March 16, 2020

Harnessing new technology to complement treatment of mechanically ventilated COVID-19 patients to control infection, reduce cross-contamination and maximize clinical resources.

Many COVID-19 patients will require mechanical ventilation. Mortality rates associated with COVID-19 and mechanical ventilation are extremely high. When the viral infection and subsequent hyperimmune response are able to develop, infections and bacteria entering the lower airways of patients result in acute respiratory distress syndrome (ARDS) or pneumonia. **ARDS is the leading cause of death in these patients.**[2,3,5,6]

ARDS' rapid progress makes breathing difficult or impossible. This necessitates mechanical ventilation. ARDS is an immune response so the virus will eventually stimulate it, especially if the patient has other comorbid and health-related issues such as diabetes, cardiovascular disease, sepsis, a drug overdose, or burns. Controlling the micro-aspiration of contaminated fluids into the lungs after intubation for mechanical ventilation is **an important intervention to reduce ARDS progress and mitigate further insult to lungs already damaged by ARDS.**

Because the virus is so contagious and deadly, particularly in this subset of ventilated COVID-19 patients, governments and institutions are quickly mobilizing task forces to improve preparedness, protect healthcare providers, improve outcomes, and manage strained resources.

New technology allows for the **automated capture of infectious secretions in ventilated patients** to prevent micro-aspiration of the secretions from passing into the lower airways. A new automated subglottic aspiration system, the SIMEX *cuff* system, is described in detail -- a system that improves respiratory supportive care by **automating subglottic aspiration drainage in a way that is more effective than current modalities, significantly increasing the volume of secretions collected from the subglottic region, radically reducing respiratory therapists' time and minimizing cross-contamination.** The patient and clinician benefits with respect to the COVID-19 pandemic are discussed below.

Background

When an endotracheal tube is inserted to create a patent airway for mechanical ventilation, the normal swallowing of the patient is compromised (dysphagia). Large volumes of saliva and other secretions, which are normally swallowed, pool above the endotracheal tube's ballooned cuff within the trachea. It is critical to remove these secretions before they leak around the cuff and are micro-aspirated into the sterile lower airway. A subglottic port on the endotracheal tubes is used to remove the secretions via suction. In critically ill patients, secretion volumes can be as high as 1000 ml/day.

When done manually, hourly suctioning is often recommended. Such **high frequency of manual suctioning is very difficult to maintain in an ICU environment**. The SIMEX automated system can remove up to 10 times more secretions without the manual involvement of clinical staff on an hourly basis.

Wall suction has traditionally been used for manual secretion management. Wall suction is unsafe for subglottic aspiration and has been shown to be a potential source of cross-contamination. Safe levels of

negative pressure are difficult to establish and maintain. Wall suction is neither indicated nor approved for aspiration of subglottic secretions and its use is off label.

Subglottic aspiration is the recommended protocol for aspiration of secretions by the AARC, CDC, AHRQ, ATS, AACC, and AACN. The adoption of subglottic aspiration drainage has been slow because there was no simple way (beyond off label use of wall suction and in some situations the use of manual syringes) to manage the aspiration. The SIMEX *cuff* system reduces the irregularities of non-standardized, manual protocols (wall suction, syringes) and **fully contains contaminants in its integrated canister.**

SIMEX *cuff* System

The **SIMEX *Automated Subglottic Aspiration System*** is the only FDA-cleared device for subglottic aspiration of infectious secretions. The device connects to the subglottic suction port of endotracheal or tracheostomy cannulas. It automatically aspirates secretions 24/7 and has customizable settings for negative pressure, suction frequency, and duration. The automated intermittent suctioning and custom settings maximize the amount of secretions collected. Secretions are collected in an integrated, self-contained, disposable canister, minimizing cross-contamination. **The system requires minimal clinician involvement.**

System benefit summary:

- **Drastically reduces Respiratory Therapist time**, allowing for improved therapist-patient ratios and reduced number of therapists entering ICUs
- **Automated 24/7 system removes 10x the volume of subglottic secretions** compared to manual/conventional methods
- Decreases micro-aspiration of subglottic secretions to the bronchial passages and lungs, thus reducing complications and infection risks (ARDS and VAP)
- Collects subglottic secretions in an integrated, self-contained, disposable canister, **eliminating contact with infectious secretions**
- Eliminates leakage around the tracheostomy tube keeping stoma, bedding and clothing dry
- May reduce duration on mechanical ventilation and overall need for antibiotics

SIMEX System Relevance in COVID-19 Pandemic

Registered Respiratory Therapist, educator and author, Dr. Jerry Gentile, EdD, MEd, MSHA, MPH, MBA, BSRT, BSHA, RRT, was a researcher and early adopter of the SIMEX *cuff* system in his practice in the U.S. He has worked extensively with the SIMEX cuff system and believes it should be used in conjunction with mechanically ventilated patients, including COVID-19 patients. According to Gentile, "By removing large volumes of contaminated aspirate in the subglottic space, the system may help mitigate ARDS. Use of the system can help to **manage further insult to the lungs in COVID-19 patients by reducing secondary infection risk and possible further damage in the lungs**." Overall, Gentile has found it to be more effective than other currently used modalities of treatment, less time consuming for staff and more effective in minimizing cross-contamination.

Other Experience with the SIMEX System in Patients with Comorbidities

The SIMEX *cuff* system has been utilized in Europe for many years. The SIMEX system was introduced in the Asklepios Clinic in Hamburg, Germany in 2014. Prior to that time, its Director, Dr. Markus Wolf, had long recognized the effectiveness of subglottic secretion drainage, but faced many practical and formidable obstacles to establishing a consistently dependable protocol in the busy ICU. Clinical staff were required to manually suction secretions multiple times daily. Soiling of bedding, clothing, and the constant need for fresh trach dressings compounded the difficulties and risk of contamination as staff members worked to deal with large volumes of secretions.

Dr. Wolf's clinic treats a highly-compromised patient population with serious comorbidities, similar in many ways to the most vulnerable patients infected with COVID-19. In addition to Dr. Wolf's patients presenting with chronic respiratory disease, many patients also have cardiovascular, neurologic, gastrointestinal, metabolic, and oncologic complications. Sepsis, organ failure, and severe critical illness polyneuropathy (CIP) are common.

Dr. Wolf's experiences have direct and positive implications for ICUs facing overwhelming secretion levels among critically ill COVID-19 mechanically ventilated patients today. In a 2016 journal article, Dr. Wolf stated, "An observation in our unit is that **the amount of secretions we are able to suction subglottically using an automated system substantially exceed the amount of secretions collected [in earlier] cited publications**. We believe automated intermittent subglottic aspiration offers the means to overcome the practical problems associated with implementing subglottic suctioning."[1,4]

Summary

The high levels of subglottic secretions associated with COVID-19 patients and other critically ill patients on mechanical ventilation pose serious and time-sensitive threats to patient survival, caregiver safety, and overall capacity of our health care system addressing the pandemic.

The SIMEX system offers an automated 24/7 intervention designed specifically to address the clinical necessity of **effective subglottic secretion removal while maximizing the effective use of scarce clinical resources and minimizing staff burden and risk**.

FloSure™

Contact Name: Hamid Khosrowshahi
Contact Email: hkhosrow@flosuretechnologies.com
Contact Phone Number: 914-772-7326

References

1. Gentile G, Fendler H. "Advances in subglottic secretion drainage", Respiratory Therapy, Spring 2016, 11:2:39-47.

2. Liu Y et al., "Clinical features and progression of acute respiratory distress syndrome in coronavirus disease 2019". Medrxiv, 2020, https://doi.org/10.1101/2020.02.17.22024166

3. Murthy S, Gomersall C, Fowler R., "Care for critically ill patients with COVID-19.", JAMA, Published online March 11, 2020, doi: 10.1001/jama.2020.3633, https://jamanetwork.com/journals/jama/fullarticle/2762996

4. Wolf M., "The role of subglottic secretion drainage in VAP prevention: ICU experience with an automated intermittent subglottic secretion drainage system.", Respiratory Therapy, Fall 2016,11:4:28-33.

5. Yang X, Yu Y, Shu H, et al., "Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study." The Lancet Respiratory Medicine, www.thelancet.com/respiratory. Published online February 21, 2020, https://doi.org/10.1016/52213-2600(20)30079.5

6. CDC Device-associated Module VAE, "Ventilator-Associated Event (VAE), Published online January 2020. cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf