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Abstract
Subglottic secretion drainage (SSD), the aspiration of subglottic secretions above the ballooned cuff of endotracheal (ET) and tracheal tubes (TT) containing an integrated suction lumen, is key to preventing Ventilator-Associated Pneumonia (VAP). Subglottic secretion drainage prevents contaminated secretions consisting of saliva, oropharynx secretions, and gastric reflux aspirate, from leaking around the ballooned cuff into the lower airways, causing VAP and life-threatening, costly complications. Mechanically ventilated patients, and other intubated patients without the ability to swallow are at high risk. Traditional SSD, using manual syringes or wall suction, has been shown in randomized, controlled studies, to be effective in reducing the incidence of VAP, but has been impractical, inconsistent, and improvisational in practice. Suction devices and methodologies have not kept pace with incremental improvements in subglottic ET and TT design. This paper presents a history of SSD spanning 20 years, including trial results showing the benefits and limitations of traditional SSD. A new, FDA-cleared, and SSD-specific system (Simex *cuff* system), offering fully automated intermittent subglottic secretion drainage, is described.

Keywords
Ventilator-Associated Pneumonia (VAP), Subglottic Secretion Drainage (SSD), Mechanical Ventilation, Pneumonia, Respiratory Tract Infections, Automated Intermittent Subglottic Secretion Drainage

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Introduction

Ventilator Associated Pneumonia (VAP) is the second most common nosocomial infection in the United States.[12] It is estimated to occur in 9-25% of all ICU patients alone and is a costly complication of hospitalization that increases length of stay and increases morbidity and mortality.[6,12,19]

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Aspiration of oropharyngeal pathogens, or leakage of secretions containing bacteria around the endotracheal or tracheal tube cuff, have been identified as the primary routes of contamination of the lower respiratory tract.[18]

Over the last 20 years subglottic tracheal and endotracheal tubes have been developed that enable the aspiration of subglottic fluids through a specially designed integrated suction lumen. Randomized Controlled Clinical Studies have demonstrated that it is possible, through proper aspiration of secretions, to control and reduce the incidence of Ventilator-Associated Pneumonia (VAP). While these special subglottic tubes have been a very important development, the development of suction devices specifically designed to work with these tubes have not kept pace. Clinicians have found ways to improvise using currently available suction modalities but until now there has been no device specifically designed to work with these specialty tubes and optimize the results of SSD. Failure of proper suction or poor suction techniques can lead to exogenous contamination of the respiratory tract which in turn can lead to VAP.[3]

The majority of the literature on the subject of subglottic secretion drainage and the prevention of VAP, presents results in terms of reductions in VAP rates. Prior to 2013, surveillance was limited to VAP, and commonly used definitions of VAP were found to be less than ideal, because of the subjectivity of radiographic technique, interpretation, and reporting, and because of reliance on clinical signs and symptoms, which are subjective and may be poorly or inconsistently documented in the medical record.[26]

In 2011, the CDC convened a Working Group to address the limitations of the NHSN (National Healthcare Safety Network) pneumonia definitions, and to propose a new approach to surveillance — Ventilator-associated Events (VAE), implemented in January of 2013. There are three definition tiers within the VAE algorithm: 1) Ventilator-Associated Condition (VAC); 2) Infection-related Ventilator-Associated Complication (IVAC); and 3) Possible VAP (PVAP).[26]

The current VAE surveillance system is now considered to be based on more objective, streamlined, and potentially automatable criteria that identify a broad range of conditions and complications that occur in mechanically-ventilated adult patients. The VAE definition algorithm is for use in surveillance; it is not a clinical definition algorithm and is not intended for use in the clinical management of patients.[26]

In 2010 a first-of-its-kind fully automated subglottic aspiration pump, specifically engineered for the automated intermittent aspiration of subglottic secretions, was introduced in Europe. Four years later, with over 500 patients treated, clinicians are reporting no complications with the use of the SIMEX Automated Intermittent Subglottic Aspiration System, and are achieving up to a 10-fold increase in the amount of secretions collected. It has now been adopted by those facilities as their standard of care.

This device has now been cleared, by the FDA, for use in the US. It is the first and only suction pump cleared by the FDA that is specifically indicated for the intermittent aspiration of subglottic secretions to be used specifically with specialty subglottic endotracheal and tracheal tubes. It provides automated, customizable intermittent aspiration, which can be tailored to each patient's needs. Randomized control studies are now under way in the US to quantify the benefits of this technological breakthrough.

In order to properly evaluate this new modality it is helpful to fully understand the use of SSD in all its forms over time and to understand where over 20 years of research have led us. It is helpful to examine where we are today and how we should assess, choose and evaluate current modalities of treatment. This document will present a brief history of SSD and explore the clinical benefits and limitations of traditional modalities of treatment, currently in wide use. In addition, new modalities now available will be presented.

Purpose of Subglottic Secretion Drainage

The purpose of subglottic secretion drainage (SSD) is simple – to prevent saliva and gastric secretions, which carry bacteria, from leaking down into the lungs of ventilated patients. Most people create at least one liter of saliva daily, which is typically swallowed.[5] When the ventilated patient is unable to swallow, this saliva turns into an infectious fluid that can infiltrate the lungs and cause infection.

- **Aspirating at the source.** SSD is designed to collect and remove secretions at the source (above the ballooned cuff of Tracheal or Endotracheal tubes), where they are highest in the airway and easiest to remove.
- **Preventing infectious material from entering the lungs.** By removing the secretions "above the ballooned cuff," SSD prevents this infectious material from entering the lungs.
- **Endotracheal aspiration is required as a result of the failure of subglottic secretion drainage.** Endotracheal aspiration, where fluid is removed from the lower airways and lungs, is time-consuming, very invasive and painful for patients. It can be prevented by removing more of the secretions above the ballooned cuff, before leakage into the lungs occurs.
- **Preventing ventilator-associated pneumonia.** Subglottic secretions are the primary source of the infectious material that leads to VAP. Collecting them before the bacteria in the saliva can colonize the lungs significantly reduces the incidence of nosocomial infection, reduces length of stay, and saves lives.
- **Lowering antibiotic use.** By preventing the lungs from being exposed to infectious material, SSD can also reduce the use of antibiotics for ventilated patients.
- **Reducing costs.** All of these factors combine to make subglottic secretion drainage highly cost effective. It is faster and easier to remove the liter of saliva near the source (above the ballooned cuff) than trying to remove it after it enters the lungs. Preventing VAP and lowering antibiotic use, while allowing patients to recover faster, reduces major cost burdens on the facility. VAP is associated with more than $40,000 in increased hospital costs per patient.[12]

Traditional Modalities of Treatment

Ventilator-Associated Pneumonia (VAP) is one of the most common and deadly forms of nosocomial infection in healthcare facilities.[12,19] Mechanical ventilation causes oral or gastric secretions to aspirate into the lungs and cause infection. The best way to prevent VAP is to remove these secretions before they reach the lungs.

Subglottic Secretion Drainage (SSD) is the method by which these secretions are removed. Either a wall suction regulator or syringe is attached to the integrated suction lumen of the subglottic tracheal or endotracheal tube and used to pull the oral and gastric secretions from the tube, where they can be disposed of safely.[18]

Endotracheal tube with subglottic port used for SSD

Tracheal tube with subglottic port used for SSD

Figure 1. Examples of subglottic Endotracheal and Tracheal tubes with integrated suction lumen.

Endotracheal (Bronchial) Aspiration

If subglottic secretions are not drained at the source, they leak down into the airways and the lungs. Left alone, they often cause pneumonia. In this situation the only option is to use a catheter inserted into an endotracheal tube to suction the lower airways and lungs to remove these secretions.

Ineffective subglottic secretion drainage that allows these secretions to escape into the airway and lungs leads to more of these procedures, which are highly invasive for the patient, take substantial staff time to perform, and can actually increase secretions due to increased irritation to the airway. Proper subglottic secretion drainage above the ballooned cuff and before it penetrates the lungs and bronchi can greatly reduce the need for endotracheal aspiration procedures as well as incidences of VAP.

Suction Systems in Traditional SSD: Performance and Contamination Considerations

In traditional subglottic secretion drainage, if syringes are not used as the source of manual intermittent suction, other traditional suction systems are used. The traditional suction systems, whether centralized, built-in systems, or other general purpose systems, have component parts in which design and methods of use directly affect the risk of infection and VAP. The components are the pump, piping, suction regulator, suction collection canister, and the patient attachment. The regulator, frequently used in combination with wall suction in acute care

settings, and the protocols for disposal of canister collections, are of particular importance in SSD.

The clinical application of suction depends on appropriate levels of pressure, and on adequate flow, the volume the system is able to withdraw per unit time. The National Fire Protection Agency (NFPA) requires the wall suction outlets to provide a minimum flow of approximately 85 liters per minute. In a study of 5 brands of commonly used continuous regulators, the majority could not deliver adequate flow unless set at potentially unsafe pressure levels.[23]

In traditional intermittent suction, an intentional, and high frequency backflow from the regulator is created (as many as 3600 aspirations daily). The most commonly used traditional protocol pauses suction for intervals of only 16 seconds, a virtually continuous application of suction, which may be damaging to tissue, and because of backflow from the regulator, may create a contributory infection vector to the patient.[25]

In a study of regulators used in hospitals, it was found that 37% (173 of 470), were found to be colonized with pathogens, including well-established nosocomial infections.[11] The same study included a suction circuit model that showed pathogens can disseminate throughout the circuit (retrograde and antegrade). It showed that contaminants can spread from a suction regulator to the wall-side canister within 30 minutes, and can also spread back to a simulated patient stomach within 24 hours. Most suction protocols recommend that collection canisters be changed a minimum of every 24 hours, although in a literature review of published canister change protocols, no evidence was cited in support or to disprove the 24-hour minimum.[25]

Backflushing of regulators using 100cc of a cleaning agent commonly is recommended by regulator manufacturers, but has been shown to be inadequate for cleaning and decontaminating the internal passages of regulators.[24] Not all regulators are alike in performance and in susceptibility to colonization. However, traditionally-used devices still in wide use have been shown to have many drawbacks with regard to preventing the spread of infection.

Two prospective, observational studies, in a 496-bed university-affiliated hospital in San Antonio, Texas, one in 2013 and one in 2014, recorded actual suction pressures applied among intubated medical-surgical ICU patients (38 patients and 18 patients, respectively). In the 2013 study, the mean negative pressure recorded was -335.3 mmHg ±99.8, with the maximum recorded -516 mmHg, far higher than the AARC recommended -150 mmHg. In 2014, the mean negative pressure recorded was -210.5 mmHg ±32.9, a statistically significant improvement, but still out of adherence with the AARC guideline.[9,22]

Continuous Drainage uses wall suction or general suction devices that are not FDA cleared for subglottic secretion drainage. The pump operates continuously at very low pressure. The guideline for continuous pressure is -20 mmHg in order to protect the airways from undue pressure that can be irritating and cause an increase in secretions and to prevent drying of the mucous membrane. The benefit of this method is that minimal staff time is needed. The drawback of this is that pressure levels are often not powerful enough to remove secretions. In some situations, in order to facilitate better drainage, pressure levels are increased beyond the recommended levels. It also yields minimal amounts of secretion — an estimated 10-30 ml per day. Three Randomized Controlled Clinical Trials involving 601 patients, using continuous suction resulted in a combined average of 45.8% reduction in incidence of VAP[17,18,20] (see Fig. 8-9).

Traditional Intermittent Drainage is virtually continuous but at a much higher pressure, with short pauses in aspiration of less than 30 seconds. An example would be a device that aspirates for 8 seconds and then pauses for 16 seconds. Wall suction or general purpose suction are generally used for intermittent subglottic secretion drainage, but are not designed or FDA-cleared for such use. The American Association for Respiratory Care (AARC) guidelines call for pressures not to exceed -150 mmHg. Pressure levels on these devices cannot be completely regulated to ensure compliance with guidelines. Nominal amounts of secretions are collected with this method. Three Randomized Controlled Clinical Trials involving 813 patients, using intermittent suction resulted in a combined average of 49.3% reduction in incidence of VAP[1,3,19] (see Fig. 8-9).

Manual Intermittent Drainage uses a syringe to remove subglottic secretion drainage. Studies show that the pressure exerted by the syringe is between 4 and 5 times higher than the AARC recommended pressure (-150 mmHg).[7] Most protocols recommend hourly secretion drainage, though this can be difficult given limited staff time, and can take a respiratory therapist two hours per bed per day to administer. The procedure yields approximately 30 ml of fluid daily.[2] Three Randomized Controlled Clinical Trials involving 758 patients, using manual intermittent suction resulted in a combined average of 53.2% reduction in incidence of VAP[2,4,16] (see Fig. 8-9).

Fully Automated Intermittent Drainage is the only device cleared by the FDA and indicated for subglottic secretion drainage. The aspiration pressure can be adjusted according to the patient and based on the AARC recommended range of -80 to -150 mmHg, and the aspiration frequency can be adjusted to anywhere from 5-60 seconds of ON time and for 1-60 minutes of OFF/Pause time. It utilizes a specially engineered, virtually silent pump with a self-contained collection canister that prevents cross contamination. The device operates automatically and requires very little staff time. The volume of secretions collected with this method has been shown to be up to 10 times higher than collected with continuous or, wall suction intermittent and manual intermittent aspiration[7] (see Table 1).

The Proven Clinical Benefits of SSD

Summary: In the last 15 years, at least nine randomized, controlled clinical trials have been conducted to observe the benefits of SSD in preventing Ventilator-Associated Pneumonia. These studies with a total of 2,172 patients have conclusively proved that removing these secretions significantly reduces incidents of VAP.

These studies have all shown consistent, substantial reductions in VAP, ranging from 37.2% to 64.2% over control groups. None have reported significant adverse events with the use of subglottic secretion drainage. The results have been remarkably consistent, with an average reduction in VAP right around 50% and little difference between the different methods. Many studies have also shown a corresponding reduction in antibiotic usage, the amount of days spent on the ventilator, and/or the amount of days spent in the hospital[1-6] (see Fig. 8).

Table 1. Comparison of Traditional Modalities of SSD Treatment Versus Fully Automated System

	Traditional Approaches			Automated Approach
	Continuous	*Intermittent*	*Manual*	*Intermittent*
Method	Wall Suction or General Suction	Wall Suction or General Suction	Syringe	Specialized Suction Device
Pressure	-20 mmHg (may be too low to aspirate viscous secretion and increased above recommended guidelines)	-150 mmHg (high frequency aspiration – virtually continuous at a much higher pressure)	-580 to -720 mmHg (nearly 4-5 times higher than recommended)	Tailored by patient, -50 to -150 mmHg
Accuracy of Pressure Delivered	Not reliable	Not reliable	Always Higher than recommended Guidelines	Accurate/reliable
Frequency	Continuously, 24/7	Aspirating virtually continuously with short pauses (16 seconds), 24/7	Hourly (often less regularly)	Tailored by patient, Aspiration for 10 - 20 seconds and pause for 5 - 20 minutes, 24/7
Daily Aspirations	Non-Stop Aspiration	1,440 - 3,600 aspirations daily	24 aspirations daily	24 -144 aspirations daily
Noise Level	Highly Noisy	Highly Noisy	None	Quiet
Staff Time (per bed per day)	10 minutes	10 minutes	120 minutes	10 minutes
Volume of Secretions	10 - 30 ml	10 - 30 ml	30 ml	100 - 500 ml
FDA Cleared	No	No	No	Yes
Specifically Designed for SSD	No	No	No	Yes
Potential for Cross Contamination	Yes	Yes	Yes	Minimized

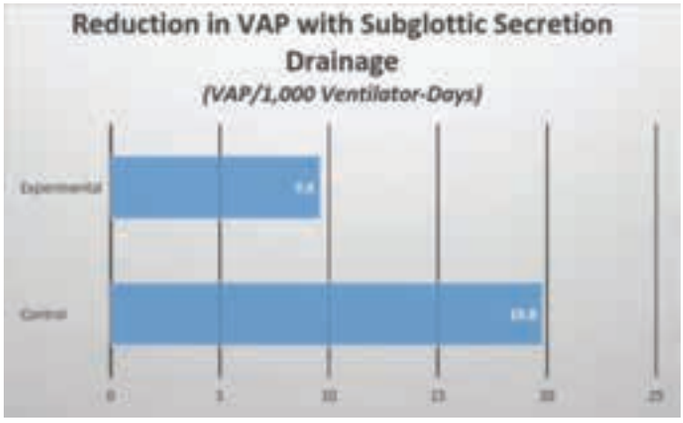

Figure 2. Damas P, Frippiat F, Ancion A, et al, Prevention of Ventilator-Associated Pneumonia and Ventilator-Associated Conditions: A Randomized Controlled Trial with Subglottic Secretion Suctioning, Critical Care Medicine Journal, 2015;43:1:22-301.[1]

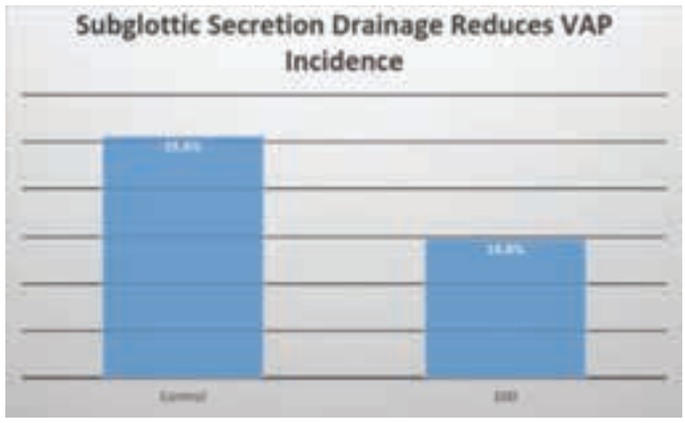

Figure 3. Lacherade JC, De Jonghe B, Guezennec P, et al. Intermittent Subglottic Secretion Drainage and Ventilator-associated Pneumonia: A Multicenter Trial. Am J Resp Crit Care Med. 2010;182:910-917.[2]

> "This study confirms the effectiveness of subglottic secretion suctioning in decreasing the rate of VAP even in ICUs with an operational VAP bundle."[1]

In this randomized, controlled clinical trial to assess the benefits of subglottic secretion drainage, the authors demonstrated a significant reduction in VAP and antibiotic use with SSD (see Fig. 2). A suction pump was set to -100 mmHg (within the -150 mmHg AARC Guideline), and operated for thirty seconds each minute. This would be considered an intermittent aspiration, with suction applied at least once a minute throughout the day, which is equivalent to 1440 aspirations daily.

A total of 352 patients were randomized into either the SSD group or the control group. In the control group 17.6% of patients acquired VAP, while only 8.8% of patients who received SSD acquired the nosocomial infection. Using SSD significantly ($p = 0.0076$) reduced the chance of VAP by 51.5% and also showed a significant reduction in antibiotic use. Patients who did not receive SSD were twice as likely to require antibiotics as patients who did.

> "The results of this randomized, multicenter study demonstrated that intermittent subglottic secretion drainage significantly reduces the incidence of microbiologically confirmed VAP, including late-onset VAP, without any noticeable adverse events. These results should encourage ICU physicians to progressively integrate SSD into their VAP preventative measures."[2]

The largest multi-site clinical study to evaluate the ability of SSD to prevent ventilator-associated pneumonia, this trial evaluated 333 patients at four different sites (see Fig. 3). Manual Intermittent Secretion Drainage was performed approximately every 90 minutes, a median of 18 times per day, utilizing a 10 ml syringe. An average of 14 ml of subglottic secretions were collected daily. The procedure was intended to occur every hour, though the staff was only able to perform it every 90 minutes.

The control group averaged a VAP rate of 25.6%, as opposed to 14.8% with manual intermittent subglottic secretion drainage. The authors demonstrated that incorporating SSD significantly ($p = 0.02$) reduced the incidence of VAP by 42%. The study also showed that SSD was effective in reducing VAP in both early-onset (80% reduction, $p = 0.02$) and late-onset (43.6%, $p = 0.01$).

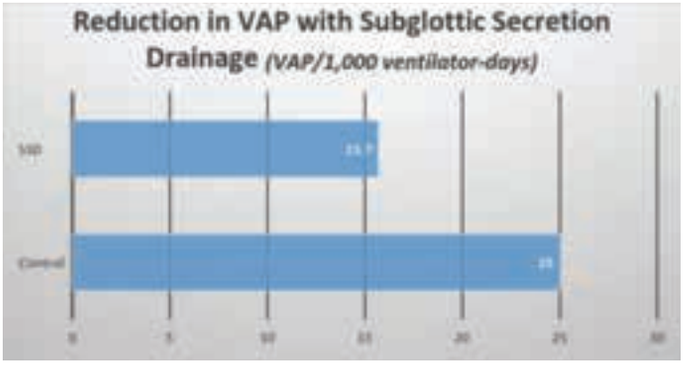

Figure 4. Juneja D, Javeri Y, Singh O, Nasa P, Pandey R, Uniyal B. Comparing influence of intermittent subglottic secretions drainage with/without close suction systems on the incidence of ventilator associated pneumonia. Indian Journal of Critical Care Medicine. 2011;15:3:168-172.[3]

> "We would emphasize the fact that the use of intermittent subglottic secretion drainage is beneficial in preventing VAP."[3]

In this controlled clinical trial of 311 patients, SSD was performed utilizing a subglottic endotracheal tube with a traditional intermittent suction device (see Fig. 4). VAP was shown to be significantly (p = 0.04) reduced with the use of intermittent subglottic secretion drainage. The VAP rate was 25.0 / 1,000 ventilator-days in the control group compared to 15.7 with secretion drainage, a 37.2% reduction.

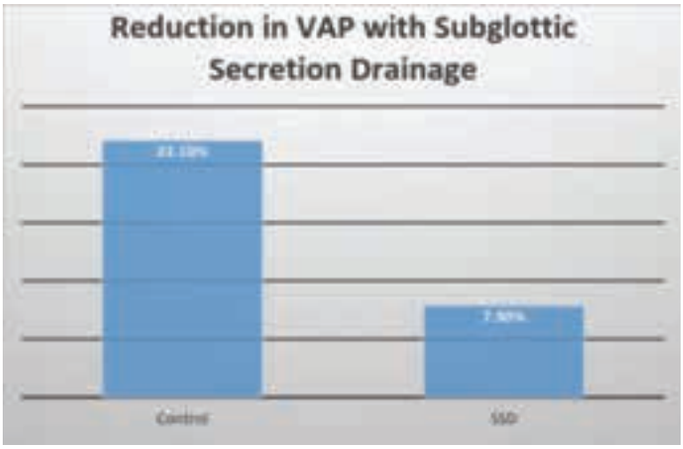

Figure 5. Lorente L, Lecuona M, Jimenez A, Mora M, Sierra A. Influence of an endotracheal tube with polyurethane cuff and subglottic secretion drainage on pneumonia. Am J Resp Crit Care Med. 2007;176:1079-1083.[4]

> "The main contribution of our study is the finding that [SSD], besides preventing early-onset VAP, also prevents late-onset VAP."[4]

In this randomized clinical trial, intermittent aspiration was performed at one hour cycles utilizing a 10 ml syringe (see Fig. 5). Subglottic drainage by intermittent aspiration was used because continuous subglottic drainage was found to be injurious to the tracheal mucosa in some studies.[14,21] In this trial conducted with 280 patients in a 24-bed ICU, intermittent subglottic secretion drainage was shown to reduce the incidence of VAP from 22.1% to 7.9% (p = 0.001), a 64.2% reduction. SSD was shown to significantly reduce the risk of both early-onset (p = 0.02) and late-onset (p = 0.01) VAP.

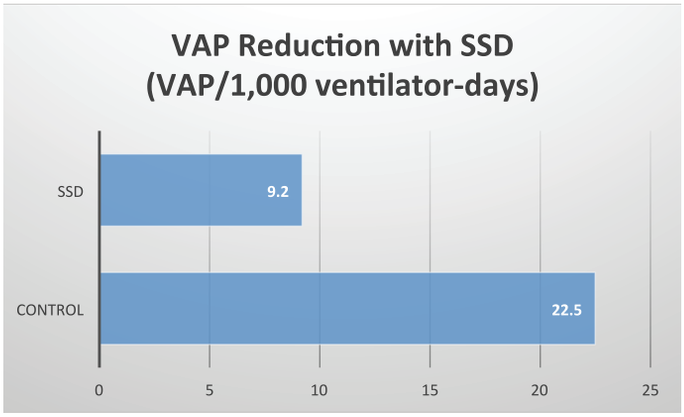

Figure 6. Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C. A randomized clinical trial of intermittent subglottic secretion drainage in patients receiving mechanical ventilation. Chest. 2002;121:3:858-862.[19]

> "Intermittent subglottic secretion drainage reduces the incidence of VAP in patients receiving mechanical ventilation"[19]

In this randomized, controlled clinical trial with 150 ICU patients, intermittent subglottic secretion drainage was shown to significantly (p = 0.001) reduce the incidence of VAP (see Fig. 6). In the control group, patients acquired VAP at a rate of 16%, while in the SSD group the rate was 4%. The wall suction regulator was used. Overall the authors saw a 59% reduction in incidence of VAP with subglottic secretion drainage. Because of the lower pressure guidelines for continuous suction, the authors used intermittent suctioning at -100mmHg, with 8-seconds on at intervals of 20 seconds. This is equivalent to over 3000 aspirations daily at -100mmHg pressure.

It is important to note that this study also required respiratory therapists to perform endotracheal secretion drainage procedures every four (4) hours, which was not performed in any of the other studies and likely inflated the reduction in VAP demonstrated in this study. Repeated, scheduled endotracheal procedures are not standard practice in most facilities, although endotracheal drainage is often necessary in response to secretions draining into the lungs. Endotracheal aspirations take substantial staff time, are extremely invasive for the patient, and can be counter-productive by causing irritation to the airways which increases subglottic secretions and can damage the tracheal mucosa.

Table 2. Dezfulian C, Shojania K, Collard HR, Kim HM, Matthay MA, Saint S. Subglottic secretion drainage for preventing ventilator-associated pneumonia: a meta-analysis. Am J Med. 2005;118:11-18.[6]

First Author (Reference)	Number of Patients in RCT	Methodology	% Reduction of VAP Rate
Mahul[16]	145	Hourly Aspiration using Syringe	53.5
Kollet[17]	343	Continuous Wall Suction	39
Valles[18]	190	Continuous Wall Suction	49.7
Smulders[19]	150	Intermittent Wall Suction	59.1
Bo[20]	68	Continuous Wall Suction	48.8

> "Subglottic secretion drainage appears to be an effective method to prevent ventilator-associated pneumonia, shorten the duration of mechanical ventilation, and shorten the length of ICU stay among patients expected to require mechanical ventilation for more than 72 hours."[6]

This meta-analysis of previous controlled, clinical trials to investigate the ability of secretion drainage to reduce VAP included five different trials totaling 896 patients (see Table 2). The results supported the ability of SSD to prevent VAP, as well as reduce the length of time on ventilation and the time in the ICU.

Subglottic secretion drainage appears to be an effective method to prevent ventilator-associated pneumonia, shorten the duration of mechanical ventilation, and shorten the length of ICU stay among patients expected to require mechanical ventilation for more than 72 hours.[6]

Current Limitations of SSD

Despite the proven benefits of subglottic secretion drainage for ventilated patients, there remain several significant challenges in providing the highest quality of care to patients.

1. Ensuring Frequent Secretion Drainage

> "Respiratory therapists are instructed to drain the secretions for each patient on ventilation every hour, which is often difficult to accomplish with the volume of patients and high patient to staff ratio."[7]

Current traditional protocols call for intermittent subglottic secretion drainage to occur every hour for every ventilated patient, which can be a huge challenge for the staff at hospitals. In the clinical trials conducted, the staff was unable to meet their required protocols. In one multisite study that evaluated the frequency of drainage, they determined that the staff was only able to conduct the procedure every 90 minutes, rather than every hour.[2] Assuming the procedure takes 5 minutes, the respiratory therapist would need 2 hours (24 procedures x 5 minutes each = 120 minutes) with every patient each day — time that is often not available with current staff to patient ratios.

The challenge of ensuring that each patient is seen hourly is fundamental to the effectiveness of subglottic secretion drainage. Each time the protocol is not followed, is a chance for the secretions to be aspirated into the lungs and causing VAP or bronchial aspiration. It is likely that many of the cases of VAP that are seen in the clinical studies in the SSD group were caused by too long a period between procedures, and could be reduced even further with more frequent procedures.

2. Ensuring Proper Suctioning Force Levels

> "Current methods for subglottic drainage put between 2 and 5 times more force on the airway than is recommended."[7]

The American Association for Respiratory Care (AARC) has very specific guidelines for the pressure that is to be put on the airway of the patient, a maximum of -150 mmHg in intermittent treatment.[8] Pressure higher than this can put too much force on the airway, cause irritation for the patient and produce inflammation which can actually increase the volume of secretions and damage delicate mucous membranes.

Interestingly, the two methods of intermittent subglottic secretion drainage currently available and widely used, wall suction regulators and syringes, both exert more force on the airway than is recommended by AARC. Studies have found that 97.7% of procedure utilizing these modalities exceeded recommended pressure levels.[9] With wall-mounted suction, the pressure was measured at 123% higher than recommended, and with a syringe it was even higher.

Figure 7. Pressure gauge used to measure actual pressure generated by 10 ml syringe.

Depending on size, a syringe puts -578 to -722 mmHg of force on the airway, nearly 4 and 5 times more pressure than is recommended by the AARC[7] (see Table 3).

Table 3. Test to measure peak vacuum pressure of syringes with different volumes

Volume of syringe	Vacuum/Pressure (mmHg)			
	1	2	3	Average
2 mL	-578	-578	-578	-578
5 mL	-671	-671	-671	-671
10 mL	-706	-706	-706	-706
20 mL	-722	-722	-722	-722

3. Low and Variable Amounts of Secretion Drainage

> "Large variations in the volume of retrieved subglottic secretions have been previously reported. In one observational study, secretions were retrieved in less than 50% of collection attempts with suctioned volume ranging from 0.3 to 15.0 ml. This variability was confirmed in our study."[2]

An issue that is noted in many of the clinical trials is the low

and variable amount of secretions collected.[2] Among the factors that play into this are secretion viscosity, the effectiveness of suctioning and appropriate pressure, difficulties in maintaining the suction line, and frequency of drainage.

It seems clear that with current protocols reporting only 0.3-15.0 ml being removed each day,[2,10] a substantial amount of secretions are being missed, which have the potential to drain into the lungs and cause infection. Even though all the clinical trials observed major improvements in VAP rate with the use of SSD, it is worth noting that overall VAP rates remained high. The data suggests that VAP rates could be further lowered with effective, targeted subglottic secretion drainage that increases the amount of secretions collected. Current techniques using wall suction or manual suction with a syringe are improvised solutions and not specifically designed for subglottic secretion drainage.

With the advent of new automated intermittent subglottic secretion devices it is now possible to increase the volume of secretions routinely collected by up to 10 times.

4. Risk of Contamination

> "In addition to identifying suction regulators as potential reservoirs for nosocomial pathogens, this study demonstrated that contaminants can spread from a suction regulator to the wall-side canister within 30 minutes and can also spread back to a simulated patient stomach within 24 hours. Thus, suction regulators might be contaminated by one patient and then transmit pathogens to the stomach of a subsequent patient."[11]

In a study of 11 ICUs and 470 wall-mounted suction devices, 37% (173) were found to be contaminated with pathogens, including *Staphylococcus aureus*, *Psuedomonas aeruginosa*, and *Enteroccocus faecium*. Five different types of regulators were included in the testing, demonstrating this is a universal concern with wall suction. One common misconception is that after "cleaning" a regulator after patient use, the regulator is free of contamination. Current manufacturers' protocols state that back-flushing a regulator with disinfectants can remove contamination; however, there exist no data to support the efficacy of this practice. In addition, the internal flow paths in suction regulators can be convoluted, and bacteria can become trapped and can be aerosolized back during the venting cycle. The most effective method to ensure that a contaminated regulator does not contain pathogens is to sterilize it, which is costly and is not the presently recommended practice. Most brands cannot be safely sterilized. Identifying the suction regulator as a potential source of infection is noteworthy, and additional investigation is needed to clarify the risk that contaminated regulators pose to patients and to indicate optimal methods and protocols for disinfection.[11]

5. Limitations of Continuous Secretion Drainage

Because it is applied to the patient continuously, the AARC guideline for continuous secretion drainage is only -20 mmHg (compared to -150 mmHg for intermittent SSD). This low pressure is often not strong enough to remove many secretions, particularly those with high viscosity. It is tempting for respiratory therapists to increase the pressure settings to remove more secretions, but it is important to keep the pressure level low because continuously higher pressure levels cause drying of the mucous membrane.[2,4,14,15] This can cause irritation and lead to increased secretions.

6. Limitations of Manual Intermittent Secretion Drainage

There are two primary limitations with regard to manual secretion drainage. The first is the force exerted by the syringe. Depending on the size of the syringe, pressure levels as high as -722 mmHg can be exerted, which is substantially higher than the AARC recommended guideline of -150 mmHg. This is unsafe and can lead to complications. The second stumbling block is the demands on staff time given average staff to patient ratios. It is difficult to ensure that each patient receives the manual procedure hourly, as recommended. In clinical trials, this one hour interval was often longer than recommended and resulted in patients not receiving the recommended number of secretion drainage procedures each day. The volume of secretions collected, using manual intermittent secretion drainage have been measured at 33 ml per day.

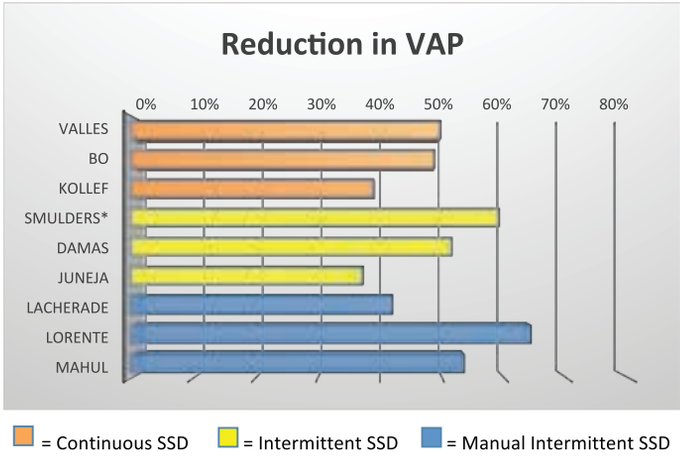

Figure 8. Reduction in VAP by Treatment Modality

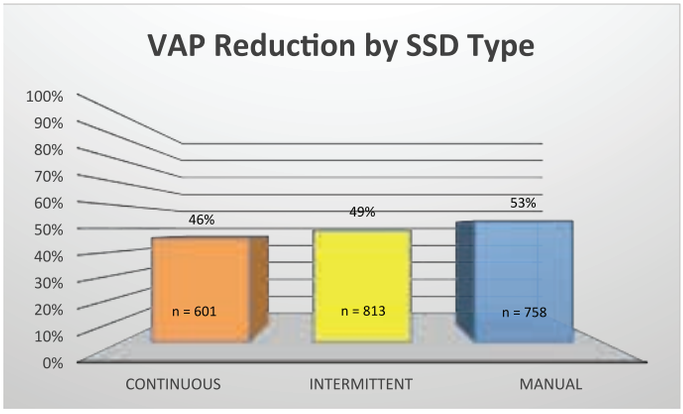

Figure 9. Average Reduction in VAP by Treatment Modality

Benefits of a Novel System in Addressing Limitations

With the FDA clearance of the SIMEX *cuff* Automated Intermittent Subglottic Secretion Drainage System, it is now possible to provide SSD in an optimal form, based on extensive research with specialty subglottic tracheal and endotracheal tubes.

1. Ensuring Frequent Secretion Drainage

With automatic intermittent SSD the frequency and pressure levels are preset according to patient needs. The recommended timeframe for aspiration ON time is 10-20 seconds and aspiration OFF/Pause time every 5 to 20 minutes, depending on the amount and type of secretion drainage. This can be customized to each

patient and reduces demands on the respiratory therapist to visit each patient every hour and ensures the frequency of drainage procedures.

The automated intermittent SSD device is electric and/or battery powered, is virtually silent and is designed to operate 24/7 at the patient's bedside. This ensures drainage is achieved at recommended intervals at reliably calibrated pressure levels. This allows for substantially more (up to 10 times more) secretions being removed compared to other methods. The secretions are removed from above the ballooned cuff and before they can reach the lungs to cause infection.

2. Ensuring Proper Suctioning Force Levels

The pressure level of the pump can be digitally set within the AARC guidelines for intermittent subglottic secretion drainage of -80 to -150 mmHg and can be customized according to patient needs. For example, thin secretions may allow for lower pressure levels than highly viscous secretions. Larger volumes of secretions may require decreasing the "OFF" time to allow for more frequent drainage. These customizable pressure levels, along with extended OFF times, significantly reduce excess strain on the airway of the patient, drying of tracheal mucosa and irritation of the airways. Additionally, in ongoing trials the amount of secretion collected averages up to 10 times more than with manual or continuous drainage.

3. Increasing Secretions Collected

"In our experience, the amount of material drained increases by up to 10 times over what we were seeing."[7]
— Dr. Markus Wolf, Asklepios Klinik, Hamburg, Germany

Figure 10. Patient with secretions of > 500 ml per day, E. coli, Pseudomonas, and Klebsiella. (Courtesy of Dr. Wolf)

By increasing the frequency of drainage and optimizing the pressure level for each patient, the optimal volumes of secretions can be collected and prevented from reaching the lungs. In trials with automated intermittent drainage, the amount of secretions collected was approximately 100-500 ml each day.[7,12] In the clinical trials with manual intermittent secretion drainage, the authors reported high variability and low volumes of secretions collected per day.[2,10] A recent study showed that switching from manual to automated intermittent drainage, the volume of secretions collected rose from 33 ml to 400 ml — a ten-fold increase. That is nearly 370 ml of infectious material that could have made its way into the lungs.[13]

Conclusion

The Promise of Automated Intermittent Subglottic Secretion Drainage

Based on the latest research, clinicians now have an innovative device to optimize treatments and outcomes to help reduce the incidence of VAP through true Intermittent SSD. Facilities that have adopted specialty subglottic tracheal and endotracheal tubes now have a state-of-the-art device to optimize their use as well.

When technology, driven by evidence-based research is fully engaged it can be used to design and engineer the breakthrough devices that will improve, optimize and change the way we administer proven therapies. The promise of the new SIMEX *cuff* device for Automated Intermittent SSD has been demonstrated in Europe in over 500 patients with no adverse events. Randomized control studies and multi-center trials are now underway in the US to further evaluate its efficacy.

We know that SSD can:

- Reduce the incidence of VAP in ventilator assisted patients by approximately 50% (37-64%)
- Reduce both early and late onset VAP
- Reduce the need for antibiotics
- Reduce the length of hospital stay

We know that the limitations of existing modalities of treatment include:

- Inability to accurately operate within AARC recommended pressure guidelines
- Exposing patients and clinicians to contaminants
- Limited volume of secretions collected
- Depending on modality, can require very low, ineffective pressure levels which limit the volume of secretions collected
- Are utilized at pressure levels that are too high and can injure the airways and tracheal mucosa
- Are dependent upon limited staff time due to high staff to patient ratios

And we know that Automated Intermittent SSD can:

- Be optimized to recommended pressure recommendations
- Be fully customized to individual patient needs
- Reduce staff time
- Reliably control pressure levels due to digital programming
- Run at optimal ON and OFF cycles to maximize secretion collection while minimizing injury to the airways and tracheal mucosa
- Collect up to 10X more secretions daily than other modalities
- Operate in virtual silence at the patient's bedside
- Significantly reduce cross contamination through use of an integrated, self-contained, disposable collection canister

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Advances in Subglottic Secretion Drainage
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