

Volume 15 Number 3 Fall 2020

Respiratory Therapy™

The Journal of Pulmonary Technique





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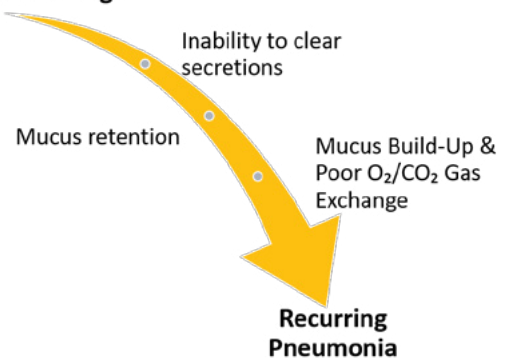
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News

■ Fall 2020

Getinge Ramps Up Production

Getinge, the world market leader in advanced ventilators for intensive care units, announced another ramp-up in production capacity, to 26,000 ventilators in 2020. The increase equals a growth of 160% compared to 2019, when 10,000 ventilators were produced. The demand for advanced ventilators for the intensive care units in hospitals continue to increase globally as a result of the COVID-19 pandemic outbreak. Getinge is ramping up the production capacity stepwise at its production facility in Solna, Sweden, and is now increasing production capacity to 26,000 in 2020, compared to the previous planned 16,000 unit level that was communicated on March 17. The ramp up will start immediately and progress in close collaboration with Getinge's suppliers. "We continue to ramp up to be able to respond to the increasing demand from our customers", says Elin Frostehav, Vice President Critical Care at Getinge. "We work closely with our sub-contractors and the ramp up is of course pending availability of supply parts". In 2019, Getinge produced 10,000 ventilators at the production facility in Solna. Since the start of 2020, Getinge has increased its production capacity with 160%, compared to 2019. The estimated increase in demand and production capacity of ventilators is expected to be accretive to Getinge's result. Learn more about Getinge's products at www.getinge.com.

Zenith Award Handed Out

In a year which will be heralded as one of the toughest that healthcare has had to endure, with the COVID-19 pandemic pulling on all hospital and clinician resources, the role of companies supporting these healthcare workers and their patients has become critical. Aerogen, the global leader in aerosol drug delivery, has been selected by over 47,000 respiratory clinicians to receive the prestigious 2020 Zenith Award from the American Association of Respiratory Care. This year marks the seventh time that Aerogen has been selected as a recipient of the Zenith Award. The award, which is in its 32nd year, represents a means for respiratory care professionals to recognize excellence from companies and service suppliers to the hospital. The award spans a wide range of criteria including equipment and supplies, the accessibility and helpfulness of their sales personnel, responsiveness, service record, truth in advertising, and their support of the respiratory care profession. "Aerogen exemplifies the qualities represented in the criteria and, because of this; we salute [Aerogen] and [its] employees", said Thomas J. Kallstrom, MBA, RRT, FAARC, Executive Director/CEO. Adding to this sentiment John Power, CEO of Aerogen said, "We are honored to be recognized by the respiratory therapy community in this way. As a seventh time

recipient, we are proud to retain the confidence and trust of respiratory care professionals especially during this difficult year. Our purpose has always been to make a meaningful difference to those most critically in need of care and we do everything we can to ensure this is achieved daily." Aerogen will receive this award at AARC's 66th International Respiratory Congress this November during a virtual ceremony. More information at www.aerogen.com.

Free Spirometry Training Offered

NDD Medical Technologies is the leading provider of pulmonary function equipment, dedicated to the early detection and accurate diagnosis of COPD and other chronic lung diseases. In line with its continued commitment to supporting respiratory professionals—particularly in the wake of the COVID-19 pandemic—NDD is now offering free, live spirometry training sessions to provide professionals with renewed confidence in lung function testing for the most accurate results. The EasyOne product line was developed for health care providers to offer accurate and reliable diagnosis at the point of care and start immediate treatment. This helps avoid irreversible lung damage for millions of patients while significantly reducing healthcare costs. NDD is now offering live training webinars that will detail how to perform spirometry with the highly reliable and accurate EasyOne Air and Easy-on PC spirometers. The webinars took place in September. Webinars were recorded and are available to view after the live events. Spirometry testing is dependent on patient effort, and proper coaching and a good understanding of technique are therefore vital. Staff turnover and delays caused by the COVID-19 pandemic are some of the many reasons NDD has decided to offer free refresher training courses focusing on

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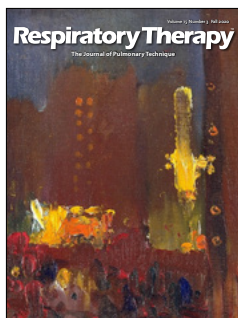


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best practices in obtaining good quality spirometry results. NDD's lung function testing products are used globally by leading pulmonologists and medical researchers due to the product line's portability and accuracy. NDD has always invested in pulmonary function education for its customers, and this new program of live spirometry training webinars will expand to include the diffusing capacity for carbon monoxide (DLCO) and multiple breath nitrogen washout (MBW) tests. This is another example of NDD's commitment to ensuring that all users get the most accurate results when performing pulmonary function testing. Jessica Dietrich, RRT, US Training Manager at NDD commented, "NDD has a long-standing commitment to providing the best devices, continued support, and education to the healthcare community. In a COVID-19 world, where facilities are now beginning to start testing again, we are offering important refresher training to help offices achieve the best quality results as they get back on their feet." NDD's revolutionary EasyOne portfolio includes the EasyOne Air, Easy on-PC, EasyOne Pro, and EasyOne Pro LAB. EasyOne products are among the most accurate devices available and deliver reliable, real-time lung function results at the point of care—enabling early diagnosis of chronic lung diseases such as COPD. For more information about NDD's lung function testing products, visit www.nddmed.com.

Bronchitis in Childhood Tied to Worse Lung Health in Adulthood

Children who suffer a bout of bronchitis at least once before their seventh birthday are at increased risk for developing lung problems such as asthma and pneumonia later in life, a study suggests. "Our findings strengthen the evidence that adult lung disease can originate in early childhood and that childhood bronchitis may adversely affect lung health in middle age," Dr Jennifer Perret of the University of Melbourne, Australia, said in a statement from the European Respiratory Society Virtual International Congress, where she presented her research September 9. Perret and her team analyzed the association between childhood bronchitis and lung problems in middle-aged adults participating in the Tasmanian Longitudinal Health Study, which has been following more than 8,500 people born in Tasmania in 1961. When they joined the study as children, their lung function was assessed and their parents provided information on whether

the children had suffered asthma or bronchitis by age seven. The participants have been followed for an average of 46 years. The researchers categorized 3,085 study participants into four groups based on parent-reported childhood bronchitis at age seven years: no bronchitis (n=1,616, 53%), non-recurrent bronchitis, with one to five episodes lasting less than a month (n=873, 28%), recurrent bronchitis, with at least six episodes lasting less than a month (n=555, 18%), protracted recurrent bronchitis, with six or more episodes lasting a month or more (n=41, 1.3%). Compared with the "no bronchitis before age seven" reference group, people who had non-recurrent, recurrent or protracted recurrent episodes of bronchitis as children had a 1.4-fold, 2-fold and 3.2-fold increased risk of pneumonia, respectively, by the time they reached the average age of 53. They also had a 1.3-fold, 2.7-fold and 6.4-fold increased risk of ever having asthma, respectively.

Disproportionate Rate of Coronavirus Deaths Found in Polluted Areas

The industrial plants in the riverside Louisiana city of Port Allen have worried Diana LeBlanc since her children were young. In 1978, an explosion at the nearby Placid oil refinery forced her family to evacuate. "We had to leave in the middle of the night with two babies," said LeBlanc, now 70. "I always had to be on the alert." LeBlanc worried an industrial accident would endanger her family. But she now thinks the threat was more insidious. LeBlanc, who has asthma, believes the symptoms she experienced while sick with the coronavirus were made worse by decades of breathing in toxic air pollution. "That is the one time in my life I thought, I'm not going to survive this," she said. "I'm going to become a statistic. I was that sick." New research shows she could well be right. COVID-19 can be made more serious—and, in some cases, more deadly—by a specific type of industrial emission called hazardous air pollutants, or HAPs, according to new peer-reviewed research by ProPublica and researchers at the State University of New York College of Environmental Science and Forestry. The study found this association in both rural counties in Louisiana and highly populated communities in New York. The analysis examined air pollution and coronavirus deaths in the roughly 3,100 U.S. counties and found a close correlation between levels of hazardous pollutants and the per-capita death rate from COVID-19. The US Environmental Protection

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Agency defines HAPs as chemicals known or suspected to cause cancer and other serious health problems. Under the Clean Air Act, industrial facilities emitting these pollutants are subject to regulations. Hazardous air pollution may help explain the disproportionate number of COVID-19 deaths in communities like West Baton Rouge Parish, home to Port Allen. With 39 deaths as of Sept. 7, the parish's per-capita death rate from COVID-19 ranked it among the top 3% of all U.S. counties with at least 30 deaths. Several of its neighbors in Louisiana's industrial corridor also rank near the top of the list. Because the virus affects the respiratory system, researchers have rushed to study the potential association between mortality rates and air pollution. Early studies, including one looking at particulate matter—distinct from HAPs, but often found with them—have suggested a link.

Oral Masitinib Phase 3 Results Promising for Severe Asthma

The rate of severe asthma exacerbation was significantly reduced after 36 weeks of treatment with oral masitinib in a phase 3 randomized, placebo-controlled trial. At a dose of 6 mg/kg daily, masitinib, a tyrosine kinase inhibitor, was effective in patients with severe, persistent asthma not controlled with high-dose inhaled corticosteroids, long-acting beta agonists (LABAs), or oral corticosteroids, regardless of baseline eosinophil levels. The 240 patients in the masitinib group experienced a significant 35% reduction in the rate of severe exacerbations, compared with the 115 patients in the placebo group (rate ratio [RR], 0.64; 95% CI, 0.47 - 0.90; P = .0103). Patients with the highest dependency on oral corticosteroids—a cumulative dose of more than 1500 mg—benefited most, with a 72% reduction in exacerbations. In the subgroup of patients with a baseline eosinophil count of at least 150 cells/ μ L, the 181 patients in the masitinib group showed a significant 38% reduction in severe exacerbations, compared with the 87 patients in the placebo group (RR, 0.62; 95% CI, 0.42 - 0.91; P = .0156). “Overall, the safety was equivalent between the two arms—placebo and masitinib—and there was no difference in serious adverse events,” said Pascal Chanez, MD, PhD, from the University of Aix-Marseille in France, who presented the study results at the virtual European Respiratory Society International Congress 2020 (ERS2020). No new safety concerns were evident during the 36-week trial, Chanez reported, adding that the team might conduct a blinded extension study out to week 96. Masitinib is different from current treatments in that those generally are targeted toward patients with higher levels of blood eosinophils, said Michael Blaiss, MD, executive medical director of the American College of Allergy, Asthma and Immunology. Blaiss was not involved in the study. The new drug has the advantage of being effective for people with high and low eosinophil counts, and is taken orally, not injected, he explained. The field welcomes an effective treatment for this population, which has high rates of emergency department use and hospitalizations, he noted. And because flare-ups can't be controlled with inhaled corticosteroids or LABAs, quality of life is diminished for these patients. Only 3% to 10% of adults living with asthma have severe disease. However, an estimated 60% of all asthma-care costs go to treating this small subset of patients, a 2017 review reports, primarily because of medication costs. “We don't have the agents out there that are efficacious for what we would call type 1 severe asthma,” Blaiss said.

Study Finds Opioid-Induced Respiratory Depression in the Hospital More Common and Costly

Medtronic announced the publication of primary data from

PRODIGY (PRediction of Opioid-induced respiratory Depression In patients monitored by capnoGraphY), a Medtronic-sponsored, prospective observational, multi-center study to quantify the incidence and identify patients at high risk of opioid-induced respiratory depression (OIRD), a potentially life-threatening form of respiratory compromise that may impede breathing. Importantly, conclusions from the study data enabled the development of the PRODIGY Risk Score, an easy-to-use risk prediction tool to identify patients at high risk of respiratory depression who would benefit from continuous monitoring with capnography and pulse oximetry. The study, which analyzed 1,335 patients across 16 sites in the United States, Europe and Asia, found that respiratory depression, as defined by changes in pulse oximetry and capnography monitoring parameters, occurred in 46% of medical and surgical patients evaluated who were receiving IV opioids for pain. This incidence rate is significantly higher than previously reported in clinical literature. The complete study results are published online in *Anesthesia and Analgesia*, the official journal of the International Anesthesia Research Society (IARS). “PRODIGY data confirms that respiratory depression in patients receiving parenteral opioids occur frequently and are potentially unknown to hospital healthcare providers,” said Ashish K. Khanna, M.D., primary study investigator and an associate professor of Anesthesiology, section head for Research and intensivist at the Wake Forest School of Medicine. “Together with risk assessment using the PRODIGY Risk Score, the use of capnography and oximetry for continuous monitoring of patients identified as high risk for respiratory depression may increase safety when parenteral opioid analgesia cannot be avoided.” Currently, there are no universally accepted guidelines to direct effective and safe assessment and monitoring practices for patients receiving in-hospital opioid analgesia. In addition to providing insight into the rate of respiratory depression, a key objective of PRODIGY was to develop and validate an accurate and easy-to-use risk assessment scoring tool. The PRODIGY Risk Score uses risk factors including: age > 60 years, male gender, opioid naïvety, sleep disorders and chronic heart disease for respiratory depression events risk prediction. “The PRODIGY Risk Score has acceptable accuracy for risk stratification using several robust methods of internal validation, addressing significant gaps in preventing this common and potentially deadly condition,” said Frank Chan, vice president and general manager of the Patient Monitoring business, which is part of the Minimally Invasive Therapies Group at Medtronic. “Patients with respiratory depression were more likely to experience an adverse event that prolonged hospitalization and more likely to require rescue action, including rapid response team activation.” The PRODIGY study is the largest known study using continuous capnography and pulse oximetry data on surgical and medical patients collected by Medtronic Microstream and Nellcor monitoring technology. The study design used an innovative mechanism of data collection whereby bedside providers were blinded to continuous monitoring systems and all alarms were also silenced. All patients experiencing respiratory depression were reviewed and confirmed by an independent clinical event committee of physicians with expertise in perioperative respiratory medicine.

CPAP Maker Debuts Its Softest Nasal Mask Ever

ResMed announced the launch of its AirTouch N20 nasal mask, the company's first CPAP nasal mask with a memory foam cushion and softest nasal mask ever. AirTouch N20 uses the same patented UltraSoft memory foam cushion as the full face

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AirTouch F20 mask introduced in 2017. Both adapt to the curves and contours of each face, creating a soft, personalized fit designed to increase comfort and CPAP adherence. In a clinical study, 90 percent of CPAP users gave the UltraSoft foam cushion a high rating for comfort—a 4 or 5 out of 5. This unique comfort also comes with added convenience: The foam cushion doesn't require cleaning when replaced on an appropriate schedule. Most important, AirTouch N20's comfort and convenience can help increase patient satisfaction, adherence, and benefit from long-term therapy. Additional features include:

- Quick-release elbow allows patients to easily disconnect from tubing without removing their mask, and magnetic clips guide the headgear to the frame quickly and easily
- AirFit N20's mask frame fits both AirFit N20 silicone and AirTouch N20 memory foam cushions, allowing clinicians to conveniently switch between the two during fittings or send patients home with both to see which cushion type they prefer
- A seal designed for therapy pressures up to 30 cm H₂O

"CPAP therapy should be simple, comfortable, and easy to use – and AirTouch N20 delivers on all three," said Jim Hollingshead, ResMed president of Sleep and Respiratory Care.

"The foam cushion is uniquely comfortable, adapts to give everyone a personalized fit, and doesn't need cleaning. It's ideal for nasal CPAP users and their providers." AirTouch N20 is the latest in ResMed's family of innovative CPAP masks, connected devices, and digital health technologies for helping millions with sleep apnea, COPD, and other chronic diseases sleep, breathe, and live better. AirTouch N20 is now available in the U.S., Canada, and most of Europe, with Asia-Pacific launches planned for later this year. For more information, visit ResMed.com/AirTouchN20.

Patients Survive Ventilator, But Linger in a Coma

Leslie Cutitta said yes, twice, when clinicians from Massachusetts General Hospital in Boston called asking whether she wanted them to take—and then continue—extreme measures to keep her husband, Frank Cutitta, alive. The first conversation, in late March, was about whether to let Frank go or to try some experimental drugs and treatments for COVID-19. The second call was just a few days later. Hospital visits were banned, so Leslie couldn't be with her husband or discuss his wishes with the medical team in person. So she used stories

to try to describe Frank's zest for life. "Frank used to joke that he wanted to be frozen, like Ted Williams, until they could figure out what was wrong with him if he died," said Leslie Cutitta. It wasn't a serious end-of-life discussion, but Cutitta knew her husband would want every possible lifesaving measure deployed. So the Cutittas hung on and a small army of ICU caregivers kept working. On April 21, after 27 days on a ventilator, Frank's lungs had recovered enough to remove the breathing tube. After the removal, it typically takes hours, maybe a day, for the patient to return to consciousness. The body needs that time to clear the drugs that keep the patient sedated and comfortable—able to tolerate intubation and mechanical ventilation. But doctors across the

US and in other countries have noted a troubling phenomenon associated with some COVID cases: Even after extubation, some patients remain unconscious for days, weeks, or longer. There's no official term for the problem, but it's being called a "prolonged" or "persistent" coma or unresponsiveness. Frank Cutitta, 68, was one of those patients. He just didn't wake up. "It was a long, difficult period of not—just not knowing whether he was going to come back to the Frank we knew and loved," said Leslie Cutitta. "It was very, very tough." Doctors studying the

Continued on page 26...

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Humidification Gap in Low-Flow Oxygen Therapy: A Narrative Review

Ruben D Restrepo, MD RRT FAARC FCCP

Abstract

Long-term administration of low-flow oxygen therapy has dramatically increased over the last few years. Delivery of low-flow oxygen therapy via nasal prongs offers advantages over other types of oxygen delivery devices. However, one significant disadvantage is lack of current devices that can optimally heat and humidify dry oxygen delivered through the nasal prongs at low flows. On the other hand, heated and humidified high flow nasal cannula has proven to be extremely beneficial to patients with respiratory disease in a variety of clinical settings. Despite the well-known disadvantages of delivering dry gas when administering low-flow oxygen therapy, there is still a gap in identifying the best way to optimize its delivery. The goal of this article is to review low-flow oxygen therapy, its indications, limitations, current strategies to optimize its delivery, adherence, and few lessons learned from high flow nasal cannula that can potentially improve its administration.

Introduction

It is calculated that over 1.5 million adults in the United States use supplemental oxygen.¹ According to Croxton and Bailey, reimbursements for costs related to oxygen in patients with COPD using long-term oxygen therapy can exceed \$2 billion per year in the United States alone, and that this figure has been estimated to increase 12-13% annually.² Long-term oxygen therapy (LTOT) is defined as oxygen use for at least 15 hours per day and for ≥ 30 days.³ While the most common indication for oxygen therapy is the presence of hypoxemia, its use as LTOT in the form of low-flow oxygen administration in diseases, such as chronic obstructive pulmonary disease (COPD) is associated with reduction of pulmonary hypertension, improvement of hypoxia, reduction of hospital stay, and improvement of life expectancy.¹

Nasal cannula is the most common interface used to deliver low-flow oxygen therapy (LFOT) on the spontaneously breathing patient. The advantage of delivering oxygen through nasal prongs is that the jet of oxygen is directed to the middle of the nose versus that of a nasal catheter that is directed against the mucous membranes. Oxygen is a dry gas and the cooling effect increases proportionally to the flow rate. In addition, the absolute amount of water required to humidify a higher flow of oxygen in the nose increases. Therefore, clinicians should

be aware of this cooling effect of humidification and use the smallest flow rate that is sufficient to oxygenate a patient.⁴ Since the upper respiratory tract can provide up to 75% heat and moisture to make the inhaled air comfortable, the discomfort associated with non-humidified LFOT to patients is extremely variable.⁶

Current Limitations of LFOT/LTOT

Despite the existing evidence supporting LTOT for several clinical outcomes in patients with moderate to severe COPD, compliance with oxygen therapy limits the effectiveness of the treatment.⁸ The most commonly listed factors associated with poor compliance to LFOT are inconvenience, discomfort or embarrassment. Patients requiring oxygen at flows greater than 3 L/min are limited to inadequate and physically unmanageable portable oxygen delivery options such as oxygen conservers at home that tie patients to the equipment and limit activities of daily living. Ambulatory sources for LFOT such as the E-cylinder may limit mobility and ambulation, as it is typically wheeled by the patient. Lighter, more portable, oxygen sources have been designed, but these are not available for all patients due to expense. Furthermore, a recent report from the American Thoracic Society (ATS) confirms that liquid oxygen (LOX) has virtually disappeared from some parts of the United States as an option. Without LOX, patients who require higher flow oxygen for mobility, and cannot lift heavier metal tanks, now often find themselves homebound.

Current Strategies for Humidification of LFOT

Delivery of LFOT to a patient is a process that involves artificial conditioning by humidifying, warming, and filtering of the medical gas being delivered. Oxygen delivered by nasal cannulas may or may not be humidified depending on the clinical setting and the patient care provider's preference. While oxygen, regardless of how much flow is used, is routinely humidified clinically in some Asian countries,⁹ in Europe and North America, oxygen is not routinely humidified unless flow is ≥ 5 L/min.¹⁰

Old World Health Organization guidelines have recommended humidification of oxygen whenever a nasopharyngeal catheter is used. For nasal catheters and nasal prongs, no humidification is necessary.¹¹ While the AARC and other clinical practice guidelines do not routinely recommend humidification of oxygen to adults by nasal cannula at flows ≤ 4 L/min^{12,13} other guidelines support delivery the humidification of inhaled oxygen in long-term and low-flow oxygen therapy.¹⁴

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Table 1. Incidence of complications associated with humidified vs. non-humidified LFOT.

Complications	# of studies	Higher incidence with		OR	95% CI	P value*
		Humidified	Non-humidified			
Dry nose	4		X	1.21	0.76 - 1.93	0.42
Dry nose and throat	9	X		0.93	0.78 - 1.10	0.39
Cough	2	X		0.80	0.42 - 1.52	0.50
Nosebleed	6		X	1.34	0.77 - 2.34	0.30
Chest discomfort	4	X		0.91	0.53 - 1.55	0.72

OR: odds ratio; CI: confidence interval

*P <0.05: statistically significant

Despite the inconsistency associated with humidification of low-flow oxygen therapy (LFOT), several new randomized controlled trials (RCTs) on the superiority of humidified and non-humidified oxygen in low-flow oxygen therapy have been performed.

While the great majority of hospital guidelines always recommend the humidification of oxygen in infants, recommendations for LFOT in pediatric and adults vary significantly. A recent clinical trial by Lorente Sanchez et al in infants with bronchiolitis found that humidification during the administration of LFOT was shown to be associated with significant reductions in the number of nasal lavages, in the heart rate, and in the length of stay and oxygen requirements of infants.¹⁵

Bubble Humidifiers. Cold bubble humidifiers are the most common method of humidifying inspired oxygen. Patients using LFOT via a nasal cannula or face mask often require a bubble humidifier. A bubble humidifier consists of a bottle of reservoir partially filled with water attached to a conduction system that allows the inspired medical gases below the water surface. Dry gas is guided through a capillary system inside the water bottle and passively picks up humidity as it flows through the sterile water before exiting through the outlet port to the interface used with each patient. Since a cold bubble humidifier is independent from any external energy source or external water supply, it is considered a passive method of humidification.

If heated, bubble humidifiers are known to cause excessive condensate that could obstruct the small-bore tubing that connects the humidifier output and the patients' interface. Prolonged use has been associated with relief valve dysfunction. This type of humidifier is contraindicated for patients with an endotracheal tube, a tracheostomy, or tenacious secretions.

Unheated bubble humidifiers can achieve an absolute humidity (AH) between 15 and 20 mg/L. They should be operated between flows of 2 L/min and no greater than 6 L/min, as they start losing their efficiency in providing humidity.¹⁶ Despite its common use with LFOT, a recent randomized clinical trial by Franchini et al demonstrated that, compared to dry long-term LFOT, cold bubble humidification was not an efficient method to humidify inspired oxygen and did not prevent deterioration of mucociliary clearance (MCC), mucus dehydration, and decline in pulmonary function. The unheated bubble humidification (AH 21 mg/L) performed no better than no humidification (AH 9 mg/L).¹⁷

Complications Associated with Dry and Unheated Humidification During LFOT

Dry nasal LFOT has been widely used clinically to prevent bacterial contamination of the water reservoir.^{18,19} However, the

inhalation of dry or inadequately humidified air may cause ciliary dysfunction, alterations in mucus properties, and impairment in MCC.^{20, 21, 22} Studies investigating dry LFOT on airway symptoms reported acute dryness in the mouth, nose, and trachea as well as headache and chest discomfort in healthy subjects and in patients after 92 days. After humidification, there was some relief of nasal symptoms.^{23,24}

On the other hand, Edward et al evaluated, on a daily basis, the subjective complaints of patients who were placed on oxygen via nasal cannula at flow rates of 5 L/min. Their data did not support the possibility that increasing duration of nasal oxygen therapy results in increasing symptoms related to drying of the upper airway, nor did it suggest that long-term nasal oxygen therapy requires humidification of the delivered oxygen.²⁴

Infection. Healthcare-associated infection (HAI), particularly pneumonia and surgical wounds affects about 4% of patients who are hospitalized and is considered one of the most frequent medical complications.²⁵ Mechanical ventilators, oxygen humidifiers, and nebulizers have been identified as the most important vectors of fungi and bacteria.²⁶

Bubble humidifiers are known to produce micro-aerosols contaminated with hydrophilic bacteria species such as *Pseudomonas* and *Legionella*.^{27,28,29} This contamination is associated with the difficulty in cleaning or changing the water in the reservoir of a multiple-use bubble water humidifier. The microbiological contamination of humidifiers used with ventilators is also possible in bubble humidifiers attached to an oxygen concentrator used for LFOT.^{30 31} A recent evaluation of humidifiers for oxygen therapy by Fauci et al revealed high rates of microbial contamination observed in samples from reusable oxygen humidifiers employed in medical (83%), surgical (77%) and emergency (50%) areas. The most relevant pathogens were *Pseudomonas aeruginosa* and *Staphylococcus aureus*. On the other hand, disposable oxygen humidifiers have been found to be safely used for 30 days and could remain sterile for up to 77 days.^{18,32,33}

Nasal Mucosa Irritation, Cough, Chest Discomfort. A Chinese survey conducted by Yang et al found that non-humidified oxygen was associated with more complications than humidified LFOT.³⁴ On the other hand, the most recent systematic review determining effects of LFOT with and without humidified oxygen (bubble humidifiers) in adult patients revealed that non-humidified LFOT offers more advantages in reducing bacteria contaminations of humidifier bottles (OR 0.16; CI:0.06-0.43; p <0.05), the mean nursing operating time (OR -35.84; CI:-44.51- -27.17; p <0.05), and respiratory infection (OR 0.39; CI:0.21-0.73; p <0.05). No significant difference between humidified and

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non-humidified LFOT was found on incidence of complications such as dry nose, dry nose and throat, cough, nosebleed, chest discomfort (Table 1). The authors concluded that the quality of most clinical trials included in the review was poor. Therefore, the results should be interpreted with caution. More rigorously designed, large-scale randomized controlled trials are still needed to clearly define the benefit of bubbler-humidified oxygen when administering LFOT.³⁵

Nasal Mucociliary Clearance. In a study by Franchini et al, neither dry and cold bubble humidifier during LFOT reached the level of humidity recommended by guidelines (9 mg/L, 21 mg/L and 44 mg/L, respectively).¹ The inability to provide optimal temperature and humidity significantly impacts the rheological characteristics and volume of airway secretions. As a result, nasal clearance is reduced and inflammations is enhanced as a reaction to lower airway temperature. Heated humidification preserves the MCC and pulmonary function.

Mucus hypersecretion and chronic productive cough are particular features of a large portion of patients with COPD and result in overall deterioration of lung function as well as MCC.^{36,37,38} Inadequate humidification of oxygen over time causes nasal MCC to slow down clearance, a factor associated with function decline.³⁹

Adherence to Long-Term Oxygen Therapy (LTOT)

Evidence of adherence to prescribed oxygen therapy, although considered fair, is difficult to obtain from patients on LTOT as the vast majority of them underuse it since they tend to overestimate their daily time on oxygen.⁴⁰ Most reports on the adherence to LTOT come from patients using oxygen cylinders and concentrators.^{41,42,43,44} Use of extra oxygen during sleep and exercise (increase of resting oxygen flow by 1L/min) can significantly bias the results of evaluating adherence during the day.⁴⁵

Neri et al reported that only one in five patients used oxygen more than 15 hours per day. Most (84%) patients possessed an oxygen cylinder, but only 40% declared they used it daily, 'shame' being indicated as the principal barrier. On the physicians' side, they found that the criteria used in prescribing did not always correspond to evidence-based recommendations.⁴²

Lessons Learned from High Flow Oxygen Therapy

Heated high flow oxygen therapy (HFOT) is a therapy where oxygen, in conjunction with compressed air are heated and humidified prior to being delivered to a patient at rates of flow (up to 60 L/min) higher than those delivered traditionally via LFOT. This method of oxygen delivery has been found to improve not only comfort but also gas exchange and reduce work of breathing.⁴⁶

While LFOT requires minimal setup, HFOT requires use of a blender connected to a wall outlet, a humidifier, heated tubing and nasal cannula. When used in COPD patients for the management of exacerbations after resulting in clinical improvement,⁴⁹ HFOT is always transitioned to LFOT but without proper or in the best-case scenario, poor heat and humidification.

High flow oxygen therapy (HFOT) has been compared to conventional LFOT in a recent systematic review by Lee that included twelve clinical trials. Nine studies yielded data on

patients. Six out of the nine studies that included data on comfort or subjective dyspnea assessment reported reduced sensation of shortness of breath with HFOT versus LFOT, while two studies failed to show any difference. Three studies revealed HFOT was associated with better patient comfort than LFOT and one study showed inferior overall comfort in patients receiving HFOT.⁴⁷ Three studies showed no difference in overall comfort between these two groups.⁴⁸

In March of 2019, the most recent systematic review and meta-analysis on the safety and efficacy of high flow nasal cannula (HFNC) in patients with acute hypoxemic respiratory failure by Rochberg et al was published. They found that in patients with acute hypoxemic respiratory failure, HFNC may decrease the need for tracheal intubation without impacting mortality.⁴⁹

Future Direction and Conclusion

Addition of heat and humidification to dry oxygen are the basic foundation for using HFOT. Therefore; why aren't clinicians heating and humidifying oxygen for patients on LFOT? Despite the significant heterogeneity of the studies evaluating benefits of heat and humidification during the administration of oxygen at low flows, it is clear that existing humidification devices used for LTOT perform very poorly. Should clinicians reevaluate the benefits learned from administration of HFOT and extrapolate to LFOT as optimization of gas delivery? Although basic physiology explains that unheated and non-humidified medical gas delivery is not physiological, most clinicians have a natural tendency to underestimate the potential adverse effects based on controversial evidence. Should application of heat and humidity be limited to a particular time of use or flow range in liters per minute? Inhalation of any amount of dry and cold medical gas for any period of time imposes a risk to the airways. These adverse effects are proportionally related to dose (liters/minute) as well as duration of administration. Considering that the most significant advantage of providing high flow through a nasal cannula is the ability to prevent the humidity deficit associated with delivery of dry oxygen, clinicians should reevaluate the use of LFOT without adequate humidification.

Heated humidification during LFOT provides a better temperature and humidity of inspired gas, preserving mucociliary clearance and pulmonary function. Current humidification devices such as the "bubblers" are far from representing optimal conditioning of oxygen delivery.

Use of newer devices to humidify and heat oxygen at low flows may provide the answer to the previously explored questions. In the meantime, contrasting HFOT and LFOT only on terms of flow does not seem to be a fair comparison.

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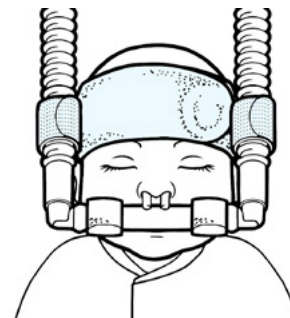
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Driven to Continuous Improvement with the Vivo 65

Jorge Bolano RRT, RCP

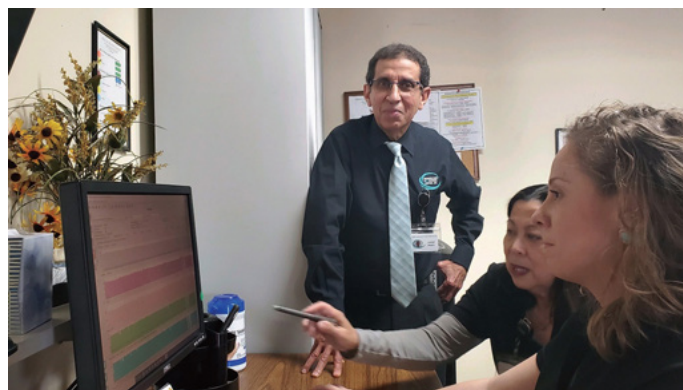
As a respiratory therapist since 1981 and founder of Health Care Solutions Group, Inc. since 2000, Jorge Bolano RRT, RCP has crusaded to improve the quality of life for his respiratory patients. He established his company with the commitment to, in his own words *“focus on providing better outcomes and delivering the high level of care that the patient needs.”* To that end, he has had his clinical respiratory care services accredited by the Joint Commission since 2006. Through the years he has seen significant improvement in the quality of care delivery to his patients. The company motto sums up his attitude, *“Success is gained in the pursuit of excellence and our success is measured by better patient outcomes.”*

Health Care Solutions Group, Inc. specializes in complex respiratory cases with use of high-flow therapy systems, invasive and non-invasive ventilators, and assessments in the home for patients' with diseases that range from neuromuscular illness to COPD.

Jorge's need for constant improvement led him to the Breas Vivo 65 ventilator. As he describes it, the Vivo 65 *“...provides the ability for our patients to have better outcomes...”* Currently about 60% of his ventilator patients are using Vivo 65 ventilators. He has numerous stories about how the Vivo 65 improves the quality of life for his ventilator patients.

Jorge attributes many of these quality-of-life improvements to the Vivo 65's unique and patented eSync trigger and leak independent technology that reduces patient ventilator asynchrony. Contrasted to other ventilators that use a flow or pressure changes to sense patient inspiratory effort, eSync technology uses airway gas flow velocity acceleration generated by a patient's inspiratory effort to sense and trigger breaths. With the use of flow velocity acceleration, eSync provides leak independence as the slow and constant flow typical of patient interface leaks is not sensed as airway gas accelerations associated with patient inspiratory effort.

The patient comfort provided by eSync's leak independence is a key factor for many of his patients. For example, patients receiving non-invasive ventilation on other ventilators with full face masks whose masks were constantly tightened to stop leaks. Some of the patients have muscular twitches that make it difficult to keep the mask on their face. Jorge says, *“The head*



Jorge and his staff reviewing ventilation data from a patient on a Vivo 65 using Breas PCSW.

gear kind of gets impregnated in their skull and they are not able to talk. They can't do anything.” With a change to a Vivo 65 ventilator, the leaks no longer affect the treatment. Some patients no longer need a full-face mask. They can be ventilated by using a nasal mask or even a nasal canula. They still maintain the CO₂ levels that indicate they are being properly ventilated. As he says, *“I believe that if I put a patient on a Vivo, you'll definitely have a better chance to have a better quality of life and have the little things that people, like us, take for granted. When you're on any other ventilator 24/7, you are unable to talk. You have to rely on a speaking valve to talk, having to overcome the resistance of this valve, and work so hard to be able to breathe through a valve that is restricting the air that you're bringing in. It's a significant game changer in my opinion, when you get to talk without the need of a speaking valve like the patients on Vivo 65 do.”*

With increased use of the Vivo 65 ventilator in his practice, Jorge has seen a reduction in the number of masks that he is called out to replace to try to fix leaks. With other ventilators he sometimes replaces masks multiple times trying to find one that does not leak, an expensive proposition. The Vivo 65 ventilator has eliminated this problem due to its leak independence.

Jorge has other patients who were intubated with a cuffed tracheostomy tube. The cuff pressure had been increased repeatedly in an effort to stop the leaks to the point the patient could no longer talk. With the change to the Vivo 65, the cuff could be deflated and as a result, they could talk again. As he says, *“they could talk and that's better outcome in my book. I believe that losing the ability to talk, as a result of*

Jorge Bolano RRT, RCP – Respiratory Therapist, Home Respiratory Care Provider – Driven to Continually Improve Patient Care and Outcomes


an overinflated cuff because you have to take care of a leak, otherwise the ventilator will not work; those are the things that drive me to believe that my patients have better outcomes" with the Vivo 65.

Jorge also attributes eSync trigger technology with another outcome improvement related to patients' reduced work of breathing. He measures the improvement versus other ventilators by evaluation of minute ventilation as well as by what patients tell him. "They tell us, "When I'm on this machine, I feel like I'm not so tired anymore." They have to work so hard to overcome the asynchrony from the machines that it's really difficult to breathe sometimes and they have to work so hard to get the air... With the Vivo 65 breathing is much easier." One unexpected result seen is patient weight gain. He theorizes that this is because they are not burning as many calories to breathe.

Another Vivo feature Jorge likes is the Pre-use Test that measures and calibrates the ventilation delivery from the resistance and compliance it measures in the circuit. With this test he knows that regardless of the length or type of circuit used, the Vivo will deliver the same ventilation. Many flow cycle ventilators do not have a circuit calibration test, so clinicians have to adjust the pressure to increase the volume without knowing how accurate it is in many cases.

Jorge's pursuit of continuous improvement to better the outcomes for his respiratory patients led him to the Vivo 65. He now uses his experience to influence doctors and other therapists who send him referrals, especially those with patients that have failed on other ventilators. He seeks out referrals who are open to new concepts and the pursuit of excellence like himself. "I believe that this ventilator is the way of ... ventilating people in the future. There's just no doubt in my mind and clinically I see it."

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The Role of The Life2000® Ventilation System, a Novel NIV Device, During a COVID-19 Outbreak and National Ventilator Shortage

Background and Purpose

According to a February 14, 2020 report from Johns Hopkins Center for Health Security,¹ there are approximately 8,900 stockpiled ventilators in the United States. American hospitals have an additional 62,000 fully featured ventilators and 98,000 ventilators that can provide basic functions in an emergency standard of care. Additionally, on March 15, 2020, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, reported an updated number of 12,700 ventilators in the national strategic stockpile during a televised press-conference.²

Worldwide, there have been varying reports of the percentage of patients testing positive for COVID-19 requiring ICU admission (and presumably a fraction of those requiring mechanical ventilation) with 5% in China and 12% in Italy.³ There are several reasons these countries could have seen differing percentages including co-morbidities (e.g., China with more male smokers and Italy with the world's second highest elderly population) and respective preparedness and response strategies to the outbreak.

Currently, the US has a population of 327.2 million people⁴ and assuming that 40%-70% are estimated to contract the novel COVID-19 virus, there could be 130.8 million to 229 million infected Americans which could mean an estimated 6.5 million to 27.5 million people requiring hospital admission, potentially requiring ventilatory support in a fairly short period of time (weeks to months) for COVID-19 cases alone. As of the date this paper was published, according to the 2020 American Hospital Association (AHA) Hospital Statistics Report⁵, there are about 55,663 med-surg ICU beds, 15,160 cardiac ICU beds, and 7,419 ICU beds classified as 'other' nationally. A report from the Imperial College of London⁶ anticipates critical care bed capacity, in an unmitigated pandemic, would be exceeded as early as the second week in April 2020, with an eventual peak in ICU or critical care bed demand that is over 30 times greater than the maximum supply in the US.

These estimates pose several potential threats to the capacity of hospitals and healthcare providers' ability to source and utilize medical equipment. For this reason, clinicians will likely need to be especially judicious with decisions on when to initiate and wean mechanical ventilation (MV) and look to alternative modes of support, such as non-invasive ventilators (NIV) that offer similar ventilatory capacity sufficient to meet patient need

in order to protect limited resources. NIV's apply end-expiratory positive airway pressure increasing functional residual capacity and opening collapsed alveoli, thereby improving ventilation-perfusion matching and reducing intrapulmonary shunt as well as improving lung compliance, thus reducing respiratory load.⁷

Description of Life2000 Ventilator

The Life2000 Ventilator is an FDA cleared volume-control ventilator for adult patients requiring partial or total life support and is indicated for invasive or non-invasive ventilation with a maximum positive end-expiratory pressure (PEEP) of 10 cmH₂O and peak inspiratory pressure (PIP) of 40 cmH₂O as seen in appendix 1. In the acute care setting, the device can use wall O₂, wall air, cylinders, or its own compressor. Fraction of inspired oxygen (FiO₂) is based on liter flow bleed-in or entrainment and supports spontaneous breathing for patients unable to drive their own respirations and can be delivered via nasal pillows, face mask, or ET tube (see Appendix Figure 1) in conjunction with a heat-moisture exchanger (HME) for humidification and can deliver FiO₂ no higher than 50% for stand-alone units and up to 90% if using supplemental bleed-in techniques. See Table 1 for technical specs and Figure 2 and 3 for FiO₂ adjustment in which Appendix.

Waveform comparisons of the Life2000 Ventilator to a nationally stockpiled MV, LTV® 1200, show similar performance capabilities across different patient lung types/needs: healthy, obstructive, restrictive, and spontaneous breathing (appendix 2). This demonstrates that it can be used in patients needing ventilatory support who do not require ventilation that exceed maximum output capabilities of the Life2000® device.

Clinical Considerations for Applicability

- The Life2000 Ventilator's small form factor and low-profile nasal pillow interface allows for utilization across various acute care settings, including the following: ER/ED, Med/ Surg Recovery, general floor, and post-ventilator weaning support.
- Traditional face masks have a limitation of anatomical dead space where CO₂ blow off can require higher PEEP settings. This limitation can be avoided with Life2000 nasal pillows that conform to the nostril, creating a seal that prevents leakage, while eliminating the risk of nasal bridge skin breakdown and the formation of mask pressure ulcers from prolonged periods of NIV usage.⁸
- The benefits of weaning patients from MV to NIV has been well established in clinical research and meta-analysis⁹ and can significantly reduce risk for other nosocomial infections

Submitted by Hillrom, updated April 7, 2020.

Figure 1. Ventilation System Compatible Interfaces



Comfortable Breathe Pillows Interface

- Small-diameter tubing (5 mm vs traditional 22 mm)
- Patients can talk while wearing the noninvasive Breathe Pillows Interface
- Comfortable fit for around-the-clock use
- Available in multiple sizes

Breathe Universal Circuit® Connector

- Compatible with any third-party interface (including full face mask, tracheostomy tube, and intubation tube).

Figure 2. Life2000® – Delivered FiO₂

Delivered FiO₂ on a Life2000 is based on three elements

- Drive gas to the ventilator
 - Air - 21% oxygen
 - O₂ - 100% oxygen
- Entrainment Rate (R_E) – Varies w/ Peak Press. & set Peak Flow, Typically:
 - R_E = 3 when PIP ≤ 13 (Drive gas is 33% of total pat. gas)
 - R_E = 2 when 13 < PIP ≤ 26 (Drive gas is 50% of total pat. gas)
 - R_E = 1 when 26 < PIP ≤ 40 (Drive gas is 100% of total pat. gas)
- Liter flow of O₂ bled into the Inspire cannula
 - 0 to 30 lpm

Figure 3. Life2000 - Recommendations For Delivered FiO₂

For FiO₂ < 50%

- Use Air as the drive gas
- Titrate O₂ bleed flow until delivered FiO₂ is achieved

For FiO₂ ≥ 50%

- Use O as the drive gas
- Titrate O bleed flow until delivered FiO is achieved
- Note entrainment rate (RE) affects FiO₂
 - RE = 3; FiO₂ = 47% with no O₂ bleed flow
 - RE = 2; FiO₂ = 60% with no O₂ bleed flow
 - RE = 1; FiO₂ = 90% with no O₂ bleed flow

and lung injury. It is recommended that clinicians use best practices that are in line with their facilities’ standards and professional guidelines.

ARDS Specific Considerations

- Patients who are at risk for developing Acute Respiratory Failure (ARF) or have mild respiratory distress may be appropriate candidates for Life2000 Ventilator initiation to prevent escalation to MV by setting a low tidal volume (6-8mg/kg of ideal body weight) and a high PEEP (relative to Life2000’s capabilities) of 9-10 cmH₂O in accordance to American Thoracic Society (ATS) guidelines¹⁰ and may prevent the patient from developing or advancing to more severe forms of Acute Respiratory Distress Syndrome (ARDS).
- Numerous professional organizations¹⁰⁻¹¹ and other peer-reviewed studies have suggested that lying a patient prone

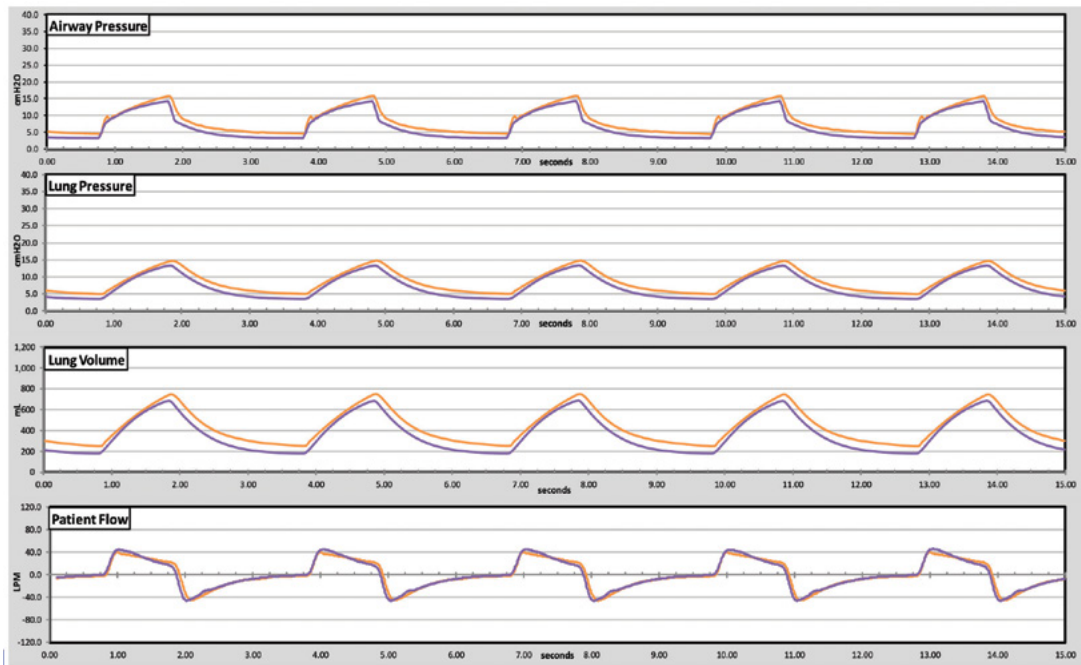
Table 1. Life2000® Ventilation System Specifications

FEATURES	LIFE2000
Product Code	NOU/CBK
Life Sustaining/Support Device	Yes
Patient Interfaces - Compatible	Nasal Cannula, NIV Masks, ET Tubes
Recognized Consensus Standards	ISO 80601-2-72 ISO 80601-2-12
Modes - Volume Mode	Proportional Open Ventilation Control and Assit Control
Essential Performance	
Max. Inspiratory Pressure (cmH ₂ O)	0 to 40
Tidal Volume (ml)	50 to 2000
Inspiratory Time (sec)	0.15 to 3.0
Breath Rate (bpm)	0 to 40
PEEP (cmH ₂ O)	0 to 10
FiO ₂ (%)	O ₂ bleed in
Patient Trigger (Adjustable)	1 to 9
Monitor/Alarms	
Peak Pressure (cmH ₂ O)	0 to 50
Respiratory Rate (bpm)	0 to 60
O ₂ liter flow (L)	0 to 60
High/Low Peak Pressure (cmH ₂ O)	
High/Low Breath Rate (bpm)	
High PEEP (cmH ₂ O)	Set PEEP + 7
Breath Time Out (Apnea)	60 sec

may help improve oxygen levels in the blood and increase survival in patients at risk or with mild to moderate ARDS. In a recent 2020 multicenter prospective cohort study,¹² investigators combined the prone technique with the addition of High-Flow Nasal Canula (HFNC) or NIV treatment and found that when patients with pneumonia secondary to influenza and other viral infections were admitted to a hospital, those with mild ARDS had a reduced risk of progressing to invasive ventilation when using HFNC/NIV in combination with a prone position (PP) when position was maintained for a minimum of 2 hours a day and had

Waveform Comparisons

Test Case 1 (Healthy): Life2000 Ventilator and LTV® 1200

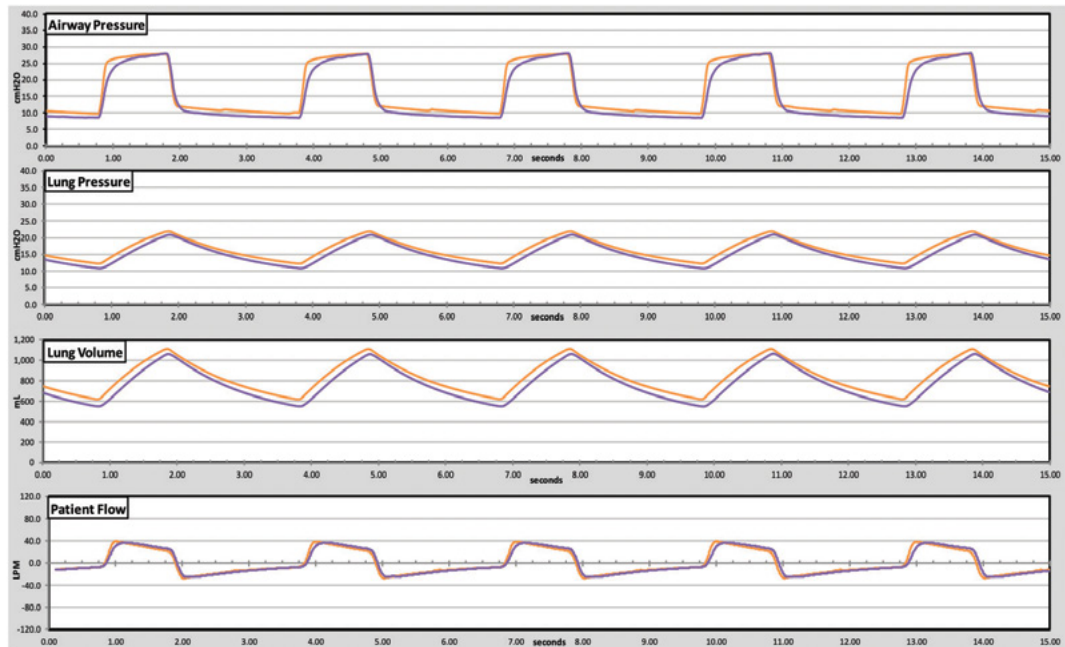


● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	15 cmH ₂ O
Peak Pressure (lung)	15 cmH ₂ O
PEEP	5 cmH ₂ O
Peak Flow	40 lpm

Test Case 2 (Obstructive): Life2000® Ventilator and LTV 1200



● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

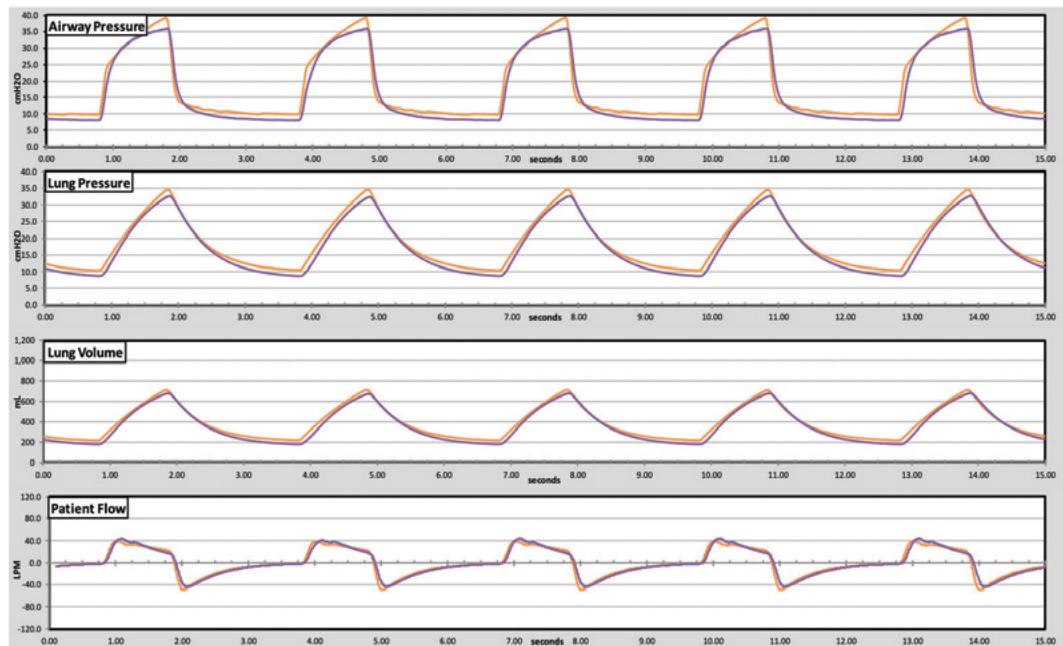
PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	28 cmH ₂ O
Peak Pressure (lung)	21 cmH ₂ O
PEEP	10 cmH ₂ O
Peak Flow	40 lpm

significantly improved PaO₂/FiO₂ in comparison to respective standalone therapies. The unique Life2000 Ventilator configuration combines the benefit of nasal pillows to reduce dead space (typically seen in HFNC) and positive pressure therapy (reserved to NIV) that may assist in patient tolerance and therapeutic effectiveness.

- It is recognized that more moderate to severe cases of ARDS may exclude the use of NIV systems like Life2000 Ventilator due to the increased demand of PEEP ≥ 12 cmH₂O and a higher rate of NIV failure in these cases. Current recommendations from The American Thoracic Society (ATS)¹⁰ state early

predictors of NIV failure include higher severity score, older age, ARDS or pneumonia as the etiology for respiratory failure, or a failure to improve after 1 hour of treatment. This sentiment was recently reiterated by the Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment Guidelines.¹³ Clinicians should use careful considerations and best practice guidelines established by the American Association of Critical-Care Nurses (AACN), ATS, and other professional organizations when evaluating patients who are at risk for or are presenting with ARDS and mode of ventilation selected.

Test Case 3 (Restrictive): Life2000 Ventilator and LTV 1200

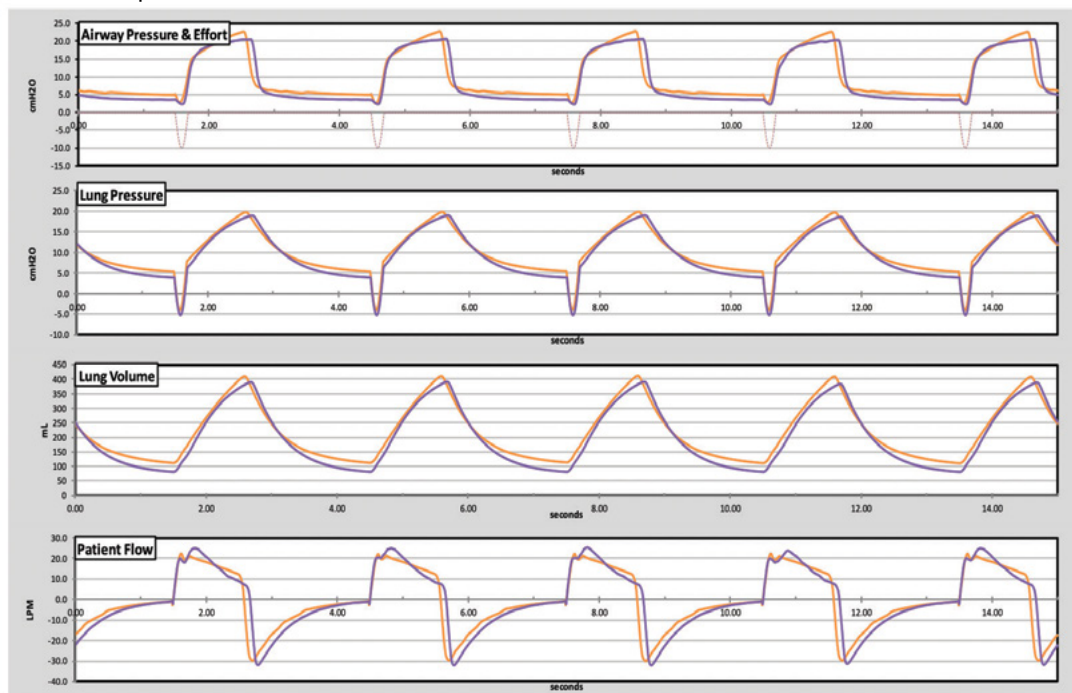


● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	500 ml
Peak Pressure (airway)	35 cmH ₂ O
Peak Pressure (lung)	35 cmH ₂ O
PEEP	10 cmH ₂ O
Peak Flow	40 lpm

Test Case 4 (Spontaneous): Life2000® Ventilator and LTV 1200



● Life2000 vs ● LTV 1200

WAVEFORM COMPARISON PARAMETERS

PARAMETER	VALUE
Tidal Volume	300 ml
Peak Pressure (airway)	20 cmH ₂ O
Peak Pressure (lung)	20 cmH ₂ O
PEEP	5 cmH ₂ O
Peak Flow	25 lpm

Conclusion

Thoughtful patient selection and NIV application can be extremely important in pandemic situations where there is a shortage of full capacity mechanical ventilators. At the core of the above clinical considerations should be interdisciplinary clinician driven protocols and guidelines that are consistent with best practices. Continued understanding of novel ventilation devices and their role in patient care is critical to improving clinician knowledge and improved patient outcomes in times of crisis. The distinctive features of Life2000 Ventilator may add clinical benefit in an acute care setting by reducing burden of

more invasive forms of ventilation without compromising patient safety and outcomes.

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News...continued from page 10

phenomenon of prolonged unresponsiveness are concerned that medical teams are not waiting long enough for these COVID-19 patients to wake up, especially when ICU beds are in high demand during the pandemic. As Frank's unresponsive condition continued, it prompted a new conversation between the medical team and his wife about whether to continue life support. Although he no longer needed the ventilator, he still required a feeding tube, intravenous fluids, catheters for bodily waste, and some oxygen support. Leslie Cutitta recalled a doctor asking her: "If it looks like Frank's not going to return mentally, and he's going to be hooked up to a dialysis machine for the rest of his life in a long-term care facility, is that something that you and he could live with?" She struggled to imagine the restricted life Frank might face. Every day, sometimes several times a day, she would ask Frank's doctors for more information: What's going on inside his brain? Why is this happening? When might something change?

Texas, Florida, California, New York Will Not Follow New US COVID-19 Testing Plan

Several large US states including Texas are not heeding new federal health officials' calls to reduce COVID-19 testing of some exposed to the virus, joining a broad rebuke of the Trump administration by public health leaders. California, Connecticut, Florida, Illinois, Texas, New Jersey and New York all plan to continue to test asymptomatic people who have been exposed to COVID-19, despite new guidance from the Centers for Disease Control and Prevention (CDC) suggesting that such tests may not be needed. "The current Texas guidance recommends testing for all close contacts of a confirmed case because it allows for early case identification among people who are at a higher risk of infection," a spokesman for the Texas Department of State Health Services in a statement. "There's not a planned change at this point." California and New York made similar statements. The Florida Department of Health said asymptomatic testing was continuing while the new CDC recommendations were evaluated, and Texas also said it would evaluate. The CDC said this week that people exposed to COVID-19 but not symptomatic may not need to be tested, shocking doctors and politicians and prompting accusations the guidance was politically motivated. Even before the CDC guidance, coronavirus testing in the United States had dropped. The United States tested on average 675,000 people a day last week, down from a peak in late July of over 800,000 people a day. Nationally, cases have fallen for five weeks in a row but infections are surging again in the U.S. Midwest with four states reporting record one-day increases in cases on Thursday as the U.S. death toll climbed above 180,000. The CDC had previously recommended testing of all people who had close contact with someone who was diagnosed with COVID-19. New York Governor Andrew Cuomo said the state of New York would not be abiding by the new guidance and challenged the assertion that politics played no role in the change. "This 180-degree reversal of COVID-19 testing guidelines is reckless, and not based on science and has the potential to do long-term damage to the (CDC's) reputation," Cuomo said in a joint statement, along with the governors of New Jersey and Connecticut, who also said their states would not be following the CDC's guidance. Admiral Brett Giroir, the assistant secretary for health at the Department of Health and Human Services (HHS), said there was no political pressure from the administration. He said that testing asymptomatic patients too early could produce false negatives and contribute to the virus's spread. CNN and The New

Continued on page 83...

Understanding the Role of Oscillation and Lung Expansion Therapy (OLE) During the COVID-19 Outbreak

Background on COVID-19

COVID-19, a disease caused by Coronavirus, SARS-CoV-2 started in late 2019 as a cluster of cases in Wuhan, China. Clinicians there described the pathology as a respiratory disease that often progressed into pneumonia with bilateral ground-glass opacities.¹

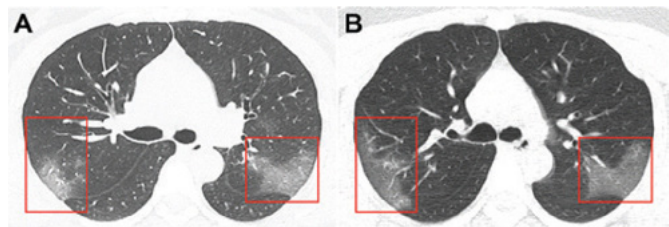


Image 1. Image from Lei et al. CT Imaging of the 2019 Novel Coronavirus (2019-nCoV). Pneumonia

The Center for Disease Control (CDC)² states that elderly patients and those with underlying conditions like hypertension, cardiovascular disease or diabetes, are more likely to develop serious complications like pneumonia secondary to COVID-19 including septicemia due to cytokine activity and fluid build-up in the lower lobe.³ Hospitalized COVID-19 patients often need respiratory support. Prominent features based on recent publications³ include cough, increased amounts of thick mucus in lower airways and respiratory distress.

Below is a list of respiratory related symptoms reported on patients with COVID-19:³

- 75% experienced cough³
- 55% of patients experienced dyspnea³
- 20-30% required ICU admission and of those, 47-71% required mechanical ventilation²
- 20-30% of patients had significant respiratory mucus production²
- 17-29% of hospitalized patients developed Acute Respiratory Distress Syndrome (ARDS)²
- 5% had hemoptysis³

Clinical considerations for treating pulmonary complications with Oscillation and Lung Expansion (OLE) Therapy

- OLE therapy delivered by the MetaNeb[®] System helps expand the lungs using Continuous Positive Expiratory Pressure

- (CPEP) and Continuous High Frequency Oscillation (CHFO) for mobilization of secretions and for prevention and treatment of pulmonary atelectasis. Therapy can be delivered with or without medicated aerosol both in spontaneously breathing patients or for use in-line with ventilators
- MetaNeb System therapy can be utilized to deliver treatment across various inpatient departments, including ED and ICU. The MetaNeb System has been shown to treat pneumonia, trauma, post-op, chronic respiratory conditions, and other conditions to improve respiratory status and reduce pulmonary complications. In studies of other patient populations, use of OLE therapy has been associated with:
 - Reduced ICU length of stay⁴
 - Reduced hospital length of stay⁴
 - Reduced time on the mechanical ventilation⁴
 - Reduction in dyspnea⁵
 - Improvement in chest X-ray⁵

Rationale for Use of the MetaNeb System in COVID-19 Patients with Pulmonary Complications

Early publications and reports on the clinical manifestations of COVID-19 suggest that up to 30% of patients with severe disease have significant pulmonary mucus production. Additionally, lung disease in many of these patients progresses to Acute Respiratory Distress Syndrome (ARDS). While there are currently no COVID-19 specific outcomes data with the MetaNeb System, the intended use of MetaNeb System therapy is for lung expansion and secretion clearance treatments regardless of etiology. The therapy may therefore be helpful in preventing and/or treating such complications. Therapy with the MetaNeb System may be appropriate either in spontaneously breathing patients or for use in-line with patients on mechanical ventilators. As with all therapies, the appropriateness of the therapy in individual patients is determined by the treating physician and the health care team.

Universal Infection Prevention & Control Recommendations with COVID-19 and Aerosolizing Therapies

Like many other respiratory illnesses, it is believed COVID-19 may be transmitted by airborne particles. As such, patients are generally placed in isolation rooms with specific infection control and prevention guidelines that must be followed.

Like all other Aerosol Generating Procedures (AGP), MetaNeb[®] System therapy can generate aerosols when using the medicated nebulizing component. Additionally, any therapy or procedure

Submitted by Hillrom, updated April 7, 2020.

that may result in patient coughing or clearing secretions is considered an AGP. The CDC recommends health care providers take airborne precautions when performing any AGP in known or suspected COVID-19 patients.² When performing these procedures:

Wear appropriate personal protective equipment (PPE) including, but not limited to an N95 fit tested respirator, gown, gloves, and face shield/eye protection:

- Limit number of caregivers in the room
- Use negative airflow rooms
- Follow cleaning and disinfection procedures promptly in guidance with hospital's protocols
- Refer to facility specific Infection Control guidelines for full recommendations

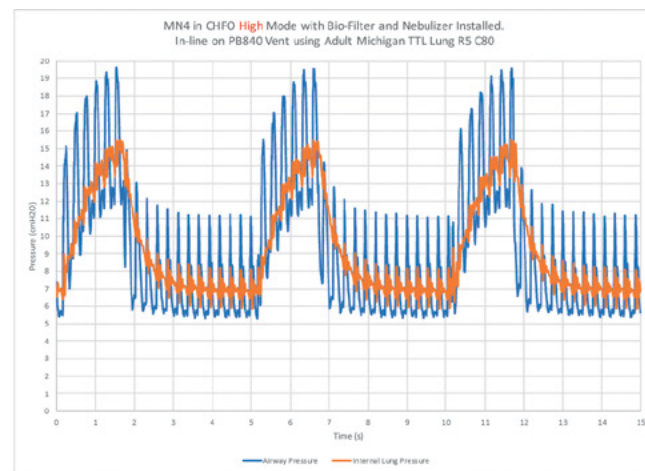
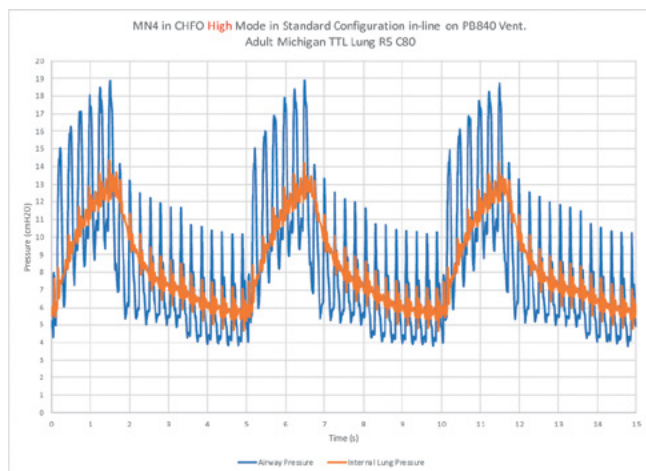
Considerations with the MetaNeb System and Device Filters:

- MetaNeb System therapy can be delivered with aerosol medication or with normal saline through the nebulizer. MetaNeb System therapy can also be delivered without aerosol medication or saline. If no medication or saline is used in the nebulizer, MetaNeb System, therapy will not generate aerosol.
- The MetaNeb System has two filters—The device has a filter screen inside the control unit and a biofilter on the Patient Circuit at the connection to the Control Unit.
 - The Control Unit's filter screen stops particles greater than 0.1mm.
 - The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1% where the particles used in the testing are sodium chloride particles ranging from 0.1 to 0.3 microns. The filter has been tested in accordance with ISO 23328-1:2008. As a reference point, N95 respirators are designed to block 95% percent of 0.3 micron particles.

Adapting the MetaNeb System for Additional Precautions During the COVID-19 Outbreak

For additional protection when used with patients under airborne precautions, additional filters can be added between the handset and patient interface connection as well the nebulizer can be placed between the filter and the patient interface. This system, when used in mechanically ventilated patients provides a barrier that contains the aerosol generated by the therapy within the ventilator circuit.

Side by side pressure results for standard setup versus biofilter setup with the MetaNeb System in CHFO High mode



The options for the use of the MetaNeb System with a filter in-line are as follows:

- 1) The filter is inserted distal to the MetaNeb System handset to contain potentially contaminated aerosol particles (from patient breathing or coughing) within the ventilator breathing circuit. With this configuration, the nebulizer is not used (Alternatively, the nebulizer can be attached with no medication or saline added for therapy Figure 1).
- 2) The filter is inserted distal to the MetaNeb® System handset and the nebulizer is inserted distal to the filter to contain potentially contaminated aerosol particles and prevent aerosolization outside of the ventilator breathing circuit. With this configuration, medication or saline may be added to the MetaNeb nebulizer for therapy (Figure 2).

Figure 1. Handset/Filter Configuration (Designed to incorporate a filter to minimize aerosolization)

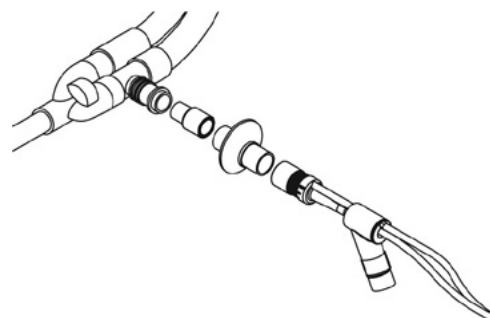
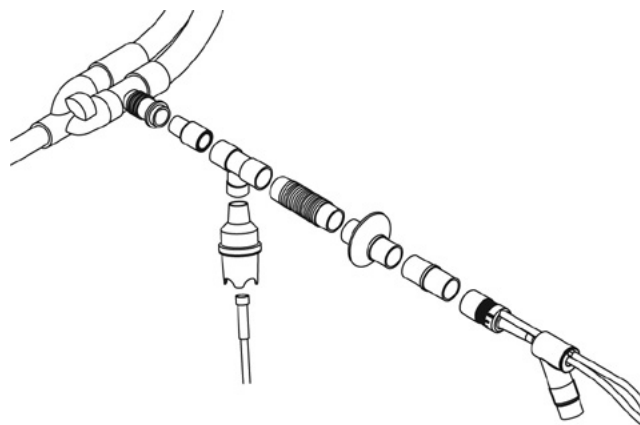


Figure 2. Handset/Filter/Nebulizer Configuration (Designed to incorporate a filter and place a nebulizer distal to the filter to minimize aerosolization)



Testing of the MetaNeb System with this additional filter configuration shows a that placing the additional filter inline has minimal impact on oscillation wave and pressure delivered by the MetaNeb System.

- Important: Limiting aerosol generation using the MetaNeb filter setup assumes that the expiratory outlet from the ventilator is also protected by a biofilter.

Disclaimer: This additional configuration was submitted to the FDA under the recently Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Viral Lung Protection with Filter Masks

Alex Stenzler

With so much in the media and healthcare proclamations surrounding masks for protecting people from the coronavirus, it is important to understand the difference between masks, how they filter, and how to select the mask that serves the desired protection needs. Listening to even scientists on TV about wearing masks reflects the poor understanding of how masks work and the complexity of protecting a person's breathing zone.

Consider masks with valves, which are typically found on many N95 masks. N95 masks can be used for both industrial and medical indications. In most industrial applications where the workers are exposed to harmful particles in the air, N95 masks with valves are frequently preferred. The valve opens only on exhalation, which allows more exhaled heat and moisture to escape the mask, while filtering all of the air that the worker inhales. This makes the mask more comfortable to wear. However, in industries such as the semiconductor industry, where they need to protect the semiconductor from any particles in the worker's breath, they only use N95 masks without valves.

In hospitals, the purpose of a surgical mask or N95 surgical mask is to protect both the healthcare worker from the patient and to protect a patient who is opened on a surgical table from anything in the medical team's exhaled breath. Therefore, these masks don't have exhalation valves. This is reflected in FDA not having approved a surgical mask or N95 surgical mask with an exhalation valve. And therefore, the only indications for use for a surgical mask are for protecting both the patient and the wearer from each other.

In managing patients with COVID-19 or most other diseases outside the operating room, there may be only a need to protect the healthcare worker and therefore, they may use masks with or without valves; however the valved masks are still not FDA cleared. Patients with respiratory infections should only wear

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masks without valves to protect other people. If the only mask available has a valve, hospital personnel may place a procedure mask over that N95 mask with a valve. Doing this maintains the protection of the healthcare worker and also protects other people from droplets in the exhaled breath passing through the valve.

It's important to appreciate that the biological load that a person is exposed to is important in the body's ability to protect itself. Inhaling a few viral particles will probably not harm a healthy person. Considering that an N95 mask only filters 95% of the particles at 0.3 micron, which means that 5% get past the mask; if the 5% of the particles could kill a person, they would be dead. When considering how infectious the coronavirus is, and how much air is moved through the mask when breathing, one might think there are a lot of viral particles inhaled, even with an N95 mask. However, viruses are much smaller than 0.3 micron. The SARS coronavirus was in the range of 0.100-0.130 micron. The recent Novel Coronavirus (2019-nCoV) has been measured in the range of 0.080-0.140 micron. These are much smaller than the 0.3 micron filtration specification of an N95 mask. But it turns out that masks are better at filtering smaller particles as well as particles larger than 0.3 micron particles.

What makes filter masks so effective is that they are non-woven materials and there is no direct path through the fibers that make

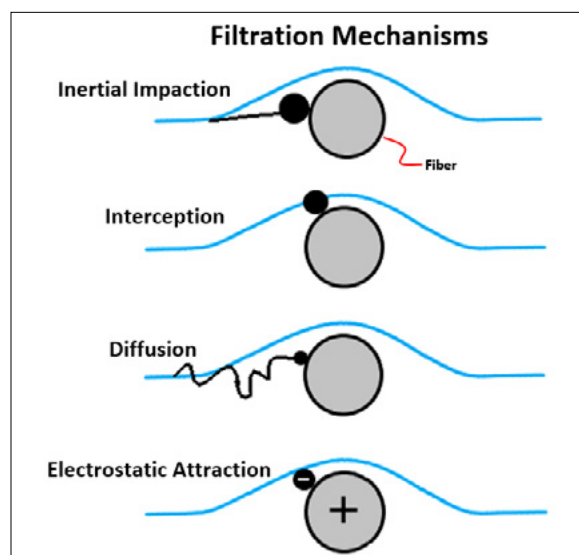


Figure 1. Filtration Mechanisms

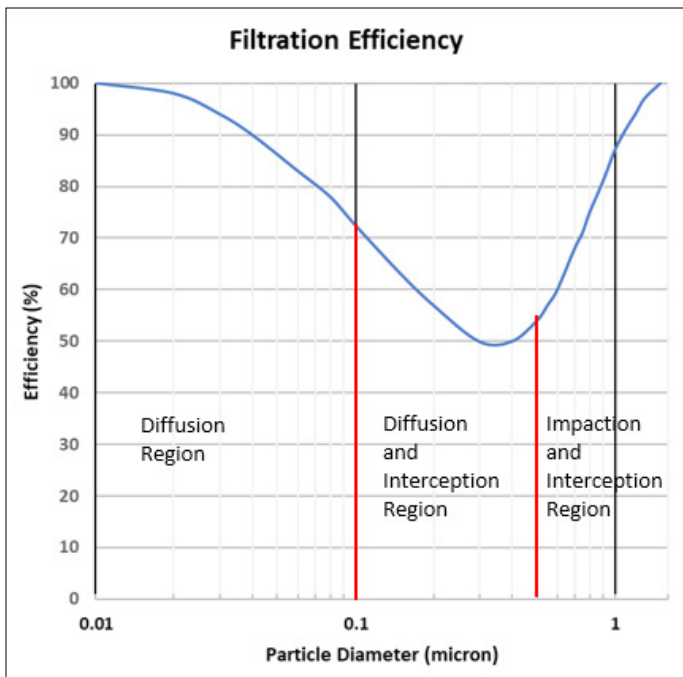


Figure 2. Filtration Efficiency vs Particle Size

up the filtration material. Millions of individual fibers are laid down and bonded together with either heat or chemicals into a flat sheet material. Therefore, the airflow and the particles it carries must turn and weave their way through the tortuous path of the filter media. There are several mechanisms for a respirator mask to stop particles from penetrating through the filter while still allowing the air needed to breathe to get into the lungs.

Most respirators stop particles by either electrostatic attraction (i.e., the particles stick to the mask) or by inertial impaction (the particles slam into the fibers and get stuck). The other two mechanisms include particle interception and diffusion. (See Figure 1). It takes a combination of these mechanisms to provide the maximum protection. N95 masks are like HEPA filters and the more particles they trap, the more efficient they become.

Very large particles in slow moving airstreams may settle out to the ground due to gravity. However, most respirable particles are too small for this mechanism. Respirable particles above 0.5 um in diameter may be captured by inertial impaction and are usually captured when the particle can't make the turn around a fiber due to its inertia and it impacts on a fiber. In the interception mechanism for these slightly larger particles, the particle holds to the streamline, but that streamline will naturally bring the particle close enough to come in contact with the fiber and it sticks. The random bouncing movement of very small particles (around 0.1 microns in diameter) wandering across streamlines due to Brownian motion, cause them to accidentally come into contact with fibers and get trapped because they are too small to be carried away in the airflow. Therefore, it is not the largest or the smallest particles that are the hardest to trap but the particles that are greater than 0.1 micron and less than 0.5 micron. These particles are large enough to be picked up by the airflow, yet small enough to travel with the airflow around most fibers. Particles of 0.3 microns are therefore considered to be the most difficult particles to trap and the object test size for the most stringent requirements for NIOSH certification of an N95 Respirator.

Figure 2 shows the interaction of the different capture mechanisms on one type of filter media (not N95) for the

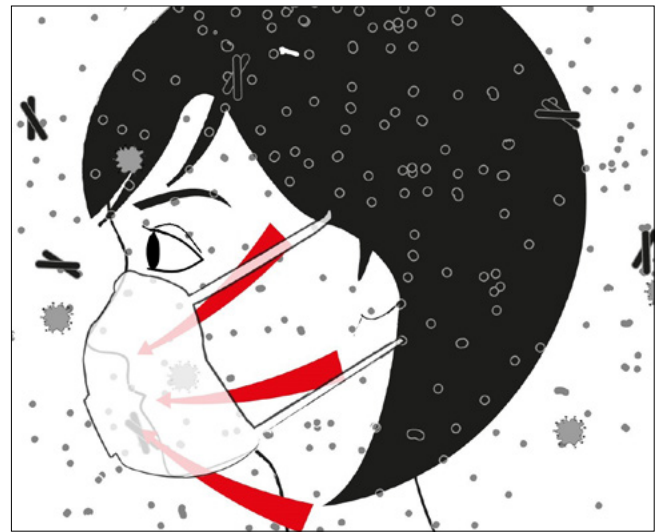


Figure 3. Breathing zone is unprotected when there's a poor facial seal

purpose of illustration. Filtration efficiency is shown as a function of particle diameter. While the filtration efficiencies are not representative of actual filters used in respirators today, which are better, it does demonstrate that most particulate filters have a region of minimum filtration efficiency somewhere between 0.1-0.5 micron. Particles in this range are too large to be effectively pushed around by diffusion and too small to be effectively captured by interception or impaction. Therefore, N95 masks will typically block >99.9% of particles in the virus particle size range, while only capturing 95% of slightly larger particles (0.3 micron).

No matter how good the filter, air always flows through the path of least resistance. If a person is wearing a mask that is not sealed on the edges, the resistance of the filter is higher than the resistance at the edges and they won't be breathing filtered air, but the air coming in the sides (Figure 3). So, the seal to the face is everything. Interestingly, almost all masks will filter 99% of viruses and many pleated surgical masks with ear loops can filter viruses; however, without a facial seal they don't protect the wearer. They still do protect others from large particles exhaled by the wearer. The reason why N95 masks are sought after is not just that they are better filters, but that they are designed to provide a better seal on the face. And this is the reason for fit testing, to assure the facial seal.

Masks for consumers are primarily indicated for people with coronavirus infections (known or asymptomatic) to minimize or eliminate the aerosolization of viral particles in the air from their breath or during coughing. The best protection from inhaling viral particles is to stay away from any environment where there are people with viral infections. Alternatively, if a person must be in that area, wearing a tight, face-fitting mask that filters out fine particles is critical.

Conclusion

While no mask can completely provide lung protection, knowing what particles are in the air and their particle size, can assist in making the right decision to wear the right mask. And independent of the filtration capability of the mask, the facial seal is the most important aspect to assure. Whenever in an environment where other people may have viral infections, everyone should be wearing a mask that can demonstrate that it filters small particles (~0.1 micron) and seals well to the face.

Graphics Analysis During Mechanical Insufflation-Exsufflation and Implications for Improving Cough Effectiveness

Jon O Nilsestuen, PhD and Venessa A Holland, MD

Abstract

Background: Graphics Analysis is used to adjust ventilator settings and improve patient-ventilator synchrony during mechanical ventilation. However, using graphics evaluation to adjust the settings and improve cough technique when using Mechanical Insufflation-Exsufflation (MI-E) has not been the standard of care.

Research Question: The projects primary purpose was to determine if graphics analysis could be used to suggest improvements in the patient-device interface with the goal of improving the ability to clear secretions.

Methods: Data cards were collected over an 18-month period from subjects with neuromuscular disease receiving cough assist support (Philips T70) and referred for monitoring and follow-up. The graphics data was used to evaluate six elements of the cough maneuver including: #1) the inspiratory flow pattern along with mask leaks; #2) target inspiratory pressure; #3) inspiratory time; #4) synchrony of the cough effort; #5) target expiratory pressure; and #6) expiratory time.

Results: The graphics analysis resulted in recommendations for changing at least two settings on 92% of the subjects (n=79). The two most frequent recommendations were related to correcting issues with inspiratory flow including mask leak and adjusting the negative pressure to prevent upper airway collapse.

Conclusions: Historically MI-E settings have been made without any objective method for evaluating efficacy. Graphics analysis supports individualizing the settings specific to each subject and improves peak cough flow. Finally, graphics analysis allows negative pressure titration in bulbar subjects in order to prevent upper airway collapse during exhalation. This approach provides clearance support to a subgroup of subjects in whom MI-E therapy was previously thought to be of little or no benefit.

This paper is written in celebration of the Life and Legacy of Venessa A Holland, MD 12/15/1956 to 2/4/2019 a pulmonary physician extraordinarily devoted to the care of her patients. Principle Investigator: Jon O Nilsestuen, PhD, RRT, FAARC. Institutional Affiliation: Professor Emeritus University of Tx Medical Branch Galveston Tx; Former Director of Research & Education at Respiratory Quality Services (RQS)-Houston Texas; Educational Consultant to Philips/Respironics.

Keywords: Mechanical Insufflation-Exsufflation; Cough Augmentation; Neuromuscular Disease; Peak Cough Flow; Airway Clearance; Noninvasive Ventilation (NIV)

Abbreviations

ALS Amyotrophic Lateral Sclerosis
MI-E Mechanical Insufflation Exsufflation Device
NMD Neuromuscular Diseases
PCF Peak Cough Flow
RQS Respiratory Quality Services;
UA Upper Airway

Introduction

Chronic neuromuscular disease is characterized by progressive respiratory muscle weakness¹ which ultimately leads to decreased vital capacity, a decrease in lung and chest wall compliance, atelectasis and an impaired ability to cough. As a result, progressive neuromuscular diseases (NMD) carry an increased risk of respiratory infection, respiratory failure, and mortality.² Principle aspects of the respiratory support strategy are non-invasive ventilation and airway clearance. Airway clearance can include both peripheral and proximal therapy³ with a wide range of techniques and protocols that have been described in literature. This paper addresses the use of a Mechanical Insufflation-Exsufflation (MI-E) or cough assist device as a proximal airway clearance device and how graphics analysis can be used to increase efficacy.

MI-E was developed to support both the inspiratory and expiratory phases of the cough maneuver. All four phases of the cough⁴ are potentially impacted by neuromuscular disease: 1) deep inspiration limited by advancing inspiratory muscle weakness,⁵ 2) loss of the ability to close the glottis in Amyotrophic Lateral Sclerosis (ALS) patients with bulbar involvement,⁶ 3) rapid compression of gas impacted by expiratory muscle weakness,⁷ and 4) expulsion: measured by the peak cough flow (PCF), and also limited by expiratory muscle weakness. Clinical studies indicate that a PCF ≥ 160 L/min is necessary for mucous clearance.⁸ Patients unable to achieve this critical threshold may develop retained secretions, pneumonia or may require more invasive ventilation.

In general, the device has four primary settings including: 1) inspiratory pressure, 2) inspiratory time, 3) expiratory pressure, and 4) expiratory time. Unfortunately, the majority of MI-E devices do not provide live graphic displays to support optimizing the settings specific to the patient. In contrast,

graphic analysis of pressure, flow, and volume have been used to improve patient-ventilator synchrony during mechanical ventilation since the early nineties.^{9,10} In this context the purpose of this study was to determine if a similar process of graphical analysis could be used to improve the patient-device interface during MI-E, with the goal of improving the PCF and thus the ability to clear airway secretions.

Methods

The graphics initiative received expedited review and was approved by the University of Texas Health Science Center San Antonio Institutional Review Board (approval number NHR 18-766). The study was conducted in accordance with the amended Declaration of Helsinki and performed at Respiratory Quality Services (RQS), a Texas based Home Care and Durable Medical Equipment company focused on providing clinical support services and education to patients with neuromuscular disorders.

The MI-E Device (Philips CoughAssist T70) used in the study automatically records the graphics data in European data format to the internal memory of the device. The graphics can then be downloaded to a secure digital card, uploaded to secure computers and then viewed using the proprietary DirectView Software. The software generates several reports including one that allows visualization of flow, pressure and volume waveforms on an expandable timeline.

We initially set up a bench model with a Michigan Instruments test lung connected to the CoughAssist T70 in order to evaluate basic graphic patterns. We also evaluated cough maneuvers from healthy respiratory therapists employed by RQS. Over time a formal six step graphics evaluation process (see Figure 1) was developed and used for the purpose of improving the settings and refining the subjects cough technique in support of

improved clearance. Each of steps in the SIX STEP process is described in more detail below.

Patients with NMD were referred to Respiratory Quality Services from ALS Clinics in The Houston Medical Center, San Antonio, El Paso and Dallas. All patients prescribed MI-E therapy were eligible for inclusion in the quality improvement project. However, patients with tracheostomies who were receiving invasive ventilation were excluded because of the different nature and settings used in this group. Data cards were collected over an 18 month period (beginning in Dec of 2016) from subjects receiving MI-E support and referred to RQS for monitoring and follow-up.

Graphic Characteristics of Normal Cough

Figure 2 introduces the flow and pressure traces associated with a normal cough effort. The graphic is similar to the display on a mechanical ventilator. With CoughAssist the flow graphic is inverted to focus our attention on the expiratory side of the graphic—specifically the PCF. The inspiratory pressure trace has the same shape and appearance as the pressure trace during pressure control ventilation. With the onset of expiration, you see the appearance of the negative pressure and some pressure fluctuations that result from the subjects' cough efforts and are pressure equivalents of the cough flows seen in the positive flow trace. During the progression of NMD, these negative pressure oscillations begin to disappear consistent with loss of the ability to generate an adequate cough. In addition, as ALS patients lose their ability to tightly close their glottis, the expiratory flow trace becomes smooth, without fluctuations, and is similar to the expiratory limb of a flow-volume loop in pulmonary function testing (a smooth slightly concave curve).

In the center of Figure 2 are a number of vertical lines used to identify the different phases of the breath.

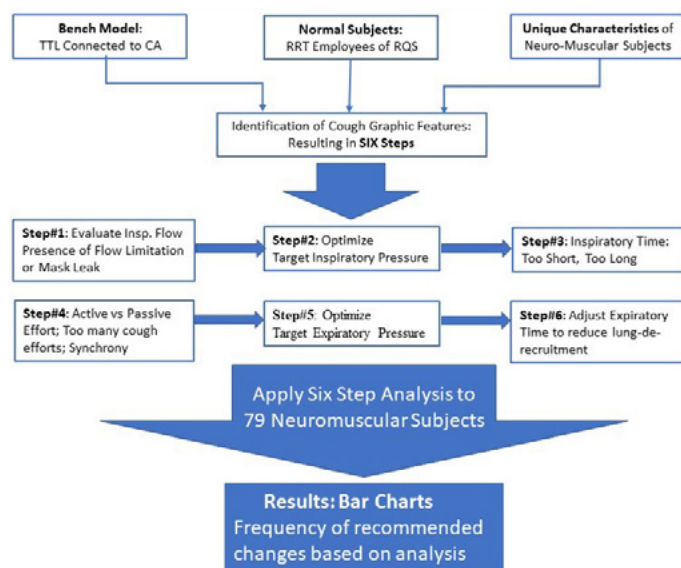


Figure 1. Flow Chart of Graphics Evaluation Process. Process for identification of the Six Steps in the graphic evaluation process. We started with a Michigan Instruments adult test lung attached to the T70 to identify basic graphic waveforms, followed by observation of graphic patterns from normal respiratory therapists employed by RQS. This formed the basis for our initial reviews of subject cough assist patterns. We then added additional steps based on the unique characteristics of NM subjects e.g. adduction, multiple efforts, synchrony, and UA collapse. With the six steps in place we applied the graphic analysis to 79 NM subjects.

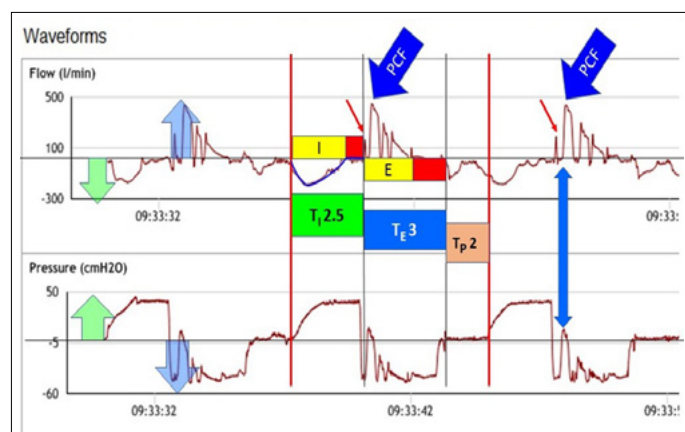


Figure 2. Graphic Characteristics of a Normal Cough. Graphic characteristics of a normal cough as seen on the waveforms display in the Direct View Software. Gas flow is plotted in the top half of the graphic; with inspiratory flow shown in the downward direction (light green arrow) and expiratory flow in the upward direction (light blue arrow). Vertical lines separate the three phases of the maneuver: T_I set at 2.5 sec (green rectangle); T_E set at 3 sec (light blue rectangle); and Pause Time (T_P) (orange rectangle) — determined by the subject when Cough Trak is on. The large dark blue arrows (labeled PCF) represent the first and second cough sequences. The yellow rectangle "E" is the subjects true inspiratory time followed by a short red rectangle — delay time until the end of T_I prior to the beginning of exhalation. Similarly, the yellow rectangle "E" is the time spent exhaling followed by delay until the set T_E is completed. Thin red arrows indicate the gas decompression spike. The double ended light blue arrow indicates flow & pressure spikes associated with glottic closures.

The yellow boxes represent the ideal length of the subject's inspiratory and expiratory flows, while the red bars indicate that both T_I and T_E were set too long. This example is normal in terms of the cough components, however demonstrates that mistakes can be made when the technique lacks the fine tuning from graphics.

One additional piece of important information: the thin red arrows that coincide with the onset of expiration are flow generated by gas decompressing from the circuit and oropharyngeal area at the moment the valve switches from inspiration to expiration. This gas flow generates a small narrow spike (fast time constant) precisely located at the transition from inspiratory positive pressure to expiratory negative pressure. This same feature is common during standard mechanical ventilation⁹ and has also been validated recently by using an external pneumotach inserted into the cough assist circuit.¹¹

Six Step Graphics Analysis Process

Each of the six sequential elements below were selected because they individually impacted the effectiveness of the cough maneuver.

Step #1. Evaluating the Inspiratory Flow Trace for:

- #1A) Inspiratory Flow Obstruction, and;
- #1B) Presence of Mask Leak

The first element in the graphics evaluation process is evaluating the inspiratory flow trace. The flow trace is a normal downward graph with an initial peak inspiratory flow and then a gradual decline in the flow signal based on the algorithm for pressure control. Two abnormal patterns may exist. The first (Step #1A) is an inspiratory flow limitation resulting from passive obstruction or active adduction in ALS subjects—see Figure 3. This characteristic has been described by Anderson and colleagues^{12,13} using trans-nasal fiberoptic visualization. They have suggested significantly lowering target inhale pressure to less than 20 cmH₂O to mitigate the flow limitation. In the future, additional flow control mechanisms might be evaluated to more effectively resolve this issue without reducing the target pressure (note: reducing the target pressure reduces the inspiratory capacity and the potential for an effective cough). As noted in Figure 3 this particular subject was able to achieve sufficient inspiratory flow,

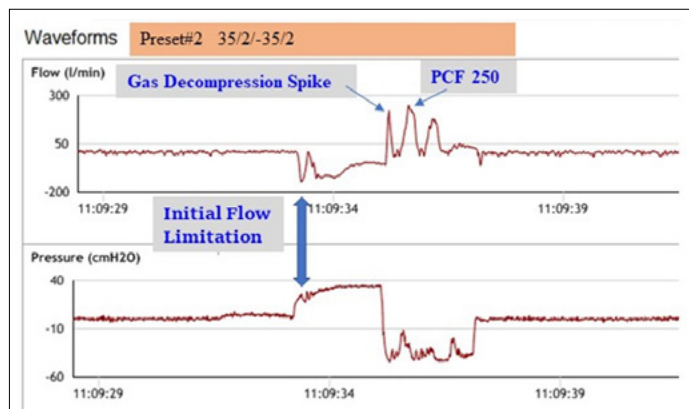


Figure 3. Step #1A: Inspiratory Flow Limitation. Flow Limitation during the inspiratory phase—either as a result of passive obstruction or active inspiratory adduction. The flow limitation is characterized by rapid initial reversal of the inspiratory flow trace with a corresponding pressure spike occurring on the front end of the pressure trace. This is in contrast to the smooth inspiratory flow and pressure patterns seen in normal and non-bulbar subjects (see Figure 4 for comparison of adduction to normal).

despite the initial adduction, to support an adequate PCF. See Figure 4 for comparison of a Normal inspiratory flow pattern vs Adduction.

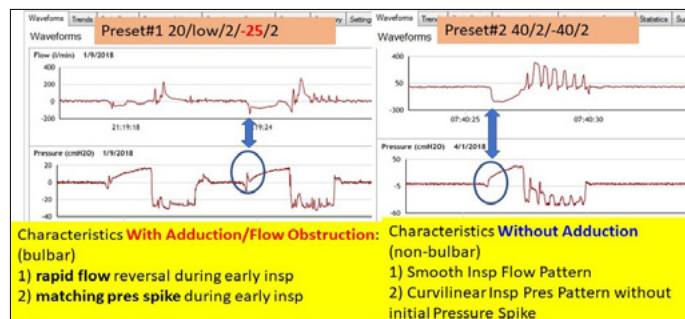


Figure 4. Step #1A: Adduction vs Normal. Left Panel: Inspiratory flow and pressure characteristics associated with flow obstruction/adduction in a bulbar subject; there is rapid flow reversal early on during inspiration accompanied with a sharp spike in the pressure trace. Right Panel: for comparison the flow and pressure graphic from a normal subject indicates a smooth inspiratory flow pattern and a curvilinear inspiratory pressure pattern without an initial pressure spike.

The second abnormal flow pattern (Step #1B) results from the presence of a mask leak—see Figure 5. During the leak the flow trace curves downward to the right, rather than returning to base line. Mask seal is essential in order to achieve adequate inspired volumes to support successful cough efforts. Our study indicates that a large percentage of patients with NMD have difficulty with mask seal requiring assistance from a caregiver to secure the interface during the therapy.

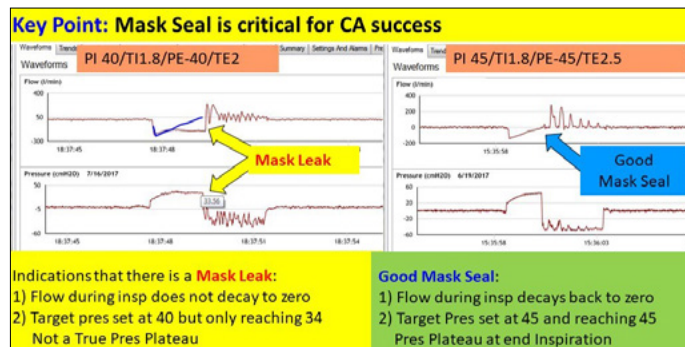


Figure 5. Step #1B: Mask Leak vs Mask Seal. The large yellow arrows in the left panel indicate that flow is not returning to zero as the breath progresses and the pressure trace has not achieved a stable plateau. The overlaid blue line shows the desired trace. In contrast on the righthand portion of the graphic the large blue arrow indicates that there is a good seal and the flow has decayed to zero with the completion of the breath.

Step #2. Setting Target Inspiratory Pressure

Targeting sufficient inspiratory pressure is also essential to achieving adequate PCF. See Figure 6 for supporting graphic illustrating how even moderate changes in target pressure positively impact PCF. A pressure of 30 cmH₂O has been identified as the minimum in order to support clearance,^{14,15} however the most frequently cited target pressure in the literature is 40 cmH₂O.¹⁶ Achieving target pressures above 40 or even as high as 60 cmH₂O or more^{16,17} are possible in managed clinics where practitioners are able to maintain the seal. Achieving mask seal in the home environment where the patient/caregiver administers the therapy can prove to be difficult. As the disease progresses in ALS, increasing peripheral muscle weakness leads to problems controlling mask leak leading to patient frustration and diminished adherence to MI-E therapy.

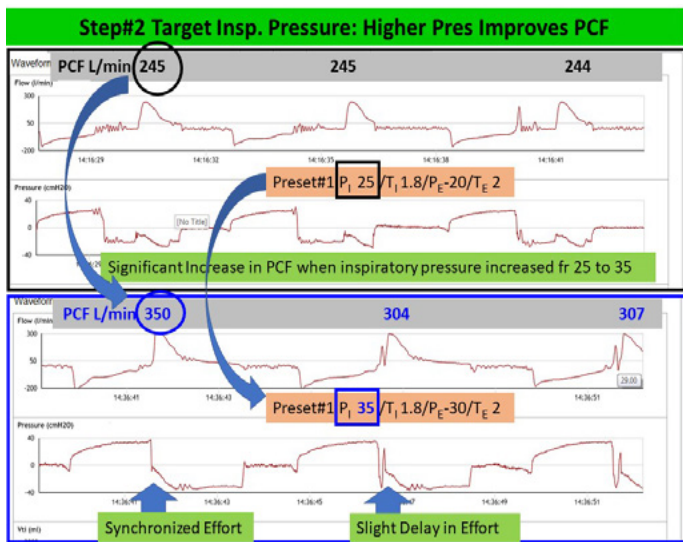


Figure 6. Step #2: Setting Target Inspiratory Pressure. The two orange rectangles indicate a change in the target inspiratory pressure from the initial setting at 25 cmH₂O in the upper graphic, followed by an increase to 35 cmH₂O in the lower graphic. To be complete there were also changes in the negative pressure from -20 to -30 cmH₂O. With correct synchrony the PCF increased from 245 L/Min (top black circle) to 350 L/min (lower blue circle).

Step #3. Setting Inspiratory Time

Subjects require adjustment of the inspiratory time to match the characteristics of their specific lung mechanics and maximum inspiratory capacity. To a great degree the correct T_I is dependent on the subject's height and is consistent with determination of predicted normal values in pulmonary function testing.¹⁸ The two side by side graphics in Figure 7 illustrate cases in which T_I was set too short and too long. A simple way to think of this is the analogy to the professional golf swing. When the golfer steps up to the tee, if the back swing is cut short (insufficient T_I) or if there is a pause at the top of the back swing (T_I too long) it will significantly reduce the result of the drive (reduced PCF).



Figure 7. Step #3: Evaluation of the inspiratory time setting illustrating instances in which the Inspiratory time was set too short (left hand panel) vs inspiratory time set too long (right hand panel). On the left hand panel the dotted horizontal blue line in the flow trace is drawn at the zero flow line. In this subject the inspiratory flow is decaying towards zero as the lung fills, but the breath is cut short (black arrows) by the inspiratory time setting. This subject was very tall with a large vital capacity and needed a longer inspiratory time to complete the breath. On the right hand panel the green rectangle represents the time necessary for the subject to complete their natural inspiratory breath at an inspiratory time of approximately 1.1 sec, however the pink rectangle indicates that the actual inspiratory time setting was 2.5 sec which was too long.

Step #4. Three Elements in the Transition to Expiration

- #4A) Passive vs Active Effort;
- #4B) Repetitive Coughs, &;
- #4C) Synchrony

Three factors occur during the transition from inspiration to expiration and impact the PCF. The first element (Step #4A) is whether the subject exerts active or passive effort. The benefit

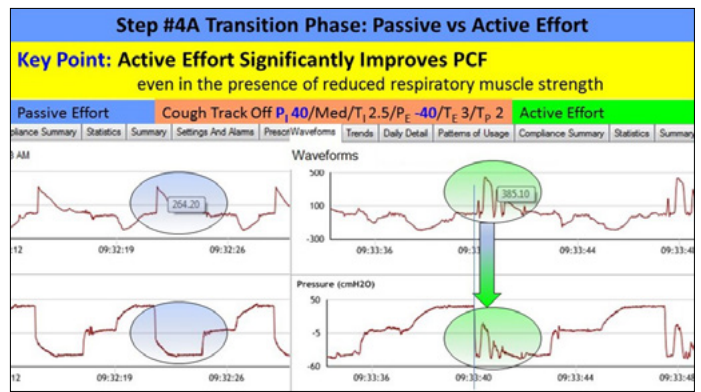


Figure 8. Step #4A: Transition Phase: Passive vs Active Effort. This graphic was from a respiratory therapist volunteer and illustrates the graphic associated with passive effort on the left panel: the traces indicate 1) no glottic closure, and absence of flow spikes in the top trace that are normally associated with glottic closures, and lack of the corresponding pressure spikes in the negative pressure trace; 2) an almost linear decline in the expiratory flow trace; and 3) achievement of a negative pressure plateau towards the end of expiratory time. In contrast the right hand panel demonstrates the characteristics associated with active subject effort: 1) single or multiple glottic closures give rise to expiratory flow and pressure spikes; 2) the first flow spike is usually the highest - starts from the largest lung volume and is associated with the highest lung recoil pressure and best length tension relationship for contraction of the expiratory muscles; and 3) counter pressure spikes are very apparent in the expiratory phase with the application of negative pressure.

of using active effort to support PCF is perhaps obvious (see Figure 8). However, for patients that lose glottic control, they become largely dependent on the target inspiratory pressure to create the gradient for gas flow out of the lung. In these instances the ability to huff adds positive pressure to the passive lung recoil pressure and supports clearance.¹⁹

The second element (Step #4B) is related to the effort portion in that subjects sometimes perform multiple cough efforts (see Figure 9) ranging from 3 to 12+ during the expiratory phase of the cough. Cough efforts beyond the first occur at progressively smaller lung volumes with less elastic recoil and result in smaller PCFs. As a result, we always coach our subjects to focus their effort into one or two maximum cough efforts during the exhalation phase.

The third element (Step #4C) is synchronizing the subject's cough effort with the switch from positive pressure to negative pressure. This is an often overlooked aspect of the Cough

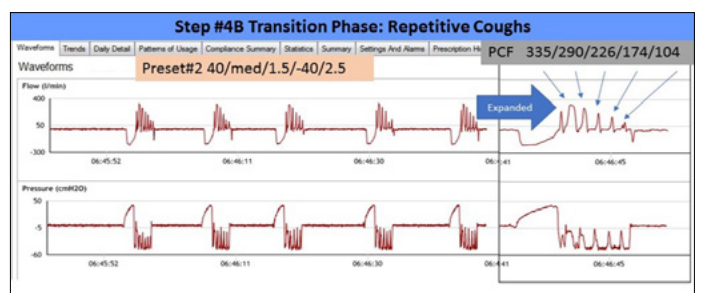


Figure 9. Step #4B: Transition Phase: Repetitive Coughs. Multiple rapid cough efforts reduce the effectiveness of the cough by partitioning the effort into small compressions rather than one or two maximum efforts. The first cough effort produces the highest PCF, while subsequent efforts occur from smaller lung volumes with less elastic recoil and result in lower PCF values. In addition the later efforts are often at PCF values below the minimum of 160 L/min required for clearance and waste precious energy in NM subjects.

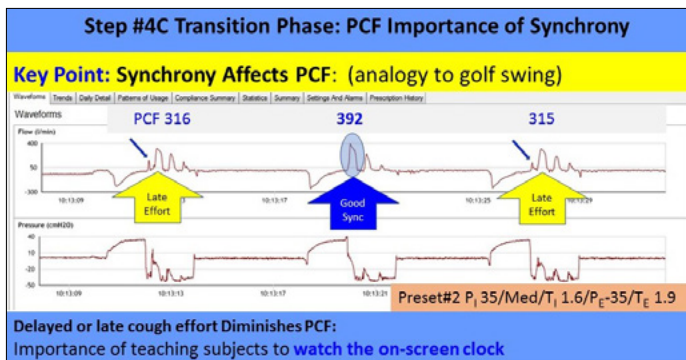


Figure 10. Step #4C: Transition Phase: Importance of Synchrony. The ability of the subject to synchronize their cough effort is important in maximizing the PCF result. The grey bar shows the PCF values for unsynchronized and synchronized efforts. The thin blue arrows identify the gas decompression spike that occurs when the internal valve switches from inspiration to expiration. Subjects can improve their PCF by watching the live screen on the device and timing their effort to coincide with the onset of negative pressure.

Assist maneuver. Asynchrony is easy to spot as a result of separation between the initial gas decompression spike and the subsequent cough effort. As illustrated in Figure 10 when the subject synchronized their effort, the resulting peak flow was significantly higher. We have validated this synchrony effect over many breaths in numerous subjects including normals. Again, this effect is also analogous to the golf swing, where the effort should be one continuous motion from upswing to downswing or inspiration to expiration. The timing of the active cough effort at the point of maximal inspiration is also consistent with the ATS-ERS guidelines for effort during forced Vital Capacity Maneuvers.¹⁸

Step #5. Setting Expiratory Pressure

The literature indicates that by far the predominant strategy for setting expiratory pressure is to balance the magnitude of the negative pressure with the positive pressure,¹⁶ although more recently a panel of experts³ recommended using larger negative pressures than positive pressures based on bench tests involving a rigid upper airway (UA).²⁰ This approach would seem to be challenged by the literature supporting that UA

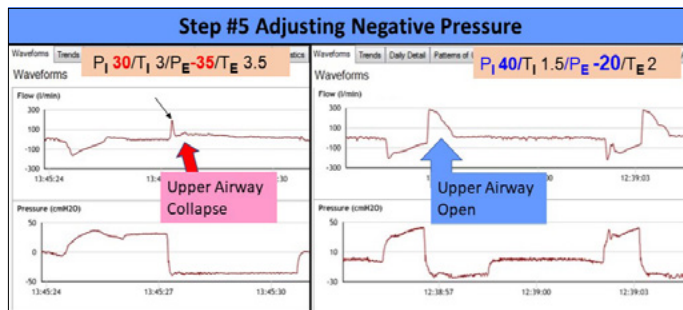


Figure 11. Step #5: Adjusting Expiratory Pressure. The graphic illustrates the result of adjusting the pressure settings on a bulbar subject that was experiencing upper airway collapse during expiration. The collapse is indicated by the thick red arrow in the left-hand panel; the thin black arrow is the decompression spike. On the right-hand panel, after increasing the target pressure from 30 to 40 cmH₂O to support positive lung recoil and reducing the magnitude of the negative pressure from -35 to -20 cmH₂O the collapse was alleviated, and the peak expiratory flow increased to almost 300 L/min.

collapse occurs with relative ease even in normal subjects^{21,22,23} and with as little as 5 cmH₂O of negative pressure.²⁴ The entire purpose of the negative pressure setting is to increase the gradient from the alveolus to the exit of the mouth thus creating the potential for higher flow in support of secretion clearance. This is reasonable in most patients, but results in UA collapse in a substantial portion of bulbar patients. This has been documented by computed tomography²⁵ and fiberoptic visualization.^{12,13} UA collapse renders the device ineffective in these patients leading to frustration and lost compliance. We have instituted a different approach to bulbar subjects by titrating the negative pressure towards ambient until the UA no longer collapses. This approach, combined with a huff cough has resulted in positive results and PCFs considerably above 160 L/min supporting clearance. Figure 11 is an example of a subject that was experiencing complete UA collapse. We were able to reverse this by increasing the target inspiratory pressure from 30 to 40 cmH₂O to support positive lung recoil and by reducing the magnitude of the negative pressure from -35 to -20 cmH₂O. This improved the PCF from a negligible value to nearly 300 L/min.

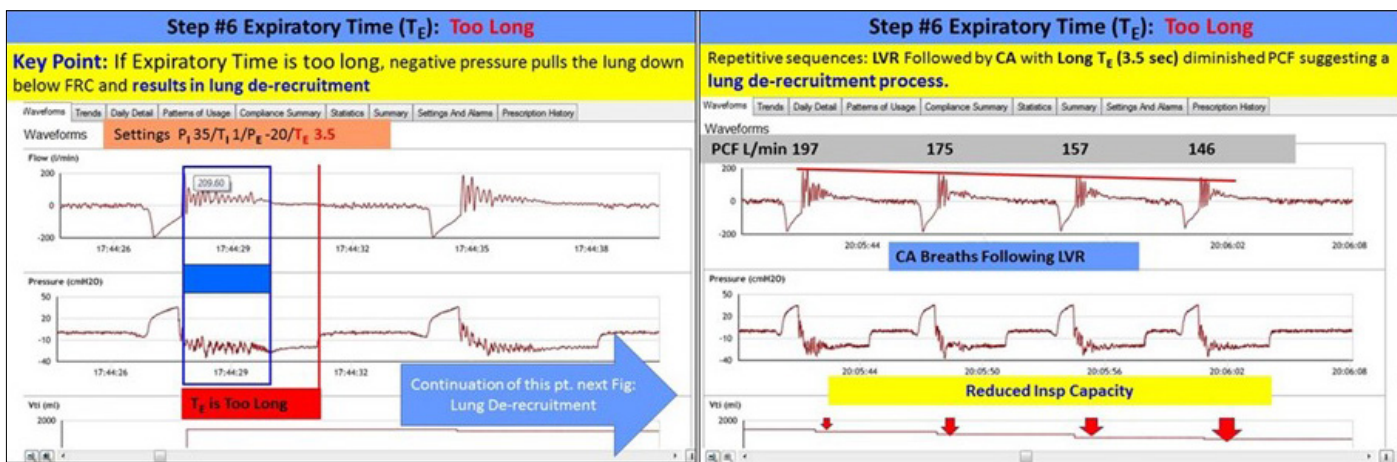


Figure 12. Step #6: Expiratory Time. The red rectangle at the bottom of the left-hand graphic indicates the expiratory time setting at 3.5 sec. The blue bar indicates the time during which there is evidence of expiratory flow. While subjects need time to complete 1 or 2 maximal cough efforts, extending expiratory time much beyond the point at which their FRC is reached runs the risk of lung de-recruitment. The right-hand graphic is from the same subject and shows the result of repetitive cough cycles using an extended expiratory time. The subject initially started the cough assist therapy with a lung volume recruitment maneuver and then followed this by performing 20 or more consecutive breaths during the therapy session. The red line sloping down to the right shows the gradually decreasing PCFs with corresponding values in the grey bar. In addition, the volume trace at the bottom of the graphic indicates that inhaled volumes were diminishing with subsequent breaths — downward pointing red arrows. This diminishing trend was repeated for 30 days in a row suggesting an increased risk for development of atelectasis or lung de-recruitment.

Step #6. Setting Expiratory Time

The last step in our graphics analysis process was evaluating expiratory time. In the past balancing the expiratory time with the inspiratory time was common practice and was considered sufficient. However, application of negative pressure beyond the time needed by the subject to complete 1 or 2 good cough efforts results in potential lung de-recruitment. After the subject has exhaled down to FRC, further application of negative pressure frequently causes UA collapse in bulbar subjects, and in all subjects runs the risk of alveolar de-recruitment. See Figure 12 for an example of a subject in which extended expiratory time resulted in de-recruitment.

Summary Graphic

The last graphic (Figure 13) illustrates many of the composite features that we commonly found in our graphics evaluation process. The following observations were made: inspiratory phase: 1) subject has a good mask seal; 2) target inspiratory pressure was set at 30 cmH2O, however it would be reasonable to increase the pressure to improve inspiratory volumes and PCF; 3) inspiratory time was set too long and contributes to the timing issue; Expiration Phase: 4) the decompression spike is clearly evident and synchrony is an issue indicating the subject would likely benefit from additional instruction; 5) Negative Pressure: this subject has bulbar symptoms and no longer demonstrates pressure spikes associated with glottic closures; however there are noticeable pressure fluctuations associated with active huffing. In light of this finding the patient needs to be followed closely since at some point the bulbar progression will necessitate reducing the magnitude of the negative pressure to prevent upper airway collapse; and 6) the expiratory time seems appropriate allowing the subject to complete their exhalation without excess time that might result in lung de-recruitment.

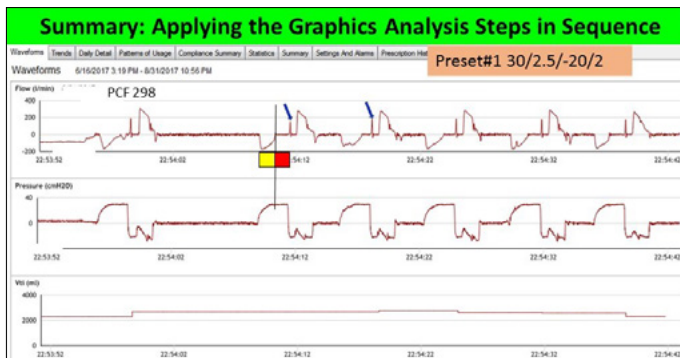


Figure 13. Summary: Application of Six Steps. The following observations were made based on the graphic: Step #1: there is a good mask seal without any apparent leak and no flow obstruction; Step #2: the target inspiratory pressure was set at the minimum value of 30 cmH2O to support clearance, but it would be reasonable to try 35 or even 40 cmH2O to increase inspiratory volumes and improve PCF; Step #3: inspiratory time as seen by the red bar extending beyond the yellow bar is set too long and contributes to the subsequent timing issue; Step #4: the decompression spike is clearly evident and synchrony is an issue (analogous to the golf swing) suggesting that the subject would likely benefit from additional instruction related to watching the timing window on the T70 screen; Step #5-Negative pressure setting: this subject has bulbar symptoms and no longer demonstrates pressure spikes associated with glottic closures. In light of this finding the subject needs to be followed closely since the bulbar progression will necessitate reducing the magnitude of the negative pressure to prevent UA collapse; and Step #6 the expiratory time seems appropriate allowing the patient time to complete their exhalation without excess time that might result in lung de-recruitment.

Results of Graphics Data Analysis

The six-step graphics analysis process was applied to a study population consisting of 79 subjects with ALS; 47 males and 32 females. See Demographics Table 1.

Two figures are included below expressing the results of this process. Figure 14 indicates the percentage of subjects with recommendations for each of the six different features observed in the graphics analysis. The two most frequent observations in the study group were: Step #1 58% -presence of leak/gas flow limitations during inspiration and Step #5 (68%) -need to adjust the negative pressure setting -frequently by reducing the negative pressure to prevent upper airway collapse (52%). Increasing target inspiratory pressure was based on the recommended target pressures of 35 to 40cmH2O and most common practice.¹⁶ Inspiratory pressure and leaks are related events, in that the progression of muscle weakness makes it more difficult for patients to maintain their mask seal; and as the pressure is increased the leak is often more apparent. There is also a relation between inspiratory time and synchrony, since short or prolonged inspiratory times make it difficult for the patient

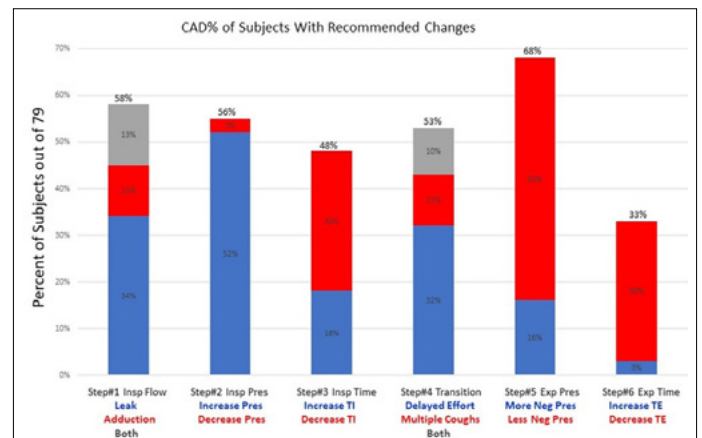


Figure 14. Percentage of subjects with recommended changes. Step #1: 34% of the subjects had evidence of mask leak during inspiration; 12% showed evidence of inspiratory flow limitation only; and 13% had evidence of both inspiratory flow limitation and mask leak; Step #2: recommendations were made to increase the target inspiratory pressure setting in 52% of subjects (this was based on evidence of a tight mask seal without leak at the minimum setting of 30 cmH2O and suggesting increasing the pressure in the 35 to 40 cmH2O range to support improved PCF; Step #3: recommendations were made based on the inspiratory flow trace to increase inspiratory time in 18% of subjects (flow trace was cut short before returning to the zero flow line) and decrease inspiratory time in 30% of subjects based on flow returning to the base line with a zero plateau prior to the end of inspiration; Step #4: During the transition from inspiration to expiration: we were in general not able to make recommendations about patient effort based on the graphic since this is best determined by patient observation and we were only evaluating SD cards returned to the home base; however we were able to make recommendations about delayed effort (32% of subjects); too many cough efforts (11% of subjects) and both delayed effort and too many cough efforts (10% of subjects); Step #5: Setting expiratory pressure: in a small percent of subjects (16%) we recommended an increase in the magnitude of the negative pressure when there was no evidence of UA collapse, in order to balance the inspiratory pressure and increase the PCF; while a much larger number of subjects (52%) had evidence of UA collapse in which case we recommended reducing the magnitude of the negative pressure to prevent the collapse; Step #6: Expiratory Time: in 3% of subjects we recommended an increase in the expiratory time when it was apparent that significant flow was still occurring at the moment that expiratory time terminated; however in 30% of subjects we recommended reducing expiratory time because expiratory flow had already returned to base line and further application of negative pressure would increase the likely hood of lung de-recruitment.

Table 1. Subject Demographics

	Number of ALS Subjects	Males	Females	Aver Age	Evidence of Insp Obstruction	Evidence of UA Collapse	Use of NPPV
With Bulbar Involvement	40	24	16	62	19	32	40
Without Bulbar Involvement	39	23	16	63	0	9	37
Totals	79	47	32	62	19	41	77

to coordinate their expiratory effort. Note we were not able to report on active subject effort during the transition phase since this is best determined by onsite observation.

Figure 15 left panel indicates the distribution of recommendations for changes in the cough assist settings, with the highest number of subjects receiving three recommendations. For the 79 total patients in the study group, only one subject had ideal settings with no recommendations for changes. Expressing the same data in a slightly different fashion, Figure 15 right panel indicates that 92% of subjects had recommendations for 2 changes or more; and 71% had recommendations for 3 changes or more emphasizing just how frequent the recommendations for improvement were.

Discussion

To our knowledge there are no journal publications addressing how graphics specifically from the MI-E device (without external transducers) can be used to improve PCF. In lieu of this information, the common practice is to use the settings recommended by the manufacturer with target pressures of 35 to 45 cmH₂O and inspiratory and expiratory times in the 2 to 3 second range. Our study indicates that ordinary or “standard settings” are in many cases inappropriate and we strongly suggest that the settings should be customized as they are during mechanical ventilation.

Further supporting the use of an individualized approach are the variation in symptoms associated with patients that have ALS. Traditionally they are classified as predominantly limb onset (symptoms begin in the arms or legs) or bulbar onset (difficulty with speech or swallowing). With progression of

the disease, both groups develop symptoms during the later stages characteristic of the other type. As it pertains to the ability to clear secretions several factors including inspiratory flow limitation and UA collapse during expiration represent significant hurdles and complicate MI-E necessitating customized therapy.

The progressive nature of the disease also supports regular monitoring and individual adjustments to the MI-E device from initial set up to hospice. We propose that graphics analysis should be used to optimize the patient’s PCF and then repeated at reasonable time increments to account for the gradual decline in the patient’s condition. We believe once a month is a reasonable frequency, but this would also depend on the patient’s rate of decline. Maintaining optimum settings is likely to translate into additional ventilator free days and improving the quality of life.

There were two important limitations of the study: lack of a live graphics display on the device makes the entire process time consuming and inefficient; and there are flaws in the current PCF statics reporting in the software preventing us from providing more complete before and after PCF results. We hope to collect these for a future article.

Conclusion

In our experience we have found the use of graphics analysis to be an essential tool for adjusting device settings and suggesting improvements in subject technique in order to maximizing the benefit of the device. This approach is applicable to all patients regardless of diagnosis. Each of the six elements/steps in the evaluation are summarized in Table 2.

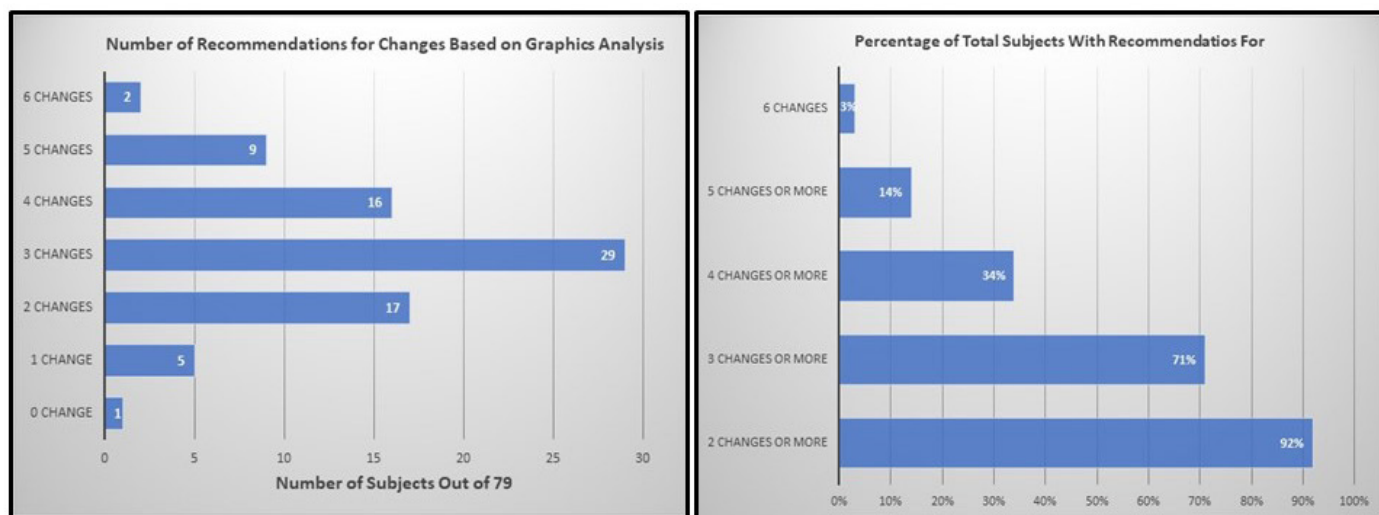


Figure 15. Number and percentage of recommendations. Left panel-number of subjects (out of 79) that had recommendations based on the six step analysis for zero changes, 1 change, 2 changes and up to 6 changes with the highest number of subjects receiving recommendations for 3 changes. Right panel -percentage of total subjects that had recommendations for at least 2 changes or more (92%), followed by percentage with at least 3 recommendations or more (71%), 4 recommendations or more (34%) and so forth.

Table 2. Graphic Recommendations During Non-invasive Use of Mechanical Insufflation-Exsufflation

Step #1. Evaluation of the inspiratory flow pattern for presence of flow limitation and mask Leak. Flow limitation is currently addressed by using the low flow setting and reducing target inspiratory pressure. Mask Seal is critical for success when using MI-E and is easily identified in the flow trace. Progressive muscle weakness with neuromuscular disease requires that the caregiver provide assistance to help with the interface seal at some point.

Step #2. Setting adequate target pressures is important in reaching maximum inspiratory capacity from which to initiate the cough. Starting at low pressures of 20 to 25 cmH₂O is fine for initial training, but by the end of the session should reach a minimum of 30 cmH₂O, the minimum value reported to support clearance. Higher pressures of 35 to 45 are encouraged and some patients may even require more pressure when secretions are increased or thickened.

Step #3. Inspiratory time needs to be individually adjusted by observing the flow trace. Taller patients require longer T_I to reach inspiratory capacity. The majority of adult patients will require somewhere between 1.5 and 3 seconds based on their inspiratory capacity; slightly longer times may be required when using the low flow setting.

Step #4. Active effort is important for maximizing the PCF. For patients unable to close their glottis they should be taught to huff cough. One or two good cough efforts are recommended; multiple efforts are often below the PCF required for clearance and waste precious energy. Synchronizing the cough effort with the onset of the negative pressure improves PCF. Patients should be taught to watch the onscreen graphic to guide initiation of the cough.

Step #5. For Non-invasive use of the MI-E, negative pressure can be set to balance positive pressure. However, in ALS patients and especially those with bulbar weakness, positive pressure should be optimized, and the negative pressure should be of smaller magnitude and titrated to prevent UA collapse.

Step #6. Expiratory time should be set to allow the patient time for one or two maximal cough efforts. In the vast majority of patients this can be accomplished in 1 to 2 sec. Expiratory Time beyond this pulls the lung down below FRC and increases the risk of lung-de-recruitment.

While observation and communication with patients are important, graphics analysis adds an objective measure for guiding adjustment of the settings and coaching patient technique. In addition, graphics analysis represents a non-invasive alternative to endoscopy procedures for identifying the presence of inspiratory flow limitation and expiratory collapse in bulbar ALS and for monitoring or evaluating adjustments for improving MI-E therapy. We have had graphics capabilities since the early nineties, but we desperately need on screen graphic tools for clinicians to make smart decisions at the bedside, and clinicians need to be trained to interpret the graphics. Until such time as on-screen graphics are available, we strongly recommend the use of laptop computers to facilitate timely adjustments and maximize cough effectiveness while in the home.

Acknowledgements

We wish to acknowledge Alex Duarte, MD, Pulmonologist at UTMB that reviewed the initial paper for suggested improvements and reduction in the length of the paper, as well as Greg Holt, PhD, Carlayne Jackson, MD and Pamela Kitrell, MSN for their assistance with IRB approval at the UT Health Science Center in San Antonio, and for reviewing the initial draft paper.

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Notation of Prior Abstract Publication/Presentation

Portions of the project have been presented by the principal investigator at the following three conferences:

- 1 ALS Clinical Conference Fort Worth TX 10-25-2018
Platform Presentation: *Graphic Analysis of Flow and Pressure on MI-E Improves Peak Cough Flow and Prevents Airway Collapse.*
- 2 Univ TX Health Science Center San Antonio Spring Seminar 3-16-2018
Platform presentation: *Cough Assist-Using the Flow and Pressure Graphics to Improve patient Outcomes*
- 3 Motor-Neuron-Disease-Association 28th International Symposium on ALS/MND: Boston Mass (12-9-2017)
Platform Presentation: *Cough Assist-Using the Flow and Pressure Graphics to Improve Patient Outcomes*
Poster Presentation: *Case Series: Graphic Analysis Allows Titration of Negative Pressures During MIE to Prevent Airway Collapse in Bulbar Patients*

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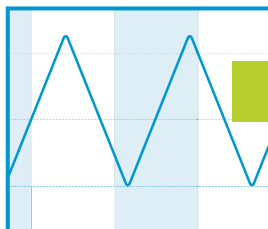
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Chronic respiratory patients getting treatment **but not feeling better?**

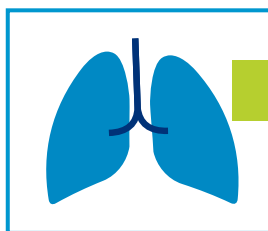
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1 The Philips InCourage system triangle waveform technology **clears more mucus than** competing technology¹



Triangle waveform

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1. Milla CE, Hansen LG, Weber A, Warwick WJ. High frequency chest compression: effect of the third generation waveform. Biomed Instrum Technol 2004; 38:322-328. Note: 8 CF comparing triangular waveform vs. sine waveform technology.
2. Data from RespirTech’s bronchiectasis patient outcomes program. Methodology: As of 6/30/19, self-reported data from over 16,000 bronchiectasis patients.

Evaluation of Pre-Analytical Error-Management and Interference Detection on the GEM® Premier™ 5000 at CHR Citadelle (Belgium)

A Randazzo and J De Marchin

Background

The GEM Premier 5000 [Instrumentation Laboratory (IL)] is a new acute care blood gas analyzer that provides rapid analysis of whole blood samples at the point of care or in a central laboratory. This analyzer contains an all-in-one cartridge PAK to provide quantitative measurements of pH, pCO₂, pO₂, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O₂Hb, COHb, MetHb, Hhb, sO₂) parameters. These measurements (and derived parameters) aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.

Introduction

Interfering substances and other pre-analytical factors are common causes of error in laboratory testing. The ability of the analytical system to detect errors and alert those who operate them when an error is encountered is critical in the clinical setting. This evaluation tested the performance of three blood gas analyzers—GEM Premier 5000 (IL), GEM Premier 4000 (IL) and ABL90 (Radiometer) in the presence of common sources of error including interfering substances and micro-bubbles in the sample for syringe and capillary devices. The test was performed in a clinical setting at the CHR Citadelle Hospital (Belgium).

Methods and Materials

Results from whole blood samples spiked (n=3) with selected interfering substances were compared against control samples (n=3) as specified in CLSI EP 07-A2 “Interfering Testing in Clinical Testing” guidelines. Observed bias was compared against acceptance criteria derived by CLIA recommendations. The capability of the systems to identify the observed bias was also included in the analysis.

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For the micro-bubble test, bubbles were introduced in whole blood samples by micro syringe (capillary device) or by agitation (syringe device). Twenty (20) replicates for syringe and ten (10) for capillary were run in each analyzer. Results were compared against samples that were not affected by the micro-bubbles. Observed error was compared against the acceptance criteria. Overall system performance was also included in the evaluation.

All tests were performed by clinical personnel at the CHR Citadelle Hospital.

Results and Discussion

Interference test results indicated that the GEM Premier 5000 and 4000 were not meaningfully affected by some of the tested substances (maltose and mannose) and that iQM/iQM2 was able to detect and flag results that were compromised by interfering substances. Furthermore, for the benzalkonium interference test, GEM Premier systems were able to detect and notify the user of the interfering substance. ABL 90 was not able to detect certain sources of error and, therefore, reported incorrect results without flags or notifications to the user. A summary of the results obtained during the evaluation are included in Table 1.

Results from the micro bubble test in syringes indicated low effect on the GEM Premier 5000 and 4000 where 10-20% were rejected or flagged and no incorrect results were reported. In contrast, the ABL 90 demonstrated a major effect with microbubbles which caused a high number of samples affected by sample rejection or flagging (~60%) and 3 unflagged incorrect results were reported by the system. A summary of the test results is included in Table 2.

Micro bubbles in capillary test show a major effect across all systems. All samples were rejected due to “insufficient sample” by the GEM Premier 5000 and 4000 (note that in many cases, the sample aspiration process would stop once the bubble was encountered, preserving the remaining sample). For the ABL 90, 30% samples were rejected due to “air detected in sample” and 70% of samples were reported and flagged with “?”.

Table 1. Results from the interference test. Results outside acceptance criteria were highlighted.

Interfering Substance (tested concentration)	Affected analyte (Allowable Error)	Observed bias on IL GEM Premier 5000	Observed bias on IL GEM Premier 4000	Observed bias on Radiometer ABL90
Benzalkonium (20 mg/dL)	Sodium (4 mmol/L)	4 mmol/L	5 mmol/L (detected by iQM)	13 mmol/L (NOT detected by system)
	Potassium (0.5 mmol/L)	0.4 mmol/L	0.4 mmol/L	1.3 mmol/L (NOT detected by system)
	Chloride (5 mmol/L)	0 mmol/L	-1 mmol/L	0 mmol/L
	Calcium (10%)	16% (detected by iQM2)	11% (detected by iQM)	20% (NOT detected by system)
Lipids as Triglycerides (5%)	total Hemoglobin (10%)	20% (detected by iQM2)	13% (detected by iQM)	39% (detected by system)
Galactose (50 mg/dL)	Glucose (10%)	4%	5%	0%
	Lactate (0.4 mmol/L)	-0.1 mmol/L	0.0 mmol/L	0.1 mmol/L
Mannose (40 mg/dL)	Glucose (10%)	9%	7%	4%
	Lactate (0.4 mmol/L)	0.1 (mmol/L)	0.0 (mmol/L)	0.1 (mmol/L)

Table 2. Results from the micro-bubbles test on syringe device.

Tested system	Samples rejected	Samples flagged	Incorrect results reported
IL GEM Premier 5000	2 (10%) as "insufficient sample" error	3% results flagged (5 out of 198): • One iQM2 IntraSpect error for Na ⁺ and Hct • Three iQM2 Absorbance errors for tHb	No incorrect results reported
IL GEM Premier 4000	4 (20%) as "insufficient sample" error	0 (0%)	No incorrect results reported
Radiometer ABL 90	4 (20%) as "air detected error"	38% results flagged (61 out of 160) with "?". All analytes were affected. Internal data listed the observed error: "Inhomogeneous sample", "Insufficient sample", "Turbidity Error", "Sensor response error", etc	3 incorrect values reported: • Glucose: 96 instead of 116 mg/dL – 17% error • Glucose: 94 instead of 116 mg/dL – 19% error • tHemoglobin: 10.7 instead of 12.2 g/dL – 12% error

Conclusion

The results obtained during the evaluation demonstrate that the IL GEM Premier 4000 and 5000 with iQM/iQM2 have the ability to detect errors and provide immediate and clear notification to users. This scheme helps avoid the potential for negative clinical consequences due to pre-analytic factors at the point of care.

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Oral Endotracheal Tube Fastener with Tube Protection Sleeve: An Intensive Care Prospective Study

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Abstract

Rationale: Endotracheal tube design has advanced to include a pilot line and subglottic suction. AnchorFast Guard Select oral endotracheal tube fastener (Hollister Incorporated, Libertyville, Illinois) is an oral endotracheal tube fastener with an integrated tube protective sleeve. This design accommodates and helps protect the endotracheal tube and pilot line while allowing for the subglottic suction to remain consistently patent.

Objective: Assess the acceptability and usability of study product AnchorFast Guard Select oral endotracheal tube fastener by clinicians caring for orally intubated patients using an endotracheal tube with the integrated subglottic suction.

Methods: Open-label, prospective, observational clinical study conducted in intensive care unit settings at four hospitals in the United States. Eligible patients who met enrollment criteria had one study device placed. Study device remained in place until no longer deemed required by a clinician. Patient care was consistent with standard health care practices; no treatment was withheld or altered during the study.

Results: In 93% (28/30) of subjects evaluated, clinicians stated it was easy or very easy to apply study product to the patient's face. In all cases, clinicians noted no damage to the endotracheal tube, pilot line, or subglottic suction lumen while the study device was in place. All clinicians agreed the protective sleeve's ability to maintain endotracheal tube patency by preventing occlusion of the endotracheal tube was acceptable.

Conclusions: No new or additional risks with use of the study device were noted. The majority of clinicians indicated positive acceptability to overall experience of patient care with the study device.

Introduction

Endotracheal intubation is a common procedure in the intensive care unit (ICU) wherein a flexible tube is inserted into the trachea through the mouth.^{1,2} The primary purpose is to establish and maintain an open airway to allow for ventilation and oxygenation of patients with acute respiratory failure. Typically, the endotracheal tube (ETT) is secured to the patient with adhesive tape or a commercial tube holder.² The ETT itself is often held in place via a holding mechanism that possibly includes adhesive, yet the integrity of the ETT is often at risk due for oral trauma because of the lack of protection inside the mouth.^{1,2} Depending on the patient's mental status, the ETT and/or pilot line can be damaged due to trauma caused by chewing or the patient biting the ETT. This can create an emergent leak in the closed circuit between the patient and the ventilator, requiring emergent ETT replacement. In addition to the ETT and pilot balloon (cuff inflation tube), many endotracheal tubes now also provide subglottic suction to help reduce the incidence of ventilator associated pneumonia. To address potential damage to any of the aforementioned tubes, AnchorFast Guard Select oral endotracheal tube fastener with an integrated tube protection sleeve, was developed to accommodate the endotracheal tube, pilot line and subglottic suction lumen. The objective of this clinical study was to assess the acceptability and usability of AnchorFast Guard Select oral endotracheal tube fastener by clinicians caring for orally intubated patients using an ET tube with integrated subglottic suction capability. In this study, the term 'clinician' refers to all healthcare providers (physician, respiratory therapists and nurses).

Methods Study Product

The study product, AnchorFast Guard Select oral endotracheal tube fastener, is an oral endotracheal tube fastener with a tube protection sleeve (ie, bite block) designed to help reduce the potential incidence of damage or occlusion of ET tubes with an integrated subglottic suction lumen and cuff inflation tube (pilot balloon). The study product is indicated for use by healthcare professionals in securing oral endotracheal tubes ranging in size from 5.0 to 9.0 mm inner diameter and endotracheal tubes with integrated subglottic suction lumen sizes 6.0 to 8.0 mm inner diameter (AnchorFast oral endotracheal tube fastener portfolio website: www.hollister.com/en/anchorfast). The suitability of the oral endotracheal tube fastener must be assessed for each patient. Endotracheal tube holders are categorized as Class 1

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Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> 18 years of age or older and require oral tracheal intubation with subglottic ET tube size 6.0-8.0mm. Required the use of a bite block per the hospital's standard of care Had intact skin on and around application site, including cheeks and lips Oral cavity was free of open sores, ulcers, wounds, and lesions Subject or LAR was able to provide informed consent for the study Qualified to participate in the opinion of the Investigator, or designee 	<ul style="list-style-type: none"> Had actual or perceived loose teeth, was without teeth, or was unable to wear upper dentures. Had facial hair that interferes with the adhesion of the skin barrier pads Had a clinically significant skin disease or condition, or damaged skin on the application site, such as psoriasis, eczema, atopic dermatitis, active cancer, sores, sunburns, scars, moles Had a medical condition, surgery or a procedure that prevented the proper application of the study product, including placement of the neck strap. Had a known or stated allergy to adhesives Concurrently participating in any clinical study which may affect the performance of the study product

medical devices in the United States and the study product bears a CE mark. Figure 1 displays an actor portrayal of wearing the study product with an ET tube with subglottic suction lumen and pilot line.

Study Design and Procedures

This was an open-label, prospective, observational clinical study where patients in ICU settings at four different hospitals in the United States who met eligibility criteria were enrolled as subjects in this study. One hospital was located in Fresno, California (Community Regional Medical Center) and the three

Table 2. Patient Demographics at Enrollment

	n; %
Number of completed subjects	30
Gender (Male/Female)	17/13; 57%/43%
Age (years) [average; range]	52.5; 21 – 84
BMI (kg/m ²) [average; range]	28.9; 18.2 – 41.6
Size of ET tube with subglottic suctioning	
7.0 mm	6; 20%
7.5 mm	16; 53%
8.0 mm	8; 27%
Reason for intubation	
Respiratory failures / Pending respiratory failure	21; 70%
Post-operative	0; 0%
Other*	9; 30%
What type of subglottic suction was being used for this subject at the time of study product application?	
Low intermittent wall suctioning suction range 80-135mmHG	16; 53%
Continuous suctioning suction range 20-100mmHG	10; 33%
Manual suction	4; 14%

BMI: body mass index

*Sepsis; Cardiac arrest; Respiratory distress (x2); Airway protection (x5)



Figure 1. Actor portrayal of wearing an AnchorFast Guard Select oral endotracheal tube fastener, with a ET tube subglottic suction lumen and pilot line.

remaining hospitals were part of the Legacy Health system (Mount Hood Medical Center in Gresham, Oregon; Emanuel Medical Center in Portland, Oregon; and Good Samaritan Medical Center in Portland, Oregon). The study objective was to assess the acceptability and usability of the study product where ET tubes had subglottic suctioning capability sizes 6.0-8.0mm. Each subject wore one study product until it either needed to be changed or was no longer deemed required by the clinicians. Patient care was consistent with standard health care practices. All clinicians received training as per the protocol and followed instructions for use for the study product. Per protocol, no treatment was withheld or altered during the course of the study.

Consent was obtained either directly from the subject or, if the subject was unable to provide consent, by their Legally Authorized Representative (LAR; typically a family member). Subjects were then screened, and if qualified for the study, enrolled in the study. Subject demographic data were collected at enrollment. Assessments of the study product, and of the subject's well-being while wearing the study product, were collected at time of study product application, at each clinician shift during study product use, and at time of study product removal.

Ethics

This study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki (Declaration of Helsinki). The study was reviewed and approved by each clinical site's local Independent Review Board (IRB); all IRB documentation has been archived within the study files. The consent and Health Insurance Portability and Accountability Act of 1996 (HIPAA) Authorization processes were conducted as described in the study protocol (ClinicalTrials.gov NCT03328182, full protocol available at <https://clinicaltrials.gov/ct2/show/NCT03328182>). A copy of the fully executed Informed Consent was provided to all subjects.

Subjects

Subjects who were 18 years or older and deemed by the study investigators to be appropriate for an endotracheal tube holder with bite-block were eligible for this study. In order to be eligible for participation in this study, each participant had to meet the inclusion and exclusion criteria presented in Table 1.

Table 3. Experiences applying the study product

Question	Positive Response
How easy was it to apply the study product to the face?	28 of 30; 93%
How easy was it to place/insert all three tubes (ET, pilot line, and subglottic lumen) into the protective sleeve?	25 of 30; 83%
How easy was it to snap and click the clamp of the study product after wrapping the ET tube with the strap?	27 of 30; 90%
How securely was the ET tube held in place by the strap and clamp of the study product?	28 of 30; 93%
How easy was it to shuttle the study product from side to side at time of application?	27 of 30; 90%

Study Outcomes

The study objective was assessed via outcomes relating to study product application, ETT placement into protective sleeve, security of ETT, ETT shuttling, oral care, ETT functioning, capability of protective sleeve to protect ETT, integrated subglottic suction lumen, and cuff inflation tube (pilot balloon), and study product removal. Overall acceptability relating to general clinician experience with the study product was also captured.

Data Collection

Electronic Case Report Forms (eCRFs) created by the Sponsor were administered via the use of a cloud-based 21 CFR Part 11 compliant Electronic Data Capture system (Medrio EDC, San Francisco, California). Edit checks on the eCRFs were implemented to enforce data entry guidelines, data consistency, and compliance to the protocol and regulatory requirements. All study data were reviewed for accuracy prior to release for data analysis.

Data Analysis

The analyses datasets included data from enrolled subjects only; subjects who were not enrolled (ie, subjects who consented but failed screening) or withdrew due to improper enrollment were excluded from analysis. Study data were summarized using standard descriptive measures—frequency and percentage for categorical outcomes; average, standard deviation, and range for continuous outcomes. Statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, North Carolina).

Sample Size

Thirty subjects were targeted for this study based on a literature review of two comparable studies and the FDA Human Factors Guidance.^{3,5} Both studies aimed at comparing effectiveness of ET tube securement techniques. In the first study, a power analysis was performed before subject enrollment that determined 17 subjects would need to be enrolled to show a difference of one standard deviation from the mean between the two fixation techniques at 80% power and 5% type 1 error. The sample size of 30 subjects was chosen to increase the power of results and include a larger variety of patients undergoing different surgical procedures.³ The second study, a randomized controlled study, included a sample of 90 patients with 30 in each arm to compare the effectiveness of three ET tube securement techniques (Twill, Adhesive, and Simple Bow) with respect to ET tube slippage, external jugular pressure measurement, oral mucosa and facial integrity and patient satisfaction after the fixation method.⁴ Details regarding the power, type 1 error, and effect size sought were not provided.⁴

Results

Subject Characteristics

Thirty-four (34) subjects were enrolled into the study. Thirty (30)

subjects completed the study; three subjects were discontinued prior to completing the study, and one subject's consent to participate was withdrawn by their LAR prior to application of the study product. The most common ET tube size was 7.5mm (Table 2). The majority of subjects were intubated due to respiratory failures. A variety of subglottic suctioning was used, with low intermittent wall suction the most common.

The study product was worn for an average of 87.2 hours (3.6 days) with wear time ranging from 1.7 hours – 286 hours (11.9 days). The majority of subjects (29/30=97%) wore the study product for 180 hours or less (7.5 days); one subject wore the study product for 286 hours.

Safety

Four Adverse Events (AE) from three subjects (3/30, 10%) were reported; three AEs were classified as 'Serious'. One serious AE (SAEs) was classified as 'Unrelated' to the study product because the subject expired due to disease progression. The two other SAEs were from a single subject and classified as 'Probably Not' related to the study product. This single subject experienced oral bleeding and loose teeth but the principal investigator determined probably not related to the study product per assessment of the subject's situation. The fourth adverse event was a Non-Serious AE and classified as 'Probably Not' related to the study product. The subject had a lesion above the lip, which may have possibly been a herpetic lesion or an underlying skin condition.

Study Product Performance

Assessments of the study product, and of the subject's well-being while wearing the study product, were collected at time of study product application, at each clinician shift during study product use, and at time of study product removal. The following sections summarize the clinicians' experiences with each phase of the study product. Unless noted otherwise, assessment responses were captured via the use of a standard 5-point Likert scale with a score of 5 being the most positive response. For the following tables, a positive response is defined as a score of 4 or 5.

Application

Table 3 displays the questions and the percentage of clinicians who responded positively. In 93% (28 of 30) of subjects evaluated, clinicians stated it was easy or very easy to apply the study product to the patient's face. Limitations noted by a few clinicians were related to untangling the tubes prior to putting them into the tube holder and separating the oral gastric (OG) tube prior to securing the clamp closed.

During Use

During study product use, at the end of each ICU shift, subjects were monitored for the events displayed in Table 4. The counts

Table 4. Observation Checklist

Event	n; %*
Biting occurred	11; 37%
Pilot line became displaced from the protective sleeve	4; 13%
Tongue Displacement occurred	3; 10%
Subglottic lumen became displaced from the protective sleeve	2; 7%
Difficulty shuttling the study product from side to side	2; 7%
Depth of ET tube was adjusted	1; 3%
Proper oral care was hindered or prevented by the study product	1; 3%
ET tube became displaced from the protective sleeve	0; 0.0%
Any of the three tubes (ET tube, subglottic suction lumen, or pilot line) were removed from the protective sleeve and not reinserted at any point during study product use	0; 0.0%
Occlusion of the ET tube occurred due to the study product	0; 0.0%
Subglottic suctioning was not working properly due to the study product	0; 0.0%

*Percentages reflect the percentage of patients (out of 30) for which the event was observed (note that each event may have occurred multiple times)

in the table reflect the occurrence of the event and not the number of times an event occurred. For example, three subjects were noted to have tongue displacement during use of the study product. Each subject may have had tongue displacement occur multiple times during the use of the study product. The most frequently observed event by the clinician was a subject biting while being intubated (37%).

Product Removal

No report of tube migration, adhesive shifting on cheeks, or study product detachment from the face was reported. The most common reason for study product removal was that the subject no longer required intubation (19 of 30 subjects). In one instance, the subject pulled the tube through the clamp. In another instance, the subject self-extubated but there was no injury to the subject. In all cases, clinicians noted there was no damage to any of the three tubes (ET tube, pilot line, or subglottic suction lumen) during study product use. Clinician experiences with the study product, after removal, are presented in Table 5.

At the time of study product and ET tube removal, all lines were inspected and no damage to the ET tube, suction lumen, or pilot line was reported. There were six instances recorded where the three tubes did not remain in the protective sleeve. Subsequently, these clinicians were surveyed to further understand their experience with the three tubes (ET tube, pilot line, or subglottic suction lumen) not staying in place inside the protective sleeve during the course of use. Three of the six clinicians provided feedback. The feedback received from two of the three clinicians indicated that the pilot line and/or the subglottic suction lumen

came out of the sleeve while the staff was either providing oral care or turning the subject. In these two cases, the clinicians decided no further action was needed and left the lines out of the sleeve. The third clinician described the pilot line coming out of the protective sleeve when the shuttle broke off of the track while turning the subject. The clinician proceeded to place the shuttle back on the track and leave the pilot line out of the protective sleeve.

In 83% of subjects who were evaluated (25/30 subjects), clinicians found it easy to shuttle the study product from side to side during the course of use. Most clinicians found the study product to be acceptable at facilitating access to the oral cavity to provide oral care (25/30 [83%]) and facilitating subglottic suctioning (30/30 [100%]). The most common limitation in both actions of shuttling the study product from side to side and access to oral cavity were a result of macroglossia and one report due to subject actively biting down on study product. Twenty-eight (28/30, 93%) found the overall performance of the study product to be acceptable. In 97% of the subjects evaluated, based on the clinicians overall experience with the study product, clinicians would like to see the study product used at their facility.

Discussion

Challenges in the current ET intubation environment exist. All intubated patients are at risk of damaging their ETT, pilot line or integrated subglottic suction due to biting or chewing. If the ETT or pilot balloon integrity is compromised, the patient may require emergency ETT replacement. Additionally, patients also can

Table 5. Experiences after removal of the study product

Question	Positive Response
How easy was it to remove the study product from the face?	25 of 28*; 89%
How acceptable was the protective's sleeve's ability to maintain the main airway by preventing occlusion of the ET tube?	30 of 30; 100%
In general, how easy was it to shuttle the study product from side to side during the course of use?	25 of 30; 83%
How acceptable was the study product at facilitating access to the oral cavity to provide oral care?	25 of 30; 83%
How acceptable was the study product at facilitating subglottic suctioning?	30 of 30; 100%
How acceptable to you is the overall performance of this study product?	28 of 30; 93%

*There were two instances in which the clinician did not remove the study product

cause tongue trauma due to the same chewing and biting while intubated. The objective of this clinical study was to evaluate the acceptability and usability of AnchorFast Guard Select oral endotracheal tube fastener, an ETT fastener that accommodates the ETT, pilot balloon and subglottic suction which was designed to help address these potential problems. In this open-label, multisite, prospective study of 30 patients, all ET tubes with subglottic suction ranged between 7.0-8.0 mm with the majority of suction being placed at low intermittent wall suctioning (80-135 mmHG). The average length of time the study product was worn was 87.2 hours with wear time ranging from 1.7 hours to 286 hours. The majority of subjects (29/30 = 97%) wore the study product for 180 hours or less (7.5 days); one subject wore the study product for 286 hours.

Of the 30 subjects, four AEs from three subjects were reported and evaluated by the investigators. Three AEs were classified as 'Serious': one 'Unrelated' to study product (subject expired due to disease progression), two were from a single subject and classified as 'Probably Not' related to study product (oral bleeding and loose teeth). The fourth Non-Serious AE was classified as 'Probably Not' related to study product (lip lesion).

Overall, the study product was given greater than 90% positivity rating for ease of placement to the subject's face, inserting all three tubes (ET, pilot line, and subglottic lumen) into the protective sleeve, and ability to snap and click the clamp after lines inserted. Limitations were related to untangling the tubes prior to putting them into the tube holder and separating the oral gastric (OG) tube prior to securing the clamp closed. There was no consensus among the study clinicians, regarding the specific order of inserting the three tubes (ETT, pilot line, subglottic suction) into the protection sleeve. In 57% of patients evaluated, clinicians placed all three tubes together into the protection sleeve, while in 43% of patients each tube was inserted separately. Regardless of insertion method there was 100% agreement that the ET tube was secure.

There was 83% agreement in ease of shuttling the ET tube from side to side during the course of the study application and 83% agreement the study product provided acceptable access to the oral cavity for oral care. The most common limitation for both of these actions were a result of macroglossia and one report due to subject actively biting down on study product.

The majority of study subjects were kept on the study product until an ET tube was no longer required. This included reasons such as respiratory function recovery, transition to comfort care, or tracheal tube placement. No report of tube migration, adhesive shifting on cheeks, or study product detachment from the face was reported. Other reasons for removal of the study product included: three subjects were transferred out of the ICU, one subject self-extubated, and one study product removed for proning therapy.

At the time of study product and ET tube removal, no damage to the ET tube, suction lumen, or pilot line was reported. In six instances, either the pilot or subglottic tubes were found displaced from its protective sleeve during some point of study; however, there were no reported concerns about the protective sleeve's ability to maintain ETT patency.

Limitations of this study include the small sample size and the absence of a control group. Furthermore, patient reported

outcomes were not collected due to the nature of the ICU setting where this device is used. However, by gathering comprehensive study data in a structured and systematic way from intensive care clinicians, this study provided thorough feedback of study product acceptability and usability. Additionally, conducting this study at multiple centers (ie four hospitals) strengthens the study results in the observed patient population.

Conclusion

In the majority of subjects studied, clinicians and providers indicated positive acceptability relating to their overall experience with the study product and recorded they would like to see the study product used at their own facility. Study results did not indicate any new or additional risks with the study product above what would normally be expected with standard of care practice in the ICU setting.

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Hollister Incorporated sponsored the study. UCSF Fresno and Legacy received funding from Hollister Incorporated for conducting the clinical study and data collection. AA, LV and BY were investigators in the study and received no funding for development of the manuscript.

Author Contributions

RM and GS were involved in study design. AA, LV and BY were involved in data collection. GS was involved in data analysis. All authors were involved in the interpretation of results; writing of the manuscript; final approval of the manuscript; and in the decision to submit the manuscript for publication.

Conflicts of Interest

AA has no conflicts of interest to declare. LV has no conflicts of interest to declare. RM is an employee and shareholder of Hollister Incorporated. GS is an employee and shareholder of Hollister Incorporated. BY has no conflicts of interest to declare.

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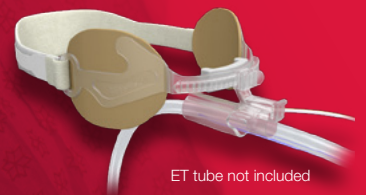


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Critical Care

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Predicting the Outcome of Nasal High Flow Therapy Using the Respiratory Rate and Oxygenation (ROX) Index

Stanislav Tatkov, MD, PhD

Background

In the last decade nasal high flow (NHF) has become a first-line therapy for patients with acute hypoxemic respiratory failure.¹ NHF can be a powerful oxygenation tool.² However, a high FiO₂ can potentially mask deterioration and delay escalation of care.

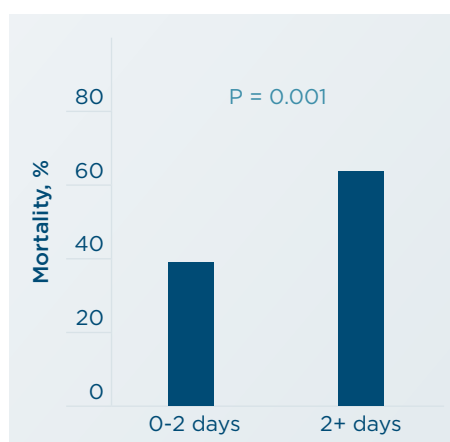


Figure 1. Patients who were intubated after more than 2 days on NHF had a higher mortality rate.⁵

The risk of delayed intubation

The risk of invasive mechanical ventilation is well understood, although delaying intubation can result in a lengthened hospital stay and increased mortality.^{3,4} In a retrospective study by Kang et al., patients receiving NHF therapy who were intubated earlier had lower mortality, improved extubation success, and fewer days on a ventilator (Figure 1).⁵

How to predict success and failure of NHF using ROX

What is ROX?

Roca and colleagues (2016) first established the ROX index to predict the success of NHF therapy.⁶ The ROX index combines three common measurements: FiO₂, SpO₂ and respiratory rate (Figure 2). NHF of 50 L/min and higher in adults exceeds inspiratory flow and reduces the entrainment of air. This makes delivered FiO₂ more precise, which may result in a more accurate ROX calculation. The index is based on two wellknown facts: sicker patients require more oxygen and have a higher respiratory rate.⁷

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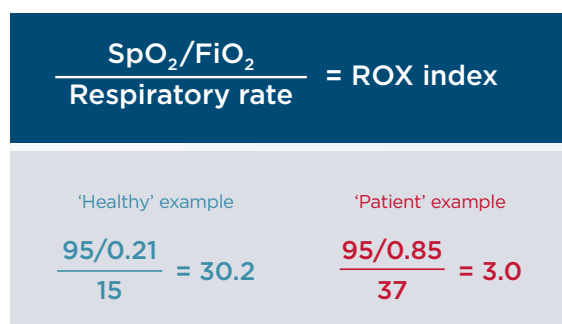


Figure 2. The ROX index, followed by examples from a healthy subject and a patient with respiratory failure.

Validating ROX

The index has been validated in a multi-center prospective study on 191 patients with pneumonia.⁸

The authors confirmed that a ROX value of ≥ 4.88 predicted the success of NHF. In addition, ROX values were provided that predict NHF failure with a high specificity (98–99%): ≤ 2.85 at 2 hours, ≤ 3.47 at 6 hours, and ≤ 3.85 at 12 hours of NHF use (Figure 3).

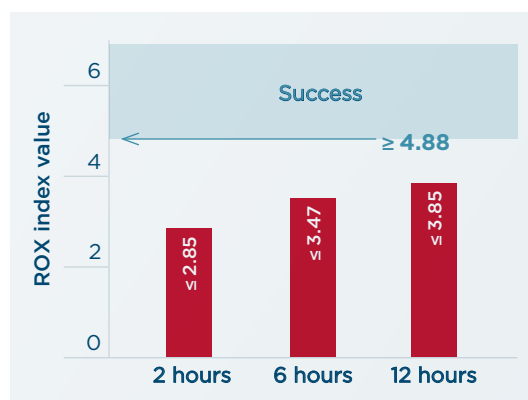


Figure 3. The ROX index value that predicts failure shown in red at 2, 6 and 12 hours and the ROX index value that predicts success above 4.88.

The importance of FiO₂

Among components of the index, SpO₂/FiO₂ had a greater weight than the respiratory rate.⁸ This is reflected in Figure 4:⁷ an FiO₂ of 0.80 or above will predict a ROX index of less than 4.88 (shown in red) and an FiO₂ of 0.50 or below will predict a higher ROX (shown in blue).

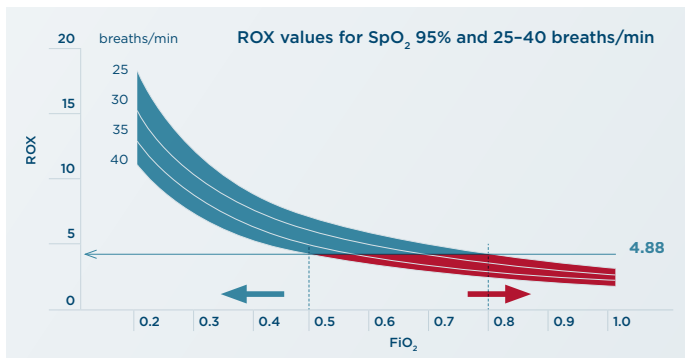


Figure 4. ROX values above 4.88 are shown in blue and below 4.88 are shown in red. FiO_2 below 0.50 predicts higher ROX and above 0.80, lower ROX for breathing rates between 25 and 40 breaths/min and SpO_2 of 95%.

What do changes in the ROX mean?

If the respiratory rate and/or FiO_2 requirement is increasing, then the patient is clearly deteriorating. The continuous monitoring of ROX may be particularly helpful when the patient is in an unstable condition.⁸ For example, two patients begin NHF treatment and both have a ROX value of 4.0 (see table below and Figure 5). Because this is only the start of the therapy, the ROX value can be monitored to see whether the index improves.

During the first 6 hours, Patient 1 has a decrease in respiratory rate and the FiO_2 has been lowered; Patient 2 has an increase in respiratory rate and the FiO_2 has been increased. As a result, the ROX value at 6 hours for Patient 1 is 6.0 and for Patient 2 it is 3.0. Based on the values provided by Roca et al.,⁸ Patient 1 has a high likelihood of NHF therapy success and can be maintained on NHF. However, Patient 2 has a trending decline and low ROX. Therefore, escalation of care should be considered.

Patient 1

No.	Date/time	SpO_2 (%)	FiO_2	RR (min-1)	ROX
1	initiation	95	0.70	34	4.0
2	2	95	0.60	32	5.0
3	6	95	0.50	32	6.0
4	12	95	0.45	30	7.0

Patient 2

No.	Date/time	SpO_2 (%)	FiO_2	RR (min-1)	ROX
1	initiation	95	0.75	32	4.0
2	2	95	0.80	34	3.5*
3	6	95	0.85	37	3.0
4	12		Therapy escalated		

*Even though a ROX index value of 3.5 at 2 hours would not indicate failure, the ROX index value has decreased since therapy initiation, indicating that escalation of care should be considered.

ROX vector

Combining the ROX values with the change in the respiratory rate and FiO_2 can indicate whether escalation is required. A proposed XY plot of the key components of ROX may show the direction of changes in vector form (see arrows in Figure 5).⁹ Vectors towards the upper right indicate a deterioration and, towards the lower left, an improvement.

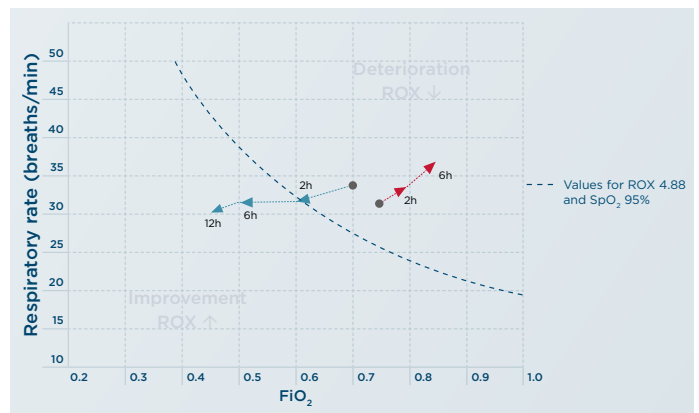


Figure 5. XY plot between respiratory rate and FiO_2 . The blue arrows in a vector form demonstrate a change towards NHF success and the red arrows demonstrate the change towards NHF failure. The dotted line shows the values for ROX at 4.88 and the SpO_2 of 95%.

Putting ROX into practice

The ROX index is a useful tool because it requires only a few data points and can be measured at the patient's bedside. The index can be used to monitor the patient and predict the likelihood of success or failure of NHF therapy. Furthermore, ROX highlights the importance of the required FiO_2 —if the required FiO_2 is high, then the patient may be at greater risk of failure.

ROX Vector App

Download the ROX Vector App on your device to calculate the ROX index and plot vectors. Available on the App Store and Google Play.



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New evidence continues to emerge showing how Optiflow™ Nasal High Flow contributes to **improved patient care and outcomes.**

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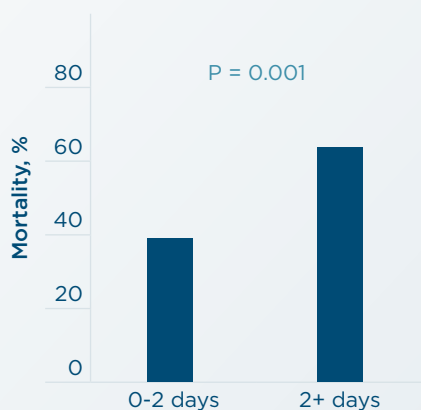


Figure 1. Patients who were intubated after more than 2 days on NHF had a higher mortality rate.⁵

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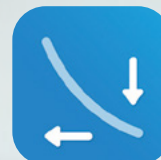
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To learn more about how Optiflow Nasal High Flow Therapy can help benefit your patients visit <https://www.fphcare.com/us/hospital/adult-respiratory/optiflow/>

FREE APP

ROX Vector App

Download the ROX Vector App on your device to calculate the ROX index and plot vectors. Available on the App Store and Google Play.



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PFT Safety Recommendations During COVID-19 and Beyond

A review of the ATS/APCCSDD Task Force and ERS Statements

Susan M Schmid BS RRT CPFT

Pulmonary function testing (PFT) has a whole new set of safety considerations in the COVID-19 world. Given the reality that PFT presents a high risk of COVID-19 transmission among patients/subjects and clinicians, the American Thoracic Society (ATS) issued a statement last April with three directives:

1. PFT should be performed only when essential for immediate treatment decisions;
2. Only the most essential tests should be performed;
3. Protective measures should be implemented for both the staff and patients.

Protective measures like wearing masks, gloves, and gowns are familiar to all of us. But what kind of protective measures do the testing devices need to have? And what about the testing procedure? And the testing environment?

ERS COVID-19 Recommendations for PFT

These questions were addressed in an article published in July's ATS Journal by a task force consisting of members of the Association of Pulmonary, Critical Care, and Sleep Division Directors (APCCSDD) and American Thoracic Society (ATS), as well in a statement released in early May by the European Respiratory Society (ERS) Group 9.1.

These 2 position papers provide a variety of safety recommendations for limiting the risk of viral transmission in testing clinics. These include criteria for resuming PFT, patient prioritization, screening and testing for SARS-CoV-2, staff protection strategies, testing and waiting area strategies, and more.

This review is limited to those recommendations that relate only to testing equipment, method, and procedures, when it has been determined that PFT is indicated.

Testing Equipment and Method

Filters – Both groups state that testing devices must have a disposable, in-line bacterial/ viral filter. Combined mouthpieces/sensors are not recommended. [Note: Actual bacterial/viral filter specifications needed for preventing cross-contamination with the COVID-19 virus are not mentioned. However, we know that the Coronavirus species ranges in size from 0.06 to 0.2 μm , so if a PFT device uses a bacterial/ viral filter, its effectiveness should be confirmed accordingly.]

Plethysmography – Both groups suggest that when lung volumes are indicated, the use of body plethysmography may be preferable, due to “containment of exhaled air” (APCCSSD/ATS Task Force), or “if droplet contamination can be contained, and local national guidelines support this” (ERS Group 9.1). [Note: With cabinless plethysmography, exhaled air is fully contained and droplet contamination is marginal during testing.]

Safety Procedures Between Patients

Disinfection/cleaning – Both groups recommend that all testing equipment surfaces, and the surrounding environment (ERS) should be disinfected/cleaned between patients. [Note: The time required for adequate cleaning may vary widely, depending on the surface area of the equipment/device.]

Calibration – The ERS Group 9.1 recommends recalibration of the lung function equipment after decontamination. [Note: Devices that perform rapid self-calibration before testing a new patient offer a time-saving advantage here.]

Room ventilation – Both groups recommend room ventilation. The ERS Group 9.1 gives a general guideline of at least 15 minutes, while the APCCSSD/ATS Task Force advises that the exact amount of time will vary depending upon whether the room is under negative pressure and whether there is concomitant use of a high efficiency particulate air (HEPA) filter or ultraviolet light decontamination. [Note: With a portable and mobile device, room ventilation does not entail any delay in treating the next patient; the unit is moved to another room.]

Total extra time required between patients – The ERS Group 9.1 estimates the total extra needed for disinfection/cleaning, calibration and room ventilation as between 30 to 60 minutes; the APCCSSD/ATS Task Force does not quantitate this time.

The MiniBox+ complete PFT device by PulmOne meets each of the above recommendations, with additional operational advantages as described below.

1. Testing is performed with a fully compliant bacterial/viral filter, which has successfully passed both BFE (Bacterial Filtration Efficiency) and VFE (Viral Filtration Efficiency) testing for organisms as small as 0.025 μm . As mentioned above, the Coronavirus species ranges in size from 0.06 to 0.2 μm .
2. As a cabinless plethysmography device, exhaled air is fully contained and droplet contamination is marginal during testing.

Susan M Schmid BS RRT CPFT, Director of Customer Service, PulmOne USA

- The disinfection and cleaning procedure consists of a 5-minute external wipedown.
- Rapid self-calibration is done automatically after each test, so there's no need to re-calibrate manually.
- As a portable device, it can be easily moved into another room for testing the next patient while the previous room is ventilated for 15+ minutes. The only downtime between patients is for the 5-minute wipedown.

For further information about the MiniBox+, visit www.pulm-one.com.

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- ERS 9.1 Statement on lung function during COVID-19 Final with Contributors.pdf. <https://ers.app.box.com/s/zs1uu88wy51monr0ewd990itoz4tsn2h>

Recommendations	ERS Group 9.1	ATS/APCCSDD Task Force	MiniBox+
Testing Equipment & Method			
In line bacterial/viral filter only	√	√	Complies
Plethysmography is preferred for lung volumes	√	√	Complies
Safety Procedure Between Patients			
Disinfect all equipment surfaces	√	√	5-minute procedure
Recalibrate after every disinfection (and after flow sensor removal when relevant)	√	√	Self-calibrates
Room ventilation	√ At least 15 minutes	√ Time varies with use of UV or negative pressure	Does not affect patient flow; unit is easily moved to another room
Total turnaround time between patients	30-60 minutes	Not quantified	5 minutes

MiniBox+™

The world's only portable LVM plethysmography device with FVC and DLCO.

Easy. Accurate. Great ROI.

Complies with all COVID-19 safety recommendations of the ATS/APCCSDD Task Force and ERS Group 9.1.



BACTERIAL/VIRAL FILTER

For 99.999% protection from Coronavirus



RAPID DISINFECTION

5-min. wipe-down



PORTABLE

Mobility for uninterrupted patient flow

Progression of ALS: Tracheostomy and Communication

Gabriela Ortiz, BSRT, RCP

Defining the problem

Amyotrophic Lateral Sclerosis (ALS) is a progressive neuromuscular disease that weakens muscles, leading to impaired functions such as walking, breathing, speaking, eating, and swallowing, and eventual death. While the onset and progression vary from person to person, interventions also may vary dependent on the particular form of ALS that a patient may have. Research shows that spinal ALS is the most common form of the disease. People with spinal onset often are able to use their own voice, eat by mouth, but show a later progression to respiratory failure. This would mean that individuals with spinal ALS may face the decision to undergo a tracheotomy much sooner than persons with other forms. The tracheotomy occurs to facilitate modalities that will help with breathing, clearing secretions, and prolonging life. Comparatively, Bulbar onset is less common and appears to progress much quicker. With the Bulbar form of ALS, dysarthria may be the first sign of disease onset, indicating the need to seek medical attention. In some, this disease will progress so quickly that the assessment for augmentative and alternative communication devices may never be addressed.

Amyotrophic Lateral Sclerosis

The Muscular Dystrophy Association (2017) educational handout outlines, “What happens to someone with ALS?” According to the Muscular Dystrophy Association, with ALS, the involuntary muscles continue to work. Involuntary muscles allow individuals to see, smell, taste, hear, think, and recognize touch (MDA, 2020). It explains that involuntary muscles such as the heart, gastrointestinal tract, bowel and bladder, and those that regulate sexual functions are not directly affected in ALS. Usually sense of smell, vision, hearing, and recognition of touch are not affected (MDA, 2017). While ALS affects people of all races and ethnicities, it is most prevalent for white males, who are non-Hispanic, and aged > 60 years. The risk to develop the disease

Gabriela Ortiz has been in the field of respiratory care since 2006. She has lived in Southern California all her life, graduating from California Paramedical College with her Associates degree in respiratory care, then gaining her Bachelor’s degree in respiratory as well. She has used her clinical knowledge to advance into clinical education and unique sales roles, being responsible for selling critical care ventilation products into the ICU, PICU and respiratory care of acute and subacute hospitals in Southern California. Gabriela is recognized for her compassion and is invited as a guest speaker at trade schools, Better Breather’s Group and the ALS Association–Golden West Chapter Support Groups to educate on the transition of invasive therapies following tracheostomy.

increases with a family history of ALS (Mehta et al, 2018). ALS has two classifications: Sporadic or Familial. Almost 90% of all cases occur in the Sporadic form, and 10% occur in the Familial form (Khairoalsindi and Abuzinadah, 2018). Familial ALS is a heredity onset, using genetic testing to investigate how it is carried in the family bloodline. Findings show that one parent may be the carrier of the gene responsible for the disease. The ALS Association has tracked mutations in more than a dozen genes that may lead to familial ALS (ALS Association, 2020).

The onset will either be Spinal or Bulbar classification, differentiated by signs and symptoms, and taking multiple studies to finalize the diagnosis. Some of the early symptoms may include muscle twitches, muscle cramps, or muscle weakness. Because dysarthria or dysphagia may also be signs of onset for other neurologically-based disorders, differential diagnosis may be difficult (ALS Association, 2020). While Spinal onset typically includes difficulty walking, tripping, or dexterity issues, Bulbar onset presents with dysarthria, dysphagia, and twitching in the muscles of the face, jaw, throat, larynx, and particularly, the tongue. Evidence supports that Spinal ALS has a slower progression than Bulbar ALS. With progression of the disease, both Bulbar and Spinal ALS will eventually have the same signs and symptoms.

Because the onset of ALS may not have overt symptoms initially, it may be overlooked in the diagnostic process in the early stages; however, gradually these symptoms develop into more noticeable weaknesses or atrophy. The current availability of modern diagnostics may lead to earlier diagnosis, allowing individuals and their families more education time and time to determine what may need to be addressed. Though it is a rare disease, with no identified cure, having knowledge of medication and technology that may aid in alleviating distress and knowing the modalities and devices that may assist provide options to improve quality of life. Because the disease may progress slowly and has variability in symptom onset, some individuals may have the ability to speak, eat, and breathe on their own for a little longer than others.

However, once diagnosed, being part of a multidisciplinary clinic will help monitor and manage the disease progression. The team usually includes specialized physicians, nurses, physical therapists (PT), occupational therapists (OT), speech-language pathologists (SLP), respiratory therapists (RT), nutritionists, and psychologists. It is also customary to see the ALS Association as part of this team. The team offers guidance, education, patient/



Figure 1. Patient with ALS using a Passy Muir Valve.

caregiver support, and advocacy to all who are involved with this debilitating disease (ALS Association, 2020).

Education

Education should be provided by clinicians and various team members in a manner that is informative and straightforward, but also empathetic. Being diagnosed with ALS comes with many life decisions and wishes about the plan of care. It often involves discussions about what end-of-life path someone with ALS will follow. Because of the long-term and permanent nature of the changes seen by patients with ALS, the end-of-life planning involves reviewing upcoming events. By considering a patient's beliefs, values, and preferences, respect for the patient, family, and the life plan are observed. Team members also help to meet the long-term needs by asking a person with ALS such questions as: Are there family life events taking place soon? A wedding, a graduation, the birth of a child or grandchild? As a primary dysfunction with ALS is the onset of respiratory compromises that limit, and even eliminate, the ability of a person to breathe independently, respiratory support is often addressed as it relates to artificial interventions. The option of a tracheostomy with mechanical ventilation are a part of the thought and planning process.

Tracheostomy

As a person's respiratory status declines, a tracheostomy aids in the application of breathing modalities to assist. A tracheostomy tube also provides better access to the lower airway and allows for improved secretion management. With initial decline, non-invasive ventilation is first attempted, which involves use of such items as a face mask. Making a life-altering decision for something like a permanent tracheostomy has many consequences. Because of these life-altering impacts, some may elect not to pursue it as the change would be too significant. This misperception occurs because the last vestiges of early surgical procedures still exist, and they often led to a loss of a person's voice and their ability to swallow. If patients are not provided a well-rounded perspective that offers knowledge of both the pros and cons, the process becomes even scarier. While there are some negative aspects to a tracheostomy, the benefits and improvement in care, with proper care and maintenance, may outweigh the negative for most.

The American Lung Association has a saying that "if you can't breathe, nothing else matters." Since with ALS, it is just a matter

of time before breathing becomes compromised, discussions about the options for respiratory interventions are a necessity. The body can be supported by Respiratory Assist Devices (RADs) or mechanical ventilators. Initially, as breathing begins to deteriorate, the use of machines is non-invasive, with a nasal or a full-face mask. Non-invasive ventilation is initiated to alleviate shortness of breath; however, dependency on this machine will increase with time. As respiratory assistance increases, from a few minutes to hours to all-night interventions, wearing a mask may become uncomfortable and lead to painful skin breakdown. Receiving airflow via face mask also makes it difficult to understand the speech of a person wearing the mask and may interfere with hearing during communication attempts. As secretion management becomes more difficult or there is a need for prolonged mechanical ventilation, then the purpose of a tracheostomy becomes more clear.

What to expect with a tracheostomy tube

Frequent hospitalizations occur due to various issues, including injuries from falls, respiratory insufficiencies due to aspiration or shortness of breath, and significant changes in essential life functions, such as swallowing and breathing. Moving to the tracheostomy often improves the quality of life (Vianello, Arcaro, Palmieri, Ermani, Braccioni, Gallan, Soraru, and Pegoraro, 2011). In most circumstances, a person with ALS receives a tracheotomy as a lifesaving modality (Shneerson, 2011). Following a tracheostomy, the care for the patient and by the caregiver increases as a tracheostomy tube will need proper care, cleaning, and changing to help prevent infections. Caring for the tracheostomy site, known as the stoma, will need daily attention. Suctioning becomes part of the normal care routine as it allows for the removal of excess secretions. Family and caregivers are taught "trach care" and suctioning, using sterile or A-septic techniques prior to going home from the healthcare setting. While these many changes involve intensive education and care, the improvement in quality of life is significant.

What to do about the voice?

But the tracheostomy also has a negative impact on functions such as speech. With a tracheostomy tube, when the cuff is inflated, airflow is directed in and out through the tube and does not flow upwards through the vocal folds. This redirection of airflow causes a person to lose their voice which makes communication difficult, even of basic wants and needs. Bartlett, Blais, Tamblyn, Clermont, and MacGibbon (2008) noted that up to 50% of medical adverse events that occur in hospitals are preventable. A primary cause of adverse events is communication breakdown caused by language barriers and disabilities that affect communication. These breakdowns have been shown to decrease quality of care. It also has been reported that those with communication issues are more likely to experience a preventable adverse event than those who can communicate their medical history and needs (Bartlett et al., 2008).

When unable to communicate, a person will resort to other means of communication such as gestures, head nods, mouthing of words, writing, use of letter or picture boards, and common words or phrases tailored to meet individualized patient needs (Grossbach, Stranberg, and Chlan, 2011); however, their effectiveness is limited. Since these types of communication are more reliant on the listener/recipient than the speaker, often these methods do not go without error due to misinterpreting meaning with eye blinking, lip reading movements, or even just

loss of patience by the recipient of the message. As reviewed, miscommunication leads to preventable adverse events or even delayed care (Bartlett et al, 2008).

Speaking Valve

As discussed earlier, a tracheostomy with an inflated cuff causes a separation of the upper and lower airways, which causes a loss of phonation. Use of a speaking Valve can assist with restoring verbal communication while a person has the ability to use residual muscle function. The Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) is a bias-closed position, no-leak design allowing for the redirection of airflow up through the upper airway and vocal folds, enough to improve speech and swallowing. This not only allows an individual's voice to be heard for care but also assists with preserving their voice for as long as possible. Having a voice allows the patient to participate in voice or message banking; so, use of a speaking Valve may extend the time that a patient can participate in forms of banking. Voice banking is a storage of a person's voice that can be parsed for developing audio files for use in speech-generating devices. Message banking is similar in that a person can store messages, such as I love you, to be later used in a device.

Unfortunately, not all individuals will be able to use a Valve due to the debilitating nature of this progressive disease. To determine if a person may be able to use a valve, selection guidelines include that the person is awake and alert, has a patent upper airway, has a low risk for gross aspiration, and can tolerate complete cuff deflation, leaving enough room for airflow to be directed up to the upper airway around the tube. Once a patent upper airway has been identified, then a speaking Valve can be attempted. In the case of a patient with mechanical ventilation, a patent upper airway is measured by assessing for a drop in peak inspiratory pressure (PIP/PAP) or a drop in exhaled tidal volume (by at least 40% from pre-cuff deflation) when the cuff is deflated. For a patient who is not yet on mechanical ventilation but has a tracheostomy, the cuff is deflated, and finger-occlusion is used. This involves blocking the tracheostomy tube at the hub with a fingertip following inspiration and then watching for exhalation out through the mouth and nose — this can be through voicing, coughing, throat clear, or just breathing. Once the airway patency is confirmed, then the Valve can be placed, allowing for the potential of a using their own voice.

Augmentative and Alternative Communication (AAC)

Advanced technology to improve communication, like smartphones, personal computers, speech-generating devices, and electronic eye gaze, are not easily accessed, due to patient acuity, high cost, lack of insurance reimbursement, and more. Even though these devices are available to make communication possible, nothing can beat the sound of one's own voice. When patients are not able to access their voice, augmentative and alternative communication means are sought.

Beukelman, Fager, and Nordness (2011) share that eventually 80 to 95% of people with ALS will be unable to use natural speech for communicating. Implementing augmentative and alternative communication (AAC) as intelligibility begins to decrease may be difficult due to the rapid decline that can be observed; therefore, appropriate early education, awareness, and assessment are critical.

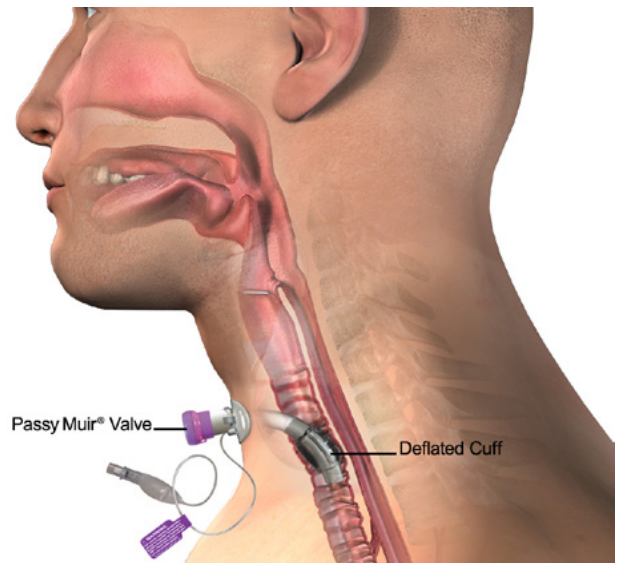


Figure 2. Use of the Passy Muir Valve requires a deflated cuff.

Conclusion

Living with ALS requires education, support, and guidance to live life to the fullest. A progressive disease makes breathing, managing secretions, and speaking challenging without the assistance of medical devices. Anger, frustration, fear, and detachment from life are negative impacts brought on by the inability to communicate (Freeman-Sanderson, Togher, Elkins, and Kenny, 2018). As patients transition through the progressive stages of decline with ALS, it is important to remember that “Communication is at the heart of who we are as human beings” (Jagoe, 2020).

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Using Ultraviolet Light to Extend the Useful Life of N95 Respirators

Allison Mulvehill, Jack Krause, Martha Hamilton, Mario Sisinni, Josh Berman, Scott Hoch, Matthew Hyman, Scott Goldman and Joseph M Bradley

Introduction

The novel coronavirus pandemic has immensely tested healthcare systems. As many states began to reopen, hospitals across the country have continued to see an influx of patients with limited numbers of ICU beds and ventilators. Intertwined with this is the ongoing need and lack of sufficient personal protective equipment (PPE) in the healthcare system, perhaps the most critical piece being the N95 filtering facepiece respirator (FFR).

Essential PPE is needed to keep frontline healthcare workers safe so they can work to save the lives of those who have fallen ill with the virus. N95 masks protect workers and patients by capturing infectious particles. N95s are made to be disposable after one use, but due to the high demand, there is a shortage of PPE and thus healthcare providers are being forced to extend use of and reuse N95s.

Because of the lack of essential PPE, decontamination offers a potential solution for extended reuse of N95 FFRs. A variety of methods have been tested including vaporized hydrogen peroxide, dry heat, microwave steam, and ultraviolet (UV) light. UV light contains a wide spectrum of frequencies (Figure 1). UV-C, the most effective of the UV spectrum for decontamination, shows great promise because of its ability to destroy DNA strands of microorganisms. It's particularly interesting for the decontamination of N95 masks because it's a chemical-free method of action and works quickly without damaging the integrity of the FFR. This is important because form, fit, and filtration are the foundation of an N95's ability to protect the wearer from harmful particles in the environment. Throughout the eight months of the pandemic, many hospitals have experimented with UV-C decontamination of N95s on their own as a way to control their PPE burn rate. The University of Nebraska Medicine released a research paper documenting a process specifically for hospitals that had no other option but to experiment with UV decontamination.¹

The authors are from the development team of MK Reactors, Inc. (Los Angeles, CA), a start-up designing and manufacturing UVGI platforms for institutional decontamination of N95 FFRs. Since the early days of the pandemic, engineers from MK Reactors have been working closely with the brightest minds in North America researching the field of N95 sterilization, including researchers at Nebraska Medicine, Applied Research Associates, UVDI and the Food and Drug Administration. MK Reactors is proud to be a part of the International Ultraviolet Association's (IUA) Coronavirus Task Force.

N95 respirators are designed to filter and trap infectious particles

To provide adequate protection to a healthcare worker, an N95 respirator must first fit snugly on the face so that it can filter effectively. Otherwise, unfiltered air will leak in from the sides which would pose a risk of infectious particles reaching the wearer. If form and fit are adequate, then by definition a minimum of 95% of the "most penetrating sized particles" will be filtered as the air is inhaled through the multiple layers of an N95.² However, this also means that up to 5% of particles in this size range (roughly 30 to 100 nm) would potentially be inhaled by the wearer.

Long known to be an effective method, UVGI shows promise for decontamination of N95s

Ultraviolet germicidal irradiation (UVGI) is a disinfection method which uses electromagnetic radiation with wavelengths between 200nm and 280nm to kill or deactivate microorganisms. While the technology is most often used for water and air disinfection, it has also been used to decontaminate N95 FFRs.^{3,4,5,6}

UV-C has proven to have germicidal effects and extensive literature exists highlighting the ability for UVGI to decontaminate FFRs at a high level. Lore, et al evaluated the effect of UVGI on two models of FDA-approved multi-layered N95 FFRs commonly found in a healthcare setting, including the 3M 1860, which were inoculated with H5N1 influenza.⁷ A greater than 4 log reduction of H5N1 was reported after a 1.8 J/cm² UVGI treatment. Mills, et al conducted a study to further the understanding of how UV-C's germicidal effects are affected by soiling agents on the FFRs.⁸ They reported significant reductions in viable virus in 12 out of 15 FFRs tested, even with mock sebum and mucin soiled FFRs.

Both the Lore study and the Mills study show the continuously evolving field of UV-C germicidal effects on the multi-layered materials of an N95 FFR. As one could imagine, this work has continued on, accelerated by the SARS-CoV-2 pandemic. Of particular interest here is the CDC's own guidance on the subject, which references the promises of the germicidal effect of UV irradiation.⁹ They reported acceptable filter performance and minimal effect on fit after FFRs were exposed to between 0.5 and 950 J/cm².

Research shows UVGI performs better than other methods in the preservation of mask integrity

Viscusi, et al measured the particle penetration for FFRs

THE ELECTROMAGNETIC SPECTRUM

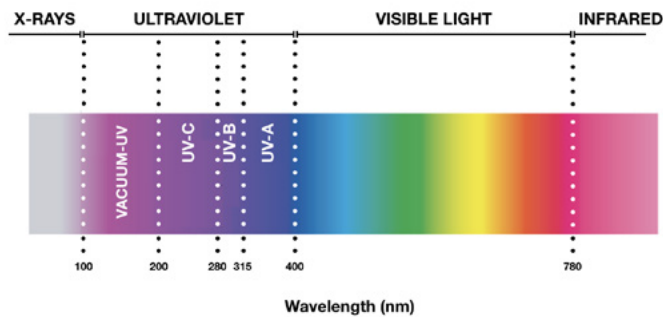


Figure 1. Spectrum frequencies of light

before and after being exposed to 0.43 J/cm^2 and 6.9 J/cm^2 UVGI.¹⁰ The average penetration and therefore filtering results were not significantly affected by either UV treatment. Their findings agreed with a study on the surface properties of generic polymeric biomaterials used for tissue engineering¹¹ and the follow-up study by Bergman.¹² Of note, this paper found that autoclaves, isopropyl alcohol, and soap and water decontamination methods lowered the filtration levels beyond NIOSH's efficiency criteria. Ultraviolet light was among the methods that maintained the FFR's performance.

Bergman, et al¹² performed a similar experiment whereby they evaluated particle penetration after three successive decontamination cycles with a delivery of 4.8 J/cm^2 total UVGI. The group found no statistically significant change in particle filtration or in air flow resistance.

Most particles settle on the N95 exterior where UV can easily disinfect them

Much has been researched into exactly how particles remain trapped in the fibers of an N95 respirator. It turns out, a significant portion of particulate actually settles on the exterior layer. A study of N95 FFR contamination during routine room cleaning procedures found that greater than 97% of filtered contamination was deposited on the external layers of the 3M 1860 mask.¹³

Particulate that becomes trapped on this exterior layer presents a potential threat of hand contamination and infection transmission following the doffing process. Particles that enter the inner filtering layer and get trapped however, pose different challenges. Some of the challenges to UVGI are due to the construction of the FFR where some filter fibers sit in front of fibers behind them that might block direct light waves (Figure 2).

Interestingly, UVGI can penetrate through an N95's layers

Fisher and Shaffer recognized the importance of understanding the ability of UV-C to penetrate the inner layers of FFRs and inactivate infectious particles.¹⁴ They found, as would be expected, that UV-C irradiance decreases with distance and is significantly affected by its need to pass through each substrate in an FFR. However, they pointed out that UV-C irradiation is also transmitted, reflected, and absorbed by the fibers in the layers of an FFR similar to what has been reported in other textiles and will be transmitted through the gaps and pores between the fibers of the layers.

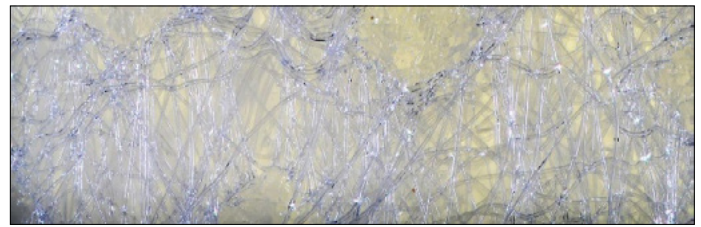


Figure 2. Microscopic image of N95 filter material

While discussing the limitations of varying dose and exposure times in their results, they concluded that UV-C exposure resulting in a dose of 1000 J/m^2 (0.1 J/cm^2) produced log reductions of greater than 3 of MS2 bacteriophage. They noted that a bidirectional target of the mask may not be essential. Limiting the exposure to one direction, from outer to inner, may still provide an adequate dose for decontamination while limiting the complexities of a two-sided bidirectional treatment.

Ontiveros, et al, investigated how UV light penetrated through different layers of an N95 respirator.¹⁵ They found layer one, the environment-facing outer layer, layer two, the inner filter layer, and layer three, the user-facing layer, block 62, 34, and 95% of UV light, respectively. None of the layers individually block 100% of the UV light, allowing adequate light to pass through.

Ontiveros, et al then studied the ability of UV-C to decontaminate *S. aureus* when it was embedded in the layers of the N95 respirator.¹⁵ They were able to achieve a greater than 3 log reduction, when *S. aureus* was inoculated in the user-facing layer and UV-C was irradiated from the environment-facing side with 2.746 J/cm^2 . With use of only 0.824 J/cm^2 , a 2.4 log reduction was still achievable.

Even though some of the ultraviolet light is blocked by exterior layers of an N95 FFR, a sufficient portion of the light is still able to reach the inner layers, providing decontamination capabilities.

There is a low risk of trapped particulate re-aerosolizing

To present an infection risk from particles embedded in the inner filtering material of an N95, they must again become airborne. In a simulated coughing experiment, using a tidal volume of 1.6 L and a peak flow of about 370L/min, a flow much higher than the air flow during normal use of FFRs, Fisher, et al found <0.21% of viruses loaded onto the N95 FFR were re-aerosolized.¹⁶

Qian, et al recognized the importance of understanding how and if particles are re-aerosolized from the inner filter fibers into the air while the FFR is in use.¹⁷ They tested re-aerosolization rates during simulated intense exhalation, such as from sneezing or violent coughing. They found the re-aerosolization rates increased with particle size. Since most larger particles are filtered by the outer surface layer, the particles that do reach the inner filtering material are more likely to be smaller and less likely to be re-aerosolized than larger particles.

With recognition that an N95 FFR can allow up to 5% of particles to pass through the filter material, the 0.21% re-aerosolization finding of Fisher is reassuring that an unsafe level of trapped particles would not be released after decontamination, even if the process was not perfect.

No risk to wearer from re-aerosolization of particles

It is therefore considered highly unlikely that an inhalation by

the wearer would cause infectious particles to be disrupted and re-aerosolized from the inner filter layers.

Lindsley, et al tested UV-C levels of 0, 0.120, 0.240, 0.470, 0.701, and 0.950 J/cm² and found all of the respirators had mean particle penetration values below 5%, even after the maximum UV exposure levels.¹⁸ This means even after UV-C treatment, the FFR's filters are still working at the level needed to classify the mask as an N95 FFR. Thus, the N95 FFR works the same to trap particles in the electrostatically charged filter layers and keep 95% of infectious particles from being released and reaching the wearer.

Caution: Recommendations indicate that the maximum number of cycles of UV decontamination of FFRs should be limited to 10 cycles as filtering efficiency has not been tested beyond that number.¹⁹

Conclusion

UVGI has long been known to be an effective method of decontamination.

Research has shown that UVGI can be a highly effective decontamination methodology against aerosolized inoculation on the outer and inner surfaces of N95 respirators and a high level of filtration integrity is maintained after UVGI treatment of an N95 FFR.

Although UV light has been demonstrated to decontaminate the inner layers of FFRs, the infectious particles that do reach the inner filtering layers, if not completely eradicated, are highly unlikely to be re-aerosolized, suggesting that absolute decontamination of these layers may be unnecessary. This may be particularly notable when the reuse is limited to the same wearer. Additionally, the use of bidirectional exposure of UV-C light to both the environment-facing exterior and the user-facing exterior surfaces may increase overall penetration and decontamination. Thus, UV germicidal irradiation is a very promising, appropriate, and potentially powerful tool to extend the useful life of N95 respirators in this time of great need in healthcare systems.

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Essential Requirements for Medical Devices Used in Telehealth Remote and Home Monitoring Applications

Bernard Garbe

Advancements in technology regularly present new opportunities in telehealth for home monitoring of respiratory conditions, helping to ease the burden of long-term care on both patients and medical professionals. Technology or devices used to monitor patients and store or share their health information must be capable of safely and securely completing the tasks required. When an app performs medical device functions, the software platform on which it is hosted must function as intended, or clinically significant results and warnings may be missed.

Why are some mobile apps classified as medical devices and why does it matter?

Regulatory Compliance

The FDA defines a medical device as: *“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals”* (Section 201(h) of the Food, Drug, and Cosmetic Act, 2017).

If software is designed to perform a medical device function, it is then a medical device regardless of the host platform. The FDA say they intend to apply regulations only to software functions that are medical devices and whose functionality could pose a risk to a patient’s safety if the device were to not function as intended. (US FDA, *“Policy for Device Software Functions and Mobile Medical Applications”*, 2019).

In general, there are two approaches to using telehealth apps in remote monitoring systems.

1. In the first approach, the app is not classified as a medical device because the medical device functionality is completed by the medical (monitoring) device.

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2. In the second approach, an app completes some of the medical device functions (eg controls the device and/or processes the raw data) meaning that the app and associated mobile platform become a medical device and require validation as such. Therefore, where the mobile platform performs medical device functions, the user’s own mobile platform should not be used without validation (see Table 1).

Telehealth Approach 1. The app is not a medical device

In this approach the cell phone or tablet app transmits the data but is not required to control the device, make measurements, process or view the results as the medical device completes

all these functions. Test results or graphs may be viewed via an app but the primary results (including user personalization where set) are generated on the device itself. A mobile telehealth app is only required to transmit the results to a clinician or cloud-based service although the app may also allow the patient to view and store data.

Having all the medical functionality built into the testing device allows it to be used in a flexible way with the app hosted on any compatible platform. Vitalograph remote respiratory monitoring and testing devices are FDA cleared, class IIa medical devices that may be used with non-medical

mobile telehealth applications (apps) developed by Vitalograph or by third parties.

The beneficial result of this approach is that telehealth apps incorporating Vitalograph respiratory monitoring and testing devices can be hosted on any platform without additional medical device validation required.

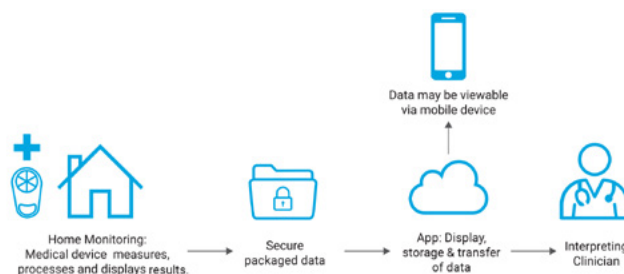
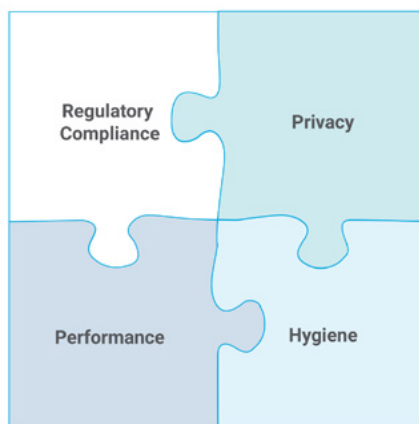


Table 1. Functions of Apps for use with remote monitoring devices

Approach 1 : App is not a medical device	Approach 2 : App is a medical device
<ul style="list-style-type: none"> • App helps your patient to document, show, or communicate potential medical conditions. • App transfers, stores, converts formats, and displays medical device data or results, without controlling or altering the functions or parameters of any connected medical device. <p>Vitalograph remote monitoring devices use this approach</p>	<ul style="list-style-type: none"> • App connects to a device for the purpose of controlling the device. • App connects to the device for the purpose of analysing medical device data. • App uses attachments, display screens, sensors or other similar components to transform a mobile platform into a medical device. • App performs patient-specific analysis. App provides patient-specific diagnosis. App provides treatment recommendations. <p>Each of these functions makes the App a medical device</p>

Figure 1. The Telehealth platform does not need to be a medical device to transfer, store, view or communicate data to healthcare providers.

Telehealth Approach 2. The app is a medical device

In this approach the device only functions in conjunction with the app, therefore the device, app and host mobile platform are all considered to be medical devices.

The advantage of this approach is that the device can be far more basic without the need to incorporate controls, process or view results. The up-front cost of the device may be lower as it harnesses the functionality of the platform hosting the mobile telehealth app.

The disadvantage is that functions carrying patient safety risk become subject to the inherent instability of a mobile platform (for example operating system updates or other apps added to the mobile device). The system then needs to be revalidated as a medical device with associated ongoing development and cost.

Devices that use an app to harness mobile device capabilities as part of the medical device function are in a race to keep up with the inexorable advance of the hardware and software platforms.

Where the app is a medical device, clinically significant results and warnings may be missed by a patient if the platform or telehealth app fails to function as intended.

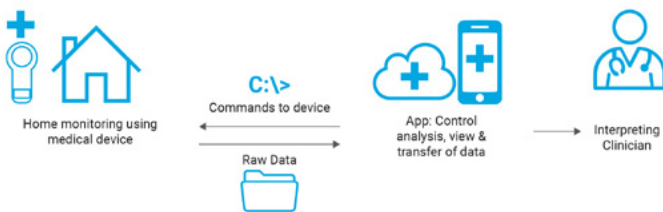


Figure 2. The mobile device, app and any platform that hosts it are medical devices.

Hygiene

The degree to which infection control risk can be managed is a very important consideration in mobile medical device technology.

For patient groups with chronic conditions which carry a risk of re-infection, the ability to keep a monitoring device clean is a key concern. For devices used for short-term monitoring or in mobile clinics, it should be possible to provide protection from cross infection without affecting the function of the device.

Vitalograph respiratory testing and monitoring devices are designed for use with Bacterial-Viral Filters (BVF). The low cost

disposable Eco BVF™ is an example. Using a BVF protects the device from contamination, the patient from cross-infection and other people in the room from aerosolized droplets exhaled during testing.



Respiratory monitoring devices used without an effective hygiene solution allow aerosols and particulate matter to be expelled into the device and surrounding air.



The Vitalograph BVF has been independently validated by testing at low and high flow rates which demonstrated cross contamination efficiency to 99.999% protection from cross infection from all pathogens including Coronavirus.

This means that where a new BVF is used for every test session, wiping the external surfaces of the device with a suitable disinfectant wipe is the only cleaning that would normally be required. Read the report at <https://vitalograph.com/downloads/view/284>

Privacy

Medical devices may collect sensitive health data which is subject to privacy protection under the Health Insurance Portability and Accountability Act (HIPAA) and other laws. A mobile telehealth app may act as a transfer medium for test data but, under privacy regulations, the user must have control over whether and where to transfer their results.

Mobile apps used as part of any telehealth solution should employ the highest level of security to ensure that data privacy is always maintained. The user should have complete control over their own data and can choose to share that data securely with whomever they deem appropriate (eg their own clinician).

- Access to a mobile telehealth app should be controlled by username and password adding an extra level of security on top of the mobile platform security.
- Data should be stored securely on the mobile platform with access to the data only allowed through the mobile telehealth app with valid credentials.
- Data should not be transmitted outside of the mobile platform unless the user decides to do so.
- If the user decides to share their data with their clinician, they should be able to choose to sign up to a secure cloud based service or secure web portal.
- Communication from the mobile telehealth app should be controlled via secure web services to ensure that privacy of personal data is maintained end to end.
- Any cloud service or web portal should be secured through its own layer of security and with additional user credentials where the user can access their own data in the cloud or decide to allow access to their own registered clinician.

Vitalograph devices transmit data securely, in real time, to the associated mobile telehealth application reducing the need for any personal identifying data to be stored on the Vitalograph device.

Performance

The data results from any telehealth mobile app are only as good as the device or technology used for the actual monitoring and/or testing of the patient.

It is therefore essential that the device is reliable, repeatable, consistent and performs to the required standards.

ISO standards are adopted by national standards agencies, eg ANSI thus bringing them into national laws. They provide technical specifications to ensure that products and services are safe and effective, ie the device performs as expected. (www.iso.org)

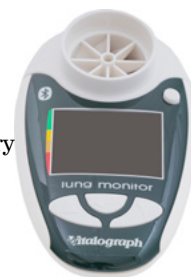
The ISO international standards system is intended to ensure that not only consumers, but also regulators and governments can have confidence that products are safe and reliable. The standards are agreed by international panels of experts drawn from users, manufacturers, designers, and technical experts to ensure product safety and performance.

Vitalograph produces respiratory monitoring and testing devices that meet ATS/ERS guidelines and ISO standards (including the mandatory ISO23747, ISO26782) and are audited frequently by regulatory authorities requiring us to provide evidence that all products are designed, manufactured and distributed to the required standard and perform as intended.

Many independent clinical studies have demonstrated the excellent reliability and performance of Vitalograph devices.

Dickens et al (2020) compared the test performance of a Vitalograph respiratory monitor against confirmatory post-

bronchodilator spirometry. The results confirmed that the accurate, easy-to-use Vitalograph device offered the opportunity to screen out non-symptomatic patients quickly and easily, saving time and resources in primary care. The respiratory monitor was described as being accurate and particularly useful as a screening device due to its simplicity of use, the minimal number of blows required and the good test performance.



Fujita et al 2020 confirmed that the Vitalograph monitoring device (copd-6) used in their study was “significantly advantageous” and yielded the best detection rates for COPD.



Using a reliable and trusted medical device is an essential part of a successful telehealth remote monitoring system and ensures accurate and valid data is recorded.

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Prevalence of Compassion Fatigue, Burnout and Compassion Satisfaction Among Respiratory Therapists at King Abdulaziz Medical City in Riyadh

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Abstract

Introduction: Respiratory therapists who work in intensive care unit with patients that suffer from cardiopulmonary diseases are affected from compassion fatigue and burnout. Intensive care unit is a stress environment due to most of patients are critically ill or unstable and when the doctor told the patient or patient family of terminal illness prognosis. Respiratory therapists work in different areas in the hospital especially in the ICUs. Sometimes respiratory therapists and other staff involved in traumatic events. After continuous exposure to traumatic events the respiratory therapists are more likely to develop compassion fatigue and burnout.

Materials and Methods: A cross-sectional study in KAMC in Riyadh among respiratory therapist. The Professional Quality of Life Scale (proQOL-5) questionnaire was used to collect data.

Results: The prevalence of compassion fatigue, burnout and Compassion satisfaction were 68.7%, 60.6% and 54.5% respectively. The level of compassion satisfaction among the participants about 52% of participants had average level of CS. About the level of compassion fatigue 63% of the participants had average level of CF. A majority (60%) of participants had average level of burnout. The mean score of compassion satisfaction was found to be 40.13 + 6.41 while the mean score of burnout was 26.89 + 7.82 and that of compassion fatigue was found to be 24.22 + 5.57.

Conclusion: High level of compassion fatigue causes a lot of problems such as feeling of helplessness, lowered concentration, and work absenteeism. After this study our suggestion is to limit the develop of compassion fatigue on the staff and find the solutions for them.

Introduction

Respiratory therapists who work in intensive care unit with patients that suffer from cardiopulmonary diseases are affected from compassion fatigue and burnout. Intensive care unit is a stress environment due to most of patients are critically ill or unstable and when the doctor told the patient or patient family

of terminal illness prognosis. Respiratory therapists work in different areas in the hospital especially in the ICUs. Sometimes respiratory therapists and other staff involved in traumatic events. After continuous exposure to traumatic events the respiratory therapists are more likely to develop compassion fatigue and burnout.

Compassion fatigue is a negative result that respiratory therapists may experience for dealing with patients. Compassion fatigue has two parts. The first part is the burnout which is the feeling of desperation and difficulty in working or doing your job effectively. And the second part talk about secondary traumatic stress. Secondary traumatic stress is a negative factor causes by fear and work-related trauma. Also, compassion fatigue can be psychological, biological and physiological effect due to constant exposure to patients suffering over a long period of time and is characterized by a gradual decrease in compassion over time. However, compassion satisfaction is the pleasure you derive from your ability to do your job well.

In 2017, a study done in undergraduate nursing students at a tertiary education institution in KwaZulu-Natal discussed that the students were suffered from compassion fatigue and burnout during their academic years due to academic workload, and they were afraid from doing mistakes in their clinical practice or in dealing with emergencies for the first time.¹ In 2018, a study done among cardiac physicians in Pakistan concluded that compassion fatigue had an average level of 58% of the practitioners and had a low level of 42% of the practitioner. However, Younger physicians were more prone to develop compassion fatigue and burnout due to lack of experience, and female physicians were more likely to develop burnout than male physicians. Also, the duration of sleep has a significant effect on the burnout. For instance, practitioners who slept for enough time were less prone to have burnout. On the other hand, practitioners who slept for a short time were more prone to develop the burnout.² In 2015, a study conducted among oncology nurses in united states and Canada concluded that a healthy work environment helps to decrease compassion fatigue and burnout. In 2013, a study done in United Kingdom among therapists who work with adult trauma clients reported the majority of therapists had average level of compassion satisfaction, average risk of burnout, and 70% of participants had high level of compassion fatigue.

The purpose of this study was to measure the prevalence of compassion fatigue, burnout, and compassion satisfaction. To

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conclude, compassion fatigue and burnout have negative effects when it develops, therefore, we need to identify and limit the sources of their development.

Methodology

The study design was descriptive cross-sectional study. The study was conducted at KAMC, Riyadh. This study was focused on various psychological aspects (compassion fatigue, Burnout and compassion satisfaction) in Respiratory therapists who work in different areas such as ICUs, wards, sleep lab, PFT lab, Emergency department etc. in KAMC. The duration of this study will be from May to December. And the sampling technique was non-randomized convenient sampling. The data will be conducted in the form of self-administered questionnaire which we took from the previous studies. The data collected was entered in MS Excel and exported to SPSS v.22 for statistical analysis. Tables and figures will be used to represent the results. Frequencies and percentages will be used for categorical variables. Continuous variables were represented as mean and standard deviation (SD) of normally distributed, median and interquartile range (IQR) will be used if the distribution is not normally. IRB approval will be obtained before starting the data collection. Prior distributing the questionnaire, an informed consent will be obtained from each participant. Participants data will be maintained confidential through the process of this research. Data access will be restricted only to the researchers where the data will be saved securely.

Results

Ninety-nine of participants that met our inclusion and exclusion criteria. A majority (44%) of participants their age between 24 to 30 years. About 50% of participant were working in the ICUs. A majority (43%) of the participants spend time from their home to reach the workplace between 15 to 30 minutes. 35% had experience more than 10 years. 42% of the participant was found to be RT1. The majority (90%) of the participants had bachelor's degree. And 59% of the participants were currently married.

The prevalence of compassion fatigue, burnout and Compassion satisfaction were 68.7%, 60.6% and 54.5% respectively. The level of compassion satisfaction among the participants about 52% of participants had average level of CS. About the level of

compassion fatigue 63% of the participants had average level of CF. A majority (60%) of participants had average level of burnout. The mean score of compassion satisfaction was found to be $40.13 + 6.41$ while the mean score of burnout was $26.89 + 7.82$ and that of compassion fatigue was found to be $24.22 + 5.57$.

There is a significant difference between gender and compassion fatigue with males having higher scores ($28.63 + 8.17$) when compared to females ($24.65 + 6.78$) with p value (0.011). Between gender and burnout there is a significant difference with males having higher scores. ($25.45 + 5.48$) when compared to females ($22.63 + 5.33$) with p value (0.012). And there is significant difference between age and burnout with participants between 24 to 30 years having higher score ($25.73 + 5.18$) with p value 0.018. Participants who spends more than 30 minutes between home and workplace have a higher score of compassion fatigue ($30.88 + 8.72$) with p value (0.003). There is a significant difference between experience and burnout with participants their experience between 2 to 5 years have higher score of burnout ($26.15 + 6.39$) with p value (0.015).

Table 2. Mean (\pm SD) of subscale categories

Category	Mean (\pm SD)
Compassion Fatigue	26.90 (\pm 7.82)
Burn out	24.22 (\pm 5.57)
Compassion Satisfaction	40.13 (\pm 6.41)

Discussion

An initial objective of the research was to identify the prevalence of compassion fatigue, burnout and compassion satisfaction. The level of compassion fatigue among the participants about 5% had low level, 63.3% had average level, and 31.3 had a high level. And the burnout level was 60.6% had average level, 39.9% had low level, and no high level finding in the burnout. And about the compassion satisfaction 45.5% of the participants had high level, 52.5% had average level, and 2% had a low level.

The current study found that compassion fatigue associated with gender. Male participants were more likely to develop compassion fatigue than females maybe due to the males affected from the patients who dead or very sick more than females.

And this study confirms that compassion fatigue is associated with participants who spends more than 30 minutes between home and workplace had a higher score of compassion fatigue due to the long time they take on the road.

And another interesting finding was that burnout is associated with gender. Males having higher score in burnout than females. However, another study of Mooney C. (2017) found that female nurses were more prone to develop burnout. And it is encouraging to compare this figure with another study that is by Ghazanfar et al (1993) who found that there is no significant association of gender with burnout at all. A possible explanation for this is that the males has more responsibilities in their lives more than females. For example, they are the responsible for their families.

Another important finding was between age and burnout. Participants between 24 to 30 years had a higher score in burnout. A possible explanation for this is that they might lack

Level of Compassion fatigue, Burn out & Compassion satisfaction.

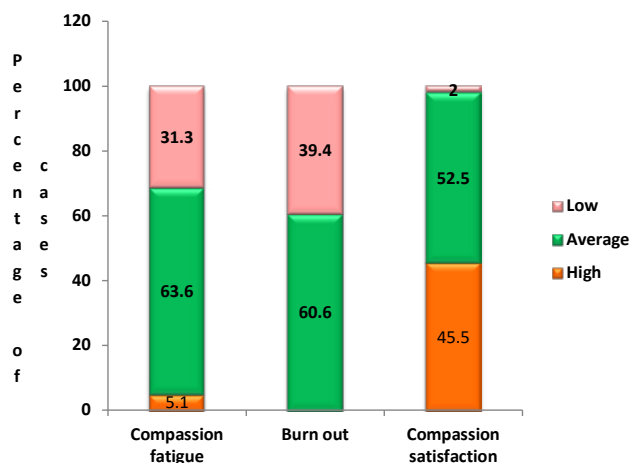


Figure 1. Percentage bar diagram representing the level of Compassion Fatigue, Burn out and Compassion Satisfaction

of experience and also that the new staff are not familiar with their work as the old staff who have more experience. This finding was also reported by Kolthoff et al (2016) who also found the new staff of nurses were prone to burnout and compassion fatigue more than old staff.

One of the limitations of our research was the large number of questions in the (proQOL-5) questionnaire. Also, the respiratory therapists didn't have time to participate due to the workload they have. And the strength of our study was given enough time to the participant to solve the questions.

Conclusion

This study done in respiratory therapists at King Abdulaziz Medical City to measure the prevalence of compassion fatigue, burnout, and compassion satisfaction and we found 63% of participants had average level of compassion fatigue that may be developed to a high level. High level of compassion fatigue causes a lot of problems such as feeling of helplessness, lowered concentration, and work absenteeism. After this study our suggestion is to limit the development of compassion fatigue on the therapists and find the solutions for them.

Contribution

This work was carried out in collaboration between all authors. Author TI was the principal investigator of the research project, responsible for designing of the entire work. Authors MA, AA, NA, SA, and AA were responsible for literature collection, data collection and preliminary write up. Authors S and WP were responsible for data management and assisted in write up.

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Converting to Online Clinical Research Practicum During Pandemic

Charles J Gutierrez, PhD, RRT, CPFT, FAARC¹, Gina Ricard, MS, RRT-NPS, RRT-ACCS¹, Peggy A Coffey, MD² and Wilson DeJesus, BSN, RN²

Abstract

Introduction: The American Association for Respiratory Care (AARC) has indicated that by 2030, an entry-level baccalaureate degree (BD) and a registered respiratory therapist (RRT) credential will be required to practice respiratory care. Earning a BD in respiratory care involves acquisition of functional clinical competencies as well as research competencies that prepare the RRT for advanced clinical practice. Our AD program formulated a foundational on-site clinical research practicum (CRP) to help sophomores gain research knowledge and skills prior to graduation. This article describes the latest installment in a three-year study of on-site CRPs that occurred in 2018, 2019 and 2020. In Spring 2020, the COVID-19 pandemic necessitated a sudden transition in CRP format from on-site to online and created an opportunity to explore differences in learning outcomes between on-site and online CRPs.

Methods: On-site CRP cohorts from 2018 (N=16), 2019 (N=10) and 2020 (N=11) were compared with an online (N=13) CRP cohort from 2020.

Results: There were no significant differences in pre-CRP quiz scores, post-CRP quiz scores or CRP satisfaction survey scores between on-site and online CRP cohorts. There was a significant ($p < 0.001$) decrease in post-CRP research skills scores for the 2020 online cohort when compared with on-site cohorts from 2018, 2019 and 2020.

Conclusion: Over a three-year study period, on-site CRPs were associated with improvements in research knowledge and skills of graduating sophomores. However, a pandemic-driven need to suddenly transition approximately half of the 2020 cohort to a predominantly asynchronous online CRP was associated with a significant decline in acquisition of research skills in the 2020 online cohort. Additional research will be needed to identify causal factors for this decline and suggest educational strategies for improving acquisition of research skills in an online CRP.

Keywords: clinical research practicum; undergraduate clinical research; problem-based learning; RT baccalaureate degree; respiratory therapy education; registered respiratory therapist; clinical research knowledge; clinical research skills;

advanced clinical practice; on-site education; online education; asynchronous content; synchronous content.

Introduction Clinically Complex Healthcare

The US healthcare system has endeavored to improve patient care while containing costs associated with operating a clinically complex milieu.¹ Healthcare researchers have suggested that improving patient care and reducing costs may be achieved by improving prevention and management of disease, increasing use of transdisciplinary teams² and embracing evidence-based diagnostics and interventions.³ Such healthcare changes have dramatically increased the need for advanced registered respiratory therapists (RRTs) who can work in a clinically complex environment characterized by systematic communication, interprofessional collaboration (IPC)^{4,5} and robust critical thinking skills. As advanced respiratory care evolves, healthcare facilities will need RRTs who are conversant with emerging research findings and who are able to critically assess scientific results and determine how those results should be used in making effective clinical decisions.^{6,7}

Baccalaureate Degree – 2030

To enable RRTs to thrive in the aforementioned clinically complex environment, the American Association for Respiratory Care (AARC) has stipulated that by 2030, those seeking to enter clinical practice must have an entry-level baccalaureate degree (BD) and RRT credential to enter clinical practice.⁸ Since use of evidence-based protocol-guided bedside-interventions are becoming widespread in clinically complex environments, it is clear that graduating students will need to have research competencies, i.e., knowledge and skills that are the core of evidence-based care. Given that research training has not traditionally been part of the typical AD curriculum,¹ it would seem prudent for AD programs to offer a “capstone” research experience even as they work to establish articulation agreements with BD-granting academic institutions or begin the process of educationally transitioning into a BD program. Our experience has shown that a foundational, clinical research practicum (CRP) is an important educational tool that helps graduating sophomores prepare for upper-level academic work and for advanced clinical practice.

Providing formal research training for students in an AD program, has recently generated considerable interest. In one report, sophomores in an AD program participated in a research seminar where they learned to review scientific

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Table 1. Comparison of on-site versus online CRP research skills rubric

Day 1	
On-site CRP Research Skills	Online CRP Research Skills
1A: Student verbally explained rationale for participation in on-site CRP.	1A: Student explained rationale for participation in online CRP by submitting four work products.
1B: First student measured physiologic variables at bedside using volumetric capnography while second student recorded data on data sheet.	1B: Student in virtual clinical environment worked independently, not in pairs. Student was given physiologic variables from PowerPoint presentation and directed to record data onto a virtual data sheet.
1C: After viewing example of RT scientific poster in hospital, student verbally explained introduction, method, result, discussion and conclusion.	1C: After viewing example of RT scientific poster in PowerPoint presentation, student submitting virtual scientific poster (work product) that included introduction, method, result, discussion and conclusion.
Day 2	
On-site CRP Research Skills	Online CRP Research Skills
2B: (Roles flipped) Second student measured physiologic variables at bedside using volumetric capnography while first student recorded data on data sheet.	2B: Student in virtual clinical environment worked independently, not in pairs.
2D: After reading a recent scientific article from <i>Respiratory Care</i> , student verbally identified randomized controlled trial, control and experimental groups, independent and dependent variables, explained p value and explained conclusion.	2D: After reading a recent scientific article from <i>Respiratory Care</i> , student answered questions pertaining to randomized controlled trial, control and experimental groups, independent and dependent variables, explained p value and explained conclusion.
2E: Student recommended modifications to chest optimization protocol (COP) at bedside.	2E: Student recommended modifications to chest optimization protocol (COP) by submitting write-up.

literature, design an experiment, conduct a research project and perform statistical analyses.⁹ Our findings have similarly shown that sophomores with the certified respiratory therapist (CRT) credential¹⁰ as well as traditional sophomores¹¹ are quite capable of learning the knowledge and skills needed to perform undergraduate clinical research in an environment modeled after undergraduate research training programs in bioscience. Recent findings have shown that some undergraduate research programs encourage active student involvement in designing and teaching elements of their research class.¹² Clearly, the impetus for undergraduate involvement in the biosciences is accelerating and this offers important lessons for undergraduate programs in respiratory care. Interestingly, undergraduates who participate in structured undergraduate bioscience research were much more likely to complete a BD in bioscience.^{13,14} Consequently, establishing a foundational on-site CRP in an AD respiratory care program could similarly enable respiratory care students to acquire research knowledge and skills needed to complete a BD and engage in advanced clinical practice.

Primacy of Undergraduate Research

Studies of academic programs in respiratory care have shown that clinical research competencies are not customarily taught in AD programs¹⁵ and students do not receive training in evidence-based practice, protocolized care or evaluation of scientific research findings.¹⁴ These core concepts are the foundation for roles and responsibilities that RRTs will need to embrace as interprofessional clinical collaborators. While the primary emphasis of respiratory care education has historically been on presenting functional subject matter related to providing direct patient care, thus relegating acquisition of research knowledge and skills to a position of secondary importance, the time has come for undergraduate research training to be seen as being equally important to functional subject matter¹⁶ and for it to be integrated into all facets of a respiratory care curriculum. Students should understand that knowledge is tentative and subject to continual modification. In addition to critical and collaborative thinking, respiratory care programs should also teach reflective thinking of the type typically encountered in

graduate-level academic programs and in forward-thinking undergraduate programs. Today's clinically complex milieu requires RRTs with research training that augments and strengthens their functional knowledge base.

Methods

Synchronous On-site (Hospital-based) CRP

Over the past three years, cohorts of sophomores have participated in an on-site CRP capstone experience prior to graduation from our AD respiratory care program. The on-site CRP was designed as a component of Clinic IV which is offered during the penultimate semester prior to graduation. In preparation for Clinic IV, sophomores were randomly scheduled to rotate through instructor-led clinical specialty practica that included on-site CRP, neonatal intensive care (NICU), polysomnography lab, pediatric intensive care (PICU), cardiac catheterization lab, pulmonary function testing lab (PFT), hyperbaric chamber and neurorespiratory care (NRC).

Each specialty practicum lasted two to four days and was intended to fully immerse students in clinical experiences that promote acquisition of specialized knowledge and skills.

Prior to commencing the on-site CRP, sophomores completed a proctored, pre-CRP quiz consisting of 20 multiple-choice questions (5 points per question) to evaluate baseline research knowledge. The pre-CRP quiz was administered prior to four full-day didactic sessions during which students studied topics that included: respiratory therapy research methods, basic statistical analysis, experimental design and measurement of physiologic variables using volumetric capnography. Students were periodically reminded that the on-site CRP was intended to prepare them for entry into a BD program and advanced clinical practice and that their task was to embrace the role of RRT clinical researcher. Students were randomly scheduled to attend the on-site CRP and were assigned to work in pairs with an on-site faculty facilitator. At bedside, students worked with an affiliate-specific clinical protocol known as the chest optimization protocol (COP).¹⁷ The COP and the research supporting it were studied in class before students attended the

Table 2. On-site CRP supplemental research agenda

1)	Day 1: Student verbally explained parts of a pathology scientific poster
2)	Day 1: Student verbally explained parts of a scientific, sleep study poster
3)	Day 1: Student assessed a weaned mechanically-ventilated patient
4)	Day 1: Student visited ICU; asked course-based questions about recent research
5)	Day 1: Student visited medical library; examined respiratory doctoral dissertation
6)	Day 2: Student asked biomedical engineer course-based questions about his/her role in clinical research
7)	Day 2: Student asked medical media specialist course-based questions about his/her role in clinical research
8)	Day 2: Student asked clinical sim lab specialist course-based questions about his/her role in clinical research
9)	Day 2: Student asked PFT lab specialist course-based questions about his/her role in clinical research
10)	Day 2: Student asked sleep lab specialist course-based questions about his/her role in clinical research
11)	Day 2: Student visited independent living iHome research project and asked course-based questions
12)	Day 2: Student visited physical therapy gymnasium and asked course-based questions about recent research projects

on-site CRP. Students were expected to recommend changes to the protocol based on data collected at bedside.

At the end of the two day on-site CRP, the on-site faculty facilitator used a semi-quantitative CRP research skills rubric to evaluate gains in research skills according to five learning objectives. Differences in on-site versus online CRP research skills rubric are shown in Table 1.¹¹ A major difference between on-site and online evaluation of skills was that onsite students worked in pairs and were evaluated in person at bedside whereas online students worked independently and were evaluated based on submitted work products.

Students who exceeded a given learning objective earned 20 points, those who met a learning objective earned 15 points and those who did not meet a learning objective were assigned 5 points to acknowledge basic participation. Exceeding all five learning objectives yielded 100 points. Earning at least 85 points was deemed evidence that students had acquired adequate foundational research skills. Research concepts presented during the four-day didactic sessions were aligned with research skills evaluated during the subsequent two-day on-site CRP. After the on-site CRP, students completed a post-CRP quiz (identical to pre-CRP quiz) to measure gains in research knowledge. Participants' scores were entered into IBM SPSS 26 data spreadsheet for analysis of variance (ANOVA) statistical modeling. Statistical significance was established at $p < 0.05$.

On-site supplemental research

While the main objective of the on-site CRP was to enable students to acquire fundamental research knowledge and skills, a substantial portion of a student's on-site training consisted of acclimation to the role of RRT clinical researcher. In order to facilitate this task, an on-site supplemental research agenda, shown in Table 2, helped students learn additional selected concepts deemed necessary for successful clinical research. Hence, while the post-CRP skills rubric was used to evaluate acquisition of specific research skills, supplemental on-site

experiences helped students appreciate the importance of collaboration in clinical research.

Asynchronous Online CRP

As a consequence of the pandemic that occurred at mid-semester, the on-site CRP was quickly converted to an online CRP in a period of three weeks. By mid-semester, 46% of the 2020 sophomore cohort ($N=11$) had completed the on-site CRP while 54% ($N=13$) were scheduled to begin the newly designed online CRP. Faculty developed an online CRP that was deemed equivalent to the on-site CRP. A sequence of narrated PowerPoint presentations was instituted to fully replace the on-site experience which was aligned with four online work-products deemed equivalent to on-site work-products. Attempts were made to produce an online experience that was accessible and flexible for students suddenly confronted with the challenge of continuing their coursework while in quarantine. While the pandemic was associated with multiple challenges, it also constituted a natural experiment that afforded the opportunity to study differences between on-site and online delivery of a CRP capstone experience.

Results

Mean age of sophomore participants ($N = 50$) in all cohorts combined was 27 years, 80% were female and 15% had an AD or higher prior to entering our two-year respiratory care program. Student cohorts from 2018, 2019 and 46% of the 2020 cohort completed a synchronous, on-site CRPs, while 54% of the 2020 cohort completed an asynchronous, online CRP. As part of quality assurance metrics instituted prior to the pandemic, RRTs who practiced in the unit of the hospital where students performed their on-site CRP were asked to take the same pre-CRP quiz taken by students at the beginning of the semester. Seven of ten RRTs completed the proctored quiz during their work shift. Of seven RRTs who took the Pre-CRP, two had associate degrees, two had baccalaureate degrees and three had master's degrees. There were no significant differences in pre-CRP quiz scores between 2018 (mean \pm SD = 52.81 \pm 12.10) on-site cohort, 2019 (mean \pm SD = 50.50 \pm 9.84) on-site cohort, 2020 (mean \pm SD = 56.81 \pm 10.78) on-site cohort, 2020 (mean \pm SD = 48.46 \pm 16.25) online cohort and RRT (mean \pm SD = 57.14 \pm 16.03) cohort, as shown in Figure 1.

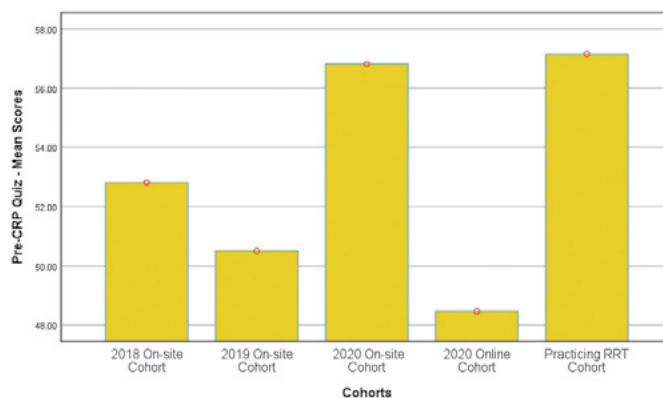


Figure 1. Pre-CRP research knowledge scores for sophomore cohorts and RRTs

There were no significant differences in post-CRP quiz scores between 2018 (mean \pm SD = 75.93 \pm 11.86) on-site cohort, 2019 (mean \pm SD = 68.50 \pm 11.79) on-site cohort, 2020 (mean \pm SD = 71.81 \pm 10.48) on-site cohort and 2020 (mean \pm SD = 63.46 \pm 13.45) online cohort, as shown in Figure 2.

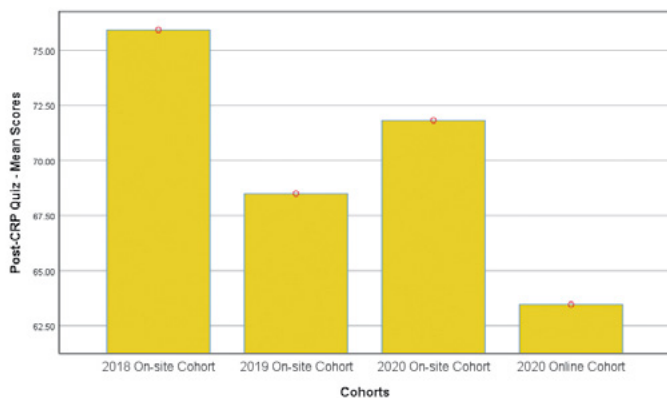


Figure 2. Post-CRP research knowledge scores for sophomore cohorts

There was a significant ($p < 0.001$) difference in research skills scores between 2018 (mean \pm SD = 93.75 ± 5.63) on-site cohort, 2019 (mean \pm SD = 94.50 ± 6.9) on-site cohort, 2020 (mean \pm SD = 96.36 ± 6.0) on-site cohort and 2020 (mean \pm SD = 86.66 ± 3.9) online cohort, as shown in Figure 3.

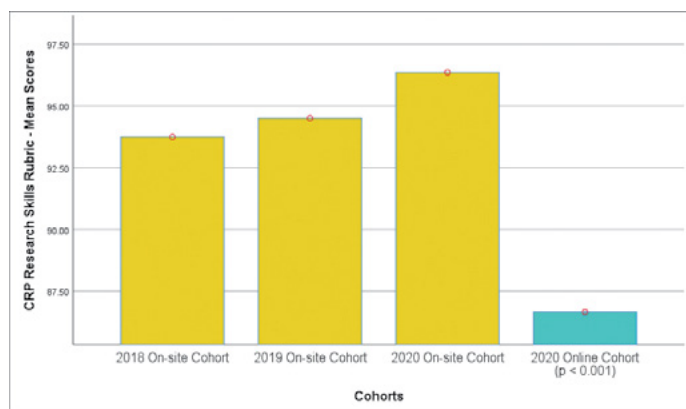


Figure 3. Post-CRP research skills scores for sophomore cohorts

There were no significant differences in post-CRP satisfaction scores between 2018 (mean \pm SD = 89.25 ± 19.39) on-site cohort, 2019 (mean \pm SD = 92.8 ± 5.8) on-site cohort, 2020 (mean \pm SD = 92.55 ± 8.7) on-site cohort and 2020 (mean \pm SD = 88 ± 11.11) online cohort, as shown in Figure 4.

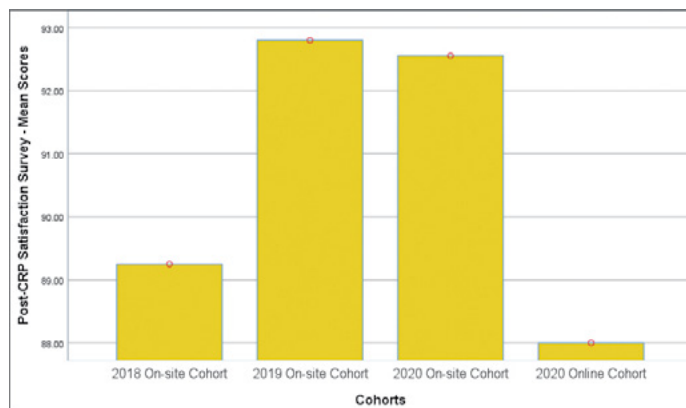


Figure 4. Post-CRP satisfaction survey scores for sophomore cohorts

Discussion

Findings from our three-year CRP study suggest that an on-site CRP capstone experience may be one strategy for improving sophomores' foundational research knowledge and skills prior

to graduation (10). In addition to teaching functional knowledge and skills, respiratory care faculty in AD programs should also teach research knowledge and skills that will help students use and produce new knowledge throughout their careers. Whether online CRP cohorts may achieve educational outcomes comparable to outcomes achieved by on-site CRP cohorts requires further study.

Pre-CRP quiz scores

The lack of a significant difference in pre-CRP quiz scores between on-site and online CRPs suggests that 2018, 2019 and 2020 cohorts entered both on-site and online CRPs, with comparable baseline research knowledge. The lack of a significant difference in pre-CRP quiz scores between students and practicing RRT cohorts was surprising, given that many RRTs in the cohort had a BD or higher and would have been expected to post higher pre-CRP scores. In this study it was assumed that research knowledge and skills are increasingly seen as a valuable part of daily clinical practice in many respiratory care departments and constitute an increasingly important part of a department's clinical culture. Additional research with a larger RRT cohort should be undertaken to identify strategies aimed at improving practicing RRTs' research knowledge and skills. This will be especially important as more students begin arriving at the hospital workplace with research skills which they fully expect to implement as part of their mission to improve patient care outcomes.

Post-CRP quiz scores

The lack of a significant difference in post-CRP quiz scores between on-site and online CRP cohorts suggests that comparable gains (ranging from 15 to 22 points) in research knowledge were attained by both on-site and online CRP cohorts. Practicing RRTs did not participate as students or as facilitators in the on-site CRP and therefore did not take a post-CRP quiz.

Post-CRP skills scores

Over a three-year study period, post-CRP skills scores for 2018, 2019 and 2020 on-site cohorts progressively improved. This suggests that on-site CRP participants have perennially acquired research knowledge that may help prepare them for entry into BD programs and advanced clinical practice. A significant ($p < 0.001$) difference in skills scores between 2018, 2019 and 2020 on-site CRP cohorts and 2020 online CRP cohort suggests that participation in on-site CRP produced larger gains in research skills than participation in the online CRP. Studying the effectiveness of an educational strategy, especially one that results from a natural experiment is inherently complicated, as evidenced by the dearth of high-level, randomized controlled trials of the association between specific educational interventions and learning outcomes such as knowledge and skills (18). Some researchers have called attention to the difficulty associated with comparing learning outcomes of healthcare students in a synchronous problem-based learning (PBL) environment, such as the on-site CRP versus an asynchronous PBL environment such as the online CRP (19). Additional research will be needed to ascertain how students may attain comparable research skills regardless of CRP format.

Adding synchronous learning methods to online format

Evidence-based educational practices from the biosciences provide numerous educational strategies that may augment the learning experience for students engaged in a predominantly

asynchronous online CRP. Use of synchronous modalities that include timely, customized, instructor feedback may very well play a key role in enabling students in an online CRP to achieve research skill levels commensurate with levels achieved by students in an on-site CRP. Selected evidence-based synchronous learning methods such as the ones listed below, have been found to augment asynchronous learning in biosciences²⁰ and may play a similar role in respiratory care:

- **Short writing sessions:** participants get two minutes to briefly write about a research topic or concept that they need to think about more deeply.
- **Whole group discussion:** a short list of course-related questions is provided, after which participants discuss in whole group setting.
- **Ponder-Pair-Present:** present course-related question and have participants silently reflect for a minute or two. Students then pair up, compare thoughts with their associate and present a synthesized consensus to the group.
- **Brain-blitz:** students select tough topics from content and collaborate with classmates to clarify the issues. Volunteers then present their ideas, which are listed on a chalkboard or whiteboard, so that the class may talk through each idea presented.
- **Reflection time-out:** when presenting, reviewing or discussing material, small time-outs allow students to think about what is being presented or to remember when/how this topic was presented. After a brief time-out, ask if anyone needs clarification.

Further research may help determine which combination of synchronous learning methods may improve acquisition of research skills in an online CRP format.

The lack of significant differences in post-CRP satisfaction scores between on-site and online CRPs suggests that both formats were associated with comparable levels of student satisfaction. Nevertheless, satisfaction level for the 2020 online cohort was the lowest of all cohorts studied. It has been observed that education interventions that offer a high level of interaction as encountered in synchronous formats, are often deemed highly satisfying by participants.¹⁹ Our findings are in agreement with this observation in that on-site CRP cohorts that exhibited gains in knowledge and skills also posted high satisfaction scores. Whether increasing the level of synchronous learning in a predominantly asynchronous online CRP increases the level of satisfaction in the future, will need to await further research.

Toward 2030

The profession of respiratory care began by performing limited clinical tasks. Its practitioners now provide a spectrum of advanced clinical services that require high-level cognition and expert clinical case-management. At the same time, a burgeoning increase in scientific information has catalyzed a paradigm shift toward evidence-based clinical practice. As 2030 nears, BD-prepared RRTs will be called upon to combine high-quality scientific findings, clinical expertise and patient preferences to deliver advanced, customized, patient care in ways that are safer, more efficacious and more cost-effective. In preparation for this clinically complex milieu, respiratory care students in AD programs should receive clinical research training from their first day in class. Their curriculum should be structured to unambiguously convey the central role that scientific research plays in informing clinical practice even as

students learn physical assessment, modalities of mechanical ventilation, laboratory values, etc. A curriculum that promotes the development of research knowledge and skills will likely increase the prospect that its graduates will become involved in research activities that will advance their careers and enhance their profession.

Conducting research and teaching research skills has historically been a formal goal for medical and graduate schools.^{21,22} Teaching undergraduates to critically evaluate scientific findings, appraise scientific methodologies, take part in scientific studies and place research findings in their proper clinical context introduces a real world dimension to undergraduate functional coursework. Respiratory care faculty in AD programs should lead the way in inculcating curiosity, skepticism, reflection, analysis and the art of balanced argument in their students, especially at this critical junction in the profession's transition to the entry-level BD. Every member of the transdisciplinary healthcare team is being tasked with becoming an intelligent consumer and producer of scientific research as a method for improving patient care. AD programs should use education strategies that help students develop research competencies in simulation labs and in on-site and online clinical practica.

Limitations of study

In preceding installments of our three-year study,^{23,24} we acknowledged the limitation of small sample sizes. We have endeavored to address this limitation by adding an annual student cohort to what has become a longitudinal study. Although cognizant of the limitations imposed by a possible batch-effect arising from analysis of annual cohorts, the 2020 cohort would have doubled the total number of on-site subjects, perhaps then enabling more definitive andragogical statements to be made about the ability of on-site CRPs to augment students' research competencies. The pandemic-driven need to suddenly switch to a predominantly asynchronous online CRP resulted in a natural experiment in which on-site (quasi-control) and online (quasi-experimental) cohorts were compared. While we considered inclusion of traditional control groups in earlier reports, we instead opted for a pre- / post- experimental design in which participants served as their own controls.

Conclusion

Over a three-year period, sophomores in a respiratory care AD program participated in an on-site CRP and gained research knowledge and skills intended to facilitate entry into BD programs and prepare for advanced clinical practice. A pandemic-mediated transition from on-site to online CRP delivery resulted in decreased acquisition of research skills for the online CRP cohort. The sudden transition from on-site to online CRP format, revealed important lessons about the inherent synergy between synchronous and asynchronous content delivery methods and its ability to enrich an on-site and/or online CRP capstone experience. Predominantly asynchronous online formats may need to be supplemented with specific synchronous learning methods to enable acquisition of research skills comparable to those obtained via on-site formats. CRPs appear to play a key role in the ability of AD programs to provide sophomores with foundational, research training. During the transition to a BD-level program, we will continue searching for evidence-based best practices aimed at imparting clinical research knowledge and skills and for retrospectively evaluating the extent to which these competencies facilitate participants' entry into BD programs and advanced clinical practice.

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Comparing Flow-safe Disposable Continuous Positive Airway Pressure (CPAP) When Treating Acute Cardiogenic Pulmonary Edema

Chris Campbell

When it comes to deciding what is the best way to treat the most serious medical conditions, hospitals are in constant need of the most up-to-date data to inform those decisions.

Hospitals need to know such things as how effective certain treatments are, as well as a cost analysis in relation to those treatment options. For instance, is a certain device being portable compared to another treatment considered a distinct advantage in some situations?

So many questions and yet often so few studies available for hospitals to make sure crucial decisions.

This is why a team led by Ilhan UZ from Ege University Faculty of Medicine in Izmir, Turkey launched a prospective study into treatment options for Acute Cardiogenic Pulmonary Edema (ACPE).

This 12-month study, conducted in 2018 at a centre that averages 200,000 emergency visits a year, compared Flow-safe Disposable Continuous Positive Airway Pressure (CPAP) with Non-invasive Mechanical Ventilation (NIMV) when treating ACPE.

“Although there are few studies on FSD-CPAP-S-like CPAP systems, we have not found any study that compares the effectiveness and cost analysis of FSD-CPAP-S with NIMV in ACPE,” wrote the authors. “The aim of this study was to investigate and compare effectiveness and cost analysis between NIMV and FSD-CPAP-S in the early treatment of patients with ACPE admitted to the emergency service.”

The resulting study is called *Is the flow-safe disposable continuous positive airway pressure (CPAP) system as effective as non-invasive mechanical ventilation (NIMV) in the treatment of acute cardiogenic pulmonary Edema?* (The spelling of edema is “oedema” in Europe, but has been changed to the American spelling for this article.)

What the authors concluded was that the flow-safe disposable CPAP system can be as effective as NIMV in patients with ACPE.

Background

The authors describe ACPE a common cause of acute respiratory failure, making up around 10%-20% of acute heart failure syndromes and potentially causing death.¹

“The aim of this study was to investigate and compare effectiveness and cost analysis between NIMV and FSD-CPAP-S in the early treatment of patients with ACPE admitted to the emergency service.”

“Acute cardiogenic pulmonary edema usually presents with sudden dyspnoea at rest, impaired exertion capacity, tachypnoea, tachycardia and hypoxia,” the authors write. “Increased endogenous catecholamine levels and hypertension due to stress are common in cases with good left ventricular function. Cough is a frequent finding in these cases. In the presence of severe edema, patients may produce foamy or pink sputum. In these patients, the primary goal is to ensure adequate tissue oxygenation in order to prevent organ dysfunction and multiple organ failure.² Treatment options for the management of ACPE in patients with severe respiratory failure include loop diuretics, vasodilating agents, oxygen, non-invasive positive pressure ventilation (NPPV) and endotracheal intubation.^{3,4} Several studies report that using NPPV in the early period of ACPE treatment rapidly improves physiological parameters and reduces endotracheal intubation rates as well as the associated complications and mortality.⁵ Two main modes of NPPV are applied in the treatment of ACPE: continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP). It has been shown that both CPAP and BiPAP are well tolerated and do not cause any serious side effects.^{6,7} Various CPAP systems have been developed for use in the hospital and, more often, in the pre-hospital period, wherein technological advance processes tend to vary.⁸ In recent years, the flow-safe disposable CPAP system (FSD-CPAP-S) has also been used in both pre-emergency and emergency services as an alternative to NIMV for the treatment of respiratory failure in ACPE.”

Study Methods

Patients presenting with sudden-onset severe respiratory distress with tachypnea, tachycardia, hypoxia and acute heart failure findings (paroxysmal nocturnal dyspnoea or orthopnoea, foamy pink or white sputum, moist rales, S3 heart sounds, peripheral oedema, among others) or acute exacerbation of chronic heart failure were evaluated by the emergency physician, said the authors.

“After the evaluation of history and physical examination, patients diagnosed with ACPE were treated by the same

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physician,” the authors wrote. “The diagnosis of ACPE was confirmed by both of the cardiologists and emergency physicians as a result of laboratory and radiological tests (chest x-ray, lung ultrasonography, measurement of plasma natriuretic peptide level and bedside echocardiography). The study included patients aged over 18 years who were admitted for acute respiratory distress, started on conventional treatment (diuretic, vasopressor, oxygen) following the diagnosis of cardiogenic pulmonary edema, had a respiratory rate of N25 breaths/min and SatO₂ < 90%, lacked any condition that would prevent non-invasive positive pressure support and were planned to receive NPPV support.”

A total of 181 patients were included in the analysis after others were excluded for not meeting study criteria.

Results and Conclusions

Based on the results of the study, the authors called NPPV “one of the most important steps in the treatment of respiratory failure in ACPE” and just as effective as NIMV in multiple areas.

“We found that FSD-CPAP-S is as effective as NIMV in improving blood pressure, pulse, respiration rate and blood gas parameters in patients with ACPE,” the authors wrote. “In addition to the factors that increase the utility of FSD-CPAP-S in emergency practice, such as the fact that FSD-CPAP-S is not an electronic system, its portability, and its individual and disposable use, we believe that FSD-CPAP-S can be used as an effective alternative to NIMV in the treatment of ACPE, especially in emergency services with little to no mechanical ventilation available and large number of incoming patients. Nowadays, many centres apply NPPV as a standard treatment for ACPE in addition to conventional treatments. The European Society of Cardiology states that the respiratory rates and saturation values at the time of admission of patients with acute heart failure also serve as a guide for NPPV treatment, and that in patients with a respiratory rate N 25 breaths/min and an SpO₂ b 90%, NPPV should be administered as early as possible (recommendation class IIa, level of evidence B).³ The guideline also recommends saturation monitoring (recommendation class I, level of evidence C) as well as monitoring for blood pH, pCO₂ and, if possible, lactate (recommendation class IIa, level of evidence C) during acute heart failure. In the present study, we compared the effectiveness of FSD-CPAP-S and NIMV in ACPE treatment by using the parameters suggested by the guideline and a scoring system (Ege-ACPOSS) that has been planned and developed to be used in the emergency service, and which we believe will provide the means for a more objective evaluation. We found that the patients for both group, blood pressure, pulse respiratory rate, saturation values, pH, pCO₂ and lactate parameters, base excess (BE) and HCO₃ values approached normal values in parallel with their clinical improvement. At the same time, we found that normalization of carbon dioxide levels between 0 and 60 min was more effective in the NIMV group.”

The authors also discuss about how limited NIMV might be in emergency rooms and so alternative devices that are as effective as NIMV are indeed necessary.

When it came to cost, the authors said the average cost of FSD-CPAP-S treatment is higher than NIMV, but “the difference is small. Considering that the device cost is not included in this calculation because the NIMV device is a fixed asset and that the treatment cost is calculated only for equipment such as masks

and hoses, the difference between the two treatment methods is very small.”

The flow-safe disposable CPAP system would found to be “as effective as NIMV in patients with ACPE. Considering the overall improvement observed in the physiological blood gas and other parameters as well as the mortality and cost-related considerations, FSD-CPAP-S can be preferred in emergency services if there are insufficient NIMV devices.”

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Automated Closed-Loop Oxygen Control: A Review

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Overview

Physiologic Closed Loop Oxygen Control (PCLC) has been used since the late 1970's, including a non-invasive closed loop control solution described in 1979.¹ There have been numerous studies with results supporting the feasibility of clinical use of automated closed loop oxygen control.²⁻⁸ The fundamental functions of Proportional-Integral-Derivative (PID) or fine control—fast stepwise closed loop control algorithms has been described.^{3-7,9} Of these, the 2016 review by Fathabadi et al., provides a comprehensive technical overview, suggested future directions, and safety considerations of neonatal automated oxygen control algorithms.⁹ Additional discussion describes how these systems can be integrated into the oxygen blenders of portable ventilation systems.¹⁰ To date, PCLC algorithms have been used clinically in oxygen tents,^{1,11,12} mechanical ventilators,¹³⁻¹⁶ nasal continuous airway pressure and high flow nasal cannula.^{7,17-20} The concept of PCLC has been present for some time as previously alluded. Significant effort in developing ideal settings and testing of these algorithms exists in four published validation accounts in dogs,²¹ pigs,¹⁰ sheep,²² and lambs.²³

Both scientific and clinical discussion has centered around the use of algorithms in closed loop control systems in maintaining SpO₂ at studied physiologic targets deemed acceptable specifically in the preterm infant population.²⁴⁻²⁸ The closed loop controllers monitor arterial blood oxygen saturation (SaO₂) most commonly via the use of pulse oximetry (SpO₂) in real-time. As the SpO₂ values fluctuate above or below a set point or range, a central processor computes the necessary adjustment in the fraction of inspired oxygen (FiO₂) that is being delivered. The intention is that a PCLC can react faster than a human caregiver to apply oxygen when needed, but also minimize potential overshoot, and therefore limit oxygen exposure to which the patient is subjected over time, particularly incidences above the specified target range.^{1,8,14,29-31} For all the aforementioned benefits of PCLC, including the provision of clinical flexibility, the attendant clinical management and standard of care towards the patient should still remain unchanged, as ultimate responsibility for the patient is in the clinicians.

Optimal Oxygen Target Level in Neonates

As oxygen control is relevant to both neonatal and adult patient

populations, it is also prudent to mention that contention exists in literature on which SpO₂ target ranges to use, especially for the case of preterm infants, where oxygen saturations can affect mortality and retinopathy of prematurity.^{26,32,33} Defining and establishing an optimal neonatal oxygen target is important, though clinically challenging. Based on the NeOProM meta-analysis study of some of the largest randomized controlled trials, including SUPPORT, Benefits of Oxygen Saturation Targeting II (BOOST II), and the Canadian Oxygen Trial (COT), the European Consensus Guidelines recommended an oxygen saturation target of between 90% and 94%, with suggested alarms limits of 89-95%.³⁴

Currently, after much evaluation of suggested oxygen target ranges in neonates, both the American Academy of Pediatrics (AAP) and European Union on Oxygen Saturation Standards (EUOSS) have evolved in a similar fashion with smaller variation making suggested target ranges narrower based on available information from the literature. The SpO₂ upper alarm limit recommended to be 95% by both bodies, however there is some variation on lower alarm limits. The EUOSS has suggested 89% as the lower SpO₂ alarm limit, while the AAP has not committed to a lower target number due to both practical and clinical factors.³⁵

Physiology/Pathophysiology

Premature infants are patients that often require careful oxygen supplementation, targeting a specific range of blood oxygen saturation. There is a clinical challenge of managing a delicate balance of avoiding both hypoxemia and hyperoxemia until their lungs are sufficiently developed to maintain appropriate physiological oxygenation without support. Oxygen lability yields to a critical state in premature infants where saturation and oxygen exposure need to be addressed to help prevent iatrogenic contribution to the development of diseases such as retinopathy of prematurity (ROP) and bronchopulmonary dysplasia (BPD) as a result of hyperoxia, as well as necrotizing enterocolitis (NEC), increased risk of mortality, and long term neurological effects secondary consequences to prolonged hypoxia. Physiological mechanisms that typically respond to hypoxia (e.g., control of ventilation and circulation) in term newborns are not fully developed in many premature infants. The difficulty lies in not only the infant's lack of autoregulatory mechanism control of hypoxia, but also physiological protection against iatrogenically induced hyperoxia.³⁶

Clinical Challenges in Management

The oxygenation challenge for clinicians in management of

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preterm infants is what is essentially a negative therapeutic index; optimal oxygenation and elimination of hypoxia, whilst preventing consequences of hyperoxia. Supplemental oxygen use in neonates has been a common practice since 1940. PCLC is one tool that helps clinicians address minimization of hypoxic and hyperoxic concerns in premature infants. As such, automated control of oxygen, using PCLC react faster than a human caregiver to apply appropriate oxygen when necessary, minimizing overcorrection, and limiting oxygen exposure.^{29,30}

Challenges Related to Maintaining Infants' Oxygen Levels Within Target Saturation Range in Non-PCLC Attempts

Many factors may affect adherence to target oxygen goals in a neonatal clinical setting. Several interventions might improve compliance, such as decreasing nursing workload, increasing training and awareness of the target saturation range, as well as establishing titration protocols. In a prospective observational study of preterm infants receiving supplemental oxygen and CPAP, continuous oxygen monitoring over 24 hours showed that infants were in the target SpO₂ range only 31% of the time.¹³ In a systematic review of 16 studies involving 2935 nurses and 574 infants investigating adherence to target oxygen levels in preterm infants, the authors concluded that compliance in targeting oxygen in preterm infants is low, especially in maintaining SpO₂ below the upper limit.²⁶ One retrospective observational study linked nurse-patient assignment data with continuous oxygen saturation data and determined the proportion of the time oxygen saturation was within target range. The authors concluded that fewer patients per nurse may be associated with improved rates of meeting oxygen saturation goals in premature newborns.³⁷ The presence of policy-specific saturation limits is associated with a reduction in the influence of individual nurse opinion on target saturation.³⁸ Another study showed that narrow oxygen saturation alarms led to increased alarm incidence, which then resulted in alarm fatigue and its associated negative consequences.

Goals of Supplemental Oxygen in Neonates

The primary goal of oxygen supplementation in neonates is to support their metabolic needs while avoiding the adverse effects of hypoxia and hyperoxia. Hypoxia occurs when tissue oxygenation is insufficient, is associated with increased morbidity and mortality in neonates. In a recent meta-analysis, the NeOProm collaboration group concluded that a lower SpO₂ range was associated with a higher risk of death and necrotizing enterocolitis.²⁷ The same group also confirmed that lower SpO₂ leads to a greater risk of patent ductus arteriosus requiring surgical ligation, as well as a higher rate of mortality at postmenstrual age of 36 weeks and at hospital discharge with the lower SpO₂ group. In addition to NeOProm, a post-hoc analysis of the Canadian Oxygen Trial (COT) demonstrated that prolonged hypoxemic episodes lasting at least 1 minute during the first two to three months after birth were associated with late mortality or neurodevelopmental impairment at 18 months.³⁹ Similarly, a subgroup analysis of the Surfactant Positive Pressure and Pulse Oximetry Randomized Trial (SUPPORT) found that mortality in the lower SpO₂ group was greater for small for gestational age SGA infants.⁴⁰

In the opposite direction to hypoxia, hyperoxia is also associated with adverse effects in neonates, including BPD, due to oxygen toxicity to the lungs, and ROP, the result of excessive tissue oxygen resulting in reactive oxygen species that damage retinal

blood vessels in premature infants. Published in 2000, the Supplemental Therapeutic Oxygen for Pre-threshold Retinopathy of Prematurity (STOP-ROP) trial showed a higher SpO₂ target in preterm neonates was associated with a greater risk of BPD and longer durations of hospitalization than those assigned to the lower SpO₂ target.⁴¹ Furthermore, when compared to a high SpO₂ target, a lower SpO₂ target group was associated with fewer incidents of ROP requiring treatment.²⁴

PCLC Clinical Evidence

Published closed loop oxygen control clinical trials in neonates agree that clinically relevant oxygenation performance is at least as good with automated control as with conventional manual control. It is reported that in automated control there was a marked improvement for time spent in target SpO₂ range, less time spent below designated range, lower overall oxygen exposure, and reduced FiO₂ manual adjustments. The device used for most of the recent clinical trials in neonates is Avea-CLiO₂ (CareFusion; Yorba Linda, CA, USA). In a non-peer reviewed article Wilinska and Wasco document their use of CLiO₂ "routinely for about 1 year and have found it to be very effective in a broad range of patients."⁴² These authors published a more recent paper introducing their registry, which at publication was at 121 infants from 5 units, which showed no reports of the device not working and a perception of improved care. The authors state that the data will be analyzed and published when the registry reaches 1,000 infants.⁴³

Claire and colleagues, who developed the CLiO₂ algorithm, conducted a pilot clinical trial with this system in 2009.⁴⁴ The study involved sixteen infants with frequent hypoxemia episodes and compared maintenance of SpO₂ within the intended target range during one 4-hour period of manual adjustment and one 4-hour period of automatic adjustment. This randomized study was conducted using the Avea infant ventilator with automated FiO₂ adjustment function built in. The authors concluded that "automated FiO₂ adjustment improved maintenance of SpO₂ within the intended range with less exposure to supplemental O₂" and that further randomized trials are needed to detect clinical outcome effects. A subsequent additional study conducted the largest randomized controlled trial to date at the time, enrolling thirty-two infants.⁴⁵ This study involved two consecutive 24-hour periods, one with FiO₂ adjusted manually and the other by the CLiO₂ system. Again, improved maintenance of SpO₂ in the intended range while reducing integrated oxygen exposure was demonstrated. Staff effort was also noticeably reduced compared to manual adjustment.

In 2014 and 2015, three additional trials, all using the Avea-CLiO₂ system, were published.^{16,46,47} These studies were in agreement that SpO₂ performance under automated control is at least as good as with manual control, with additional benefits of decreased both hyperoxia and hypoxia. Similarly, Hallenberger et al in the CLAC study, demonstrated that another neonatal-focused algorithm improved both time in target range (61.45 vs 71.2%; p < 0.001) and reduced time below range assisting to avoid hypoxia, with added benefit of reduced workload related to manual adjustments. This study was implemented with mechanical ventilation and nCPAP using a three-hour run-in phase followed by two consecutive 24-hour periods of a randomized combination manual/automated. In contrast to comparing improvement in only a single target SpO₂ range, another study in neonates (n=50 noninvasive support and n=30 mechanical ventilation) determined the efficacy and safety of

the CLiO₂ system in both a lower (89-93%) and a higher (91-95%) range. The study was implemented with consecutive 24-hour study arms of a randomized combination manual/automated, with a second stage of randomization for the lower and higher SpO₂ target ranges. Consistent with the previous studies, this study showed that automated FiO₂ improves the time in target range regardless of the lower (62% vs 54%; p < 0.001) or higher (62% vs 58%; p < 0.001) SpO₂ ranges, further noting a greater improvement in the lower SpO₂ target range, and reduced manual FiO₂ adjustments. Secondary analyses of the study highlighted reduced time in target range, independent of target range, with only a reduction in hyperoxemia for the lower (89-93%) target range.⁴⁸

Two proportional-integral-derivative (PID) algorithm for automated control of FiO₂ in neonates trials came to press being treated with (1) the CLiO₂ system in mechanical and noninvasive ventilation,⁴⁹ and (2) a novel algorithm in nCPAP or HFNC.⁷ In the recent CLiO₂ system the algorithm was implemented as a standard of care and the authors performed a retrospective analysis of manual and automated control with a 90-95% target range. It was demonstrated that over 9 months, automated control improved the time in target SpO₂ range (48.4% vs 61.9%; p < 0.01) and decreased the time below and above target range, thereby significantly reducing the patient hyperoxemia but not hypoxemia exposure.⁴⁹ A similar study duration was used in a separate trial for four hours and the time spent within the target saturation range was significantly greater for automated control compared to manual (81% vs 56%; p < 0.001).³⁰ Additionally, these studies showed that the infants spent less time receiving extreme high and low FiO₂ concentrations with a virtual elimination of prolonged episodes of hypoxia and hyperoxia.

In 2019, the latest neonatal randomized controlled crossover study, compared routine manual care to two 'versions' of a closed-loop automated control (CLAC) algorithm—fast and slow responding oxygen titration.⁵⁰ The slow response algorithm was studied in 2014, wherein neonatal patients on automated control exhibited greater time in target range.⁵¹ CLAC_{fast} and CLAC_{slow} were conducted in NICUs neonates were randomized for 8 hours each in three FiO₂ modes: (1) routine manual care, (2) CLAC_{fast}, and (3) CLAC_{slow}. Comparison of time in target range showed: (1) the two automated modes were non-inferior to each other (Mean±SD [95%CI]: CLAC_{fast} 68%±11% [65% to 71%] vs CLAC_{slow} 65%±11% [61% to 68%]), p<0.001, and (2) the CLAC_{fast} was superior to routine manual control (CLAC_{fast} 68%±11% [65% to 71%] vs Manual 58%±11% [55% to 62%], p<0.001).⁵⁰

Prior PCLCs, providing automated control of oxygen have been solely designed, developed and implemented as a primary use in pressure-based respiratory support systems. A novel PCLC, Oxygen Assist Module (OAM; currently a CE-marked product), is the first PID PCLC with the sole aim to be implemented with high velocity nasal insufflation (HVNI), a form of NIV shown to augment breathing through a nasal cannula patient interface. In 2018 Reynolds, et al completed a randomized clinical trial designed to provide clinical validation for the OAM (Vapotherm, Exeter, NH, USA) used in conjunction with the Vapotherm Precision Flow device for titrating oxygen to neonates requiring non-invasive respiratory support. Data analyzed from 30 preterm infants were included in the results of the OAM (denoted as Intello₂ at the time of the study) clinical trial. Time in target range is denoted by SpO₂ target range designated at 90-95% (or considered 90-100% if FiO₂=21%). The time in the target

SpO₂ range (median) was achieved significantly more in the automated vs manual control (80% vs 49%; p < 0.0001). The OAM recorded data every 1 second on multiple patient parameters, of which SpO₂ was included. The automated control provided significantly less SpO₂ variation (0.03 vs 0.06; p < 0.00001) as demonstrated in the coefficient of variance calculation. The mean FiO₂ for the 30 patient data sets analyzed was significantly different between automated vs control (0.34 vs 0.29; p < 0.0001). The most common FiO₂ in the automated arm was at 0.21 (air) vs 0.30 for manual control. In addition, during OAM automated control, the patients were significantly less likely to be hypoxic and hyperoxic. Further, the OAM's automated control reduced the duration of these hypoxic and hyperoxic episodes as well.⁸

Conclusion

Clinical evidence to date has shown the performance and safety of automated closed-loop oxygen control in treating premature infants. Automated oxygen control has been shown to maintain target SpO₂ and decrease hypoxia and hyperoxia in premature infants. Along with targeting SpO₂ goals, automated control offers clinical flexibility in accommodating patient needs through more specific control of oxygen targets and alarms. Automated oxygen control can assist care givers in maintaining preterm infants in recommended specified targeted oxygen saturation ranges as reported by SpO₂ and help optimize care giver time to tend to other needs these fragile patients may have. Automated oxygen control is available in Europe, therefore the question remains: does the benefit outweigh the risk of not implementing these automated oxygen control systems worldwide so long as the same level of care and supervision remains in place for these challenging neonates? Additional data on long term outcomes can be gathered through a registry and compared to historical controls.

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York Times reported that US public health officials were ordered by high-level members of the Trump administration to push forward with the changes. CDC Director Robert Redfield issued a statement on Thursday that “everyone who needs a COVID-19 test, can get a test,” but “everyone who wants a test does not necessarily need a test.” Globally, many nations advocate early testing. The World Health Organization (WHO) on Thursday said that resources permitting, people exposed to the novel coronavirus should be tested even if they do not show immediate symptoms of infection. European governments have used broad testing and isolation to control the virus. France, for instance, recommends that anyone who thinks they need a test should get one and in Germany, people with close contact of 15 minutes or more with a person with COVID-19 are advised to have a test.

Statins Linked to Reduced Mortality in COVID-19

Treatment with statins was associated with a reduced risk of a severe or fatal course of COVID-19 by 30%, a meta-analysis of four published studies has shown. In the analysis that included almost 9000 COVID-19 patients, there was a significantly reduced risk for fatal or severe COVID-19 among patients who were users of statins compared with non-users (pooled hazard ratio [HR], 0.70; 95% CI, 0.53 - 0.94). Based on the findings, “it may be time we shift our focus to statins as the potential therapeutic options in COVID-19 patients,” authors Syed Shahzad Hasan, PhD, University of Huddersfield, UK, and Chia Siang Kow, MPharm, International Medical University, Kuala Lumpur, Malaysia, wrote in a joint emailed comment. The study was published online August 11 in *The American Journal of Cardiology*. The analysis included four studies published up to July 27 of this year. Eligible studies included those with a cohort or case-control designs, enrolled patients with confirmed COVID-19, and had data available allowing comparison of the risk of severe illness and/or mortality among statin users vs non-users in adjusted analyses, the authors note. The four studies—one of “moderate” quality and three of “good” quality—included a total of 8990 COVID-19 patients. In the pooled analysis, there was a significantly reduced risk for fatal or severe COVID-19 with use of statins compared to non-use of statins (pooled HR, 0.70; 95% CI, 0.53 - 0.94). Their findings also “discredited the suggestion of harms with the use of statins in COVID-19 patients,” the authors conclude. “Since our meta-analysis included a fairly large total number of COVID-19 patients from four studies in which three are large-scale studies that adjusted extensively for multiple potential confounding factors, the findings can be considered reliable,” Hasan and Kow write in their article. Based on the results, “moderate-to-high intensity statin therapy is likely to be beneficial” in patients with COVID-19, they said. However, they caution that more data from prospective studies are needed to substantiate the findings and to determine the appropriate regimen for a statin in COVID-19 patients. Reached for comment, Yibin Wang, PhD, of the David Geffen School of Medicine, University of California, Los Angeles, said, “This is a very simple meta-analysis from four published studies which consistently reported a protective or neutral effect of statin usage on mortality or severe complications in COVID-19 patients.”

Large Study Links Asthma, Allergic Rhinitis to Severe COVID-19

People with allergic rhinitis and asthma may be slightly more prone to contracting COVID-19 and considerably more to developing severe disease when infected, according to *Continued on page 86...*

The Role of a Slow Inspiration and Expiratory Flow Bias in Secretion Movement

Are we giving correct instructions to patients performing oscillatory positive expiratory pressure Therapy?

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Introduction

It is common practice to give similar instructions to patients performing positive expiratory pressure (PEP) therapy and oscillatory positive expiratory pressure (OPEP) therapy. This is despite the fact that PEP and OPEP devices have different physical characteristics, which can affect mechanical outcomes such as flow and pressure. These instructions typically revolve around having the patient maintain an inspiratory to expiratory ratio of 1:3 or 1:4, which makes sense for PEP therapy but not necessarily for OPEP therapy. The purpose of this article is to provide a current look at instructions for use for PEP and OPEP devices and offer an alternative method for OPEP use based on the concept of expiratory flow bias.

Overview of Current PEP Instructions

A review of the literature found several published articles or textbooks which list instructions for use for PEP devices.¹⁻⁵ These usually contain three main components: 1) deeper breath than normal, but not all the way to total lung capacity (TLC) 2) active, but not forceful, exhalation to a pressure of 10 to 20 cmH₂O and 3) I:E ratio of 1:3 or 1:4. These instructions appropriately match the goal for PEP therapy, which is to increase functional residual capacity (FRC) thereby moving air behind secretions through collateral ventilation channels.

Overview of Current OPEP Instructions

OPEP tends to be performed similar to PEP with little delineation between the two. Some recommend adding an inspiratory hold while others say that exhalation should be with the help of abdominal muscles.^{6,7} The issue regarding I:E ratio is either not addressed or is recommended to be the same as PEP therapy. Therefore, instructions for use for OPEP devices may include: 1) deeper breath than normal but not all the way to TLC, 2) short breath hold, 3) active or forceful exhalation, but not all the way to residual volume, and 4) I:E ratio of 1:3 or 1:4. These instructions are sufficient to produce oscillation thereby helping to decrease viscoelastic properties of mucus, but are not optimal in order to drive mucus cephalad toward the oropharynx.

Concept of Flow Bias

Flow bias is the overall net movement of gas flow based on inspiratory and expiratory flowrates. As an analogy, two steps forward and one step back is overall net movement forward whereas two steps forward and three steps back is overall

net movement backwards. A higher peak inspiratory flow (PIF) than peak expiratory flow (PEF) generates overall flow movement toward the periphery of the lung. This is referred to as **inspiratory** flow bias. A higher PEF than PIF generates overall flow movement toward the mouth. This is referred to as **expiratory** flow bias.

Flow Bias in Secretion Clearance

In order to move secretions cephalad toward the oropharynx, researchers have shown there needs to be an expiratory flow bias. This means that PEF needs to exceed PIF by 17 l/m or by at least 10% (PEF/PIF ratio > 1.1).^{8,9,10} When inspiratory flow exceeds expiratory flow, the opposite will occur, that is mucus will move caudad toward the periphery of lung. The issue of flow bias and secretion clearance is specifically addressed in the following three studies.

In a bench study, Volpe et al conducted a crossover experiment in which twelve physiotherapists were asked to perform manual hyperinflation (MH) using a self-inflating resuscitation bag, a lung model, and simulated secretions.¹¹ The goal was to determine which method of MH, usual practice or recommended practice, resulted in the greatest movement of secretions outward. The study found that when the physiotherapists performed MH according to their usual practice a mean **inspiratory** flow bias of 55 l/m was created, moving secretions toward the test lung. In an actual patient situation this would drive secretions further down the lung instead of moving them cephalad toward the oropharynx. When they performed MH with a very slow insufflation and rapid release of the bag (recommended practice), a mean **expiratory** flow bias of 27 l/m was created, moving secretions away from the test lung. In clinical practice this would move secretions cephalad toward the oropharynx. The study's conclusion was that in order to remove secretions, MH should be performed with a slow inspiration so as to cause the greatest possible expiratory flow bias.

In another recently released article by the same group of authors, expiratory flow bias was studied in the context of mechanical insufflation-exsufflation (MI-E).¹² The study examined the effects of fast vs. slow insufflation on secretion displacement in three different lung model scenarios. They found that when the MI-E maneuver was applied with a slow insufflation, there was greater outward mucus displacement when compared to a fast insufflation. This was due to lower inspiratory flowrates and a higher expiratory flow bias when the MI-E device was set for slow insufflation.

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Finally, Li Bassi et al conducted an animal study with eight healthy pigs.¹³ The animals were intubated and ventilated while mucus velocity was fluoroscopically tracked using radiopaque markers. Inspiratory and expiratory flowrates were monitored as inspiratory time was prolonged. Six different I:E ratios were used: 1:2.9, 1:2, 1:1.4, 1:1, 1.5:1, and 3:1. The study found that expiratory flow bias and cephalad mucus movement improved as inspiratory time was prolonged. This was due to the reduction in inspiratory flow as the inspiratory time was increased.

Applying Expiratory Flow Bias to OPEP Therapy

Although instructions for use vary among OPEP devices—manufacturers, practitioners, and educators alike tend to recommend that exhalation last between three and four times longer than inspiration (I:E ratio of 1:3 or 1:4). However, this specific instruction when applied to OPEP therapy favors an inspiratory flow bias rather than an expiratory flow bias. Consider the following example of an adult patient with a predicted inspiratory capacity of 3.0 liters. He is performing OPEP therapy at a respiratory rate of 15 breaths per minute and a deeper than normal tidal volume of 1500 ml. If the patient is to maintain an I:E ratio of 1:3, inspiration would be one second and expiration would be three seconds. In this situation, the inspiratory flowrate would be 90 l/m. If the patient is then instructed to exhale “actively but not forcefully”, it is unlikely they will be able to generate the expiratory flow necessary to produce an expiratory flow bias. Now consider the same patient breathing at a slower respiratory rate of 10 breaths per minute and an I:E ratio of 1:1 (3 second inspiration and 3 second expiration). Assuming the same tidal volume of 1500 ml, the patient’s inspiratory flowrate would be 30 l/m. In this situation there is a greater chance of creating an expiratory flow bias since the inspiratory flowrate is lower.

To clinically illustrate these examples, a retrospective analysis of 42 healthy volunteers performing OPEP therapy found that only one subject consistently achieved an expiratory flow bias.¹⁴ This was due to the average inspiratory time among subjects being fairly short at 2.02 seconds, which tended to produce higher inspiratory flowrates. In fact, the mean maximum PIF in the study was 99 l/m ± 29.9 while the mean maximum PEF was 54 l/m ± 13.6, producing a mean PEF/PIF ratio of 0.55. In clinical practice, these metrics would produce a 45 l/m inspiratory flow bias driving secretions further down the lung. Clearly had the average inspiratory time been longer and inspiratory flow lower—the mean PEF/PIF ratio would have been higher and a greater number of subjects would have achieved an expiratory flow bias. It is worth mentioning that all of the subjects received the same exact pre-instructions highlighting the subjectivity of the phrase, “take in a slow, deeper than normal breath.”

Alternative Method: Coach the Patient to Slow Down Inspiration

Coaching patients to slow down inspiration is imperative in order to optimize secretion clearance during OPEP therapy. Simply giving pre-instructions will not result in maximum efficacy. Constant teaching and feedback is necessary during the session. Instead of worrying about maintaining a specific I:E ratio, a more rational approach would be to first have the patient slow down their respiratory rate as much as possible during the OPEP session. This will allow for a greater cycle time so that the patient can perform three critical elements: 1) inhale as slow as possible, 2) perform a short breath hold, and 3) exhale forcefully through the device. These elements are crucial in

order to generate an expiratory flow bias, increase distribution of ventilation, and create adequate oscillatory flow amplitude. Again, continuous coaching during the session is the key to efficient therapy.

Conclusion

Instructing the patient to maintain an I:E ratio of 1:3 or 1:4 during OPEP therapy is not conducive to producing an expiratory flow bias. An inspiratory to expiratory ratio of 1:1 or even slightly inverse is not out of the question and is actually more in line with creating the PEF/PIF ratio necessary to move mucus cephalad toward the oropharynx. Furthermore, we need to move away from thinking about OPEP devices in terms of pressure and instead think about them in terms of flow. Expiratory flow bias will be maximized when the respiratory care practitioner sets the OPEP device on the lowest resistance and instructs the patient to take the slowest inspiration possible.

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a nationwide cohort study from South Korea. The risk was especially high for individuals with non-allergic asthma, who were more than four times as likely to have severe COVID-19 as those without asthma, Dr Jee Myung Yang of the University of Ulsan College of Medicine, in Seoul, and colleagues found. The team says their study provides strong evidence of a link between respiratory allergic diseases and the risk of contracting COVID-19 and/or having worse clinical outcomes of the infection. Studies of COVID-19 and asthma to date have had mixed results, and small sample sizes, the authors note in the *Journal of Allergy and Clinical Immunology*. They looked at data from South Korea's Health Insurance Review and Assessment Service for more than 219,000 adults who underwent COVID testing between January 1 and May 15, including 14.9% diagnosed with asthma, 63.1% with allergic rhinitis and 3.9% with atopic dermatitis. A total of 7,340 tested positive for SARS-CoV-2, including 725 with asthma (9.9%), 4,210 with allergic rhinitis (57.4%) and 136 with atopic dermatitis (1.9%). The rate of SARS-CoV-2 positivity was 2.3% for people with asthma and 2.2% for those without asthma (adjusted odds ratio 1.08; 95% confidence interval, 1.01 to 1.17) and 3.3% and 2.8% for those with and without allergic rhinitis, respectively (aOR, 1.18; 95% CI, 1.11 to 1.25). The increase was greater for those with non-allergic asthma (aOR, 1.34; 95% CI, 1.07 to 1.71) than those with allergic asthma (aOR, 1.06; 95% CI, 0.97 to 1.17). Severe clinical outcomes occurred in 6.9% of patients with asthma and 4.5% of those without (aOR, 1.62; 95% CI, 1.01 to 2.67), and in 4.7% of patients with allergic rhinitis and 3.7% of those with no allergic rhinitis (aOR, 1.27; 95% CI, 1.00 to 1.64). The odds of developing severe COVID-19 was more than quadrupled for patients with non-allergic asthma (aOR, 4.09; 95% CI, 1.69 to 10.52), while the risk increase was less pronounced for those with allergic asthma (aOR, 1.40; 95% CI, 0.83 to 2.41).

Lung Simulators Produced to Fill Shortage

Michigan Instruments, a leading manufacturer in Lung Simulation, has delivered an unprecedented number of lung simulators to organizations around the world to help in respiratory technology research and critical ventilator development and manufacturing to combat the shortages caused by the COVID-19 pandemic. Many countries, including the United States, are continuing to see a rise in COVID-19 cases, which brings to light the extreme lack of medical resources like ventilators available to hospitals and critical care facilities. In response, the world has seen an incredible response in the development and manufacturing of ventilators as researchers attempt to create a cost-effective and efficient lifesaving solution. Michigan Instruments has been at the forefront of this response by working with organizations to deliver Lung Simulators designed for validating and testing these ventilators. Organizations like NASA, Ford Motor Company, Cornell University, Michigan Technological University, University of California San Diego, OperationAir, and the Royal Women's Hospital, Monash University and the Alfred Hospital in Australia have all used Michigan Instruments lung simulators to aid in the development and discovery of several potential ventilator solutions. A group of engineers from NASA's Jet Propulsion Laboratory have developed a high-pressure ventilator that can mechanically breathe for patients with the most severe cases of COVID-19. Students and faculty from Cornell University, Michigan Technological University, and the University of California San Diego have all developed versions of effective, low-cost ventilator systems created using inexpensive materials

or materials readily available. OperationAir has also developed a prototype called the AIRone, an easily producible emergency ventilator that can be used when shortages occur due to the pandemic. Production has already started on the device and its design is open source and available globally. A team of researchers from the Royal Women's Hospital, Monash University, and Alfred Hospital have successfully tested, in a simulated environment, the potential to ventilate two lungs of different compliances from a single ventilator using only commonly available hospital equipment. These lung simulators provide developers with cutting edge technology that can aid in the design, engineering, testing and manufacturing of devices like ventilators by replicating hundreds of healthy and diseased lung conditions to evaluate a ventilator's performance with accurate measurement and data reporting.

Risk of Secondary COVID-19 Transmission Low in Most Settings

The risk of secondary transmission is less than 4% overall among close contacts of people diagnosed with COVID-19 and varies by settings and disease severity, new research shows. Lei Luo, PhD, with the Guangzhou Center for Disease Control and Prevention, China, and colleagues used contact tracing to test 3410 close contacts of 391 COVID-19 index cases between January and March in Guangzhou. Researchers identified cases through surveillance testing, screening symptomatic patients who presented to a healthcare facility, or tracing and screening people in close contact with those diagnosed with COVID-19. Among the close contacts, 127 (3.7%) became infected. Of those 127, eight (6.3%) were asymptomatic. Of the 119 symptomatic cases, 20 (16.8%) were mild, 87 (73.1%) were moderate, and 12 (10.1%) were severe or critical. The findings were published online August 13 in the *Annals of Internal Medicine*. To learn how risk varied by contact locations, they stratified contacts according to where they interacted with the index patient, including household, public transportation, health care settings, entertainment venues or workplaces, and multiple settings. Risks for secondary infection were highest for household contacts, at 10.3% (95% CI, 8.5% - 12.2%), followed by those exposed in health care settings, at 1.0% (95% CI, 0.3% - 1.8%; odds ratio [OR] relative to household exposure, 0.09), and on public transportation, at 0.1% (95% CI, 0.0% - 0.4%; OR, 0.01). The authors note that the 10.3% household transmission rate was consistent with previously reported secondary infection rates among household members of 11.2% in other cities in China and 10.5% in the United States.



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¹ Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB, Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, Journal of the American College of Surgeons (2019)

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