suction duration/10 minute suction intervals. We were initially collecting volumes between 70-200 ml/day. After we "redefined" tracheostomy cuff pressures and "ideal minimal occluded volume," our collection volumes ranged from 90 to 300 ml/day. This indicates that patient micro aspiration was previously occurring due to leakage around the tracheostomy cuff. As we increased the tracheostomy cuff pressures in both control and study patients, aspirate/secretion volume also increased.

Maceration of tissue surrounding the stoma has decreased significantly, resulting in less soiled clothing and less need to frequently change tracheostomy ties. Patients have reported that they have been very comfortable on the SIMEX subglottic aspiration device, with no reports of tracheal discomfort or signs of tracheal wall abrasion.

Figure 5. Subglottic tracheostomy tube that is connected to SIMEX device

Respiratory Therapists report that the SIMEX device is simple to program, monitor, and maintain. Suction collection canister changes are simple and contained. There have been no reports of spills or leaks.

Our current 4-month RCT study has 25 patients on the device and a 15 patient control group. We are 3 months into the trial and of the 25 patients on the device, we have had 2 confirmed cases of VAP (8%). We believe that 1 of these patients developed VAP through an emergent tracheostomy change due to cuff failure. Both patients were on the SIMEX device for 33 days. The control group of 15 patients has developed 5 confirmed cases of VAP (33%) since the start of the RCT. The SIMEX subglottic aspiration system, working in conjunction with our five-step VAP prevention program, has significantly decreased our VAP rates. The facility has saved a considerable amount of resources in VAP treatment, as well as decreased transfer rates to hospital ERs. We are looking forward to further researching the efficacy of the SIMEX subglottic aspiration system and its application in the prevention of ventilator-associated pneumonia.

Conclusion

The diagnosis of VAP is best accomplished by combining qualitative measures (such as CPIS), with the more definitive and quantitative, sputum sample for culture and sensitivity, which provides for targeted antibiotic therapy. Targeted antibiotic therapy decreases the risk of more drug resistant strains associated with the use of broad spectrum antibiotics.

Use of the SIMEX automated subglottic aspiration system provided for patient comfort and efficient removal of large secretion volumes, 90-300 ml/day, compared to previously-used manual suction via 20mm syringes where only 20-40ml/day of secretions were collected. The automated system also provided the means for measuring the effectiveness of various VAP prevention approaches, for example, the means for precise measurement and comparison of secretion volumes when cuff pressures were adjusted.

Three months into the planned 4-month randomized controlled clinical trial of the automated system, an interim VAP rate of 8% has been confirmed in the active SIMEX group of 25 patients. In contrast, an interim VAP rate of 33% has been confirmed in the control group of 15 patients. As a result, a considerable amount of center resources have been saved, and the rate of transfers of patients to hospital ERs has been greatly reduced.

Tracheostomy cuff pressures set at the commonly recommended pressures of 20-25 cmH2O (minimal occluded volume), have been shown not to provide an adequate seal, allowing for leakage of secretions past the cuff, and raising the risk of VAP. In conjunction with use of the SIMEX subglottic aspiration system in the RCT, cuff pressures were individualized for each patient, allowing for higher pressures if required to establish a good seal. In selected patients, higher "redefined" tracheostomy tube cuff pressures resulted in 30% increases in secretions collected.

As part of the RCT, a more effective tracheostomy tube design has been developed, one that has a 360-degree subglottic aspiration port. Future development of the new design holds promise for allowing decreased pooling volume and risk of leakage, and for more effective subglottic suctioning at greater patient angles in the range of 70-90 degrees, for patients in chairs or wheelchairs.

Since this RCT study represents the first trial of its type of the automated intermittent subglottic secretion system in the United States, additional trials will be needed to further define the efficacy and overall cost effectiveness of the novel system.

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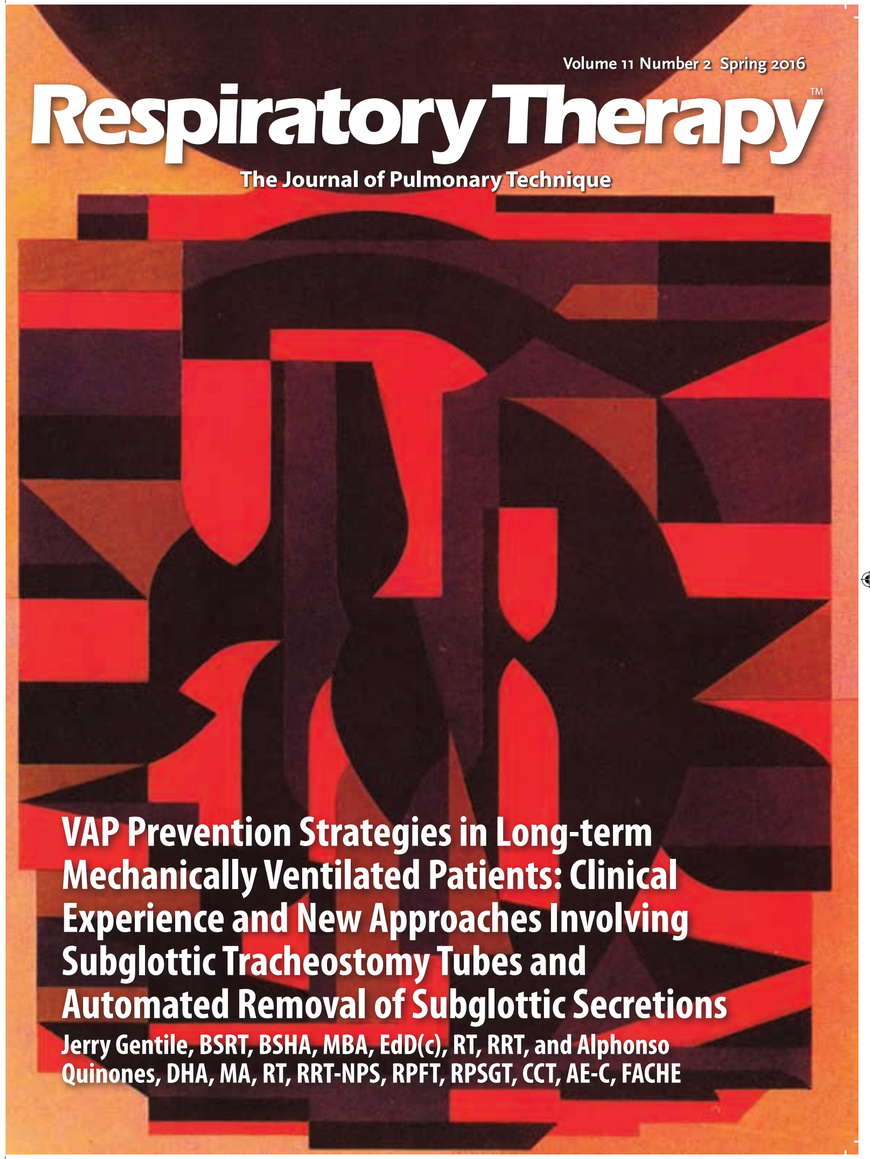

VAP Prevention Strategies in Long-term Mechanically Ventilated Patients: Clinical Experience and New Approaches Involving Subglottic Tracheostomy Tubes and Automated Removal of Subglottic Secretions

Jerry Gentile, BSRT, BSHA, MBA, EdD(c), RT, RRT, and Alphonso Quinones, DHA, MA, RT, RRT-NPS, RPFT, RPSGT, CCT, AE-C, FACHE

Abstract

Ventilator-Associated Pneumonia (VAP) is the most common nosocomial infection among mechanically ventilated patients. VAP is associated with high morbidity and mortality rates, increased hospital stays and time on mechanical ventilation, as well as increased costs to treat. Prevention strategies to mitigate the risk of VAP continue to evolve. The introduction of tracheostomy and endotracheal tubes with integrated suction lumen for subglottic suctioning are recent advances, but shortcomings in their designs and practical uses have been identified.

This paper focuses on the optimization of tracheostomy cuff pressure settings, and on suction portal design, and provides a summary of clinical experience in a long-term care setting with subglottic tracheostomy tubes and the removal of secretions from the subglottic space. An additional goal is to educate Respiratory Therapists and enhance their VAP prevention strategies. Interim results of a randomized, controlled clinical trial of an automated, intermittent subglottic secretion aspiration system are presented.

Keywords

Subglottic Secretion Drainage (SSD), Ventilator-Associated Pneumonia (VAP), Mechanical Ventilation, Tracheostomy Cuff Tubes, Cuff Pressure, Automated Intermittent Subglottic Secretion Drainage, Subglottic Suction Port

Background

Ventilator-Associated Pneumonia (VAP) is a nosocomial infection that develops 48 hours + post admission to the long-term ventilator unit. It develops in patients who are tracheostomized and on mechanical ventilation. VAP is the most common nosocomial infection among mechanically-ventilated patients (Davis KA, 2006). VAP rates are important in long-term ventilator units because ventilated patients that acquire VAP have close to a 45% increase in mortality rates (Ibrahim EH, et al 2001). These mortality rates are high primarily due to the patients' comorbidities and the virulence of the bacterium colonizing the lower airway. VAP is not just responsible for increased mortality rates, but also for increased discharges to the hospital ER, lost revenue, increased duration of mechanical ventilation, and costs exceeding $40,000 per incident (Guterl G, 2013).

The presentation of VAP/pneumonia is essentially the same in both non-ventilated and ventilated patients. Clinical symptoms include fever, tachycardia, tachypnea, increased volume and thickness of purulent secretions, and worsening hypoxemia (Bartlett JG, 2008). We currently use two methods for the diagnosis of VAP. One is a more clinically based or qualitative method called the Clinical Pulmonary Infection Score (CPIS). We examine clinical signs and symptoms to determine if the pulmonary infection is a true pneumonia. This method of diagnosis is not very accurate nor specific, primarily because the clinical presentation can mimic symptoms caused by other conditions (Chastre J, et al, 2002). The second and more definitive/quantitative method is the sputum sample for culture and sensitivity. This is a more invasive method to match clinical presentation to a known causative bacterium. By culturing the sputum and determining the specific organism, targeted antibiotic therapy can be initiated, decreasing the risk of further creating more drug resistant strains of organisms through the use of broad spectrum antibiotics (Davis KA, 2006).

The lower airways of the lung are normally sterile. When bacteria are introduced and colonize, VAP develops. The most common bacteria found in cultured sputum of ventilated patients include: gram negative-pseudomonas aeriginosa, klebsiella pneumoniae, and escherichia coli. Gram-positive bacteria include staphylococcus aureus. Tracheostomized and mechanically-ventilated patients are more at risk for acquiring these organisms because of the bypassing of the normal airway defenses. The longer the patient is both tracheostomized and mechanically ventilated, the greater the risk of developing VAP. Pseudomonas aeruginosa and staphylococcus aureus have become much more difficult to treat due to drug resistant strains. These strains result in higher numbers of VAP morbidity and mortality (Bartlett, 2006). Due to the placement of the tracheostomy tube, the normal defense mechanisms of the upper and lower airways are compromised (Pneumatikos IA, et al, 2009). If bacteria are introduced into the normally sterile lower airway, they allow for colonization and an infectious process. The tracheostomy tube disrupts the mucociliary escalator and impairs clearance. It also impairs the cough reflex and allows for a direct pathway to the lower airway. The tracheostomy tube not only disrupts normal airway defense mechanisms; it also injures the tracheal tissue.

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VAP is a two-step process that begins with the aspiration of contaminated secretions in the lower airway and the colonization of the bacteria. VAP on the long-term ventilator unit can develop at any time. In our facility we do not define VAP as early or late onset, however, we do distinguish between nosocomial and community acquired. If the patient is admitted to the unit from the hospital or other long-term care unit and spikes a fever within 48 hours, the patient is worked up for possible VAP. If sputum culture and sensitivity and chest radiograph confirm VAP, we consider this community acquired. If after 48 hours the patient spikes a fever and we confirm VAP, it is considered nosocomial.

Clinical Experience at Eastchester Rehabilitation and Healthcare Center

VAP rates in our 40-bed long-term ventilator unit have averaged between 12.5% to 20%. The transfer rate to the hospital for these patients has averaged 50%. Mortality rates for those transferred patients have averaged 20%. Therefore, preventing VAP in the long term ventilator unit has been a priority. One of the major problems that contributes to the level of VAP in long term care has been the tracheostomy tube itself. It directly interferes with normal respiratory defense systems and is an open gateway to the lower respiratory tract for bacterial colonization.

The tracheostomy tube cuff is used to seal the airway to provide positive pressure mechanical ventilation. This cuff also can provide a platform for secretions to pool and eventually leak around the cuff. Most Respiratory Therapists set cuff pressures to "minimal occluded volume," which is between 20 to 25 cmH2O. This prevents lymphatic flow obstruction (edema), venous flow of obstruction (congestion), and decreased venous-capillary blood flow (ischemia). However, our research is finding that these cuff pressures are too low to prevent leakage of contaminated secretions from around the cuff. Our preliminary research has found that cuff pressures at approximately 30.0 cmH2O (±5 cmH2O) are ideal for prevention of secretions from leaking around the tracheostomy cuff. Our results are similar to that of (Chendrasekhar A, et al, 2013). They concluded that ETT cuff pressures of 29.5 (±3.2 cmH2O) were needed to maintain secretions above the cuff.

The recommendations for cuff pressures of 20 to 25 cmH2O we feel inherently expose patients to a higher risk of VAP. We propose the concept that it is better for the Respiratory Therapist to implement pressures that are clinically ideal versus meeting a set number. Each patient's ideal cuff pressure will be different. The Respiratory Therapist may still use the minimal occluded volume technique, but use a pressure that is ideal for the individual patient. If the pressure necessary to seal the airway is 32 cmH2O, then use 32 cmH2O. This will further decrease the incidence of VAP in tracheostomized patients. Our new protocol for cuff pressures is between 25 to 35 cmH2O. Once the cuff has sealed the airway sufficiently to prevent leakage of contaminated secretions, the secretions then need to be removed from the airway. Otherwise, the subglottic secretions can be aspirated by the patient and bacterial colonization can occur (O'Keefe-McCarthy S, et al, 2008). The micro-aspiration of the subglottic secretions is a preventable factor in the development of VAP (Safdar N, et al, 2005).

The American Association for Respiratory Care (AARC), the American Thoracic Society (ATS), and the Centers for Disease Control and Prevention (CDC) all recognize the need and importance of removing secretions from the subglottic space as a measure to prevent VAP. There are, currently, a few long-term ventilator units that implement subglottic tracheostomy tubes and regular subglottic suction.

Switch to Tubes with Subglottic Ports

Once the patient is admitted, the Respiratory Therapist changes the standard tracheostomy tube to a subglottic suction version—we are currently using Portex Blue Line. This tracheostomy tube bypasses the upper airway, which eliminates air filtration, humidification, and mucociliary clearance. These normal airway defense mechanisms filter out contaminants in the air before they can reach the lower respiratory tract (Pneumatikos IA, et al, 2009). The tracheostomy cuff is the only separation between the contaminated upper airway and the sterile lower respiratory tract in mechanically ventilated patients. Without subglottic secretion aspiration, the subglottic space becomes a region of potentially infectious gram negative bacteria that can be micro aspirated by the patient.

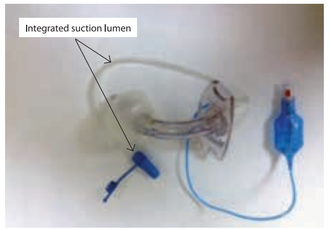

Figure 1. Subglottic Tracheostomy tube with integrated suction lumen

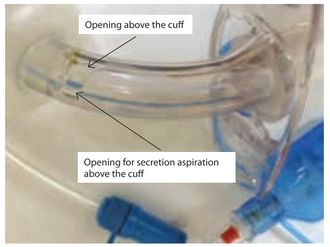

Figure 2.

VAP Risk Factors

In the long-term mechanically-ventilated patient, the presence of the tracheostomy tube places the patient at risk for development of VAP. There are, however, other factors that increase this risk. Comorbidities, such as COPD or decreased level of consciousness can be considered patient-related risk factors. Equipment-related risk factors could include suction tubing or ventilator circuits. Failure to maintain hand hygiene increases the risk of bacteria introduction into the ventilator circuit (ie, when changing HMEs) and is considered a personnel-related risk factor (Augustyn B, 2007).

VAP Prevention Strategies

The main goal in the prevention of VAP is decreasing the risk of bacterial contamination and colonization of the oropharynx and lower respiratory tract. Airway protection is decreasing the risk of micro aspiration of contaminated secretions around the tracheostomy cuff. Implementing new respiratory clinical practice guidelines and new preventive technologies will assist in reduction of VAP. We have developed a five-step VAP program that includes: (1) Head of bed 30 to 45°; (2) DVT prophylaxis; (3) proton pump inhibitor; (4) chlorohexidine 0.12% oral rinse; and (5) daily weaning from mechanical ventilation. (Efrati S, et al, 2010; O'Keefe-McCarthy S, et al, 2008). This had a small impact on our VAP rates, but did not significantly reduce our average of 16.25%. We were hopeful that implementation of subglottic suctioning would further reduce this rate.

Tracheostomy Cuffs and Ideal Subglottic Design

The objective of the tracheostomy cuff is to seal the airway for mechanical ventilation, as well as in preventing the aspiration of secretions entering the subglottic space. This can only be accomplished, however, if the cuff is inflated to form a good seal between the tracheostomy tube itself and the tracheal wall. If the cuff is improperly inflated and a good seal is not made, subglottic secretions will leak around the cuff. This enables contaminated secretions to enter the otherwise sterile lower airway. This leads to the development of VAP (Gentile MA, et al, 2010). With this in mind, attention has focused on the cuff material itself. Research has shown that polyvinyl material is not as effective at creating a good seal as silicone or polyurethane. Polyvinyl tends to be a thicker material and is prone to allow leakage around its seal (Deem S, et al, 2010). A study has found that polyurethane cuffs set to minimal occluded volume and use of subglottic suction has significantly reduced VAP rates when compared to a polyvinyl, non-subglottic group (Lorente L, et al, 2007). Polyurethane cuffs seem to trap subglottic aspirate more effectively than polyvinyl, which then allows it to be removed more efficiently. VAP prevention can only occur if the secretions are trapped above the cuff. The subglottic aspiration device can only be effective if there are secretions to be removed.

Throughout the randomized controlled clinical trial (RCT) we have used standard subglottic tracheostomy designs. Our research data has brought to light some potential issues with current subglottic tracheostomy aspiration port designs. Current models of subglottic tracheostomies have a small suction port located at the posterior section of the tube. This works well at lower angles (10-50 degrees). However, patients in long term ventilator units are sometimes sitting up in chairs or wheelchairs at angles from 70-90 degrees. Posterior suction ports are less effective at these angles. We are currently working on a new proprietary concept (patent pending) of a tracheostomy tube with 360 degree suction port design. This will allow for effective subglottic suctioning at any patient angle.

Early Clinical Results with an Automated Subglottic Aspiration System

The prevention of secretion accumulation in the subglottic space is key to the prevention of VAP. The goal is to eliminate aspiration of the pooled secretions above the tracheostomy cuff. In September, 2014, we switched all patients to subglottic suction tracheostomy tubes. The Respiratory Therapists were manually aspirating the subglottic ports 4x/day, which became labor-intensive. The subglottic ports would also frequently occlude, resulting in the Respiratory Therapist having to lavage ports, further increasing the risk of VAP. The average manual suction volume obtained by manual aspiration with a 20cc syringe was 30-40 ml/day. In March, 2015, we instituted a trial of five SIMEX Automated Subglottic Aspiration System devices. Trial suction pressures were started at -100 mmHg pressure/10 second duration/10 minute intervals. The Respiratory Therapist adjusted the settings based upon clinical presentation—patient comfort level, secretion volume, or evidence of tracheal tissue trauma. Over the course of the eight-month evaluation, we have had the SIMEX Subglottic Aspiration Device on 10 patients. The VAP rate on these 10 patients was zero during the evaluation period. Due to this promising outcome, we decided to perform a randomized controlled clinical trial. The RCT involves 25 study patients using SIMEX device and 15 control patients using a combination of conventional suction devices and manual aspiration.

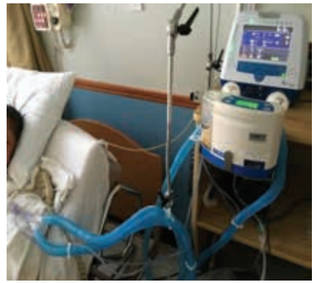

Figure 3. SIMEX device setup on a patient in facility

Figure 4. SIMEX subglottic aspiration container with subglottic secretions

Three months into the RCT, we have determined that optimal subglottic suction settings are -150 mmHg pressure/12 second