A Single-center, Randomized Controlled Study Comparing the Efficacy of the Simex Automated Intermittent Subglottic Aspiration System in the Prevention of Ventilator-associated Pneumonia and Ventilator-associated Events in Long-term, Tracheostomized, Mechanically-ventilated Patients

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Introduction

Ventilator-acquired pneumonia (VAP) continues to be a significant cause of morbidity and mortality, increased hospital stays, increased antibiotic use, and increased costs. VAP is the most common and preventable nosocomial infection among mechanically ventilated patients (Davis, K., 2006). Research suggests that subglottic suctioning decreases incidence of VAP; preventing aspiration of contaminated secretions into the sterile lower airways. High mortality rates among VAP patients are primarily due to patients' comorbidities and the virulence of the colonizing bacterium. The SIMEX Automated Intermittent Subglottic Aspiration System has been utilized in Europe, in over 1000 patients, with excellent clinical outcomes.

This Randomized Control Trial (RCT), the first of its type in the world, measured the effects of the SIMEX Automated Intermittent Subglottic Aspiration System in a long-term, 40-bed ventilator unit. Working in conjunction with a 5-step VAP protocol, the SIMEX Subglottic Aspiration System yielded significant positive clinical outcomes.

Importance of VAP Prevention

- VAP rates are important in long term ventilator units due to 45% increase in mortality rates (Ibrahim, EH., et al, 2001).
- VAP is responsible for increased morbidity rates, decreased revenue, increased duration on mechanical ventilation, and treatment costs that may exceed $40,000 (Guterl, G., 2013).

RCT Methodology

- 25 patients randomized to treatment – (designated Group A, device group) See Figure 1.
- 15 patients – (designated Group B, non-device control group).
- RCT was 4 months in duration.
- Amount of aspirate recorded daily.
- Portex Blueline subglottic tracheostomy tube – with dorsal lumen – was used for subglottic access.
- Most effective settings used in the trial was suction pressure -150 mmHg /12-second suction duration/10-minute suction intervals.

Clinical Problems Associated with Tracheostomy Tubes

- Due to tracheostomy tube placement, normal airway defense mechanisms are compromised.
- If bacteria are introduced into the normally sterile lower airway – colonization and infection begin.
- Tracheostomy tubes disrupt the mucocilliary escalator and impair the cough reflex.
- Tracheostomy tubes can cause injury to the tracheal tissue.

Redefining Tracheal Cuff Pressures

- The tracheostomy cuff is used to seal airway to provide positive pressure mechanical ventilation.
- The cuff can provide a platform for secretions to pool and eventually leak around the cuff.
- Most Respiratory Therapists set cuff pressures to "minimally occluded volume" – between 20-25 cmH_2O.
- Our research found that "minimally occluded volume" pressures are too low to prevent leakage of contaminated secretions.
- We found that cuff pressures of 30 cmH_2O (+/- 5 cmH_2O) are ideal for leak prevention. Results are similar to (Chendrasekhar, A. et al, 2013).
- Average cuff pressures in RCT were 28-33 cmH_2O without adverse tracheal wall damage or patient discomfort.

Respiratory Care Protocol

- Once admitted, Respiratory Therapist changes tracheostomy tube to subglottic version.
- Patient is connected to SIMEX Automated Intermittent Subglottic Aspiration System.
- Active humidification is discontinued and switched to Heat and Moisture Exchanger (HME).
- Medication nebulizers are discontinued and switch to MDIs.
- VAP Protocol allows differentiation between nosocomial and community acquired.
- If patient is admitted to the ventilator unit and spikes a temperature within 48 hours, patient is worked up for a possible VAP – considered a community-acquired VAP.
- 5-step VAP program initiated: (1) head of bed 30-45 degrees; (2) DVT prophylaxis; (3) proton pump inhibitor; (4) chlorhexidine 0.12% oral rinse; and (5) daily weaning from mechanical ventilation.

Benchmarks Prior to Introduction of SIMEX Automated System and New VAP Protocol

- Prior to use of SIMEX subglottic devices VAP rate averaged 16.25% – with VAP protocol in place.
- Transfers to hospital with VAP averaged 50%.
- Mortality rates for transferred patients averaged 50%.
- Respiratory therapists manually aspirated subglottic ports 4x/shift – very labor intensive.
- Average manual suction volume with 20cc syringe – 30-40 ml/day.
- Suction pressures with 20cc syringe were dangerously high (-700 mmHg) – potentially causing tracheal tissue damage.
- Difficult to apply consistent and safe suction pressures.
- No way to ensure maximal aspiration of subglottic volume.

Randomized Controlled Trial Results

- Initial subglottic secretion volumes ranged between 60-120ml/day. See Figure 3.
- After "redefining" "minimal occluded volume" – collected subglottic volumes ranged between 130-420 ml/day. This indicated leakage of subglottic secretions at lower tracheostomy cuff pressures. See Figure 3.
- Tracheostomy subglottic suction port design and position play an important role in efficiency and effectiveness of subglottic suctioning.
- Maceration of tissue surrounding the stoma decreased significantly resulting in less soiled clothing and need for frequent tracheostomy tie changes. See Figure 2.
- Conclusion of RCT – 25 patients on SIMEX device Group A resulted in VAP rate of 8% versus VAP rate of 33% in 15 patient control Group B.
- Post RCT Statistics – 40 patients on SIMEX device – past 8 months (March – October, 2016) – 2 confirmed VAP – 1 treated in-house – 1 required transfer to hospital and returned within 7 days.
- No mortality with VAP.
- Respiratory therapists report SIMEX device simple to program, maintain, and monitor.

Conclusion

The SIMEX Automated Intermittent Subglottic Aspiration System, working in conjunction with the 5-step VAP protocol, significantly decreased the incidence of VAP in our ventilator unit. These results are important considering the 50% VAP mortality rate. We have saved significant facility resources and keep patients in beds – increasing revenue. We have also decreased the 30-day transfer rates back to feeder hospitals, improving our relationships while improving patient care. Lastly, we have decreased time on mechanical ventilation and improved quality of life.

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FIGURE 1
SIMEX Automated Intermittent Subglottic Aspiration System – setup on a patient in facility with subglottic secretions collected in the aspiration container.

FIGURE 2
Subglottic Tracheostomy tube connected to the SIMEX Aspiration System.

FIGURE 3

Optimal Suction Settings on the SIMEX Automated Intermittent Subglottic Aspiration Device	
-150 mmHg – 12 second duration – 10 minute intervals	
Cuff Pressures	**Subglottic Secretion Volume**
18 – 25 cmH_2O	60 – 120 ml/day
25 – 30 cmH_2O	130 – 250 ml/day
30 – 35 cmH_2O	250 – 420 ml/day

References

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[3]Guterl, G. (2013). Cost implications of VAP. Advance Healthcare Network for Respiratory Care & Sleep Medicine. Retrieved from http://respiratory-care-sleep-medicine.advanceweb.com/Features/Articles/Cost-Implications-of-VAP.aspx.

[4]Chendrasekhar, A., & Timberlake G.A., (2013). Endotracheal cuff pressure threshold for prevention of nosocomial pneumonia. Journal of Applied Research, 13 (3). Retrieved from http://www.jrnlappliedresearch.com/articles/Vol3Iss3/Chendrasekhar.htm – (concluded that ETT cuff pressures of 29.5 cmH2O (+/- 3.2 cmH2O) were ideal to prevent leakage around cuff).