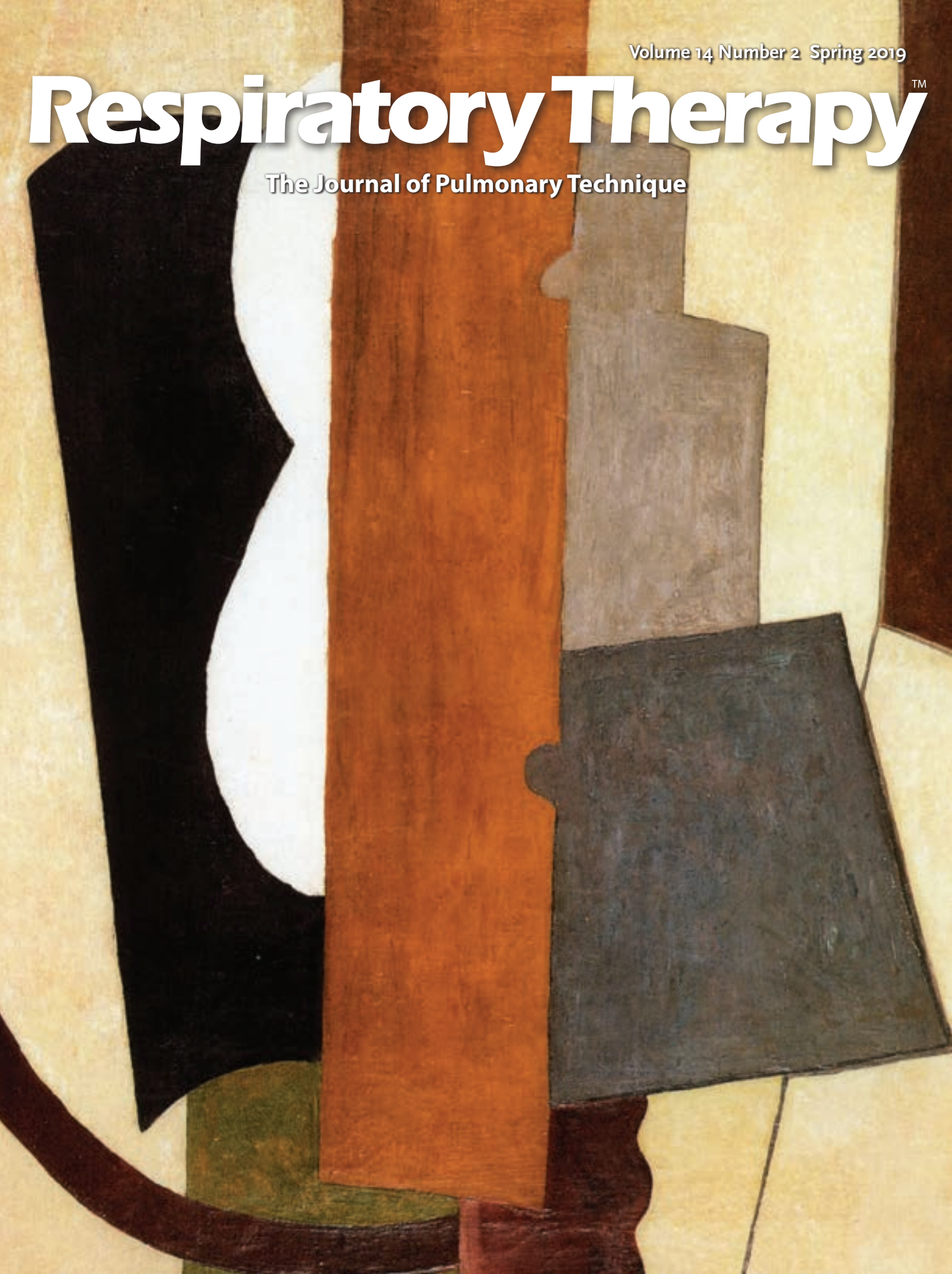


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Hydrocortisone Does Not Reduce BPD in Premies

Systemic hydrocortisone (HC) does not reduce the risk for bronchopulmonary dysplasia (BPD) or for a composite endpoint of BPD or death in very preterm infants receiving mechanical ventilation, a randomized trial shows. However, a planned secondary analysis suggests that HC may reduce the risk for death when analyzed as an endpoint on its own. "Our study shows that HC does not reduce BPD. Our finding that it does reduce death is somewhat surprising, although trials on prophylactic HC use indicated that this might be a benefit from HC," senior author Anton H. van Kaam, MD, PhD, from the department of neonatology, Emma Children's Hospital, Amsterdam UMC, University of Amsterdam, the Netherlands, said. Wes Onland, MD, PhD, from the department of neonatology, Emma Children's Hospital, Amsterdam UMC, University of Amsterdam, the Netherlands, and colleagues published their findings online January 29 in JAMA for the Systemic Hydrocortisone To Prevent Bronchopulmonary Dysplasia in preterm infants (SToP-BPD) Study Group. Dexamethasone is effective at reducing the risk for death or BPD in this patient population. "However, this benefit may be outweighed by an increased risk of neurodevelopmental impairment. As a result, clinicians started using dexamethasone less frequently, in lower doses, and at later postnatal ages. Furthermore, international guidelines recommended investigating whether hydrocortisone would be an effective and safe alternative to dexamethasone," the authors write. The researchers conducted a double-blind, placebo-controlled randomized trial to determine whether systemic hydrocortisone treatment started between 7 and 14 days after birth decreased the incidence of death or BPD at 36 weeks' postmenstrual age in ventilator-dependent very preterm infants. The study included 372 infants (mean gestational age, 26 weeks; 55% male) in 19 neonatal intensive care units with a gestational age of less than 30 weeks and/or birth weight below 1250 g. The infants were randomly assigned to receive systemic hydrocortisone (cumulative dose, 72.5mg/kg; n =

182) or placebo (n = 190) for 22 days. One infant treated with hydrocortisone was withdrawn from the study by the parents. The study's primary composite endpoint was death or BPD at 36 weeks' postmenstrual age. Overall, 73 infants (20%) died and 195 survivors (53%) were diagnosed with BPD. Death or BPD occurred in 128 infants (70.7%) in the hydrocortisone group and in 140 infants (73.7%) in the placebo group (adjusted risk difference, -3.6%; [95% confidence interval (CI), -12.7% to 5.4%]; adjusted odds ratio [OR], 0.87 [95% CI, 0.54 - 1.38]; P = .54), after adjustment for the stratification variables of gestational age and study center. Eight of 29 secondary outcomes were significantly different between the two groups. Death at 36 weeks' postmenstrual age was less likely among infants in the hydrocortisone group (15.5% with hydrocortisone vs 23.7% with placebo; risk difference, -8.2% [95% CI, -16.2% to -0.1%]; OR, 0.59 [95% CI, 0.35 - 0.995]; P = .048).

Circassia Acquires US and Chinese Commercialization Rights to Novel Nitric Oxide Product AirNOvent

Circassia Pharmaceuticals announced that it is acquiring exclusive commercialization rights from AIT Therapeutics Inc. to its ventilator compatible nitric oxide product, AirNOvent, in the United States and China. The rights cover all potential indications in the hospital setting for the administration of inhaled nitric oxide, which includes hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN). PPHN is a life-threatening circulatory and respiratory condition in newborns that results in decreased blood flow and oxygen to the lungs and extreme difficulty breathing. Estimates of PPHN in the US vary widely, from 1,500-26,200 newborns annually; approximately 10% of babies with PPHN die. Inhaled nitric oxide is a pulmonary vasodilator which is approved in the United States for use as part of a regimen in the treatment of hypoxic respiratory failure associated with PPHN. AirNOvent is a portable system that utilizes an electric voltage to produce precise quantities of nitric oxide from the nitrogen and oxygen in air. It uses disposable smart filters to remove unwanted NO₂ produced during the process. In the United States, only one inhaled nitric oxide product is currently available, INOMAX. It is used in neonatal intensive care units (NICUs) and its delivery system administers nitric oxide from pressurized cylinders in conjunction with ventilator systems. The product generated estimated US revenues of over \$400 million in 2017. Unlike INOMAX, AIT's AirNOvent is cylinder-free and is smaller, significantly lighter and more convenient than the INOMAX system. It is designed for compatibility with current ventilators, and does not require special storage and handling. These features will make this essential and life-saving treatment more accessible to NICUs and smaller clinics without the facilities required to manage nitric oxide cylinders. AIT anticipates applying to the FDA for Premarket Approval for AirNOvent in Q2 2019 for use in the treatment of PPHN, and Circassia anticipates launching the product in the first half of 2020, once approved.

ResMed's First Top-of-Head CPAP Mask Now Available across US

ResMed introduced AirFit N30i, its first top-of-head-connected nasal CPAP mask, across the United States, with a newly designed nasal cradle cushion that sits just under the wearer's nose. The top-of-head connection keeps tubing out of the wearer's way, letting them move and sleep in any position. The nasal cradle cushion — ResMed's first — is designed to reduce facial markings and irritation. AirFit N30i is also convenient

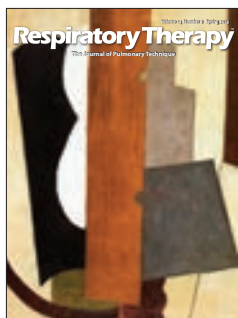


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for equipment providers and sleep labs — it fits 96 percent of PAP users with just two frame sizes and four cushion sizes. How AirFit N30i compares to the market-leading nasal top-of-head mask: In side-by-side comparisons, three out of four users preferred AirFit N30i over the other nasal mask with a top-of-head connection. A majority stated they loved AirFit N30i and would take it home as their mask of choice, with many claiming it was “very comfortable,” it’s “easy to use,” or that it “caused little disruption to their bed partner.” “AirFit N30i is a great choice for nasal mask wearers who move when they sleep,” said Jim Hollingshead, president of ResMed’s Sleep business. “It’s all about freedom — users are free to sleep however they want and enjoy a comfortable, reliable seal. And AirFit N30i is so easy to fit, sleep professionals are going to be freed up to serve more people.” AirFit N30i is also available in Canada, Australia, New Zealand, and most of Europe, with other countries planned to follow later this year.

Nova Biomedical Awarded Multi-Year Critical Care Blood Gas Analyzer Agreement from Premier

Nova Biomedical has been awarded a multi-year group purchasing agreement for critical care blood gas analyzers from Premier. This agreement provides Premier members access to Nova’s new Stat Profile Prime Plus critical care blood gas analyzer. Prime Plus features maintenance-free sensor technology to provide 20 essential critical care tests including BUN, Creatinine, Ionized Magnesium, blood gases, electrolytes, metabolites, hematology, and co-oximetry. Prime Plus also provides new and patented, non-lysing whole blood co-oximetry technology, along with automated quality control (QC), powerful data management, bidirectional connectivity, and extensive cybersecurity protection. Effective October 18, 2018, the current agreement now allows Premier members, at their discretion, to take advantage of special, pre-negotiated pricing and terms for Prime Plus analyzers and consumables in addition to Nova’s 10-test Prime analyzers. “We are pleased that Premier has awarded a group purchasing agreement to our innovative, maintenance-free Prime Plus,” said John Britt, Director of Corporate Accounts for Nova. “This agreement allows Premier members access to the entire Stat Profile Prime platform including its new flagship analyzer, Prime Plus. Prime Plus introduces innovative technology

that expands critical care testing with unique assays and eliminates sensor and co-oximeter maintenance, all of which improves uptime and reliability while reducing costs. Prime Plus represents the latest in critical care testing technology and further demonstrates Nova’s leadership and history of innovation.” Prime Plus incorporates Nova’s innovative, maintenance-free sensor technology with individual MicroSensor cards, calibrator cartridges, and quality control cartridges. This design eliminates sensor and co-oximeter maintenance, improves analyzer uptime, and reduces testing costs for the compact and easy-to-use Prime Plus. Premier is a leading healthcare improvement company, uniting an alliance of approximately 4,000 US hospitals and 165,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost.

Daily Aspirin May Curb COPD Exacerbations

Daily aspirin use appears to reduce the risk of exacerbations and have other beneficial effects in patients with chronic obstructive pulmonary disease (COPD), according to an observational study. As Dr Ashraf Fawzy said, “We found that aspirin users with COPD had fewer flare-ups of their disease over three years, reported better quality of life and less shortness of breath compared to a similar group of participants who did not use aspirin.” In a paper online December 26 in *Chest*, Dr Fawzy of Johns Hopkins School of Medicine in Baltimore, Maryland, and colleagues note that there is some evidence that aspirin use may reduce all-cause mortality in COPD, but its association with morbidity has not been defined. The researchers examined data on nearly 1,700 participants in the SPIROMICS study of patients with COPD. Of these, 764 reported taking aspirin daily. Information about dose, adherence and duration of therapy was not available, but to help minimize differences, the researchers studied 503-propensity-matched pairs. On average, they were 66.5 years old, had a post-bronchodilator lung function (FEV1) of 62% predicted, and 23% were home oxygen users. They were followed via quarterly telephone questionnaires for a median of 2.7 years. Overall, aspirin users had an estimated 22% lower incidence rate of acute exacerbations (adjusted incidence rate ratio, 0.78; 95% confidence interval, 0.65

to 0.94). This was similar for events deemed moderate, but did not reach significance for those considered severe (IRR, 0.86). In subgroup analysis, a reduced incidence of exacerbation was most strongly associated with symptoms of chronic bronchitis at baseline. Aspirin use was also significantly associated with lower total St. George Respiratory Questionnaire score and reduced odds of moderate-severe dyspnea and COPD Assessment Test score. "This study highlights that adding aspirin to current treatment regimens may potentially improve the well-being of patients suffering from a burdensome chronic disease while reducing healthcare utilization," Dr Fawzy said. "However," he added, "more research is necessary before making any definitive recommendations. Specifically, a randomized controlled trial of aspirin use in patients with COPD is warranted to rigorously assess whether aspirin is beneficial in this patient population." Dr Robert A. Wise of Johns Hopkins Asthma & Allergy Center, also in Baltimore, who was not involved in the study, noted that an estimated 22% reduction in COPD exacerbations "is of similar magnitude to most other COPD maintenance treatments. The results were most striking in patients who had chronic bronchitis with regular cough and phlegm." "These findings, though not definitive, provide a strong rationale for a randomized controlled clinical trial of low-dose aspirin in exacerbation-prone COPD patients," he said. "Daily aspirin holds promise as a safe, inexpensive maintenance treatment for COPD patients with chronic bronchitis."

New Sensors Receive FDA Clearance

Masimo announced that RD SET sensors with Masimo Measure-through Motion and Low Perfusion SET pulse oximetry have received FDA clearance with improved SpO2 accuracy

specifications for all patients > 3 kg. RD SET single-patient-use sensors with the improved accuracy specifications are now available. The new RD SET sensors' SpO2 accuracy specifications during patient motion have improved for adult, pediatric, and infant patients to 1.5% (at 1 SD), compared to previous accuracy specifications of 3%. In addition to offering improved accuracy, RD SET sensors are designed to enhance patient comfort, optimize clinician workflows, and help hospitals meet green initiatives. The sensors are lightweight and have a flat, soft cable with smooth edges, so that they lie comfortably on a patient's hand or foot. The sensors feature an intuitive sensor-to-cable connection. Their lightweight design results in up to 84% less waste, and their sleek, recyclable packaging reduces storage and shipping space. The clinical benefits of Masimo's revolutionary SET pulse oximetry have been demonstrated in a variety of clinical conditions. Joe Kiani, founder and CEO of Masimo, said, "We're delighted to be able to announce our continued innovation in our foundational SET® pulse oximetry. Thanks to the brilliance and dedication of our engineers and the continuing support of our customers, we've been able to once again raise the standard for pulse oximetry performance. Even though no one has been able to create pulse oximetry that outperforms SET, we have not allowed that to stop us from continuing our pursuit of perfecting the technology. We have significantly improved our accuracy during motion and this is just the start of further improvements in what clinicians can expect from pulse oximetry." In addition to excellent accuracy and reliability, the SET platform with rainbow is also the only oximetry technology that also allows clinicians to measure physiological parameters such as total hemoglobin, carboxyhemoglobin, methemoglobin, and PVi.

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Hypertonic-Saline Inhalation Boosts Lung Function in Infants With Cystic Fibrosis

In infants with cystic fibrosis (CF), preventive inhalation with hypertonic saline (HS) during the first months of life is safe and well tolerated and results in clinical improvements, according to a study recently published in the American Journal of Respiratory and Critical Care Medicine. Mirjam Stahl, M.D., from the University of Heidelberg in Germany, and colleagues randomly assigned 42 infants (aged <4 months) with CF to twice-daily inhalation of 6 percent HS or 0.9 percent isotonic saline for 52 weeks to assess the feasibility, safety, and efficacy of preventive inhalation strategies. The researchers found that inhalation of HS and IS was generally well tolerated, with no difference in the number of adverse events between the groups ($P = 0.49$). The change in lung clearance index during the study period was larger in CF infants treated with HS versus those treated with IS ($P < 0.05$). Further, in infants treated with HS, weight gain improved over that of the IS group ($P < 0.05$). Pulmonary exacerbations and chest magnetic resonance imaging scores did not differ between the groups. “This initial randomized controlled trial supports that preventive treatment with inhaled hypertonic saline is safe and well-tolerated, and has therapeutic benefits on lung function and thriving in the first year of life,” the authors write.

FDA Approves First Digital Inhaler With Tracking App

The US Food and Drug Administration (FDA) has approved the first and only digital inhaler with a built-in sensor that connects to a companion mobile application that can monitor

usage as well as strength of the user’s inhalation. The ProAir Digihaler, from Teva Pharmaceutical Industries, contains albuterolsulfate 117 µg powder for inhalation. The new inhaler is approved for use in people aged 4 years and older to treat or prevent bronchospasm in individuals with reversible obstructive airway disease and to prevent exercise-induced bronchospasm. The approval is based on review of a supplemental new drug application submitted by Teva to the FDA. “The digital technology built into ProAir Digihaler provides patients with data on their inhaler use, which may help them to have a more informed dialogue with their healthcare provider regarding their asthma or COPD [chronic obstructive pulmonary disease] management,” Sven Dethlefs, Teva executive vice president, global marketing and portfolio, said in a news release. “There are 25 million Americans living with asthma, many of whom use inhalers as part of their treatment regimen. Despite advancements in care over the years, we know that many are using their rescue medications incorrectly or too often,” Tonya Winders, president and CEO of the Allergy and Asthma Network, said in the release. “The FDA approval of ProAir Digihaler is significant because it may help patients track their inhaler usage and provide data that can be used to work more closely with their HCPs [healthcare providers] on their asthma management. This approval is a major step forward and is indicative of how medications are evolving through technological innovations,” Winders said. Teva said the ProAir Digihaler will be available in 2019 through a small number of “early experience” programs, which will be conducted in partnership with healthcare systems in limited geographic areas, in order to gather real-world experience. A national launch is planned for 2020.

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Routine Spirometry Measure Useful for Monitoring Idiopathic Subglottic Stenosis

Peak expiratory flow (PEF) is a simple, efficient method for monitoring progression of idiopathic subglottic stenosis and predicting receipt of surgical intervention, researchers report. “We were surprised to find that the most simple measure of pulmonary function — peak expiratory flow — correlated with airway stenosis as closely as the more complex measures, EDI (expiratory disproportion index) and TPF (total peak flow),” said Dr James J Daniero of the University of Virginia, in Charlottesville. “This unanticipated finding provides great promise for patients to be able to self-monitor their condition by tracking biometric data obtained from a basic hand-held peak flow meter which can be recorded in a smart phone application,” he said. Many patients with idiopathic subglottic stenosis (iSGS) can be treated successfully with endoscopic intervention, but more than 85% of these patients require repeated intervention within five years. EDI is highly sensitive and specific for diagnosing and monitoring iSGS, but its measurement is complex. Daniero’s team evaluated the ability of PEF, relative to the validated measures of EDI and TPF, to differentiate the degree of luminal obstruction and predict the receipt of surgical intervention in 42 patients with iSGS. The mean PEFs and TPFs decreased progressively with increasing stenosis grade, while the mean EDIs increased with increasing stenosis grade. PEF had an accuracy of 85.5% (as measured by area under the curve) for predicting operative intervention in patients with iSGS. The optimal cutoff value of 4.4 L per second yielded 84.4% sensitivity and 82.0% specificity, the researchers report in JAMA Otolaryngology-Head & Neck Surgery, online November 1. By comparison, EDI had an accuracy of 85.3%, and its optimal cutoff value of 54.0 yielded 80.6% sensitivity and 80.4% specificity. TPF had an accuracy of 83.6%; with an optimal

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1. Barto T, et al., Registry outcomes for HFCWO vest therapy in adult patients with bronchiectasis, Am Thor Soc Ann Meet, San Francisco, CA, May 2016, Poster P1496.

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cutoff value of 7.4 L per second, it yielded 86.4% sensitivity and 78.0% specificity. “EDI is still an important measure in the diagnosis of laryngotracheal stenosis,” Dr Daniero said. “EDI maintains the ability to discriminate between asthma, COPD, and other pulmonary diseases. The PEF is less specific and should be used after a diagnosis is already established to follow the longitudinal effect of progressive stenosis. It appears the TPF provides no additional benefit over PEF in this population.” “This low-tech solution is commonly used in tracking the breathing status of asthmatics, and its use could potentially be broadened to patients with airway stenosis,” he said. “However, the effectiveness of patient self-monitoring using biometric data will have to be specifically studied in this population.”

Company Closes Deal

3B Medical announced closing on a deal for the exclusive global licensing and acquisition of VBOX, a Minnesota research and development company. Through a decade of research and development, VBOX has amassed a number of patents for innovation in the portable oxygen product space, a billion dollar industry. With this agreement, 3B Medical, Inc. gains exclusive global licensing of a large portfolio of intellectual property, consisting of 14 US patents, 6 US patents pending, and 8 foreign patents, along with the design and regulatory approvals for the world’s smallest and lightest portable oxygen concentrator. “The agreement provides 3B Medical with a very quick ramp to market for the most technologically advanced wearable oxygen concentrator in the world. We are really excited by being able to finalize this deal because it positions 3B Medical as a global leader in the portable oxygen concentrator product space.” said Alex Lucio, CEO of 3B Medical. 3B Medical is a leader in the

development; marketing and distribution of medical products for the treatment of sleep disordered breathing and oxygen therapy.

Skip Pulse Oximetry in Bronchiolitis, Say Experts

Healthcare providers should avoid pulse oximetry in young children with bronchiolitis, according to a research analysis. “Pulse oximetry as a technology represents a major and significant advance in medicine.... However, its increasing and widespread use in stable infants and young children with bronchiolitis, a self limited disease with a generally benign course, has led to technology driven overdiagnosis of hypoxaemia — fueling uncertainty, increased use of resources, and patient harm,” write Ricardo Quinonez, MD, from Baylor College of Medicine in Houston, Texas, and colleagues. The American Board of Internal Medicine Foundation (ABIM) recognizes this problem in its Choosing Wisely campaign, which is aimed at decreasing overuse of unnecessary medical practices. In 2013, the Society of Hospital Medicine published a list of five tests and treatments to avoid in hospitalized children as part of that effort. That list includes avoiding continuous pulse oximetry in children admitted for respiratory illness who are not receiving supplemental oxygen. Updated American Academy of Pediatrics (AAP) clinical practice guidelines also advise against use of continuous pulse oximetry in bronchiolitis. At the same time, guidelines and clinical practice differ on standard definitions for hypoxemia. The AAP has set lower thresholds for hypoxemia, at 90%, on the basis of research suggesting that this level is safe and may have better outcomes than higher thresholds. The UK National Institute for Health and Care Excellence guidelines recommend a higher threshold, at 92%. However, the evidence from three randomized controlled trials suggests that “exposing children to lower probabilities of diagnosis of hypoxaemia seems to be safe and could also lead to improved outcomes,” the authors write. Most studies have been too small to find a measurable benefit of increased pulse oximetry in short- to medium-term outcomes such as mortality, rehospitalization, or need for increased care, the authors explain. Some studies have suggested reduced mortality rates or possible cognitive benefits, but these have been done in developing countries, in critically ill children, or in children with chronic disease; therefore, the results may not apply to those in developed countries or otherwise healthy children. Aside from live births, bronchiolitis represents the leading cause of hospital admission in US infants during the first year of life. Bronchiolitis is a viral infection of the lower respiratory tract that mostly affects children up to age 2. Treatment is mostly supportive. Admissions for bronchiolitis have almost tripled during the last 30 years, mirroring the increased use of pulse oximetry for measuring blood oxygen saturation. As bronchiolitis-related disease severity and mortality have not decreased during that time, some experts suggest that borderline low oxygen levels, likely detected by increased use of pulse oximetry, have led to overdiagnosis of hypoxemia. The best-documented harms of such overdiagnosis are unnecessary hospitalization and increased length of hospital stay, the authors write. Both can increase the risk for hospital-acquired infections and other adverse events. Unnecessary admission and overly aggressive care also increase healthcare costs. At least one study estimates the cost of bronchiolitis at approximately \$652 million per year. An economic analysis of data from one trial found lowering oxygen saturation thresholds may decrease costs by \$377 per patient; those savings increase after factoring in other variables including travel and missed work. “The cost savings from preventing overdiagnosis could prove significant, both for individual patients and at a societal level,” the authors explain.

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“The current body of evidence suggests that we should challenge assumptions regarding the detection and aggressive management of borderline hypoxaemia in non-critically ill infants with bronchiolitis,” they stress. “The most impactful intervention may be to decrease overdependence on pulse oximetry as a major decision point in admission of children with bronchiolitis,” the authors conclude.

CPAP Safe for Obesity Hypoventilation Syndrome With Apnea

Most patients with obesity hypoventilation syndrome and sleep apnea can safely switch to continuous positive airway pressure (CPAP) ventilation therapy after at least 3 months of bilevel positive airway pressure (BiPAP) therapy, new research shows. “We were astonished,” said lead investigator María Paola Arellano-Maric, MD, from Pontifical Catholic University of Chile in Santiago. “We all felt pretty neutral on this when we started, but our results were very positive.” Noninvasive BiPAP ventilation provides a higher pressure for inhalation and a lower pressure for exhalation. With CPAP, pressure is consistent. There has been a belief that “if you have a pressure gradient for inhalation and exhalation, it’s more comfortable for the patient, but our patients didn’t find that,” Dr Arellano-Maric explained at the European Respiratory Society International Congress 2017. She and her colleagues demonstrated that once patients were stabilized after using BiPAP for at least 3 months, most could be safely switched to CPAP. The patients “didn’t have any respiratory insufficiency under CPAP,” she reported. For their study, the team recruited 42 stable patients with obesity hypoventilation syndrome who had been receiving noninvasive ventilation at home for an average of 34 months (interquartile range, 13.7 - 57.4 months). All 19 women and 23 men had severe obstructive sleep apnea and 52.3% had chronic obstructive pulmonary disease (COPD) classified as GOLD stage I or II. Average body mass index (BMI) in the study cohort was 45.1 kg/mg², and 83% of the patients were current or ex smokers. Every patient spent one night in the hospital receiving automatic positive airway pressure (APAP) so that the proper amount of pressurized air could be determined. If blood gases, polysomnography, and lung function were adequate, patients were sent home with a CPAP machine. “Surprisingly, the pressure for many was about 14 centimeters of water,” Dr Arellano-Maric reported. “That was high. We were worried they wouldn’t be able to sleep.” After 3 weeks, each patient returned to the hospital to undergo whole-night polysomnography. “One after the other, the patients told us they were sleeping better,” she said. After 6 weeks of home CPAP, daytime levels of partial pressure of carbon dioxide in arterial blood were 45 mm Hg or less in 30 of the 42 patients (71%; 95% confidence interval [CI], 55% - 84%). Current guidelines do not recommend auto-titrating CPAP machines for patients such as the ones in this study because initial treatment with CPAP often fails, and there is a “lack of studies on switching,” Dr Arellano-Maric explained.

OSA May Increase Risk of Atrial Fibrillation

Obstructive Sleep Apnea (OSA) may increase the risk of developing atrial fibrillation (AF), according to new research presented at the ATS 2017 International Conference. OSA is characterized by repetitive episodes of shallow or paused breathing during sleep that lead to a drop in blood oxygen level and disrupted sleep. AF is one of the most common cardiac arrhythmias characterized by a rapid and irregular heartbeat that can lead to stroke and related heart problems. “There is strong biologic plausibility that obstructive sleep apnea may

increase the risk of developing atrial fibrillation through a number of mechanisms,” said lead author Tetyana Kendzerska, MD, PhD, assistant professor of medicine at the University of Ottawa in Canada. “There is emerging evidence from animals and smaller studies in humans that OSA may increase the chances of developing AF through oxidative stress, increased sympathetic activity, metabolic abnormalities, endothelial dysfunction and cardiac stretch from intrathoracic pressure swings.” Researchers in Canada reviewed the records of 8,256 adults (average age 47) referred with suspected OSA, but free of any physician-diagnosed heart rate abnormalities, including AF at baseline. Participants were followed for up to 13 years. During that time, 173 developed AF resulting in hospitalization. Before controlling for established risk factors for AF, the researchers found that measures of OSA severity such as the number of times an individual partially or completely stopped breathing per hour of sleep and sleep time spent with oxygen saturation lower than normal (< 90 percent) were significant predictors of AF. Those who developed AF were more likely to be older, current or former smokers and have a high level of comorbidities. After adjusting for these and other known risk factors, the authors found that oxygen desaturation in sleep, but not the number of times an individual stops breathing, remained a significant predictor of AF hospitalizations. They also found the association between oxygen desaturation and AF hospitalization was stronger in women than men.

Inhaled Budesonide May Yield Mixed Results in Premature Infants

Inhaled-glucocorticoid therapy does not appear to boost the longer-term risk of neurodevelopmental disability in extremely premature infants, but might increase mortality, according to a randomized controlled trial. “Thanks to the new study results, neonatologists can now make informed decisions regarding the use of inhaled glucocorticoids for the prevention of” bronchopulmonary dysplasia (BPD), chief author Dr Dirk Bassler, chief of neonatology at University Hospital Zurich said. “When making this decision, they need to carefully balance the risks of potentially increased mortality owing to early inhaled corticosteroids against those of decreased rates of BPD with no effect on neurodevelopment in survivors at 2 years of age.” BDP itself is the most common chronic complication of extremely preterm birth. It is associated with higher mortality, growth failure, neurodevelopmental delay and both chronic respiratory and cardiovascular impairment. It can be prevented with systemic glucocorticoids, but those carry a higher risk of neurodevelopmental impairment such as cerebral palsy, and intestinal perforation. So doctors often try inhaled glucocorticoids. “Despite much study and progress in neonatology in recent years and some modest improvements in survival, both the incidence and severity of BPD have not changed much. To this day, approximately half of the infants born with a gestational age of less than 28 weeks suffer from BPD,” Dr Bassler said. The popularity of glucocorticoid treatment varies widely. It was estimated a few years ago that it was prescribed for about 25% of premature infants in the United States versus about 70% in Japan. The latest findings, reported in *The New England Journal of Medicine*, are a follow-up to the group’s 2015 study in the *Journal*, which found that while inhaled budesonide lowered the dysplasia risk, it elevated the mortality rate. The new work evaluated data on 629 babies randomly assigned to placebo or budesonide at a corrected age of 18 to 22 months. All were at a gestational age of at least 23 weeks and less than 28 weeks at the time therapy began. In the trial, done at

40 centers in nine countries, the budesonide babies received 400 micrograms of the inhaled drug every 12 hours, with the daily dose reduced to 200 micrograms from day 15 until the babies didn't need respiratory support. Drug treatment ended at 32 weeks. The rate of neurodevelopmental disability — a composite of cognitive delay, deafness, blindness or cerebral palsy — was 48.1% among the 308 budesonide recipients and 51.4% among the 321 who got placebo (P=0.40). The Bassler team also found no evidence that individual elements of that composite scale were affected by inhaled budesonide therapy. Budesonide recipients were more likely to die during the study (19.9% vs. 14.5%, P=0.04). “This is unexpected,” Dr Bassler said, and “there is no biologically plausible hypothesis to explain the seeming excess of deaths in treated infants, and the causes of death in our study did not differ considerably between the groups. The mortality findings may be attributed to chance, but we can't be sure about this assumption.” He said the results need to be seen in the context of other studies. “There are now updated meta-analyses including our short-term outcomes that address the use of inhaled glucocorticoids as compared with placebo or no intervention,” Dr Bassler said. “All updated systematic reviews and meta-analyses found a modest, but significant reduction in the composite outcome of death or BPD at 36 weeks. In these updated meta-analyses, inhaled glucocorticoids were associated with a significant reduction in BPD with no effect on mortality.”

FDA Accepts Filings for Two Antibacterial Agents

Merck, known as MSD outside the United States and Canada, announced that the US Food and Drug Administration (FDA) has accepted for review regulatory filings for two antibacterial agents. These filings are: (1) a NDA accepted for Priority Review

for the combination of relebactam, the company's investigational beta-lactamase inhibitor, with imipenem/cilastatin (MK-7655A, IMI/REL), for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) caused by certain susceptible Gram-negative bacteria, in adults with limited or no alternative therapies available; and (2) a sNDA accepted for Priority Review for ZERBAXA (ceftolozane and tazobactam) to treat adult patients with nosocomial pneumonia, including ventilator-associated pneumonia caused by certain susceptible Gram-negative microorganisms. The Prescription Drug User Fee Act (PDUFA) target action date for IMI/REL is July 16, 2019, while the PDUFA target action date for ZERBAXA is June 3, 2019. In the US, ZERBAXA is currently indicated for the treatment of adult patients with cUTI, including pyelonephritis, caused by certain susceptible Gram-negative microorganisms, and is also indicated, in combination with metronidazole, for the treatment of adult patients with cIAI caused by certain susceptible Gram-negative and Gram-positive microorganisms. Corresponding applications for both medicines have been filed with the European Medicines Agency (EMA) and are currently under review. “There is a major unmet need for new treatment options to address the growing danger of serious and potentially life-threatening infections caused by Gram-negative bacteria,” said Dr Nicholas Kartsonis, senior vice president, head of clinical research for infectious diseases and vaccines, Merck Research Laboratories. “In a space where there are currently very few treatment options, these filings underscore Merck's ongoing commitment to delivering new antibacterial agents to healthcare practitioners and patients.” The IMI/REL (MK-7655A) NDA is based on the results of the pivotal Phase 3 RESTORE-IMI 1 trial, which were presented at the 28th

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European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) meeting in Madrid, Spain, in April 2018. The ZERBAXA sNDA is based on the pivotal Phase 3 ASPECT-NP trial in adults with ventilated hospital-acquired bacterial pneumonia or ventilator-associated bacterial pneumonia. Merck plans to present results from the ASPECT-NP study at a future scientific conference. Relebactam is an investigational, intravenous, class A and C beta-lactamase inhibitor currently being evaluated in combination with imipenem/cilastatin for the treatment of certain Gram-negative bacterial infections. The FDA has designated the combination of relebactam with imipenem/cilastatin for intravenous use as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI) and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP). ZERBAXA is an antibacterial combination product for intravenous infusion consisting of the cephalosporin antibacterial drug ceftolozane sulfate and the beta-lactamase inhibitor tazobactam sodium. ZERBAXA 1.5g (ceftolozane 1g and tazobactam 0.5g) is approved in the United States and is indicated in adult patients for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Pseudomonas aeruginosa*. ZERBAXA used in combination with metronidazole is indicated in adult patients for the treatment of complicated intra-abdominal infections (cIAI) caused by certain Gram-negative and Gram-positive microorganisms.

Adult Survivors of Preterm Birth Have Smaller Airways

The airways of adult survivors of preterm birth are smaller than those of their peers born full-term, which may help to explain their worse lung function, according to findings. Airway obstruction at rest is a “hallmark finding” in adults who had been born prematurely, Dr Joseph W. Duke of Northern Arizona University in Flagstaff, who helped conduct the study, noted. On average, he added, premature birth is associated with a 20% to 30% reduction in lung function, with expiratory flow limitation (EFL) and reduced inspiratory volume during exercise. Dr Duke and his team used dysanapsis ratio (DR), an indirect measure that accounts for maximal flow, static recoil and vital capacity, to compare airway size in three groups of adults (mean age, 22 years): 14 who had been born at least eight weeks premature and had bronchopulmonary dysplasia (BPD), 21 born at least 8 weeks premature without BPD, and 24 term-born controls matched by age, sex and height. DR was 0.16 for the preterm adults without BPD, 0.10 for the BPD group, and 0.22 for the controls. DR correlated significantly with both peak expiratory airflow at rest ($r=0.42$) and expiratory flow limitation during exercise ($r=0.60$). The researchers used two different equations to measure DR, with consistent results: DR was significantly smaller for the preterm adults with or without BPD than for the controls, and those with BPD had significantly smaller DR than those without BPD. Given the findings, standard treatments for asthma and chronic obstructive pulmonary disease, which work by dilating the airways, may not be effective in these patients, Dr Duke noted. “We need to do some studies looking at these traditional medicines to reverse airflow obstruction and see what effect, if any, they have on adult survivors of preterm birth,” he said. He and his colleagues conclude: “The data in the present study suggest that smaller than normal airways explain, at least in part, the lower expiratory airflow rate in PRE (ie, without BPD) and BPD. The present findings add important information

to our understanding of the cardiopulmonary physiology of PRE and BPD.”

Air Pollution Tied to Low Birthweight Risk

Air pollution, but not traffic noise, appears to be linked to an increased risk of having low-birth-weight babies, reports a new study from the UK. Previous studies have tied road traffic air pollution to low birth weight. Road traffic produces noise as well as pollution, but studies of noise pollution have had conflicting results, say the authors. “We know that noise is associated with adverse health effects, eg sleep disruption, increased blood pressure, and cardiovascular disease, so it could plausibly have an impact on mothers’ health in pregnancy and the health of unborn babies,” study leader Dr Rachel Smith at the School of Public Health of the Imperial College said. Smith’s team wanted to investigate the effect of exposures to both traffic-related air and noise pollution during pregnancy on babies’ birth weight. “We found increased risk of babies being born with low birth weight or small for gestational age, at term, to mothers with higher exposure to air pollution from road traffic during pregnancy. We did not see an independent effect of road traffic noise on birth weight,” she said. Smith and colleagues used national birth registers to identify over 540,000 live, single, full-term births occurring in the Greater London area between 2006 and 2010. Specifically, the study team was interested in low birth weight (<5.5 pounds) and being born small for gestational age. Mothers’ home addresses at the time of birth were used to estimate the average monthly exposure to traffic-related pollutants including nitrogen dioxide, nitrogen oxides, and fine particulate matter, or PM_{2.5}. The researchers also estimated average day and night-time road traffic noise levels. Increases in traffic-related air pollutants, especially PM_{2.5}, were associated with 2% to 6% increased odds of having a low birth weight baby and about 1% to 3% increased odds of a baby being small for gestational age, even after taking road traffic noise into account. The risk associated with air pollution should be considered in context, ie the size of the effect of air pollution on an individual baby’s birth weight is relatively small compared to the well-recognized effect of smoking, said Smith. “However, at the population level the impact could be large, because collectively more women are exposed to air pollution than are exposed to smoking during pregnancy,” she said. There is a limit to what individuals can do to reduce their exposure to air pollution because making major changes to lifestyle, travel or where they live is just not feasible for the vast majority of people. Improving air quality and reducing air pollution in our towns and cities, and thus reducing health impacts of air pollution, requires action by policymakers, said Smith. The study “should increase awareness that prenatal exposure to small particle air pollution is detrimental to the unborn child,” Sarah Stock and her colleague wrote. Stock, a researcher at the University of Edinburgh Queen’s Medical Research Institute in Edinburgh, UK, said air pollution from traffic is well known to be detrimental to child and adult health. “This study provides further evidence that air pollution from traffic is also harmful to unborn babies. However, it shows that traffic noise is unlikely to be related to low birth weight in babies,” Stock, who was not involved in the study said. Pollution should be high on agendas at a local and national level, with pollution control integrated into development planning, said Stock. “Key initiatives include enforcing emission control technologies in motor vehicles; ensuring easy access to affordable and efficient public transport; encouraging walking and cycling; and mandating clean air zones,” she said. Unfortunately, women have few options to reduce their risk on

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a personal level, said Stock. “Avoiding air pollution is difficult, and we have no evidence that lifestyle measures, or wearing protective masks actually reduces chronic exposure to harmful pollutants. We do know avoiding exposure to tobacco smoke is really important. More research in this area is needed to find out the best ways for women to reduce their risk,” she said.

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Discuss the range of your oximetry products' applications.

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Measured CO-oximetry Parameters

Analyte	Units	Reporting Range
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	g /L	20-250
	mmol/L	1.2-15.5
nBili	mg /dL	2.0-30.0
	µmol/L	34-513
sO2	%	0-100
FO2Hb	%	0-100
FHHb	%	0-100
FCOHb	%	0-100
FMetHb	%	0-100

What oximetry products do you have in development?

Future technologies are not available for publication at this time.

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Initial Results from Med Systems Electro Flo 5000 Efficacy Study

Leigh J Mack, MD, PhD, FAPCR, CPI

Abstract

The research is an observational study that was designed to ascertain the efficacy of Electro Flo 5000 (K031876) percussor for the clearance of mucus from the lungs. The study was conducted remotely having the participants report pulse oxygenation levels, before and after use along with spirometer measurements of lung function before and after use of the device. The study was conducted in order to apply for a new Medicare reimbursement code specific to the device and offer a more cost-effective device compared with vest systems on the market. The percussor system is about 35% of the cost of typical vest clearance systems. The study is currently underway, and the findings are showing some marked improvement from 183 participant study days observed thus far.

Methods

Study Design and Participants

The present study is designed as a multi-center, non-randomized, single-blind, one-arm group trial with 70 participants per arm. Participants were between the ages of 18 to 55 years of age, male and female.

Inclusion Criteria

- Previously diagnosed with cystic fibrosis (mild, moderate or severe)
- Prescribed (licensed medical provider) airway clearance device/system for at home, self-treatment for airway clearance
- Physically able to perform self-treatment or treatment by an at-home medical provider

Exclusion Criteria

- History of tobacco use
- History of excessive alcohol consumption, more than 2 drinks per day, 10 per week
- Any other medical condition that would preclude use of an airway clearance device
- Previously diagnosed with major cardiological disease

Dr Mack is a Certified Principal Investigator (CPI) with the Association of Clinical Research Professionals (ACRP) and a Fellow of the Academy of Physicians in Clinical Research. He teaches American Medical Association (AMA) Category 1 Continuing Medical Education (CME) for the ACRP on Cloud-Based Clinical Trials. He has over 10 years of marketing and sales experience and most recently was the Lead Research Physician with American Biotech Labs. He has also been a consultant for other biotech companies. Dr Mack proudly served seven years as a combat arms soldier and officer in the US Army National Guard.

Medical Treatment

The Electro Flo 5000 is intended to assist in airway clearance therapy when the physician's choice of therapy is external manipulation of the thorax. Additionally, the Electro Flo 5000 is indicated for external manipulation of the thorax to promote airway clearance and improve bronchial drainage.

Duration of Study Participation

The estimated study duration that served as the assumption for sample-size calculations is 11 months. Each participant shall be active in the trial for a period of 28 days following enrollment. All participants will be followed to a common study end date, which is estimated to occur when the last randomized patient has been followed for one (1) month, based on a one (2) week recruitment period.

Primary Objective

To specifically illustrate and measure both clinical and empirical efficacy described by (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy (1991) for external manipulation of the thorax for postural drainage therapy and the secretion clearance, or presence of atelectasis caused by mucus plugging.

Outcome measured by:

Percentage change of oxygen levels in the blood (pulse oximetry). SpO₂ will be monitored using the standard pulse oximeter system (K131111). Change from baseline before treatment and measure again up to 3.5 hours after treatment.

Outcome measured by:


Percentage change of lung function. Evaluate expiratory forced vital capacity (FVC) and forced expiratory volume (FEV₁) will be monitored with the spirometer model MSA100 Peak Flow Meter (K133975). Change from baseline before treatment and measure again up to 3.5 hours after treatment.

Secondary Objective

To observe the quality of sleep that participants experience during the use of the device during the trial period. Participant were surveyed before and during the study for lifestyle quality.

Outcome Measures

The percentage change of oxygen levels in the blood (pulse oximetry). SpO₂ was monitored using the standard pulse oximeter system (510K device K131111). Pulsed arterial oxygen saturation (SpO₂) was measured transcutaneously at rest. Participants were instructed to take an initial SpO₂ reading



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within 30 minutes of waking. In addition, participants were instructed to take a FEV1 measurement using a hand-held spirometer model: MSA100 Peak Flow Meter (K133975) within 30 minutes of waking.

These measurements were recorded on the participants' Apple health and Android devices. The SpO2 measurements went directly from the device to the Health app with no participant interaction. The FEV1 levels were recorded by the participant on the same device and app but entered by the participant.

Participants then used the Electro Flo 5000 Airway Clearance System to self-clear, as prescribed by their pulmonologist, until the participant felt they had cleared all sputum possible during that treatment session.

Three hours post treatment with Electro Flo 5000 Airway Clearance System participants took measurements again of SpO2 and FEV1 levels with data recorded on participant personally owned devices (iPhone and Android). Data was then uploaded to the investigator via HIPAA (21CR Part 11 and 45 CFR Part 160/164) compliant secure email service for data collection.

The participants also answered a questionnaire about the efficacy and experience with the Electro Flo 5000 Airway Clearance System

after early permanent discontinuation of study medical device. The results are from a total of 183 days of participant data. The average age of the participants was 31, and the percentage of male participants to female participants was 30%. The average initial SpO2 upon waking was 91.8%; three hours after treatment rose to an average of 95.3%. FEV1 increased an average of 2% from 3 to 3.5 hours post treatment compared to initial measurement after waking up.

Participants have stated the device is easy to travel with compared to vest clearance systems. Many participants found they could actually target specific hard to clear areas of mucus more effectively compared to vest systems that they currently use. Initial survey results have suggested the participants feel they had better lung function after treatment.

Results

This study is ongoing, so limited results have been disclosed. All adjudicated events occurring from randomization to the study end date (inclusive) were counted, including events occurring

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BETTER IS FASTER



The Aerogen Ultra high performance aerosol delivers six times greater lung dose¹ in half the time² resulting in:

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 - ✓ 32% reduction in patient admissions⁴
 - ✓ 37 minute reduction in ED median length of stay⁴
- compared to a traditional small volume nebulizer.



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Decreasing the Work of Breathing Using the Precision Medical Heliox Blender

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Gary Phelps, currently licensed in California as a Respiratory Care Practitioner.

Respiratory Therapy: What are the main objectives when utilizing the Precision Medical Heliox Blender?

Gary Phelps: The intent is to decrease the work of breathing by using the properties of the lighter and less viscous gas to improve gas distributions throughout the lung and overcome any obstructions that might be present.

RT: What Heliox gas mixture should we start with? 80/20, 70/30, 60/40...?

GP: I believe that the 80/20 mix is the best place to start. With the 80/20 mix and the 80/20 Heliox blender as it provides the most flexibility and allows the use of any FiO₂ needed to meet the needs of the patient.

RT: What are the contraindications of using Heliox?

GP: There are only a few soft contraindications. They are really precautions. First, due to the thermoconductivity of the gas, heating of the gas is required to avoid cooling the patient. Next, any FiO₂ greater than 40% loses its effectiveness and is off-label use of the gas.

RT: What is the ideal FiO₂ when delivering Heliox via the Precision Medical Heliox Blender?

GP: The ideal FiO₂ is the lowest FiO₂ required to get the desired effect of improved oxygenation and decreased work of breathing.

RT: How long does it take to observe the benefit of Heliox use?

GP: The effects of Heliox would be seen almost immediately, due to the inherent properties of the gas being lighter and less viscous.

RT: How does Heliox reduce the work of breathing?

GP: Heliox is an inert gas that is 6 times less dense than the other gases in the lungs making it lighter and less viscous, which allows it to easily pass down the airways and around any partial obstructions.



Precision Medical HeliO2 PM5480

RT: How do I connect the Precision Medical Heliox blender to our large Heliox H tank?

GP: It is easily connected using a Heliox specific regulator with DISS to connect the hose from the cylinder to the Heliox blender inlet. A collar clamp and a mounting pole are placed onto the threaded portion of the Heliox cylinder. Onto the pole, a pole clamp is used to affix the blender, with an option to add an analyzer to the pole assembly

RT: How has the Precision Medical Heliox Blender changed the use of Heliox in your facility?

GP: This has made the application of Heliox standard amongst all of the staff and adjustments to the Heliox mix is easily performed without the need of changing out cylinders for different Heliox mixtures. Therefore, eliminating confusion when obtaining a cylinder from storage because you only need to stock the 80/20 mixture, and decreasing cost and waste to the healthcare organization. Due to the simplicity of the Heliox setup, the administration of Heliox can occur in a fraction of the time as it did previously. A cylinder can be setup with this configuration for emergency application in the ED and/or ICU. The staff become more comfortable and efficient in the application of Heliox for partial airway obstruction.

Gary Phelps, MPH, RRT- NPS, RCP, is a Registered Respiratory Therapist with over 32 years of experience, of which over 15 years are in a supervisory or managerial role. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Bronchiectasis and HFCWO Airway Clearance Survey

International Biophysics, manufacturer of the AffloVest Mobile HFCWO Airway Clearance vest conducted a survey in their booth at the 2018 AARC conference in Las Vegas. The survey was open to all attendees. Eighty (80) attendees took the iPad-based survey. The results of the survey are outlined below.

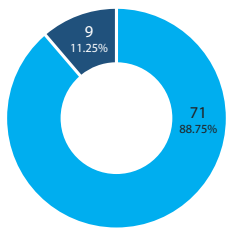
International Biophysics Corporation

As many as 1 in 2 COPD patients may have bronchiectasis. Bronchiectasis can be tricky because it often presents like COPD, but won't respond to COPD therapy. Studies show it's much more prevalent than what's being diagnosed.

Mobile HFCWO therapy is an Airway Clearance Therapy (ACT) that can help mobilize and loosen secretions in the lungs, which may help reduce exacerbations, hospitalizations, and antibiotic use.

Would you say you are more Hospital Based or Clinic Based?

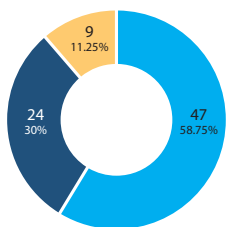
Results based on 80 responses to this question



88.75% (71) Hospital Based
11.25% (9) Clinic Based

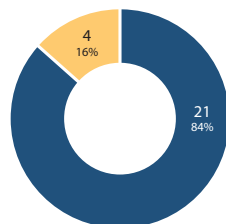
Which of these statements best describes your level of awareness/knowledge about bronchiectasis?

Results based on 80 responses to this question



58.75% (47) Pretty basic level
30.00% (24) I know quite a bit more about it than most
11.25% (9) I know as much about it as most pulmonologist do

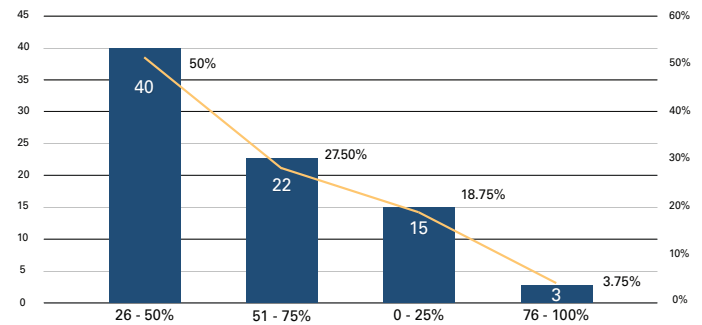
Which HFCWO do you recommend to your patients?



Afflovest® by International Biophysics
Monarch® by Hill Rom

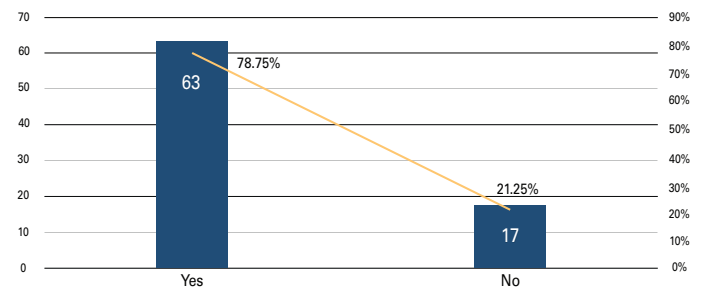
Did You Know...When it comes to Mechanical Oscillation, 84% of RT's surveyed at AARC preferred the AffloVest® with Optimal Oscillation technology vs Monarch® by Hill Rom?

What % of your COPD patients would you estimate have bronchiectasis?



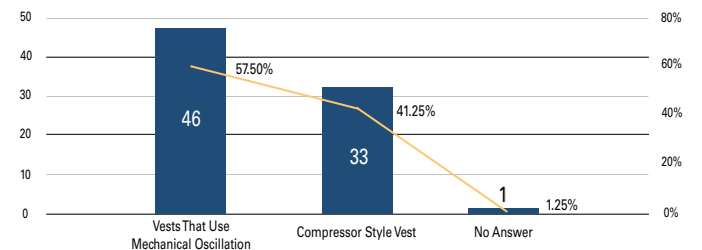
Did You Know...That 50% of RT's surveyed at AARC believe that 50% of their COPD patients may have bronchiectasis and over 27% think its even higher (51-75%)?

Do you ever recommend HFCWO airway clearance therapy for COPD patients with bronchiectasis?



Did You Know...Over 78% of RT's surveyed at AARC recommend High Frequency Chest Wall Oscillation (HFCWO) to their COPD patients with bronchiectasis for their airway clearance needs!?

Which of the two types of HFCWO modes of operation do you prefer for your patients?



Did You Know...That a majority of RT's surveyed at AARC prefer vests that use mechanical oscillation Vs older style vests that use hoses and compressors?

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Comparative Study of Durability of Three Disposable Pulse Oximeter Sensors

Nicole Clark, BSN, RN and Karen Rhoades, MS, RN

Abstract

Background: Pulse oximetry is ubiquitous in health care. Disposable adhesive sensors are used to decrease cross-contamination between patients, improve wear-ability and improve ease-of-use for clinicians. This study introduces a new sensor for consideration by respiratory therapists and other clinicians.

Aims: The purpose of this study was to compare durability of the Philips M1139A SpO₂ sensor to Nellcor Max N and Masimo LNCS Neo-L sensors in the adult and pediatric populations. The aspects of durability evaluated were comfort, pressure marks, and mechanical and electrical functionality.

Method: Part 1 was a 48-hour Clinical Study in which 15 adult and 15 pediatric subjects wore Philips, Masimo and Nellcor adhesive sensors for 48 hours in their homes while conducting normal activities. Sensor comfort, SpO₂ functionality, skin integrity and usability of labeling were assessed. Part 2 Actual Use Study compared performance of the three sensors for patient comfort, security of fit, and skin integrity. All sensors were placed by 15 licensed clinical users.

Results: The Philips sensor scored as well or better than the Masimo and Nellcor sensors on key durability metrics. The sum of all tasks and questions for the Philips sensor was higher than the sum for the other sensors ($p < 0.05$).

Limitations and Implications: Although the sample size of 15 participants from each user population meets the minimum required for human factors validation testing, a larger sample size is desirable. Respiratory therapists and other clinicians may consider using the Philips sensor in clinical practice.

Conclusion: The Philips M1139A sensor is a durable option for respiratory therapists and other clinicians.

Introduction

Pulse oximetry is ubiquitous in health care today. Many health care institutions prefer disposable adhesive sensors to decrease cross-contamination between patients to improve wear-ability (patient comfort and durability) and improve ease-of-use for

respiratory therapists and other clinicians (Johnson & Olson, 2012). Many pulse oximeters are designed to operate solely with a specific brand of sensor. To increase choice for clinicians, some pulse oximeters can accommodate sensors from more than one pulse oximeter brand (more sensor options). The Philips FAST pulse oximeter system is an example of a system that supports some Nellcor and some Masimo sensors as well as Philips sensors. Philips has recently designed a pulse oximetry sensor that is similar to the Nellcor Max N and the Masimo LNCS Neo-L sensors and is also compatible with the FAST pulse oximeter system. The newly developed Philips M1139A sensor is a disposable adhesive single-patient use sensor that can be used in adults weighing >40 kg and pediatrics weighing >20 kg.

Purpose

The purpose of this study was to compare the durability of the Philips M1139A SpO₂ sensor to the Nellcor Max N and the Masimo LNCS Neo-L sensors in the adult and pediatric populations. The aspects of durability that were evaluated in this study were comfort, pressure marks, mechanical functionality (maintained adhesiveness) and electrical functionality (amount of time the sensor worked without electrical failure). Additional goals of this study were to confirm that the Philips M1139A sensor is safe and effective; that “Customer Requirements” are met (fits well and is easy and obvious to place); and that risks are mitigated (user instructions are clear and easy to understand) (Martin-Pressman, 2017).

Review of the Literature

The review of the literature included searches of PubMed and CINAHL databases for years 2003-2018. Search terms included the following: *pulse oximetry*, *pulse oximeter sensors*, *pulse oximeter sensors + comparison*. Only studies involving human subjects were included in the review.

Numerous studies have determined the accuracy of various pulse oximeters (Singh, Sahi, Mahawar & Rajpurohit, 2017; Harris, et al., 2016; Jones, et al., 2015; Pupim, Filho, Takeshita, & Iwaki, 2013; Weaver, Churchill, Deru, & Cooney, 2013; Milner & Mathews, 2012). One study related to sensor application (Louis, Sundaram, & Kumar, 2013) and another reported pressure injury from sensors (Lee & Eisenkraft, 2014). One study compared a forehead sensor with a digit sensor in pediatric patients (Berkenbosch, 2006). One study compared durability of two disposable sensor designs (Johnson, & Olson, 2012) and another compared longevity of two different sensors in infants (Erler, Avenarius, Schmidt, & Klaber, 2003).

Nicole Clark is a Staff Nurse at Rose Medical Center in Denver, Colorado. Karen Rhoades is an Affiliate Nursing Faculty at Regis University in Denver, Colorado and Clinical Coordinator at Lutheran Medical Center in Wheat Ridge, Colorado.

Table 1. Summary of Adult Subject Findings

Clinical Use Assessment	Part 1					Part 2					
	Adult Use Assessment	Comfort	Pressure Marks	Mechanically Functional (hours)	Electrically Functional (hours)	Part 1 Overall Average	Obvious to Place	Ease to Place	Sensor Fit	Correct Placement	Part 2 Overall Average
Masimo LNCS Neo-L Sensor	4.1	4.0	4.9 (46.9)	4.9 (46.9)	4.5	4.4	4.5	4.4	4.5	4.5	4.5
Philips M1139A Sensor	4.5	3.8	5 (48.0)	4.9 (46.9)	4.6	4.7	4.6	4.6	4.7	4.7	4.6
Nellcor Max-N Sensor	4.2	3.8	4.9 (46.9)	4.7 (44.8)	4.4	4.8	4.6	4.6	4.4	4.6	4.5

Note: The scores for the mean hours in Part 1 questions '3–Mechanically Functional (adhering)' and '4 - Functional SpO₂ reading were included in the total summation of all tasks and questions using the 1 to 5 scale. In Part 1, questions 3 & 4 were measured in total hours for each subject. The mean hours were calculated for all subjects. The mean hours were converted to a score from 1-5 in increments of 9.6 hrs per range (48 hrs/5 = 9.6 hrs). The Max possible time = 48 hrs; 5 = 48 hrs, 4 = 38.4 hrs - 47.9 hrs, 3 = 28.8 hrs - 38.3 hrs, 2 = 19.2 hrs - 28.7 hrs, 1 = 9.619 hrs - 2 hrs.

Ethics

Informed consent was obtained for all study participants. Confidentiality of persons was maintained throughout the study process. IRB approval was obtained from Salus Independent Review Board, 2111 West Braker Lane, Suite 400, Austin, TX 78758, for the April 12, 2017 final revision Study ID# PR-2016-209 dated August 23, 2017.

Sample Selection Sample Size Rationale

Federal Drug Administration (FDA) guidance for Human Factors study states, “validation testing should include at least 15 participants from each user population” and “the human factors validation test participants should be representative of the range of characteristics within their user group” (FDA, 2016). Therefore, 15 clinical users (RN’s or RRT’s) participated. All were clinically familiar with patient monitoring and pulse oximetry. Volunteer subjects (15 adult and 15 pediatric) were consented and enrolled in Part 1 and 2 studies.

Inclusion for Volunteer Subjects

Adult volunteer subjects weighed >40 kg. and pediatric volunteer subjects weighed >20 kg. All volunteer subjects were free from deformities or injuries that would not allow a pulse oximeter sensor to fit on the fingers or the big toes. All were willing to participate in all study procedures.

Design and Method

This study was conducted in two parts. Part 1 was a 48-hour clinical trial while part 2 was a procedure and use assessment. The three adhesive sensors used in the comparison were the Nellcor Max N sensor (Fig. 1), Masimo LNCS Neo-L sensor (Fig. 2), and Philips M1139A sensor (Fig. 3). Other equipment used in this study included: Masimo LNCS adapter cable for Philips monitors, Philips M1943AL adapter cable, Philips IntelliVue MP40 monitor with Fast Pulse Oximetry module (Fig. 4), and Speer Scientific Light Meter. All three adhesive sensors were plugged in to the FAST module, using the appropriate adapter cable.

Part 1. Clinical Study

The Clinical Study tested the functionality of the Philips, Masimo and Nellcor adhesive sensors on 15 adult and 15 pediatric subjects. Trained clinicians placed all three sensors on volunteer subjects, who wore them for 48 hours in their homes while conducting normal activities. Subjects visited the laboratory approximately every 8 hours for sensor changes and nurse evaluation. The sensors were worn on the index, middle, and ring fingers for adults and index finger and thumb for pediatric subjects. When the sensors were changed, they were moved to the opposite hand. This was done at least 6 times over 48 hours (~every 8 hours), or as long as the adhesive remained effective. The following were assessed: sensor comfort, SpO₂ functionality, skin integrity and usability of labeling.

Part 2. Actual Use Study

The Actual Use Study compared the performance of the Philips M1139A sensor to the Masimo LNCS Neo-L sensor and the Nellcor Max N sensor for patient comfort, security of fit, and skin integrity. This study included 15 licensed clinical users (14 RNs, and 1 RRT). A proctor administered the test to one clinical user with one to three subject participants. The licensed clinical user placed each sensor on the subjects multiple times over a period of up to 3 hours. Sensors were applied to the index, middle, and ring fingers in adult subjects, and to the big toes and thumbs of pediatric subjects. Each clinical user answered a set of questions and completed a series of tasks using the device. The proctor analyzed and graded the accuracy of task completion by the clinical user. The subject participants (‘patient surrogate’) answered questions about the comfort of the device.

Findings

Adult and Pediatric Findings

In the Part 1 48-hour clinical use trial (comfort, pressure marks, adhesive, electrically functional) and Part 2 proctored actual use assessment (obvious and easy to use, sensor fit, correct placement) the Philips M1139A sensor performed as well as or better than the Masimo and/or Nellcor sensors. The Part 1 clinical use trial demonstrated that the sensor met the use-

Table 2. Summary of Pediatric Study Findings

Part 1 Findings				
Pediatrics 48-hour Trial	Q1 Comfort	Q2 Pressure Marks	Q3 Mechanical Functional (hours)	Q4 Electrically Functional (hours)
Philips M1139A Sensor Thumb*	4.3	3.9	4.9 (47.4)	4.6 (44.2)
Philips M1139A Sensor Index	4.2	3.8	4.9 (47.4)	4.7 (44.8)
Part 2 Findings				
Pediatric Use Assessment	Obvious to Place	Ease to Place	Sensor Fit	Correct Placement
Philips M1139A Sensor Big Toe	4.7	4.7	4.2	3.9
Philips M1139A Sensor Thumb*	4.7	4.9	4.8	4.3

All subject scores were averaged.
*Primary pediatric application site

related Customer Requirements, the risk mitigations identified in the Safety Risk Assessment are effective in the adult & pediatric populations and the Instructions for Use are effective & comprehensible. The Philips M1139A sensor was found to be safe and effective for the intended users, uses and use environments. In the Part 2 proctored actual use assessment, the Philips M1139A scored better than the Nellcor Max N and/or the Masimo LNCS Neo-L Sensor (see “Part 2–overall average”) with $p < 0.05$. It is also important to note that the Philips M1139A sensor could be worn continuously for two days in an environment more strenuous than a hospital setting and remain functional.

Adult Subjects

For the Adult subjects in this study, using the 1 to 5 scale (5 being the best), the sum of all tasks and questions in Part 1 and Part 2 for each of the sensors was as shown on Table 1.

The findings from Table 1 demonstrate that for the ‘Part 1 study–Adult subjects,’ the Philips M1139A scored better than Nellcor Max N (average of 4.6 vs 4.4) and the Masimo LNCS Neo-L Sensor (average of 4.6 vs 4.5) and therefore met the acceptance criteria for the Part 1 study.

With respect to the ‘Part 2 study–Adult Subjects,’ the results in Table 1 demonstrate that the Philips M1139A sensor received a score of >3 from all adult users/subjects and therefore met the acceptance criteria for the Part 2 study.

Pediatric Subjects

For the pediatric subjects in this study, using the 1 to 5 scale (5 being the best), the sum of all tasks and questions in Part 1 and Part 2 for the M1139A sensor is as shown on Table 2.

The findings from Table 2 demonstrate that for “Part 1 study–Pediatric subjects,” the Philips M1139A sensor received a score of >3 from all pediatric users/subjects and therefore both the thumb and index finger met the acceptance criteria for the Part 1 study. With respect to the “Part 2 study–Pediatric Subjects,” the findings from Table 2 demonstrate that the Philips M1139A finger and toe sensors received a score of >3 from all pediatric users/subjects and therefore met the acceptance criteria for the Part 2 study. Note: For the pediatric population, the Philips M1139A sensor was not compared to Masimo and Nellcor because the Masimo LNCS Neo-L sensor and the Nellcor Max N sensor used in this study are not intended for the pediatric population.

Discussion

Although several recent studies compare the accuracy of pulse oximeter sensors in clinical settings, few compare the durability of sensors (Fernandez, et al, 2007; Milner & Mathews, 2012; Mort, et al, 2016). The “longevity” of Masimo and Nellcor pulse oximeter sensors worn by infants in NICU settings was compared in 2003 (Erler, et al). Durability of Philips and Nellcor sensors was compared in a MICU and Step-Down Unit at the University of Colorado Hospital in 2012 (Johnson & Olson).

In evaluating disposable pulse oximeter sensors, “durability” is a key concept. Clinicians want to know “How long will the pulse oximeter sensor last, stay on a patient’s skin and provide a valid SpO₂ reading?” “Durability” means the sensor still performs in terms of these two study parameters remains adhesive or “mechanically functional” and still provides a valid SpO₂ reading or “electrically functional.” Therefore, a “durable” disposable pulse oximeter sensor remains adhesive and provides a valid SpO₂ reading for at least 48 hours.



Figure 1. Nellcor Max N



Figure 2. Masimo LNCS Neo-L



Figure 3. Philips M1139A



Figure 4. Philips FAST Module

This study is significant for several reasons. First, adult users and trained clinicians concluded the Philips M1139A was as or more durable than two commonly-used sensors (Nellcor Max N and Masimo LNCS Neo-L): Table 1–Part 1 and Table 1–Part 2. Second, pediatric users found the Philips M1139A durable on the same performance measures as actual adult users (Table 2). Third, this study showed that the Philips M1139A was durable under more strenuous daily living conditions (rather than typical in-hospital, in-bed conditions). Fourth, this study demonstrated that all three disposable pulse oximeter sensors used in this study work well with the Philips Fast Pulse Oximeter.

Limitations and Recommendations for Future Research

The major limitations of this study are the sample size and exclusion criteria. The sample size was 15 adult and 15 pediatric subjects, and 15 clinical users which meets the minimum required sample size for human validation testing. A larger sample size is desirable for a better representation of the population. A larger sample size can also reduce the margin of error and possibility of outliers. The exclusion criteria of <20kg for pediatric population and <40kg for the adult population is a limitation because those people are not represented in the study. Future research is needed with a larger and more diverse sample of patients. Additional research in the hospital setting is recommended. This would allow evaluation of this sensor on patients with low SpO₂.

Conclusion

These study results demonstrate that the Philips M1139A Adhesive SpO₂ sensor, a new market entrant, is as durable (remains adhesive and provides a valid SpO₂ reading for 48 hours or more) as the Nellcor Max N and/or the Masimo LNCS Neo-L sensors, in the adult population. Adult and pediatric users found the sensors comfortable, easy-to-wear, adhering without slipping and functional (with sensors repositioned about every eight hours) even under more strenuous out-of-hospital daily living conditions for 48 hours. Trained clinicians found that the sensor is easy-to-place and fits securely and correctly even with multiple applications over three hours' time. The Philips M1139A sensor is compatible with the Philips Fast Pulse Oximeter and is a durable option for respiratory therapists and other clinicians in diverse health care settings today.

Commercial Sponsor and Study Site

The Commercial Sponsor for this study was Philips Medical Systems, 3000 Minuteman Road, Andover, MA 01810-1099. The Study Site was Clinimark, LLC, Avista Two Medical Plaza, 80 Health Park Drive Suite 20, Louisville, CO 80027.

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Aerosol Delivery with High Velocity Nasal Insufflation: A Survey of Practice

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Executive Summary

Treating respiratory disorder patients frequently requires combined use of high velocity nasal insufflation therapy (HVNI) with concomitant aerosolized medication delivery. Currently, little definitive data exists to describe safe use of nebulizers concurrently in patients receiving HVNI.

The purpose of this paper is to describe how aerosol therapy is currently being performed on patients receiving HVNI therapy, to describe associated challenges, to explore how those challenges are best addressed so to provide clinicians resource information to help them decide which methods are best to provide safe and effective aerosol therapy during HVNI in their institution.

A literature review explored published research related to aerosol medication delivery with HVNI. Clinical expert interviews (n=21), followed by clinician surveys (n=70), were conducted to ascertain delivery options, their associated challenges, and methods used to overcome these challenges to deliver aerosol therapy during HVNI.

Estimates of relative intermittent and continuous aerosol use varied widely, with median response being 85% intermittent: 15% continuous. Pediatric settings tended toward 50:50 utilization. 78% (intermittent) and 83% (continuous) of respondents indicated they do not pause HVNI therapy for aerosol therapy, and majority use a vibrating mesh nebulizer. Areas of concern associated with integrating nebulizer use with HVNI were poor drug deposition, fluid condensate accumulation, and excessive flow delivery (jet nebulizer only). When a nebulizer was not integrated into the HVNI system, either a mask or mouthpiece nebulizer treatment was given with/without discontinuation/pause of HVNI. When applicable,

use of a mouthpiece was preferred for adults with mask use for children for whom a mouthpiece was not appropriate.

Our findings indicate a variety of practice methods are employed to effectively deliver aerosolized medications during HVNI. Further, this study reveals a need for additional bench study and clinical trial research to better describe how aerosol therapy should be performed during HVNI.

Introduction to Aerosol Medication Use with HVNI

Patients may experience many different forms of respiratory distress that requires respiratory support which can range from simple oxygen therapy to full ventilatory support via invasive ventilation. Because oxygen therapy is often inadequate and invasive ventilation has significant morbidities, other, non-invasive techniques have been developed. High Flow Nasal Cannula (HFNC) is one such technique that has gained popularity over the last decade. High velocity nasal insufflation (HVNI) is a form of HFNC that involves the delivery of humidified gas at high volumetric flow rates delivered employing increased velocities, through a nasal cannula. HVNI has been shown to provide ventilatory support comparable to NIPPV and positive pressure therapy across a range of breathing disorders.¹⁻⁴ Patients with respiratory disorders frequently require combined use of HVNI with aerosolized medication delivery. Currently, while much is known about aerosol delivery during HFNC, there is very little definitive data to support the effective concomitant use of nebulizers and HVNI therapy.

“Our findings indicate a variety of practice methods may effectively deliver aerosolized medications during HVNI.”

Vapotherm, Inc is the innovator of humidified high flow nasal cannula therapy (HFNC) and high velocity nasal insufflation (HVNI) and manufactures devices for acute and chronic respiratory care. For more information visit www.vapotherm.com ¹Canisius College, Buffalo, NY, USA. ²Seattle Children's Hospital and Research Institute, Seattle, WA, USA. ³University of Washington School of Medicine, Seattle, WA, USA; ⁴CIRUS, Sydney, NSW, Australia; ⁵Vapotherm, Inc, Exeter, NH, USA. Arthur Taft and Robert DiBlasi are paid consultants for Vapotherm. Robert DiBlasi is on the Speaker's Bureau for Draeger. He has also received research funding from Aerogen Pharma, Mallinckrodt Medical, Vero Biopharma, Chiesi, Neotech, and Vapotherm. George Dungan, Leonithas Volakis, and Mark Kolnsberg are employees of Vapotherm, Inc.

Many different methods to deliver aerosol during HVNI therapy are currently being used, although no single method has been shown to be superior to the others. Many clinicians choose to remove patients from HVNI for continuous and intermittent aerosol treatments, which can be problematic especially if the individual cannot tolerate being removed from the HVNI device. Other clinicians will deliver aerosolized medication with HVNI using other strategies. Because clinical evidence on the delivery of aerosol is limited, especially with HVNI, we sought to identify methods currently being used clinically to provide aerosol therapy during HVNI.

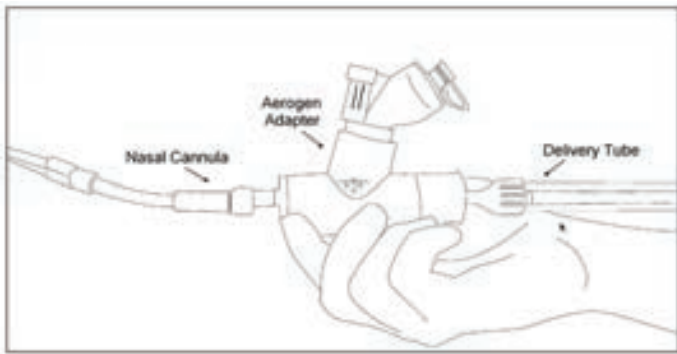


Figure 1. AAA-1 Aerosol Adapter.



Fundamentals of High Velocity Nasal Insufflation

High-flow nasal cannula is a respiratory support therapy. High flow nasal cannula can deliver up to 100% oxygen by nasal cannula.⁵ It can improve ventilation efficiency by way of extrathoracic dead-space clearance and induce a mild distending pressure.^{6,7} Vapotherm's Precision Flow provides HVNI, a modified form of high-flow nasal cannula (HFNC), that may assist spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting by augmenting dead-space purge^{6,8} and CO₂ removal by use of small-bore nasal cannulae.⁵

The Precision Flow AAA-1 Vapotherm Aeroneb Adapter T-Piece (Vapotherm Inc, Exeter, NH, USA) is available for integrating Aerogen[®] Pro or Solo Vibrating Mesh nebulizer generated aerosol medication into the HVNI gas stream for delivery via a nasal cannula or a tracheostomy mask, as shown in Figure 1.

Materials And Methods

Interviews, Survey and Data Collection

Telephone interviews and an internet survey were approved by the Canisius College Institutional Review Board. All participants provided informed consent prior to participation. The initial phase of the project included phone interviews with clinicians. The phone interviews were designed to provide formative data on how aerosol therapy is currently being performed during HVNI therapy, which were later used to guide structuring the internet survey. We first identified a group of clinical users (Registered Respiratory Therapists [RRT] and Medical Doctors [MDs]) who were experienced with HVNI therapy. These users were identified by Vapotherm's Respiratory Therapy Clinical Managers through their personal interactions with clinical users of HVNI. Selection criteria included being knowledgeable about HVNI therapy and having significant experience

Table 1. Characteristics for Phone Interview Group.

Total Respondents n=21	Categories	Responses
Credentials	RRT RRT-NPS RRT-NPS, ACCS RRT/RN MD	7 (33%) 8 (38%) 1 (5%) 1 (5%) 4 (19%)
Education level	AS BA or BS MS MD or MD/PhD	6 (29%) 8 (38%) 3 (14%) 4 (19%)
Experience ($\bar{x} \pm SD$)	18.9±10.8 yrs	
Experience with HVNI	< 1 yr 1-2 yr 2-5 yr > 5 yr	0 (0%) 5 (24%) 6 (29%) 10 (48%)
Care areas worked	ED, ICU, NICU, SICU; Med/Surg GCF; Burn Unit; Pedi GCF; LTACH	
Regions/states represented (# of institutions)	West: WA (1) Midwest: NE (2), OH(5), IA(1) Southwest: TX (3), AZ (1) Southeast: GA (2), TN(1), AL(1), FL(2), AK(1) Northeast: MA (1)	

All responses are presented as n (% of total). Total number subjects (n=21)

delivering aerosol medication therapy for Vapotherm to HVNI patients. Twenty-one clinicians were selected to participate in structured phone interviews to explore how aerosol therapy is delivered using HVNI. All interviews were performed by the same interviewer (MK) and began by asking scripted questions exploring: 1) clinical background; 2) experience with HVNI; 3) effects of clinical practice areas on performance of HVNI; 4) methods used to deliver aerosol therapy during HVNI; 5) challenges associated with delivering aerosol therapy during HVNI, and 6) methods used to overcome challenges. When interesting or unique comments were reported, follow-up questions exploring those comments more deeply were posed. All interviews were recorded and transcribed to allow accurate evaluation and assessment.

Table 2. Characteristics for Internet Survey group

Total Respondents n=70	Categories	Responses n (%)	Adjusted Responses† n (%)
Job Responsibility	Director Manager Staff Clinician Clinical Educator Supervisor RT Faculty Researcher Consultant	10 (14%) 26 (37%) 22 (31%) 5 (7%) 4 (6%) 1 (1%) 1 (1%) 1 (1%)	n/a
Experience with HVNI	None < 1 yr 1-2 yr 2-5 yr > 5 yr	3 (4%) 4 (6%) 12 (17%) 18 (25%) 34 (48%)	n/a
Care areas worked	ICU SICU NICU PICU ED Adult floors Peds floors LTAC	46 (17%) 20 (7%) 36 (13%) 31 (11%) 49 (18%) 42 (16%) 34 (13%) 3 (3%) n=270	46 (66%) 20 (29%) 36 (51%) 31 (44%) 49 (70%) 42 (60%) 34 (49%) 3 (4%) n=70

All values are presented as n (% of total responses). Total respondents n=70. † Adjusted responses are normalized to the number of respondents (n=70) instead of total number of responses (n=270) to reflect that practitioners frequently work in more than one critical/floor area.

Table 3. Purposes of Aerosol Therapy and Common Drugs Delivered from the Phone Interviews

Type of Therapy	Reason for Administering Aerosol Therapy	Drugs Utilized
Intermittent	Bronchodilation	Albuterol, Xopenex, Formoterol, Epinephrine, Atrovent, DuoNeb,
	Decrease Inflammation	Steroids (Pulmocort, Budesonide)
	Moistening upper airways	Saline
	Numbing (ie. During endoscopy)	Lidocaine
	Mobilizing secretions	Pulmozyme, Mucomyst, Hypertonic Saline
	Suppressing cough	Lidocaine, Saline
	Deliver antibiotics	Tobramycin
	Delivering pulmonary vasodilators	Prostacyclins
Continuous	Bronchodilation	Albuterol, Atrovent, DuoNeb
	Decrease Inflammation	Steroids (Pulmocort, Budesonide)
	Moistening airways	Saline
	Delivering pulmonary vasodilators	Prostacyclins, Nitric Oxide

Based on findings from these interviews, an internet survey was developed using commercially available software (Qualtrics Survey Software, Qualtrics.com) for the second phase. Survey questions included both closed-ended and open-ended questions. The initial survey was pilot tested for clarity and content by five RRTs knowledgeable about HVNI therapy. Following revision, the survey was sent out in February, 2018, to all HVNI users currently listed in a proprietary customer relationship database hosted by Salesforce.com (Salesforce.com Inc, San Francisco, CA, USA) with a respiratory job title at institutions that have Vapotherm Precision Flow units, which contained 2512 email addresses. One week after the initial offering, the survey was resent and after one more week survey responses were collated and evaluated.

Responses from both the interviews and surveys were evaluated by identifying common themes/categories and grouping responses into those categories. Interviews and surveys were evaluated and reported separately, although there was a great deal of overlap in the responses. Data was analyzed using descriptive statistics, primarily frequency of distribution.

Results Participants

Invitations to participate were sent to 2512 individual email addresses from the database, with 70 responses, for a 2.8% response rate. Participants represented all regions across the US. Characteristics of the phone interview group are shown in Table 1, showing 21 respondents with 2/3's possessing specialty credentials, 100% have at least 1 year(yr) of experience with HVNI, and work in all major care areas. Our internet survey participants comprised a good sample of HVNI users as all respondents were RRTs with 90% having more than 1 year of clinical experience with HVNI (Table 2). Likewise, all major practice areas were represented by the respondents.

Use of aerosol therapy during HVNI

Phone interviews determined that bronchodilators are the primary aerosolized drug that is being delivered, either intermittently or continuously. Table 3 provides a list of additional reasons and drugs for the aerosol delivery during HVNI therapy. Overall estimates of the relative use of intermittent and continuous aerosol varied widely. Most heavily favored intermittent, with the survey median response being 85% intermittent: 15% continuous. Participants working in pediatric settings tended more toward 50:50 utilization. Additionally, some individuals indicated that three aerosol treatments back-to-back were considered continuous aerosol therapy, demonstrating some confusion as to the definition of continuous aerosol. These percentages tracked very closely with the phone interview participant's answers. Phone interview participants stated that care areas do not really influence how aerosol therapy is performed while receiving HVNI, and that patients with respiratory compromise receive aerosol therapy as needed wherever they are. However, continuous aerosol therapy is generally only given in critical care areas such as ED and ICUs where monitoring is more robust than general floor care areas, although some respondents deliver aerosol therapy the same across all care areas where HVNI is utilized.

Intermittent aerosol therapy practices during HVNI

Most aerosol therapy involves single-dose delivery of medications or bland aerosols. The majority 78% (49 of 63) of internet survey respondents indicated they did not pause HVNI therapy while performing intermittent aerosol therapy. Of those that do not stop HVNI, 18% (3 of 17) used a VMN, while 41% (7 of 17) used a jet nebulizer. About 23% (4 of 17) used an MDI during HVNI therapy and 18% (3 of 17) used an unspecified type. No type of patient interface, mouthpiece, mask, or cannula is used most often when treating adults, but when treating children, cannula were used most often 46% (6 of 13), followed by facemask 31% (4 of 13) and mouthpiece 8% (1 of 13) while 15% (2 of 13) switched to another HFNC system. Respondents who paused HVNI during single-dose aerosol therapy, did so primarily because of concerns with medication delivery (69%, 9 of 13) or to prevent excess flow through the system 15%, (2 of 13) when an SVN is used. Other reasons included decrease in flow for patient comfort 8% (1 of 13) and patient request 8% (1 of 13) Oxygenation was maintained during the pause by using the O2 flow through the jet nebulizer 62% (8 of 13), via hyperoxygenation 8% (1 of 13) prior to disconnecting from HVNI or doing nothing 15% (2 of 13). It was also noted that 15% (2 of 13) said they just increased FiO2.

The internet survey indicated that the most commonly used nebulizer when pausing HVNI was a jet nebulizer 41% (7 of 17), followed by MDI or PDI 24% (4 of 17), VMN 18% (3 of 17), and 18% (3 of 17) used others (including BAN). When pausing HVNI the most common patient interfaces used for adults were either a mask 50% (7 of 14) or mouthpiece 43% (6 of 14), then nasal cannula 7% (1 of 14). In children, facemasks 65% (11 of 17) are used more often than mouthpieces 23% (4 of 17), almost 3:1, while one used blow-by 6% (1 of 17) and another a nasal cannula 6% (1 of 17). Upon completion of single-dose treatment, all were returned to HVNI.

Methods of performing continuous aerosol therapy during HVNI

While receiving HVNI, several methods were utilized to perform continuous aerosol therapy. Both telephone interview and

Table 4. Pros and Cons of Patient Interfaces in Adult Patients from the Internet Survey.

Pros	n	Cons	n
Nasal cannula with AAA-1 adapter			
Maintains HVNI flow without disconnection	9	Rain out	6
Convenient, easy to use	7	Ineffective medication delivery	4
Good medication delivery	6	None	4
Patient comfort	4	Excessive work	3
Maintains oxygenation	2	Excessive cost	3
		Patient intolerance	2
		Not approved (for continuous treatment)	1
Mouthpiece			
More effective/better medication delivery	9	Difficult for patient/poor compliance	13
Patient controls tx/better tolerance	5	Interferes with HVNI	5
Easy to use	4	Medication leak/loss	2
No rainout/low cost/better than mask	3	None	2
		Lack of consistency/inconvenient	2
		Rain out	1
Facemask			
Convenience/easy to use	13	Poor medication delivery	13
Effectiveness	3	Poor fit/tolerance	7
Maximum O ₂ /well tolerated/less rainout	3	Rainout	3
None	2	None	2
		Inconvenient/poor communication	2

the internet survey had several facilities indicate they used the Aerogen nebulizer connected to a syringe pump with the AAA-1 adapter and nasal cannula interface to deliver aerosol continuously, while others used a jet nebulizer and face mask over the HVNI cannula. Still others switched to a HFNC method that allowed connecting the aerosol generator to the inlet of the humidifier to limit issues of rainout and excessive workload handling that rainout. Those tended to use either the nasal cannula or a mask to deliver aerosol. One clinician described using a jet nebulizer with a facemask in critical patients and lifting the nasal prongs out of the nares, running the treatment for five minutes, replacing the prongs in the nares, and then repeating every 15-20 minutes. In that fashion, they minimized the issue with rainout while providing the benefits of continuous nebulization. Some facilities reported they never used continuous aerosol with HVNI, but, if required, may provide a number of back-to-back intermittent treatments. If the patient requires continuous aerosol they are placed on another HFNC method or NIV which facilitates continuous aerosol.

Continuous aerosol therapy is used less often than single-dose aerosol therapy, with the median for overall usage about 15%. However, the participants in the phone interviews who worked in pediatric settings indicated continuous aerosol therapy during HVNI was closer to 50% because children are more likely to require continuous therapy initially and then are changed to intermittent aerosol therapy as they improve. Most internet survey respondents 83% (50 of 60) do not stop HVNI to administer continuous aerosol therapy, while 17% (10 of 60) do stop.

Table 5. Pros and Cons of Patient Interfaces in Children from the Internet Survey

Pros	n	Cons	n
Nasal cannula with AAA-1 adapter			
Good medication delivery	6	Rainout	11
Maintains HVNI	6	Inconvenient	4
Ease of use/convenience	6	Poor medication delivery	3
Well tolerated/patient not disturbed	4	Hard to tolerate	1
Acceptable for short term	1	None	1
Mouthpiece			
Effective medication delivery	15	Poor cooperation/age	19
Easy to use	3	Poor medication delivery	2
HVNI not interrupted	1	Inconvenient	2
None	1	Must pause HVNI	1
		Rainout	1
		None	1
Facemask			
Cooperation unnecessary	7	Cannot tolerate	12
Easy to use	6	Poor medication delivery	11
Good medication delivery	3	Cannot use in very small children	1
Good for younger patients	2	Rainout	1
Good for long term	1	Discomfort	1

Frequency of responses to listing of Pros and Cons of using various patient interfaces. n = number of responses.

Of those internet survey respondents that do not stop HVNI, 51% (33 of 65) used VMN for continuous aerosol therapy, 43% (28 of 65) used jet nebulizers, 3% (2 of 65) ultrasonic nebulizers and 3% (2 of 65) use MDI for continuous aerosol delivery.

When delivering continuous dose aerosol therapy in adults, the facemask is used most commonly 63% (33 of 52), then mouthpiece 21% (11 of 52), and cannula 15% (8 of 52). In children receiving continuous dose aerosol therapy the most used patient interface is the facemask 59% (35 of 59), followed by cannula 15% (9 of 59), and mouthpiece 14% (8 of 59). Some connect in-line with vent 3% (2 of 59) while one mentioned using an “aerosol tent at times” 2% (1 of 59). Four, 7% (4 of 59) used blow-by. The responses from the telephone interviews followed the above with the use of AAA-1 with a syringe pump or use of a facemask over the HVNI cannula with the facemask connected to a VMN or Large Volume Nebulizer (LVN).

The main reason HVNI therapy was paused or stopped during continuous aerosol therapy per the internet survey was due to rain out (condensation) with AAA-1 use 36% (4 of 11). 27% (3 of 11) believed HVNI did not support continuous aerosol, and 36% (4 of 11) switched to a HFNC system when performing continuous aerosol. Likewise, telephone interview responses stated rainout management was the reason the AAA-1 was not used for continuous aerosol delivery, switched to NIV, for example or another high flow system.

When asked how oxygenation was maintained during continuous aerosol therapy when HVNI was stopped or paused, almost all 89% (8 of 9) of the internet survey participants replied they switched to another modality. Only one stated they used O₂ flow through the SVN. When pausing Vapotherm during continuous aerosol therapy, 64% (7 of 11) use VMN while 27% (3 of 11) use a SVN. One 9% (1 of 11) stated MDI was used. When stopping/pausing Vapotherm during continuous aerosol therapy in adults: 43% (3 of 7) used a facemask, 14% (1 of 7) used mouthpiece, and

Table 6. Challenges associated with Patient Interfaces in Adults from the Internet Survey

Interface	Challenge	n
Nasal cannula with AAA-1 adapter	Rain out	6
	No challenges	5
	Equipment issues (adjust flow, position nebulizer, inconsistent performance)	4
	Flow limits medication delivery	1
	Cost	1
	Patient tolerance	1
Mouthpiece	Poor cooperation/technique/ requires coaching	11
	None	1
Facemask	Mask issues (claustrophobia, keeping in place, remember to remove mask, comfort)	7
	Medication issues (poor delivery, eye exposure)	6
	Sometimes only option	1

Table 7. Challenges associated with Patient Interfaces in Children from the Internet Survey

Interface	Challenge	n
Nasal cannula with AAA-1 adapter	Rain out (in adapter and on face)	8
	Inconvenient to remove adapter between treatments	6
	None	3
	Adequate medication delivery	1
Mouthpiece	Poor cooperation/technique	10
	Age dependent	2
	None	2
Facemask	Mask issues (keep in place, claustrophobia, effectiveness, eye irritation)	8
	Adequate medication delivery	2

43% (3 of 7) said they used cannula (likely related to switching to another system). When pausing/stopping Vapotherm during continuous aerosol therapy in children: 31% (4 of 13) used a facemask, 8% (1 of 13) used mouthpiece, 46% (6 of 13) said they used cannula (likely related to switching to a HFNC system), and 15% (2 of 13) stating they switched to another HFNC system. If HVNI is stopped or paused during continuous aerosol therapy, once aerosol therapy is completed either HVNI is reapplied (46%, 6 of 13) or patient is switched to HFNC (54%, 7 of 13). The telephone participants were not asked this question.

Adjusting HVNI flow and temperature settings during aerosol therapy

Most of the internet survey users do not adjust HVNI flow during aerosol therapy in either adults 91% (10 of 11) or children 92% (12 of 13). Those that do adjust flow do so to maintain oxygenation. One phone interviewee stated “When using the Aerogen adapter we decrease the flow to insert the adapter and increase the flow after inserting the adapter. That way the patient doesn’t notice the disruption of therapy or get “blasted” with flow after reconnecting.” Similarly, most 91% (10 of 11) do not adjust HVNI temperature settings during aerosol therapy with adults. If temperature setting was changed for adults, it was decreased somewhat, with one respondent stating drop to 34°C. No respondent adjusted the temperature setting on HVNI when delivering aerosol to pediatric patients.

Pros and Cons of Patient Interfaces

Internet survey respondents listed pros and cons of using the various interfaces for both adults (Table 4) and children (Table 5). Paradoxically, medication delivery is both a pro and a con for both adult and children irrespective of interface. Telephone interview results were similar to those of the internet survey.

Challenges associated with using the various interfaces are shown for adults (Table 6) and children (Table 7). In both adults and children rain out was the greatest challenge when using the nasal cannula interface followed by equipment issues in adults and inconvenience in children, which were mentioned as indicators of increased staff work load. For the mouthpiece, patient cooperation was the main challenge in both adult and children. Likewise, facemasks presented similar challenges in both adults and children, which were mask and medication issues.

Discussion

This study found that there is no consensus on how to deliver aerosol therapy with HVNI and a dearth of literature on the subject. Currently there are a variety of methods currently being utilized to perform clinically effective intermittent and continuous aerosol therapy during HVNI. Because there is little published evidence regarding best practices for delivering aerosol during HVNI, most respiratory therapists use current best practices for providing aerosol therapy in general.⁸ Many institutions deliver aerosol directly through the HVNI nasal interface using the AAA-1 Adapter, which is least intrusive for the patient, although efficiency of drug delivery decreases. To improve medication delivery, some utilize nebulized drug delivery through a mouthpiece if the patient is willing and able to cooperate with the therapy, or via a face mask when they cannot. The interface of choice for continuous therapy in both adults and pediatrics is the face mask, with over 50% using it. Some would lift the HVNI nasal prongs out of the nose while placing the mask over the face, others left the nasal prongs in place, putting the mask on the face while continuing HVNI. Interestingly, a mouthpiece was used as the patient interface in 16% of pediatric and 19% of adult patients while receiving continuous therapy. It is difficult to see how a continuous aerosol treatment could be performed through a mouthpiece while receiving HVNI. This is likely related to the confusion around defining continuous aerosol therapy. Some individuals indicated they considered performing treatments repeatedly in a close temporal relationship as continuous therapy. This would include using pMDI, DPI, BAN, or even jet nebulizer to deliver one or several actuations in a row, with a pause between while receiving HVNI.

The study results indicate that most aerosol therapy associated with HVNI for adults is intermittent, and for pediatric and neonatal areas it is evenly split between intermittent and continuous. The results also indicate that intermittent or single dose therapy is administered anywhere HVNI is used while continuous aerosol therapy is mostly given in the ED or critical care units and used primarily for bronchodilation. One of the phone survey participants, a pediatric intensivist, stated that children admitted to the ICU with asthma, most likely receive continuous aerosol therapy initially and then progress to intermittent therapy, while other patients may not require continuous therapy at all. Adult patients are more likely to receive intermittent therapy initially and never require continuous therapy. This dichotomy may be explained because

children have smaller airways and bronchospasm may cause more severe effects than in adults.

While there is controversy about methods of delivering aerosol during HVNI, four physicians (2 emergency department MDs, 1 neonatologist, 1 pediatric intensivist) interviewed via telephone all stated they obtained expected clinical responses when their RT staff provided aerosol therapy to their patients receiving HVNI. Subjective clinical improvement included decreased WOB, decreased wheezing, and improved airflow. All respiratory therapists interviewed likewise stated they saw appropriate clinical responses irrespective of the methods used to deliver aerosol during HVNI. This is likely because RTs would tend to not continue using methods that do not provide acceptable clinical responses. So, while efficiency of drug delivery may be diminished when delivered concurrently with HVNI, if drug delivery results in improvement in subjective clinical assessment, according to AARC Clinical Practice Guide (CPG) the appropriate aerosol generator has been chosen.⁸ Using radiolabeled isotopes and scintigraphy, Reminiac et al, showed negligible drug delivery when a facemask aerosol treatment was placed over HFNC therapy in a primate model.⁹

Additional research is needed to determine whether drug delivery can be accomplished using mask or mouthpiece nebulizer treatments.

Several challenges were identified with performing nasal delivery of aerosol therapy during HVNI therapy when using the (AAA-1) Adapter. The AAA-1 provides for an inlet from the heated high flow HVNI delivery tubing, a mixing chamber allowing an orthogonal introduction of aerosolized medication, a rainout management plate, and a connection for the nasal cannula. The capture and management of condensed medication and any rainout permits the passage of properly aerosolized medication, now incorporated into the heated humidified high flow medical gas stream, into the nasal cannula attached to the adaptor. For single dose administration, this bulk liquid accumulation provides minimal volumes for management. For continuous nebulization (long duration high volume dosages) the accumulation of bulk liquid can be more challenging, as the liquid accumulates in the holding chamber and must be periodically emptied at 30 to 60-minute intervals. After delivery of the intermittent aerosol treatment, the AAA-1 must be removed from the airway gas circuit. Failure to do so could result in an accidental lavage of the patient's airway. While rainout is a minor issue with intermittent therapy, it is more prevalent and concerning with continuous therapy and especially with in-line therapy using the cannula interface where failure to drain condensate from the AAA-1 could result in a fluid bolus being delivered to the airway resulting in significant airway obstruction, especially in small airways of neonates and infants. For this reason, some institutions switch to a different system that allows placement of the nebulizer before the humidifier to diminish the problem of patient lavage, however, rainout still occurs even in the heated wire circuits and must be managed, making inadvertent lavage possible. Others will drain the AAA-1 adaptor frequently which results in frequent breaking into the circuit. According to AARC CPG on Care of the Ventilator Circuit breaking into the circuit increases risks of VAP and should occur infrequently.¹⁰ However, it is unknown if frequent breaking of the circuit increases infection risk with HVNI because patients are not intubated and upper airway defenses remain intact. If the AAA-1 is used for continuous aerosol delivery, staff workload

increases as the need to frequently drain the adaptor occurs. Respiratory therapy departments are frequently overwhelmed by the volume of work assigned, so any increase in workload may interfere with care for other patients and should be minimized wherever possible.

“While there is controversy about methods of delivering aerosol during HVNI, ... physicians interviewed via telephone all stated they obtained expected clinical responses when their RT staff provided aerosol therapy to their patients receiving HVNI.”

Specific to HVNI, only two citable sources, one published¹¹ and one abstract¹² were identified. Perry et al demonstrated that using HVNI with high flow rates reduced deposition, and concluded that HVNI may not deliver a sufficient dose for clinical relevance.¹¹ However, they also stated that it is possible that a clinical response may be seen since albuterol has been demonstrated to have clinical benefit in low doses. The combination of small-bore cannula, high humidity, non-occlusive interface and high resistive forces in nasopharynx from high velocity flow are all factors that could help explain why aerosol delivery has been low when compared to other delivery options.¹³ Based on findings from Perry et al, the inspired dose (percent of nominal dose) for each cannula size and flow rate was 2.5%, 0.8%, 0.4%, and 0.2% for the adult cannula at 5, 10, 20, and 40 L/min, respectively; 1.2%, 0.6%, 0.1%, and 0.0% for the pediatric cannula at 3, 5, 10, and 20 L/min, respectively; and 0.6%, 0.6%, and 0.5% for the infant cannula at 3, 5, and 8 L/min, respectively.¹¹ They found that most (62-80%) of the loaded albuterol dose accumulated within the adaptor. For each cannula size, there was a significant decrease in the inspired dose with increasing flow rates, $p=0.026$ (infant), $p=0.001$ (pediatric), and $p<0.001$ (adult). The inspired dose increased with increasing cannula size for 5, 10, and 20 L/min ($p=0.007$, $p<0.001$, and $p=0.005$, respectively).

Conversely, Rojas et al, delivered HVNI with a nasal cannula interface in eight preterm infants. They showed that patients had similar clinical responses (increased heart rate, decreased respiratory rate and FiO₂) to levalbuterol delivered through an ultrasonic neb (Aerogen) and an in-line aerosol adaptor during HVNI when compared to aerosol delivered through the mechanical ventilator circuit prior to extubation.¹² In addition to Rojas, internal studies performed between VapoTherm & Aerogen have demonstrated in both infant and adult models using the AAA-1 with HVNI that drug delivery is within upper limits reported with other aerosol devices used in critical care. In vitro testing of the AAA-1 has demonstrated dose efficiency during HVNI of 4.5-9.1% with simulated infant vent parameters at flows ranging from 1-8 L/min. Using adult breathing parameters, inhaled dose was 4.5% at a median flow of 30 L/min, and 3.1% at 40 L/min. Operated between 1 and 40 L/min, this delivered drug efficiency is well within the thresholds of efficiency reported with other aerosol devices (Unpublished Data; on file and available upon request from VapoTherm). This level of drug delivery is consistent with adequate clinical delivery by other means. Likewise, our results indicate that clinicians reported obtaining desired clinical effects during HVNI irrespective of the patient interface and delivery method used.

HFNC, as well as HVNI aerosol drug delivery is influenced by four key factors: age-appropriate administration & practice, breathing patterns and inspiratory flow, aerosol device selection (SVN, pMDI, DPI), and device interface/integration within gas stream (BAN, holding chambers, AAA-1, masks).^{9,14-19} With a large focus on SVNs, various interfaces and adaptors for aerosol delivery have been evaluated & assessed.^{9,12,17,20-22} Most studies have focused on HFNC, with aerosol bench studies demonstrating that delivered dose is increased at lower flows.^{9,11,15,18,21,23,24} Ari et al²⁵ further demonstrated that the presence of heliox, instead of oxygen, improves dose delivery 2-fold or greater as flows increased 3LPM to 6LPM, and that while reducing flow rate increased drug delivery it also decreased the impact of heliox on drug delivery. In DPIs, Okuda et al demonstrated that medication delivery is influenced by flow, dose concentration, and device placement in the circuit.²⁴ Bhashyam et al also demonstrated that cannula type & simulator effected dose delivery, with substantial loss in the heated circuit – giving rise to placement concerns.²³ Following this work, studies have demonstrated that aerosol device placement prior to the heated and humidified circuit may also increase dose delivery.^{9,18,22,26} Further, Sunbul et al, studied the effect of device position on dose delivery – concluding that siPAP dosing was lower than HFNC & bubble CPAP, and that aerosol deposition with HFNC was <2%, but higher than measured in bubble CPAP.²⁶ Due to the unique design of the VapoTherm vapor-transfer cartridge, positioning the nebulizer before the humidifier is not currently an option when delivering aerosol during HVNI. Our results indicate that many institutions overcome this challenge by delivering aerosol through the mouth using a jet nebulizer, BAN, or MDI. Morgan et al, further demonstrated no change in dose delivery with HFNC when comparing HFNC and VMN versus facemask & jet neb, although using HFNC and VMN with a nasal cannula reduced patient agitation.²² It can be inferred from publications that use of nasal cannula to deliver aerosol during HFNC can reduce likelihood of patient agitation when compared to a mask, and nasal cannulae are not subject to limited age-appropriate administration and practice.^{20,27,28} Our results concur with these observations. However, anecdotal references have noted skin irritation during combined HFNC & aerosol therapy using albuterol.²⁹ In referencing current practices, publications have not demonstrated any difference in effectiveness of concurrent delivery of aerosol with HFNC via mouthpiece or mask.

The ability to deliver aerosol medication to patients requiring respiratory support has improved significantly in the last decade.^{8,20,27,28,30,31} Use of a nasal interface with in-line aerosol delivery has been successfully demonstrated, including evaluation of the factors affecting aerosol delivery, thereby highlighting the most effective methods to maximize nominal dose delivery.^{14,15,18,28,30,32} Common practice may arise from clinician-noted effectiveness. Delivery by nasal interface has also caused a controversy over effectiveness, delivery methods, and subsequent clinical utility.^{15,27,28,30}

One clear point that studies have stated remains the need for more robust and objectively quantifiable evidence and clinical work on these technologies.^{14,19,20,27,28}

Limitations

This study utilized telephone interviews of experienced respiratory therapists and physicians selected by Clinical Managers at VapoTherm based on their knowledge and

interactions. It is possible that a biased sample was obtained that did not truly reflect practice throughout the universe of HVNI users. Although our sample came from institutions across all regions of the US, more southern states had representation than other regions and our results may over represent practice in the southern US. Another limitation is that only 70 individuals responded to our internet survey for a 2.8% response rate, which is a small number of responses which might be the result of not providing monetary compensation to respond. It is possible that leaving the survey active for only two weeks may have limited participation. However, evidence exists that 80% of responders to an internet based survey respond within 7 days and 91% within two weeks, indicating that two weeks was a reasonable time period to allow responses.³³

In addition, the results from our internet survey were very similar to those from our phone survey suggesting that opinions of those 70 respondents reflected actual practice. It is also possible that some individuals that participated in the phone survey also participated in the internet survey since we did not screen for previous participation and it is highly likely that phone survey participants were included in the salesforce.com database used to identify participants for the internet survey. If so, this would tend to increase similarity in results between the two techniques. Since our results closely mirror practices recommended by AARC CPG, we do not believe that resulted in additional bias in the results. Finally, this study dealt with the clinical behavior of clinicians delivering aerosolized medication using VapoTherm HVNI Therapy, therefore these findings are particular to only that technology, and extension of these findings to other delivery devices may not be appropriate.

Clinical Implications/Conclusion

Clinical ‘best practice’ evolves with time, after introduction of new therapies, and as evidence is developed. The AARC CPG on aerosol delivery device selection for spontaneously breathing patients⁸ fails to take aerosol medication delivery with HFNC/HVNI into consideration. Our results reveal that respiratory therapists use a variety of methods to effectively deliver aerosol therapy during HVNI, such as vibrating mesh nebulizer through the nasal cannula interface or any type nebulizer through a mouthpiece or mask, which are in general compliance with those AARC guidelines even though they do not include mention of aerosol delivery with HVNI. Choice of aerosol generator and patient interface is determined by the patient’s age, physical and cognitive ability, among other issues. One option the CPG did not consider is using a nebulizer and delivering aerosol through a nasal cannula. With the advent of HFNC/HVNI this option became available. In our study, this was a popular option.

Summary of Reported Practice

Based upon the results of our surveys and literature search, the following practices for aerosol delivery for an intermittent or closely-timed intermittent dose in patients receiving HVNI may include:

1. Aerosol delivered through a mouthpiece whenever possible, or a mask or the nasal cannula if the patient is unable to use a mouthpiece.
2. If clinically tolerated, HVNI therapy may be paused for aerosol therapy, again with preference for a mouthpiece used with a pMDI or BAN. Duration of the pause should be kept to a minimum.
3. When HVNI therapy cannot be paused, the flow on HFNC may be weaned as low as tolerated to reduce impactive drug

losses so that aerosol deposition and delivered lung dose of medication can be optimized.

4. When HVNI therapy cannot be paused for patients, using a vibrating mesh nebulizer to deliver aerosol through a nasal cannula may be considered, although the oral route is still preferred. Care must be exercised when using a jet nebulizer to deliver aerosol medication concurrently with HVNI because of the added gas flow driving the nebulizer.
5. When HVNI therapy cannot be paused because patients cannot clinically tolerate interrupting HVNI, higher target doses may be required to accomplish the therapeutic goal. Individualized goals with appropriate monitoring should be considered for each patient.

Based upon the results of our surveys and literature search, the following practices for aerosol delivery for continuous-dose delivery in patients receiving HVNI may include:

1. Aerosol may be delivered through the nasal cannula using a vibrating mesh nebulizer. Condensate must be managed when delivering via a nasal cannula with a vibrating mesh nebulizer or consider placing the patient on a different respiratory support device.
2. Care must be exercised when using a jet nebulizer in line with HVNI in that it adds flow delivered to the patient. Decreasing HVNI flow should be considered to prevent excessive total flow to the patient.
3. Delivering aerosol medication with a mask over the HVNI nasal cannula is also an option, as it will reduce issues with condensation.
4. In order to optimize aerosol deposition and delivered lung dose of medication and reduce impactive drug losses the HVNI flow setting may be weaned as low as reasonably tolerated.
5. Higher target medication doses, if clinically appropriate, may be required to accomplish the therapeutic goal, so individualized goals with appropriate monitoring should be considered for each patient.
6. Consider switching to an alternative mode of ventilatory support (eg, NIPPV or HFNC).

Further research

This study has revealed a lack of evidence exists to guide decisions about performing aerosol therapy during HVNI clearly further research is needed. There is a need for additional bench studies as well as clinical trials to better describe how aerosol therapy should be performed during HVNI. We recommend further study on the effect of the various patient interfaces and nebulizers on efficiency of drug delivery and particle size, as well as comparing clinical effects in appropriate patient populations, and looking at outcomes such as costs, length of stay, long term morbidity, and mortality. Novel methods of drug delivery that decrease staff work load and address challenges of drug delivery should be explored further, such as adding drug to the water reservoir before it is injected into the vapor transfer cartridge or methods using enhanced particle growth techniques. Additional study of methods to limit rainout and accidental lavage of patients is also warranted to diminish complications associated with in-line aerosol treatments.

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Algorithms for Interpreting Capnography Waveforms

Gina Farquharson, MS, MBA, RRT-NPS, CPPS; Gregory K Spratt, BS, RRT, CPFT

Capnography was first proposed for use in the operating room in 1978 and has since become the standard of care for monitoring ventilation.¹ Capnography is rapidly growing in use for intubated and non-intubated applications across hospital environments including the ICU, resuscitation, procedural sedation, and postoperative monitoring of patients receiving opioid analgesia.^{1,2}

When used appropriately, capnography has been cited as meaningful in providing key, often life-sustaining, information in dozens of different clinical applications. These range from common indications such as monitoring for apneas, hypoventilation, hyperventilation, and airway integrity during procedural sedation or in postoperative patients; to monitoring ETT placement, quality of chest compression, and return of spontaneous circulation during resuscitation efforts; to screening for diabetic ketoacidosis, pulmonary embolism, bronchospasm, and even sepsis in the emergency setting.¹⁻⁴ This value has led to capnography being recommended or required for various applications by over 80 clinical societies in over 100 guidelines, standards, and statements in just the past 8 years.

Despite the vast number of societal guidelines and clinical articles touting its value, I have met clinicians who state they do not see much value in capnography. What's the difference between these two groups? Does it work for some and not for others? Of course not. The difference is in their knowledge and ability to correctly apply and interpret the results in a meaningful manner. With any monitoring parameter, effective application is dependent upon interpreting the parameter values (eg, etCO₂, RR, waveforms, and trends) within the broader context of the patient's signs, symptoms, and other clinical data available, and then using their expertise to assimilate this information to inform best interventions. Capnography waveforms can be insightful for clinical intervention and require a similar systematic approach, much like ECG interpretation.

Systematic approaches to waveform interpretation for other parameters have been documented and published. The development of clinical decision tools can be used for waveform interpretation and a systematic approach could possibly reduce

errors of interpretation or clinical intervention. Such a tool can serve as a bridge to fill gaps in knowledge while the clinician develops a better understanding of the basic principles of interpretation. Like all physiologic monitors, each has limitations and requires a standardized method for interpretation and translating this information into clinical practice.⁵

A systematic approach for capnography waveform analysis is presented here in Table 1 (intubated patients) and Table 2 (non-intubated patients) below. Changes in the waveform provide the earliest indication of problems when ventilation becomes abnormal. For example, a patient experiencing an apnea will have a flatline capnography waveform immediately after the apnea begins, and yet oximetry may not indicate a desaturation for several minutes.

Begin by looking at the shape of the waveform following the algorithms in the tables. Many clinicians will only look at the etCO₂ value itself. In doing so, a clinician would be missing some key information for making clinical interventions. The trend, shape, height, and width of the waveform all provide useful clues as to the quality of ventilation and appropriate interventions. For example, does it plateau, indicating that you're getting a true alveolar sample?

When looking at the end-tidal carbon dioxide (etCO₂) reading, start by noting the patient's baseline value, does it fall in the 35-45 mmHg normal range? Changes in this reading, with a clear alveolar plateau, can indicate changes in ventilation, perfusion, or metabolic status as indicated in the examples seen in the flow chart. Also consider the respiratory rate derived from the etCO₂ readings, and changes caused by tachypnea or bradypnea to the end-tidal reading.

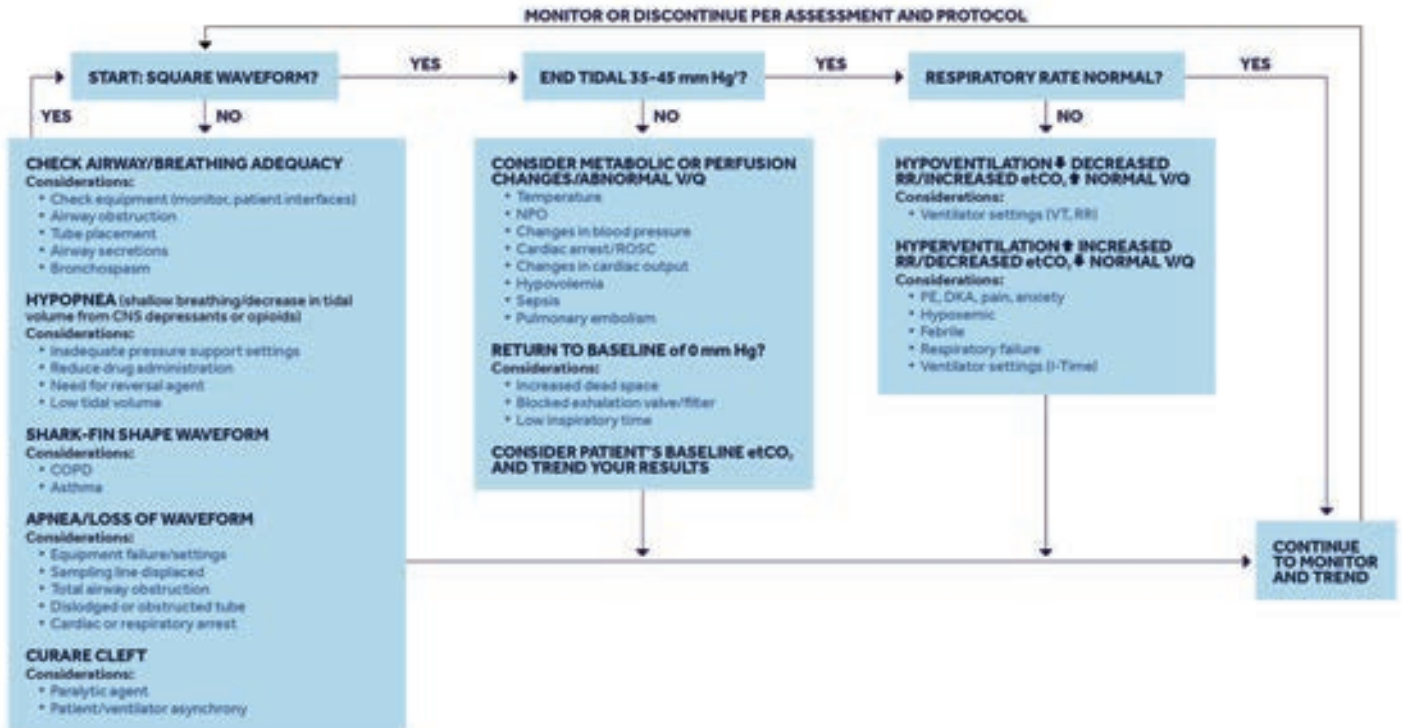
Finally, trend graphs can be helpful for looking at changes over time. A good example is a patient with obstructive sleep apnea, where etCO₂ values will show repetitive drops and increases subsequent to apneic/hypopneic events.

In the example, Figure 1, you will notice the capnograph reading and the etCO₂ of five. First, look at the shape of the waveform. It is not square in shape, so the clinician should evaluate equipment and proper placement of the sampling line (eg, cannula), check the airway for integrity (eg, reposition and jaw thrust), considering possible airway obstruction or hypopneic breathing (suspect shallow breathing when waveforms are non-plateauing). This patient had received a benzodiazepine and opioid narcotic

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Table 1. Capnography waveforms for intubated patients⁶⁻¹⁵

A SYSTEMATIC APPROACH FOR INTUBATED PATIENTS



(Patient baseline may be higher or lower than normal 35–45 mm Hg)

for procedural sedation and as the patient did not exhibit symptoms of airway obstruction, the patient was encouraged to take deep breaths and sedation medication was reduced which brought the waveform back to a normal appearance and the etCO_2 reading back to a normal range. Note that the SpO_2 reading is normal (97%) as oxygen desaturations generally lag minutes after the onset of changes to ventilation, especially when supplemental oxygen is in use. Although the alarm is alerting the clinician to the low etCO_2 , the first intervention is to assess airway and breathing adequacy and intervene appropriately. A number of additional example waveforms can be viewed by downloading this interactive tool at <http://www.medtronic.com/covidien/en-us/clinical-education/catalog/interactive-pdf-capnography-waveforms.html>.



Figure 1. Capnograph waveform and etCO_2 reading.

Summary

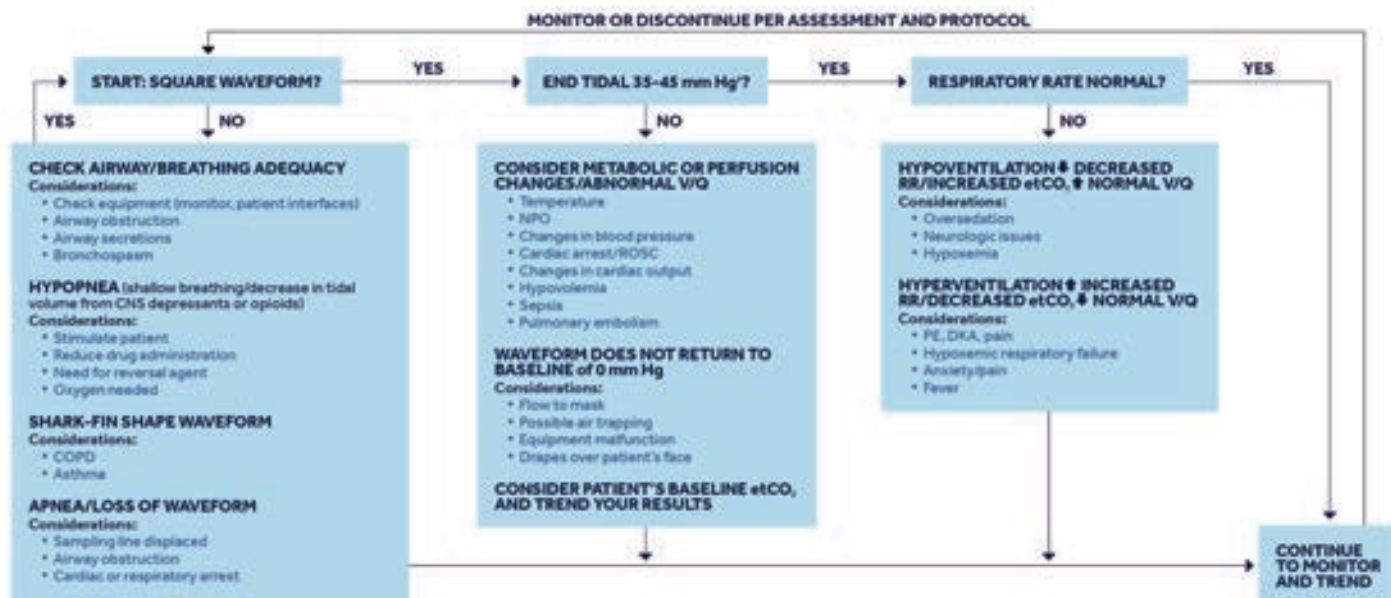
Capnography and the associated waveforms can provide the clinician with useful information to inform intervention for a variety of clinical scenarios for both intubated and non-intubated patients. Data from the capnograph should always be assessed within the context of the patient's overall condition including signs, symptoms, vital signs, and other monitoring parameters. A systematic approach to the interpretation of the waveform could lead to earlier intervention with appropriate clinical response and treatment.

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Table 2. Capnography waveforms for non-intubated patients⁶⁻¹⁵

A SYSTEMATIC APPROACH FOR NONINTUBATED PATIENTS



This resource is intended for educational purposes only. It is not intended to provide comprehensive or patient-specific clinical practice recommendations for capnography monitoring. The clinical choices outlined in this text may or may not be consistent with your own patient requirements, your clinical practice approaches, or guidelines for practice that are endorsed by your institution or practice group. It is the responsibility of each clinician to make his/her own determination regarding clinical practice decisions that are in the best interest of patients. Readers are advised to review the current product information, including the Indications for Use currently provided by the manufacturer. Neither the publisher, authors, nor Covidien LP, a Medtronic company, assumes any responsibility for any injury and/or damage to persons or property resulting from information provided in this text.

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Four Ways Continuous Surveillance Transforms Respiratory Therapy

Sarah Williams, MBA, RRT

Among the most patient-facing of all clinical professionals, respiratory therapists (RT) are presented with a unique opportunity to assume a position of leadership in the development and implementation of comprehensive, reliable and scalable patient safety initiatives.

Health systems are under significant pressure from regulatory bodies, such as The Joint Commission and the Centers for Medicare & Medicaid Services (CMS), to enhance overall patient safety and mitigate adverse events in both acute care and intensive care units. For example, CMS' Hospital-Acquired Conditions Reduction Program (HACRP) penalizes health systems for high rates of ventilator-associated injuries and other hospital-acquired illnesses.¹

In addition to regulatory factors, patient safety is a multi-faceted challenge that counts clinical communication, technology, insufficient monitoring practices, workflow and even facility design among its primary pain points. General health trends within the patient population add yet another dimension to a complex problem. According to the National Center for Health Statistics, 157 million Americans will be managing a chronic condition—with more than half that number dealing with co-morbidities—by 2020.² In other words, patients are being admitted into the hospital much sicker than they used to be, which complicates the health system's ability to keep them safe or prevent escalation to higher acuity (and more expensive) beds.

Addressing these challenges requires the ability to capture a holistic, real-time picture of the patient's condition and where it is trending over time, and route actionable information to the respiratory therapists and other members of the clinical team. Fortunately, continuous surveillance checks all of these boxes for the respiratory therapist—and more.

Continuous surveillance is capable of safely managing patient populations across the enterprise, reducing the cost of care, aligning with reimbursement and regulatory incentives, enhancing clinical workflow and decision making and closing many of the workflow inefficiencies and patient observation gaps inherent in traditional monitoring protocols.

A growing body of peer-reviewed literature, use cases and market analyses has positioned continuous clinical surveillance as an auspicious opportunity to drive comprehensive patient safety initiatives. To cite just one example, a recent health IT market report by KLAS Research, notes that “clinical surveillance tools hold the promise of giving caregivers clinically actionable insights that decrease mortality, reduce readmissions, and improve overall patient outcomes, and clinicians expect these alerts to be embedded directly within their workflow.”³

Pitfalls of Patient Monitoring

For respiratory therapists, current monitoring practices are susceptible to inefficiencies that can build over time, then cascade to failure.

To begin with, RTs are not bedside sentinels. Like other direct-patient caregivers, they care for multiple patients in different locations in the course of a shift. Patients that require the attention of an RT may actually be located in separate units or floors of the health system.

Even at bedside, the duration of an RT visit can be limited depending on workload, and the window for successfully spotting adverse changes in a patient's condition is quite narrow. According to Jungquist, et al, in 42 percent of confirmed cases of opioid-induced respiratory depression (OIRD), “the interval between the last nursing assessment and the detection of respiratory depression was less than two hours, and in 16 [percent] of the cases, it was within 15 minutes.”⁴

Traditional patient monitoring, including vital-sign spot checks and single-parameter device monitoring, is insufficient to support the typical RT's workflow. Even if additional devices, processes or redundancies were leveraged as a kind of stop-gap measure, the essential problem of patient monitoring is actionable data.

Additionally, the devices tethered to patients ostensibly meant to alert RTs that an intervention is required are rarely actionable. For example, many long-term care and rehabilitation facilities encourage patient mobility as part of the recovery process. However, moving around or talking or coughing can easily set off device alarms.

The problems associated with alarm proliferation are so severe that it regularly makes the ECRI Institute's annual list of the nation's most significant patient safety threats,⁵ and in 2016,

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the Joint Commission mandated comprehensive clinical alarm management as a National Patient Safety Goal.⁶

4 Ways Continuous Surveillance Transforms Patient Safety

Unlike patient monitoring, continuous surveillance allows RTs to discern the signal from the noise through real-time, continuous data flow from multiple sources that can be filtered and intelligently analyzed for significant trends and prospective intervention. There also is growing evidence that continuous clinical surveillance facilitates actionable interventions in advance of life-threatening events.⁷

Here are four of the most significant ways continuous surveillance can benefit respiratory therapists:

1. Data is actionable, comprehensive and real-time. Patient monitoring is episodic, and depending on the number of devices tethered to the patient, narrow in scope. In addition, a shortcoming of many clinical alarm management efforts is the exclusive focus on alarm reduction, rather than the enhancement of actionable and prospective notifications. By contrast, continuous surveillance is designed for ongoing, comprehensive and prospective clinical decision-making, because it relies on real-time multivariate trends, rather than individual alarms, to intelligently capture and interpret significant trends in the patient's condition over time.

2. Improved patient care. Until recently, patient safety has been largely a reactive process. With real-time access to patient data and alarms, health systems can begin to anticipate patients trending toward distress, and intervene before costly rescues and escalations are required. Two recent studies point to clinical surveillance's efficacy in reducing the need for emergency rescues.

In a study of patients at risk for OIRD, Supe et al, passed multiple data time series through a multi-variate rules engine that monitored the values of HR, RR, SPO₂ and ETCO₂ and reduced the number alerts sent to clinicians phones by 99 percent. In addition, no clinical events were missed and while several patients did receive Naloxone to counteract OIRD, none required a Rapid Response Team call, intubation or transfer to the ICU.⁸ In a 21-month study on the impact of pulse oximetry surveillance on rescue events and ICU transfers, Taenzer et al, observed that continuous surveillance techniques decreased rescue events from 3.4 to 1.2 per 1,000 patient discharges and ICU transfers from 5.6 to 2.9 per 1,000 patient days.⁹

3. Improved quality and reporting. Continuous surveillance eliminates the need for individual recollections and faulty memories for the completion of management and audit committee reports. Clinical surveillance capabilities gives empowers every RT with a clear, evidence-based picture of every event. The data aggregated from ventilator devices can be used to assess performance and identify potential areas of need. Additionally, because clinical surveillance automates processes that were previously done manually, such as manual ventilator checks, RTs can focus more on the patient rather than the ventilator.

4. Improved clinical workflow. Clinical surveillance also can be adapted to fit seamlessly with an institution's clinical workflow. This is especially important outside the ICU, where the staff-

to-patient ratio is lower than in critical care. In these care settings, a solution that can be integrated with their mobile communication platform ensures that alerts will be received on a timely basis.

However, workflow is ultimately improved because RTs are no longer responding to individual ventilator devices, but to relevant changes in the patient's condition that have been intelligently captured and interpreted by a clinical surveillance platform.

The Future is Now

Clinical surveillance is no longer in the realm of the possible. It's a reality that more health systems are actively exploring. RTs are beginning to recognize that continuous surveillance can deliver better, more consistent, more efficient and safer patient care.

Patient safety in the modern hospital system is complex and fraught with known and unknown risks. Clinical surveillance presents a game-changing opportunity to help RTs practice clinical excellence at the top of their license, and help hospitals align with the standards, regulations and expectations of modern patient safety initiatives.

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HFCWO Therapy: Weighing the Evidence

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High frequency chest wall oscillation (HFCWO), also known as vest therapy, is a form of chest physiotherapy used for airway clearance therapy (ACT). The most common design uses an inflatable vest attached to an air pulse generator that creates rapid compressions to the chest, helping to loosen, thin and mobilize mucus so it can be expelled through coughing or suctioning. This therapy is considered a medically appropriate intervention for a large number of disease states where the normal mechanisms for clearing mucus are impaired or lacking.

Originally conceived to treat cystic fibrosis (CF) in the early 1990's, much of the supporting evidence for the therapy dates from that time, often in the form of small, uncontrolled studies. Since its introduction, the use of HFCWO therapy has expanded well beyond CF to include a long list of hereditary and acquired conditions, including non-cystic fibrosis bronchiectasis (referred to as NCFB or "bronchiectasis" in this paper). Airway clearance plays an important role in treating symptoms and reducing health care utilization for bronchiectasis and other chronic respiratory conditions.¹ The clinical community has long sought a definitive study unequivocally demonstrating that HFCWO is shown to improve clinical outcomes.^{2,3} The existence of such evidence would further bolster what many clinicians have seen in everyday practice—the maintenance or improvement of lung health in individuals with chronic respiratory conditions.

Many studies do exist, however, demonstrating the value of HFCWO as part of an ACT treatment regimen. To better understand the current evidence landscape, it is useful to explore the challenges inherent in implementing a large-scale, long-term study in these patient populations. At the same time, this review of the currently available evidence addresses the popular misconception that few valuable ACT studies exist. There are in fact many studies from across the globe that examine the utility of various methods of ACT within respiratory conditions featuring chronic mucus hypersecretion. This article will review what is known about the evidence behind HFCWO and suggest a pathway for strengthening the research base for the future.

The Need for ACT

A healthy individual clears mucus from the respiratory system through ciliary action and coughing. Cystic fibrosis, non-cystic fibrosis bronchiectasis, some forms of chronic bronchitis,



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chronic obstructive pulmonary disease (COPD), and certain neurological disorders can exhibit the production of excess mucus and/or the inability to adequately clear secretions. Patients with these conditions often experience accumulation of secretions in bronchi, particularly in the small airways, limiting adequate gas exchange in the lungs. Inadequately cleared secretions can become a culture medium for pathogens, leading to serious complications including degradation of lung function⁴ and increased lung infections.^{4,5} In addition, mucus blockage may lead to further infections and inflammation resulting in bronchiectasis.⁶ Bronchiectasis can also be a co-morbidity of chronic bronchitis.⁷

Goblet cells in the respiratory tract secrete mucus to form a protective lining of the inner airways. Bacteria and other airborne particles trapped in this mucus are mobilized by cilia and eventually cleared by expectoration or swallowing. Excess mucus is further expelled from the airways through coughing or suctioning. Acute illness and a progressive decline in lung function can occur when this normal mucus-clearing function is impaired or disrupted on a chronic basis.⁸ Secretions that are not cleared can promote chronic inflammation, repeated infections, irreversible lung damage and impaired respiratory function.^{9,10} Other symptoms and signs of chronic respiratory diseases include dyspnea, cough, wheezing, hyperventilation and hemoptysis. Conditions that result in chronic mucus hypersecretion are considered candidates for ACT, including HFCWO. ACT is intended for patients who are unable to clear excess secretions without external manipulation or therapeutic intervention, and the range of such conditions is wide and often overlapping.

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HFCWO Therapy May Be Considered for ACT for Patients with the Following Conditions

- Cystic Fibrosis
- Bronchiectasis (NCFB)
- COPD
- Neuromuscular disorders associated with impaired airway clearance such as:
 - Acid maltase deficiency
 - Anterior horn cell diseases, including amyotrophic lateral sclerosis
 - Cerebral palsy
 - Familial dysautonomia
 - Hereditary muscular dystrophy
 - Multiple sclerosis
 - Myotonic disorders
 - Other myopathies
 - Paralysis of the diaphragm
 - Post-polio
 - Quadriplegia

The Challenges of ACT Research

Studies involving airway clearance therapy are intrinsically difficult to perform.¹¹ Many of the disease states have small populations making recruitment of adequate numbers of subjects challenging and expensive. This factor makes it problematical to define an appropriate control group as the disease itself may be heterogeneous, making it hard to understand and control for hidden confounding factors. Even if potential confounders are recognized, they may be numerous and it is often unclear which of them are independently associated with outcomes. Additionally, it is impossible to fully blind subjects to the use of airway clearance devices; therefore, studies of effectiveness will always blend the outcome with the patients' perceptions and responses to their own treatment. Some means of ACT require patient cooperation, and many require continuous, conscious effort to be effective. However, no therapy can be effective if it is unused, and studies that do not measure, let alone control for, adherence suffer from a serious deficiency.¹² Moreover, there has been no agreement about which outcomes are clinically relevant. Many early studies use sputum production as an outcome,¹³ which is a reasonable proxy for airway clearance effectiveness. However, sputum production relies on patient effort and the proportion of hydration of the sputum, both of which are highly variable. Many studies have simply relied on self-reported sputum volume, or self-reported success of airway clearance in general, with the unsolved issue of biased self-reporting. Lastly, studies have shown that the degree of education and support given to a chronically ill patient can have major effects on the success of any therapy, particularly one that requires extended voluntary effort.¹⁴ It is, perhaps, an academic concern whether success is due to the device itself or the support surrounding it; both are intertwined in actual clinical practice, and both are necessary for successful treatment.

Cystic Fibrosis and Origin of HFCWO Therapy

Various forms of percussion therapy have long been used for patients with CF. Conventional chest physical therapy (CPT) has been shown to improve respiratory function. Percussion may be combined with postural drainage (P&PD), which uses gravitational flow, diaphragmatic breathing and controlled coughing to mobilize secretions. These methods were among the first to help patients with cystic fibrosis manage their airway clearance; however, the need for trained caregiver

involvement on a daily basis with these methods often leads to poor adherence to the prescribed treatment plan.¹⁴ Hence, HFCWO was introduced as an alternative to these more manual approaches. In the U.S., HFCWO is often considered standard care in cystic fibrosis treatment.¹⁵ Multiple studies in cystic fibrosis patients found vest therapy equivalent¹⁶⁻²³ or superior^{13,24-27} to other airway clearance methods including positive expiratory pressure (PEP), postural drainage, CPT, and intrapulmonary percussive ventilation (IPV). A randomized comparison of PEP and HFCWO found no significant difference in pulmonary function tests, quality of life scores or patient satisfaction scores between the two ACT methods.²¹ In this study, average forced expiratory volume in one second (FEV₁) lung function improved in both the HFCWO and PEP groups, and there were statistically fewer exacerbations for all study participants, including the HFCWO patients, than in the general CF population.

Most adult patients can use vest therapy without the aid of caregivers.²⁴ Health care providers rely on the consistency of treatment that vest therapy offers. Vest therapy is technique-independent and simple to do correctly,²⁸ and effective treatment contributes to ongoing compliance.²⁵ For payers, successful ACT treatment with vest therapy may improve or maintain health status, reducing medical and ancillary care costs associated with refractory lung disease.²⁹

A Cochrane review of 15 studies³⁰ compared CPT to PEP, active cycle of breathing, autogenic drainage, and mechanical devices including airway oscillators, mechanical percussion devices, and HFCWO. No significant difference was shown between CPT and other airway clearance therapies in terms of lung function, and studies of acute lung infections showed improved lung function regardless of type of treatment. Ten of the 15 studies in the review showed patient preference for self-administered techniques such as HFCWO.

Several studies have compared chest physiotherapy to HFCWO alone. A retrospective chart review comparing prior CPT use to HFCWO showed that the introduction of HFCWO slowed or reversed degradation of FEV₁.³¹ These improvements were sustained over the four-year period included in the review. A different 30-month study compared HFCWO to no treatment: the HFCWO group had less pulmonary function decline than non-HFCWO group, and males showed FEV₁ improvement.²⁷ Two additional retrospective chart reviews showed that FEV₁ stabilized or improved after HFCWO was initiated.^{25,32}

HFCWO has been demonstrated to deliver superior secretion clearance²⁶ and superior sputum volume relative to CPT. A long-term crossover study further demonstrated that both superior sputum production and improved pulmonary function tests (PFTs) were maintained with the use of HFCWO over 1.5 years.¹³ Triangle waveform HFCWO specifically was found to produce more sputum than sine wave devices³³ or CPT delivered by certified respiratory therapists.²⁷ The triangle waveform HFCWO is intended to mimic the sharp, brief "thumps" of CPT via a caregiver, yet can be self-administered.³³

The majority of patients prefer the independence afforded by vest therapy.³⁴ A short-term prospective study (n=50) comparing HFCWO to CPT indicated that 88% of the CF patients favored HFCWO in terms of patient satisfaction.¹⁶ Another short-term study of similar size (n=51) found that 47% of hospitalized CF

patients preferred HFCWO compared to 26% for percussion and postural drainage (P&PD).³⁵ The patient satisfaction component of ongoing care for chronic conditions is a notable factor as higher satisfaction may lead to better therapy adherence.³⁰

Neurological Conditions and HFCWO Therapy

HFCWO therapy is useful for many patients with neuromuscular/neuromotor conditions who require airway clearance.³⁶ These disorders often result in respiratory muscle disability, making patients more susceptible to pneumonia and infection due to the inability to clear accumulated secretions through coughing. The secretions may contain microorganisms, environmental substances or other debris that activate pulmonary defense mechanisms, which can lead to ciliary dysfunction, additional secretion development and inflammatory response.³⁷

A randomized controlled trial comparing CPT to HFCWO in 23 patients with severe neuromotor/neuromuscular disease showed that adherence to HFCWO was markedly superior to CPT, with HFCWO adherence rates exceeding 70%.³⁸ Additionally, the HFCWO group showed a strong trend toward fewer hospitalizations. Similar results were found in a study of 15 children with severe neuromuscular or neuromotor disorders, which showed a three-fold reduction in hospital days after HFCWO treatment for at least one year compared with days hospitalized during a retrospective year of CPT.³⁹ None of the patients in this study required ICU care during HFCWO therapy. Another study of children with severe quadriplegia compared 12-month retrospective clinical data to CPT therapy with 12-month prospective HFCWO therapy data. Analysis showed a 50% reduction in pneumonias and a 67% reduction in hospitalizations after the introduction of HFCWO therapy for 20 minutes per day.⁴⁰ A randomized controlled study of changes in respiratory function in patients with ALS found that HFCWO users had less breathlessness and more coughing than untreated patients.⁴¹ The authors also concluded the HFCWO showed a slowing in the decline of forced vital capacity (FVC). A cohort study of 426 patients (adults and children) compared healthcare claims before and after initiation of vest therapy for patients with chronic neuromuscular disease.⁴² The study found that monthly medical costs per member decreased by \$1,949 (18.6%) after initiation of vest therapy ($p=0.002$). Inpatient admission costs decreased by \$2,392 (41.7%, $p=0.001$), and pneumonia costs decreased by \$514 (18.1%, $p=0.015$).

Non-Cystic Fibrosis Bronchiectasis and HFCWO Therapy

HFCWO has found growing acceptance for addressing the airway clearance needs of patients with bronchiectasis. This is a pulmonary disorder characterized pathologically by permanent bronchial dilatation and severe bronchial inflammation, clinically by chronic productive cough and recurrent infectious exacerbations, and confirmed with computed tomography (CT) scans. The presence of cystic fibrosis, immune disease and recurrent infections are all contributing factors in the development of bronchiectasis, which is considered to be the end point of various lung disorders.⁴³

There are ample data showing that untreated or undertreated bronchiectasis is a risk factor for increased hospitalizations, reduced quality of life, and ultimately mortality.^{7,44} Earlier intervention may avoid worsening conditions and the need for more serious interventions at a later stage of care.⁴⁵ Nicolini et al compared the safety and efficacy of HFCWO with CPT

in patients with NCFB.⁴⁶ Participants were randomized into three groups: HFCWO, positive expiratory pressure (PEP) and a control group of medical therapy only. The authors reported that the HFCWO group showed a significant increase in FVC and in FEV₁ after treatment. The HFCWO group also showed a greater increase of sputum volume, significantly reduced cough, and significant improvement in both dyspnea and quality of life measures. The authors concluded that HFCWO should be among the main choices for chest physiotherapy.

A Cochrane review, Lee et al, evaluated the results of seven ACT studies involving patients with clinically stable NCFB.² The authors concluded that ACT is beneficial for treatment of NCFB and results in improved pulmonary outcomes. The authors noted that the positive effects of HFCWO on sputum production, dyspnea and health-related quality of life are important clinical outcomes. In contrast, a different study of 75 NCFB patients found adherence to standard medical treatment was low, with only 16% of patients adhering to all treatments.⁴⁷ As chronic conditions persist, the ability to consistently adhere to prescribed therapy is a significant factor in maintaining or improving health status.

Though lung function measures are often used as a surrogate for ACT device performance, patient-centered outcomes are becoming increasingly important in assessing therapies.⁴⁸ An outcomes database proprietary to Respiratory Technologies, Inc. involving NCFB patients showed measurable benefits associated with the use of vest therapy.⁴⁹ Updated numbers from the same source⁵⁰ show the number of patients who required no respiratory-related hospitalizations increased from 49% in the year before vest therapy to 76% in the year after starting vest therapy. During this time, the yearly rate of hospitalization dropped 60%. Those who rated the “ability to clear your lungs” as good, very good, or excellent increased from 11% to 72% over the same time. Though the improvements cannot exclusively be attributed to the use of HFCWO therapy, the data strongly suggest a positive role for vest therapy in these improvements and others.

Increasing Awareness of COPD/Bronchiectasis Overlap

There is growing awareness of the association between moderate-to-severe COPD and bronchiectasis.⁵¹ This overlap appears to be so common, in fact, that some experts have proposed the use of a term that captures the frequent, concurrent nature of these two disease states – “Bronchiectasis-COPD Overlap Syndrome.”⁵² Some authors consider COPD to be a cause of bronchiectasis,⁵³ while others describe it as being associated.⁵⁴ Nevertheless, there is a high prevalence of airway wall abnormalities (thickening, dilatation) in COPD. A meta-analysis of six observational studies involving 881 patients shows the mean prevalence of bronchiectasis in patients with moderate-to-severe COPD to be nearly 54.3%, with ranges from 25.6% to 69%.⁵⁵ In the U.S., approximately 7.48 million patients have currently been diagnosed with moderate-to-very severe COPD (GOLD stages II-IV).⁵⁶ Applying a ~50% prevalence rate to this population yields a figure of more than 4 million people who may have bronchiectasis, yet up to 681,000 have been diagnosed.⁵⁷

The use of HFCWO in adults with a COPD-only diagnosis has been studied very little.⁵⁸⁻⁶⁰ A 2011 study compared the use of HFCWO to conventional treatment for patients with

COPD, defined as patients following their existing COPD management regimen including use of prescription medications (bronchodilator, inhaled corticosteroid, anticholinergic inhaler), regular exercise, and cough clearance of sputum.⁶¹ The results showed the vest therapy device was well tolerated with good reported compliance, reduced symptoms and improved quality of life.

While the use of vest therapy for COPD-only diagnoses is evolving, the clinical and cost consequences of the COPD-bronchiectasis overlap may be significant. (In 2011, the cost of COPD-related readmissions, which included bronchiectasis cases, was estimated to be \$924 million).⁶² A study of 201 COPD patients with bronchiectasis-like airway abnormalities demonstrated an association with exacerbation and was predictive of mortality over a two-year period.⁶³ Another study showed patients with NCFB and associated COPD having a 5-year mortality rate of 55% compared to 20% in those with bronchiectasis without COPD.⁶³ Changes in the airways caused by bronchial tree dilation and damage can reduce the ability to clear secretions,⁶⁴ which can contribute to declining pulmonary function, recurring respiratory infections, and eventually, death.⁴³ Moreover, there is a clear association between chronic mucus hypersecretion and hospitalization due to COPD.⁶⁵

Recent European guidelines suggest that bronchiectasis should be evaluated in COPD patients who demonstrate chronic mucus hypersecretion and severe airflow obstruction ($FEV_1 < 50\%$), who have been hospitalized for an exacerbation in the previous year, or whose sputum cultures have indicated the presence of potentially pathogenic microorganisms. These are all risk factors of the presence of bronchiectasis.⁶⁶

Path to Better Understanding

Many studies conclude that “additional data are needed” when it comes to demonstrating the impact of various ACT methods.² The need becomes more acute as the burden of proof for medical therapies evolves, and as new evidence emerges to draw our focus to disease states whose importance has been under recognized in the past. The problems of conducting airway clearance studies in rare diseases will not change, just as the difficulties of designing fair, clinically relevant studies will always be present. Nonetheless, the medical community, partnered with industry, must take responsibility to show that these devices improve patients’ lives and justify the costs of using them.⁶⁷ A valuable but untapped resource will be large and growing registries of patients.⁶⁷ Often, the information necessary to conduct post-hoc observational research is already available and offers an avenue to answer pertinent questions regarding efficacy and other outcomes. At this writing, Respiratory Technologies’ database of NCFB patients contains over 14,000 records, followed closely by the European Bronchiectasis Registry (EMBARC) database with greater than 12,000.⁶⁸ Such observational studies will outline the association of HFCWO therapy with clinically relevant outcomes such as hospitalization rate and quality of life. Extending these data to demonstrate the cost effectiveness of vest therapy is possible as well as necessary. However, without larger, better controlled trials, it will never be clear whether the effectiveness found in observational studies is truly due to HFCWO treatment or to association only. Accordingly, despite their known difficulties, randomized control trials will be necessary, and such trials will require significant time and resources.

Until then, consensus statements and guidelines^{66,69,70} will need to fill the gap.⁸ Cystic fibrosis,^{15,71} certain neuromuscular⁷² and other conditions^{73,74} have guidelines for airway clearance, but in most cases the use of HFCWO therapy is governed by coverage considerations. Presently, HFCWO can be reimbursed by Medicare for most of the conditions listed above, but coverage by private payers is variable, and determinations of “experimental” and “not medically necessary” regularly occur. The disconnect between patient need and approved treatment is the result of a reimbursement system that relies on disease categories rather than a patient’s symptomatic need. Recently, there has been increasing attention given to the concept of “treatable traits.”⁷⁵ This simple but useful idea states that teasing out the underlying mechanisms and comorbidities of a complex disease is not necessary for effective medical therapy. In the case of airway clearance therapy, evidence of the patient’s need is underscored by the presence of excess sputum that cannot be coughed out or cleared without help. Addressing this treatable trait can greatly enhance the patient’s outcome.

Conclusion

Diseases and conditions requiring airway clearance therapy tend to be serious and progressive, with declining respiratory function due to recurrent infections, permanent changes in the architecture of the airways, and co-morbidities. In reviews, there is general agreement that all airway clearance methods can be effective, and that the choice among them depends on the particular circumstances of the patient and the method most likely to be used.^{19,23,28,35,45,76,77} As an ACT option, HFCWO therapy is safe for use with a broad range of acute and chronic conditions, and a growing body of evidence supports the clinical, economic and quality of life advantages of this form of therapy.

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Tracheostomy Tube Cuff: Purpose and Practice through Team Management

Michael S Harrell, BS, RRT

Care of patients with tracheostomy has become a frequent topic of discussion in the medical industry and publications. Due to this focus, details related to the care plan of such patients are of concern and must be considered. This brief discussion highlights one aspect of patient care which has been noted to be of importance, the safety and efficacy of cuff deflation, especially when using a bias-closed position, no-leak Valve.

Purpose of a Cuff

The purpose of the inflated tracheostomy tube cuff is to direct airflow through the tracheostomy tube. This is typically during mechanical ventilation when the ventilator circuit must be closed to control and monitor ventilation for the ventilator patient, who frequently has a more seriously compromised system than patients not on a ventilator. The inflated cuff also may be important in cases of gross emesis or reflux when gross aspiration is present, to limit the penetration of aspirated material into the lower airway. The definition of aspiration is when any food, liquid, or other matter passes below the vocal folds. Therefore, the cuff cannot prevent aspiration as it is located below the vocal folds (see Figure 1). When neither mechanical ventilation or a risk of gross aspiration is present, the cuff should be deflated. Another consideration is to change the patient to a cuffless tracheostomy tube.

The definition of aspiration is when any food, liquid, or other matter passes below the vocal folds. Therefore, the cuff cannot prevent aspiration as it is located below the vocal folds.

Inflated Cuff Considerations

The inflated cuff should be avoided whenever possible because it has the potential to cause multiple complications, such as:

- 1) Increased risk of tracheal injury, including mucosal injury, stenosis, granulomas, and more;
- 2) Diminished ability to use the upper airway, leading to disuse atrophy over time; and
- 3) Restriction of laryngeal movement (laryngeal tethering) which may impact swallowing negatively.

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Cuff Deflation

Deflating the tracheostomy tube cuff, when appropriate, has been shown to have multiple patient benefits, including:

- 1) Reducing the risk of potential tracheal mucosal damage;
- 2) Returning the patient to a more normal physiology, including closing the system using a bias-closed position, no-leak Valve;
- 3) Restoring speech and improving communication;
- 4) Allowing for the possible improvement of the swallow;
- 5) Potentially lowering the risk of aspiration;
- 6) Allowing rehabilitation to begin as early as possible; and
- 7) Decreasing the time to decannulation.

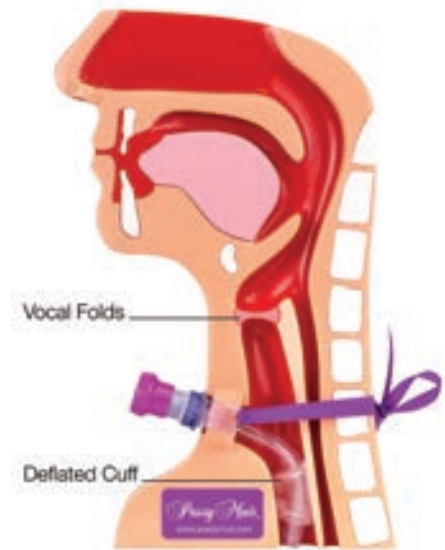


Figure 1.

Cuff deflation is a recognized important step in the care plan for a patient with a tracheostomy (Speed & Harding, 2013). The benefits of cuff deflation can be safely and effectively extended to a patient with mechanical ventilation, when appropriate assessment and patient selection is performed (Sutt, Caruana, Dunster, Cornwell, Anstey, & Fraser, 2016). This early cuff deflation may decrease delays in the rehabilitation process, and potentially avoids the negative consequences related to the inflated cuff. The earlier that a patient has their cuff deflated, the earlier the patient may be weaned or decannulated. When decannulation is not a possible goal, cuff deflation may still accommodate the benefits outlined above on a long-term basis.

It has been demonstrated that a team of appropriately trained professionals armed with evidence-based guidelines significantly improves care and reduces negative outcomes for the patient with tracheostomy (de Mestral, 2011; Speed & Harding, 2013). A team approach assists with continuous monitoring and patient care plan management. As with any medical procedure or device, thorough education is important in achieving the desired outcomes. Providing the education, and competency verification necessary, is the duty of the organization providing healthcare services.

It is the responsibility of healthcare professionals to provide the best possible care to their patients. Proper cuff management, including cuff deflation, contributes significantly to the best practice plan of care for the patient with a tracheostomy. The safety and efficacy of the plan depends largely on the education and competency of the team caring for these individuals, as well as a commitment from the healthcare facility to a multidisciplinary tracheostomy team approach for patient care.

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Understanding the Management of Patients Undergoing Prolonged Weaning from Mechanical Ventilation: A Multidisciplinary Approach

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The variability of the potential influences on weaning success has created awareness that the process is facilitated by a “best practice” of collaborative multidisciplinary care. O’Bryan et al. (2002) described weaning protocols for a system of long-term acute care hospitals that included a consistent approach and protocol to weaning, the participation of rehabilitation services, and both early and aggressive intervention, as well as nutritional support.¹ There is evidence that implementing standardized weaning protocols may reduce the duration of mechanical ventilation and length of stay in the Intensive Care Unit (ICU) patients.² However, it is important that when applied specifically to the subset of patients with weaning difficulty, the use of “weaning protocols” are tailored to the individual patient, reflecting a holistic, multidisciplinary assessment, with consideration for the underlying cause and aggravating factors contributing to prolonged mechanical ventilation.

Patients presenting with respiratory failure are now surviving with the help of medical advances, including tracheostomy tubes and mechanical ventilation. The care of patients on mechanical ventilation has changed significantly over recent decades. Since the 1950s, there has been a shift from devices delivering negative-pressure mechanical ventilation to invasive positive pressure ventilation modes. Frequently, ventilation is delivered via tracheostomy tubes and permits prolonged mechanical respiratory support for most individuals with respiratory failure. The presence of the tracheostomy tube accomplishes multiple airway management goals; establishing a patent airway, as well as providing a connection to assisted ventilation.³

A uniform and broadly accepted definition of the term “weaning” is crucial to avoid confusion and is an essential prerequisite for interpreting the literature and guiding clinical decision-making. Weaning from mechanical ventilation is defined as “the process of withdrawing ventilator support”.⁴ It is commonly accepted that the process of weaning starts with the first spontaneous breathing trial (SBT), during which the patient is allowed to breathe for a relatively brief period of time (30–120 min) through a T-tube, or with low levels of either CPAP (2–5 cmH₂O) or pressure support (< 8cmH₂O). When the SBT is successful, the patient is considered weaned and ready to be extubated, provided that the natural airway is not at risk for obstruction.

A recently proposed and largely accepted classification based on the difficulty and duration of the weaning process includes: (1) simple weaning, i.e., the patient passes the initial SBT and is successfully extubated at the first attempt; (2) difficult weaning, i.e., up to three SBT or 7 days from the first SBT are necessary to withdraw mechanical ventilation and extubate the patient; (3) prolonged weaning, i.e., more than three SBTs or 7 days from the first SBT are required.⁵

In the ICU, most patients may be successfully liberated from mechanical ventilation without difficulty.⁶ However, up to 50% of the time a patient spends on the ventilator may be involved in the process of weaning from mechanical ventilation and approximately 14% of patients receiving mechanical ventilation undergo a “prolonged weaning” process.⁷⁻⁸

The Burden of Prolonged Weaning

A report from the UK revealed that 8% of ICU patients had “weaning delay” (defined as the need for ventilatory support for more than 2 weeks in the absence of any non-respiratory factor preventing weaning) and 7% had so-called “weaning failure” (if this state persisted for 3 weeks or more).⁹ While for approximately 70% of patients, the weaning process is simple and successful; for the remaining 30%, the initial attempt fails, making the weaning difficult and worsening prognosis. ICU mortality has been reported to be as high as 25% in these patients, with about half progressing to prolonged weaning.⁴ Furthermore, patients with prolonged weaning account for 6% of all ventilated patients but consume 37% of ICU resources.¹⁰ From an economic perspective, US annual costs for mechanical ventilation are estimated to be 27 billion dollars, corresponding to more than 10% of all hospital costs. Each year, about 300,000 people receive prolonged mechanical ventilation in ICU’s in the US, and this number might double within the next decade, with costs increasing up 50 billion dollars.¹¹ Therefore, prolonged weaning carries not only a medical but also a significant social and economic burden.

The Role of Specialized Weaning Units and Multidisciplinary Teams

The appropriateness of the ICU environment for long-term management of patients undergoing prolonged weaning may be questioned by the detrimental consequences on the psychological and cognitive function of these patients, coupled with a paucity of ICU beds failing to adequately address demand. An otherwise stable patient who remains on mechanical ventilation may be considered for transfer to a specialized

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weaning unit (SWU). Though there is not a precise definition, SWU can be considered as highly specialized and protected environments for patients requiring mechanical ventilation despite resolution of the acute disorder. The philosophy of such units lies in the delivery of holistic care from a truly multidisciplinary team encompassing a variety of specialties, including skilled nursing staff, physio-therapists (a designation used outside the US; within the US, the team would have respiratory therapists and physical therapists), physicians, speech-language pathologists, dieticians, psychologists, mental health services, social workers and palliative care.

Such an approach to “difficult weaning” would include an appreciation of the existence of underlying medical and psychological problems that may be contributing to weaning delay in each patient that may have been unrecognized in a busy ICU setting. These include the presence of chronic hypoventilation (failure to breathe rapidly enough or deeply enough), parenchymal lung disease (a group of lung diseases affecting the interstitium (the tissue and space around the air sacs of the lungs), neuromuscular conditions, cardiac disease, electrolyte abnormalities, nutritional deficiencies, inadequate muscle mass, and significant critical illness neuropathy. The tenets of care in specialized weaning units aim to focus on privacy, sleep quality, utilization of weaning protocols tailored to the individual patient, and optimizing comorbid medical conditions in an environment away from an acute ICU with the absence of invasive monitoring or multi-organ support.⁹

To highlight the benefits of such an approach, a prospective study of 262 patients receiving prolonged invasive mechanical ventilation admitted to one such specialized unit in the UK over an 8-year period reported a successful outcome from weaning (i.e. liberation from invasive ventilation) in 64% of the patients.¹² Of those who were successfully weaned, 62% of those participants discharged were alive 12 months post discharge. Other observational studies report that 34–60% of patients in specialized weaning units can be weaned successfully from ventilatory support and suggest successful weaning can occur up to three months after admission to these SWU’s, without adversely affecting long-term mortality.⁵

Initial Strategies for Patients Undergoing Prolonged Weaning

A preferred initial strategy is to maintain mechanical ventilation at nighttime; therefore, ensuring the patient has adequate “rest” during this period whilst aiming for either progressive ventilatory independence or a gradual reduction in the level of ventilator support in the daytime, depending on the individual patient. This initial approach is supplemented by regular detailed review of the patient’s swallow and bulbar function. When possible, progressive periods of tracheostomy cuff deflation during the daytime and patients talking through speech devices, such as the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve, are utilized. Allowing the patient to talk, regaining the sensation of taste and resuming oral, nutritional intake, as early as feasible during the weaning process, carry significant physical and psychological benefits. The tracheostomy may also be downsized, permitting the introduction of Non-Invasive Ventilation (NIV) early in the weaning process, if deemed safe and appropriate, while still enabling the patient to receive ventilation by tracheostomy, if required. It also is imperative to ensure that aggressive secretion management

occurs in patients, if successful liberation from tracheostomy ventilation is to occur.

Non-Invasive Ventilation

The application of NIV in subjects with weaning difficulty has been shown in the literature to represent a useful strategy.¹³⁻¹⁴ Ferrer et al. (2003) investigated the use of NIV in weaning by randomizing 43 participants undergoing invasive mechanical ventilation who had failed a 2-hour T-piece trial for 3 consecutive days to either extubating and NIV or a “conventional” weaning plan consisting of continued daily weaning attempts.¹⁵ Liberation from invasive ventilation and 90-day survival were both greater in the NIV arm, where there was a significantly decreased incidence of nosocomial pneumonia and septic shock. A randomized controlled trial conducted in thirteen ICUs comprised of 208 participants with chronic hypercapnic respiratory failure (respiratory failure with increased arterial carbon dioxide levels), who had failed an SBT, found that the group who was extubated to NIV had a significantly reduced occurrence of acute respiratory failure post-extubation compared to those extubated to oxygen therapy or those who continued a weaning strategy using Intermittent Mandatory Ventilation (IMV).¹⁴ The results from these studies suggest that NIV represents a useful tool in the management of patients undergoing a prolonged weaning process.

High Flow Nasal Oxygen Therapy

Another technique that has a potentially useful application in the weaning process is that of High Flow Nasal Oxygen Therapy (HFNOT). HFNOT aims to derive greater physiological benefit by delivering heated and humidified oxygen therapy through a nasal cannula at higher flow rates (up to 60 liters/minute) when compared to standard oxygen delivery devices.¹⁶ This results in greater washout of the upper airway dead space facilitating removal of carbon dioxide. It also results in delivery of a small degree of Positive End Expiratory Pressure (PEEP), allowing alveolar recruitment, thus aiming to reduce the work of breathing as well as maintaining patient comfort through the delivery of warm humidified gas. At present, there is a paucity of high-quality evidence examining the utility of HFNOT in subjects undergoing prolonged weaning despite some data pointing to improvements in oxygenation with HFNOT in this cohort.¹⁷ In a multi-center study comparing 604 extubated patients deemed at high risk of re-intubation randomized to either HFNOT or NIV post-extubation, no significant differences were noted in the rate of re-intubation or in-hospital mortality.¹⁸ Whilst such data is encouraging, further research is needed in this area to identify those subgroups of patients with weaning difficulty who may benefit from the use of HFNOT as a tool in the liberation from mechanical ventilation.

Management of Comorbidities

Adequate management of comorbidity also is integral to the management of patients with weaning difficulties. For example, it is important that healthcare professionals pay attention to fluid overload and to the optimization of cardiac function during the weaning process. A weaning strategy that includes fluid management driven by serum B-type natriuretic peptide (BNP) levels has been shown to confer superior outcomes in terms of duration of weaning and time to successful extubation when compared to a more conventional approach with no significant differences in terms of incidence of electrolyte abnormalities and renal failure between the two groups. A potential mechanism postulated to explain the beneficial outcomes reported of such a

biomarker-based approach may lie in the reduction of Ventilator Associated Pneumonia (VAP) as pulmonary edema may affect the alveolar bacterial clearance.¹⁹

Role of Allied Health Professionals and Trach Teams

The role of Physical Therapy and Occupational Therapy at an early stage in the management of patients aiming to be liberated from mechanical ventilation cannot be over-emphasized. Early physical and occupational therapy is feasible from the onset of mechanical ventilation, despite high illness acuity and presence of life support devices. Adverse events are uncommon, even in this high-risk group.²⁰ This includes multiple domains such as early mobilization and transferring, attention to posture and balance, maintenance of muscle mass, peripheral muscle training, airway secretion management, and respiratory muscle training.²¹ To emphasize the importance of rehabilitation, the “real world” service review reported that 48.1% of patients admitted to a specialist weaning unit in the UK were discharged to the referring hospital for on-going rehabilitation needs.¹²

Another area of utmost importance in the management of subjects with weaning difficulty is the role of Clinical Psychology and Mental Health services. The impact of prolonged mechanical ventilation and the events leading to the ICU admission may carry a significant burden both on patients and family members in terms of depression, anxiety, and other mental health issues and this may be overlooked by healthcare professionals in a busy ICU environment. In a seminal study, depressive disorders were found to be present in 42% of patients undergoing weaning difficulty and were associated both with weaning failure and an elevated mortality rate.²² These issues may persist even after the weaning period; highlighting the importance of creating a structured holistic follow-up program for patients following discharge from the hospital. Beyond healthcare professionals simply recognizing such conditions, it is worth appreciating that such a traumatic experience may greatly alter the patient's perception of the environment around them, their progress during the process of being liberated from the ventilator, medical interventions and actions of healthcare professionals caring for them. Nutritional status is integral in the weaning process. Patients with tracheostomy who are dependent on ventilators, and who have decreased nutritional intake, may experience protein-calorie malnutrition, which reduces respiratory muscle strength and function. Registered Dietitians play an integral part in the nutritional management of such patients. Through special enteral feeding formulas and oral supplements, dietitians can address hypoalbuminemia (low level of albumin in the body) and heal and prevent pressure ulcers, while maintaining optimal support for weaning. When an oral diet is recommended, Speech-Language Pathologists and Registered Dietitians work closely together to maximize caloric intake, modifying consistencies as needed to achieve appropriate nutrition and hydration in the safest and most effective manner.

Placement of a tracheostomy tube may be necessary for patients in the ICU with respiratory failure. In fact, the incidence of tracheostomy seems to be increasing out of proportion to the increased need for mechanical ventilation. This has led some hospitals to develop specialized tracheostomy teams to standardize and deliver specialized patient care to reduce perioperative tracheostomy-related complications; typically delivered by multiple providers, including the primary physician, resident, mid-level providers, consulting surgeon, nurse, respiratory therapist, and speech-language pathologist.

Multidisciplinary tracheostomy and wean teams have been successful in improving patient outcomes. One study showed that the addition of a post-tracheostomy care bundle to a multidisciplinary tracheostomy service significantly improved rates of decannulation and tolerance of oral diet.²³ Standardized care provided by a specialized multidisciplinary tracheostomy team also was associated with fewer tracheostomy-related complications and an increase in the use of speaking valves.²³

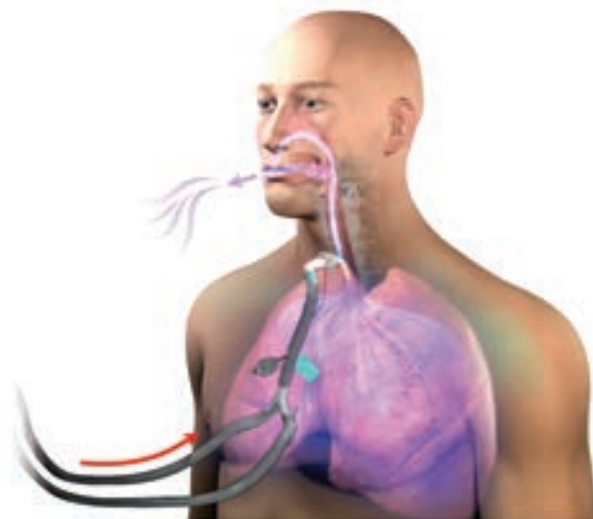


Figure 1. Passy Muir Valve in-line during mechanical ventilation.

Role of the Speech-Language Pathologist (SLP) in Patients Undergoing Prolonged Weaning

Speech-Language Pathologists (SLPs) address the communication and swallowing needs of the tracheostomized and ventilator-dependent population throughout the course of the patient's recovery. Adults who are tracheotomy and ventilator dependent or who are undergoing prolonged weaning are some of the most challenging patients in the caseload of an SLP. Airway issues influence many aspects of patient care, including swallowing. The medical issues for patients with these complex cases greatly affect their rehabilitation. Physicians, SLPs, and other members of the multidisciplinary team must work together in their management, especially to understand the influence of pulmonary physiology on swallowing and swallowing dysfunction. Often, these tracheostomized and ventilator dependent patients have long-term alternative feeding methods placed early in their acute medical course. Without SLP intervention, these patients may never return to an oral diet. Communication and swallowing management can greatly enhance the quality of life for these long-term mechanically ventilated individuals.

Swallowing

For those individuals where weaning from mechanical ventilation is not possible, the ability to take even a small amount of oral intake can greatly improve their quality of life.²⁴ The clinical literature does not support a direct, causal relationship between tracheostomy, mechanical ventilation, and swallowing impairment; however, the clinical course of these medically fragile patients typically includes a disruption of swallowing function.²⁵ Many of these patients receive feeding tubes simultaneously with the tracheotomy, without a swallow assessment. This may result in the patient's long-term non-oral status, influencing an important aspect of quality of life. The consequences of pulmonary aspiration may be more significant

for patients already in an immuno-compromised state, who are often malnourished, have multiple medical issues, and are receiving polypharmacy.²⁶

Communication

This is a key issue for ventilated patients, who find the inability to speak distressing.²⁴ Difficulties with communication for this patient population with tracheostomies have been associated with social withdrawal, depression, lack of motivation to participate in care,²⁸⁻²⁹ poor sleep, and increased anxiety and stress levels,²⁹⁻³⁰ which have both short-term and long-term impacts on patient outcomes in ICU and post ICU stays. By demonstrating the potential physiological benefits on top of the already known and more obvious psychological benefits, speaking valves present an excellent way to improve patient care in the ICU.

Use of Speaking Valves

The inability to communicate during periods of mechanical ventilation (MV) can significantly increase psycho-emotional distress²⁹ and has been associated with depression and post-traumatic stress disorder.²² One-way speaking valves can be used to restore verbal communication for patients who require MV. The Passy Muir® Valve is the only bias-closed position, no-leak valve that can be used during MV. The Passy Muir Valve opens during inspiration and closes at the end of inspiration, re-directing exhalation through the vocal cords and out through the mouth and nose, which allows for verbal communication. The restoration of airflow, sensation, and positive airway pressure to the aerodigestive tract returns the upper airway to a more normal physiologic condition and may also have other clinical benefits for the patient who requires tracheostomy and MV. Speaking valves can be used in-line with mechanical ventilation but use of these requires deflation of the tracheostomy cuff.

It is not uncommon, however, for the SLP to meet resistance when requesting cuff deflation. There is still the misconception that the cuff prevents aspiration. There is also a fear that adequate ventilation cannot be achieved. The SLP can provide education and evidence to alleviate these concerns. It has been demonstrated that ventilation and stable respiratory parameters can be achieved with the cuff fully deflated and with placement of a Passy Muir Valve. Most recently, clinicians in a cardiothoracic ICU were able to reveal that deflating the cuff and using the Passy Muir Valve increased end expiratory lung impedance, therefore serving as a lung recruitment intervention.²³ Due to these findings, use of Passy Muir Valves with ventilator patients increased from 0% to 70% and is now the standard of care in that ICU.

It has been demonstrated that ventilation and stable respiratory parameters can be achieved with the cuff fully deflated and with placement of a Passy Muir Valve.

The SLP must work closely with the Respiratory Care Practitioner (RCP) and Respiratory Therapists (RTs) to understand how particular ventilator settings and the level of patient control of breathing may impact the patient's ability to synchronize breathing and swallowing. Using the Passy Muir Valve in-line may require ventilator adjustments to assure patient

comfort, safety, adequate ventilation and ability of the patient to perform speech and swallow tasks. These adjustments are made by the RCP/RT trained in such procedures under the guidance of the physician. For the ventilated patient, the team determines the roles of the RCP and SLP as related to cuff deflation and placement of the Valve in-line with the ventilator circuitry. The RCP typically is responsible for procedures such as downsizing the tracheostomy tube and adjustments to the ventilator settings as stipulated in the facility's Policy and Procedures.

Therefore, the SLP-RCP team is presented with a unique opportunity to co-treat patients who require tracheostomy ventilation to provide not only a way to communicate, but also to restore airflow and engage the glottis, restore positive pressure to the aerodigestive tract, and address rehabilitation of the aerodigestive system as needed. This therapy may enhance weaning and rehabilitation by promoting safer swallowing to reduce aspiration, improved swallow and cough,³⁰ reducing respiratory infections, promoting alveolar recruitment and by enhancing early mobilization efforts.²³⁻²⁴

Conclusion

In summary, prolonged weaning from mechanical ventilation constitutes a significant burden in terms of morbidity and mortality in the ICU. Successful liberation of such patients from mechanical ventilation lies in availing a multidisciplinary approach to care in any setting, developing specialist weaning units, and following standard weaning protocols. When working with patients who are being weaned from mechanical ventilation, clinicians must appreciate the interaction between respiration, swallowing, and communication systems. Impairment in these systems is closely linked; and in conjunction with other comorbidities of chronic illness, such as recurrent infections and decreased nutrition, the ventilator weaning process is often challenging. Multidisciplinary teams must work together to facilitate patient recovery and liberation from mechanical ventilation.

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