

Endotracheal Tube Securement Study: The Effect of Adhesive Versus Endotracheal Tube  
Fastener in Critically Ill Adults

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## **1.0 Study Summary**

**Title:** Endotracheal Tube Securement Study: The Effect of Adhesive Tape Versus Endotracheal Tube Fastener on Lip Integrity, Tube Dislodgement, and Ventilator Associated Pneumonia in Critically Ill Adults

- A single center randomized controlled trial of endotracheal tube securement with adhesive tape versus endotracheal tube fastener in the incidence of lip ulcers, tube dislodgement, and ventilator associated pneumonia.

**Study Site:** Vanderbilt University Medical Center Nashville, TN

**Background:** During endotracheal intubation there are many potential complications including laryngeal trauma, bronchospasm, hypotension, airway perforation, and vertebral column injury. Following intubation for mechanical ventilation, there are several techniques to secure the endotracheal tube. The optimal stabilization method in reducing complications is unknown. We propose a randomized controlled trial to compare the effect of adhesive tape versus endotracheal tube fastener on complications including lip ulcers, endotracheal tube dislodgement, and ventilator associated pneumonia among critically ill adults requiring intubation and mechanical ventilation.

### **Primary Aim:**

- To compare the effect of adhesive tape versus endotracheal tube fasteners on the incidence of lip ulcers, tube dislodgement, and ventilator associated pneumonia among critically ill adults undergoing endotracheal intubation

### **Primary Hypothesis:**

- The use of an endotracheal tube fastener will reduce the incidence of lip ulcers, tube dislodgement, and ventilator associated pneumonia among critically ill adults undergoing endotracheal intubation

### **Inclusion Criteria:**

1. Patient is admitted to an ICU at Vanderbilt University Medical Center
2. Patient requires intubation and mechanical ventilation
3. Intubated for less than 12 hours before enrollment in the study
4. Patient anticipated to be intubated 24 hours or longer
5. Age > 18 years

### **Exclusion Criteria:**

1. Presence of oral mucosa or facial skin breakdown before study enrollment
2. Nasotracheal intubation
3. Patients with documented allergy to tape
4. Patient has facial anatomy which prevents the use of endotracheal tube fastener

5. Prisoners
6. Pregnant patients

**Consent:** Given that both techniques for securing endotracheal tubes are used in practice, appear to be arbitrarily chosen by the RT or medical team, and that there is a lack of established risk or benefit between the two techniques, this trial poses no increased risk beyond usual ICU care to the patients. Also, over 90% of patients undergoing endotracheal intubation in the ICU cannot consent for the procedure itself and choosing a securement strategy is time-sensitive as endotracheal tube securement must occur at the time of intubation, therefore it is impractical to obtain informed consent for research prior to the procedure. Given the minimal risk interventions and impracticability of informed consent, a waiver of informed consent will be requested.

**Randomization:** Using opaque envelopes available in the patient care area participating in the study, participants will be randomized 1:1 to adhesive or endotracheal tube fastener

Study Interventions:

- Endotracheal tube securement
  - Adhesive Tape: (1) Use skin preparation pad (tincture benzocaine) to prepare area over cheeks and upper lip where adhesive tape will be secured (2) Use tape to tape approach to decrease adhesiveness of tape to back of neck / hair area. (3) Secure tape around patient's neck. (4) Encircle the adhesive tape around the tube and fix to the maxilla about the upper lip and down the lower lip.
  - Endotracheal tube fastener: (1) Place upper lip stabilizer so it rests on skin between nose and lip; place skin barrier pads on cheeks. (2) Secure ETT wrap with non-slip grippers and one-click security clamp. (3) Position gliding tube shuttle; reposition as needed for oral care and pressure relief.
  - Repositioning: Frequency of repositioning of endotracheal tube in both groups will be left to the applicable ICU protocol (or discretion of the provider if no applicable protocol) and will be documented accordingly.

**Primary Endpoint** (All endpoints are collected non-invasively and are already a part of clinical data obtained in usual ICU care at the bedside or in the medical record):

- Composite of any of: presence of lip ulcer, endotracheal tube dislodgement, or facial skin tears from the time of randomization to the earlier of death or 48 hours after extubation

Secondary Endpoints:

- Presence of Lip Ulcer
- Endotracheal tube dislodgement
- Ventilator associated pneumonia incidence

- Facial skin tears
- Ventilator-free days

## **2.0 Background**

### **2.1 Complications of endotracheal tube securement**

Effective endotracheal tube securement is imperative in providing safe mechanical ventilation. Various techniques have been utilized to ensure endotracheal tube stabilization in order to maintain a patent airway and prevent complications. One common complication of endotracheal tube securement is lip ulcers. The development of lip ulcers is not rare and is associated with increased financial burden and potentially increased length of stay. Endotracheal tube dislodgement is another common complication of tube securement. It is imperative for the tube to be correctly positioned to maintain optimum airway passage and promote effective mechanical ventilation. If the tube is not secured correctly, it can become dislodged which may result in unplanned extubation, bronchospasm, and tracheal injury. Additionally, endotracheal intubation and mechanical ventilation is associated with ventilator associated pneumonia. Proper oral hygiene is essential in decreasing the incidence of ventilator associated pneumonia. Utilizing an endotracheal tube securement technique that enables providers to perform oral hygiene is imperative. It is thought that modifying endotracheal tube securement technique could reduce these complications.

## **3.0 Rationale, Aims, and Hypotheses**

In order to determine the effect of adhesive versus endotracheal tube fasteners on prevalence of lip ulcers, endotracheal tube dislodgement, and ventilator associated pneumonia among intubated critically ill patients, a randomized trial is needed.

### **Study Aims:**

#### **Primary:**

- To compare the effect of adhesive tape versus endotracheal tube fasteners on adverse effects (lip ulcers, endotracheal tube dislodgement, or facial skin tears) among critically ill adults undergoing endotracheal intubation

#### **Secondary:**

- To compare the effect of adhesive tape versus endotracheal tube fasteners on ventilator-free days among critically ill adults undergoing endotracheal intubation

### **Study Hypotheses:**

#### **Primary:**

- The use of an endotracheal tube fastener will reduce the incidence of any of lip ulcers, endotracheal tube dislodgement, or facial skin tears among critically ill adults undergoing endotracheal intubation

**Secondary:**

- The use of endotracheal tube fastener will reduce the incidence of endotracheal tube dislodgement, ventilator associated pneumonia, and facial skin tears among critically ill adults undergoing endotracheal intubation
- The use of endotracheal tube fastener will increase the number of ventilator-free days among critically ill adults undergoing endotracheal intubation

#### **4.0 Study Description**

In order to address the aims outlined above, we propose a randomized trial evaluating the impact of adhesive tape versus endotracheal tube fastener on the incidence of lip ulcers, endotracheal tube dislodgement, ventilator associated pneumonia, and facial skin tears among critically ill adults undergoing endotracheal intubation. Patients admitted to the study ICU who are deemed by their clinical team to require intubation and fulfill inclusion criteria without meeting exclusion criteria will be enrolled and randomly assigned to adhesive tape versus endotracheal tube fastener. If patients were intubated prior to admission to the intensive care unit and the intubation time was less than 12 hours from the time of admission, they will be included in the study. Data will be collected at the time of intubation and prospectively from the medical record in order to determine the effect of the assigned intervention on short- and long-term outcomes. All data are collected non-invasively and are already a part of clinical data obtained in usual ICU care at the bedside or in the medical record. No additional data will be collected that are not observed at the bedside or obtained from the medical record.

#### **5.0 Inclusion and Exclusion Criteria**

##### **5.1 Inclusion Criteria**

We will include endotracheal tube securement events in which:

1. Patient is admitted to the intensive care unit at Vanderbilt University Medical Center.
2. Planned procedure is endotracheal intubation and mechanical ventilation OR
3. Patient is intubated prior to arrival, however the intubation occurred less than 12 hours prior to admission to the intensive care unit
4. Patient is likely to be intubated > 24 hours.
5. Age > 18 years old

##### **5.2 Exclusion Criteria**

We will exclude airway management events in which:

1. Patient has presence of oral mucosa or facial skin breakdown before study enrollment

2. Patient will require nasotracheal intubation
3. Patients with documented allergy to tape
4. Patient who have facial anatomy which prevent the use of endotracheal tube fastener
5. Prisoners
6. Pregnant patients
7. Patient who the team feels must have either adhesive tape or endotracheal tube skin fasteners as the securement device

## **6.0 Enrollment/Randomization**

**6.1 Study Sites:** ICU at Vanderbilt University Medical Center

**6.2 Study Population:** The study population will be all critically ill adults admitted to an ICU service for whom the clinical team has decided to perform endotracheal intubation or for whom endotracheal intubation has been performed within 12 hours prior to admission. Patients will be excluded if they were intubated greater than 12 hours prior to admission, if they have oral mucosa or facial skin breakdown before enrollment, if they require nasotracheal intubation, or have a documented allergy to tape.

**6.3 Enrollment:** All patients will be enrolled at the time the clinical team decides that intubation is required and the patient meets inclusion but no exclusion criteria. If the patient arrives in the MICU already intubated, but has been intubated less than 12 hours and does not have exclusion criteria, they will be eligible for randomization as soon as possible (but must occur within 12 hours of the intubation) when their endotracheal tube is undergoing securement.

**6.4 Consent:** Because the intervention studied (1) is FDA approved and used according to its FDA approval as a part of routine care, (2) is an intervention the patients would arbitrarily be exposed to even if not participating in the study, and (3) is an equivalent option from the perspective of the clinical provider (otherwise patient is excluded), we feel the waiver of consent involves no more than minimal risk. Additionally, obtaining informed consent in the study would be impractical. Endotracheal intubation of acutely ill patients is frequently a time-sensitive procedure. Despite the availability of a formal informed consent document for the procedure itself, time allows discussion of risks and benefits in less than 10% of airway management events in the ICU. Because the study interventions represent minimal risk, would not adversely affect the welfare or privacy rights of the participant, and consent would be impracticable, we will request a waiver of informed consent. Information regarding the study will be available for patients and families.

**6.5 Randomization:** Computerized randomization using permuted blocks of two, four, or six will be conducted in order to generate a series of study assignments deliberately exceeding the planned enrollment number. Study assignments will be placed in opaque randomization envelopes and will be available to operators in the ICU at VUMC. Study group assignment will remain concealed to study personnel and

operators until after the decision has been made to enroll the patient in the study. Once it has been determined by the treating team that intubation is required, (or maintenance of endotracheal tube securement in patients intubated less than 12 hours prior to admission) the operator will open the envelope and follow the assignment of either adhesive tape or endotracheal tube fastener.

## **7.0 Study Procedures**

### **7.1 Study Interventions**

#### **7.1.1 Endotracheal Tube Securement**

Once the envelope is opened and group assignment known, the clinical team will either secure the endotracheal tube with either adhesive tape or the endotracheal tube fastener. In patients randomized to adhesive tape, the respiratory therapist will secure the endotracheal tube with adhesive tape as demonstrated in figure 1. In patients randomized to endotracheal tube fastener, the respiratory therapist will secure the endotracheal tube with the Hollister endotracheal tube fastener per the manufacturer's instructions (demonstrated in figure 2).

#### **7.1.2 Endotracheal Tube Repositioning**

Prior studies investigating endotracheal tube securement techniques require that the endotracheal tube is repositioned and retaped every 24 hours (1,2). However, due to the pragmatic design and intent of this protocol, the endotracheal tube will not routinely be repositioned specifically as part of the study protocol. The tube will be repositioned as needed according to ICU policy or protocols or at the discretion of the provider, bedside nurse, or respiratory therapist.

#### **7.1.3 Oral hygiene**

Oral hygiene will be performed every 12 h and oral moistening every 2 hours based on policy of the ICU.

## **8.0 Data Collection**

All data will be collected non-invasively and will already be a part of clinical data obtained in usual ICU care at the bedside or in the medical record. No additional data will be obtained beyond that which is obtained by bedside observation and from the electronic medical record.

**Baseline:** Age, gender, height, weight, race, active medical problems at the time of intubation, active comorbidities complicating intubation, indication for intubation, whether it is a reintubation, whether the face was soiled during the intubation

**Periprocedural:** Depth of tube as measured at lip line and position in mouth (ie 22 cm at the lip, midline) at time of securement

**In-Hospital Outcomes:** days on mechanical ventilator, ICU mortality, mortality for ventilator free days, oral mucosa assessment, facial skin integrity assessment, frequency of endotracheal tube repositioning, endotracheal tube dislodgements – defined as either complete

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dislodgement of the endotracheal tube (i.e. accidental extubation) or needing to reposition the endotracheal tube more than 1 cm (i.e. need to pull ETT back 2+ cm or move it down 2+ cm).

The following study endpoints will be collected if they occur anytime between randomization and the earlier of death, hospital discharge, tracheostomy placement, or 48 hours after extubation: lip ulcers, facial skin tears, tube dislodgement, and ventilator associated pneumonia.

Ventilator-free days will be collected from the time of randomization through study day 28. In order to get credit for a ventilator-free day, a patient must be both alive and free of mechanical ventilation. Patients who are extubated and reintubated will only be credited with being free of mechanical ventilation for days after the last extubation. Patients who die before study day 28, regardless of whether or not they ever achieved unassisted breathing, will be assigned zero ventilator-free days. Patients who are still on the ventilator at study day 28 will also receive zero ventilator-free days. Patients who are discharged from the hospital prior to study day 28 free of mechanical ventilation will be assumed to remain free of mechanical ventilation through study day 28. Patients who are discharged from the hospital prior to day 28 on mechanical ventilation will try to be followed at the discharge location for date of extubation – however, if the date is not able to be obtained, they will be assumed to have zero ventilator free days in the analysis.

## **9.0 Risk and Benefits**

In patients for whom the treating team has decided endotracheal intubation is required, there are currently no established risks or benefits to endotracheal tube securement with adhesive tape or endotracheal tube fastener. Additionally, previous studies of endotracheal tube securement of critically ill adults suggest that in routine care, respiratory therapists arbitrarily decide to use adhesive tape or endotracheal tube fastener. At this time, there is no reason to believe that participation in this study would expose patients to greater medical risks or benefits than those experienced by critically ill patients requiring endotracheal intubation and securement as a part of routine care. The greater benefit of the study would be to improve understanding of safe and effective endotracheal tube securement for critically ill patients.

A potential risk to patients participating in this study involves the collection of protected health information (PHI). In order to limit the associated risks, the minimum amount of PHI necessary for study conduct will be collected. After collection, the data will be stored in a secure online database (REDCap) only accessible by the investigators. After publication, a de-identified database will be generated to protect participant privacy.

## **10.0 Safety Monitoring and Adverse Events:**

### **10.1 Safety Monitoring**

This study will take place in the environment of the intensive care unit. At the time of the study intervention, the patient will have in the room a critical care nurse and respiratory therapist.

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Additionally, there will be continuous invasive or non-invasive monitoring. Additionally, study personnel will readily be available to answer questions at any time during the study course. Even after randomization if any healthcare provider participating in the endotracheal tube securement study believes that the study interventions cannot be performed for the safe performance of the procedure or the safety of the patient, the study intervention is halted and the patient has the endotracheal tube secured in the manner which the clinical team judges to be safest.

## **10.2 Adverse Events**

An adverse event is defined as any untoward medical occurrence in a clinical investigation participant administered an intervention that does not necessarily have to have a causal relationship with this treatment. An adverse event therefore can be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an intervention, whether or not the incident is considered related to the intervention.

A serious adverse event (SAE) is defined as any unexpected and untoward medical occurrence that is probably or possibly related to the study and meets any of the following criteria:

- a. Results in death
- b. Is life-threatening (defined as an event in which the participant was at risk of death at the time of the event and NOT an event that hypothetically might have caused death if it would have been more severe)
- c. Requires inpatient hospitalization
- d. Prolongs an existing hospitalization
- e. Results in persistent or significant disability or incapacity
- f. Results in a congenital anomaly or birth defect
- g. Important medical event that requires an intervention to prevent any of a-f above.

The Principal Investigator will be responsible for overseeing the safety of this trial on a daily basis. She will be available at any time for questions from the bedside nurses or respiratory therapists, who will also be monitoring the patients continuously for adverse events and serious adverse events. Serious and unexpected adverse events associated with study interventions will be recorded in a case report form in the study record and reported to the IRB within 10 business days.

## **11.0 Study Withdrawal/Discontinuation**

Patients can be withdrawn from study participation in the following circumstances:

- The investigator or medical team decides that the patient should be withdrawn for safety considerations.

- There is a significant protocol violation in the judgment of the PI.

The reason and date of every withdrawal will be recorded in the patient study records. Follow-up will be performed for all patients who discontinue due to an adverse event or any other safety parameter. Follow-up will also be performed for all patients who end participation in the protocol for another reason, but who also have an adverse event or other safety parameter that could have led to discontinuation. Follow-up will be conducted until the condition has resolved, until diagnosis of the adverse event or safety parameter is deemed chronic and stable, or as long as clinically appropriate. This follow-up will be documented in the patient study record as well.

## **12.0 Statistical Considerations**

### **12.1 Sample Size Determination**

We estimated the incidences of tube dislodgement to be 20 per 1000 ventilator days and the incidence of lip ulcer development in the previous 12 months was 1.1 per 1000 ventilator days. Using the sum of these overall incidences of 21.1 per 1000 ventilator days and a standard deviation of 15 per 1000 ventilator days, we calculated a need for 142 patients in each arm to detect a clinically meaningful change of 5 episodes per 1000 ventilator days with 80% power at a two-sided alpha level of 0.05. We plan to enroll 500 patients which would allow for a 5.6% dropout or loss to follow-up rate. We used PS software to calculate the sample size.

### **12.2 Statistical Analysis**

#### **Analysis principles**

- Primary analysis will be conducted on an intention-to-treat basis (patients with protocol violations are analyzed per the assigned treatment arm).
- All hypothesis tests will be two sided, with an  $\alpha$  of 0.05 unless otherwise specified.
- All analyses will be unadjusted unless otherwise specified.
- Subgroup analyses will be performed irrespective of treatment efficacy.

#### **Trial profile:**

- We will present a Consolidated Standards of Reporting Trials diagram as Figure 1 to detail the movement of patients through the study. This diagram will include total number of patients meeting inclusion criteria, number excluded and reason for exclusion, number enrolled and randomized in the study, number followed, and number analyzed.

### **12.3 Baseline Characteristics**

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To assess randomization success, we will summarize in Table 1 the distribution of baseline variables across the study arms. Categorical variables will be reported as frequencies and percentages and continuous variables as either means with SDs or medians with interquartile ranges. Variables reported will include Demographics (age, gender, race, BMI); Indication for intubation; Active illnesses at the time of intubation; Severity of Illness (APACHE II score, blood pressure); Location of intubation (ICU, ED, OSH)

#### **12.4 Primary Analyses**

The primary endpoint will be the continuous variable of incidences of lip ulcers, tube dislodgement, or ventilator associated pneumonia per 1,000 ventilator days. The differences between the two groups will be compared using the Mann-Whitney U test. All other comparisons will be considered secondary analyses.

#### **12.5 Secondary Analyses**

*Analysis of Secondary and Tertiary Outcomes.*

We will conduct unadjusted analysis examining the treatment effect of endotracheal tube securement method on each of the pre-specified secondary and tertiary outcomes. Continuous outcomes will be compared with the Mann-Whitney U test and categorical variables with the Chi-square or Fisher Exact testing as appropriate.

*Subgroup Analyses.*

We will conduct unadjusted analysis examining the treatment effect of endotracheal tube securement technique on incidence of lip ulcers, tube dislodgement, and VAP in each of the pre-specified subgroups. Data will be presented as odds ratios and 95% confidence intervals for categorical variables and as mean differences and 95% confidence intervals for continuous variables.

#### **12.6 Presentation of Statistics**

Continuous variables will be described as mean and standard deviation or median and 25th percentile – 75th percentile or bootstrapped 95% confidence intervals as appropriate. Categorical variables will be given as percentage and number. All between-group comparisons with continuous variables will be performed using Mann-Whitney U tests and Chi-square or Fisher's exact test for categorical variables

#### **13.0 Privacy/Confidentiality Issues**

At no time during the course of this study, its analysis, or its publication will patient identities be revealed in any manner. The minimum necessary data containing patient or provider identities will be collected. All patients will be assigned a unique study ID number for

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tracking. Data collected from the medical record will be entered into the secure online database REDCap. Hard copies of the data collection sheet completed at the time of the airway management event will be stored in a locked file cabinet in a locked room until after the completion of enrollment and data cleaning. Once data are verified and the database is locked, all hard copies of data collection forms will be destroyed. All data will be maintained in the secure online database REDCap until the time of study publication. At the time of publication, a de-identified version of the database will be generated.

#### **14.0 Follow-up and Record Retention**

Patients will be followed after enrollment for 28 days or until hospital discharge, whichever occurs first. Data collected from the medical record will be entered into the secure online database REDCap. Hard copies of the data collection sheet completed at the time of the airway management event will be stored in a locked room until after the completion of enrollment and data cleaning. Once data are verified and the database is locked, all hard copies of data collection forms will be destroyed. All data will be maintained in the secure online database REDCap until the time of study publication. At the time of publication, a de-identified version of the database will be generated.

#### **15.0 References**

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