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Risk Factors for Ventilator-Associated Pneumonia in the Adult Trauma Patient: A Retrospective Case-Control Study From a Level I Trauma Center

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RISK FACTORS FOR VENTILATOR-ASSOCIATED PNEUMONIA IN THE ADULT TRAUMA PATIENT: A RETROSPECTIVE CASE-CONTROL STUDY FROM A LEVEL I TRAUMA CENTER

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EXECUTIVE SUMMARY

Introduction: Ventilator-Associated Pneumonia (VAP) continues to be a common complication among the adult trauma population. Little advancements have been made to decrease the incidence, suggesting further research is needed to establish modifiable risk factors. The purpose of this study was to test for an associated link between prehospital intubation and the development of VAP in the adult trauma patient.
Methodology: A retrospective, case-control study design was utilized. The sample included 494 adult trauma patients who required endotracheal intubation and mechanical ventilation for a minimum of 24 hours. All patients presented as a priority one or two trauma to the Charleston Area Medical Center (CAMC) between January 1, 2005 and May 1, 2012. The sample was divided into two groups: VAP group (n = 247) and No-VAP group (n = 247). Patient demographics (age, gender, body mass index), Injury Severity Score (ISS), Glasgow Coma Score (GCS), location of first intubation, length of time on ventilator, Intensive Care Unit (ICU) and hospital Length Of Stay (LOS) were gathered. The hypothesis was tested using logistic regression. Additional regression analysis and correlation studies assessed for additional risk factors for the development of VAP. Linear regressions analyzed for factors associated with an increased ICU LOS and hospital LOS.
Results: Trauma patients who were first intubated in the prehospital setting were 1.6 times more likely to develop VAP than those intubated by anesthesia upon arrival to or during their stay at the trauma center. Of those intubated by anesthesia, ICU and floor intubations were 3.2 times more likely to develop VAP compared to others intubated within the trauma center. Patients experiencing first intubation by anesthesia personnel upon arrival to Emergency Department (ED) were 2.5 times less likely to develop VAP than those intubated either in the prehospital setting or by anesthesia personnel in the operating room or after admission to the medical unit or ICU. Increased ventilator time and ICU LOS were found to have a statistically significant correlation to VAP. The presence of VAP, lower systolic blood pressure in ED, higher ISS, increased length of time on the ventilator, and intubation in the ICU or medical floor were significantly associated with the ICU length of stay. Higher ISS, presence of VAP, time on the ventilator, and ICU length of stay were associated with length of hospital stay.
Discussion: Prehospital intubation was associated with a significantly increased risk of developing VAP and those trauma patients who were first intubated in the prehospital setting were 1.6 times more likely to develop VAP than those who were intubated by anesthesia personnel after arrival to the trauma center. Additionally, patients who required emergent intubation after admission to the ICU or medical floor were 3.2 times more likely to develop VAP than any other patient who experienced the first intubation by anesthesia within the trauma center. Situational Airway management providers must be aware of this increased risk and practice techniques to minimize the risk of aspiration or tracheal contamination during intubation. Additionally, this study represented an area where there were not standardized Rapid Sequence Induction (RSI) protocols in place in the prehospital setting therefore standardization of prehospital RSI protocols should be initiated with follow-up prospective studies testing these benefits.
Conclusion: The high correlation between prehospital intubation and ventilator-associated pneumonia demonstrated in this study suggests that prehospital care may influence subsequent development of VAP.

Key Words: trauma, ventilator-associated pneumonia, prehospital intubation, intubation, risk factors

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INTRODUCTION

Background and Significance of the Problem

Hospital-Acquired Pneumonia (HAP) is one of the most common infections acquired among hospitalized patients (Kollef, 2005). Ventilator-Associated Pneumonia (VAP) refers to HAP acquired at least 48 hours after admission in patients requiring mechanical ventilation. Timing is critical when diagnosing VAP to avoid misdiagnosis of a pneumonia that was acquired in the community prior to hospitalization. VAP has been categorized as either early-onset, occurring between 48 hours and five days of mechanical ventilation, or late-onset, occurring after five days. According to the Institute of Healthcare Improvement, VAP has been defined as pneumonia occurring at the time of or within 48 hours of an intubation and there is no minimum time of mechanical ventilation to classify as VAP (IHI, 2011).

In 2001, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) announced four core measures of quality assurance for hospitals, one of which was pneumonia (Joint Commission, 2012). Since then, the Centers for Disease Control and Prevention (CDC) established the National Healthcare Safety Network (NHSN) for surveillance of healthcare-associated infections. The NHSN has developed an algorithm for identifying VAP and plans to implement mandatory reporting of VAP-suspected events beginning early in 2013 (CDC, 2012).

As of October, 2010, the Department of Health and Human Services and specifically the Centers for Medicare and Medicaid Services (CMS) released new rulings regarding reimbursement to hospitals based on quality assurance performance (DHHS, 2010). Hospitals were mandated to report incidence of complications and readmissions of certain quality measures. Pneumonia has been on the list of quality measures since 2004 and was one of 27

chart-abstracted measures and one of 15 claims-based measures reported to ensure patient safety. CMS and other third-party payers will no longer reimburse hospitals for costs associated with VAP (DHHS, 2010). Controlling VAP would save the hospitals substantial financial resources and improve patient outcomes.

Trauma patients have shown an increased incidence of VAP compared to other mechanically ventilated patients and VAP has been the most common complication reported in the mechanically ventilated adult trauma patient (Magret et al., 2010). The rise in antibiotic-resistant microorganisms has made treating VAP more difficult and has lead to increased delivery of inappropriate antibiotics with an increased mortality (Kollef, 2005). Previous studies have linked VAP with an increase in hospital length of stay, Intensive Care Unit (ICU) stay, ventilator days, and increased medical care costs by as much as $40,000 per patient (Warren et al, 2003Augustyn, 2007; Restrepo et al, 2010). Other studies have had conflicting results whether VAP increases mortality in the trauma patient (Magnotti, Croce, & Fabian, 2004; Magret et al, 2010; Decelle, Thys, Zech, & Verschuren, 2011; Monaghan et al, 2012; Piskin et al, 2012).

Literature Review

In 2011, Wahl, Zalewski, & Hemmila studied mechanically ventilated patients in the surgical ICU for the rate of VAP and found that 59% of early Broncheo-Alveolar Lavage (BAL) specimens and 47% of late BAL specimens grew aspiration-type organisms (Wahl et al, 2011). These results show supporting evidence that contamination of the trachea by gastric contents can lead to VAP which can occur during the process of endotracheal intubation.

Gagani, Vyas, & Kar, documented the incidence of VAP was 37% with an increased mortality rate noted in patients who developed late-onset pneumonia (66%) compared to 41% in the non-VAP patients (2010). In this study associated risk factors included duration of ventilator support, reintubation, supine position, advanced age, and altered level of consciousness. The average length of ventilator support for the patients with VAP was 19 days compared to 10 days for the non-VAP group. All ICU patients mechanically ventilated for at least 48 hours were included and prospectively followed. The sample consisted of medical, surgical, and trauma ICU patients with a total study population of 100 participants (Gagani et al, 2010)

A prospective study in 2003 evaluated the differences in morbidity and mortality in acute trauma patients who were either intubated prehospital or upon arrival to the Emergency Department (ED). This literature noted a 1.5 times greater risk for developing nosocomial pneumonia in the patients intubated in the prehospital setting. The researchers prospectively followed 191 trauma patients and focused mainly on mortality in the participants, however the rate of pneumonia was also noted in the sample. Of the 191 participants, 78 were intubated in the prehospital setting and were found to have significantly longer ICU and hospital lengths of stay. Of the 78 prehospital intubations, 49% developed nosocomial pneumonia compared to 32% in the ED intubations (Bochicchio, Ilhai, Joshi, Bochicchio, & Scalea, 2003).

Another prospective study performed over a 15 month period of time followed ICU patients for the rate of VAP and risk factor stratification. This research identified emergent intubation as the most significant attributable risk. Other significant risks identified included the presence of a tracheostomy tube or nasogastric tube, decreased consciousness, and the use of Intravenous sedatives (Joseph, Sistla, Dutt, Badhe, & Parija, 2009). This study included any patient that was admitted to the ICU and not just the trauma patients.

In 2005, a prospective study of trauma patients performed to predict risk factors for late-onset pneumonia documented a 3.4-fold increased likelihood in developing late-onset VAP when a non-depolarizing muscle relaxant was used for tracheal intubation. Other factors increasing late-onset of VAP included duration of intubation and mechanical ventilation, length of ICU stay, the need for central IV access and arterial line, and exposure to prior antimicrobial treatment (Leone et al., 2005).

In 2010, Evans, et al. published a retrospective review specifically designed to evaluate the association between the timing of intubation and the development of VAP. This study was performed utilizing an Emergency Medical Services (EMS) system with a well-established Rapid Sequence Induction (RSI) protocol in place. RSI is a technique utilized during the time of tracheal intubation to decrease the risk of aspiration of gastric contents. It should also be noted that the population consisted of 572 patients of whom 412 of them were intubated prehospital and only 101 developed VAP for the entire group. However, of the 101 with VAP, 70 of them were intubated in the prehospital setting. These researchers found no significant association between prehospital intubation and VAP, but did identify a history of drug abuse, lowest recorded emergency department Systolic Blood Pressure (SBP), and Injury Severity Score (ISS) as independent risk factors (Evans et al., 2010). However, because of the RSI protocol in place in the prehospital setting these results cannot be inferred to the population of the current study design where a standardized RSI protocol was not implemented. This may serve to suggest the need for standardization of RSI protocols in the prehospital setting.

A ten year retrospective review of all trauma patients at a level I trauma center requiring mechanical ventilation for greater than 24 hours were performed. This researcher categorized prehospital intubations and emergency department intubations into one group called urgent

intubations and compared that group to those who were later intubated after admission. The study did not exclude patients that were transferred to the facility already intubated. The urgent intubation group was found to have a higher rate of VAP (Eckert et al., 2006). The design of that study was similar to the current design except in the current study the intubations in the ED were all performed by anesthesia personnel and were separated from those intubated prior to hospital arrival where there was not an established RSI protocol in place.

In 2004, a retrospective analysis was performed utilizing the trauma registry from a single facility to establish risk factors for trauma patients. In this review, 571 patients comprised the population. Twenty-five percent developed pneumonia. Those that developed pneumonia were more likely to be older, had a higher ISS, lower Glasgow Coma Score (GCS), longer Intensive Care Unit (ICU) and hospital lengths of stay. Prehospital intubation was named as an independent risk factor for the development of post-traumatic pneumonia (Eckert et al., 2004).

A large prospective study evaluated 2,436 patients across nine European countries for etiologies and outcomes of VAP in trauma and non-trauma patients. Approximately 36% of intubated trauma patients developed VAP during the ICU stay linking trauma as a high risk indicator for developing VAP. The characteristics defining the trauma patient from the non-trauma critical patient were markedly different. The trauma patient was characteristically male, younger, with fewer coexisting diseases than the typical critical care patient requiring mechanical ventilation, yet the trauma cohorts were at higher risk of developing VAP (Magret et al., 2010). For this reason, further examination needs performed to evaluate what makes individual trauma patients at even greater risk in hopes to discover factors that can be modified or prevented.

Statement of the Problem and Research Purpose

Ventilator-Associated Pneumonia is of great concern in the adult trauma patient. In the current setting, there are no consistent standardized Rapid Sequence Induction protocols in place to decrease the likelihood of aspiration during tracheal intubation performed outside of the hospital among the varying types of EMS providers in this area. There are also currently no active preventative protocols to decrease the risk of developing pneumonia in the ventilated patient in the intensive care unit. The study subjects were evaluated for differences to determine other risk factors that may make specific trauma patients more at risk for developing VAP over other trauma patients.

The purpose of this study was primarily to evaluate the association between prehospital intubation and the development of Ventilator-Associated Pneumonia.

METHODOLOGY

Research Hypothesis

This retrospective study was designed to test the hypothesis that adult trauma patients intubated in the prehospital setting have a higher risk of developing VAP than those intubated by anesthesia personnel after arrival to the trauma center.

Research Design and Setting

A retrospective, case-controlled study design was utilized to test the hypothesis. This design was chosen over prospective design for several reasons. The data was routinely collected and readily available. A retrospective design allowed for collection of accessible data which increased convenience and efficiency of untrained researchers and decreased the time required

for data collection. Additionally, retrospective reviews were less costly than prospective designs (Shultz & Grimes, 2002).

The study was conducted at Charleston Area Medical Center (CAMC), a level I trauma center located in West Virginia. The CAMC hospital system is a non-profit, 838 bed academic medical center with a level I trauma center and free-standing children's hospital. CAMC services the entire state of West Virginia through referral and tertiary care. The CAMC hospital system has four divisions: Memorial, General, Woman and Children's, and Teay's Valley (CAMC, 2012). The CAMC General Division serves as the area's level I trauma center and was the setting of the current research (CAMC, 2012b).

Sample Description

The study sample consisted of adult trauma patients aged 18 to 64 years old, who were admitted to CAMC General Hospital between January 1, 2005 and May 1, 2012 and required endotracheal intubation with mechanical ventilation for a minimum of 24 hours. A convenience sample of 494 patients from the CAMC trauma registry was divided into two groups: VAP group (cases), no-VAP group (control). All patients that fit the inclusion/exclusion criteria within the stated time frame who had the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) codes: 997.31 for VAP, 486 for pneumonia with the organism unspecified, or 482.9 for bacterial pneumonia were extracted from the trauma registry for inclusion into the VAP group (West Virginia Department of Health and Human Services, 2008). The patients were further evaluated using the Electronic Medical Record (EMR) for verification the pneumonia was likely ventilator-associated (McKesson Corporation, 2012).

The remaining priority 1 or two trauma patients, who were admitted within the same timeframe and required intubation with mechanical ventilation, were randomly selected utilizing computer randomization to select of sample of 247 no-VAP patients to match the sample size of the VAP group. Each no-VAP patient's medical record was analyzed to ensure no diagnosis of pneumonia existed on the EMR, no positive respiratory cultures had been obtained without a pneumonia diagnosis noted on the EMR, and that each patient fit with the inclusion/exclusion criteria set up for the study.

Inclusion criteria consisted of: 1) 18 through 64 years of age, 2) endotracheal intubation with minimum mechanical ventilation time of 24 hours, 3) priority one or two trauma. Patients were excluded if any of the following applied: 1) less than 18 years or greater than 65 years of age, 2) transferred from another facility, 3) incomplete data records, 4) death or documented brain death within 48 hours of admission, 5) patients suffering burns, asphyxiation, or drowning.

Procedure and Protocol

Extracted patient data included: age, gender, Body Mass Index (BMI), ISS, GCS, location of first intubation, mechanism of injury (blunt or penetrating), lowest recorded SBP in ED, number of days on ventilator, total length of ICU stay, and total hospital Length Of Stay (LOS). Primary outcome measured was the development of Ventilator-Associated Pneumonia (VAP).

BMI has been defined by the CDC as a measure of body fat based on the patient's height and weight. Using the metric system, the formula to calculate the BMI equals weight (in kilograms) divided by the height (in meters) squared (CDC, 2011). ISS was defined as an anatomical scoring system that provided an overall score for the patient's injuries based on six

major areas of injury. The scoring system was based on criteria established by trauma physicians and recognized as a standard nationally (Champion et al, 1990). The patient's injuries were given a numeric score based on severity in six categories. The three highest scores were then squared and added together to achieve the total ISS. A score of 6 in any category indicated un-survivable injury and the patient was immediately given the maximum possible ISS score. The highest possible score is 75 with this score recognizing presence of an un-survivable injury. A score of 15 has been recognized as the threshold for classification of major trauma (Champion et al, 1990). The ISS score was assigned to all trauma patients by the trauma physician upon arrival to the ED and was documented on the CAMC trauma registry.

Location of intubation was defined as either by EMS personnel prior to arrival to the hospital, referred to as pre-hospital intubation; or as intubation by anesthesia personnel after arrival to the trauma center in one of the following locations: ED, ICU or medical floor, and Operating Room (OR). The lowest recorded SBP was defined as the lowest SBP documented in the ED medical record for each subject. The number of days on the ventilator was determined using the time of intubation as the starting point and a new day began at the same time 24 hours later.

Data Collection and Instruments

After the Institutional Review Board approval, a retrospective chart review was conducted on all patients admitted to CAMC General Hospital between January 1, 2005 and May 1, 2012 who fit the initial inclusion criteria. Data was extracted from CAMC's trauma registry and the EMR (West Virginia Department of Health and Human Services, 2008). Verification of the data from the trauma registry and additional patient information was obtained utilizing the

EMR system at CAMC (McKesson, 2012). The initial data collection tool was developed to acquire pertinent patient information while maintaining patient privacy (Appendix A). A second data collection worksheet organized the variables for study collection: age, gender, ISS, BMI, GCS, lowest recorded SBP, ventilator days, ICU LOS, hospital LOS, location of first intubation, mechanism of injury (Appendix B).

Statistical Design and Analysis

It was hypothesized that adult trauma patients who underwent endotracheal intubation prior to arrival to the emergency room were at increased risk of developing VAP. This hypothesis was evaluated utilizing a logistic regression with VAP as the dependent variable and the main independent variable being location of intubation.

The main independent variable was the location of the tracheal intubation: pre-hospital intubation versus intubation by anesthesia personnel in the emergency room, in the ICU or medical floor, or in the OR. Additional independent variables included control variables (age, gender, BMI), lowest recorded systolic BP in emergency room, total hospital LOS, total ICU LOS, ventilator days, GCS, ISS and mechanism of injury. *T-test* was used to compare the study groups for mean differences for the following variables: age, BMI, lowest recorded SBP in ED, total hospital LOS, total ICU LOS, ventilator days, GCS, ISS. Additionally, categorical variables collected were evaluated using a Pearson's Chi-squared test to establish potential differences between the two groups. These variables included: gender, location of first intubation, mechanism of injury, and injury type.

Logistic regression (forward conditional method) was performed to test the hypothesis that patients intubated in the prehospital setting would be at increased risk for VAP.

Additionally, correlation statistics were computed with a $p < .01$ which was considered statistically significant. In order to recognize additional risk factors, a second logistic regression was performed after eliminating ventilator time and ICU LOS due to the high correlation between those variables and the dependent variable. A third and final regression was performed to establish which patients intubated by anesthesia personnel within the trauma center presented the highest risk for VAP. Additional linear regressions (enter method) were performed to evaluate factors influencing the ICU LOS and hospital LOS. A *p* value < .05 was considered statistically significant. All statistical analyses were conducted using SPSS Version 20.0 software (SPSS IBM, 2012).

Ethical Considerations

The study was approved by CAMC and West Virginia University/Charleston Division Institutional Review Board on August 9, 2012 (Appendix C).

RESULTS

The study sample consisted of 494 adult trauma patients admitted to CAMC General between January 1, 2005 and May 1, 2012. All patients required endotracheal intubation and mechanical ventilation for a minimum of 24 hours. A sample of 247 VAP cases and 247 no-VAP controls were analyzed (Table 1). The VAP group consisted of 184 (74.9%) males and 63 (25.5%) females with a mean age of 40.6. The no-VAP group consisted of 188 (76.1%) males and 59 (23.9%) females with a mean age of 39.5. Neither age nor gender were found statistically different between the groups ($P > .05$). Additionally, there was no statistically significant difference between the two study groups regarding BMI ($p > .05$), (Table 1).

An independent T-test noted statistically significance differences between the means of the two study groups for the following variables: ISS, (VAP 28.5 vs. no-VAP 20.5; p = .001), GCS (VAP 7.3 vs. no-VAP 9.2; p = .001), ventilator days (VAP 12.7 vs. no-VAP 2.9; p = .001), ICU LOS in days (VAP 13.7 vs. no-VAP 4.49; p = .001), hospital LOS in days (VAP 23.94 vs. no-VAP 10.72; p = .0001), and lowest SBP in ED (VAP 110.8 vs. no-VAP 115.9; p = .032), (Table 1).

Table 1: Comparison of Patient Characteristics between Ventilator-Associated Pneumonia and Control Groups in Adult Trauma Patients

Variable	Study Groups		Statistical Values
	VAP N = 247 Mean ± Standard Deviation	No-VAP N = 247 Mean ± Standard Deviation	p-value (2-tailed t-test)
Age	40.6 ± 13.8	39.5 ± 13.3	.406
ISS	28.5 ± 10.9	20.5 ± 10.8	.001*
GCS	7.3 ± 5.2	9.2 ± 5.3	.001*
Vent (Days)	12.7 ± 8.9	2.9 ± 2.3	.001*
ICU stay (days)	13.7 ± 7.1	4.5 ± 3.2	.001*
Hospital (days)	23.9 ± 12.3	10.7 ± 8.1	.001*
BMI	28.2 ± 6.1	28.9 ± 6.8	.231
SBP	110.9 ± 27.6	115.9 ± 24.4	.032*
Gender: Male n(%) Female	N= 184 (74.5) N= 63 (25.5)	N= 188 (76.1) N = 59 (23.9)	NS
Injury type: Blunt n(%) Penetrating	N = 232 (93.9) N = 15 (6.1)	N = 211 (85.4) N = 36 (14.6)	.002**
Location of first intubation: n(%) Prehospital ED ICU/floor OR	 N = 108 (43.7) N = 80 (32.4) N = 36 (16.2) N = 19 (7.7)	 N = 70 (28.3) N = 136 (55.1) N = 20 (8.1) N = 21 (8.5)	 .001** .001** .001** NS

*Indicates Statistical Significance at $p < 0.05$ during t-test; ** Indicates statistical significance by Pearson Chi-squared analysis; Injury Severity Score (ISS), Glasgow Coma Score (GCS), Ventilator time in days (Vent), Intensive Care Unit Length of Stay in days (ICU stay), Hospital Length of Stay in Days (Hospital), Body Mass Index (BMI), Lowest recorded systolic blood pressure (SBP)

For location of the first intubation, a Pearson Chi-squared analysis showed significant differences between the groups for the following intubation locations: Prehospital intubations (VAP 107 vs. no-VAP 70), (p = .001); ED intubations (VAP 81 vs. no-VAP 136), (p = .001); ICU/floor intubations (VAP 40 vs. no-VAP 20), (p = .006). The OR intubations (VAP 19 vs. no-VAP 21) were not significantly different. (Table 1) Overall, 43% of the VAP group was intubated in the prehospital setting compared to 28.3% in the no-VAP group (p = .001). The ED intubations predominated in the no-VAP group comprising 55.1% of those intubations compared to the 32.4% who were intubated in the ED in the VAP group, (P = .001); (Table 1).

Overall, blunt trauma predominated in both groups, with 93.9% suffering blunt traumatic injury in the VAP group and 85.6% in the No-VAP group. Motor vehicle accident (49%), all-terrain vehicle accident (13.4%), motorcycle accident (7.7%), and falls (7.9%) were the predominating mechanisms of injury in the study population (Figure 1). Penetrating traumatic injury made up the remaining 6.1% (VAP) and 14.4% (No-VAP) of each group, which was significantly different between the groups; p = .002. Of the 51 patients sustaining penetrating injury in the study, 59% suffered gunshot wounds and 22% endured stab wounds.

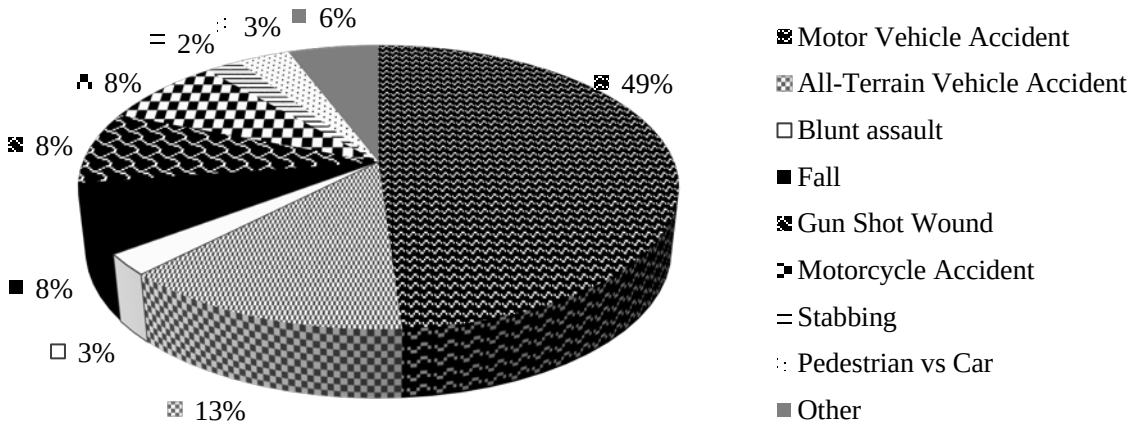

Figure 1: Mechanism of Injury for Adult Trauma Patients (Percent of Entire Study Sample)

A Pearson Chi-squared test indicated a statistical difference between the groups for prehospital intubation when compared to all intubations performed by anesthesia within the trauma center (p = .001),(Table 2). A standard residual of 2.0 shows significance for prehospital intubation in the VAP group. The odds ratio for prehospital intubation versus intubations performed within the trauma center was 1.9.

Table 2: Comparison of Prehospital Intubation to Intubation After Arrival to Trauma Center in Adult Trauma Patients

prehospital intubation * pneumonia Crosstabulation

			pneumonia		Total
			no pneumonia	VAP	
prehospital intubation	no	Count	177	139	316
		Std. Residual	1.5	-1.5	
	yes	Count	70	108	178
		Std. Residual	-2.0	2.0	
Total		Count	247	247	494

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	12.682[a]	1	.001*		
Continuity Correction[b]	12.023	1	.001		
Likelihood Ratio	12.756	1	.001		
Fisher's Exact Test				.001	.001
Linear-by-Linear Association	12.656	1	.001		
N of Valid Cases	494				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 89.00.
b. Computed only for a 2x2 table

Risk Estimate

	Value	95% Confidence Interval	
		Lower	Upper
Odds Ratio for prehospital intubation (no / yes)	1.965	1.352	2.855
For cohort pneumonia = no pneumonia	1.424	1.158	1.752
For cohort pneumonia = VAP	.725	.611	.861
N of Valid Cases	494		

Additional Chi-squared analysis for location of the first intubation revealed statistical significance between the VAP group compared to the control group (p = .001). The standard

residual for prehospital intubation with the VAP group was 2.0 and -2.0 in the no-VAP group. Additionally, the ED intubations were significant with a standard residual of 2.7 in the no-VAP group and -2.7 in the VAP indicating the increased likelihood of not developing VAP if the first intubation occurred in the ED (Table 3).

Table 3: Comparison of Intubation Location between Ventilator-Associated Pneumonia and Control Groups in Adult Trauma Patients

Location of first intubation * pneumonia Crosstabulation

			Study Groups		Total
			no VAP	VAP	
Location of first intubation	prehospital	Count	70	108	178
		Std. Residual	-2.0	**2.0**	
	ED	Count	136	80	216
		Std. Residual	**2.7**	-2.7	
	ICU/floor	Count	20	40	60
		Std. Residual	-1.8	**1.8**	
	OR	Count	21	19	40
		Std. Residual	.2	-.2	
Total		Count	247	247	494

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	29.398[a]	3	.001*
Likelihood Ratio	29.757	3	.001
Linear-by-Linear Association	.021	1	.886
N of Valid Cases	494		

*indicated statistical significance (P < .05)

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 20.00.

Correlation coefficients showed a significant correlation between the presence of VAP and the length of time on the ventilator, ICU LOS, and hospital LOS (p = .001), (Table 4). There was also a significant positive correlation between prehospital intubation and VAP (p = .001) and between ICU/floor intubations and VAP (p = .006). For intubations that occurred after arrival to the trauma center, the ED intubations showed a decreased risk for developing

pneumonia represented by the statistically significant negative correlation coefficient (p = .001), (Table 4). Increased time on the ventilator was highly correlated with VAP (p = .001), prehospital intubation (p = .001), and ICU LOS (p = .001), (Table 4).

Table 4: Correlation between Ventilator-Associated Pneumonia and Location of First Intubation, Ventilator Time, and Intensive Care Unit Length of Stay in Adult Trauma Patients

	VAP	Ventilator time	ICU LOS	Hospital LOS
ICU/floor Intubation	.124 (.006)*	.038 (.403)	.118 (.009)*	.098 (.029)
OR Intubation	-.015 (.742)	-.031 (.767)	-.013 (.767)	.057 (.203)
ER Intubation	-.229 (.001)**	-.132 (.001)**	-.196 (.001)**	-.136 (.002)**
Prehospital Intubation	.160 (.001)*	.128 (.001)*	.130 (.004)*	.041 (.363)
Ventilator time	.592 (.001)*	---	.846 (.001)*	.722 (.001)*
Hospital LOS	.545 (.001)*	.722 (.001)*	.763 (.000)*	___
ICU LOS	.640 (.001)*	.846 (.001)*	---	

Expressed: Pearson Correlation Coefficient (p-value)
*Indicated statistical significance with a positive correlation (P < .01)
**Indicated statistical significance and a NEGATIVE correlation (P < .01)
Ventilator-Associated Pneumonia (VAP); Ventilator time in days (Ventilator time); Intensive Care Unit Length of Stay (ICU LOS): Hospital Length of Stay (Hospital LOS)

The initial binary logistic regression revealed the time on the ventilator and ICU length of stay as significant risk factors for the development of VAP (p = .001); (Table 5). The intubated trauma patient with an increased length of ICU stay was 1.5 times more likely to develop VAP. Additionally, the intubated trauma patient who had longer time on the ventilator was 1.2 times more likely to develop VAP, (Table 5).

Table 5: Logistic Regression and Risk Factors for Ventilator-Associated Pneumonia in Adult Trauma Patients

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	ICUlos	.375	.032	141.320	1	.001	**1.454**
	Constant	-3.032	.266	129.777	1	.001	.048
Step 2[b]	**ICUlos**	.209	.054	14.812	1	.001*	1.232
	ventLOS	.218	.049	19.851	1	.001*	**1.243**
	Constant	-3.033	.271	124.898	1	.001	.048

*Indicates statistical significance with p < .05; Intensive Care Unit Length of Stay (ICUlos), Ventilator time (ventLOS); Variables entered into forward (conditional) Logistic regression but not significant: Preshospital intubation vs ED/inpatient intubation (preVShosp); Injury Severity Score (ISS); Glasgow Coma Score (GCS); Blunt or penetrating type trauma (INJURYtype); ventilator time in days (ventLOS); Basal Metabolic Index (BMI); lowest recorded systolic blood pressure in emergency room (SBP).

Due to the high correlation between the presence of VAP and the length of time on the ventilator, the ICU LOS and hospital LOS, a second regression was performed after removing ventilator time, ICU LOS, and hospital LOS from the equation to better identify other factors that increase the risk for VAP (Table 6). The second regression showed significance for prehospital intubation (p = .001) and a high ISS (p = .001) together as risk factors for VAP (Table 6). This analysis recognized the patients who were intubated in the prehospital setting to be 1.6 times more likely to develop VAP than those intubated inside the hospital.

Table 6: Logistic Regression for Pneumonia in Adult Trauma Patients after Correcting for Increased Ventilator Time and Intensive Care Unit Length of Stay

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	ISS	.063	.009	48.513	1	.001	1.065
	Constant	-1.539	.239	41.373	1	.001	.215
Step 2[b]	ISS	.060	.009	43.491	1	.001*	1.062
	Prehospital vs in hospital	.495	.201	6.044	1	.014*	**1.641**
	Constant	-1.649	.246	44.868	1	.001	.192

*Indicates statistical significance (p < .05)

a. Variable(s) entered on step 1: Injury Severity Score (ISS).

b. Variable(s) entered on step 2: prehospital vs in hospital intubation.

c. variables entered but not significant: Glasgow Coma Score (GCS); Blunt or penetrating type trauma (INJURYtype); Basal Metebolic Index (BMI); lowest recorded systolic blood pressure in emergency room (SBP).

In order to analyze the in-hospital intubations to establish which locations showed higher risk of developing VAP, a third binary regression analysis was performed differentiating the locations of intubation provided by anesthesia inside the hospital (Table 7). Therefore, prehospital intubations were excluded from this analysis and the remaining 316 patients were analyzed. This regression analysis showed if trauma patients experienced the first intubation in the ICU or medical floor they were 3.17 times more likely to develop VAP compared to all other intubations performed by anesthesia inside the hospital (p = .001); (Table 7).

Table 7: Logistic Regression Analysis for Intubations Performed Inside the Trauma Center by Anesthesia Personnel on Adult Trauma Patients

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	ICUfloor	1.154	.302	14.566	1	.001*	**3.172**
	Constant	-.461	.128	12.910	1	.000	.631

a. Variable(s) entered on step 1: ICUfloor.
b. Other variables entered into regression but not significant: Emergency Department intubations (ED), Operating Room intubations (OR)

The minimum amount of time on the ventilator for either group was 24 hours per the inclusion criteria, with the maximum ventilation time for the no-VAP group being 14 days with only six patients in this group required mechanical ventilation for 10 days or longer. However, in the VAP group, the maximum time of mechanical ventilation was 63 days and 156 patients required mechanical ventilation for more than 10 days. All study participants who required mechanical ventilation for greater than 14 days acquired VAP (Figure 2).

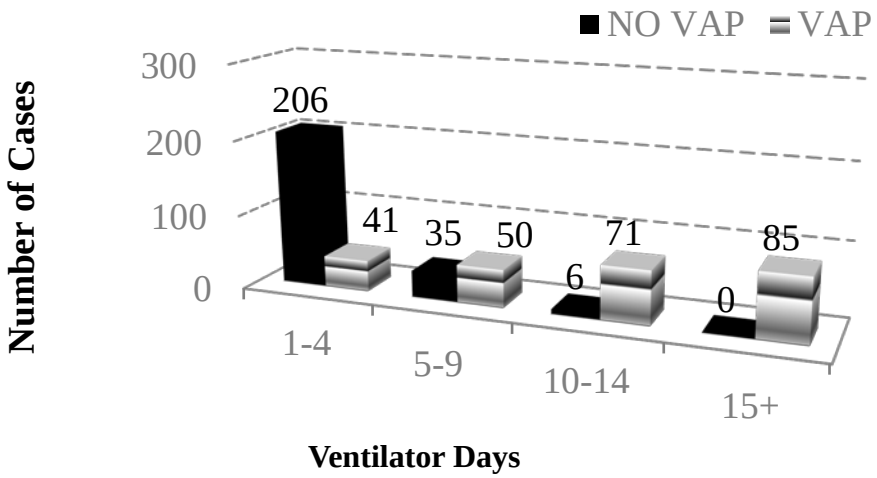

Figure 2: Comparison of Mechanical Ventilation Time (In Days) Between Ventilator-Associated Pneumonia Group and Control Group in Adult Trauma Patients

The mean ICU length of time for the VAP group was statistically significantly longer than that of the non-VAP group (13.7 days vs. 4.5 days, respectively), p = .001. A linear regression analysis (enter method) evaluated associations with increased ICU LOS showed significance for ICU/floor intubations (p = .005), the presence of pneumonia (p = .001), increased time on the ventilator (p = .001), increased ISS (p = .047), and lowest SBP (p = .015), (Table 8). Prehospital intubation did not prove to be a predictor to increase ICU LOS (P = .188), (Table 8).

Table 8: Linear Regression for Intensive Care Unit Length of Stay in Adult Trauma Patients

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	2.316	1.450		1.597	.111
	OR intubation	.596	.661	.023	.901	.368
	prehospital intubation	.630	.477	.042	1.319	.188
	ICU floor intubation	1.710	.603	.078	2.835	**.005***
	AGE	.013	.013	.024	.997	.319
	GENDER	-.215	.380	-.013	-.566	.572
	ISS	.032	.016	.051	1.994	**.047***
	GCS	.015	.050	.011	.294	.769
	Injury type	-.730	.557	-.031	-1.311	.191
	BMI	.023	.026	.020	.879	.380
	pneumonia	2.710	.414	.188	6.540	**.001***
	lowest SBP	-.016	.007	-.059	-2.445	**.015***
	Ventilator DAYS	.616	.026	.696	24.006	**.001***

Dependent Variable: ICU Length of Stay (days)

b. Predictors in the Model: (Constant), Ventilator DAYS, Body Mass Index (BMI), GENDER, ICU floor intubation), Injury type, OR intubation, lowest SBP, AGE, prehospital intubation, ISS, pneumonia, GCS

c. EXCLUDED variables: ER intubation

Increased ISS (p = .003), the presence of VAP (p = .035), time on the ventilator and length of ICU stay (p =.001) were significantly associated with an increased length of time in the hospital (Table 9). Prehospital intubation did not show a significant association with length of hospital stay in the linear regression (p = .871). Even though there was a statistical significant difference between the means of the groups for GCS and injury type (blunt or penetrating), these variables did not have a statistically significant association with the hospital LOS.

Table 9: Linear Regression of Hospital Length of Stay in Adult Trauma Patients

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-2.041	3.096		-.659	.510
	AGE	.041	.027	.046	1.537	.125
	GENDER	-.713	.810	-.025	-.880	.379
	ISS	.100	.034	.095	2.971	**.003***
	GCS	.121	.106	.053	1.141	.254
	Injury type	1.291	1.188	.032	1.087	.278
	Ventilator DAYS	.386	.081	.257	4.767	**.001***
	ICU Length of Stay (days)	.816	.097	.480	8.404	**.001***
	BMI	.026	.055	.014	.472	.637
	pneumonia	1.948	.921	.080	2.116	**.035***
	lowest SBP	.020	.014	.043	1.418	.157
	ICU floor intubation	-.312	1.295	-.008	-.241	.810
	prehospital intubation	-.887	1.018	-.035	-.871	.384
	OR intubation	2.101	1.409	.047	1.492	.136

a. *Indicates Statistical Significance ($p < .05$); Injury Severity Score (ISS), Glasgow Coma Score (GCS), Blunt or Penetrating (Injury type), Body Mass Index (BMI), lowest recorded Systolic Blood Pressure in the emergency room (Lowest SBP), Operating Room intubation (OR intubation)
b. Dependent Variable: Hospital Length of Stay (days)
c. Entered but Excluded: ER intubation

DISCUSSION

It was hypothesized that adult trauma patients who underwent endotracheal intubation in the prehospital setting prior to arrival to the trauma center were at increased risk of developing VAP. This hypothesis was evaluated utilizing binary logistic regression analysis with VAP as the dependent variable and the main independent variable being location of intubation. Even though the initial regression analysis failed to support this hypothesis, the subsequent regression analysis did. After analysis of the strong correlations between the ventilator time, ICU LOS, and hospital

LOS, these variables were excluded from subsequent analysis to evaluate a clear association between the independent variables and the development of VAP (dependent variable).

The results of this study of adult trauma patients requiring intubation and mechanical ventilation for a minimum of 24 hours suggests that those intubated in the field prior to arrival to the hospital were at the highest risk of developing VAP than those intubated after arrival to the hospital. In fact, the patients who required intubation and subsequent ventilation upon arrival to the ED had statistically significant less events of VAP than those intubated in other locations. This supports the findings by Eckert et al who reported prehospital intubation but not ED intubation of trauma patients was an independent risk factor for pneumonia (2010). When comparing patients whose first intubation was after arrival to the trauma center, the patients who were admitted to a medical floor or intensive care and later required emergent intubation had 3.17 times higher risk for developing VAP than those intubated in the operating room or in the trauma bay upon arrival. The VAP group also demonstrated a statistically significant lower GCS (on arrival to trauma center) and higher ISS score, required longer mechanical ventilation, and had longer ICU and hospital stays than those who did not develop VAP. The presence of VAP, lower SBP, higher ISS, and longer time on the ventilator all increase the risk of having longer ICU stays. Eckert et al. also reported prehospital intubation to be associated with a lower GCS and higher ISS (2010). Pneumonia was associated with longer ICU stays and longer hospital stays in that study as well (Eckert et al., 2010).

This study focused on identifying patients within the trauma subgroup that may be at higher risk of developing VAP in an attempt to better prevent VAP in this population. The process begins with endotracheal intubation and the potential for tracheal contamination or aspiration of gastric contents during intubation has been named as a potential causative factor for

the development of VAP. Bochicchio et al reported an association between prehospital intubation and increased risk of VAP in trauma patients (2003). Evans et al. reported prehospital intubation of trauma patients did not result in a higher risk of VAP (2010). Eckert at al. noted prehospital intubation but ED intubation of trauma patients to be an independent risk factor for the development of post-traumatic pneumonia (2004).

In addition, most previous research has named emergent intubation as an independent risk factor for the development of VAP, but those studies have grouped both prehospital and ED intubations together in one category (Croce, Tolley, & Fabian, 2003; Leone et at, 2005; Eckert et al, 2006; Carr, Kaye, Weibe, Gracias, Schwab, & Reiley, 2007; Joseph, Sistla, Dutta, Badhe, & Parja, 2009). Therefore, in this study, actual location of first intubation was recorded so comparisons between the different locations could be made.

Obtaining and maintaining a patent airway in the severely injured trauma patient can be a life-saving technique. There continues to be much nationwide variation in the delivery of care to patients in the prehospital setting. A variety of first responders with various training and background, perform numerous life-saving techniques in the prehospital setting, but at different levels of expertise. Some research has suggested potential adverse outcomes to patients that were intubated in the prehospital setting and continues to be an area of controversy (Bochicchio et al, 2003; Shafi & Gentilello, 2005; Fakhry et al, 2006). A prospective study in 2003 reported patients intubated in the prehospital setting had a 1.5 times greater risk of developing nosocomial pneumonia than those intubated after arrival to the trauma bay (Bochicchio et al, 2003). That study followed 191 trauma patients over a 12 month period of time. The current retrospective study supported this finding and implied a similar risk for those intubated in the field.

Evans et al. stated no association exists between prehospital intubation and VAP (2010). However, it should be noted that in this retrospective research there was a standardized RSI protocol in place in the prehospital setting, which was not the case in the current study. RSI is part of the variation that exists within the prehospital care provided by the varying levels of trained emergency medical service care providers. The differing results from the current study where there was an increased risk for VAP to those intubated in the field without an RSI protocol in place may suggest and support the need to implement an RSI protocol in the prehospital setting. To the best of the researcher's knowledge, there have been no prospective studies about prehospital intubation with an RSI protocol in place with VAP as the primary outcome measured.

Emergent intubation alone did not prove to be a risk factor as suggested in other research (Eckert et al, 2006; Carr, Kaye, Weibe, Gracias, Schwab, & Reiley, 2007; Joseph et al, 2009). The current study consisted of primarily emergent intubations with very few non-emergent intubations which may explain this difference. However, when comparing all patients intubated by anesthesia personnel after arrival to the hospital, the patients requiring emergent intubation after admission to a medical floor or to the ICU were 3.17 times more likely to develop VAP than those intubated in the ED or in the OR. To the researcher's best knowledge, no previous studies have been done regarding an association with VAP and ICU or floor intubations specifically. The prior stated research focused on emergency or urgency of intubation but not on the actual individual locations. When research has been done utilizing location of first intubation, the ICU and floor intubations are generally not included or specified (Leone et at, 2005; Eckert et al, 2006; Carr, Kaye, Weibe, Gracias, Schwab, & Reiley, 2007).

Statistically significant differences were noted between the study groups for GCS; although this did not show significance on a regression analysis, it may be explained in part by the need for emergent prehospital intubation in patients with lower GCS often suffering from head trauma. Eckert et al also noted a significantly lower GCS among trauma patients who acquired pneumonia (2010). Trauma patients suffering from decreased level of consciousness may be unable to adequately protect their airway or may hypoventilate encouraging stagnation of secretions and ateletcasis. This alone may make those patients prone to aspiration even before emergency responders arrive. In the VAP group, 132 patients had a GCS of three representing 53.4% of this group. The no-VAP group included 91 patients with a GCS of three, representing 36.8% of that group. This difference was statistically significant and may help explain part of the reason why the prehospital intubations posed a higher risk of VAP simply because of the potential for aspiration exists even before EMS arrival and also the need for ventilation may be prolonged due to the presence of traumatic brain injury. However, when comparing only those intubated in the prehospital setting, the mean GCS was 3.1 with no difference between the ones that acquired VAP and those who did not.

The patients at increased risk for VAP also included those with a higher ISS. This is consistent with findings from other researchers (Croce, Tolley, & Fabian, 2003; Eckert et al, 2004; Evans et al, 2010, Magnotti,). Additionally, those with a higher may have required intubation and mechanical assistance longer than others simply due to the nature of the injury sustained in the trauma. In the current study, the VAP group presented with a maximum ISS score of 59 and 82% of that group presented with an ISS greater than 17 with 24.5% being greater than or equal to 35. The No-VAP group included a maximum ISS of 55 with 55.1% presenting with an ISS greater than or equal to 17 with only 8.5% above 35. However, as

previously noted, the gold standard for the designation of a major trauma is an ISS greater than 15. The mean ISS of both the groups in this study was greater than 20, indicating both groups suffered similar numbers of major traumatic events so this variable alone does not explain the increased rate of VAP in the trauma patient.

Increased length of time on the ventilator plays a critical role in the development of VAP. All patients in this study who were intubated greater than 14 days (85) developed pneumonia. This finding is consistent with findings in most all previous research regarding VAP (Croce, Tolley, & Fabian, 2004; Gadani, Vyas, & Kar, 2010). It was observed in the current study that 79.4% of the VAP patients were intubated more than five days and 57.7% were intubated ten days or longer. All patients in the current study who underwent mechanical ventilation for greater than 14 days acquired VAP. There was a significant risk for development of VAP with each additional day on the ventilator.

Study limitations

Several limitations exist for the current study. The retrospective design of this study is in itself a self-limiting factor. Retrospective studies are only as good as the information on the medical record and are subject to improper documentation, misinterpretation of past clinical data, and bias (Schulz & Grimes, 2002). The lack of standardized criteria for the diagnosis of VAP may account for the high incidence of VAP in the current study. Part of the difficulty in researching VAP has been the lack of continuity in definition and diagnosis of VAP. All patients were included in the VAP group based on interpretation of clinical data performed by the attending physician at the time of the hospitalization. The diagnosis of pneumonia was associated with the timing of the mechanical ventilation and was necessary for inclusion into the VAP group. Any patients with positive respiratory cultures without a diagnosis of pneumonia on the

chart were excluded and therefore no attempts at differential diagnosis were made retrospectively. Prospective follow-up utilizing standardized protocol for the diagnosis of VAP would help provide a consistency in the research about VAP and better identify modifiable risk factors in the development of VAP.

None of the patients were placed on intravenous antimicrobial therapy for prevention of VAP; however the use of antimicrobial agents for open wounds or surgical prophylaxis or other forms of inhaled or oral antimicrobial therapy was not addressed in this study and may have impacted whether the patient developed VAP.

Additionally, the location of intubation in this study represents only the location of the patient's initial intubation The need for subsequent or multiple intubations due to improper placement, ruptured cuff, self-extubation, frequent trips to the operating room, or decline in patient condition were not addressed in this study.

Other possible explanations for the results of this study included the patients who were intubated in the prehospital setting often were more severely injured, designating the need for prehospital intubation, leading to longer time on the ventilator and longer ICU length of stay. However in this study, both groups presented to the trauma center with a mean ISS greater than 20, therefore severity of injury cannot be the only explanation.

The findings of the study were based on significant correlations and associations and do not indicate causality. A positive correlation between the time on the ventilator and VAP does not demonstrate that longer ventilator times alone cause VAP.

CONCLUSION

The goal of this study was to evaluate for an associated link between the location of intubation and the development of ventilator-associated pneumonia. The high correlation between prehospital intubation and ventilator-associated pneumonia demonstrated in this study suggests that prehospital care may influence subsequent development of VAP.

All emergency care providers and anesthesia personnel should be aware of the potential risks involved at the time of intubation and practice extreme vigilance to prevent aspiration or contamination of the airway.

IMPLICATIONS AND RECOMMENDATIONS

Studies that have been performed in areas with well-established standardized RSI protocols in the prehospital setting have demonstrated no relationship between the location of intubation and the development of nosocomial pneumonia. However, the current setting design there were not standardized RSI protocols in place throughout the prehospital setting. The findings of this study support other research where RSI protocol has not been well-established and adds to the understanding of the potential role of prehospital care in the trauma patients' eventual outcomes. RSI protocols should be standardized across all emergency service personnel who respond to trauma calls and have the ability to provide advanced airway management.

Additional implications of this study include: 1) initiation of active pneumonia prevention protocols on all trauma patients requiring mechanical ventilation should be employed 2) establishment of a standardized method for diagnosis and appropriate treatment of VAP or suspected VAP should also be initiated 3) prevention protocols should include education to staff, nursing care, diagnostic parameters, treatment, weaning, quality assurance and feedback 4)

follow-up prospective studies after the implementation of prevention protocol should be warranted (Coffin et al., 2008). Additionally, the conditions surrounding emergent intubations on the medical floor or in the ICU also need to be addressed. Thorough, frequent assessments of medical and ICU patients to determine the need for intubation or airway protection possibly preventing the need for sudden emergent placement may deem useful at decreasing that risk. Employing non-invasive positive pressure ventilation when medically appropriate may also be reasonable to improve patient outcomes and decrease time needed on mechanical ventilation, thus decreasing risk of VAP. Ensuring access to suctioning and airway supplies to perform emergent floor intubations in a timely manner may also be helpful. Additional training for the proper application of cricoid pressure for those assisting anesthesia during floor intubations may be warranted. Further research regarding this population of trauma patients may prove to provide much needed answers to decreasing VAP.

Additional prospective studies to evaluate other variables in place at the time of intubation would be helpful to determine other areas of modifiable risks to further decrease the risk of VAP in the adult trauma population. Valuable future research regarding VAP should include: explicit evaluation of coexisting diseases, complications encountered during the hospitalization, injuries attained during the trauma, antimicrobial exposure, the use of sedation and continuous muscle relaxation, the events surrounding the intubation, number of attempts at intubation, and the need for multiple intubations. A prospective, randomized clinical trial of prehospital RSI protocols may provide definitive data in preventing VAP. Continued efforts are needed to decrease the prevalence of VAP thus improving patient care and saving hospitals thousands of dollars.

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APPENDIX A: DATA COLLECTION TOOL NUMBER ONE

Patient Study Number	**Patient Medical Record Number**	**Patient Identification Number**
1		
2		
3		
4		
…		
494		

APPENDIX B: DATA COLLECTION TOOL NUMBER TWO

Study number	Age (yrs)	Gender Male= 1 Female= 0	BMI	ISS	GCS	Location of Intubation	Injury Blunt= 1 Penetrating=0	Lowest BP in ED	Days on vent	Length of ICU stay	Length hospital stay
1											
2											
3											
4											
…											
494											

APPENDIX C: Institutional Review Board Approval Letter

Charleston Area Medical Center

ROBERT C. BYRD HEALTH SCIENCES CENTER
OF WEST VIRGINIA UNIVERSITY/ CHARLESTON DIVISION

August 9, 2012

Cassy Taylor, DMP, CRNA
3110 MacCorkle Avenue SE
Room 2041
Charleston, WV 25304

RE: Your application dated 7/27/2012 regarding study number 1997221: Risk factors for developing ventilator-associated pneumonia in the adult trauma patient: a retrospective case control study from a level one trauma center

Dear Dr. Taylor:

Your request for expedited approval of the new study listed above has been reviewed. This type of study qualifies for expedited review under FDA and DHHS (OHRP) regulations because this study is the secondary use of existing non-research data.

This is to confirm your application is approved. The protocol Version 1: July 20, 2012 is approved. The HIPAA Waiver of Authorization signed 7/20/2012 is approved. The data set associated with this study is considered identifiable. The accrual goal of 1000 medical records is approved. You must submit a request to the IRB to increase enrollment beyond the approved accrual goal.

You are granted permission to conduct your study as described in your application effective immediately. The study is subject to continuing review on or before 8/9/2013, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved prior to implementation. Some changes may be approved by expedited review; others require full board review. Contact the CAMC/WVU Institutional Review Board office (388-9973; fax 388-9976) if you have any questions or require further information. Your continued cooperation is appreciated.

Sincerely,

John C. Linton, Ph.D.
Chair, Institutional Review Board

cc: Summer Chapman