	
F_AIS	2.05 / 0.08	2.00 / 0.05	
C_AIS	3.34 / 0.14	3.14 / 0.07	
A_AIS	2.71 / 0.14	2.83 / 0.10	
E_AIS	2.44 / 0.07	2.57 / 0.04	
S_AIS	1.20 / 0.03	1.12 / 0.01	
AGE	36.66 / 1.36	36.59 / 0.89	
Males	123	372	
Females	32	93	
A_BP	139.32 / 2.91	136.57 / 2.61	
A_PR	104.86 / 2.29	97.16 / 1.24	
ICP_RR	4	15	
TUBED_RR	15	184	

PH	7.36 / 0.01	7.36 / 0.01
PO2	294 / 14.2	192 / 6.81
PCO2	34.8 / 0.94	38.61 / 0.59
BE	-4.44 / 0.59	-3.40 / 0.27
BLD_ALCO		
NOT DONE	86	151
Result of 0	30	145
Detect but less than .08	9	25
In excess of legal limit	30	144
DRUG_SCREE		
Not Done	97	246
Negative	21	133
Positive	37	76
THC/Cannabis	13	17
Cocaine	3	15
PCP	0	4
Benzodiazapines	26	13
Barbiturates	1	3
Narcotics/Opiates	6	22
Amphetamines	7	29
Methamphetamines	6	13
CRANI	23	100
THOR	2	3
LAP	14	37
BOLT	11	54
VENTRIC	8	18
COMPLICATIONS Abscess	0	1
ARDS	3	30

Aspiration/Pneumonia	6	13
Atelectasis	7	54
Empyema	0	1
Fat Embolus	0	0
Hemothorax	0	1
Pneumonia	20	72
Pneumothorax(barotrauma)	2	11
Pneumothorax(iatrogenic)	2	9
Pneumothorax(recurrent)	0	5
Pneumothorax(tension)	0	0
Pulmonary Edema	0	2
Pulmonary Embolus	0	3
Respiratory Failure/Distress	0	16
Upper A/W Obstruction	0	0
Pleural Effusion	1	7
Other	11	13