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

Jerry Gentile, BSRT, BSHE, MBA, MPH, ErD(Sc), RT, RRT | Director, Cardiopulmonary Services | Eastchester Rehabilitation & Healthcare Center, Bronx, NY
Alphonso Quinones, DHA, MA, RT, RRT-NPS, RPFT, RPSGT, CCT, AE-C, FACHE | Associate Professor of Allied Healthcare Science, Molloy College, Rockville Centre, NY

Introduction
Ventilator-associated 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 Controlled 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.

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 defenses 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.
- Respiratory Therapists manually aspirate subglottic secretions while improving patient care. Lastly, we have decreased the 30-day transfer rates back to feeder hospitals, improving our relationships with feeder hospitals, improving our relationships with the hospital and improving patient care.

Redefining Traacheal 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 cmH2O.
- Our research found that “minimally occluded volume” pressures are too low to prevent leakage of subglottic secretions.
- We found that cuff pressures of 30 cmH2O (+/- 5 cmH2O) are ideal for leak prevention. Results are similar to (Chendrasekhar, A. et al, 2013).
- Average cuff pressures in RCT were 28-33 cmH2O without adverse tracheal wall damage or patient discomfort.

RCT Methodology
- On admission, Respiratory Therapist changes TRACHEA tubes if necessary and positions to MDIs.
- Post RCT – 40 patients on SIMEX device Group A resulted in 8% versus VAP rate of 33% in 15 patient control Group B.
- All patients admitted to the study were on SIMEX Automated Intermittent Subglottic Aspiration System.
- Active humidification is discontinued and switched to MDIs.
- Medication nebulizers are discontinued and switched to MDIs.
- New VAP Protocol and 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 60%.
- Respiratory Therapists manually aspirate substantial subglottic secretions 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 stable suction pressures.
- No way to ensure maximal aspiration of subglottic volume.

Randomized Controlled Trial Results
- Initial subglottic suction volumes ranged between 60-120ml/day. See Figure 3.
- After “redefining” “minimally occluded volume” – collected subglottic volumes ranged between 130-420ml/day. This indicated leakage of subglottic secretions at lower tracheostomy cuff pressures. See Figure 3.
- Tracheostomy suction port design and position play an important role in efficiency and effectiveness of subglottic suctioning.
- Measurement 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.
- 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

Trial Results
- Optimal Suction Settings on the SIMEX Automated Intermittent Subglottic Aspiration Device

<table>
<thead>
<tr>
<th>Cuff Pressure (cmH2O)</th>
<th>Subglottic Secretion Volume</th>
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</thead>
<tbody>
<tr>
<td>18 – 25</td>
<td>60 – 120 ml/day</td>
</tr>
<tr>
<td>25 – 30</td>
<td>130 – 250 ml/day</td>
</tr>
<tr>
<td>30 – 35</td>
<td>250 – 420 ml/day</td>
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</tbody>
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Optimal Suction Settings on the SIMEX Automated Intermittent Subglottic Aspiration Device

- 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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References
5. The Neurocure Clinical Research Center, Technical University of Munich, Munich, Germany.