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FloSure Technologies Reference Documentation List:

1. Advances in Subglottic Secretion Drainage – Spring 2016

2. SIMEX Presentation to Dr. Change (AHRQ) – June 13, 2022

3. The Role of SSD in VAP Prevention- ICU Experience with Automated System- Wolf 2016

4. Secretion Management – Comparing Various Drainage Methods

5. Syringe Bench Testing – March 2014

6. Are we Suctioning the Life Out of Our Ventilated Patients- UT Health Science Center 2013

7. Challenges- Suction/Aspiration Apparatus – OCT 2021

8. Automated Subglottic Aspiration System in Reduction of VAP and Secondary Lung Infection in COVID Ventilated Patients - Oct 28, 2021

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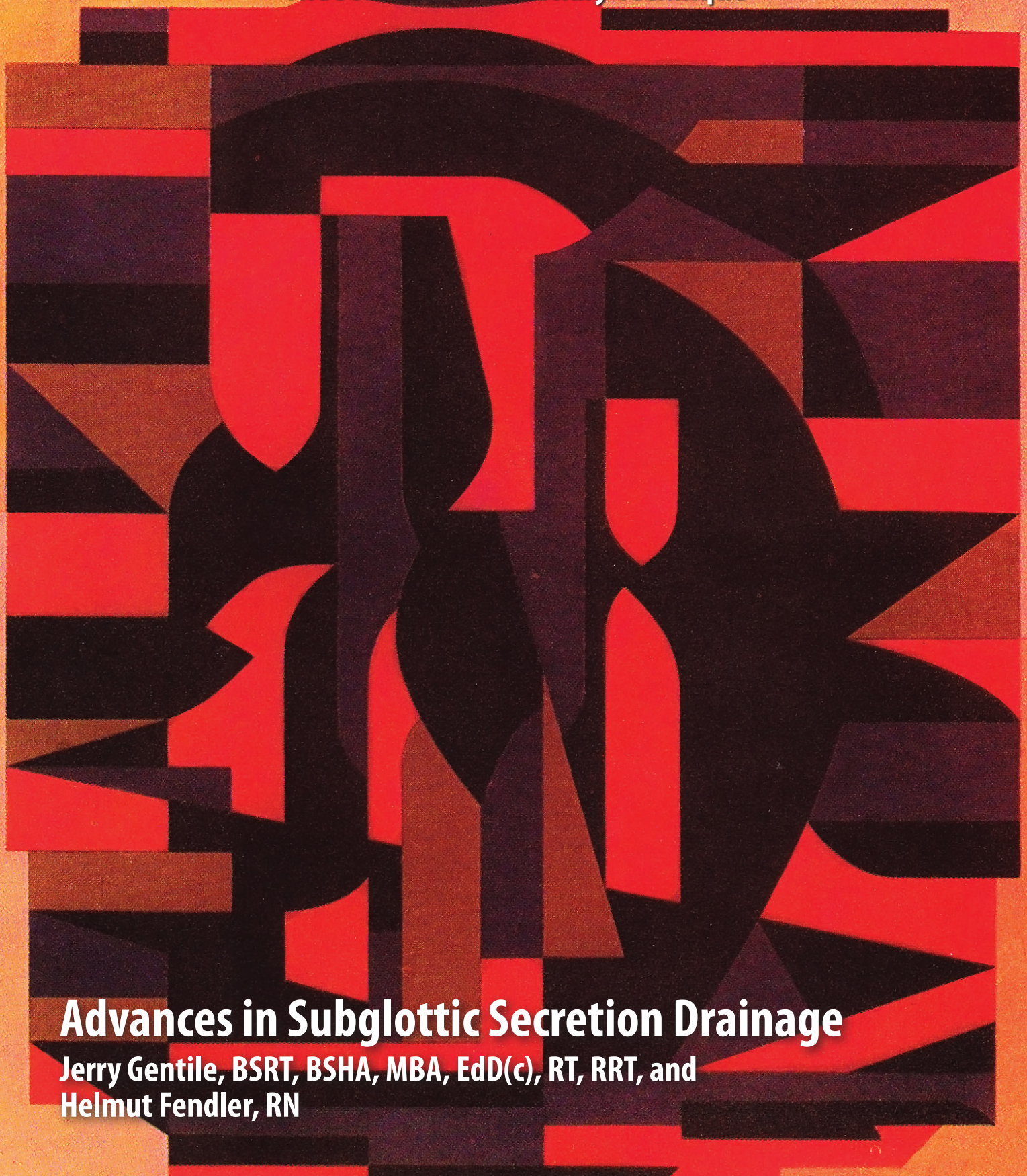

Advances in Subglottic Secretion Drainage

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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

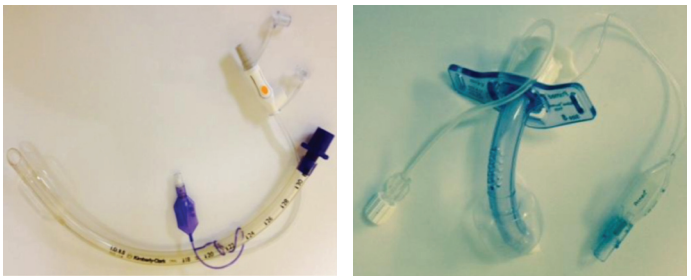
The purpose of subglottic secretion drainage (SSD) is simple – to prevent saliva and gastric secretions, which carry bacteria, from leaking down into the lungs of ventilated patients. Most people create at least one liter of saliva daily, which is typically swallowed.[5] When the ventilated patient is 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

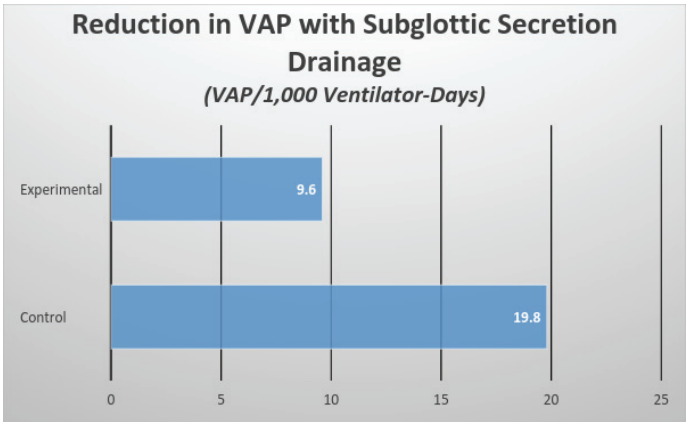


Figure 2. Damas P, Frippiat F, Ancion A, et al, Prevention of Ventilator-Associated Pneumonia and Ventilator-Associated Conditions: A Randomized Controlled Trial with Subglottic Secretion Suctioning, Critical Care Medicine Journal, 2015;43:1:22-301.[1]

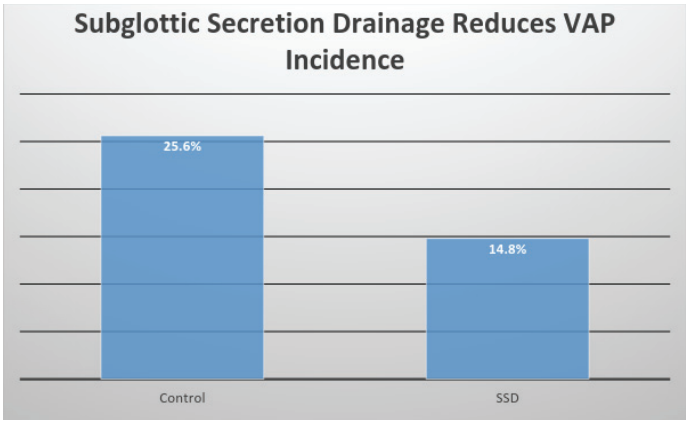


Figure 3. Lacherade JC, De Jonghe B, Guezennec P, et al. Intermittent Subglottic Secretion Drainage and Ventilator-associated Pneumonia: A Multicenter Trial. Am J Resp Crit Care Med. 2010;182:910-917.[2]

> "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%, $p = 0.01$).

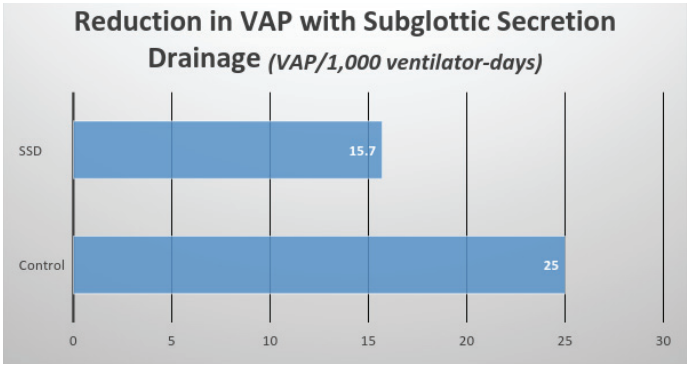


Figure 4. Juneja D, Javeri Y, Singh O, Nasa P, Pandey R, Uniyal B. Comparing influence of intermittent subglottic secretions drainage with/without close suction systems on the incidence of ventilator associated pneumonia. Indian Journal of Critical Care Medicine. 2011;15:3:168-172.[3]

> "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.

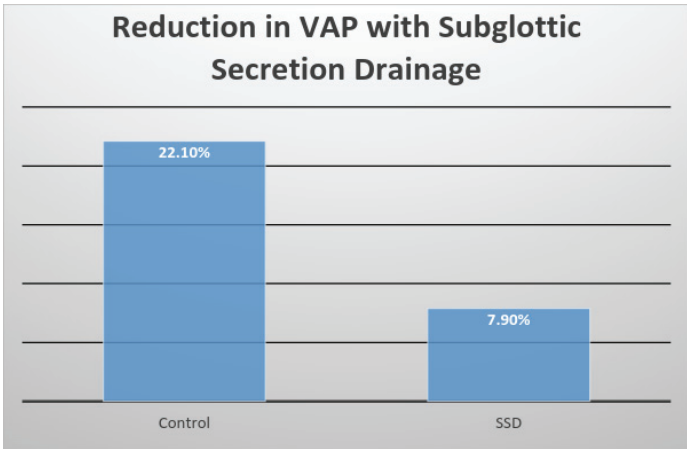


Figure 5. Lorente L, Lecuona M, Jimenez A, Mora M, Sierra A. Influence of an endotracheal tube with polyurethane cuff and subglottic secretion drainage on pneumonia. Am J Resp Crit Care Med. 2007;176:1079-1083.[4]

> "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.

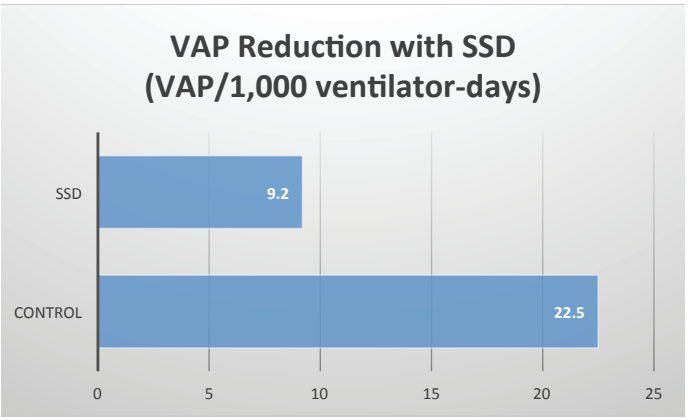


Figure 6. Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C. A randomized clinical trial of intermittent subglottic secretion drainage in patients receiving mechanical ventilation. Chest. 2002;121:3:858-862.[19]

> "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.

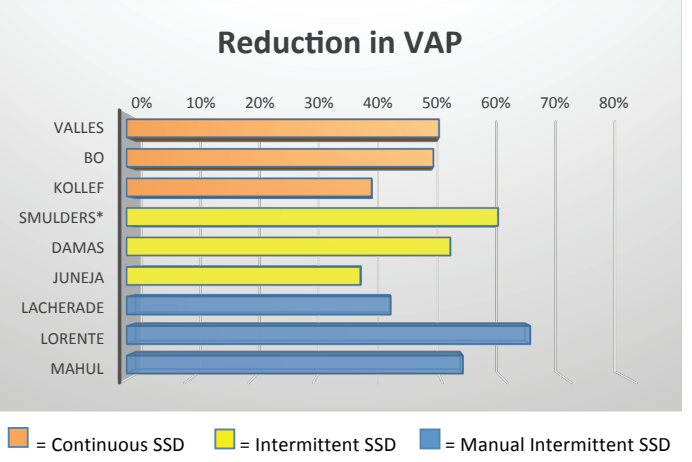


Figure 8. Reduction in VAP by Treatment Modality

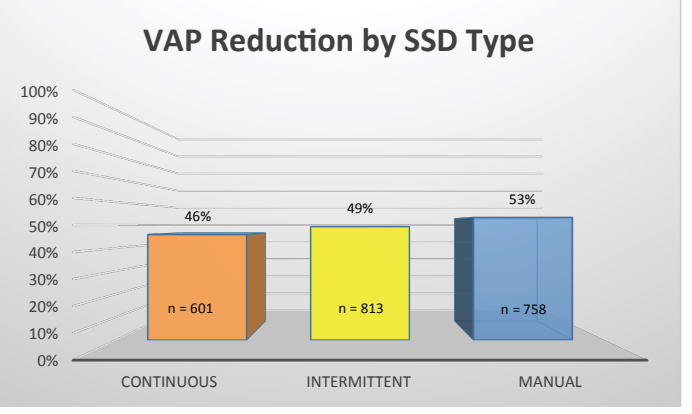


Figure 9. Average Reduction in VAP by Treatment Modality

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

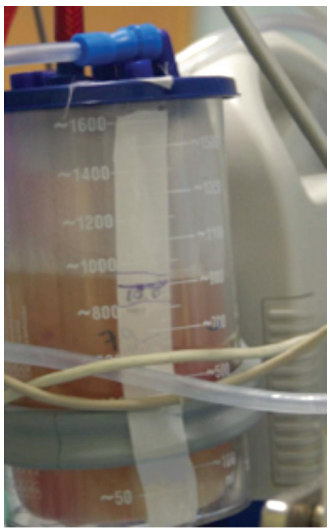


Figure 10. Patient with secretions of > 500 ml per day, E. coli, Pseudomonas, and Klebsiella. (Courtesy of Dr. Wolf)

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
Jerry Gentile, BSRT, BSHA, MBA, EdD(c), RT, RRT, and Helmut Fendler, RN

Reprinted from Respiratory Therapy, The Journal of Pulmonary Technique
Volume 11 Number 2. Spring 2016

Reference # 2

Ref #2

SIMEX

Subglottic Aspiration System

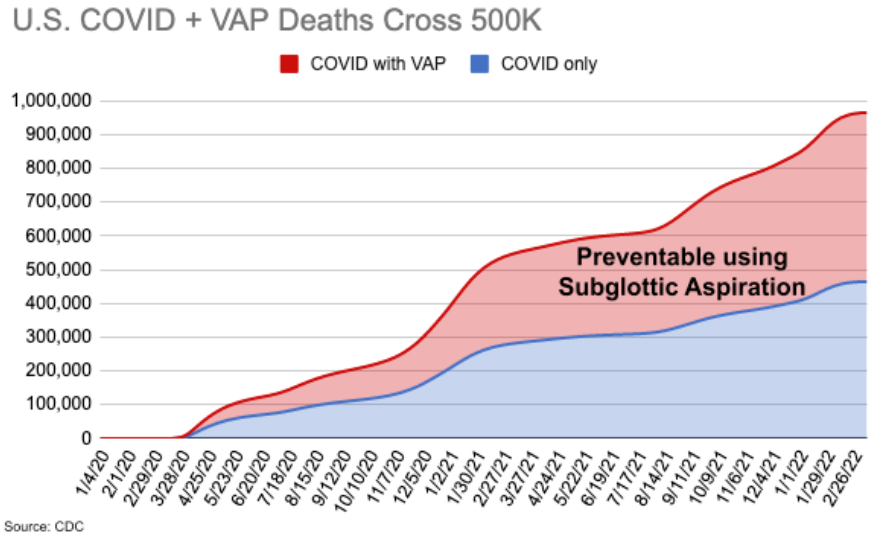
A Novel Device to
Prevent VAP Pneumonia & Save Lives

FloSure™

Background

Half a million COVID Ventilated Patients have died because of Secondary Bacterial Infections or VAP Pneumonia – 3/15/2022**

This is *PREVENTABLE*



https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm **

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Background

This Represents $22 Billion Cost to Healthcare Systems and CMS

Average cost of one VAP incident is **$44,300**[1]

500,000 x $44,300 = **$22.1 Billion**

1- Understanding the Economic Impact of Health Care-Associated Infections: A Cost Perspective Analysis -CDC's Dr. Doug Scott – 2019
https://pubmed.ncbi.nlm.nih.gov/30817421/

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Science

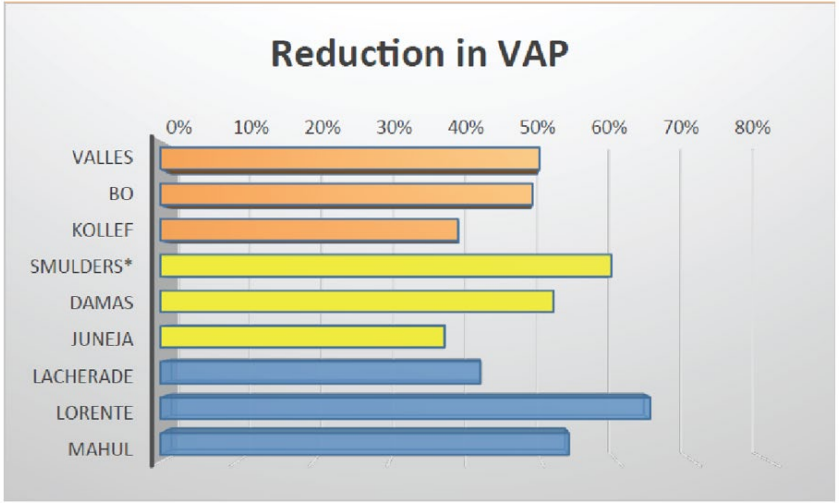
- Per **Dr. Fauci**, *“The majority of deaths in 1918-1919 pandemic resulted directly from secondary baterial pneumonia caused by common upper respiratory tract bacteria”*
- The CDC, ATS, AARC, AACN, SHEA and Johns Hopkins all recommend the use of Subglottic Secretion Drainage (SSD) for VAP prevention
- 25+ years and more than 20 RCTs using SSD have demonstrated 50% reduction in VAP rates
- 100 years ago we did not have the mitigation tools to prevent deaths due to VAP Pneumonia
- Today, we DO

FloSure™

Science | Evidence

Here is an image of the 9 RCTs since 1992 showing an average reduction in VAP rates by 50% using subglottic aspiration.

Mahul (1992), Valles (1995), Kollef (1999), Bo (2000), Smulders (2002), Lorente (2007), Lacherade (2010), Juneja (2011) and Damas (2015).



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SIMEX | The Solution

cuff S

cuff M

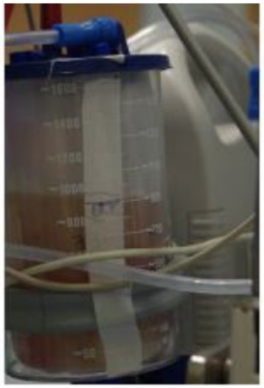
The 1st and only, FDA-cleared system for effective subglottic aspiration

- Decreases micro-aspiration into lower airways
- Automated 24/7 secretion removal
- Reduces time on ventilator
- Reduces need for antibiotics
- Reduces ICU stay

FloSure™

SIMEX | Clinical Benefits

- Removes 10x the volume of subglottic secretions compared to manual methods
- Lowers VAP incidence by +50%
- Reduces weaning time (2-3 days)
- Reduces need for bronchial aspiration and associated lung tissue damage
- Prevents leakage and maceration at stoma site
- Reduces need for antibiotics
- Virtually reduces cross-contamination



M.K. m 75y 79 d AECOPD, OHS
Dysphagia, ICUAW
E. coli 3MRGN, Pseudomonas, Klebsiella
500-1000 ml per day watery

R.H. m 83y, 29 d post emergency ACB-OP
cardiog. shock, acute on chronic renal failure
obesity ° II, severe CIP / CIM
250-350 ml mucopurulent

DJVA. M. f 63y, 38 intubated pneumonia
dysphagia, multiple sklerose 20y
400-600 ml watery

FloSure™

Secretion Management |

Micro-Aspiration into Lungs

Indicated and safe for SSD
(FDA Cleared)

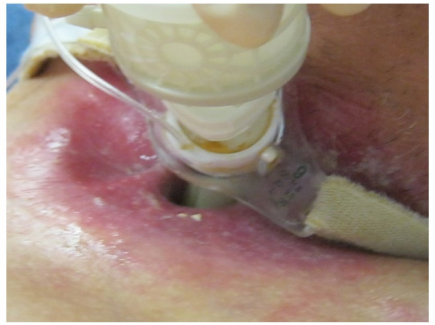
N/A

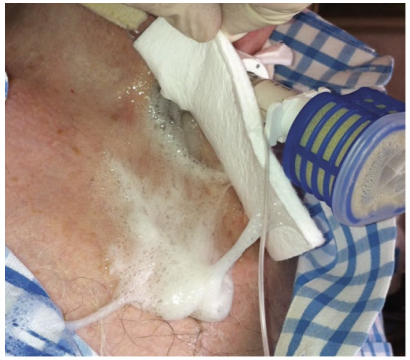
Notes: **(a)** with standard tracheal and endotracheal tubes, secretions drain past the cuff down into lungs. Tracheal suctioning is then used to remove secretions from the lung, **(b)** with **syringe**, an average of (20ml) is removed from above the cuff but the majority drains into lungs and tracheal suctioning is needed to remove it. **(c)** with **wall suction**, an average of (30ml) is removed from above cuff and the majority drains into lungs requiring repeated tracheal suctioning **(d)** with **SIMEX**, a majority (300ml) of secretions are removed from above the cuff with minimal secretions draining into the lungs thus requiring limited tracheal suctioning.

SIMEX | Clinician and Staff Benefits

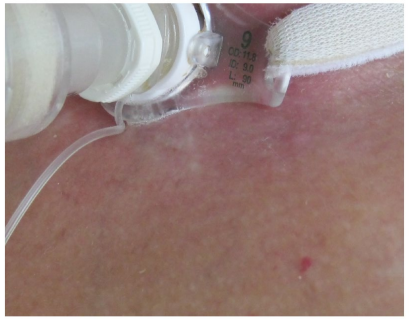
- Automated aspiration of secretions eliminates need for manual drainage
- Self contained disposable canister virtually eliminates staff exposure to infectious secretions
- Reduced leakage around tracheostomy tube:
  - Reduces stoma care (maceration of surrounding tissue)
  - Drastically reduces need for constant bedding and clothing change

Before SIMEX





5 days after SIMEX



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Challenges

- VAP is not tracked in hospitals – Most hospitals report ZERO VAP!
- "*You can not Prevent it if you can not Measure it*"
- CMS does not believe VAP is preventable, yet CDC recommends using SSD for VAP prevention
- Lack of education and awareness
- Prevention vs. Treatment of VAP
- No Scientific and Medical benefits of allowing colonized secretions to penetrate the sterile lower airways and the lungs

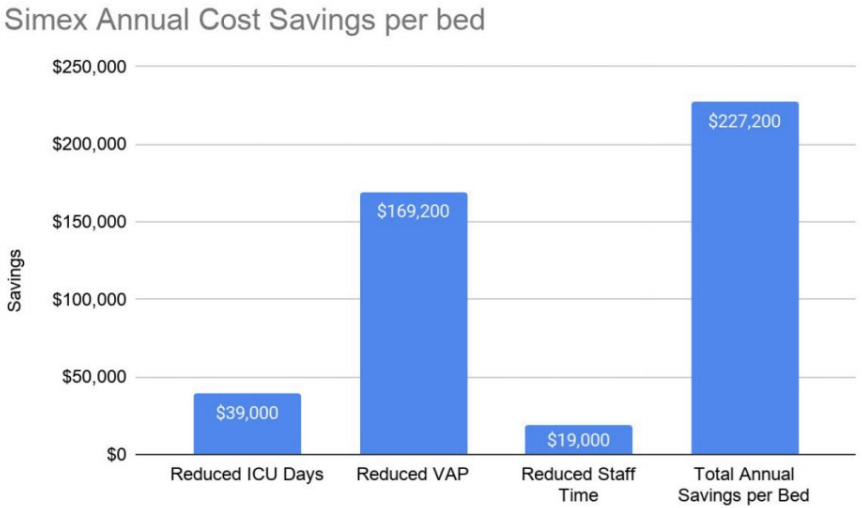
FloSure™

Cost Benefits

SIMEX Subglottic Aspiration System is the least expensive and most impactful preventative mitigation strategy for COVID ventilated patients.

Increased secretion removal, reduced weaning time and automation create cost savings with respect to:

- **VAP incidence / antibiotic usage**
- ICU days per patient
- Staff productivity
- Consumables



FloSure™

Expert Testimonial

“By removing large volumes of contaminated aspirate in the subglottic space, the system can help mitigate ARDS. Use of the SIMEX system can help to manage further insult to the lungs in COVID-19 patients by reducing secondary infection (VAP) risk and possible further damage in the lungs.”

Dr. Jerry Gentile, EdD, MEd, MSHA, MPH, MBA, BSRT, BSHA, RRT,
a researcher and early adopter of the SMEX aspiration system in his practice

FloSure™

Statement of ASK

Because our novel device can help prevent VAP pneumonia and save lives of patients on a mechanical ventilator, we respectfully request of AHRQ the following:

- Since 2015, AHRQ has extensively performed a systematic review of the use of Subglottic Aspiration and acknowledged its use for VAP prevention
- Initiate, support and fund a follow-up review of SSD using an Automated Subglottic Aspiration System
- Re-iterate and re-affirm to your stakeholders the use and benefits of SSD in the effective prevention of VAP for COVID as well as Non-COVID ventilated patients

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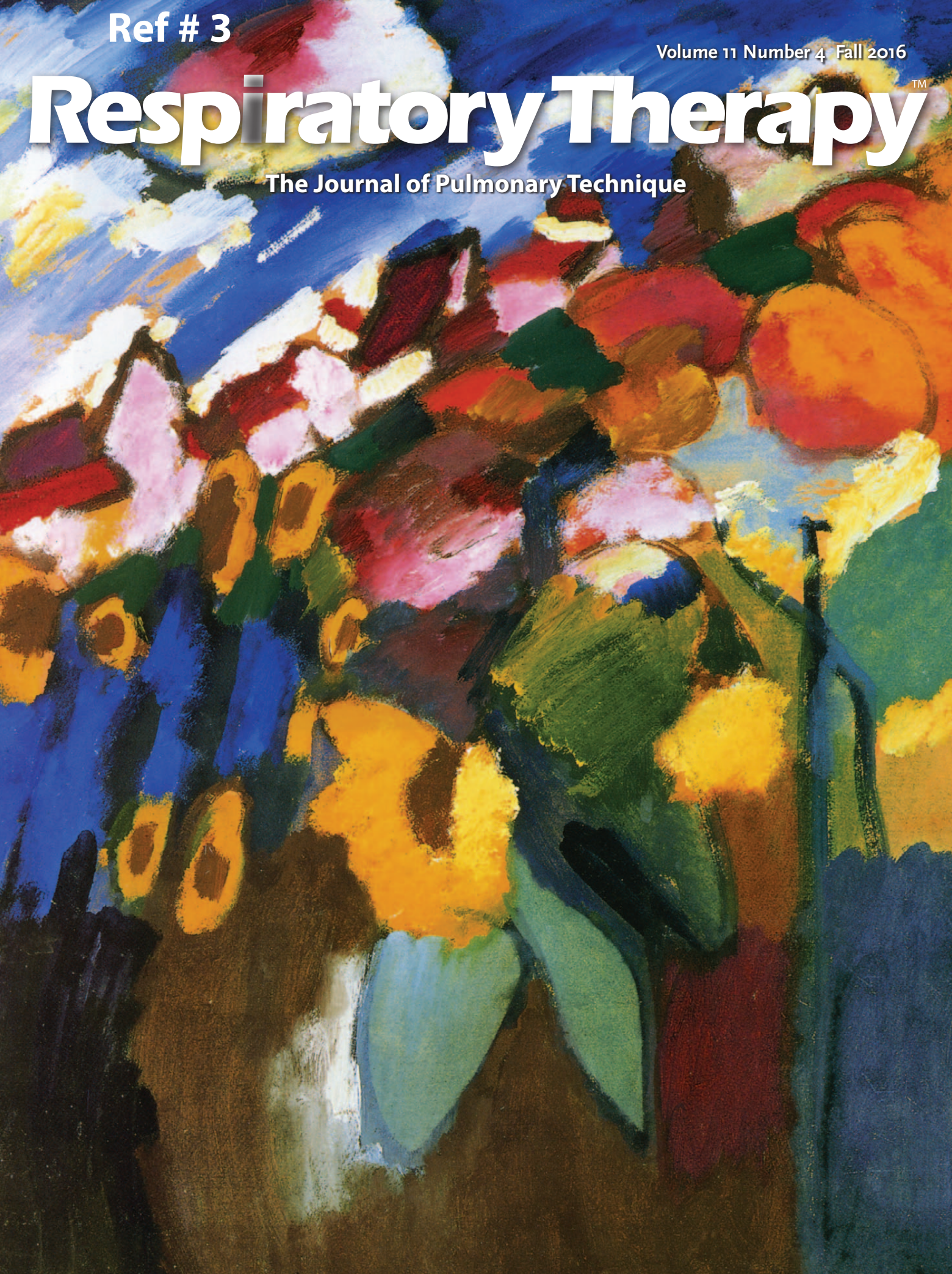
Reference # 3

Ref # 3

Volume 11 Number 4 Fall 2016

Respiratory Therapy™

The Journal of Pulmonary Technique



The Role of Subglottic Secretion Drainage in VAP Prevention: ICU Experience with an Automated Intermittent Subglottic Secretion Drainage System

Dr med Markus Wolf

Abstract

The most difficult and challenging cases in the ICU involve long periods of mechanical ventilation which are associated with a high risk of ventilator-associated pneumonia (VAP). Patients with VAP face prolonged hospital stays and significantly increased risk of mortality. Efforts to prevent VAP have included selective oral decontamination (SOD), elevation of head rest and subglottic suctioning of secretions.

This paper describes a new approach that combines the use of tracheal and endotracheal tubes containing ballooned cuffs and integrated suction ports, with the use of an automated intermittent subglottic secretion aspiration system, in an 18-bed ICU in Hamburg, Germany. The author provides an overview of the cases of 16 patients on the automated devices visited during a single day on unit rounds, as well as a description of an additional, and particularly challenging, paradigmatic case. The cases are intended as a "snapshot" of clinical experience gained with the system in over 4 years and in approximately 500 patients.

Keywords: Ventilators, Mechanical, Pneumonia, Respiratory Tract Infections, Ventilator Associated Pneumonia (VAP), Ventilator Associated Events (VAE), Subglottic Secretion Drainage (SSD), Automated Intermittent Subglottic Aspiration

Introduction

Ventilator-associated pneumonia (VAP) is the most common and serious type of hospital-acquired infection (HAI) in the ICU. The reported incidence varies in different studies on the subject which is in part due to complexity, and differences in the applied criteria such as epidemiological variables, diagnostic tests, use of antimicrobials, and other management strategies. A large current observational study in 27 ICUs of 9 European countries found 18.3 episodes of VAP per 1000 ventilator-days and an increase in mortality of 6% as well as an increase of duration of ventilation and length of stay.[1] VAP continues to be a serious problem, despite progress in the understanding of its origins, and improvements in treatment protocols.

The 18-bed ICU unit at Asklepios Klinik Barmbek in Hamburg specializes in weaning long-term ventilated patients from the ventilator. The patients treated are almost exclusively referrals from mainly surgical ICUs in the Hamburg area and at the time of transfer in general have been ventilated for about 20 days. The average length of stay is 34 days and at any time point about 90% are invasively ventilated, and 90% of those have a tracheal cannula. This specialized weaning unit was created in 2008 and expanded thereafter. Subglottic suctioning and selective oral decontamination (SOD) were not practiced until 2012 when the decision was made to implement a VAP prevention bundle, based on several observations in this cohort of long-term ventilated patients. In about half of the patients we saw what was described as "hypersalivation." These patients always had a lot of saliva in the mouth, and the tissue surrounding the tracheostoma was always wet and patients required a higher frequency of endotracheal (bronchial) suctioning. In addition, some of these patients had subfebrile temperatures that we could not find a reason for, and the rate of purulent bronchial secretions was deemed elevated. Further observations of these patients for several minutes revealed that swallowing was not present. We therefore concluded that their problem was a deficit in swallowing rather than hypersalivation.

We looked at the published evidence for measures to reduce VAP and found that all proven interventions had something to do with reducing the likelihood of pathogens passing from the upper gastrointestinal tract to the lung, first noting a more than 50% reduction in VAP when postpyloric feeding was compared with the conventional gastric feeding.[2] We also noted that at the gastric level, avoiding the use of proton pump inhibitors, which elevate the gastric pH and thus favor bacterial survival, can reduce VAP by more than 50%.[3] Looking at the next level in the supposed pathway, the oropharynx, we reviewed a large meta-analysis showing a 44% reduction of VAP when using selective oral decontamination.[4]

We then turned to evidence involving the last step in the pathway, which is the prevention of oropharyngeal and subglottic secretions from entering the lower respiratory tract via the outside of the cuff. A study comparing intermittent vs. continuous control of ballooned cuff pressure showed a 44% VAP reduction when continuous cuff pressure was used.[5] A current meta-analysis of 17 studies including 3369 patients noted a 0.58 relative risk for VAP using subglottic suction.[6] Looking on these results together it seems obvious that there is a common mechanism as all these interventions hinder the ascension of pathogens from the gastrointestinal tract to the lung. This is in accordance with the observation that the rate of VAP is not reduced when a closed suction system is used.[7]

Dr Markus Wolf is Senior Physician Weaning Station, Department of Pneumology and Intensive Care, Asklepios Klinik Barmbek, Hamburg, Germany.

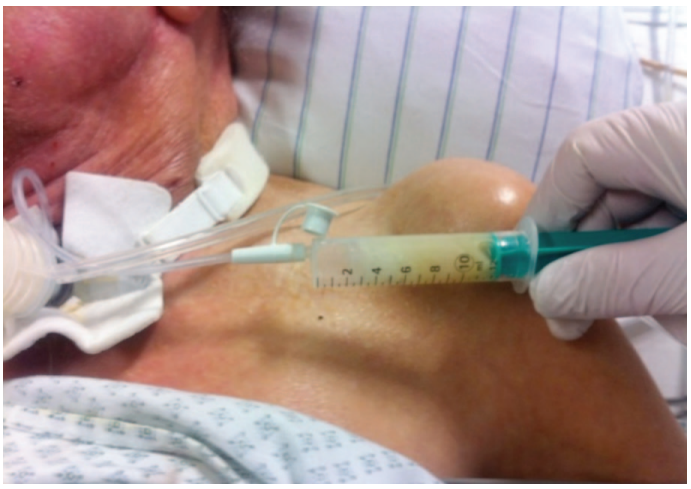
The hypothesis of VAP being a consequence of the movement of pathogens from the gastrointestinal tract to the lung is strengthened by a study from Johannesburg published in 1999.[8] Researchers in the Johannesburg study looked for the time course of the appearance of pathogens in the oropharynx, stomach, lower respiratory tract, and inside the endotracheal tube, every 6 hours after intubation. After the first 12 hours following intubation, gram positive pathogens, especially Staphylococcus, appeared in the pharynx. After about 1.5 days, gram negative pathogens, for example Klebsiella, Pseudomonas, E. coli, Proteus, Enterobacter, and Enterococcus appeared about simultaneously in the stomach and in the oropharynx. After about 3 days, they appeared in the lower respiratory tract, and only after that appeared on the inside of the cannula. This sequence of events strengthens the hypothesis that the pathogens that cause VAP reach the lung traveling with contaminated oral secretions via the outside of the cannula passing the cuff of the endotracheal tube rather than being introduced by the staff through the lumen of the tube.

Based on our review of the evidence, we decided that our VAP prevention bundle should include:

- a preference for postpyloric feeding and PEG/PEJ thus avoiding nasogastric tubes
- systematic use of SOD
- continuous cuff pressure control, and
- subglottic suctioning

The introduction of SOD did not pose any problems while the introduction of continuous cuff pressure control was not possible for economic reasons.

Figure 1. Manual suctioning using a syringe. Similar to that used in the French study protocol[9] for SSD.



The practical problems with subglottic suctioning became evident when looking closely at a randomized controlled SSD study conducted in France.[9] The study included 333 adult patients in 4 centers and yielded similar results as the above cited meta-analysis, reducing the relative risk of VAP to 0.55. The protocol called for manual suctioning hourly with a 10 ml syringe, and called for the recording of the amount of secretions removed. Actual suctioning took place at approximately 90-minute intervals. The volume of secretions on average was 14 ml per day with a span of 8-22 ml, with a minimal value of 0 and a maximum value of 197 ml. The suctioning of every patient at least every 90 minutes consumes a lot of manpower and represents a great challenge to ICU staff. With only 6 nurses per shift on our 18-bed unit, hourly manual suctioning would not have been possible (see Fig 1).

In reviews of the SSD literature, both wall suction regulators and manual syringes had been shown to exert more force on the airways than recommended by guidelines.[10] In addition, prior experience on our own unit where various brands of wall suction had been evaluated for use in SSD, the wall suction proved insufficient for controlling negative pressures and suction time intervals, and unsuitable for removing the different types and volumes of secretions among our patients. Therefore we began using an automated subglottic secretion drainage device immediately when we introduced our VAP prevention bundle.

> "…prior experience on our own unit where various brands of wall suction had been evaluated for use in SSD, the wall suction proved insufficient for controlling negative pressures and suction time intervals, and unsuitable for removing different types and volumes of secretions…"

Figure 2. Automated Intermittent Subglottic Secretion Aspiration System.

October 2014 Unit Rounds Snapshot

During a single day in October of 2014, each patient on our 18-bed unit was visited during rounds, with the goal of creating a snapshot of our challenging patient population to serve as a basis for discussing the lessons learned in our efforts to prevent VAP using the automated aspiration system. On that day, 16 devices were available and utilized in the treatment of the patients described in Table 1.

Table 1 shows the patient characteristics (where captured and recorded) for all 16 patients on the automated aspiration device. The cases are typical of cases on the unit at any given time. Disease categories documented included cardiovascular, respiratory, neurologic, gastrointestinal, metabolic, and oncologic. Sepsis, organ failure, and severe CIP were noted. The pathogens documented, many drug resistant, are those frequently associated with VAP. Large amounts of secretions, of varying viscosities, were removed daily. Dysphagia was noted in the majority of the patients.

Table 1. Automated Subglottic Aspiration System Patients

Pt	M/F	Age	Condition	Pathogen(s)	Secretion/Daily	Other Observations
01	M	63	Coronary artery bypass OP. Cerebeller infarction	Morganella morgagnii	100 ml mucopurulent (fecal smell)	Delirium Dysphagia
02	M	85	Valve replacement. CHF. Diabetes	E.coli. Morganella morgagnii. Stenotrophomonas	150-250 mucopurulent	Delirium Dysphagia
03	M	67	55 day post esophagectomy for cancer. COPD		400 ml watery	Gastric regurgitation
04	M	74	Coronary artery bypass OP with aortic valve replacement. Acute persistent renal failure. Severe critical illness polyneuropathy. Slow recovery due to axonal type		150 ml mucopurulent. 1400 ml total collected within a few days	Dysphagia Depression
05	M	83	29 days post emergency coronary artery bypass OP. Severe critical illness polyneuropathy		250-350 ml mucopurulent	
06	F	79	48 hours post intubation for AECOPD	Stenotrophomonas maltohilia	50 ml mucopurulent. 600 ml total collected within a few days	Dysphagia Anxiety disorder
07	F	63	Intubated for pneumonia. MS for 20 years		400-600 ml watery	Dysphagia
08	M	75	AECOPD	Enterobacter. Serratia	50-100 ml Mucoid, hemorrhagic secretions	Delirium Dysphagia
09	M	75	AECOPD. ICU weakness. CIP. CIM.	E.coli. Pseudomonas. Klebsiella. Multi resistant against 3-4 major antibiotic classes.	500-1000 ml watery	Severe dysphagia
10	M	71	92 days post ARDS, following spondylodiscitis with sepsis and fibrotic lung	Enterococcus resistant to 4 major antibiotic classes		De-cannulated but later died not wanting further treatment
11	M	66	37 days post pneumonia. Sepsis. Multiple organ failure. Severe weakness		50-100 ml mucopurulent	Delirium Dysphagia
12	F	82	Valve replacement for endocarditis. ICU acquired weakness	Multi-resistant Klebsiella and E. coli	50 ml Mucoid, hemorrhagic secretions	Delirium
13	F	73	32 days post op for aortic dissection	Stenotrophomonas in sputum. Non-invasive ventilation		
14	F	69	AECOPD. Extreme weakness	Very resistant MRSA and Enterococcus	50-150 ml mucopurulent	Dysphagia
15	F	48	123 days post pulmonary embolism. Slightly obese	Klebsiella in sputum on non-invasive ventilation		
16	M	67	26 days intubated for pneumonia and AECOPD	Klebsiella oxytoca	500 ml watery	Dysphagia Delirium

Two Patient Populations

From clinical experience we make a distinction between two patient populations. Group 1 has massive aspiration of a saliva-type fluid. From the subglottic port we remove 400-1000 ml of secretions per day and we adjust the settings of the automated aspiration device to a rather low pressure because the fluid is not very viscous. We also use a very short interval of 5 minutes because the watery fluid can microaspirate and pass the ballooned cuff quickly. You can appreciate the practical impossibility of using manual suction when such frequent suctioning is needed. Group 2 patients have a small-to-medium amount of thick, mucopurulent secretions, in the range of 20-200 ml per day. We adjust the parameters of the automated device differently, using higher negative pressures because the secretions are viscous, with longer intervals to allow accumulation of the secretions on top of the ballooned cuff. This approach facilitates the suctioning of the fluids, while avoiding inadvertent suctioning of the tracheal wall.

Secretions in Group 2 seem to develop primarily in the space between the vocal cords and the cuff. This space is around 20 ml and in normal life it is ventilated all the time, passing some 15 liters of air every minute. When a cuff is in place, this space is no longer ventilated but the mucous membranes continue to produce mucus that then accumulates on top of the cuff. There is no effective barrier to oropharynx pathogens passing into this space and inoculating the above mentioned mucus.

> "Group 1 [patient population] has massive aspiration of saliva-type fluid [400-1000 ml per day]....Group 2 patients have a small-to-medium amount of thick, mucopurulent secretions [20-200 ml per day]."

As the temperature in this space is 37°C, and because there is no ventilation, conditions are very favorable for bacterial growth. The mucus then turns to a purulent and highly infectious material. It is of critical importance to prevent this from entering the lung. Regular suctioning above the cuff is therefore warranted.

Negative pressure settings for the automated intermittent aspiration system range from -60 to -300 mbar (-45 to -225 mmHg). Suction interval settings range from 10-60 seconds (ON), and from 3-60 minutes (OFF). SSD guidelines from the AARC recommend the use of negatives pressures from -80 to -150mmHg.[11]

A Paradigmatic Case

A 58-year-old man was initially admitted to another hospital with decompensated heart failure. He was known to have insufficiency of the aortic and mitral valves. On holiday, he had hiked in the mountains and overstressed his capacity. They tried to recompensate him medically, but after that failed, an emergency double valve replacement was done and the patient's condition further deteriorated and remained critical. He had severe shock (cardiogenic or septic), and developed renal failure and subileus. A pneumothorax occurred. Nonetheless, he began to improve soon after the operation.

He was extubated on Day 6 post op and put on non-invasive ventilation. Dysphagia became apparent on Day 6 post-extubation, and on the 10th day post-extubation the patient was reintubated. On the 12th day they performed a tracheotomy. A pericardial effusion was drained. He had atrial fibrillation and a catheter-associated infection with E. faecium.

When we first saw the patient on our unit he had a very reduced vigilance and an extremely pronounced muscle weakness such that he was almost tetraplegic. He appeared to be hyperventilating. He had a fever and his CIP was very strong. As the tracheotomy was performed only a few days prior to his transfer to our unit and the cannula used had no port for subglottic suctioning for the first 4 days of his stay we could not perform subglottic suctioning. In this period we had to suction frequently endotracheally and from the mouth as there were large amounts of saliva type secretions. These procedures were very unpleasant to this patient.

On his 4th day on our unit, we successfully put in a tracheal cannula with a subglottic port, and using the automated device suctioned a large amount of secretions. The frequency of endobronchial suctioning and suctioning from the mouth required was immediately reduced. Almost 900 ml of secretions per day were being removed subglottically. Very little endobronchial secretions remained. By the 5th day we could already start with short intervals of spontaneous breathing and by Day 6 the use of a speaking valve was possible. Day 7 there was still a large amount of subglottic secretions, and some dysphagia persisted, but he no longer required ventilation. By Day 14, only 50 ml a day were being removed subglottically. On Day 18, we were able to remove the tracheal cannula and discharge him.

The case is typical in that patients frequently respond very positively after having large volumes of secretions removed by the device that previously would have descended into the lungs. The case seemed special, and somewhat atypical, from

Figure 3. Example of watery secretions collected (400-600ml daily) – Pat. # 7 in Table 1.

Figure 4. Example of watery secretions collected (500-1000ml daily) – Pat. # 9 in Table 1.

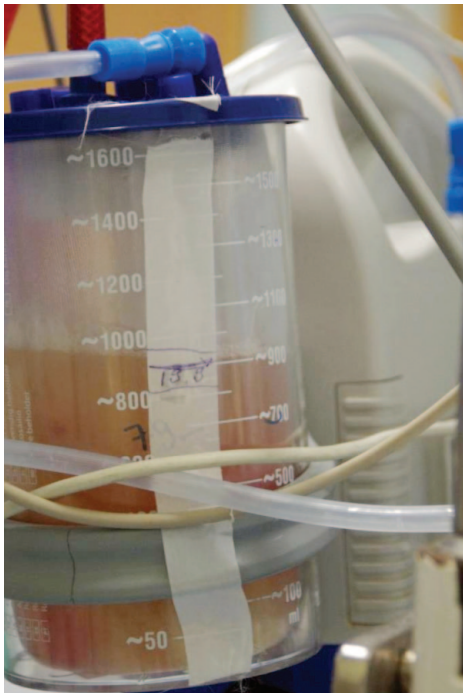


Figure 5. Example of mucopurulent secretions collected (150-250ml daily) – Pat. # 2 in Table 1.

the standpoint of the dramatically short time that was required for the patient to recover from his serious and threatening conditions. His problem, and the reason why he could not be weaned before we started subglottic suctioning was the huge amount of secretions that were passing to his lungs due to a severe dysphagia caused by his critical illness polyneuropathy.

The Practical Application of Subglottic Secretion Drainage

Since 2012 we have used a bundle of measures for the prevention of VAP. When patients are admitted, we change as soon as possible to a cannula with a subglottic port and start automated intermittent suctioning. We do selective oral decontamination (SOD) on all patients using polyhexanide.

We do FEES (fiberoptic endoscopic evaluation of swallowing) on all patients before oral feeding. If we find a relevant amount of dysphagia, we insert a PEG (percutaneous endoscopic gastrostomy tube) and if there is regurgitation we proceed to postpyloric feeding. We start training with a speaking valve early when the patients are still dependent on the ventilator. Even if we know a patient is dysphagic, we start to put him on the speaking valve for periods of 15 minutes to re-ventilate the subglottic space which helps to reconstitute its sensitivity and the swallowing reflex. All patients receive specialized logopedic training and repeat FEES evaluations to see if the training is working. When we start feeding, we color the food with methylene blue in order to see whether there is still aspiration. We also engage head-of-bed elevation, and emphasize early mobilization. We do not use PPI treatment because it has been shown that reducing the acidity of the stomach allows gastrointestinal pathogens to pass into the oropharynx.

As a common initial setting for the automated device, we frequently use -200 mbar (-150 mmHg), with a suction time of 20 seconds and a pause between suctioning of 5 minutes. Manual aspiration has to be done every 8 hours because the machine cannot replace the nurse or doctor or the respiratory therapist—it is a means to help in their work. The responsibility is still with the human being.

Discussion

Our experience with the benefits of subglottic suctioning are in accordance with the large body of evidence for its use that has prompted the German commission for hospital hygiene and infection prevention at the Robert Koch Institute, an organization with similarities to the US CDC, to recommend its use. The KRINKO[12] recommendations issued in 2013 call for the use of an endotracheal tube with a subglottic port for suctioning if the time of ventilation is expected to be greater than 72 hours. In addition, consideration of the exchange of a conventional endotracheal tube to one with an integrated subglottic suctioning port is recommended if the benefits are deemed to outweigh the risks of the procedure. The category of the recommendation is 1A, the highest possible.[12]

Even though the benefits of SSD for patients are undisputable, its use is not as widespread as it should be. It is our belief that this stems from the practical problems with instituting its use in a hospital environment where nursing time is an issue. With the use of an automated system this problem has been overcome in our institution. Our guidelines call for manual suctioning only every 8 hours which proved to be practical. 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 cited in publications. Our explanation is that in the intervals of 90 minutes and more for manual suctioning a substantial amount of these secretions bypass the cuff while the automated system is able to suction every five minutes when necessary to collect the secretions. An additional benefit of the automated subglottic aspiration system is that it is less traumatic to the tracheal wall. Syringes have been shown to create a vacuum equal to a negative of 1000 mbar (-750 mmHg), while the negative pressure created by the automated pump is strictly limited to -300 mbar (-225 mmHg). Automated subglottic aspiration results in less manipulation of infectious material because the material is contained, and greatly reduces the amount of manpower that was previously devoted to suctioning. In an era of growing concern with antibiotic resistant bacterial infections in hospitals, subglottic suctioning provides a means to reduce bacterial infections in a very vulnerable patient population. A recent study showed that subglottic secretion drainage and continuous control of ballooned cuff pressure, implemented together, save health care costs. Thus, the costs of the interventions should no longer be an issue.[13] Looking on VAP as an evitable hazard to our patients, we should consider all efforts to prevent VAP an obligation to all medical institutions.

"An observation in our unit is that the amount of secretions we are able to suction subglottically using an automated system substantially exceed the amounts of secretions collected cited in publications."

From our experience we therefore strongly recommend the use of subglottic suctioning at least in the here-reported population of long-term ventilated patients. We believe automated intermittent subglottic aspiration offers the means to overcome the practical problems associated with implementing subglottic suctioning.

"Thus, the costs of the interventions should no longer be an issue. Looking on VAP as an evitable hazard to our patients, we should consider all efforts to prevent VAP an obligation to all medical institutions."

Conclusion

Automated intermittent subglottic suctioning in our experience offers a lower rate of VAP than manual and other methods, less endotracheal (bronchial) suctioning, less atelectasis, easier use of a speaking valve, shortened ICU stays, and lowers staff burden. Further studies and clinical evaluation of automated SSD are warranted.

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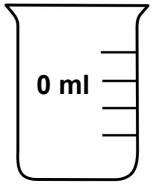
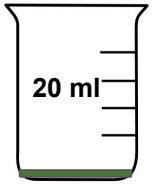
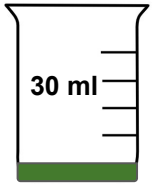
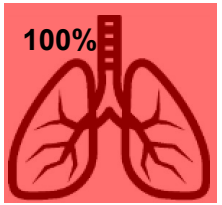
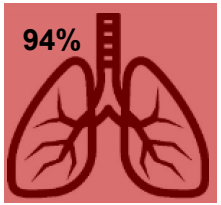
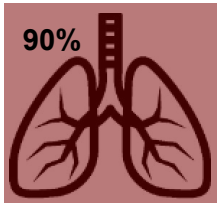
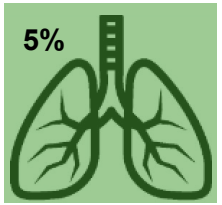
Ref # 4

Secretion Management | Comparing Drainage Methods

	Standard Tubes	Subglottic Tubes + Syringe	Subglottic Tubes + Wall Suction	Subglottic Tubes + SIMEX
Daily Secretion Volume (Removed from above the cuff)				
Micro-Aspiration into Lungs				
Indicated and safe for SSD (FDA Cleared)	**N/A**	✗	✗	✓

Notes: **(a)** with standard tracheal and endotracheal tubes, secretions drain past the cuff down into lungs. Tracheal suctioning is then used to remove secretions from the lung, **(b)** with **syringe**, an average of (20ml) is removed from above the cuff but the majority drains into lungs and tracheal suctioning is needed to remove it. **(c)** with **wall suction**, an average of (30ml) is removed from above cuff and the majority drains into lungs requiring repeated tracheal suctioning **(d)** with **SIMEX**, a majority (300ml) of secretions are removed from above the cuff with minimal secretions draining into the lungs thus requiring limited tracheal suctioning.

FloSure™

Reference # 5

Ref # 5

March 2014

Determination of the amount of Negative Pressure that is generated by Syringe using various size Syringes (Bench Test)

Various size syringes 2, 5, 10 and 20 ml syringes were utilized to measure the amount of Negative Pressure that each syringe generates. A calibrated pressure sensor was used to measure the amount of negative pressure in mmHg. For each syringe the test was repeated 3 times and the results are tabulated in the following table. The photo below demonstrates how the syringe is connected via a tube to the pressure measuring device.

This bench test[1], clearly demonstrates that the larger the syringe, the higher the negative pressure it generates. The most common size syringe used in hospitals for removal of secretion from respiratory airway is 10 ml syringe. As it is shown in the table below, all size syringes generate negative pressure in excess of the -770 mbar or -578mmHg which is quite high and four (4) times the AARC recommended MAXIMUM pressure range of -200 mbar or -150 mmHg. The results of this bench test are in line with other published test and data demonstrating the fact that syringes do generate higher suction pressure.[2-3]

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

1- Internal bench test performed at the R&D facilities in Germany – March 2014
2- Knox T, et.al Nasogastric tube feeding-which syringe size produces lower pressure and is safest to use? Nursing Times, 14 July 2009 Vol 105 No 27: 24-26
3- http://www.bd.com/posiflush/support/

Reference # 6

Are We Suctioning the Life Out of Our Ventilated Patients?

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Introduction

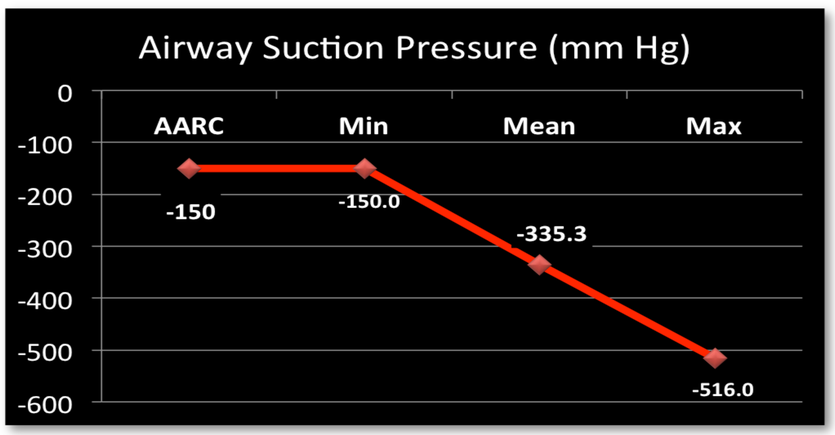
- When taking care of patients with artificial airways, a major hindrance is secretion clearance. Endotracheal suctioning is considered one of the most often performed procedures in the ICU and one of the worst experiences patients recall while in the ICU. *"Having the life sucked out of you"* is not far from the patient's description of the suction event.
- Endotracheal suction has been associated with adverse events that include tachycardia, hypertension, hypoxemia, and atelectasis. Patients at higher risk for decrecruitment have a greater tendency to take longer to recover baseline parameters after the suctioning event. Although the AARC CPG recommends suction not to exceed 150 mmHg of negative pressure in adults, this pressure is not routinely monitored and rarely documented.
- The goals of our study were to determine the amount of negative pressure used in ICU patients, the magnitude of deviation from AARC recommendation, and to identify any differences between day and night shifts.

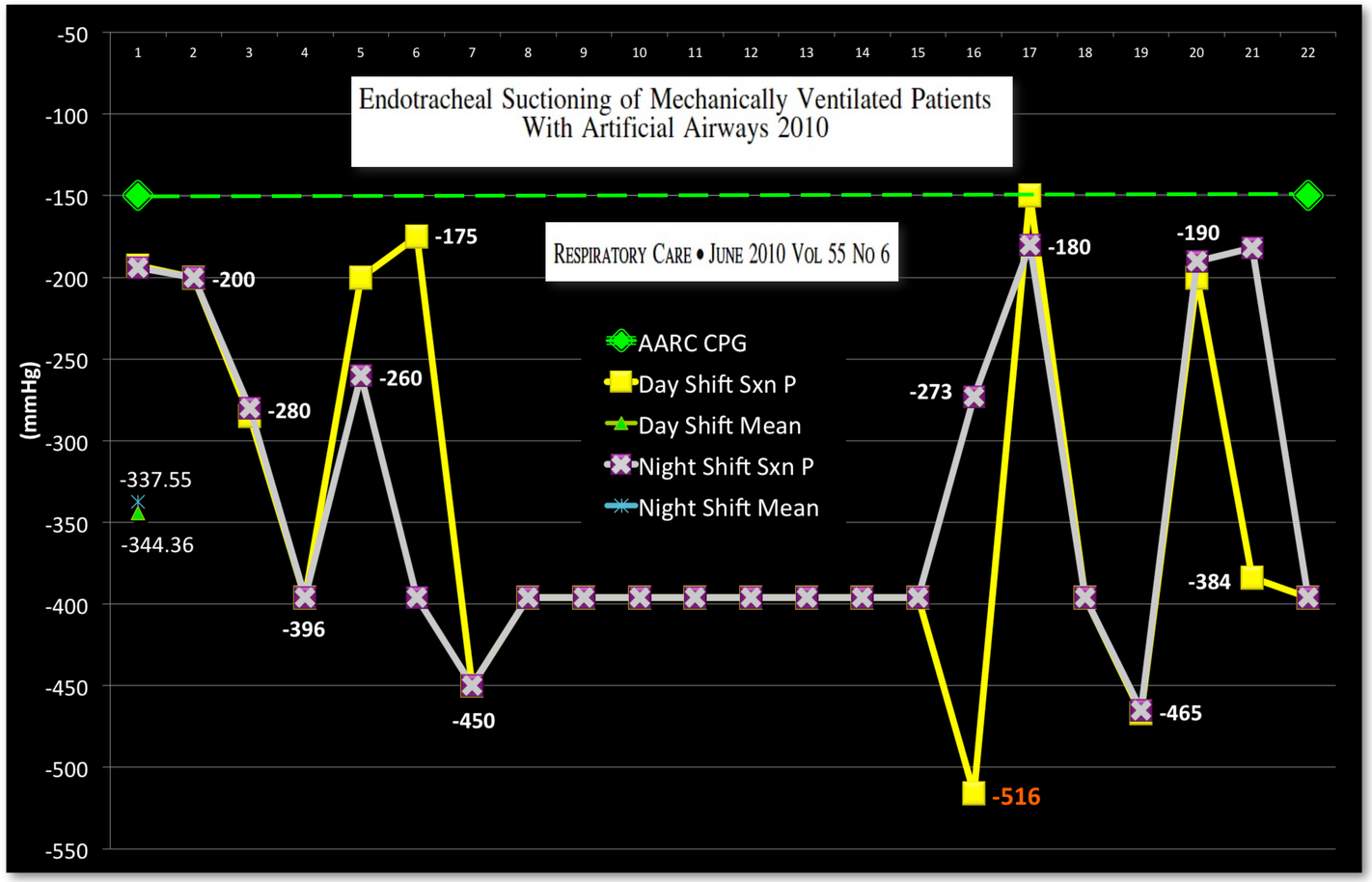
Materials and Methods

- Prospective observational study at a university-affiliated, 496-bed hospital, in San Antonio, Texas. We collected data from 38 patients admitted to the MICU and SICU who had either an endotracheal tube (ETT) or tracheostomy tube (TT) both during several day and night shifts in May of 2013.
- Respiratory therapy students, under direct supervision of faculty, recorded the amount of negative pressure displayed in the manometer after occluding the end of the suction tubing used for airway suction.
- Day shift and night shift data was collected in 22 patients for comparison.
- These values were compared to the recommended suction pressures to calculate percent deviation.

Results

- The mean negative pressure recorded **(-335.3 mmHg +/- 99.8; range: -150 to -516 mm Hg)** was significantly higher than the recommended by the AARC CPG **(-150 mm Hg)** by **185.3mm Hg (123.5% higher) [p<0.01]**. Only 1 measurement **(2.3%)** during day shift was consistent with the recommended suction pressure.
- No significant differences were observed on the suction pressure between patients with TT (-336.2 mm Hg +/- 110.2) or ETT (-339.3 +/- 93.1) [p = 0.36] or between day (-344.3 mm Hg +/- 107.3) and night shift (-337.5 mm Hg +/- 96.0) [p = 0.82). Negative pressure was adjusted down during night shift in 3 out of the 38 patients (7.8%) by an average of 145.33 mmHg (10 – 224) and was adjusted up during day shift in the same number of patients by an average of 103.66 mm Hg (30 - 221).





Conclusions

Although our study revealed consistent suction pressures within multiple intensive care units for both day and night shifts, it became apparent that suction pressures were set markedly above the AARC recommended guideline of -150 mmHg for adult patients.
Suction pressures should be routinely monitored, recorded, and always readjusted by the clinician before suctioning each patient with an artificial airway to ensure overall safety of the patient and to provide standard of care.

Study sponsored by an educational grant from Teleflex Medical

AARC ENDOTRACHEAL SUCTION CLINICAL PRACTICE GUIDELINE: IS IT IMPACTING OUR PRACTICE IN THE ICU?

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Introduction

- Secretion clearance is considered one of the most common procedures performed in the ICU. To prevent any adverse reactions while suctioning, it is crucial to monitor the negative pressure generated by the suctioning circuit manometer and properly document these values in practice.
- Our study in 2013 revealed that excessive negative pressures (402.3 ± 112.3 mm Hg) were used to suction the airway in a medical-surgical ICU.
- These pressures far exceed the AARC CPG recommended negative pressure (-150 mmHg) in adults.

RESPIRATORY CARE • JUNE 2010 VOL 55 NO 6

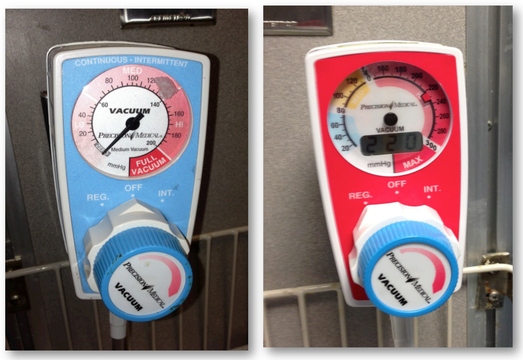
AARC Clinical Practice Guidelines

Endotracheal Suctioning of Mechanically Ventilated Patients With Artificial Airways 2010

- The goal of this study was to evaluate if the practice was affected a month after the results of the previous study were communicated to the RT department.

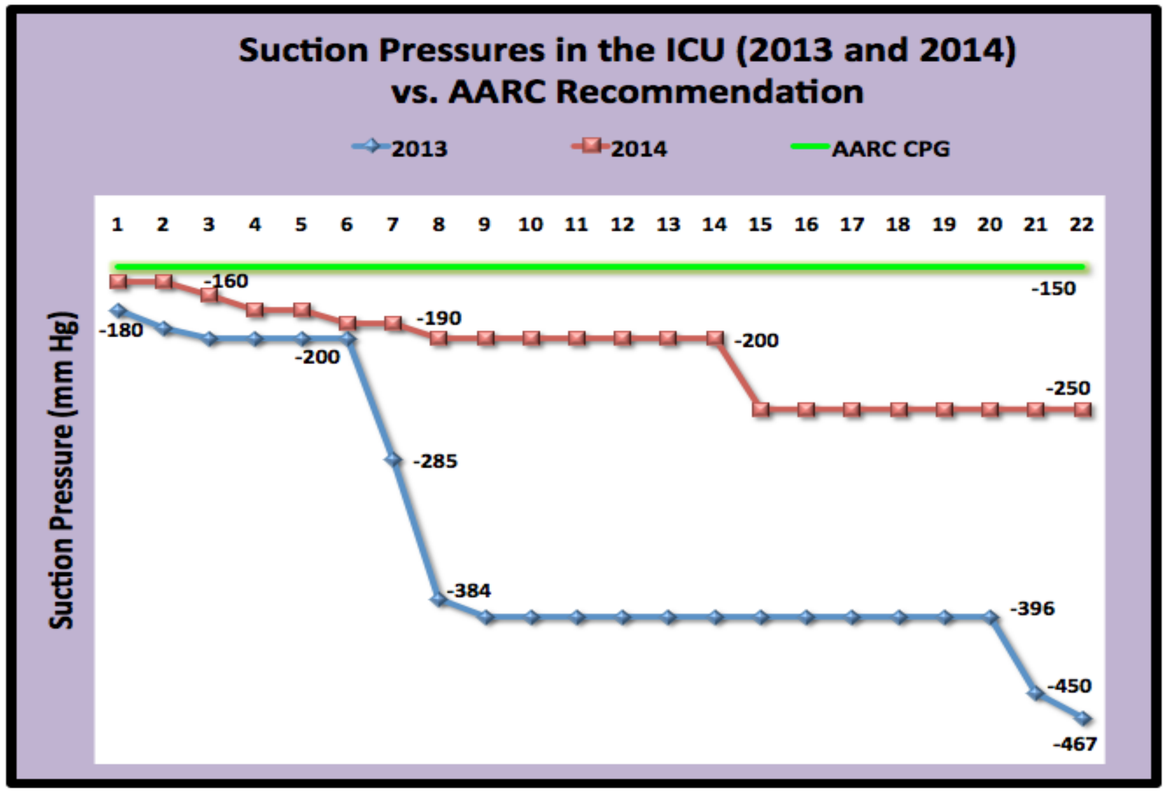
Materials and Methods

- Prospective observational study at a university-affiliated hospital, in San Antonio, TX. We collected data from 18 patients admitted to the MICU and SICU who had either an endotracheal tube (ETT) or tracheostomy tube (TT) during the last week of May of 2014.
- The results showing lack of adherence to the AARC CPG were sent via email by the director of the RT department to all RTs working in the ICU to show what we discovered in the previous observational study.
- We recorded the amount of negative pressure displayed in the manometer after occluding the end of the suction tubing used for airway suction. These values were compared to the suction pressures receommended by the AARC and those found the previous year.



Results

- The mean negative pressure recorded was greater than recommended (-210.5 mmHg ± 32.9).
- No significant differences were observed on the suction pressure between patients with oral endotracheal tubes and tracheostomy tubes (-198.6; P = 0.33).
- There was a significant difference between mean suction pressures recorded in 2013 (-341.4) and 2014 (-210.5) (P=0.0003)



Conclusions

- The amount of negative pressure routinely used for these patients in ICU significantly exceeded the recommended suction pressures.
- This practice has not significantly changed after presenting evidence of inadequate settings just few weeks ago.
- An educational module explaining the guidelines and reviewing all potential adverse effects of suction could potentially improve the practice of setting, monitor, and record the suction pressure used for artificial airways.

Study sponsored by an educational grant from Teleflex Medical

Reference # 7

Ref # 7

Challenges: Suction/Aspiration Apparatus

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

	Traditional Approaches			Automated Approach
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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

Gentile J. et al. Advances in Subglottic Secretion Drainage, Respiratory Therapy, 2016; 11(2): 37-45

Reference # 8

Ref# 8

Automated Subglottic Aspiration System in Reduction of VAP and Secondary Lung Infection in Ventilated Covid Patients

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Health IQ, LLC
Brooklyn, New York, USA

Presented virtually at Critical Care Conference, UK - Oct 28, 2021

Presentation Objectives

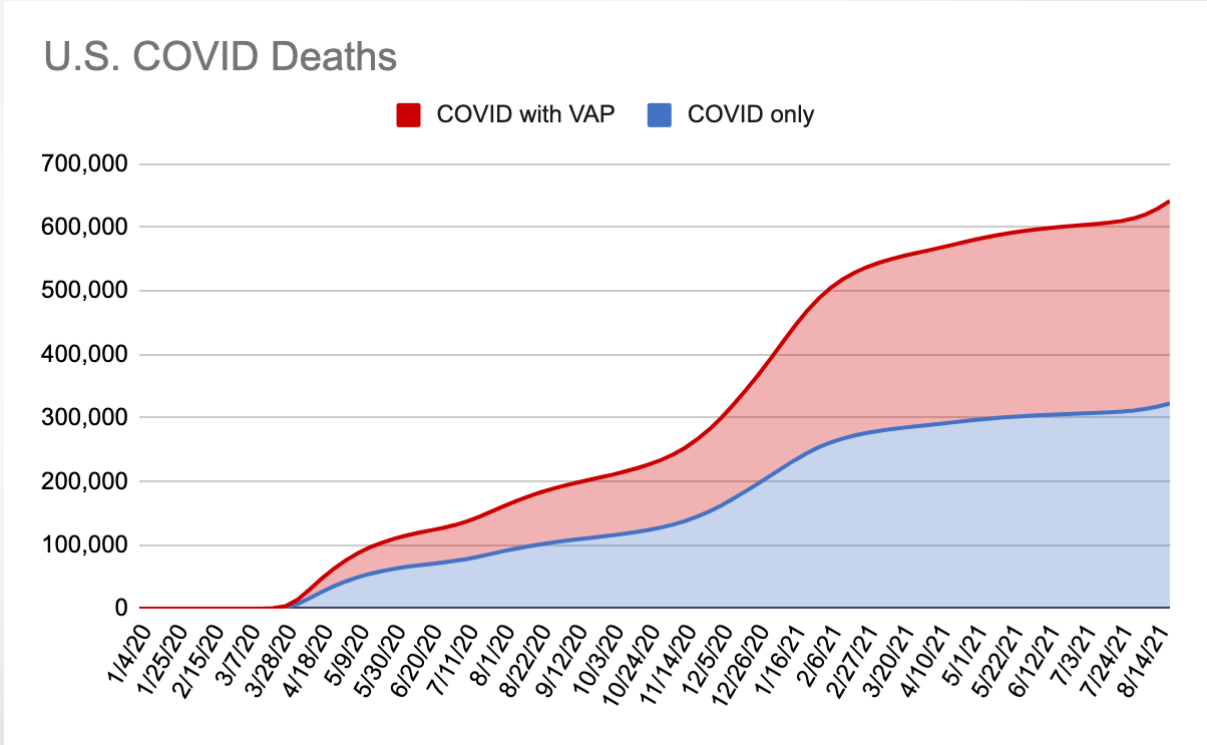
- Review the impact of secondary bacterial infections in ventilated COVID patients
- Challenges faced in caring for ventilated patients
- Current evidence-based clinical intervention to prevent VAP
- Harnessing new technology for better management of secretions and significantly reducing risk factors and cost

Mechanical Ventilation

- Major harm and side effect of mechanical ventilation is microaspiration of colonized secretions into the sterile lower airways, resulting in secondary bacterial infection or Ventilator Acquired Pneumonia (VAP)
- Per Dr. Fauci, the majority of patients who died during the 1918-19 Spanish Pandemic, died from aspiration of colonized secretions from the upper airway tract down into the lower airway tract causing secondary bacterial infection
- Affects both mechanically ventilated Covid-19 and non-Covid-19 patients

Rate of VAP During COVID

- Per new CDC data, 49% of ventilated COVID patients died due to COVID pneumonia and 51% due to secondary bacterial infection (causing VAP).
- Yet, most hospitals in the US report Zero VAP, since all VAP is now tracked under VAE Ventilator Associated Events
- If VAP rate is Zero how can hospitals be incentivized to take preventative measures to reduce the rate of VAP?



Source: CDC https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm

Changes in the 2020 Healthcare-Associated Infections (HAI) Compared to 2019 Quarters in the US

- This 2021 report highlights the need for hospitals to continue to reinforce IPC practices in their facilities and regularly review HAI surveillance data to identify areas that need to be improved, plus address any gaps in prevention practices
- Providing new and advanced tools to clinicians is critical to the fight against COVID-19, HAIs, and AMR

	2020 Q1	2020 Q2	2020 Q3	2020 Q4
CLABSI	↓ -11.8%	↑ 27.9%	↑ 46.4%	↑ 47.0%
CAUTI	↓ -21.3%	No Change[1]	↑ 12.7%	↑ 18.8%
VAE	↑ 11.3%	↑ 33.7%	↑ 29.0%	↑ 44.8%
SSI: Colon surgery	↓ -9.1%	No Change[1]	↓ -6.9%	↓ -8.3%
SSI: Abdominal hysterectomy	↓ -16.0%	No Change[1]	No Change[1]	↓ -13.1%
Laboratory-identified MRSA bacteremia	↓ -7.2%	↑ 12.2%	↑ 22.5%	↑ 33.8%
Laboratory-identified CDI	↓ -17.5%	↓ -10.3%	↓ -8.8%	↓ -5.5%

Weiner-Lastinger LM, Pattabiraman V, Konnor RY, etal. The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020:
A summary of data reported to the National Healthcare Safety Network. *Infection Control & Hospital Epidemiology. 2021:1-14. Doi:10.1017/ice.2021.362*

Significance of Ventilator-Associated Pneumonia in COVID Patients

New data shows **45.2% death rate due to VAP pneumonia** in COVID infected patients and highlights the microaspiration of colonized secretions from upper airway to lower airway as the culprit for VAP

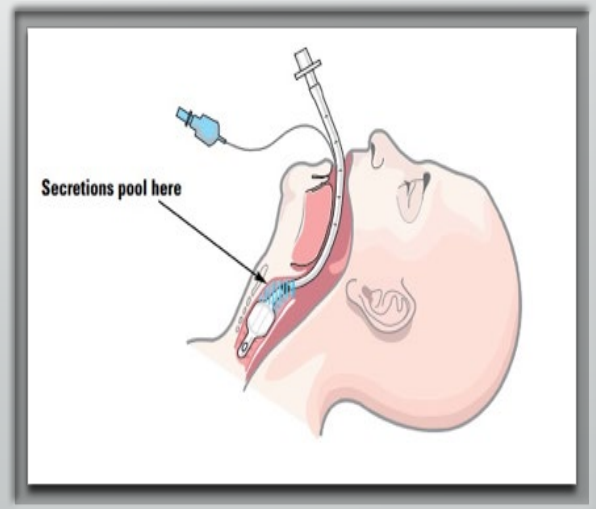
Below are important take away from this paper:

- "Acknowledging this secondary infection control problem will also lead to better VAP prevention strategies, improved patient outcomes, and augmented pandemic countermeasures"
- "VAP prevention protocols such as careful cuff pressure control, elevated head-of-the-bed position, oral hygiene with chlorhexidine, and hand hygiene are well studied, effective, and for the most part non-modifiable. Improvements in mechanical ventilation, antibiotic therapy, subglottic secretion drainage"
- "Of note, significant improvements to the current protocols will likely be in the form of changes in airway devices design, as VAP is caused by the microaspiration of pathogenic fluid from the upper airways into the lower airways along the body of the airway device"
- "Strategies to mitigate microaspiration are an area of significant research and innovation"

The Significance of VAP in SARS-CoV-2 Patients: A Systematic Review May 2021: https://trcjm.com/article/the-significance-of-ventilator-associated-pneumonia-in-sars-cov-2-patients-a-systematic-review/

Regular ET or TT tubes used in Ventilated Patients

- Colonized secretions are pooled in the upper airway tract above the ballooned cuff
- Secretions microaspirate and seep into lower airway and the lungs
- Resulting in secondary bacterial infection or VAP pneumonia which requires antibiotics
- During COVID, 75% of antibiotics are drug resistant due to AMR
- Longer stay on MV and ICU
- High mortality
- Create a huge challenge for Respiratory Therapists
- Financial cost associated with VAP- $19,000 to $80,000



Patient on a regular ET tube

Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital-Acquired Conditions. Content last reviewed November 2017. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/hai/pfp/haccost2017-results.html

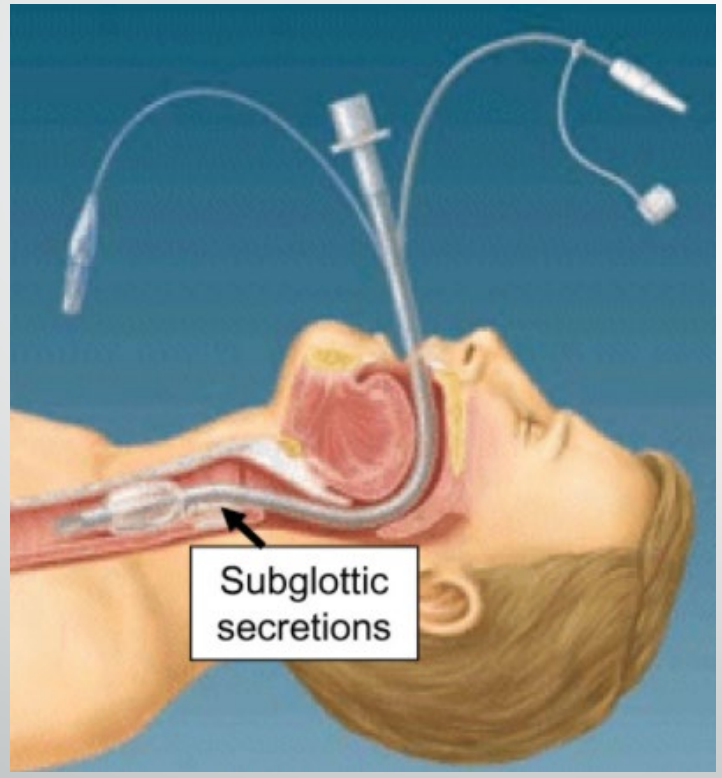
What should be the IDEAL solution and objectives of any hospital treating ventilated patients?

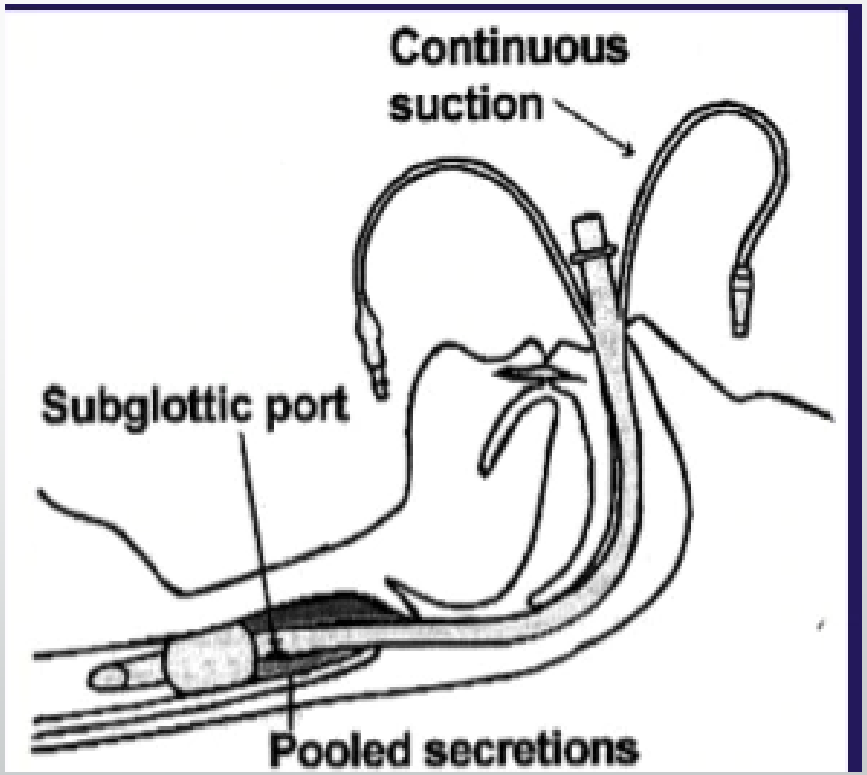
- Effective management of secretions to minimize/prevent microaspiration
- Follow strict VAP Bundle Guidelines recommended by major organizations
- Faster weaning, get patients off of the ventilator as quickly as possible
- "Sedation Vacations" - the more awake the patient the quicker the recovery
- Less usage of antibiotics and its impact on AMR
- Less tracheal suctioning, preventing potential trauma to lower airway tissue
- Less time in ICU, which frees up the bed for next patient
- Adhering to the above steps will help reduce overall cost for the facilities

VAP is preventable

- VAP is preventable if hospitals and healthcare institutions implement effective secretion management methods
- Pooled secretions are the root cause of how colonized secretions microaspirate from upper airway down into lower airway
- Eliminate or remove the colonized secretions at the source – the patient's upper airway tract
- Removing secretions before they penetrate the lower airways will help prevent VAP

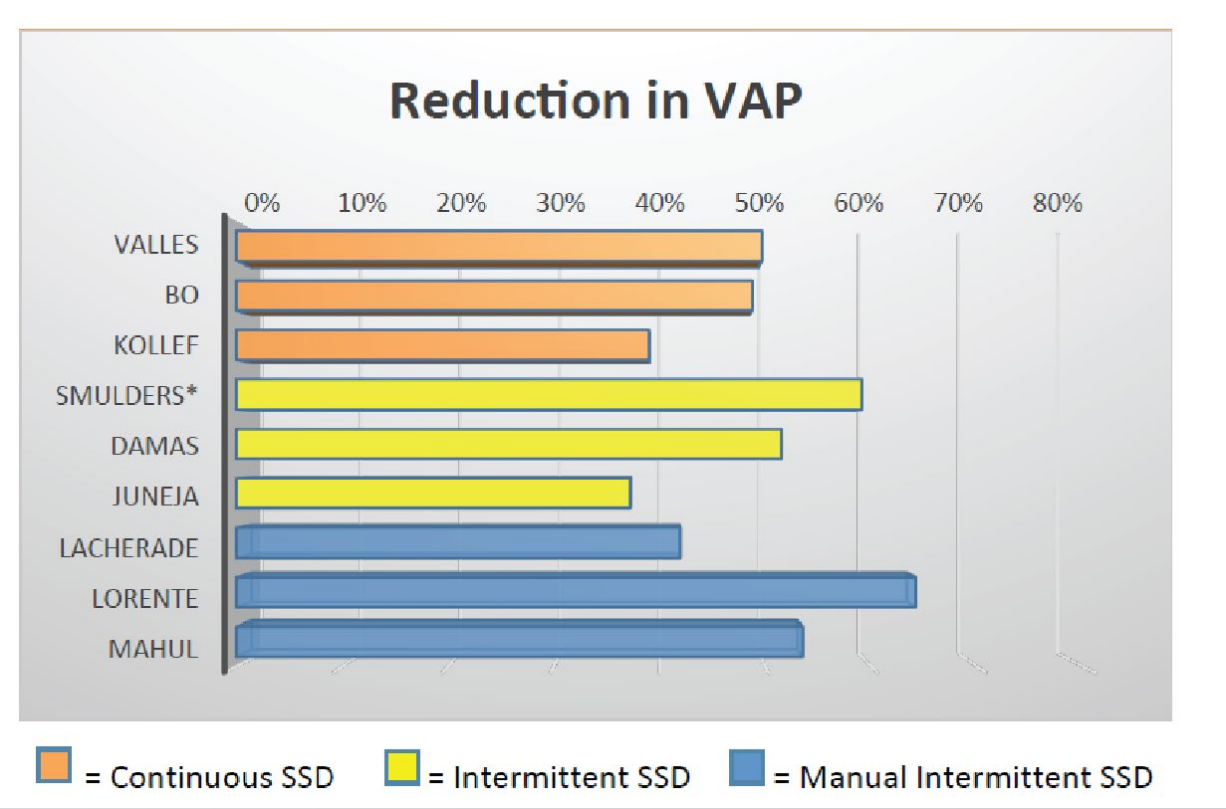
Subglottic ET or TT tubes used in Ventilated Patients





Effectiveness of Subglottic Aspiration in the Reduction of VAP Rate

Among 9 published RCTs since 1992, Average Reduction in VAP rate using manual intermittent (Syringe) is higher than both Continuous and Intermittent Wall suction.

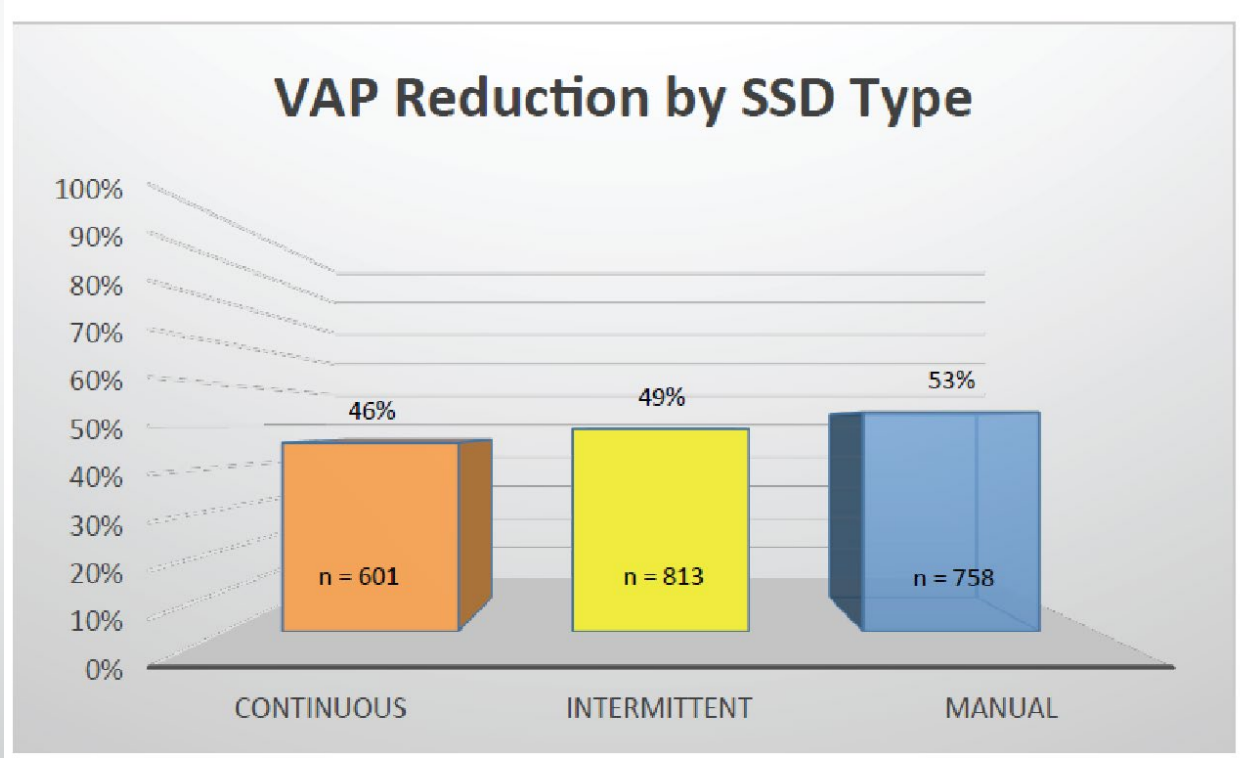


Gentile J. et al. Advances in Subglottic Secretion Drainage, Respiratory Therapy, 2016; 11(2): 37-45

Continuous vs. Intermittent Aspiration

Average Reduction in VAP rate using Intermittent (Syringe or wall suction) is higher than Continuous Wall suction

Syringe is not practical or safe to use. Syringe generates up to 720 mmHg pressure which is 4-5 times higher than the AARC recommended pressure



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VAP Bundle

Ventilator Care Bundle consists of the following interventions:

- Head-of-bed elevation to 30-45 degrees (semi-Fowlers position)
- Daily "sedation vacation" and assessment of readiness for extubation
- Use of Subglottic Secretion Drainage ETT and TT tubes
- Effective oral hygiene care using Chlorhexidine 0.12%
- Use of proton pump inhibitors (reduction of GERD)
- DVT prophylaxis

Clinical Experience

- 40 bed long-term ventilator unit with patients connected to SIMEX and subglottic tracheostomy tubes
- Instituted 6-step VAP Protocol
- Resulted in no recorded VAP for 4 months
- Reduced antibiotic usage and cost
- Increased revenue from reduction in transfers to hospital
- Increased weaning rates and reduction of time on mechanical ventilation
- Improved patient's quality of life

Automated Subglottic Aspiration System

SIMEX cuff M automated subglottic aspiration device connected to the suction port of a subglottic tracheostomy tube

The suction port of subglottic endotracheal tube can also be connected to the SIMEX cuff M

Benefits of using SSD-ETT or SSD-TT tubes with Automated Subglottic Aspiration System

By removing the colonized secretions from the upper airway shall result in:

- Patients weaned off 2-3 days sooner
- Less time in ICU, freeing up beds
- Less use of antibiotics and issues relating to AMR
- Shorter time required for rehab
- Fewer resources used
- Improved quality of life for patients
- Less time spent by clinicians caring for the patients
- Preventing VAP saves the hospital in excess of $40k per incident
- Cost effective

Thank you