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Patient Discomfort and Agitation in the ICU: ETT movement effects

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

by

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Acknowledgement

My dissertation has been a wonderful learning experience, providing me the opportunity to collaborate with many generous, enthusiastic professionals along the way.

I would like to express my deepest gratitude to my NIH/NINR NRSA sponsor and VCU Chair, Dr. Mary Jo Grap, for her guidance, patience and willingness to share her expertise in both clinical knowledge and conduct of professional nursing research. Without her support and encouragement, this dissertation would not have been possible. She has truly been an exceptional educator, advisor and mentor, as well as a cherished friend.

A special thank you to my dissertation committee: Dr. Curt Sessler, Dr. Angela Starkweather and Dr. Paul Wetzel, who have generously given their time, thoughtful feedback and expertise to better my work and my experience. I thank them for their contribution, diligence, patience and sense of humor as we worked through unexpected challenges along the way. Dr. Starkweather's agreement to step into a dissertation already in progress, as well as her invaluable contributions, are appreciated beyond measure. After years of collaboration with both Dr. Sessler and Dr. Wetzel, working together on this dissertation has been especially rewarding and I am eternally grateful for their time, input and feedback.

I must acknowledge, as well, the many friends, colleagues and supporters who have facilitated my doctoral journey. A special thank you to the following:

• The staff of the MRICU at VCUHS, for their interest in and support of my study.



- NIH/NINR, for my pre-doctoral fellowship award which funded my dissertation and training program.
- Dr. Deborah Jones, who was my first mentor in research as an undergraduate student, encouraged me to follow this path and has been a cheerleader for me along the way. Her friendship, support and encouragement have sustained me in ways that only she could have provided.
- Dr. Mary Lou Sole of University of Central Florida, for her support, time and willingness to share with me her innovative research.
- My doctoral cohort, for their constant encouragement, commiseration and application of humor.
- My family and friends, who have endured the times of stress and periods of near neglect with understanding, support and love.
- My parents who have provided immeasurable support in every way possible.
 They have encouraged me when I encountered challenges, cheered me on in times of progress, listened sympathetically in times of discouragement, and have never wavered in their conviction that I would complete this dissertation successfully.
- And finally, Russell Green, my confidant, dearest friend, voice of reason, ardent supporter and biggest fan. His constant encouragement and willingness to read again and again, providing invaluable feedback, has been a source of comfort and confidence. My gratitude for his support and love throughout the doctoral journey is beyond words.



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Abstract

PATIENT DISCOMFORT AND AGITATION IN THE ICU: ETT MOVEMENT EFFECTS

By Virginia Anne Hamilton, MS, RN, FNP

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2014

VCU Chair: Mary Jo Grap, PhD, RN, FAAN Professor, Adult Health and Nursing Systems School of Nursing

Critically ill patients who require MV are at risk for a number of complications, including the development of ventilator-associated events (VAE) and agitation that may require the use of sedation. Patients experience anxiety and discomfort during mechanical ventilation from a variety of sources including unfamiliar breathing assistance and an inability to communicate anxiety and pain verbally, but a primary cause of discomfort identified by these patients is the simply the presence of the endotracheal tube (ETT). Discomfort often leads to agitation and may be exacerbated by ETT movement. Management of agitation typically involves the use of sedative therapy and has been shown to increase the length of stay in the hospital. Additionally, when ETT cuff pressure is not adequately maintained, risk of microaspiration increases and these microaspirations increase the risk of ventilator-associated events. ETT movement may adversely affect the cuff seal against the tracheal mucosa, increasing leakage around the cuff and microaspiration. To date, no studies have described the



effect of ETT movement on patient comfort and agitation. Noting the frequency of ETT movement during the provision of nursing care and plausible inadvertent consequences on discomfort and agitation, a research model was created and specific instruments selected in order to study this topic. This dissertation will provide a review of the literature regarding the role of the ETT in microaspiration, as well as detail a study that explores the frequency and amount of ETT movement and its potential effect on agitation.



Introduction

While ICUs account for only a small percentage of hospital beds, ICU costs make up a larger proportion of the inpatient costs and much of this cost can be attributed to interventions such as mechanical ventilation (MV). Mechanically ventilated patients have longer ICU length of stay (LOS), incur significantly higher costs per day than non-mechanically ventilated patients and have a crude mortality rate that is significantly higher.¹ Critically ill patients who require MV are at risk for a number of complications, including the development of ventilator-associated events (VAE) and agitation that may require the use of sedation.² MV is often prolonged in patients who develop such complications related to MV. Given the high daily costs, and considering the number of patients who require critical care for sustained periods of time, attention to interventions that result in even nominal decreases in duration of MV or ICU LOS have the potential to significantly reduce overall hospital costs.

Patients experience anxiety and discomfort during mechanical ventilation from a variety of sources including unfamiliar breathing assistance³ and an inability to communicate anxiety and pain verbally.⁴ . A primary cause of discomfort identified by these patients, however, is the simply the presence of the endotracheal tube (ETT).^{5, 6} This discomfort often leads to agitation⁵ and may be exacerbated by ETT movement. Agitation is most often described as excessive restlessness, usually non-purposeful physical activity, associated with internal tension, anxiety, or emotional distress.^{7, 8}



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Agitation has been shown to increase the length of stay in the hospital.^{9, 10} Management of agitation involves the use of sedative therapy, as most ICU patients receive intravenous (IV) sedation to help alleviate the pain, anxiety and agitation accompanying MV.^{11, 12} Topical local anesthetics applied to the ETT have been shown to mitigate ETT discomfort¹³ resulting in reduced need for IV sedative agents in MV patients.¹⁴ Reducing agitation and the use of sedation is associated with shorter duration of MV and ICU length of stay. Therefore describing ETT movement and its effect on discomfort and the resulting agitation is a first step towards developing interventions that may improve outcomes in critically ill patients.

The design of the ETT used during MV includes a cuff that surrounds the distal aspect of the tube and is inflated against the tracheal wall. The inflated cuff prevents leakage of air and subsequent loss of pressure from the lungs during MV, and reduces the aspiration of oral secretions into the lower airway.¹⁵ However, these oral secretions may move beyond the ETT cuff even when the cuff is properly inflated.^{16, 17} Therefore, when ETT cuff pressure is not adequately maintained, risk of microaspiration increases and these microaspirations increase VAE risk.¹⁸ ETT movement may adversely affect the cuff seal against the tracheal mucosa, increasing leakage around the cuff and microaspiration. Chapter 2 will detail the existing literature regarding the ETT and the role of the ETT cuff in microaspiration and demonstrate the need for further research in this area.

To date, no studies have described the effect of ETT movement on patient comfort and agitation. Noting the frequency of ETT movement during the provision of nursing care and plausible inadvertent consequences on discomfort and agitation, a research



model was created and specific instruments selected in order to study this topic (Figure 1). The primary aim of this study was to describe ETT movement and its effect on patient discomfort and agitation. A secondary aim was to describe the effect of nursing care and patient activities on ETT movement.

Figure 1





Not only do patients move themselves, but critically ill patients are moved frequently during their care, to reduce complications of immobility, for medical and nursing procedures and for comfort. As a result, the ETT with the attached ventilator tubing is frequently moved from side to side and up and down during these care activities. This ETT movement may cause discomfort that can lead to agitation. Agitation in the critically ill has a significant negative impact on patient outcomes due to its physiologic complications, increased duration of MV and ICU length of stay, as well as increased hospital costs.¹⁹ Therefore description of ETT movement and its effect on discomfort



and the resulting agitation is an important first step in reducing the negative consequences of agitation in the critically ill.

In summary, MV is a common intervention in the critically ill and the costs of associated complications, both human and economic, are high. Therefore it is important to identify all factors that may affect the development of these complications. Although no studies to date have described the effect of routine ETT movement on patient comfort and agitation, these relationships may have a significant impact on patient outcomes. The study discussed in Chapter 3 will be the first to describe ETT movement and its effect on patient discomfort and agitation and may provide data to develop interventions to reduce these effects in the MV population. Twenty-one MV patients were continuously monitored for ETT movement, as well as indicators of discomfort and agitation, for up to four hours. It was found that the ETT moves nearly continuously and often large distances over time. While this analysis did not show strong correlations between ETT movement and discomfort/agitation (likely due to small sample size), it did illustrate the need for further research regarding the impact of this routinely large amount of ETT movement.



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HEART & LUNG

The role of the endotracheal tube cuff in microaspiration

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ARTICLE INFO

Article history: Received 19 July 2011 Revised 4 September 2011 Accepted 5 September 2011 Online 30 December 2011

Keywords: Cuff leak Cuff pressure Endotracheal tube Microaspiration Ventilator-associated pneumonia

ABSTRACT

The cuff of the endotracheal tube (ETT) is designed to provide a seal within the airway, allowing airflow through the ETT but preventing passage of air or fluids around the ETT. Deliberate or inadvertent movement of the ETT may affect cuff pressure or shift folds in the cuff, mobilizing pooled secretions. When this seal is compromised, microaspirations contaminated with gastric contents or bacterially colonized oral secretions can occur that leave the patient susceptible to a host of problems, such as hypoxia, pneumonitis, and respiratory infections. These complications are costly in terms of morbidity and mortality, as well as hospital expense. We will discuss the role of the ETT cuff in microaspiration and identify potential directions for future research to improve outcomes in mechanically ventilated patients.

Cite this article: Hamilton, V. A., & Grap, M. J. (2012, MARCH/APRIL). The role of the endotracheal tube cuff in microaspiration. Heart & Lung, 41(2), 167-172. doi:10.1016/j.hrtlng.2011.09.001.

Leakage of fluid around the cuff of the endotracheal tube (ETT) into the airway is a potentially serious form of microaspiration. The cuff is designed to provide a seal with the airway, allowing airflow through the ETT but preventing passage of air or fluids around the ETT. When this seal is compromised, microaspirations contaminated with gastric contents or bacterially colonized oral secretions can occur that leave the patient susceptible to a host of problems, such as hypoxia, pneumonitis, and respiratory infections.

Hypoxic events have been shown to accompany aspiration in mechanically ventilated patients.¹ Pneumonitis and ventilator-associated tracheobronchitis (VAT) can also result from aspiration of gastric contents. VAT has been suggested to be an early stage of the ventilator-associated pneumonia (VAP) pathway.² VAP is associated with increased duration of mechanical ventilation (MV), intensive care unit (ICU) length of stay (LOS), mortality, and overall hospital costs.^{3,4}

There are many factors that contribute to the development of VAP as a result of microaspiration, including the presence (or absence) of accumulated subglottic secretions above the cuff (Figure 1) and the inability of the ETT cuff to maintain a seal within the airway.⁵ This article will discuss the role of the ETT cuff in microaspiration and identify potential directions for future research to improve outcomes in mechanically ventilated patients.

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^{0147-9563/\$ -} see front matter @ 2012 Elsevier Inc. All rights reserved. doi:10.1016/j.hrtlng.2011.09.001



Figure 1 — Pooled secretions above the cuff leaking into the airway. Image used by permission from Nellcor Puritan Bennett LLC, Boulder, Colorado, doing business as Covidien.

MATERIALS AND METHODS

Microaspiration: Relationship to Ventilator-Associated Tracheobronchitis and Pneumonia

VAT is not uncommon among intubated acutely ill patients,⁶ with a 2010 review finding an incidence as high as 11.5%.⁷ VAT represents an intermediate process between lower respiratory tract colonization and VAP.⁸ In the most recently published guidelines of the American Thoracic Society and the Infectious Disease Society of America on health care-associated pneumonia,⁹ VAT is regarded as a type of lower respiratory tract infection and as an alternative diagnosis for patients with possible VAP. VAT is defined using the following criteria: fever (>38°C) with no other recognizable cause, purulent sputum production, positive culture of respiratory specimen at significant threshold, and no radiographic signs of new pneumonia.¹⁰ This infection is characterized by lower respiratory tract inflammation and increased sputum production that result in weaning difficulties and longer duration of MV.¹⁰ VAT is often the precursor to VAP. In a randomized controlled trial conducted by Nseir et al,¹¹ 58 patients with clinically diagnosed VAT were randomly assigned to routine treatment or antibiotic therapy. A significant reduction in ICU mortality (18% vs 47%; P = .047) and VAP (13% vs 47%; P = .011) was identified in the antibiotic treatment group, indicating that intervention early in this pathway may prevent the development of VAP.

VAP is defined as a pulmonary infection that occurs 48 hours or more after endotracheal intubation (in patients with no evidence of pneumonia at the time of intubation).⁹ Microaspiration of subglottic contents is a contributing factor to the development of VAP.⁵ During MV, oral secretions move from the oral cavity and pool above the ETT cuff. Colonization of these secretions with pathogenic organisms is nearly unavoidable, and the relationship with microaspiration of these secretions and VAP is well established.¹²⁻¹⁵ Of patients requiring MV, up to 8% to 28% develop VAP.^{16,17} Studies have shown that patients with VAP have significantly longer ICU LOS,¹⁸ an additional \$40,000 in hospital costs,^{4,19} and mortality rates up to 76% versus 32% compared with MV patients without VAP.4,20,21 With increased overall costs and mortality rates, it is critical to identify all factors potentially contributing to VAP to reduce risk. Healthy People 2020 (archived health status objective 14-20e) includes a goal to reduce the incidence of VAP in ICU patients by at least 10%.²² The American Thoracic Society update of research priorities for nursing addresses an "emphasis on nursing interventions that decrease the incidence of ventilatorassociated pneumonia."23 In addition, the 5 Million Lives Campaign to reduce ICU mortality, initiated by the Institute for Healthcare Improvement, has at its core, interventions to reduce VAP, that is, the VAP bundle.²⁴ This continued focus on VAP prevention illustrates the importance of interventions aimed at reducing risks.

Factors Affecting Microaspiration

Subglottic Secretions

One of the primary preventive measures for VAP includes reducing the risk of aspirating oral secretions by preventing accumulation of bacteria-laden secretions above the ETT cuff or minimizing leakage between the cuff and the tracheal wall. Four randomized prospective studies have evaluated the effect of removal of the secretions via intermittent or continuous aspiration of subglottic secretions (CASS) on the development of VAP.^{12,13,15,25} In all 4 studies, the incidence of VAP was reduced. In 101 randomized patients, Yang et al²⁶ demonstrated that those with CASS had significantly lower morbidity of VAP (25% vs 46.5%, P = .032) and delay of onset of VAP (7.3 \pm 4.2 days vs 5.1 \pm 3.0 days, P = .100). In another randomized study that spanned 2 years and included 714 patients undergoing cardiac surgery, subglottic secretion removal demonstrated a significant reduction in the incidence of VAP, ICU LOS, antibiotic use, and overall mortality.²⁷ Evidence showing that removal of subglottic secretions reduces the incidence of VAP suggests that reducing microaspiration is an appropriate and effective method to also reduce VAP.

Endotracheal Tube Cuff Pressure

To prevent potential microaspirations around the ETT cuff, maintenance of adequate cuff pressure is essential.²⁸⁻³⁰ Although sealing the airway around the ETT cuff by high inflation pressure would be effective, high pressures threaten perfusion and integrity of the

tracheal mucosa.^{28,31} Excessive pressure may compromise the microcirculation of the tracheal mucosa and cause ischemic lesions.^{29,32} ETT cuff pressure is recommended to be maintained within 20 to 30 cm H₂O to provide an adequate seal without compromising mucosal perfusion.^{5,33} However, insufficient cuff pressure impedes ventilation with positive pressure and may allow the passage of subglottic secretions.³⁴ Rello et al³⁵ analyzed the effect of cuff pressure on the development of VAP in 83 patients undergoing CASS and showed that CASS failure (when subglottic secretions were not continuously removed) and persistent intracuff pressures less than 20 cm H₂O were associated with a significantly increased risk of pneumonia. They demonstrated that leakage around the cuff is the risk factor of greatest importance for VAP within the first 8 days of MV.

Valencia and colleagues³⁶ assessed the efficacy of an automatic ETT cuff pressure control device in optimizing cuff pressures and preventing VAP development. MV patients (n = 142) with no prior diagnosis of pneumonia were randomly assigned to the treatment group (continuous cuff pressure control) or control group (routine ETT cuff care), with the end point being the incidence of VAP. Investigators were able to maintain ETT cuff pressures within target range (20-30 $cm H_2O$) in approximately 80% of the treatment group. Only .7% of the treatment group patients had cuff pressures less than 20 cm H₂O compared with approximately 45.3% in the control group (P = .001). Although investigators did not demonstrate a statistically significant difference in the pneumonia rate between the groups (29% control vs 22% automatic cuff), a few possible explanations exist for this finding.

Automatic devices might generally maintain cuff pressure well, but the response time during a coughing episode might be too slow and allow a compromise in airway seal for just milliseconds.³⁶ This can lead to the unnoticed microaspiration that occurs with constant cuff pressures. Although 20 cm H₂O is the commonly used pressure to provide sufficient sealing with minimal damage to mucosa, as changes occur in the airway (with movement or coughing), a constant pressure may not be adequate to ensure a constant seal. Chadha et al³⁷ showed in a randomized controlled study in a porcine model (n = 10) that dynamic cuff pressure modulation (varying with inspiration and expiration) significantly reduced laryngotracheal mucosal injury while providing a more consistent seal with the trachea. These findings suggest that research into the effects of movement on ETT cuff pressure in MV humans is warranted.

Sole and colleagues³⁸ demonstrated that ETT cuff pressures change over time by measuring cuff pressures of 23 intubated patients at 4-hour intervals over a 12-hour shift. All patients showed statistically significant decreases in cuff pressure at each measurement interval (4, 8, and 12 hours), with many experiencing clinically significant (>10%) decreases in pressure.³⁸ In a multisite survey, Sole and colleagues³⁹



Figure 2 — Microchannels form as the result of variations in patient airways. A polyurethane cuff designed to eliminate leakage through these folds is shown. Image used by permission from Nellcor Puritan Bennett LLC, Boulder, Colorado, doing business as Covidien.

found that ETT cuff pressures are typically checked, according to institutional policies, only at change of shift (every 8 to 12 hours) or as indicated by suspicion of cuff leak. Frequently estimated by palpation of the pilot balloon, ETT cuff pressure is often significantly lower than estimated by caregivers.⁴⁰ These periods of insufficient pressure leave the patient susceptible to microaspiration, because secretions pooled on top of the ETT cuff may move past it. Movement of the ETT may affect cuff pressure enough to provide this avenue into the lungs.

In a 2011 crossover design study including 32 orally intubated patients, Sole and colleagues⁴¹ used alarms as triggers for intervention to correct out of range cuff pressures. They found that 51.7% of cuff pressures were out of range during the control period compared with 11.1% during the intervention (P < .001). Sole and colleagues^{38,42} have shown that continuous cuff pressure monitoring is possible and may be necessary to consistently monitor and maintain optimal cuff pressure.^{37,41}

Folds in Endotracheal Tube Cuff

The ETT cuff is designed to provide enough pressure to seal the airway without causing perfusion problems in the tracheal mucosa. The cuff itself is made of a pliable medical grade polyvinylchloride (PVC) and forms to the airway as it is inflated.⁴³ Because patients have physiologic and anatomic differences, it can require different amounts of air injected to reach target ETT cuff pressure. As a result, the cuff is inflated in a slightly different configuration with a potentially different volume of air with each ventilated patient. This high-volume, lowpressure (HVLP) "one size fits all" PVC cuff leaves room for an incompletely inflated cuff that, while inflated to recommended pressures, can create channels or passageways for secretions to circumvent the ETT cuff (Figure 2).⁴³ The leakage of secretions despite using clinically appropriate ETT cuff pressure has been hypothesized to be related to the formation of folds in the cuff that allow longitudinal leakage.⁴³⁻⁴⁶ Movement of the ETT may exacerbate the effect of these folds, shifting them and mobilizing pooled oral secretions.

The elimination of leakage around the cuff has been achieved with the use of lubricating gels that fill the cuff channels.^{47,48} Blunt and colleagues⁴⁷ placed dye in the subglottic space and observed for leakage into the tracheobronchial tree in 2 different studies. In their in vitro model, leakage was 0% for cuffs treated with water-soluble gel and 100% for non-treated cuffs. In a double-blind randomized study in anesthetized patients (n = 36), the lubricated group had 11% leakage and the non-lubricated group had 83% leakage (P < .0001).

Another study targeting leakage around the ETT was conducted by Young and colleagues.⁴⁹ They used the dye-leakage method to test a low-volume, lowpressure (LVLP) ETT cuff in a rigid tracheal model, an in vitro pig trachea model, and a randomized controlled trial of 38 anesthetized patients. Leakage was 0% for the rigid tracheal model and the pig trachea model in the LVLP cuffs, whereas it was 100% and 79%, respectively, in the standard HVLP cuffs. In the patient trials, leakage was 5% in the LVLP group and 67% in the HVLP group.⁴⁹ Because the LVLP cuff requires a lower volume, it theoretically does not form the longitudinal folds that an HVLP cuff does when inflated to seal, whereas it provides reliable pressure against the tracheal wall. However, it has not, been demonstrated whether these improvements in ETT cuff seal will lower the incidence of VAP.

The use of different types of ETT cuffs has also been investigated to reduce the incidence of cuff folds. A variety of different materials and designs have been investigated, including latex, silicone, and polyurethane. Several studies have shown that polyurethane cuffs are superior to conventional PVC cuffs in the prevention of microaspiration.⁵⁰⁻⁵³

Endotracheal Tube Movement

Securement of the ETT is generally driven by institutional policy. The ETT is frequently secured with surgical tape that holds the tube at a specific depth, but does little to limit lateral movement of the tube around that site. Multiple studies have attempted to determine which method of securement is ideal,⁵⁴⁻⁵⁷ but there is little evidence that any particular device or technique is superior to any other.⁵⁸ Overall, the data suggest that it is less expensive, more convenient, and just as effective to use standard white surgical tape to secure the ETT as any other alternative method.^{54,56} Unfortunately, none of these studies has examined the amount or effect of lateral and longitudinal movement of the ETT based on securement method.

When nursing care is administered, the ETT is often moved deliberately or inadvertently. The ETT is deliberately moved periodically to prevent breakdown of oral mucosa and often repositioned to improve access when providing patient care and to facilitate effective oral care. The ETT also moves when the patient is turned (manually by nursing staff or automatically by specialty mattress/bed), when the patient moves independently, or when the ventilator tubing is disturbed. Although the tube is secured well enough to maintain the depth of intubation, anecdotal evidence suggests that nurses often provide patient care without extra attention paid to lateral and rotational movement of the ETT tube. Kim et al,⁵⁹ using a fiberoptic bronchoscope, observed movement of the ETT tip in 24 anesthetized adults during flexion, extension, and rotation of the head. Although Kim et al documented measurements only related to distance from the carina, they demonstrated clear movement of the ETT during these positional changes.59 It is possible that this movement affects cuff seal, although this has not been specifically investigated. Because movement of the ETT, both deliberate and inadvertent, is frequent and often not considered during routine care, closer investigation of the potential impact of ETT movement is warranted.

CONCLUSIONS

It is clear that microaspiration continues to be a significant contributor to the development of VAP despite advances in the design and care of the ETT cuff. Although continuous removal of bacteria-laden subglottic secretions has been shown to reduce the incidence of VAP, complete removal of all potential pathogens is difficult, and removal of subglottic secretion is not included in VAP prevention bundles. It has been demonstrated that maintenance of ETT cuff pressures in the recommended target range is, at times, not adequate to prevent microaspirations. Changes in cuff pressure occur and can affect the ETT cuff's ability to maintain a seal against the tracheal wall, increasing the risk of aspirating oral secretions. Determining the role of the ETT cuff in microaspiration is the first step toward understanding how movement of the ETT itself may affect the risk of microaspiration and the subsequent development of VAP.

DIRECTIONS FOR FUTURE RESEARCH

Identifying and understanding actions that increase a patient's risk of life-threatening complications is only

the first step in reducing risk. Research to describe the types of ETT movement and the nursing care that affects movement is currently under way. Further research into oral care interventions that reduce the level of colonization of oral secretions and studies to determine the best method of ETT securement to reduce lateral movement are areas of potential interest. Using ETTs with cuffs made of various materials or studies that test methods to reduce the impact of folds in the cuff are possible avenues to reach better patient outcomes. Future research may be directed toward nursing interventions that minimize the impact of ETT movement. As we understand more about the impact of nursing interventions on the movement of the ETT, we can direct future research specifically to address improvement in patient outcomes.

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Endotracheal Tube Movement: Effect on patient discomfort and agitation

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INSTITUTION AT WHICH WORK WAS PERFORMED: Virginia Commonwealth University Health Systems

GRANT SUPPORTING THIS STUDY: F31 NR011373

KEY WORDS: Endotracheal tube, discomfort, agitation



ABSTRACT

Background: Critically ill patients who require mechanical ventilation (MV) are at risk for a number of complications, including the development of ventilator-associated events and agitation that may require the use of sedation. The longer the duration of MV, the higher these risks may be. Patients experience anxiety and discomfort during mechanical ventilation from a variety of sources and discomfort often leads to agitation, which might be exacerbated by ETT movement. Most ICU patients receive sedation to help alleviate the pain, anxiety and agitation accompanying MV. Reducing agitation and the use of sedation can reduce duration of MV and ICU length of stay.

Objectives: The primary purpose of this study was to describe ETT movement and explore its effect on discomfort and the resulting agitation, as a first step toward developing interventions that may improve outcomes in critically ill patients. A secondary aim was to describe nursing and patient activities associated with ETT movement.

Methods: Thirty three intubated patients from a medical respiratory ICU were enrolled and data was collected for up to four hours. During the study period, ETT movement was measured with a magnetic tracking system, agitation was measured with both continuous actigraphic monitoring on the arm and leg and periodic assessment with the Richmond Agitation Sedation Scale, and comfort was evaluated with the Behavioral Pain Scale. Continuous observation during the study period allowed recording of visual confirmation of activities that affect ETT movement.

Results: There were 58.5 hours of direct patient observation with a mean of 2.8 hours of observation per patient. Very weak correlations were found between ETT movement and both actigraphy (arm: r = 0.11; p<.001 and leg: r = 0.07; p<.001) and measures of discomfort (r = -.06; p = 0.78) and agitation (r = .30; p = 0.19). On average 26.4 minutes were spent in nursing or patient activities that affected ETT movement. However, there was no association between



total ETT movement and total time spent in any activity (r = 0.06; p = 0.81) by subject, nor were there any significant associations among ETT movement and any category of nursing or patient activity

Conclusions: This paper reports the first description of ETT movement other than ETT migration. Critically ill patient experiences of pain and discomfort, as well as risk of microaspiration, are a critical focus of nursing care, but standards of care for managing ETTs do not necessarily focus on ETT movement, except to ensure ETT stability related to depth. Although we did not find an association in this study, additional movement, as we have shown, occurs continuously (side to side, up and down) and may add to further pain and agitation as well as the potential to reduce cuff pressure resulting in microaspiration. To further reduce overall risks and complications of MV, exploration of the effect of ETT movement on both agitation causing discomfort and cuff pressure changes that could increase risk of ventilator-associated events due to microaspiration is in order. A reduction in these complications may have a positive impact on patient outcomes including decreasing duration of MV, ICU and hospital length of stay.



Critically ill patients who require mechanical ventilation (MV) are at risk for a number of complications, including the development of ventilator-associated events (VAE), such as ventilator-associated pneumonia, and agitation that may require the use of sedation.¹ The longer the duration of MV, the higher these risks may be, therefore factors that may increase the amount of time a patient is intubated are important to understand. The endotracheal tube (ETT) design includes a cuff that, when inflated, contacts the tracheal wall and creates a seal that allows air to flow through the tube and prevents bacteria-laden oral secretions from entering the lower airways. It has been well-documented that changes in head and neck position affect ETT cuff pressures,²⁻⁵ which may increase the risk of microaspirations and/or tracheal wall damage due to wide fluctuations in cuff pressure. Much literature exists about ETT movement, in terms of displacement and how that may affect cuff pressure. One recent study showed that after position change, 91.7% of patients had ETT tube displacement. Of these patients, 48% of ETT moved \geq 10 mm, 86.3% had changes in cuff pressure and there was a slight but significant correlation between ETT movement and change in cuff pressure. MINOLittle is known, however, about lateral and/or rotational ETT movement, i.e., how frequently it occurs, the degree of movement and the types of activities associated with this movement. ETT movement may also increase microaspiration as the cuff seal in the trachea or cuff pressure may be adversely affected during ETT movement.⁶ In addition, studies have shown that the presence of an endotracheal tube is a major source of discomfort,⁷⁻¹⁰ but the effect of ETT movement on that discomfort and agitation is yet unknown.

Patients experience anxiety and discomfort during mechanical ventilation from a variety of sources¹¹such as unfamiliar breathing assistance and an inability to communicate anxiety and pain verbally,¹² but a primary cause of discomfort in these patients is the presence of the ETT.¹⁰ This discomfort often leads to agitation which might be exacerbated by ETT movement; conversely patient movement accompanying agitated behavior may affect ETT movement, as well. Most ICU patients receive intravenous (IV) sedation to help alleviate the pain, anxiety and



agitation accompanying MV.^{13, 14} Topical, local anesthetics on the ETT have been shown to mitigate discomfort¹⁵ and reduce the need for sedation in MV patients.¹⁶ Reducing agitation and the use of sedation also reduces duration of MV and ICU length of stay. However, there are no data that describe the type and amount of ETT movement, activities or the level of agitation associated with ETT movement. Therefore the primary purpose of this study was to describe ETT movement and explore its effect on discomfort and the resulting agitation, as a first step toward developing interventions that may improve outcomes in critically ill patients. A secondary aim was to describe nursing and patient activities associated with ETT movement.

METHODS

Subjects and Setting

This study was conducted at the Virginia Commonwealth University Health System (VCUHS) in Richmond, Virginia, a 933-bed tertiary care university medical center with a 232bed critical care hospital, located in an urban area. Approximately 48% of admissions are African American, 42% white, 5% Hispanic, and 5% other/unknown. The hospital offers a wide range of patient care services, including all critical care specialties. This study was conducted in the Medical Respiratory Intensive Care Unit (MRICU). This study was approved by the University's Institutional Review Board and consent for participation was obtained from each patient's legally authorized representative (LAR) prior to enrollment in the study.

A projected sample of up to 35 subjects was to be enrolled from all patients admitted to the MRICU. Male and female adults from all racial/ethnic backgrounds were recruited. Exclusion criteria were: patients with chronic, persistent neuro-muscular disorders (such as cerebral palsy or Parkinson's disease) and patients with head trauma or stroke, as these may affect patient movement and study measurements.

Key Variables and Their Measurement

ETT Movement. A TrakStar magnetic tracking system (Ascension Technologies, Shelburne, VT) was used to measure movement of the ETT relative to the patient. Pilot testing



of this innovative technique was performed to establish the most effective and accurate methods for data collection. To identify ETT movement independent of head movement, one small sensor (2mm) was placed in the center of the patient's forehead, as a reference point for movement of the ETT tube, and one was placed directly onto the ETT as close to the lip as possible. The transmitter that received signals from these sensors was affixed to the head of bed (HOB) so that any movement of the bed itself would not alter the perceived position of the reference point. The tracking system recorded data at 60Hz (60 times per second) and collected information regarding the positions of the 2 sensors on the x, y and z axis, including orientation angles for azimuth, elevation and roll. These values were used to determine the magnitude of ETT movement.

Discomfort. Discomfort was measured using the Behavioral Pain Scale (BPS),¹⁷ a commonly used tool in intubated patients who are unable to communicate, which assigns a value of 1 through 4 to three categories: facial expression, upper limb movement, and compliance with ventilation with an overall score ranging from 3 to 12. Each pain indicator is scored from 1 (no response) to 4 (full response), with the assumption that a relationship exists between each score and pain intensity. The BPS is based on a sum score of these three items. Scores greater than 6 are often considered to indicate the need for pain interventions. The BPS demonstrated good validity when used during noxious and non-noxious stimulation and had inter-rater reliability ranging from .50 -.71.^{17, 18} Chanques et al.,¹⁹ evaluated pain using the BPS (in nonverbal patients) and numeric self-report (NRS) and found no significant difference in the rate of severe pain events between the two groups.

Agitation. Two measures of agitation, actigraphy and the Richmond Agitation Sedation Scale (RASS) were used. The actigraph (Basic Motionlogger, Ambulatory Monitoring Inc, Ardsley, NY) was placed on the wrist and the ankle and used to measure agitation. Actigraphs were placed on both the wrist and the ankle to capture any movement of either upper or lower limbs as a result of agitation. The Motionlogger actigraph is a small, lightweight, limb-worn



activity monitoring device that measures long-term gross motor activity and integrates degree and intensity of motion. It contains a single omnidirectional accelerometer that is capable of sensing any motion with minimal acceleration of 0.01 g and integrates occurrence, degree and intensity of motion to produce activity counts. Internal memory and programming allows the actigraph to store data for long periods of time. Through a wireless data transfer system, data from the actigraph can be read and exported to a data base program.

Wrist actigraphy has been used to monitor activity levels in subjects for sleep, circadian rhythms, pain, or drug response and has been found to be a reliable method of assessing activity/agitation in the critical care setting.²⁰ Actigraphy is easy-to-use and has a long history of use in other populations. It has been used to track circadian rest-activity cycles²¹ and to identify states of wakefulness and sleep.²² Automatic scoring of wrist and ankle activity will provide valuable continuous information about patient activity and agitation. In a prospective evaluation to test procedures for the measurement of agitation of 20 adult medical ICU patients, it was found that actigraphy was significantly correlated with the RASS (p < 0.001), and the Comfort Scale (p < 0.05).²⁰ When compared to presently used sedation scales and direct observation of behavior, actigraphy has been shown to be a valid method to assess sedation and agitation in the critically ill population²⁰ and differentiates among behavior states (restless, calm, agitated).²³

The RASS is a 10 point scale, ranging from -5 (unarousable) to 0 (calm and alert) to +4 (combative), based on observation of specific patient behaviors. It has been validated against a visual analogue scale of sedation and agitation and tested for inter-rater reliability in 5 adult ICUs.²⁴ It has also been validated against other published sedation scales and tested for reliability using bedside nurses compared to trained instructors.²⁴ Additional reliability and validity was demonstrated in a prospective cohort study of 38 medical ICU patients for reliability testing (46% receiving mechanical ventilation) and an independent cohort of 275 patients receiving mechanical ventilation for validity testing.²⁵ The RASS demonstrates excellent interrater reliability and criterion, construct, and face validity and is the first sedation scale to be



validated for its ability to detect changes in sedation status over consecutive days of ICU care, against constructs of level of consciousness and delirium, and correlates with the administered dose of sedative and analgesic medications. The RASS is a broadly used sedation-agitation scale and is routinely used in the target ICU. In the recently published clinical practice guidelines for managing pain, agitation, and delirium from the Society of Critical Care Medicine²⁶, the RASS received the highest score among all sedation/ agitation instruments for psychometric properties and strength of evidence for utility.

Respiratory rate. Respiratory patterns, specifically respiratory rate may affect ETT movement, as the ETT may move with each ventilated and/or spontaneous breath. To determine the amount of ETT movement that is related to factors other than respiratory patterns measurement of respiratory rate is critical. Therefore, breath to breath respiratory rate was measured continuously in real time using the Non-Invasive Cardiac Output monitor (NICO₂). The NICO₂ monitor, a device designed to measure non-invasive cardiac output (NovaMetrix Medical Systems, Inc., Wallingford, CT) produces a linear and calibrated output as a function of flow through a fixed-orifice differential pressure pneumotachometer which is attached between the end of the ETT and the ventilator tubing. Exhaled gas flowing through the sensor produces a slight pressure decrease across the two tubes connected to the sensor. This pressure decrease is transmitted through the tubing to a differential pressure transducer inside the monitor and is correlated with flow according to a factory-determined calibration. Continuous analog voltage signals corresponding to volume exhaled by the patient ventilator will be sampled at a rate of 250 samples per second or every 4 milliseconds and stored for later analysis.

<u>Nursing care and patient activities</u>. A variety of nursing care activities may also affect ETT movement and result in changes in ETT cuff pressure, potentially increasing patient risk.²⁷ Although ETT cuff pressure was not monitored in this study, description of ETT movement is the first step to determine its associated risks. During a pilot study, a list of common nursing activities that may affect ETT movement, including patient responses, was devised, revised and



validated. (Table 1) These activities were recorded categorically through an electronic observation recording system that allowed simultaneous events to be recorded in real time.

<u>Subject Demographics</u>. Information was obtained to describe the sample and included subject age, gender, race/ethnicity, duration of endotracheal intubation (in hours), ICU length of stay (in days), ventilatory settings and severity of illness. Individual patient differences related to severity of illness may also affect patient response to ETT movement. Patients who have greater severity of illness may require higher doses of opioids and sedatives which deepen sedation levels and may affect ETT movement. Therefore severity of illness was documented on study enrollment using the APACHE III.²⁸ The APACHE III is based on the concept that the pretreatment risk of death of an acutely ill patient is determined by type of disease, physiologic reserve, and severity of disease. The APACHE III scoring system has been validated and widely used to stratify patients into well-defined groups and to ensure that research treatment and control groups had equivalent severity of illness.²⁹

Procedures

An in-service about the study was provided to the unit nurse managers, nursing staff members and respiratory therapists prior to study implementation and to inform the staff of the study purpose and procedures. Daily rounds were made in the MRICU by one of the investigators (AH) to evaluate patients as potential subjects for the study, to conduct all informed consent processes and to enroll all subjects. Data collection was completed by one investigator (AH) and occurred during any period of the hospital stay as long as the inclusion criteria were met

A four hour direct observation period was used for data collection to provide a time frame that would ensure the capture of routine nursing care (i.e. oral care, turning of the patient, regular assessments), as well as any incidental movement. The timing of this 4-hour direct observation of the subject was not specified as to time of day to provide more flexibility in accommodating patient care needs and family preferences for individual subjects, since



examination of circadian effects was not a study focus. Data obtained did not affect the subject's care and was not used in the clinical management of discomfort or agitation. The bedside nurse managing the care of the patient continued to evaluate the patient's level of discomfort and agitation in the routine manner and was not involved in any aspect of data collection. Once the subject was enrolled in the study, descriptive data concerning subject demographics and ICU admission information was collected from the medical record along with Information for the APACHE III, which was based on the 24 hours prior to study enrollment.

During the observation period the investigator sat unobtrusively by the bed and documented data regarding the origin of ETT movement, either initiated by staff or the patient, using a "toggle box" which consisted of toggle switches associated with the 8 categories of ETT movement (Table 1). These data were downloaded to a laptop computer and allowed for time-stamped observation of simultaneous events that affected ETT movement.

Continuous measurement of ETT movement, respiratory parameter (RR), and actigraphy occurred during the entire four hour period. Data for intermittent measures, discomfort (BPS) and agitation (RASS), were collected prior to any contact with the subject, at baseline and again every half hour during the data collection period. In order to score the RASS, the subject must be stimulated to respond if not obviously awake and alert. Therefore, collection of the RASS data occurred after the measure of discomfort (BPS) so that the stimulation required for scoring the RASS did not affect the BPS.

Data from each continuous measurement (ETT movement, RR, actigraphy) was time stamped upon arrival to a laptop computer and imported into a database for further analysis. The time stamping of data allowed time alignment and correlation of data with other observational measurements.

Data Analysis

Data were collected 60 times per second for ETT movement, every second for actigraphy and with each breath for the NICO. All of these data were then averaged over a one



second interval to provide a common epoch across measures. The mean value for ETT movement, actigraphy, RR over a one minute interval was then used for analysis. This process resulted in a single observation for every minute for a period of up to 4 hours for ETT movement, actigraphy, and RR.

The primary aim of this study was to describe ETT movement and explore its effect on discomfort and the resulting agitation. To achieve this first aim, descriptive statistics were used to describe ETT movement, patient discomfort and agitation. Multivariate analyses were used to determine if ETT movement and key variables (BPS, actigraphy and RASS scores) are significantly related. Descriptive statistics were used to describe the amount and frequency of ETT movement.

RESULTS

Thirty-three subjects were enrolled in the study. Twelve were excluded from analysis as a result of deterioration in clinical status (n=3), family withdrawal of subject (n=1), equipment (TrakStar) failure (n=8). The majority of the sample used for this analysis (n=21) was male and African American with a mean age was 58 years of age (Table 2). The mean score on the Acute Physiology and Chronic Health Evaluation III (APACHE III) was 88.2 and the median stay in the ICU was 17 days. Thirty eight percent of patients had physical restraints, with wrist restraints being the most commonly observed method (Table 2).

<u>ETT Movement</u>. Over the entire study period, there were 58.5 hours of direct patient observation with a mean of 2.8 hours of observation per patient. The majority of subjects had less than the target of 4 hours of observation due to clinical demands that required removal of study equipment (i.e. patient travelled for diagnostic studies or nurse requested removal for therapeutic intervention). However, this resulted in almost 50 hours of data for each of the major variables (Table 3). One subject had neither arm nor leg actigraphy data, and one subject had leg actigraphy only. Eighteen subjects had data for all variables of interest -- ETT movement (TrakStar), agitation (actigraphy, RASS) and pain (BPS). It was noted that ETT



movement occurred continuously resulting in no minute of data collection without movement, even during times with no documented activities or events that would affect ETT movement. It was also noted that 83% of the observed movement of the ETT was patient initiated.

ETT Movement, Discomfort and Agitation. There were 132 BPS measurements over the observation period in the 21 subjects with a mean of 3.3, range 3 to 9. (Table 3) There was no significant association between ETT movement and the average Behavioral Pain Scale (r = -...06; p = 0.78) or RASS (r = ...30; p = 0.19) by subjects. Levels of ETT movement by BPS value are shown in Figure 1. Multivariate analyses showed weak correlations between ETT movement and arm actigraphy (r = 0.11; p<.001) and ETT movement and leg actigraphy (r = 0.07; p<.001) (Table 4). Patterns across subjects for all continuous measurements (TrakStar, actigraphy) and average pain level (BPS) are shown in Figure 2. However, no obvious patterns were identified.

Since the ETT moves continuously it was theorized that this continuous movement may be associated with respiratory patterns. Therefore an analysis of this association was conducted, identifying a weak correlation (r = 0.18; p<.001) but the strongest correlation among all variables (Table 4).

<u>Nursing care and patient activities</u>. Nursing care and patient activities were totaled by subject based on number and duration of activities in minutes. (Table 3) Of the total hours of observation, on average 2.8 hours per subject, 26.4 minutes were spent in nursing or patient activities that affected ETT movement. However, there was no association between total ETT movement and total time spent in any activity (r = 0.06; p = 0.81) by subject, nor were there any significant associations among ETT movement and any category of nursing or patient activity (shift vent tubing r = -0.07, p = 0.77; patient turned by staff r = -0.07, p = .78; HOB raised/lowered r = 0.06, p = 0.81; ETT suction r = 0.11, p = 0.79; turns head r = 0.16, p = 0.57; shifts body r = -0.29, p = 0.37; other patient movement r = 0.10, p = 0.69).



DISCUSSION

While much has been published regarding ETT migration, in terms of depth, there is very little known about other types of ETT movement and the effect of that movement on patient discomfort and agitation. The ETT is a primary source of discomfort for intubated patients,^{7, 10, 11} and further studies have shown that a topical anesthetic applied to the ETT cuff can reduce discomfort¹⁵ and the need for sedative and analgesic use by up to 40%.¹⁶ We found in this sample of critically ill subjects in the MRICU that ETT movement occurs continuously and is associated with measures of agitation (both arm and leg actigraphy), but not associated with a measure of pain (BPS). Since ETT movement was noted to be continuous, associations with respiratory patterns were explored and shown to also be significant, again likely due to the large sample size. However, although this association was the strongest identified in this study, it most likely does not explain all the sources of ETT movement.

It was expected the amount of ETT movement found would be associated with activities (nursing or patient) that included moving the ETT, however this was not the case. Since the analysis was conducted by subject (N=20; one subject did not have activity data), it was based on a small sample size that may have affected the ability to detect significance. Further exploration including an analysis of activities per minute may prove more fruitful in determining the specific factors that affect ETT movement.

This paper reports the first description of ETT movement other than ETT migration (changes in depth). Critically ill patient experiences of pain and discomfort, as well as risk of microaspiration, are a critical focus of nursing care. Standards of care for managing ETTs do not necessarily focus on ETT movement, except to ensure ETT stability related to depth. Although we did not find an association in this study, additional movement, as we have shown, occurs continuously (side to side, up and down) and may add to further pain and agitation as well as the potential to reduce cuff pressure resulting in microaspiration. Patients routinely complain about pain and discomfort associated with the ETT.^{10, 11} Nurses move the ETT and



attached ventilator tubing frequently and may have little awareness of the effect. Data show that when topical anesthetic is applied to the ETT cuff, one of the most likely areas of irritation during ETT movement, there was a significant reduction discomfort¹⁵ and analgesic and sedative use.¹⁶ One study that explored specific areas of discomfort related to the ETT found that when asked, almost a third of patients described the discomfort as located in the chest approximately at the level of the ETT cuff.¹⁰ Further exploration of the effect of ETT anesthetic is warranted.

To further reduce overall risks and complications of MV, exploration of the effect of ETT movement on cuff pressure changes that could increase risk of ventilator-associated events due to microaspiration or tracheal trauma (cuff pressure >30cm H2O) are in order. A reduction in these complications may have a positive impact on patient outcomes including decreasing duration of MV, ICU and hospital length of stay.



TABLE 1

NURSING CARE AND PATIENT ACTIVITES DURING ETT MOVEMENT

1	Shift ventilator tubing for access
2	Patient turned by staff
3	Raise/lower HOB
4	ETT is re-taped/moved
5	ET suction
6	Patient turns head
7	Patient shifts body
8	Patient Movement – Other (patient coughs, attempting to speak, pulls tube, etc)



TABLE 2

SAMPLE CHARACTERISTICS FOR ALL SUBJECTS ENROLLED (N=21)

	Mean	SD	Range
AGE (YEARS)	58.4	13.3	24 – 81
APACHE III	88.2	26.7	47 – 154
	Median	IQR	Range
ICU LENGTH OF STAY (DAYS)	17	11.75, 22.25	1 – 72

	Count	Pe	ercent	
LENGTH HOSPITAL STAY (DAYS)	22	16.25, 30.25	1 - 117	
			• • -	

	Count	Fercent
GENDER		
MALE	14	66.7
FEMALE	7	33.3
RACE		
AFRICAN AMERICAN	12	57.1
CAUCASIAN	9	42.9
RESTAINTS		
UPPER EXTREMITY	8	38.1
NONE	13	61.9



Variable	N (Subjects)	N	Mean	Range	SD
		Minutes (Hours)	Minutes	Minutes	Minutes
ETT Movement (cm) by minute	21	3215 (53.6)	763.6	0.3 – 17,967.2	835.5
Arm Actigraphy (count by minute)	20	2982 (49.7)	273.4	0 - 6458	723.5
Leg Actigraphy (count by minute)	19	3223 (53.7)	150.1	0 – 5123	373.5
Respiratory Rate by minute	18	3077 (51.3)	16.0	5.8 - 40.7	4.9
	N (Subjects)	N (Total	Mean	Range	SD
		Scores)			
BPS (Total Score) by measurement	21	132	3.4	3 – 9	1.0
RASS Measurements – Scores by	N (152 total	Percent			
category	scores)				
restless/agitated (+1, +2, +3, or +4)	16	10.5%			
alert/mildly sedated (-2, -1 or 0)	84	55.3%			
moderate/deeply sedated (-5, -4,	52	34.2%			
or -3					
	N (Subjects)		Duration		
		Event Count	(HR:MIN)		
Total amount of observation time			51:24		
All Events	20	752	8:48		
Shift vent tubing for access	20	127	0:24		
Patient turned by staff	17	53	0:46		
Raise/lower HOB	19	53	0:15		
ETT is re-taped/moved	2	6	0:08		
ET suction	8	18	0:05		
Patient turns head	15	267	1:06		
Patient shifts body	12	250	1:00		
Patient Movements (Other*)	18	314	5:54		

 Table 3. Summary statistics for major study variables per observation

*Other = patient cough, attempting to speak, pulls tube



Table 4.Correlations (R) among ETT Movement, Arm Actigraphy, Leg Actigraphy,Respiratory Rate

	Arm Actigraphy	Leg Actigraphy	Respiratory Rate
ETT Movement	0.11**	0.07**	0.18**
Arm Actigraphy		0.60**	0.04*
Leg Actigraphy			0.13**

* p < .05; ** p < .001





Figure 1. ETT Movement (TrakStar) by Level of Pain (BPS)



Figure 2. Major Variables by Subject







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APPENDIX A

Richmond Agitation-Sedation Scale (RASS)*

<u>Score</u>	Term	Description
+4	Combative	Overtly combative or violent. Immediate danger to staff
+3	Very agitated	Pulls on or removes tube(s) or catheter(s), or has aggressive behavior towards staff
+2	Agitated	Frequent nonpurposeful movement or patient-ventilator dysynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, but has sustained (> 10 sec) awakening, with eye contact, to voice
-2	Light sedation	Briefly (< 10 sec) awakens with eye contact to voice
-3	Moderate sedation	Any movement (but no eye contact) to voice
-4	Deep sedation	No response to voice, but any movement to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

PROCEDURE

1. Observe patient. Is patient alert and calm? (Score 0)

Does patient have behavior consistent with restlessness or agitation? (Score +1 to +4 using criteria listed above)

2. If patient is not alert, in a loud speaking voice state patient's name and direct patient to open eyes and look at speaker. Repeat once if necessary. Can prompt patient to continue looking at speaker.

Patient has eye opening and eye contact which is sustained for > 10 sec. (Score -1) Patient has eye opening and eye contact, but this is not sustained for 10 sec. (Score -2) Patient has any movement in response to voice, excluding eye contact. (Score -3)

3. If patient does not respond to voice, physically stimulate patient by shaking shoulder, then rubbing sternum if no response to shaking shoulder.

Patient has any movement to physical stimulation (Score -4) Patient has no response to voice or physical stimulation (Score -5)

*Sessler, C. N., Gosnell, M. S., Grap, M. J., Brophy, G. M., O'Neal, P. V., Keane, K. A. et al. (2002). The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. *Am.J.Respir.Crit Care Med.*, *166*, 1338-1344.



APPENDIX B

The Behavioral Pain Scale*

Item	Description	Score
Facial expression	Relaxed Partially tightened (e.g., brow lowering) Fully tightened (e.g., eyelid closing) Grimacing	1 2 3 4
Upper limbs	No movement Partially bent Fully bent with finger flexion Permanently retracted	1 2 3 4
Compliance with ventilation	Tolerating movement Coughing but tolerating ventilation most of the time	1 2
	Fighting ventilator	3
	Unable to control ventilation	4

Each of the three categories—facial expression, upper limbs, and compliance with ventilation is scored from 1 to 4. The values are added together for a total score between 3 and 12.

*From Payen, J-F., Bru, O., Bosson, J-L., Lagrasta, A., Novel, E., Deschaux, I., Lavagne, P., & Jacquot, C. (2001). Assessing pain in critically ill sedated patients by using a behavioral pain scale. Critical Care Medicine, 29(12), 2258-2263.



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