Highlights of Recent Experience in Long-term Care Settings with an Automated Intermittent Subglottic Aspiration System

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Abstract

Subglottic aspiration is a standard requirement in protocols and guidelines to prevent serious respiratory infections in patients requiring mechanical ventilation, and for other dysphagic patients intubated with tracheal/endotracheal tubes with a ballooned cuff. Research in subglottic secretion drainage (SSD) using a variety of traditional suction methodologies comes from studies done in ICU settings. Many advances in SSD are directly applicable to long-term care. This paper summarizes various SSD approaches and presents recent clinical experience with an automated intermittent subglottic aspiration system in long-term care facilities in Germany and the United States.

Introduction

When mechanical ventilation is required and patients are intubated with a cuffed endotracheal or tracheal tube, secretions are known to accumulate above the ballooned cuff. Aspiration of these secretions is a top priority for a host of reasons, with the goal of preventing short- and long-term Ventilator-Associated Pneumonia (VAP) frequently being the primary concern. The more advanced and newer cuffed endotracheal and tracheal tubes include a separate integrated port (suction lumen), designed to facilitate suction of subglottic secretions.

In most long-term care settings, patients typically have been suctioned by staff members using 10 or 20 ml syringes recommended at hourly intervals, or via continuous or intermittent suction using general purpose suction devices. In long-term acute care hospitals, regulated wall suction also has been applied continuously and/or intermittently. These conventionally used suction methods have presented practical and multi-faceted challenges related to: applying appropriate suction pressures consistent with guidelines, maximizing secretion aspiration volume, reducing tissue damage, preventing cross-contamination and nosocomial infections, contributing to patient comfort and rehabilitation, relieving staff burden, and reducing treatment costs.

In this paper we present retrospective information and highlights of five years' of clinical experience in Germany (as well as initial US experience) in long-term care with an automated system designed specifically for intermittent subglottic aspiration.

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Goals and Evolution of Subglottic Secretion Drainage (SSD)

Most clinical experience and evidence to date related to mechanical ventilation and the use of different SSD methodologies come from studies conducted in intensive care settings. In the ICU, VAP is estimated to occur in 9% to 25% of patients,[1-3] with mortality attributed to VAP ranging as high as 27%.[4] Each day of mechanical ventilation increases patient risk for VAP by 1% to 3%,[5] and occurrences are associated with increased ICU and hospital stays. Increased hospital costs of over $40,000 per patient have been estimated.[3]

Parallel incentives to improve subglottic secretion drainage (SSD) methodologies and outcomes exist in long-term care. Patients with neurological, traumatic or medical disorders such as ALS, hypoxic brain damage, traumatic head injuries, strokes, and bleeds, often correlate with severe dysphagia, among a number of obstacles to weaning from ventilation and successful rehabilitation. As in the ICU, SSD is required to remove accumulated secretions from the pool above the ballooned cuff of the tracheal tube. The secretions, a combination of salivary aspirate, oropharynx secretions, and gastric reflux aspirate, contain pathogens. Because of the anatomy of the trachea, some leakage around the ballooned cuff is inevitable, allowing for potential drainage into the lungs. Suboptimal SSD therefore increases the risk of VAP. Coma patients are at substantial risk for pneumonia.

VAP Reductions Across Methodologies in SSD Randomized Controlled Trials

Efforts to prevent, delay, and shorten VAP using SSD have evolved and been effective when applied according to the latest guidelines. In nine randomized controlled trials in a total of 2,172 patients, a majority expected to be ventilated for greater than or equal to 48 hours, the incidence of VAP was reduced significantly, with VAP reductions among SSD groups ranging from 37.2% to 64.25% compared to respective control groups.[6-14] Reductions were significant for all SSD methodologies applied in the research (manual syringe suction, continuous suction, and intermittent suction). Syringes, general purpose pumps and regulated wall suction were all used as suction sources among the various studies.

Practical Issues Effecting SSD in Practice

Although controlled studies demonstrate the value of SSD in significantly reducing VAP, many practical issues associated with widely used methodologies and suction sources deserve attention and study. For example, continuous suctioning is sometimes used but is known to cause drying of the tracheal mucosa and tissue damage. Too much suction and too frequent suctioning are also known to stimulate the production of additional saliva and other secretions.[12,13,20,21]

Guidelines established by the AARC suggest the use of -80 to -150 mmHg of suctioning pressure. Both 10 ml and 20 ml syringes have been shown to exert over -700 mmHg of pressure, many times higher than recommended.[17] Guidelines also recommend hourly suctioning of patients when manual syringes are used. In practice as well as research, and because of patient-to-staff ratios and workloads, it often has been difficult to adhere to hourly suctioning. If spontaneous aspiration occurs around the stoma as a result of a buildup of secretions, maceration of the skin occurs, foul odors proliferate, clothing can be repeatedly soiled, and the patient may be stigmatized. In addition, relatively small volumes of aspirate (median average of 14 ml/day) are typically removed via manual syringe suction.[12]

Wall suction and general purpose suction pumps, widely used for SSD, serve a number of other purposes in the ICU and in long-term acute care. Neither were designed specifically for SSD. Actual pressures may vary from the regulated settings. In addition, studies have shown nosocomial infections can be spread through contaminated wall suction, despite protocol measures for cleaning of regulators and other parts.[19]

Unblocking a continuously blocked tracheostomy tube carries a high risk of pneumonia if any pooled secretions aspirate into the airways. At the same time, unblocking is essential and unavoidable for patients for normalizing airflow, key pharyngeal awareness training, rediscovering/relearning vital protective functions and developing laryngeal reflexes.

Application of Automated Intermittent Suction Technology to SSD: Development and Clinical Experience in Long-term Care in Germany [Helmut Fendler, RN and Katja Fain, SLP]

We began our collaboration more than 7 years ago, combining knowledge from backgrounds in long-term nursing care, wound care and respiratory care. Our goal was to improve subglottic secretion drainage in patients intubated with tracheal or endotracheal tubes – tubes with an integrated suction lumen.

The Gesundheits Manager Institute for wound care, nursing care, hygiene management, and respiratory care, services the Intensive Care Clinic, IPK (intensive.pflege.klinik GmbH & Co. KG), an independent long-term care facility in Nuremberg, specializing in the care of traumatic brain injury patients, and other patients neurologically severely impaired. A staff of over 25 multi-disciplinary specialists cares for 60 patients at any given time in the IPK, 40 of whom on average are coma patients of two types.

Ninety percent of the patients are Awake Coma, patients who sleep at night and open their eyes in the morning. They cannot talk, but have day and night routines. The remaining patients are classified Coma, with eyes closed 24/7.

Our decision to explore and refine automated subglottic secretion drainage began as a logical response to dissatisfaction with traditional suction methods and the search for efficient alternative solutions. People produce 1-2 liters of saliva a day, equivalent to 333-666 ml every 8 hours.[16] Those who are able to swallow, do so 1000-3000 times a day. For our impaired population, with severe dysphagia and even absent spontaneous swallow response, we were seeking a practical way to capture the saliva and other secretions above the ballooned cuff of the tracheal tube, to prevent VAP, skin problems around the stoma, and patient discomfort.

Over the past 5 years, at the IPK and in surrounding clinics in the Nuremberg area, we have treated 60 patients using automated intermittent aspiration of subglottic secretions by means of a new device, the SIMEX Subglottic Aspiration System. There are two SIMEX pump models, the cuff M and the cuff S, which are identical with respect to their modes of operation, and only differ in size and weight and different collection canisters. The cuff M is designed for mobile use, for example by wheelchair- bound patients. The cuff S is for stationary use, at the patient bedside and in surgical settings. In the clinics, we have used both models.

Beginning with our earliest experiences with the system, we focused primarily on three parameters: suction pressure, the duration of suction, and the interval between individual suction periods. Our goal was to tailor the suction pressure to the needs of the individual patient depending on the amount of secretions and the viscosity, while keeping overall suction to a minimum and within the AARC recommended pressure guidelines. The SIMEX system allows for pressure settings ranging from -15 to -225 mmHg. Suction intervals can be set at from 5-60 seconds "ON," time and from 1-60 minutes "OFF" time. AARC recommends the use of -80 to -150mmHg.

We were encouraged by the initial responses observed. Secretions were readily collected in the canisters. We observed immediately that the amounts of secretions being collected were much higher (several-fold), than with the use of syringes. Maceration around the stoma of patients was reduced, and later frequently prevented, as experience with the system was gained. In contrast with the manual suctioning of patients using syringes, which frequently causes coughing, sometimes severe, and an increase in body tone, heart rate and respiration, the automated suctioning using the system was quiet and very well tolerated. Vital signs remained constant.

5-Patient Study and Caregiver Survey Results

In another step to quantify treatment results with the system as well as to gather data on the use of resources, and feedback from caregivers, Fain led the development and conduct of a study within the facility that included a survey of caregivers. From March 13-24, 2014, 5 patients requiring SSD were selected from the population in the clinic. Patients were observed for a total of 10 days. Each patient received manual suctioning by syringe for the first 5 days, followed by use of the SIMEX cuff S in the final 5 days. The system settings were determined according to each patient's condition, and ranged from -75 to -150mmHg. The "ON" time of aspiration was set at 10-15 seconds, and "OFF" time at 10-15 minutes. A total of 26 nurses took part in the survey. Results are shown in the table above.

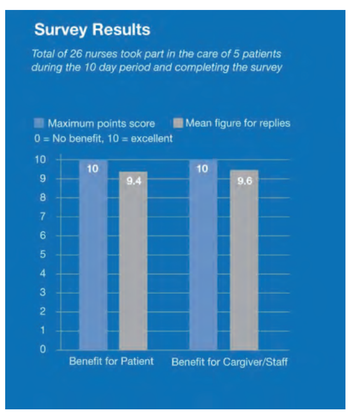
Results

(Based on mean average of 5 patients who were observed for total 10 days. Manual aspiration used during initial 5 days and automated aspiration used in final 5 days. The system parameters tailored to each patient's condition. Aspiration pressure ranging between -100 to -200 mbar, aspiration ON time of 10-15 sec, and OFF time of 10-15 min.)

	Manual ballooned cuff aspiration using a 20 ml syringe	Automated Intermittent Subglottic Aspiration System – SIMEX *cuff* S
	Tracheostomy tubes used: Portex, BlueLineUltra, Suctionaid Gr. 8 or 9	
Mean aspirate volume removed	approx. 33 ml	approx. 400 ml
Duration	5 days => 8 times daily during 8 hour shift	5 days automatic intermittent aspiration
Materials used	40 syringes (20ml), 40 pairs of gloves, 50 dressings	1 *cuff* S aspirator, 1 aspirator collection container, 1 suction tube
Results	- aspiration only possible on an interval-type basis - increased risk of sputum to microaspirate into the lungs - time-consuming - severe cough stimulus during aspiration - stoma remains macerated and extremely damp as a result of the enormous amounts of sputum that come out due to overflow - additional stoma care, need for dressings and changes of clothing and bedding - erythematous skin around the stoma - high frequency of endotracheal/ bronchial aspiration	- automated intermittent aspiration – 24/7 - minimized risk of any sputum to microaspirate into the lungs - unobtrusive sounds during aspiration - aspiration does not have a negative impact upon breathing, the cough stimulus or physical tone - stoma is dry and less irritated from the first day onwards - immediate positive feedback from nursing staff => see survey - reduction in the frequency of endotracheal bronchial aspiration

Our clinic nurses were asked the following questions:

1. In your opinion, is the automated intermittent aspiration system beneficial to the patient? If so, what are the benefits?
2. Does automated intermittent aspiration make your job easier? How much and in what ways does it make the job easier?
3. Does automated intermittent aspiration bring you any benefits in your job? If so, what are the benefits? See survey results in graph below.

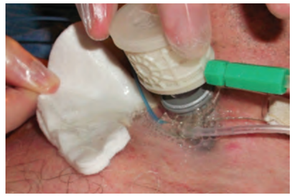


Longest Individual Patient Use

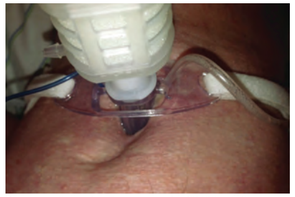
The SIMEX cuff S model was used in one of our first experiences with automated SSD, in an Awake Coma patient, beginning in January of 2010. Prior to that time, the patient was suctioned via syringe, with consistently small amounts of secretions removed. The patient's stoma at that time was moist, irritated and reddened. In November of 2012, after nearly 3 years, we compared aspiration volume removed with the system, to what had previously been removed with syringe. We also compared differences in materials used and nursing time. Remarkably, the patient remains on the system, after the 3 additional years since 2012, and continues to comfortably tolerate the suction and benefit from the improved environment provided by the system. The calculations from 2012 are shown in the table below.

Comparative Results
(Automated intermittent subglottic aspiration system versus conventional manual syringe sytem for long-term care coma patient)

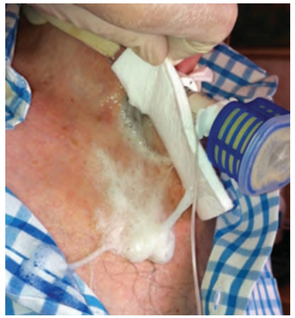
Date: Jan 2010 to Nov 2012 (1,064 days)	SIMEX cuff S Actual Values Recorded	Manual Syringe Extrapolated Values
Total Aspiration Volume	118,334 ml	38,304 ml (est. 1.5 ml/hour)
Disposable Materials Used	132 collection bags 132 suction tubes	25,536 syringes 25,536 pairs of gloves
Nursing Time Spent for Aspiration	Minimal to none	127,680 minutes (2.91 months)(24 x daily 6 min)
Tissue/Skin Condition	Stoma dry	Stoma moist, irritated, macerated and reddened
Patient Reaction to Aspiration	No discomfort	Cough irritation, body tension
Not Considered		Nursing time requirements for • change of wet dressing • change of wet garment/ linen • paratracheal aspiration



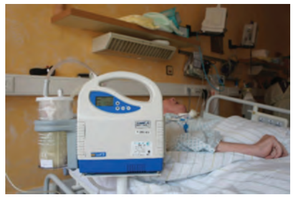
Leakage of Secretions from Manual Aspiration



Dry stoma Following Treatment with SIMEX cuff S



Leakage of Secretions from Manual Aspiration



SIMEX cuff S Automated Intermittent Subglottic Aspiration System

Initial Long-term Care Experience in the United States Eastchester Rehabilitation and Healthcare Center, Bronx, NY [Jerry Gentile, BSRT, BSHA, MBA, EdD(c), RT, RRT]
The facility specializes in Respiratory Care, consisting of a 40-bed ventilator and a 15-bed tracheostomy step down unit. Our staff consists of 20+ Registered Respiratory Therapists (RRTs), as well as a Speech Pathologist and Registered Nurses that work closely with the Respiratory Care Department.

Sixty percent of the patients on the ventilator unit have Glasgow Coma Scores (GCS) of 12 or below. The remaining forty percent are patients with GCS of 12 or above that have daily interaction with staff, as well as rigorous physical, occupational, and speech therapy routines. These departments work closely with the respiratory therapists in the development of the therapies and care plans.

Ventilator Associated Events (VAE)
In 2013, the CDC developed the Ventilator Associated Events (VAE) surveillance definition algorithm to streamline and identify a broad range of conditions and complications that arise in mechanically ventilated adult patients. There are 3 definition levels with the VAE algorithm: (1) infection-related ventilator-associated complication (IVAC); (2) ventilator-associated condition (VAC); and (3) possible VAP.

The initial VAE rate on the ventilator unit peaked at 18%, with a resulting hospital transfer rate of 14%. In response to this high rate of nosocomial pneumonia, the Respiratory Care Department developed a new VAE protocol. In collaboration with the Department of Nursing, we instituted the new protocol for all 40 patients. This protocol consists of: (1) head of bed 30 to 45°; (2) chlorhexidine 0.12% daily; (3) DVT prophylaxis; (4) proton pump inhibitor; and (5) daily weaning from mechanical ventilation.

The initiation of the VAE protocol had a moderate impact. The unit VAE rate dropped from 18% to 12%, with a hospital transfer rate of 7%. This was a significant improvement, but we felt this rate could be much lower.

Subglottic Suction Tracheostomy
In September, 2014, we decided to switch all tracheostomy tubes to subglottic suction models. We did this in anticipation of the VAE rate decreasing due to the promise of secretion removal from above the cuff. This wound up being labor-intensive for the Respiratory Therapists, as each subglottic port had to be suctioned manually via a 20 ml syringe. This method was not practical and presented many challenges, such as applying consistent suction pressure (according to AARC guidelines), ensuring maximal aspiration of secretion volume, patient comfort level, minimizing tissue damage, and risk of nosocomial pneumonia. Respiratory Therapists reported that the subglottic ports would frequently clog, resulting in saline lavages that further increase the risk of VAE. The addition of the subglottic suction tracheostomy tube resulted in no change of the 12% VAE rate over the course of five months.

SIMEX cuff M
In March, 2015, we instituted a trial of five SIMEX cuff M devices in our ventilator unit. We started the trial at -100 mmHg suction pressure/10-second suction duration/10-minute suction intervals. We adjusted the settings based on aspirate volume, patient comfort level, and evidence of tracheal tissue trauma. In the course of the eight-month trial, we have had the SIMEX cuff M devices on 10 patients. We have determined that optimal suction settings are -150 mmHg suction pressure/12 second suction duration/10-minute suction intervals. Secretion collection averaged 60 to 150 ml/day. Maceration of tissue surrounding the stoma has decreased significantly, as well as soiling of tracheostomy ties and surrounding clothing. Patients have tolerated these subglottic suction settings very well, with no reports of tracheal discomfort.

At the end of the eight month, 10 patient trial, two of the patients in the study developed VAC - non VAP related complications. This was probable resorption atelectasis due to mucus plugging of the airway. In both of these cases, the HME (heat and moisture exchanger) was discontinued and heated humidification initiated, along with deep tracheal suctioning. The patients recovered without incident.

The trial was in conjunction with the new VAE protocol instituted for all mechanically ventilated patients. There was a dramatic improvement in our VAE rates and significant enough to warrant further study. We have recently begun a 25 patient/15 control RCT to further study the potential of the SIMEX cuff M in decreasing VAE risk.

Current RCT Trial
We would like to report that three weeks into the RCT, the patients are tolerating the SIMEX cuff M well. Of the 25 patients on the device, we have not had a reported VAE to date.

Based on our initial clinical experience, we have already begun to discuss ways in which research and design efforts focused on current models of subglottic suction tracheostomy tubes (the patient interface) might further enhance the effectiveness and use of automated subglottic secretion drainage. Port size and location are of particular interest, as is the angle of the patient, because each variable effects the surface area for actual suction. We have many patients that sit up in wheelchairs and/or Geri chairs at greater than 60° angles. From our initial observations, the subglottic suction seems to be less effective at patient angles of greater than 50°. When the patient returns to a 40° or less angle, the subglottic suction is most effective. We will be investigating these variables further in our RCT.

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