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Prehospital Intubation is Associated with Favorable Outcomes and Lower Mortality in ProTECT III

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Abstract

Objective: Traumatic brain injury (TBI) causes more than 2.5 million emergency department visits, hospitalizations, or deaths annually. Prehospital endotracheal intubation has been associated with poor outcomes in patients with TBI in several retrospective observational studies. We evaluated the relationship between prehospital intubation, functional outcomes, and mortality using high quality data on clinical practice collected prospectively during a randomized multicenter clinical trial.

Methods: ProTECT III was a multicenter randomized, double-blind, placebo-controlled trial of early administration of progesterone in 882 patients with acute moderate to severe nonpenetrating TBI. Patients were excluded if they had an index GCS of 3 and nonreactive pupils, those with withdrawal of life support on arrival, and if they had documented prolonged hypotension and/or hypoxia. Prehospital intubation was performed as per local clinical protocol in each participating EMS system. Models for favorable outcome and mortality included prehospital intubation, method of transport, index GCS, age, race, and ethnicity as independent variables. Significance was set at $\alpha = 0.05$. Favorable outcome was defined by a stratified dichotomy of the GOS-E scores in which the definition of favorable outcome depended on the severity of the initial injury.

Results: Favorable outcome was more frequent in the 349 subjects with prehospital intubation (57.3%) than in the other 533 patients (46.0%, $p = 0.003$). Mortality was also lower in the prehospital intubation group (13.8% v. 19.5%, $p = 0.03$). Logistic regression analysis of prehospital intubation and mortality, adjusted for index GCS, showed that odds of dying for those with prehospital intubation were 47% lower than for those that were not intubated (OR = 0.53, 95% CI = 0.36–0.78). 279 patients with prehospital intubation were transported by air. Modeling transport method and mortality, adjusted for index GCS, showed increased odds of dying in those transported by ground compared to those transported by air (OR = 2.10, 95% CI = 1.40–3.15).

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Decreased odds of dying trended among those with prehospital intubation adjusted for transport method, index GCS score at randomization, age, and race/ethnicity (OR = 0.70, 95% CI = 0.37–1.31).

Conclusions: In this study that excluded moribund patients, prehospital intubation was performed primarily in patients transported by air. Prehospital intubation and air medical transport together were associated with favorable outcomes and lower mortality. Prehospital intubation was not associated with increased morbidity or mortality regardless of transport method or severity of injury.

Keywords

prehospital intubation; traumatic brain injury; TBI; air ambulance; ground transport; outcomes

Introduction

Traumatic brain injury (TBI) results in more than 2.5 million annual emergency department (ED) visits in the United States.[1] Of these, approximately 87% of patients are treated and released, 11% are hospitalized and subsequently discharged, and 2% die from associated injury during the incident hospital admission.[1] There are 5.3 million Americans living with disability from TBI.[2] The direct (treatment and care) costs of TBI are estimated to be $9.22 billion per year, with productivity losses estimated at $51.21 billion.[3] Productivity losses associated with TBI are estimated to be higher than those associated with any other traumatic injury (ex: spinal cord, torso, system-wide).[3]

Research over the past three decades has not identified a pharmacologic agent that improves outcomes after TBI.[2,4] The phase III Progesterone for Traumatic Brain Injury Experimental Clinical Treatment Trial (ProTECT III) studied the effect of intravenous (IV) progesterone on outcome in subjects with acute TBI.[2] Important data on non-protocol specific clinical care choices, such as ET intubation, were collected for the ProTECT III subjects. Previous research has described significant concerns regarding the relationship between aggressive approaches to endotracheal intubation (i.e., prehospital intubation) among those with TBI.[5–10] Our own previous research in a retrospective observational study of 981 patients showed a correlation between emergent intubation (ED and field intubations combined) and increased risk of morbidity and mortality in patients with TBI, even after controlling for potential selection biases, such as injury severity.[11] This increased risk ranged from an odds ratio (OR) of 14.3 (95% CI = 9.4–21.9) in a simple association to an adjusted OR of 5.9 (95% CI = 3.2–10.9) in a multivariable analysis.[11]

Others have also reported an association between out-of-hospital endotracheal intubation and adverse outcomes after severe TBI, including increased odds of poor neurologic outcome (OR = 1.61; 95% CI = 1.15–2.26) and decrease in survival (OR = 0.36; 95% CI = 0.32–0.42).[6,10] Registry data have previously demonstrated that ED intubation is associated with increased risk of fatal outcome when compared with non-intubated patients (OR = 3.1; 95% CI = 2.1–4.5) and field intubations (OR = 3.0; 95% CI = 1.9–4.9).[12] Interestingly, an Australian study of adults with severe TBI found that prehospital rapid sequence intubation by paramedics increased the rate of favorable neurologic outcome at 6 months compared

with delayed intubation in the hospital.[13] Recent literature describes the challenges of balancing the risks and benefits of out-of-hospital endotracheal intubation in TBI and how optimal outcomes should require choosing the right patients and avoiding hyperventilation after intubation in these patients.[14]

The ProTECT III clinical trial was a rigorously conducted study with strict guidelines on in-hospital management. This study provides a unique opportunity to examine the effects of prehospital intubation on a well-controlled population of moderate to severe TBI patients.

Our hypothesis prior to initiating the exploration of our data was that prehospital endotracheal intubation would be associated with worse outcomes when compared to similar patients who were not intubated in the population of patients participating in the ProTECT III trial.

Methods

The ProTECT III clinical trial methodology has been described in detail previously.[2] Briefly, PROTECT III was a multi-site, randomized, double-blind, placebo-controlled clinical trial that was designed to determine the efficacy of early administration of IV progesterone versus placebo for treating subjects with acute nonpenetrating TBI caused by a blunt mechanism. This trial was funded by the National Institute of Neurological Disorders and Stroke (NINDS) and was conducted through the NINDS-funded Neurological Emergencies Treatment Trials (NETT) Network.

The ProTECT III trial was performed at 49 trauma centers in the United States. Eligible patients were adults with severe, moderate-to-severe, or moderate TBI due to blunt mechanism of trauma, with a Glasgow Coma Scale (GCS) score of 4 to 12. The index GCS was defined as the highest GCS prior to enrollment (whether obtained in the field or at the hospital prior to enrollment). All three components (eyes, verbal, motor) were required to be documented in order for it to be considered valid. Patients who met inclusion criteria were enrolled if the study treatment could be initiated within 4 hours of injury. Patients were excluded if they had an index GCS of 3 and nonreactive pupils, if they had withdrawal of life support on arrival, and if they had a documented prolonged episode of hypotension and/or hypoxia. The primary objective of ProTECT III was to determine whether progesterone is associated with an increase in favorable outcome after TBI. Adherence to both study protocol and the TBI clinical standardization (CST) guidelines were monitored daily by a central monitoring team. ProTECT III was conducted under FDA code 21 CFR 50.24, exception from informed consent for emergency research.

Each participating site was required to train emergency medical technicians (EMTs) on the trial protocol, including performance and documentation of the three-part GCS in the field, along with prehospital treatment expectations, including: avoidance of low oxygen saturations (<90% saturation) and/or prolonged hypotension in the field (SBP <90 mmHg). Different EMS systems were allowed to intubate or not based on their standard treatment protocols. Whether a subject was intubated in the field or not was recorded along with other clinical data.

Eligible patients were randomized to receive an infusion containing progesterone or placebo. Randomization was performed with the use of a combination of minimization and biased-coin algorithms to avoid imbalances in initial injury severity, sex, age, and enrollment site. The primary endpoint was defined as functional recovery determined by the use of the Extended Glasgow Outcome Scale (GOS-E) at 6 months after randomization. A favorable outcome was defined with the use of a stratified dichotomy of the GOS-E scores in which the definition of favorable outcome depended on the severity of the initial injury (see Table 1). This allows for comparison of outcomes based on the original severity of injury, thus a patient with a severe injury may be as likely to have a favorable outcome as a moderate injury and favorable outcomes in patients with mild injury may not be detectable. We selected variables for our analyses that were included in the measures obtained during the primary study. We are limited by the lack of other known confounders such as RSI, mechanism of injury and other variables used for the propensity score used in previous literature.[6] However, in these large retrospective studies, the propensity scores tended to *decrease* the negative impact of intubation on morbidity and mortality.[6] Race/ethnicity was of interest to assess differences in the clinical trial participation and outcomes. We found that adjustment was needed for transport method, iGCS score at randomization, age and race/ethnicity in the analysis of favorable outcome and mortality vs. pre-hospital intubation.

The primary objective of this secondary analysis is to determine the association between prehospital intubation on favorable outcomes and mortality in the ProTECT III trial. The specific hypothesis to be tested was if prehospital intubation is associated with excess morbidity and mortality, even after controlling for other known clinical confounders.

Statistical Analysis

Proportions were calculated for categorical data and means and standard deviations for continuous data. Statistical tests of association for categorical variables were assessed using the chi-square test and the independent samples t-test was utilized for continuous variables…

We assessed separate multivariable logistic regression models for two primary outcomes: favorable outcome and mortality. Independent variables identified and included in the models were prehospital intubation, method of transport, iGCS score at randomization, age, and race/ethnicity. All tests were two-sided and the level of significance was set at $\alpha = 0.05$. Statistical analyses were performed using Stata 14 (StataCorp, College Station, TX).

Results

A total of 882 subjects were randomized into the ProTECT III trial. In the original study, the groups were well balanced with respect to demographic and baseline characteristics.[2] In this study, we assessed demographic and baseline characteristics after stratifying by prehospital intubation (Table 2). Of particular notice, among those that were prehospital intubated, 80% arrived to the hospital by air and 20% by ground, whereas among those that did not have a prehospital intubation, 8% arrived by air, 91% by ground, and 1% other not ground certified. There were also differences in who was intubated when assessed by race. Blacks were less likely to be intubated in the pre-hospital setting (16%) compared to Hispanics (37%) and

non-Hispanic whites (49%). Those classified as “severe” by the iGCS score at randomization were more likely to have a prehospital intubation compared to “moderate” and “moderate to severe” categories (61.5% of severe patients compared to 27.6% and 38.8%, respectively).

Outcomes at six months, stratified by prehospital intubation are shown in Table 3. Favorable outcome was higher in the prehospital intubation group (57.3%) compared to those that were not intubated in the prehospital environment (46.0%) ($\chi^2 = 11.3$, $p = 0.001$). Mortality was lower in the prehospital intubation group (13.8%) when compared to the non-prehospital intubated group (19.5%) ($\chi^2 = 4.9$, $p = 0.03$). These results show a statistically significant association between prehospital intubation and favorable outcome (OR = 1.62; 95% CI = 1.22–2.15), as well as prehospital intubation and mortality (OR = 0.66; 95% CI = 0.45–0.95).

Overall, significant differences were found in favorable outcomes and mortality based on severity level and transport method. Of note, among patients transported by air, mortality was 12.2%; whereas, among ground transported patients, mortality was 20.3%. Thus, there was a statistically significant association between transport method and mortality (OR = 0.54; 95% CI = 0.37–0.81. Also, mortality was lowest in the moderate group (13.0%) compared to the moderate-to severe (16.1%) and severe groups (27.6%) ($p < 0.001$).

We conducted a sub-analysis limiting the analysis to patients with more severe injury, GCS 4–8. Compared to those with GCS score 9–12, we found that 567 (64%) of the entire study sample of 882 subjects had a GCS score between 4–8 and 254 (29%) had a GCS score between 9–12. As reported earlier, for the entire study sample, among those with a prehospital intubation, 61% had a favorable outcome and 14% died. Among those with GCS 4–8 and a prehospital intubation, 67% had a favorable outcome and 14% died. Among those with GCS 9–12 and a prehospital intubation, 39% had a favorable outcome and 4% died. Lastly, among those with GCS 4–8 and air transport, those with a prehospital intubation had 68% with a favorable outcome and 13% died. Those with GCS 9–12 and air transport, 36% had a favorable outcome and 4% died. We also conducted analyses stratified by sites that had higher or lower levels of study subjects and prehospital intubation rates, but there were no significant differences.

Due to the high correlation of transport method and prehospital intubation, we modeled each separately before conducting multivariable analyses. Logistic regression analysis examining mortality and prehospital intubation, adjusting for index GCS score at randomization, showed that the odds of dying for those who were prehospital intubated were 47% lower than the odds for those that were not intubated (OR = 0.53, 95% CI = 0.36–0.78). When examining mortality and transport method, adjusting for index GCS score at randomization, the odds of dying for those that were transported by ground were 2.10 times higher than the odds of dying for those that were transported by air (OR = 2.10, 95% CI = 1.40–3.15). For favorable outcome and prehospital intubation, adjusting for index GCS score at randomization, logistic regression analyses showed that the odds of a favorable outcome for those who were prehospital intubated were 36% higher than the odds for those that were not intubated (OR = 1.36, 95% CI = 1.01–1.83). For favorable outcome and transport method,

adjusting for index GCS score at randomization, the odds of a favorable outcome for those that were transported by ground were 31% lower than the odds for those that were transported by air (OR = 0.69, 95% CI = 0.51–0.93).

Multivariable analyses were completed using outcomes defined as favorable versus unfavorable (Table 4). Independent variables were selected based on their potential as confounding variables and our model included prehospital intubation, transport method, index GCS score at randomization, age, and Outcomes at 6 months race/ethnicity variables. These results showed the same trend as our earlier analyses. For subjects that had a prehospital intubation, the odds of a favorable outcome were 10% higher than the odds of a favorable outcome for those that were not prehospital intubated (OR = 1.10, 95% CI = 0.69–1.76), adjusted for transport method, baseline GCS score at randomization, age, and race/ethnicity.

The multivariable model with death as the outcome (Table 5) showed that for those that had a prehospital intubation, the odds of dying were 30% lower than the odds of dying for those that were not prehospital intubated (OR = 0.70, 95% CI = 0.37–1.31), adjusted for transport method, index GCS score at randomization, age, and race/ethnicity.

Discussion

The results of this analysis were contrary to what was expected based on the literature, which shows a strong association between prehospital intubation and worsening morbidity and mortality in subjects with moderate to severe TBI.[6,10,11] Our simple bivariate analyses provided evidence of lower mortality among those treated with prehospital intubation. However, due to the high correlation between air transport and prehospital intubation, we lost power to separate the impact of prehospital transport by air and intubation in our multivariable model. In a similar manner, the number of patients intubated and transported by ground was also too low to make a strong conclusion about beneficial associations. However, the trend in these groups was still in the same direction and opposite that expected from prior studies. Overall, we still observed a negative association between prehospital intubation and mortality. Our hypothesis that patients intubated in the field would have worse outcomes when compared to similar patients who were not intubated prior to arrival in the emergency department was rejected by these results.

Our results are similar to those found by Davis et al. in a retrospective, registry-based study where they showed prehospital intubation was associated with improved outcomes from TBI when the subjects were transported by air rather than ground.[15] Our findings provide an extension of these results by using data from a multi-center prospective randomized-controlled trial. Prehospital intubation and air medical transport are not only correlated with each other but the severity of injury is greater in this group based on the iGCS.

Our secondary analyses are hypothesis generating; however, it is important to note that these results indicate the opposite direction of association from that expected given several large previously reported pre-hospital studies. Important confounders which may contribute significantly to increased morbidity and mortality associated with intubation in TBI patients

include: hyperventilation, hypotension, hypoxia, and misplaced endotracheal tubes.[5,13,16–18] The ProTECT III trial excluded patients with documented prolonged hypotension and/or hypoxia. Additionally, EMS TBI treatment guidelines published prior to initiation of the study include instructions for prehospital personnel to avoid hyperventilation. One plausible explanation for this unexpected result is the exclusion of patients with these major potential confounders (hypotension and hypoxia), EMS education regarding hyperventilation, and increased scrutiny within the clinical trial.

Limitations

This retrospective study has several important limitations. Beyond the clear inability to link causation to any of our outcomes, we are also limited by the information collected prospectively in the original RCT including the missing data noted in the tables. Overall, there were 52 subjects in the original RCT that had missing data on favorable outcome. However, the efforts to follow up with patients in this trial were extensive and the majority of patients that survived were at least evaluated over the phone. We assessed these 52 subjects compared to the other 830 subjects with complete outcome data for differences in prehospital intubation rate and transport method, our two key independent variables in our analyses. We found very similar rates (39% vs. 40% prehospital intubations and 39% vs. 36% air transports, respectively).

Prior work has raised the question whether using RSI during intubation could be associated with improved outcomes.[13] Air transport personnel may be better able to avoid misplaced endotracheal tubes, hyperventilation, hypoxia and hypotension during and after intubation and patients transported by air may be sicker.[15] Furthermore, patients transported by air had a significantly greater transport time when compared to those transported by ground (avg. 77.2 minutes vs. 40.5 minutes, $p < 0.001$) and were sicker (avg. iGCS 6.3 vs. 7.4, $p < 0.001$). Additionally, rates of exclusion due to hypoxia/hypotension were not available in our data. If it had been available and stratified by method of transport, this would help to further address the significant differences in care provided by air versus ground transport EMTs. After completing this analysis, perhaps the most important limitations are the small number of cases of air transported patients that are not intubated (41/320), the small number of ground transported patients that are intubated (69/556) and finally we do not know from our database who was intubated using rapid sequence intubation making it likely that the ground transport patients and the air transport patients are really different.

Conclusion

The lack of increased morbidity and mortality associated with intubation in the field when patients with these major potential confounders (hypotension and hypoxia) are excluded, EMS education regarding hyperventilation is given, and the increased scrutiny of prehospital care within a prospective clinical trial is new to the literature adds to the corpus of literature on this important subject and should help add to the knowledge needed to design trials in the future. Our results lead to important questions about who should be intubated in the field and how TBI patients should be transported. Future research will elucidate how we may be able to improve select patient’s outcomes through targeted airway management.

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Table 1.

Favorable outcome definition by injury severity

iGCS	iMotor Score	Favorable Outcome
4–5	2–3	Severe disability Moderate disability Good recovery
6–8	4–5	Moderate disability Good recovery
9–12		Good recovery

Table 2.

Characteristics of patients at baseline, stratified by prehospital intubation

Characteristic	Prehospital intubation (Yes) (*n* = 349)	Prehospital intubation (No) (*n* = 533)
Age – yr		
Median	36	35
Range	17–85	17–94
Male sex – no. (%)	264 (75.6)	386 (72.4)
NHW – no. (%)	273 (78.2)	290 (54.4)
Black race – no. (%)	21 (6.0)	113 (21.2)
Hispanic – no. (%)	46 (13.2)	79 (14.8)
Cause of injury – no. (%)		
Motor vehicle accident	148 (42.4)	174 (32.7)
Motorcycle, scooter or ATV accident	83 (23.8)	86 (16.1)
Pedestrian struck by moving vehicle	23 (6.6)	92 (17.3)
Other	95 (27.2)	181 (34.0)
Method of Transport – no. (%)		
Air	279 (79.9)	41 (7.7)
Ground	69 (19.8)	487 (91.4)
Other	1 (0.3)	5 (0.9)
Index GCS score at randomization – no. (%)		
Moderate	70 (20.1)	184 (34.5)
Moderate to severe	183 (52.4)	289 (54.2)
Severe	96 (27.5)	60 (11.3)
Injury Severity Score	24.8 ± 11.8	24.2 ± 11.1
AIS head score indication no injury – no. (%)	14 (4.0)	17(3.2)
Rotterdam CT classification – no. (%)		
1	5 (1.4)	10 (1.9)
2	138 (39.5)	174 (32.7)
3	151 (43.3)	242 (45.4)
4	23 (6.6)	57 (10.7)
5	25 (7.2)	43 (8.1)
6	6 (1.7)	7 (1.3)
	Prehospital intubation (Yes) (*n* = 349)	Prehospital intubation (No) (*n* = 533)

Table 3.

Outcomes at 6 months

Outcome	Prehospital intubation (Yes) (*n* = 349)	Prehospital intubation (No) (*n* = 533)
Primary outcome – no. (%)		
Favorable outcome	200 (57.3)	245 (46.0)
Missing data	20 (5.7)	32 (6.0)
According to initial injury severity – n./total no. (%)		
Moderate injury		
Favorable	24/70 (34.3)	56/184 (30.4)
Missing data	8/70 (11.4)	13/184 (7.1)
Moderate-to-severe injury		
Favorable	113/183 (61.8)	153/289 (52.9)
Missing data	7/183 (3.8)	15/289 (5.2)
Severe injury		
Favorable	63/96 (65.6)	36/60 (60.0)
Missing data	5/96 (5.2)	4/60 (6.7)
According to transport method – n./total no. (%)		
Air		
Favorable	162/279 (58.1)	21/41 (51.2)
Missing	15/279 (5.4)	5/41 (12.2)
Ground		
Favorable	37/69 (53.6)	221/487(45.4)
Missing	5/69 (7.3)	27/487 (5.5)
Death – no. (%)	48 (13.8)	104 (19.5)
Cause of death – no./total no. (%)		
Neurologic	34/48 (70.8)	68/104 (65.4)
Not neurologic	13/48 (27.1)	35/104 (33.7)
Unknown	1/48 (2.1)	1/104 (1.0)
According to initial injury severity – no./total no. (%)		
Moderate	3/70 (4.3)	30/184 (16.3)
Moderate to severe	20/183 (10.9)	56/289 (19.4)
Severe	25/96 (26.0)	18/60 (30.0)
According to transport method – n./total no. (%)		
Air	34/279 (12.2)	5/41 (12.2)
Ground	14/69 (20.3)	99/487 (20.3)

Table 4.

Logistic regression: Favorable outcome

Variable	Adjusted odds ratio	95% CI
Prehospital intubation		
No	—	
Yes	110	0.69–1.76
Method of Transport		
Air	—	
Ground	0.71	0.44–1.14
Index GCS score at randomization		
Moderate	—	
Moderate to severe	2.79	1.95–4.00
Severe	3.75	2.32–6.06
Age	0.97	0.96–0.98
Race/Ethnicity		
NHW	—	
Black	0.89	0.57–1.38
Hispanic	1.07	0.69–1.67

Table 5.

Logistic regression: Death

Variable	Adjusted odds ratio	95% CI
Prehospital intubation		
No	—	
Yes	0.70	0.37–1.31
Method of Transport		
Air	—	
Ground	1.58	0.83–2.99
Index GCS score at randomization		
Moderate	—	
Moderate to severe	1.84	1.07–3.15
Severe	5.05	2.68–9.51
Age	1.06	1.05–1.07
Race/Ethnicity		
NHW	—	
Black	0.75	0.41–1.38
Hispanic	0.72	0.36–1.43