5.15.2020

Study Title: Evaluation of the CleanSweep™ Closed Suction System on Length of Mechanical Ventilation and Ventilator-Associated Events

Principal Investigator:

J. Brady Scott, MSc, RRT, RRT-ACCS, AE-C, FAARC, FCCP

Associate Professor, Director of Clinical Education

Rush University, Department of Respiratory Care

Co-Investigator(s):

David L. Vines, PhD, MHS, RRT, FAARC, FCCP

Associate Professor, Chair and Respiratory Care Program Director

Rush University, Department of Cardiopulmonary Sciences

Robert Balk, MD

Professor of Medicine, Director of Pulmonary, Critical Care, and Sleep Medicine

Rush University Medical Center

Ramandeep Kaur, MSc, RRT, RRT-ACCS

Respiratory Therapist III

Rush University Medical Center

Kathryn Dugan, BSRT, RRT-NPS

Respiratory Care Practitioner III

Rush University Medical Center

5.15.2020

Andrew Klein, MS, RRT-ACCS, RRT-NPS, AE-C

Respiratory Care Practitioner III

Rush University Medical Center

Tyler Weiss, MSc, RRT, RRT-ACCS, AE-C

Respiratory Care Practitioner III

Rush University Medical Center

Ashley Lachowicz, MSc, RRT-ACCS, NPS, AE-C

Respiratory Care Practitioner III

Rush University Medical Center

Student (s):

Kimberly Anne Villanueva

Respiratory Care Student, Rush University

Megan Charlton

Respiratory Care Student, Rush University

5.15.2020

Specific Aims

The primary aim of this study is to evaluate the CleanSweep™ Closed Suction System on time to first successful SBT in mechanically ventilated patients in the medical intensive care unit. Secondary aims of this study are to evaluate the use endotracheal tube sweeping compared to closed suctioning effect on length of mechanical ventilation, length of ICU stay, length of total hospital stay, and occurrence of ventilator-associated events.

Introduction

Mechanical ventilation (MV) is utilized when the patient's work of breathing (WOB) exceeds their capacity to do that work, with risk of respiratory muscle failure. Approximately half of the time spent on MV is on the process of weaning and discontinuing this support as soon as possible. The focus on MV liberation is due to the associated complications, including an increased risked of pneumonia.[1] The weaning process can be challenging and is categorized as simple, difficult, or prolonged in regards to weaning success.[1] Difficult to wean patients are categorized as such by failing their initial spontaneous breathing trial (SBT) and require up to three subsequent SBTs to pass; or up to seven days to completely wean from mechanical ventilation after the initial SBT. The difficult and prolonged to wean groups account for approximately 31% of the patients weaned from mechanical ventilation. It has been reported that these groups combined account for a 25% mortality rate.[1] Others reported the incidence and mortality related to these weaning categories in a large cohort study on 257 patients, where the simple to wean group represented 59% with a mortality rate of 13%, the difficult to wean group represented 26% of patients with a 9% mortality rate, and the prolonged weaning group represented 14% of the group with a 32% mortality rate.[2]

Evidence-based guidelines were published over a decade ago to help guide the weaning process and are still applicable today. Once the acute underlying disease process associated with the initiation of mechanical ventilation has improved and spontaneous breathing efforts are evident, patients are assessed for their readiness to wean and extubate. Physiologic signs including respiratory pattern, gas exchange, hemodynamic stability, body temperature, hemoglobin levels, and mental status are all used to determine the discontinuation of mechanical ventilator support.[3] Patients are then assessed for discontinuation of mechanical ventilation by

using a SBT. A SBT involves a low level of mechanical ventilatory support or a T-piece attached to the endotracheal tube. The methods of performing a SBT are variable and the recommendations from the literature are inconsistent on this topic. The main purpose of the SBT is to mimic spontaneous breathing to assess a patient's ability to breathe without the assistance of a mechanical ventilator.[3,4]

A SBT is performed to evaluate a patient's ability to balance the respiratory load with their respiratory capacity. Factors that cause a load/capacity imbalance (e.g., increased R_{AW}, decreased lung compliance) often result in failed SBTs. Because of this, clinicians should ensure proper conditions when performing SBTs. Mucus buildup in the endotracheal tube, which results in luminal narrowing of the tube, can cause this load/capacity imbalance due to the increase in R_{AW}.[5] Mietto et al noted that ETT luminal narrowing is common and can increase in airflow resistance. They noted that this narrowing occurred despite adequate humidification and suctioning.[6] Wilson and colleagues studied the pressure drop across a sample of used ETTs and found that 33% of these tubes reflected an inner diameter change that matched an unused tube one size smaller. They also reported that in approximately 20-35% of patients, the change in pressure was greater than 5 cm H_2O.[7] Others have reported that endotracheal tube obstruction occurs more often than previously suspected and the onset can be as soon as 24 hours.[8]

We previously studied the impact of ETT scraping on R_{AW} and found a statistically significant reduction.[9] There is currently little to no data related to the frequency and impact of ETT scraping or sweeping on patient outcomes. However, we now use devices in our facility that have the ability to sweep ETTs; in addition to inline suction catheters (termed *standard* in this document) that cannot sweep ETTs. Thus, the primary aim of this study is to evaluate the CleanSweep™ Closed Suction System, which is used at Rush University Medical Center, on time to first successful SBT in mechanically ventilated patients in the medical intensive care unit. Secondary aims of this study are to evaluate the use endotracheal tube sweeping compared to closed suctioning effect on length of mechanical ventilation, length of ICU stay, length of total hospital stay, and occurrence of ventilator-associated events.

Experimental Design and methods

This is designed as a prospective, randomized control trial, in a large, urban, academic

medical center. This study will include mechanically ventilated patients (n = 272) in the medical intensive care unit (MICU) and adult intensive care unit at Rush University Medical Center. It will exclude patients with a tracheostomy on admission, those requiring extracorporeal membrane oxygenation (ECMO), or transferred from an outside facility receiving more than 24 hours of mechanical ventilation. Two groups will be randomly assigned via computer randomization. The comparison group will be placed on the CleanSweep™ Closed Suction System immediately after intubation or upon arrival to the MICU. ETTs will be cleaned with the balloon sweeping technology every time a respiratory therapist suctions the patient. The standard group will be placed on the standard in-line suction device. Airway suctioning will be performed in both groups as per department policy (Catheter advanced until resistance is met and withdrawn slowly for a duration no longer than 15 seconds while applying negative pressure). Both groups will also receive a ventilator bundle that consists of head of bed elevation, ETT cuff pressure management, DVT prevention, daily sedation interruption and SBT, and oral care every 4 hours with chlorhexidine at 12pm (noon) and 12am midnight.

Procedures Done for Research Purpose

- Comparison Group (CleanSweep™ Closed Suction System)
    - In addition to suctioning performed as per department policy, ETTs cleaned with balloon sweeping technology with every respiratory therapist suctioning.
- Standard Group (Standard in-line suction device)
    - Suctioning performed as per department policy

Subject Population

Two hundred and seventy-two orally intubated, adult patients ≥ 18 year of age will be enrolled.

Inclusion criteria:

- Age ≥ 18 y/o
- Orally intubated with endotracheal tube
- Mechanically ventilated < 24 hours prior to enrollment

Exclusion criteria:

- Age < 18 y/o
- Tracheostomy tube
- Extracorporeal membrane oxygenation
- Transfer from outside hospital with more than 24 hours of mechanical ventilation

Recruitment and Consent Procedures:

- Recruitment will be based on the inclusion and exclusion criteria.

Compensation:

- There will be no compensation provided to participants for participation in this study.

Risk to subject:

- Risks include potential desaturation during ETT scraping. To prevent or lessen the possibility of oxygen desaturation, the patient will be preoxygenated with 100% oxygen for 1 to 2 minutes before ETT cleaning is performed.

Special Precautions:

- All study material will be coded to de-identify participants and a separate list will be kept with the participant's ID and name.
- All identifiers will be removed prior to analysis. Study subjects will not be re-identified or contacted after data collection is complete.

Confidentiality:

- The study investigators, along with the IRB, will have access to the individual participant's results. Neither names nor personal information will be recorded or included in the data analysis. The investigators will strictly adhere to IRB guidelines to ensure that participant's confidentiality is maintained.

Plans for Data Analysis:

- **Calculated sample size.** Based on previous institutional data, length of mechanical

ventilation is approximately 6.3 days with a standard deviation of 3.64. Effect is estimated at a 20% reduction in the length of mechanical ventilation (6.3 x .20 = 1.26 days). Standardized effect size would be 35% (1.26/3.64). Setting alpha at 0.05 and power of .80 with standardized effect size of 0.35 would require 136 patients in each group or 272 total number of subjects. Estimated completion would be 18 to 24 months.

- Data for each patient will be recorded in REDCap, a secure web-based database. Descriptive and inferential statistics were calculated from the information collected from patients' charts. Patients were divided into two groups based on randomization. Each group's time to first successful SBT and length of mechanical ventilation outcomes will be compared using an independent T-test if the data is normally distributed. Ventilator-associated conditions and infection related ventilation associated complications rates for both groups will be compared using Chi-Square analysis. Level of significance will be set at $p < 0.05$.

References:

1. Boles JM, Bion J, Connors A, Herridge M, Marsh B, Melot C, et al. Weaning from mechanical ventilation. Eur Respir J 2007;29(5):1033-1056.
2. Funk GC, Anders S, Breyer MK, Burghuber OC, Edelmann G, Heindl W, et al. Incidence and outcome of weaning from mechanical ventilation according to new categories. Eur Respir J 2010;35(1):88-94.
3. MacIntyre NR, Cook DJ, Ely EW,Jr, Epstein SK, Fink JB, Heffner JE, et al. Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. Chest 2001;120(6 Suppl):375S-95S.
4. Pellegrini JA, Moraes RB, Maccari JG, de Oliveira RP, Savi A, Ribeiro RA, et al. Spontaneous Breathing Trials With T-Piece or Pressure Support Ventilation. Respir Care 2016.
5. Shah C, Kollef MH. Endotracheal tube intraluminal volume loss among mechanically ventilated patients. Crit Care Med 2004;32(1):120-125.
6. Mietto C, Pinciroli R, Piriyapatsom A, Thomas JG, Bry L, Delaney ML, et al. Tracheal tube obstruction in mechanically ventilated patients assessed by high-resolution computed tomography. Anesthesiology 2014;121(6):1226-1235.
7. Wilson A, Gray D, Thomas J. Increases in endotracheal tube resistance are unpredictable relative to duration of intubation. Chest 2009;136(4):1006-1013.

8. Berra L, Coppadoro A, Bittner E, Kolobow T, Laquerriere P, Pohlmann J, et al. A clinical assessment of the Mucus Shaver: a device to keep the endotracheal tube free from secretions. Crit Care Med 2012;40(1):119-124
9. Scott JB, Dubosky MN, Vines DL, Sulaiman AS, Jendral KR, Singh G, Patel A, Kaplan CA, Gurka DP, Balk RA. Evaluation of Endotracheal Tube Scraping on Airway Resistance. *Respiratory Care*. 2017;62 (11):1423-1427.