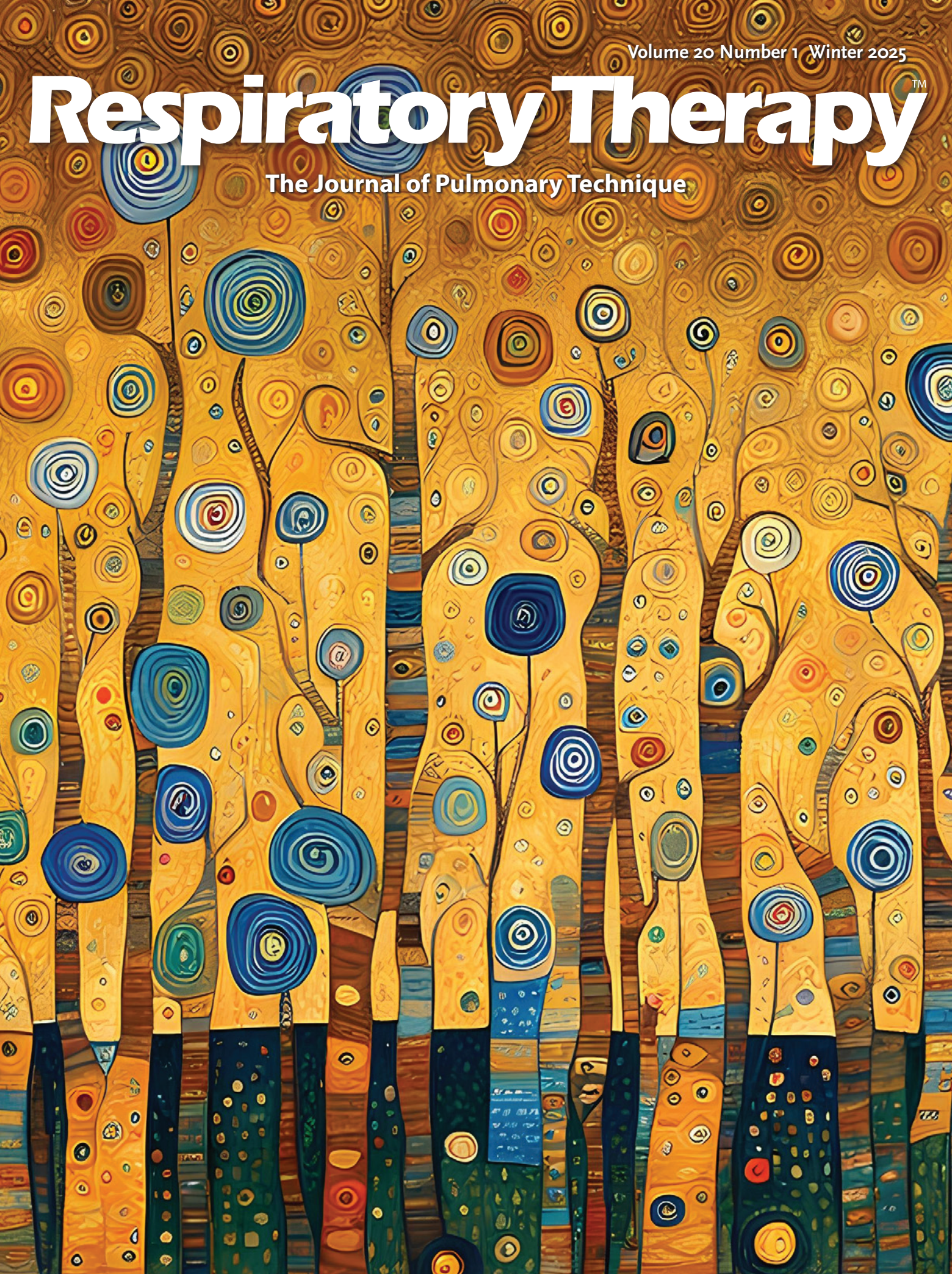
Volume 20 Number 1 Winter 2025

Respiratory Therapy™

The Journal of Pulmonary Technique



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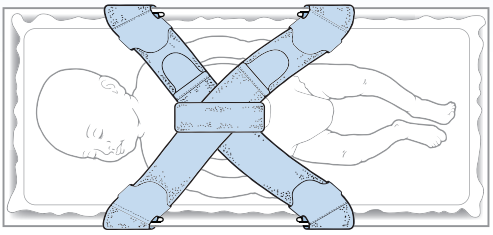

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News

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Nonin Medical secures FDA clearance

Nonin Medical, a leading global manufacturer of wearable and noninvasive medical monitoring devices, has announced its first over-the-counter (OTC) FDA-cleared fingertip pulse oximeter—the TruO2 OTC. Dedicated to providing accurate readings on adults across all skin tones, the device empowers patients and their healthcare professionals with accurate measurements, allowing them to make informed healthcare decisions. The vast majority of pulse oximeters sold directly to consumers are classified as "health and wellness devices" and are not required to meet the stringent requirements of the FDA for medical devices. This is because health and wellness products are only meant to promote a healthy lifestyle. They do not have any medical claims and are not intended to diagnose, treat, or prevent disease. In fact, several low-cost devices have shown significant errors in estimating blood oxygen saturation. By contrast, OTC devices are classified as "medical devices" and are regulated by the FDA, ensuring medical-grade technology is just as conveniently accessible to consumers as health and wellness products. "Over the past several years, the US market has been flooded with poor quality, health and wellness grade pulse oximeters which are not regulated by the FDA. This creates a confusing and frustrating experience for consumers, including those with conditions like COPD or asthma, seeking an accurate, equitable, and durable solution for home use," John Hastings, CEO of Nonin Medical, explains. The challenge with accuracy has been further compounded by the well-documented shortcomings of pulse oximeters for patients with dark skin. Data collected during the COVID-19 pandemic demonstrated that pulse oximeters missed hypoxia in patients with darker skin tones, leading to unequal access to healthcare and putting patients at risk of serious long-term health consequences. According to research, people with dark skin tones are 32% more likely to have their blood oxygen levels overestimated than white patients. "The availability of TruO2 OTC now provides all consumers with access to equitable, medical-grade technology that is designed for accuracy across all skin tones. We believe this will significantly enhance the quality and reliability of home-based monitoring, leading to better health outcomes for everyone," says Hastings. Nonin has a proven record of developing highly accurate pulse oximetry devices and has always placed a high priority on accuracy across skin pigmentation in its product development. In multiple independent studies, Nonin Medical's pulse oximetry technology has outperformed low-cost oximeters and other medical-grade oximeters, and even exceeded FDA requirements. Two studies, one conducted in 2005 on three devices and another conducted in 2024 on 11 devices, demonstrated that Nonin's pulse oximeter outperformed other devices, with participants in both studies representing a range of skin tones. The TruO2 OTC fingertip pulse oximeter builds on Nonin's legacy of developing durable and accurate pulse oximetry devices. This mission started with the company's founder Phil Isaacson, the original maker of the fingertip pulse oximeter. "For decades, we have pioneered advancements in pulse oximetry, making healthcare accessible for diverse populations, in collaboration with other organizations, including other manufacturers and the FDA. We are deeply committed to ensuring better health outcomes for everyone and are excited to launch the TruO2 OTC to further ensure access to equitable health care," concludes Hastings. The TruO2 OTC will be available directly to consumers on Amazon in December 2024 and from other online retailers soon after.

Company Earns Mark in Europe

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on harnessing the power of nitric oxide (NO) to improve the lives of patients, announced European CE mark approval of the LungFit PH system. This CE mark approval allows Beyond Air to market LungFit PH in the European Union and all other countries that recognize this certification. LungFit PH, the first device in the LungFit therapeutic platform of nitric oxide generators, leverages the company's patented Ionizer technology and has already received FDA approval in the United States. "We are thrilled to announce CE mark for LungFit PH, paving

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the way for commercial sales in Europe and other global regions. In anticipation of this approval, we partnered with Business Asia Consultants to leverage their extensive international distribution network," stated Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "I am incredibly proud of the team that made this happen over the past 30 months and look forward to initiating shipments to our Asia-Pacific partner, Getz Healthcare, and other international partners in 2025." Under the terms of Beyond Air's existing commercialization agreement with Getz Healthcare for LungFit PH, Getz will make a $1 million milestone payment to Beyond Air upon CE mark certification. In addition, Beyond Air will receive ongoing royalty payments based on LungFit PH net sales. The partnership provides access to hospitals in Australia, New Zealand, Thailand, Philippines, Taiwan, Hong Kong, Malaysia, Pakistan, Singapore and Vietnam. The specific indications for LungFit PH under CE Mark certification include: the treatment of infants ≥ 34 weeks gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation; the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function. LungFit PH uses Ionizer technology to generate unlimited on-demand NO from ambient air and deliver it to a ventilator circuit, regardless of dose or flow. The device uses a compressor to drive room air through a plasma chamber where pulses of electrical discharge are created between two electrodes. The LungFit PH system ionizes the nitrogen and oxygen molecules, forming NO with low levels of nitrogen dioxide (NO_2) created as a byproduct. The gas is then passed through a Smart Filter, which removes toxic NO_2 from the internal circuit. LungFit PH represents a significant step forward in sustainable healthcare solutions. Since the device generates NO conveniently and cleanly from ambient air, without the need for tanks or chemicals, it is highly energy-efficient, using only the power equivalent to a 60-watt light bulb. By eliminating the emissions associated with truck transport and cylinder refills, LungFit PH supports hospital sustainability initiatives, helping facilities reduce their carbon footprint while delivering critical care to patients. For the approved indications, the novel LungFit PH system is designed to deliver a dosage of NO to the lungs that is consistent with the current standard of care for delivery of 20 ppm NO, with a range of 0.5 ppm-80 ppm (low concentration NO) for ventilated patients. Each Smart Filter will last 12 hours regardless of ventilator demands, and replacing a filter only takes seconds. Potential customers can visit the LungFit PH website, www.lungfitph.com, for additional information, including the product label, and to sign up for updates.

SmartLab™ Instrumentation system with Insight™ Software

The Hans Rudolph, Inc. SmartLab™ Instrumentation System with Insight™ Software is a flexible system for measurement and analysis of respiratory signals in research applications. The base module can accept up to four pressure sensor modules for measuring flow from pneumotachs and airway or other pressures. Optional inputs include an oximeter, CO2 sensor, temperature and humidity and digital I/O. The PC software provides real time graphs and calculations of many common respiratory parameters. Data can be saved for analysis or replayed. Custom software modules can be developed for special applications.

Vanderbilt University Medical Center Integrates Masimo Radius VSM

Masimo announced that Vanderbilt University Medical Center (VUMC), a renowned healthcare facility in Nashville, Tennessee, is piloting the use of the Masimo Radius VSM patient-worn vital signs monitor with Masimo Patient SafetyNet supplemental remote monitoring in the Emergency Department (ED) and nontraditional care spaces. Launched as part of a successful pilot program aimed at tackling the ongoing crisis of emergency room congestion, Radius VSM has been used on hallway beds, in the emergency medical service offload area, and on patients in the waiting room who are typically only monitored periodically—thus providing continuous, wireless monitoring for those who may otherwise be left vulnerable to unexpected deterioration. Radius VSM combines the reliability and accuracy of a bedside monitor with the comfort and freedom of a wearable device. With its implementation alongside Patient SafetyNet, clinicians at VUMC are able to remotely monitor vital signs in real time from centralized view stations, simplifying patient data management, enabling quicker intervention during possible deterioration, and enhancing patient safety—even while a patient is up and moving. The modular, scalable monitoring platform offers a range of physiological measurements, including Masimo SET pulse oximetry, measure-on-inflation noninvasive blood pressure, continuous temperature, respiration rate, and 3-leadwire electrocardiography (ECG). By monitoring ED patients with Radius VSM, VUMC is transforming spaces that were traditionally devoid of continuous monitoring into areas of proactive patient care. This level of visibility may help clinicians reduce the use of telemetry, potentially saving time and resources and improving patient throughput and prioritization to other parts of the hospital, such as the general ward or medical and surgical wards. Additionally, Radius VSM's innovative approach not only enhances the patient and clinician experience but exemplifies how cutting-edge technology can be seamlessly integrated into high-pressure settings like the ED to help streamline continuity of care. The initial success of VUMC's pilot program is paving the way for an expanded rollout within the ED designed to elevate care for vulnerable patients. Moreover, the promising results may lead to adoption in other areas of the hospital, such as medical and surgical wards, broadening the impact of Masimo's innovative technology on patient care throughout VUMC. The program also underscores both Masimo's and VUMC's commitment to leveraging technology to rethink and improve patient care pathways, setting a new standard for how hospitals manage patient surges in the ED and beyond. "Rising patient acuity and volume at VUMC necessitate strategic initiatives to augment our care infrastructure," said Neal Patel, MD, MPH, Professor of Clinical Pediatrics and Chief Informatics Officer for HealthIT at VUMC. "Wireless physiologic monitoring in the ED enhances surveillance and vigilance of each patient's status even when they are in the waiting room." Bilal Muhsin, Chief Operating Officer of Masimo, said, "We are excited to partner with Vanderbilt University Medical Center to bring Radius VSM to vulnerable patients in the emergency department, where continuous monitoring is not the norm. A core tenet of our mission is to improve patient outcomes and reduce the

Continued on page 22…

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SPOTLIGHT ON VENTILATION

React Health

What ventilation products does your company offer?
React Health offers a complete portfolio of ventilation solutions including the V*home, V+C (Ventilator + Integrated Cough Assist (ICAT™)) and the V+Pro.

What are the new features?
IntelliPAP™ automatically adjusting PEEP algorithm was released in May 2024. The feature is intended to promote upper airway patency in individuals with respiratory insufficiency and comingled sleep disordered breathing.

React Health is also very excited to offer the V+C ventilator platform with integrated cough assist technology (ICAT™) which was recently awarded a new HCPCs code; E0468, by CMS.

The ventilator platforms also offer robust leak compensation (175 L/min @ 20 cmH2O), high flow therapy (15-60 L/min), volume targeted ventilation, and cloud-based data reporting.

Tell us about your company's current or recent R&D efforts.
React Health has multiple R&D initiatives that focus on improving patient care and minimizing the cost of healthcare across the respiratory care space. We have teams working on designs that streamline workflows across the continuum of patient care with improvements in the areas of ventilation, sleep, oxygen, diagnostics, and data management. Stay tuned for ongoing announcements as we introduce the fruits of our efforts.

Discuss the training and support services you offer.
Our training is customized to the needs of our customers and generally includes a combination of on-site and virtual product applications training. Additionally, we have a live, clinical and technical support line to help customers with urgent product-related questions. Last, but certainly not least, all React Health clinical and technical support personnel are Respiratory Therapists with backgrounds in Acute Care, HME, Adult and Pediatrics.

Where are your products used?
React Health ventilation solutions provide a seamless transition from hospital ventilation to the home as well as in the transitional and long-term care space. Our solutions have done exceptionally well for helping pediatric patients transition home.

What developments do you foresee for ventilation products and applications?
Technology, features, and/or algorithms to improve habituation and adherence to NIV in the home setting is an area where additional innovation could be very beneficial. Additionally, improvements in the areas of comfort and portability that improve the ability of the end user to receive ventilatory support while engaging in activities of daily living is another area where additional innovation may help improve the user experience as well as respiratory health outcomes.

SPOTLIGHT ON SPIROMETRY

GoSpiro® Diagnostic Spirometer
The GoSpiro® Diagnostic Spirometer from Monitored Therapeutics is designed for in-clinic and remote monitoring, meeting all of the stringent ISO standards for home testing. Its ability to meet all ATS/ERS requirements, including the requirement for measuring flows down to below 0.025 L/sec, a flow not met by any other turbine spirometer on the market, makes it the most accurate and affordable spirometer for the measurement of Forced Vital Capacity (https://bit.ly/gospiro-diag). Its use of Avatar-Assisted technology enables easy collection of laboratory quality spirometry everywhere from beside to clinic, from clinic to home. This technology has been credited with addressing the burden of undiagnosed lung disease resulting from the falling number of practicing pulmonologists by transitioning hospital quality spirometry to Primary Care Practice offices.

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Learn more about our latest innovation at **werfen.com/GEMPremier7000**.

1. O'Hara M, Wheatley EG, Kazmierczak SC. The impact of undetected in vitro hemolysis or sample contamination on patient care and outcomes in point-of-care testing: a retrospective study. *JALM*. 2020;5(2):332–341. 2. Lippi G, von Meyer A, Cadamuro J, Simundic A-M. Blood sample quality. *Diagnosis*. 2018;6(1):25–31. doi:10.1515/dx-2018-0018

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SPOTLIGHT ON BLOOD GAS

Sentec Transcutaneous Monitoring

Transcutaneous CO_2 monitoring is considered by many neonatal teams to be standard of care in the NICU for intubated patients. However, this noninvasive technology can benefit patients across care areas, including in the sleep lab and pediatric ICU. By providing continuous, accurate visibility to $tcPCO_2$, as well as SpO_2 and PR, transcutaneous monitoring can be an important tool for care teams who are prioritizing less invasive care. In the NICU, this can mean enabling neuroprotective care strategies and reduced blood draws. For patients in the PICU, transcutaneous monitoring can supplement the visibility lost when choosing noninvasive ventilation method—particularly vital in patients who may struggle on conventional mechanical ventilation. This technology can also overcome the limitations of end-tidal CO_2 monitoring, providing accurate measurements regardless of ventilation strategy or degree of V/Q mismatch—important in both the PICU and the sleep lab.

Sentec's new tCOM+ is the latest in transcutaneous monitoring technology, offering a sleek new user interface, as well as significant software advances to improve workflow for providers. The tCOM+ introduces a high-resolution touchscreen display, making navigation simple and intuitive. Providers can easily track patient progress using real-time event logging of vent changes, medication administration, and other changes or interventions. With on-screen alerts and tutorials, users can quickly resolve issues and troubleshoot, while dedicated sensor information screens support proactive management and maintenance of equipment.

The tCOM+ retains familiar, trusted features like Smart Cal-Mem—which allows temporary disconnection for bathroom breaks, repositioning, and other workflows—and connectivity with patient monitoring systems (PMS), patient data management systems (PDMS), and polysomnographic systems (PG/PSG).

To learn more about how the tCOM+ can fit into your existing workflows and protocols and offer your team more flexibility, efficiency, and options, get in touch with the Sentec team: sentec.com/contact.

Werfen GEM Premier 7000 with iQM3

The new GEM® Premier™ 7000 with Intelligent Quality Management 3 (iQM®3) is a breakthrough in blood gas testing. For the first time at the point-of-care, hemolysis—which accounts for up to 70% of all preanalytical errors and can elevate potassium results up to 152%—is flagged, and in just 45 seconds.[1,2] This helps improve the quality of critical results throughout the hospital. And, the GEM Premier 7000 with iQM3 continuously monitors the analytical process, before, during, and after each sample measurement, and detects other sources of error at the point of care, including micro-clots, bubbles, and more. Results for Arterial Blood Gas (ABG), Electrolytes, Glu, Lac, Hct, tHb, O_2Hb, COHb, HHb, MetHb, sO_2, tBili can be obtained from a single sample. Maintenance-free, multi-use, self-contained GEM PAK cartridges incorporate all components needed for testing. The GEM Premier 7000 with iQM3 is a complete solution for enhanced efficiency and patient care.

1 Lippi G, Salvagno GL, Favaloro EJ, Guidi GC. Survey on the prevalence of hemolytic specimens in an academic hospital according to collection facility: opportunities for quality improvement. *Clin Chem Lab Med.* 2009;47(5):616–618. doi:10.1515/CCLM.2009.132.

2 Lippi G, Plebani M, Di Somma S, Cervellin G. Hemolyzed specimens: a major challenge for emergency departments and clinical laboratories. *Crit Rev Clin Lab Sci.* 2011;48(3):143–153. doi:10.3109/10408363.2011.600228.

Nonin Fingertip Pulse Oximeter

The TruO2® OTC Fingertip Pulse Oximeter is an FDA-cleared device that delivers accurate blood oxygen and pulse rate readings across all skin tones.[1] Not all pulse oximeters are created equal. Many deliver unreliable readings for people with dark skin or low perfusion.[2] Made with the same medical-grade pulse oximetry technology used in Nonin pulse oximeters for patients, clinicians, and the military, TruO2® OTC delivers readings you can count on. It's inclusive pulse oximetry monitoring available over the counter—no prescription required.[1]

1 Nonin Medical, Inc. Data on File.

2 Leeb G, Auchus I, Law T, et al. The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment. EBioMedicine. 2024;102:105051. doi:10.1016/j.ebiom.2024.105051

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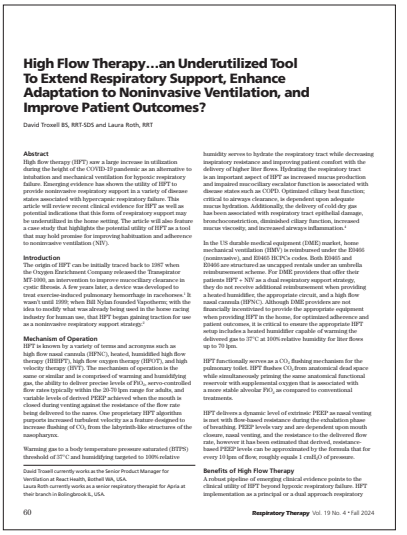
A Deeper Dive: The Respiratory Therapy Editor Takes a Closer Look at a Recent Review of Cutting-Edge Research About High Flow Therapy

This is a comprehensive follow up to the article High Flow Therapy…an Underutilized Tool To Extend Respiratory Support, Enhance Adaptation to Noninvasive Ventilation, and Improve Patient Outcomes? published in the Fall issue of Respiratory Therapy, Vol 19 No 4, pages 60-63.

This new feature from RT takes a behind-the-scenes look at how this vital piece of research was created, why it was needed and what needs to happen next to address its findings and conclusions. Our Editor wants to shine more light on the important issues detailed in this research.

Below are some questions our Editor is asking authors David Troxell BS, RRT-SDS and Laura Roth, RRT to answer to share with our readers in an easy-to-read format. Please expand on the study process and what was involved.



High Flow Therapy…an Underutilized Tool To Extend Respiratory Support, Enhance Adaptation to Noninvasive Ventilation, and Improve Patient Outcomes?

David Troxell BS, RRT-SDS and Laura Roth, RRT

Abstract

High flow therapy (HFT) saw a large increase in utilization during the height of the COVID-19 pandemic as an alternative to intubation and mechanical ventilation for hypoxic respiratory failure. Emerging evidence has shown the utility of HFT to provide noninvasive respiratory support in a variety of disease states associated with hypercapnic respiratory failure. This article will review recent clinical evidence for HFT as well as potential indications that this form of respiratory support may be underutilized in the home setting. The article will also feature a case study that highlights the potential utility of HFT as a tool that may hold promise for improving habituation and adherence to noninvasive ventilation (NIV).

Introduction

The origin of HFT can be initially traced back to 1987 when the Oxygen Enrichment Company released the Transpirator MT-1000, an intervention to improve mucociliary clearance in cystic fibrosis. A few years later, a device was developed to treat exercise-induced pulmonary hemorrhage in racehorses.[1] It wasn't until 1999, when Bill Nolan founded Vapotherm, with the idea to modify what was already being used in the horse racing industry for human use, that HFT began gaining traction for use as a noninvasive respiratory support strategy.[2]

Mechanism of Operation

HFT is known by a variety of terms and acronyms such as high flow nasal cannula (HFNC), heated, humidified high flow therapy (HHHFT), high flow oxygen therapy (HFOT), and high velocity therapy (HVT). The mechanism of operation is the same or similar and is comprised of warming and humidifying gas, the ability to deliver precise levels of FiO_2, servo-controlled flow rates typically within the 20-70 lpm range for adults, and variable levels of derived PEEP achieved when the mouth is closed during venting against the resistance of the flow rate being delivered to the nares. One proprietary HFT algorithm purports increased turbulent velocity as a feature designed to increase flushing of CO_2 from the labyrinth-like structures of the nasopharynx.

Warming gas to a body temperature pressure saturated (BTPS) threshold of 37°C and humidifying targeted to 100% relative humidity serves to hydrate the respiratory tract while decreasing inspiratory resistance and improving patient comfort with the delivery of higher liter flows. Hydrating the respiratory tract is an important aspect of HFT as increased mucus production and impaired mucociliary escalator function is associated with disease states such as COPD. Optimized ciliary beat function; critical to airways clearance, is dependent upon adequate mucus hydration. Additionally, the delivery of cold dry gas has been associated with respiratory tract epithelial damage, bronchoconstriction, diminished ciliary function, increased mucus viscosity, and increased airways inflammation.[4]

In the US durable medical equipment (DME) market, home mechanical ventilation (HMV) is reimbursed under the E0466 (noninvasive), and E0465 HCPCs codes. Both E0465 and E0466 are structured as uncapped rentals under an umbrella reimbursement scheme. For DME providers that offer their patients HFT + NIV as a dual respiratory support strategy, they do not receive additional reimbursement when providing a heated humidifier; the appropriate circuit, and a high flow nasal cannula (HFNC). Although DME providers are not financially incentivized to provide the appropriate equipment when providing HFT in the home, for optimized adherence and patient outcomes, it is critical to ensure the appropriate HFT setup includes a heated humidifier capable of warming the delivered gas to 37°C at 100% relative humidity for liter flows up to 70 lpm.

HFT functionally serves as a CO_2 flushing mechanism for the pulmonary toilet. HFT flushes CO_2 from anatomical dead space while simultaneously priming the same anatomical functional reservoir with supplemental oxygen that is associated with a more stable alveolar PiO_2 as compared to conventional treatments.

HFT delivers a dynamic level of extrinsic PEEP as nasal venting is met with flow-based resistance during the exhalation phase of breathing. PEEP levels vary and are dependent upon mouth closure, nasal venting, and the resistance to the delivered flow rate, however it has been estimated that derived, resistance-based PEEP levels can be approximated by the formula that for every 10 lpm of flow, roughly equals 1 cmH_2O of pressure.

Benefits of High Flow Therapy

A robust pipeline of emerging clinical evidence points to the clinical utility of HFT beyond hypoxic respiratory failure. HFT implementation as a principal or a dual approach respiratory

David Troxell currently works as the Senior Product Manager for Ventilation at React Health, Bothell WA, USA.
Laura Roth currently works as a senior respiratory therapist for Apria at their branch in Bolingbrook IL, USA.

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What was the primary gap in current knowledge or clinical practice that made this study necessary?
The review article on high flow therapy featuring a case snapshot was developed due to the growing interest and emerging evidence regarding the clinical utility of this form of respiratory support. Currently, the primary arena for using HFT is in the acute/ICU space for the hypoxic respiratory failure patient profile, though there is growing interest in the possible role that HFT may provide for managing chronic respiratory failure in the home setting, for example as discussed in the 2024 review article by Jacome et al.

(Cristina Jácome et al., "Effectiveness, Adherence and Safety of Home High Flow Nasal Cannula in Chronic Respiratory Disease and Respiratory Insufficiency: A Systematic Review," Archivos de Bronconeumología, Volume 60, Issue 8, 2024, Pages 490-502, ISSN 0300-2896, https://doi.org/10.1016/j.arbres.2024.05.001.)

Why do you think this gap in research or knowledge existed and needed to be addressed? Is it because the technology to address it is so new?
Although high flow therapy has been investigated as an alternative to NIV and found to be non-inferior to NIV in some patient populations, at the time of the writing of the article, no study has looked at the potential impact of a dual support strategy of HFT + NIV (HFT during activities of daily living and mask-based NIV during sleep) on habituation and adherence to NIV as well as health-related outcomes.

What do you believe will be the most significant impact of your article on clinical practice or future research in this field?
My hope is that research into the dual support strategy of HFT + NIV for chronic respiratory failure in the home setting will accelerate to inform clinicians as to the potential role and strategy for this form of respiratory support.

What additional research would you like to see conducted to further build on your findings?
My postulate is fairly straightforward, I believe that a dual support strategy of HFT + NIV has the potential to help an individual who is naïve to NIV accelerate their habituation to nocturnal NIV as well as have a positive impact on NIV adherence as compared to implementing NIV alone in the CRF patient population.

The review article was a planned first step to understand what current research exists around HFT in the home setting and to investigate whether any research exists regarding a dual strategy of HFT + NIV in the home setting. The case snapshot featuring Laura's experience with a COPD patient who used the dual approach with very positive results; including successful habituation to nocturnal NIV, might be likened to identifying a possible footprint of a signal as compared to identifying or proving that HFT definitely has a habituation signal with NIV.

A discussion is currently underway with Encore Healthcare; a well-respected software developer and data analytics

organization that provides outcome-based respiratory care programs for DME providers, to perform a retrospective data analysis of their large database of individuals prescribed home mechanical ventilatory support. The retrospective data analysis would be the first real step towards research into the dual support strategy. The concept is to analyze aggregated, de-identified, device-agnostic ventilator usage data patterns in individuals that have both HFT and a mask-based NIV mode enabled on their home mechanical ventilator versus individuals solely using mask-based ventilation. The aim of the analysis into usage patterns would be focused on whether a habituation signal exists in the cohort of HFT + NIV group as compared to the NIV-only group. If the signal exists, we would expect to see results that include longer average NIV usage patterns in the HFT + NIV group as compared to the NIV-only group. Additional subjective and objective outcome measures are also being discussed for feasibility for inclusion in the data analysis project.

The anticipated third step; pending the results of the retrospective data analysis project, would be to initiate a prospective clinical trial of individuals with a diagnosis of COPD/ CRF that are naïve to NIV so as to have more conclusive supporting evidence with better control and elimination of numerous variables.

Do any barriers exist that would impede additional research being conducted?
Currently there is no HCPCs code for use of high flow therapy in the home. If clinical research proves that HFT; as part of a dual support strategy, can help habituate a user to NIV, improve overall NIV usage patterns, and improve health outcomes, that will provide compelling evidence to CMS and other payers to allow HFT to be part of the acceptable criteria for justification of a home mechanical ventilator.

What were the key criteria for selecting the patient population in your study, and how might different selection criteria affect the outcomes?
The review article focused on chronic respiratory failure/ COPD patients in the home setting. Both the planned retrospective data analysis and the clinical research study will focus on the same cohort of COPD with CRF treated with a dual strategy of HFT + NIV or NIV only in the home setting.

How do you see your findings influencing clinical decision-making for the specific condition or treatment you researched?
If further research validates the superiority of the approach and health outcomes, then I see HFT + NIV becoming a standard ventilatory support strategy for treating COPD/ CRF in the home setting as well as having the utility of this approach investigated in other patient profiles.

How do your findings contribute to or challenge the current understanding of the disease's pathophysiology?
The case snapshot points to the potential impact of a dual support strategy of HFT + NIV, however more research is needed, which is part of the rationale for the planned second and third steps into this investigation.

What kind of feedback have you received after your study was published?
Many DME companies as well as providers seem interested in the outcomes of the planned further investigations that hopefully conclude with strong evidence that emerges out of a formal prospective clinical research trial.

A Deeper Dive: The Respiratory Therapy Editor Takes a Closer Look at a Recent Review of Cutting-Edge Research Into a T-Piece Resuscitator

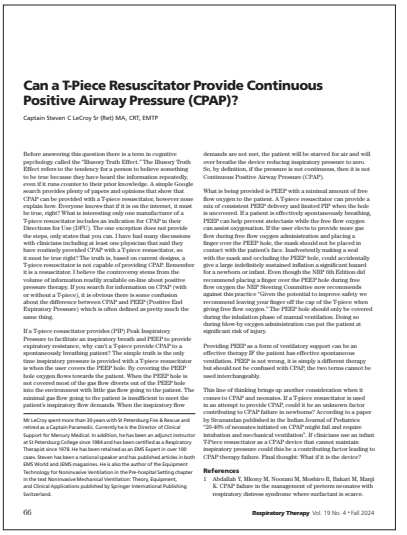
This is a comprehensive follow up to the article Can a T-Piece Resuscitator Provide Continuous Positive Airway Pressure (CPAP)? published in the Fall issue of Respiratory Therapy, Vol 19 No 4, pages 66-67.

What inspired you to write this article?
I have been a Respiratory Therapist for over 40 years and have watched the profession evolve from just following doctor's orders, to having to critically think about applying the best therapy to now where protocols limit the choices of what I can do. My current position is Clinical Director for a medical device company that focuses on respiratory products This particular topic keeps popping up and I felt it was time to educate and set the story straight.

What was the primary gap in current knowledge or clinical practice that made this paper necessary?
The increased use of CPAP for newborns and infants has increased dramatically so finding a simple and inexpensive way to provide the therapy was important and a T-piece resuscitator was something being used for resuscitation since in my opinion it's the best and safest option so why not use it to provide CPAP therapy. In theory it makes total sense. The problem is a T-piece is a resuscitator and with the current design cannot provide CPAP. The knowledge gap is compounded by the fact that some reputable organizations, guidelines and some Directions for Use recommend a T-piece for CPAP. However, they neglect to explain how.

Why do you think this gap in knowledge existed and needed to be addressed? Is it because the technology to address it is so new?
I do not think there is really a gap in knowledge when it comes to the appropriate therapy in this case CPAP. I think there is some lack of understanding that there is a difference between CPAP and PEEP, and this is evident when I have clinicians including physicians tell me CPAP and PEEP are basically the same thing and they have been providing CPAP with a T-piece for years. When in fact they have been providing PEEP to a patient that is effectively spontaneously breathing and the therapy worked. It is my belief that some patients that truly need CPAP will fail when using PEEP by itself. As far as not understanding new technology I don't think that's the case. This is not new. I think part of the problem is protocol driven therapy and the lack of critical thinking by current clinicians.

What do you believe will have the most significant impact of your article on clinical practice?
That is a really tough question. Clinical people do not like to change. What I would like to see is a new T-piece design that can not only provide resuscitation but can provide CPAP. I believe such a device would not only own the market it would improve patient care and outcomes. I would like to see clinicians challenge current practices but I am not sure the current healthcare system supports that.



Can a T-Piece Resuscitator Provide Continuous Positive Airway Pressure (CPAP)?

Captain Steven C LeCroy Sr (Ret) MA, CRT, EMTP

Before answering this question there is a term in cognitive psychology called the "Illusory Truth Effect." The Illusory Truth Effect refers to the tendency for a person to believe something to be true because they have heard the information repeatedly, even if it runs counter to their prior knowledge. A simple Google search provides plenty of papers and opinions that show that CPAP can be provided with a T-piece resuscitator, however none explain how. Everyone knows that if it is on the internet, it must be true, right? What is interesting only one manufacturer of a T-piece resuscitator includes an indication for CPAP in their Directions for Use (DFU). The one exception does not provide the steps, only states that you can. I have had many discussions with clinicians including at least one physician that said they have routinely provided CPAP with a T-piece resuscitator, so it must be true right? The truth is, based on current designs, a T-piece resuscitator is not capable of providing CPAP. Remember it is a resuscitator. I believe the controversy stems from the volume of information readily available on-line about positive pressure therapy. If you search for information on CPAP (with or without a T-piece), it is obvious there is some confusion about the difference between CPAP and PEEP (Positive End Expiratory Pressure) which is often defined as pretty much the same thing.

If a T-piece resuscitator provides (PIP) Peak Inspiratory Pressure to facilitate an inspiratory breath and PEEP to provide expiratory resistance, why can't a T-piece provide CPAP to a spontaneously breathing patient? The simple truth is the only time inspiratory pressure is provided with a T-piece resuscitator is when the user covers the PEEP hole. By covering the PEEP hole oxygen flows towards the patient. When the PEEP hole is not covered most of the gas flow diverts out of the PEEP hole into the environment with little gas flow going to the patient. The minimal gas flow going to the patient is insufficient to meet the patient's inspiratory flow demands. When the inspiratory flow demands are not met, the patient will be starved for air and will over breathe the device reducing inspiratory pressure to zero. So, by definition, if the pressure is not continuous, then it is not Continuous Positive Airway Pressure (CPAP).

What is being provided is PEEP with a minimal amount of free flow oxygen to the patient. A T-piece resuscitator can provide a mix of consistent PEEP delivery and limited PIP when the hole is uncovered. If a patient is effectively spontaneously breathing, PEEP can help prevent atelectasis while the free flow oxygen can assist oxygenation. If the user elects to provide more gas flow during free flow oxygen administration and placing a finger over the PEEP hole, the mask should not be placed in contact with the patient's face. Inadvertently making a seal with the mask and occluding the PEEP hole, could accidentally give a large indefinitely sustained inflation a significant hazard for a newborn or infant. Even though the NRP 6th Edition did recommend placing a finger over the PEEP hole during free flow oxygen the NRP Steering Committee now recommends against this practice "Given the potential to improve safety we recommend leaving your finger off the cap of the T-piece when giving free flow oxygen." The PEEP hole should only be covered during the inhalation phase of manual ventilation. Doing so during blow-by oxygen administration can put the patient at significant risk of injury.

Providing PEEP as a form of ventilatory support can be an effective therapy IF the patient has effective spontaneous ventilation. PEEP is not wrong, it is simply a different therapy but should not be confused with CPAP, the two terms cannot be used interchangeably.

This line of thinking brings up another consideration when it comes to CPAP and neonates. If a T-piece resuscitator is used in an attempt to provide CPAP, could it be an unknown factor contributing to CPAP failure in newborns? According to a paper by Sivanandan published in the Indian Journal of Pediatrics "20-40% of neonates initiated on CPAP might fail and require intubation and mechanical ventilation". If clinicians use an infant T-Piece resuscitator as a CPAP device that cannot maintain inspiratory pressure could this be a contributing factor leading to CPAP therapy failure. Final thought: What if it is the device?

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Were there any unexpected hiccups that you needed to deal with? If so, what is an example?
I did not really have any hiccups when it comes to the facts of how a T-piece functions. However, as I shared the information the push back that I received from clinicians was pretty high. For example, when I had a physician complain that the T-piece did not function correctly (the patient didn't do well) and they had to use a different device to provide manual ventilations. They were convinced that a T-piece can provide CPAP even after explaining why it does not and even showing a video of the pressure lost when attempting to do so.

How do you see your findings influencing clinical decision-making for the specific condition or treatment you researched?
In a perfect world I would like to see clinicians use patient assessment and clinical judgement on the therapies they choose. There is nothing wrong in my opinion using a device

that provides a lower flow of oxygen and PEEP to treat some patients and can be effective. They also need the option to provide true CPAP for those patients that need it. Clinicians should love options and have the knowledge to apply those options and the willingness to make the change.

How do your findings contribute to or challenge the current understanding of the therapy?
For some clinicians it turns their current thinking on T-piece resuscitators upside down. It challenges a therapy they may have used many times with success with an occasional failure that they attribute to the patient's condition deteriorating. The challenge is to select the right therapy for the right patient to avoid dyssynchrony between the therapy and the patient.

What kind of feedback have you received after your paper was published?
So far, I have very little feedback on the article. The little I have received was some push back on therapy that they have used effectively. However, after a short discussion we were in agreement that CPAP and PEEP are not the same, both therapies can be effective with the correct patient and a T-piece can't provide CPAP. The last part took some time.

What other factors may have played a role in the acceptance of a T-piece being used to provide CPAP?
There are two things that come to mind t. First, the lack of intellectual curiosity to challenge a current practice and a manufacture stating in their directions that the device can provide CPAP. But as I said in the article, they do not provide the steps on how to do it. I would think that would raise some flags.

How do you think the article contributes to current conversations on the topic?
I think this article challenges the current thinking on the topic. It opens up a topic that therapists thought they knew the answer and may have applied on numerous occasions with success and on some occasions failed to work.

What do you hope readers take away from this article?
Obviously, a better understanding of the use of a T-piece resuscitator, what it can and can't do. But the bigger picture is to challenge current thinking, use critical thinking to challenge the norm and make decisions based on what is best for the patient.

Practical Use of Transcutaneous CO_2 Monitoring in the NICU

This article is based upon the content of a webinar hosted by Anne M Geistkemper, MSc, RRT, RRT-NPS, Neonatal-pediatric section manager of respiratory care services at Rush University Medical Center and instructor in the Department of Cardiopulmonary Sciences at Rush University.

Summary
Anne M. Geistkemper, MSc, RRT, RRT-NPS discusses the practical applications of transcutaneous CO_2 monitoring in the NICU, its integration into neonatal care practices, and the evolution of this technology's adoption in the Rush University Children's Hospital NICU.

The following has been adapted from its original presentation for clarity and brevity.

Why Use Transcutaneous CO_2 Monitoring in the NICU?

The NICU admission process is fairly invasive for infants; lights, sounds, sticking for lab tests. So, the less invasive we can be within the NICU, the better. If we can introduce something that minimizes invasiveness, especially in those first 72 hours of a neonate's life, it's a valuable addition to our care regimen. Transcutaneous CO_2 monitoring, because it's noninvasive, is one such addition.

Transcutaneous monitoring provides continuous, real-time measurements of CO_2, allowing us to closely observe changes and trends. This becomes crucial when considering hypercapnia (elevated CO_2 levels) and hypocapnia (low CO_2 levels). Research has demonstrated that both hypercapnia and hypocapnia heighten the likelihood of injury to the brain, including intraventricular hemorrhage (IVH).[1] Because of this risk, we want to make sure that we're closely monitoring CO_2 to maintain levels within a safe range. Transcutaneous monitoring facilitates continuous monitoring of CO_2, providing greater visibility to support its effective management.

Clinical Applications of Transcutaneous Monitoring for Neonates

Reducing Iatrogenic Blood Loss

The most common reason for blood sampling is arterial blood gases (ABGs), which account for about 47% of neonatal blood samples.[2] One study found that neonates lost approximately a third of their blood volume within the first month of life, which is significant especially if you consider micro-preemies.[3] This blood loss can have implications for things like anemia and infection.[4]

At Rush, we're frequently getting labs, especially in the first 36 to 72 hours of life, as we strive to stabilize neonates and adjust ventilator settings in a timely fashion. If we can reduce the frequency of these blood gases, while also improving the monitoring of ventilation, that's ideal—something that transcutaneous monitoring can help us accomplish by providing continuous visibility into CO_2.

Rush University Children's Hospital NICU: An Overview

- Part of a large teaching hospital
- 60-bed level III NICU
- 700 admissions per year
  17% are very low birth weight (VLBW) infants
- Unit comprised of neonatologists, fellows, advanced practice providers (physician assistants and nurse practitioners), nurses, respiratory therapists, and ancillary staff

Continuous Monitoring on Mechanical Ventilation

Titrating mechanical ventilation is important for neonates due to their immature respiratory system. This is especially vital during the "honeymoon period," a well-known concept in the NICU, particularly for micro-preemies. It refers to the period following their birth, often after they've been given a surfactant, where settings are titrated down to minimize support. However, they can abruptly exit this honeymoon phase due to a large cytokine release, requiring prompt adjustment of settings to ensure adequate ventilation.

Because a neonate's status can constantly change, frequent adjustments are often needed. In these cases, having the option to continuously monitor CO_2 can be extremely beneficial. Instead of depending on scheduled blood gas draws to drive care decisions, continuous transcutaneous monitoring can offer greater visibility for enhanced titration support. The goal is to decrease our use of the ventilator while ensuring proper gas exchange; transcutaneous technology can give us continuous visibility into ventilatory status to help support this goal.

Continuous Monitoring on High-Frequency Oscillatory Ventilation

High-frequency oscillatory ventilation is highly effective in removing CO_2, but consequently, there's the potential for rapid fluctuations. We want to prevent these fluctuations as they can impact an infant's cerebral blood flow, which can put their brain at risk for injury, including IVH.[1] The use of transcutaneous monitoring is helpful because we can closely monitor CO_2 and catch these fluctuations, allowing for proactive management of levels in real time.

Anne M. Geistkemper, MSc, RRT, RRT-NPS, Neonatal-pediatric section manager of respiratory care services at Rush University Medical Center and instructor in the Department of Cardiopulmonary Sciences at Rush University.

Reducing Neonatal Pain

Research has shown that in newborn infants, a high number of early life skin breaks correlate with worse mental development when examined at both 8 and 18 months.[5] Furthermore, more frequent invasive procedures early in life have been associated with decreased white matter at 7 years old.[6]

We're drawing labs, we're getting gases, and maybe even placing lines. What can we do to help reduce the frequency of painful stimuli?

To minimize pain, we can employ noninvasive methods like transcutaneous CO_2 monitoring. This approach offers continuous CO_2-level visibility, helping to reduce the need for frequent heel sticks. There are also some developmentally appropriate strategies that can help reduce pain and stimuli. This includes swaddling, prone positioning, kangaroo care, or utilizing anesthetic cream or short-acting systemic analgesia for skin-breaking procedures.

Managing Specific Disease Processes

Table 1 outlines recommended CO_2 targets for neonates based on their specific disease process, as well as recommended interventions for neonates experiencing severe hypocapnia or severe hypercapnia. The use of transcutaneous CO_2 monitoring is valuable as we address the unique needs of each patient, providing enhanced titration support to maintain CO_2 levels within the targeted range.

When effectively managing CO_2, observing a reduction in CO_2 levels throughout making adjustments to ventilator settings is important. Transcutaneous monitoring provides instant visualization of the impact of our titrations. We can see the changes happening, and that can help guide effective titrations and drive care.

Special Considerations

Edema

Edema can lead to altered capillary hemodynamics and cause an increase in the blood-skin barrier due to excess fluid. As a result, transcutaneous readings can be inaccurate, making it important to avoid edematous areas when monitoring. Avoiding areas of edema can be challenging, particularly for infants who are fluid-overloaded. In these cases, however, we can still leverage transcutaneous monitoring to track the trend of CO_2 over time rather than using it for precise values.

Premature Skin

For neonates, especially in 22-23-weekers, the skin is thin and fragile, something we want to make sure we consider when using our transcutaneous monitor. To prioritize skin integrity, we should ensure the sensor is at the appropriate temperature (41°C) and that we're not leaving it on for too long (no more than 8 hours at a time). While the transcutaneous monitor will automatically apply appropriate settings, it is crucial to be aware of this consideration, so you can promptly identify deviations and take action if needed.

Note	It is recommended that the site time be evaluated and adjusted more frequently on premature skin to reduce the risk of skin injury.

Shunting and Low Perfusion

Correct sensor placement is crucial for patients with a shunt. As per AARC Clinical Practice Guidelines, it is recommended to place the transcutaneous sensor on the same side as a shunt.[7] In these cases, arterial sampling should also be done on the same side, as having these two monitoring methods aligned will allow for an accurate correlation.

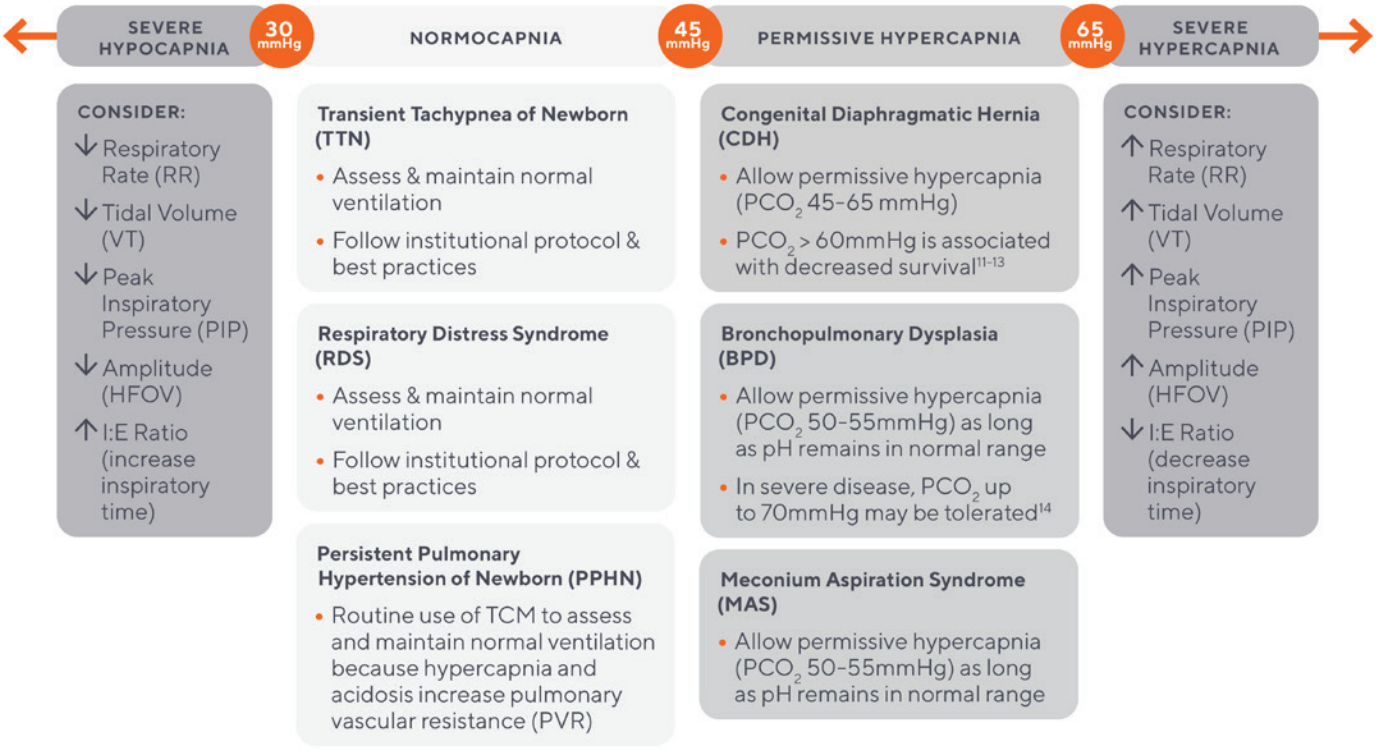

Table 1. Recommended CO_2 targets for neonates based on disease process and recommended titrations of ventilatory settings for severe hypocapnic and severe hypercapnic infants

Low perfusion may cause transcutaneous CO_2 values to be falsely high. In this situation, similar to the case of edema, it may be more helpful to utilize the monitor to trend CO_2 in order to observe patterns and track progress during care.

Hypothermia

Hypothermia is something we see often in NICUs, especially with hypoxic-ischemic encephalopathy (HIE) or post-cardiac arrest patients undergoing cooling therapy. HIE, hypovolemia, reduced myocardial contractility, and bradycardia can all lead to decreased cardiac output. Consequently, if the region experiences hypoperfusion, it is important to note that the correlation between the transcutaneous and arterial CO_2 may be poor. In this situation, prioritizing establishing a correlation between the two values, rather than focusing on the exact values, becomes more clinically valuable. Again, this can be used for tracking the trend in CO_2 throughout care.

AARC Clinical Practice Guidelines

The AARC Clinical Practice Guidelines (shown in part in Figure 1) provides recommendations for the effective use of transcutaneous CO_2 monitoring in clinical care.[7] If you're not fully utilizing your transcutaneous monitors, haven't developed guidelines or implemented it into any protocols, or don't have devices at all, the AARC clinical practice guidelines can guide you. I encourage you to develop a process for your NICU. It can be difficult to get started, but aligning with the AARC guidelines is going to create a standard practice. By adopting this approach, you can foster growth within your team, encouraging increased utilization of the technology. We have a great opportunity especially as respiratory therapists, to help drive care in an efficient, noninvasive manner.

TCM 3.0 SETTING

TCM may be performed by trained personnel in a variety of settings that include, but are not limited to hospitals, extended care facilities, and patient transport. It is utilized in the following specific clinical settings to determine the presence of hypoventilation or respiratory depression:

3.1 Mechanical ventilation, including conventional modes of ventilation, high-frequency ventilation, steady state high frequency jet ventilation, and noninvasive ventilation.

TCM 4.0 INDICATIONS

The use of TCM is indicated in patients who either lack arterial access or have the need for continuous monitoring of oxygen and carbon dioxide with minimal blood draws. TCM allows the assessment of:

4.1 adequacy of oygenation and/or ventilation

4.2 response to diagnostic and therapeutic interventions, as evidenced by $PtcO_2$ and/or $PtcCO_2$ values

4.2.1 Weaning and extubation decisions may be made based on $PtcCO_2$ measurement alone.

Figure 1. 2012 AARC Clinical Practice Guidelines for Transcutaneous Monitoring of Carbon Dioxide and Oxygen[7]

Benefits of Transcutaneous CO_2 Monitoring in the NICU

Transcutaneous CO_2 monitoring offers a noninvasive method to continuously analyze CO_2 levels in all modes of ventilation. With continuous monitoring, we're able to get real-time values for instant visualization of a patient's response to care strategies. This newer technology preserves skin integrity for delicate patients and helps reduce the need for frequent blood draws.

Additional benefits of transcutaneous CO_2 monitoring in the NICU:

- Provides accurate measurements
- Compatible with any ventilation strategy
- Supported by AARC guidelines
- Supports cost reductions
- Supports neuroprotective care
- Simplifies workflows
- Enables lung-protective ventilation strategies

Tips for Selecting a Monitoring Site

Choosing the ideal site for transcutaneous monitoring depends on your patient. The main determinant for location is perfusion, so the sensor is often placed on the thighs. This is a particularly good choice when swaddling, as there's less of a risk of the sensor falling off. However, in a 22-, 23-, 24-weeker, you might not have the real estate available in these areas, given the presence of a peripheral intravenous line (PIV) and/or other lines they may have.

In the past, we utilized the upper chest and thigh areas at our institution, but encountered challenges in achieving good correlation with these sites. In discussion with the manufacturer, we were advised to try the forehead. While some caregivers initially had concerns, once everyone embraced the idea, we saw remarkable improvements.

In most scenarios, the forehead is well-perfused, making it a great location for monitoring. For us, we keep our preemies midline for 72 hours, which also means there's typically nothing obstructing this area. And when they are being repositioned, we don't have to worry about the sensor as much, and whether there will be pressure placed on it. It's an easy-access area where we found much better correlation, and for my staff, it was less stressful to manage the sensor and troubleshoot appropriately. If you're not using the forehead yet, I challenge you to try it.

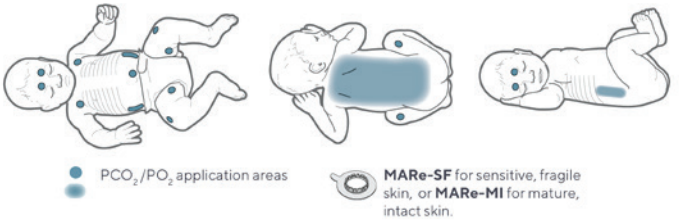

Figure 2. Recommended sensor sites for transcutaneous monitoring include the thorax, the abdomen, the back, the area low on the forehead, the temples, and the inner or anterior aspect of the thigh

Using Contact Gel: How Transcutaneous Monitoring Use Transformed at Rush

Our facility got by without using contact gel with our transcutaneous sensors for a long time. However, we were having correlation issues. We were experiencing frequent sensor errors and doing a lot of troubleshooting.

We learned from our clinical specialist that by using normal saline in place of contact gel, it meant that we were putting salt on an electrode—no wonder our membranes were struggling. When we replaced the saline with contact gel, we found our sensors were providing much better correlation. In addition, it was more cost-effective because our machines required less maintenance and troubleshooting, and we didn't have to replace membranes as frequently.

Present day, our correlation has improved significantly, and I attribute that to using contact gel, as well as using the forehead as a monitoring site. Before, we owned 6 devices and had an average of about 3-4 in use. Now, while we still own 6, we are renting additional units because our usage has increased after gaining the trust of not only the RTs, but also complete medical teams. If you are struggling with usage, I encourage you to reach out to your vendor's support team to see if there is any education to help you along the way.

The Five S's: Troubleshooting Tips for Your Transcutaneous Monitoring System

When it comes to troubleshooting your transcutaneous monitoring device, I like to refer to the "Five S's": sample, site, seal, sensor, and status. When you're trying to figure out why your transcutaneous readings aren't correlating as well as you'd like, figuring out which issue you're dealing with can help you troubleshoot appropriately.

Sample	Site	Seal	Sensor	Status
Record the $tcPCO_2$ value when you draw the sample, not when the results are read. Verify proper lab draw technique and operation of blood gas analyzer.	Check for external pressure on the sensor. Check perfusion at measurement site. Sampling site and sensor should be on same side of shunt.	Verify attachment ring is secure on the skin. Use 1-2 drops of Contact Gel during application. Ensure sensor is clipped into the ring.	Verify correct sensor temperature. Check the quality of the sensor membrane. Check when the sensor was last calibrated.	Shock, sepsis, and edema can impact the local perfusion. Consider the effect of vasoactive medications. Decreased perfusion may cause falsely high $tcPCO_2$.

Table 2. "Five S's" of troubleshooting a transcutaneous monitoring device: sample, site, seal, sensor, and status

Integrating Transcutaneous Monitoring Into NICU Protocols

At Rush, we implemented transcutaneous monitoring within our unit protocols, not only to increase the usage of the devices that we bought, but also to showcase its value and get everybody on the unit more comfortable with the technology.

If you don't have protocols in your unit yet, that's okay. You can use the AARC Clinical Practice Guidelines to start utilizing the technology and building trust. If you do have protocols, there are simple ways to implement the usage of transcutaneous monitoring in your unit, just by adding it to your existing processes.

NICU Conventional Ventilation Protocol

As part of our NICU conventional ventilation protocol, patients who are born at less than 35 weeks get a transcutaneous sensor placed on them for the first 72 hours of life, which allows us to start trending our gases with our $tcPCO_2$. Because there is a high volume of gases and labs being drawn in the first 24 to 36 hours, we're able to lay a good foundation for our correlation. This protocol also gets everybody more comfortable with transcutaneous monitoring in the NICU.

High-Frequency Jet Ventilator Protocol

As part of our care goals for our high-frequency jet ventilator protocol, any patient who goes on a jet ventilator must have a transcutaneous monitor.

Other Cases to Integrate Transcutaneous CO_2 Monitoring

Other cases where we use transcutaneous monitoring are BPD and noninvasive ventilation (NIV). While we don't necessarily have these protocolized yet, we still utilize transcutaneous monitoring to continuously monitor ventilation in these patients.

- **BPD |** Although gases are not frequently obtained from patients with BPD, their status can change quickly. These patients are often sweaty, which can make finding the proper transcutaneous sensor placement difficult. However, transcutaneous monitoring is a useful tool for this population, providing continuous CO_2 visualization when gas sampling is infrequent.
- **NIV |** Patients on noninvasive mechanical ventilation are often teetering on the verge of needing an escalation of care, perhaps requiring intubation. Or, they may have just been extubated, and there is uncertainty about their ability to thrive. To be able to have constant CO_2 monitoring in these cases is helpful in guiding our management strategies.

Summary

Transcutaneous monitoring provides clinicians with a noninvasive method to monitor CO_2. This isn't just beneficial for patients in terms of lessening pain; it has the potential to yield benefits for your hospital in terms of cost-effectiveness by supporting the reduction of blood draws. And importantly, as a respiratory therapist, it offers valuable insights into the efficacy of ventilation strategies, which helps guide care.

The more you use transcutaneous monitoring, the more comfortable you're going to be and hopefully the better you'll become at it. In the Rush University Children's Hospital NICU, we already had active protocols, so we took the opportunity to integrate transcutaneous monitoring. This not only got our staff more comfortable using it, but also allowed our bedside caregivers to begin to trust the technology and rely on it during care.

As we continue utilizing transcutaneous CO_2 monitoring, keeping up with current research remains valuable. However, actively engaging with other facilities, who are utilizing devices even more than we are, has also proven significant for our hospital. If you're looking to embrace this technology, or increase its usage, consider reaching out to your colleagues at other hospitals to gain valuable insights on successful implementation. This has played a vital role in our adoption of transcutaneous monitoring in the NICU, and our progress towards utilizing its fullest potential for our patients.

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cost of care by taking noninvasive monitoring to new sites and applications—and one of the ways we achieve that is through continued innovation. With Radius VSM, clinicians have the power of cutting-edge technology in a modular, scalable design that's both easy to use and comfortable for the patient. The applications are virtually limitless, and I cannot wait to see how the use of this technology is expanded to enhance patient safety not only in the emergency department, but across the continuum of care."

Nirsevimab Resistance Mutations Rare in RSV, Study Shows

Nirsevimab (Beyfortus), an antibody targeting respiratory syncytial virus (RSV), is indicated for newborns and infants to prevent bronchiolitis. Available since September 2023, its widespread use may lead to resistance mutations. However, according to the French POLYRES study on prospective monitoring of nirsevimab, published recently in *The Lancet Infectious Diseases*, these mutations are very rare at this stage. "The low prevalence of nirsevimab resistance mutations in treated patients is reassuring. However, escape mutations have been observed in a few RSV-Bs from treated patients, prompting caution and highlighting the importance of active molecular surveillance in the context of future wider global use of nirsevimab," commented Slim Fourati, MD, PhD, head of the Virology Unit at Henri Mondor Hospital, Paris-Est University and INSERM U955, Paris, France, and lead author, in a press release. The 2023-2024 season marked the first preventive immunization campaign against RSV with nirsevimab, which has shown a positive impact on preventing bronchiolitis in infants. Nirsevimab targets a specific epitope on the F fusion protein located on the surface of RSV that is involved in viral replication, thereby blocking the virus. Because RSV is a variable virus, there is a theoretical risk of emerging variants with resistance mutations to nirsevimab, even without antibody-driven selection pressure.

OxiWear Receives FDA Clearance as a Medical Device

OxiWear, a pioneering company in wearable health technology, is proud to announce that it has received clearance from the US Food and Drug Administration (FDA) for its cutting-edge oxygen data collection device. This certification marks a significant milestone in OxiWear's mission to revolutionize patient care and enhance the quality of life for individuals with chronic diseases. OxiWear is a cutting-edge ear pulse oximeter designed for continuous, real-time measurement of blood oxygen saturation (SpO_2) and pulse rate. This device provides unmatched accuracy and convenience while still and during motion, across all skin types, within clinical and home environments. Unlike traditional methods, OxiWear ensures that patients and healthcare providers have constant access to important oxygen saturation data. The continuous data collection capability is vital for the early detection of low oxygen levels, offering prompt haptic and emergency messaging alerts that can potentially save lives. "We are thrilled to receive FDA clearance for our OxiWear device," said Shavini Fernando, CEO of OxiWear. "This validation from the FDA underscores the rigorous testing and development that our team has undertaken to ensure the highest standards of safety and efficacy. Our goal is to provide a reliable, user-friendly solution that empowers patients and supports healthcare professionals in delivering optimal care." OxiWear's device is designed with patient comfort and ease of use in mind. The
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When the Way to the GI Tract Is Through the Nose: A Primer on Nasal Enteric Feeding Tubes

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. The webinar adapted below was presented by Linda Lord and Lauren Bruwer of the Cleveland Clinic in Cleveland, Ohio.

Tracy Cook: Hello, everyone and welcome to our webinar. My name is Tracy Cook with SACS Healthcare Communications and I'd like to show our audience how you can send in questions throughout our webinar. Our speaker will answer as many as possible at the end of the presentation, please type your questions into the questions box.

I'd like to introduce our moderator, Linda Lord. Linda Lord is a nurse practitioner and has practiced in enteral nutrition and perinatal nutrition support for over 40 years at the University of Rochester Medical Center. She has inpatient, outpatient and research experience, most recently for 30 years in the nutrition support clinic following adult individuals receiving home EN and PN. She just began a new role as a nutrition support educator at her medical center. In her nutrition support practice career, she has over 50 publications and given numerous lectures, webinars, continuously reviewed articles and peer-reviewed journals and contributes to the standards of practice. ASPEN has awarded her the Distinguished Nutrition Support Nurse Service Award. Linda, welcome.

Linda Lord: Thank you, Tracy, for that kind introduction. The title of our webinar today is When the Way to the GI Tract is through the Nose: A primer on nasal enteric feeding tubes. And speaking on this very timely topic is my colleague and one of the authors of this paper, Lauren Bruwer. So, Lauren Bruwer is an advanced practice clinical nurse specialist working in the Digestive Disease Institute at the Cleveland Clinic in Cleveland, Ohio. Lauren specializes in management of adult patients with enteral nutrition access devices. At the Cleveland Clinic, she works with a team of nutrition support nurses to bring safe enteral access for patients in the hospital from the emergency room to the critical care units.

Additionally, she sees patients in an outpatient enteral nutrition clinic where she provides clinical expertise and performs enteral device exchange, removals and management for patients with enteral feeding tubes. She is a clinical leader who is passionate about patient safety and elevating clinical practice related to the care of the patient with a feeding tube. Lauren is a highly sought-after speaker. She has presented on clinical nutrition as well as other critical topics regionally and nationally.

If you would like to participate in this feature, as a company or health-care provider, please contact Steve Goldstein at s.gold4@verizon.net. A video link to the webinar can be found here https://www.perspectivesinnursing.org/gi-tract.

The speaker disclosed no financial relationships associated with this presentation. This activity has been approved for one contact hour of Continuing Education. At the end of this webinar, you can obtain those Continuing Education credits. The URL will be provided at the conclusion of this webinar. The accreditation statements are here and this activity is supported by an education grant from Dale Medical Products Incorporated. And now, I will turn the presentation over to my friend and a fellow passionate and compassionate colleague of mine, Lauren Bruwer.

Lauren Bruwer: Thank you very much, Linda, for that kind introduction. It's really a great privilege to be able to speak to you all about this incredibly important topic and one which I'm very, very passionate about. Our learning objectives today are to review the anatomy associated with feeding tube placement. To identify clinical indications for nasal enteric feeding tube placement, safe placement technique and verification of the anatomical location of the tube tip and to discuss management of and complications associated with nasal enteric feeding tubes.

So let's talk a little bit about the significance. Approximately 189,036 pediatric patients, 248,846 adult patients, for a total of 437,882 patients receiving enteral nutrition via feeding tube for sustainment of life. That's a lot of people relying on enteral nutrition and enteral nutrition access devices. Malnutrition, however remains very prevalent amongst hospitalized patients and those in long-term care facilities. And so, we've seen an appreciable increase in the use of enteral nutrition in both the hospital and in the home setting. And with an ever expanding enteral nutrition footprint comes the increased potential for safety events associated with these tubes.

Now, not all of these patients have nasal enteric feeding tubes, which is truly the focus of our discussion today. Many of them probably have percutaneous feeding tubes; however, most of these patients highly likely started out with a nasal enteric or nasogastric feeding tube. So let's shift our focus to nasal feeding tubes. On the screen in front of you, you have a variety of images that are showing different nasal enteric feeding tubes. To the left of your screen, we see a large bore nasogastric or orogastric, also known as a Salem Sump tube. These tubes truly are designed as a drain. Now, they may be used for feeding as well and very convenient to have the access if it is readily available to switch from using it as a drain or a decompressive device to one that we can feed through and administer medications through.

These tubes, however, are not usually used for post-pyloric feeding, which means they usually are only used for gastric feeding, which means the tip of the tube remains in the patient's stomach. They may be placed either through the nose or the mouth. Note that we would only place these tubes through the mouth usually in the intensive care setting where the patients are usually intubated on a ventilator and oftentimes, have a bite block in the mouth to prevent them biting down on the tube.

Oral placement of these tubes, both the large bore and the small bore feeding tubes is actually contraindicated in awake patients with teeth, obviously because there is a risk for them biting down on the device, biting through the device and that would be quite problematic. Our large bore feeding tubes come in a large French size, so usually, a 14, 16, 18, 20 French size. And if you have a look at the image on the left-hand side, hopefully, you can see that there are multiple little side holes on this tube which allow for very good drainage and decompression of the stomach. Additionally, there is an air inlet device attached to this feeding tube and that's depicted here with that little blue tube that you see attached to the feeding tube. The air inlet device is very important for decompression or drainage purposes because it allows air to filter back into the stomach when we attach these tubes to suction for decompression so that we don't create a complete vacuum in the stomach and that's what makes them effective as a drainage device.

Now, oftentimes, you will see these tubes for feeding, especially in the critical care environment because the tubes are often placed when the patients are intubated and put on a ventilator to prevent a gastric insufflation during that intubation procedure, we can decompress the stomach and then a day or two later, even sometimes within a couple of hours when the patient is stable, we can use this for feeding. It's a very convenient access, but it's not intended for long-term feeding and it's not designed again as a feeding tube, more designed as a drain.

The other two images show you these small bore tubes that are specifically designed for feeding. These are small French size 6, 8, 10, and 12. We see the use of a 10 and 12 French tube more readily in the adult patient population and these were truly designed for feeding. There's one small fenestration or opening at the end of the feeding tube and they may also be used for medication administration as well, and I will go into that a little later in the discussion. These tubes may be placed either into the stomach or into the small bowel, so these can be used for both gastric and post-pyloric feeding.

Important to note, small bore feeding tubes are intended for short-term use. If we're going to be feeding a patient through a nasal enteric feeding tube, we are looking at short-term use of about four to six weeks. If the patients require feeding beyond the four to six week period, we really should be looking at a tube transition plan or discussion about a more long-term form of access in the form of a percutaneous feeding tube.

So what does this look like from the inside? I like to always say it's such a privilege for us to be able to view our patients from the inside out, and so I love to look at imaging and radiographic views of my patients and their devices. It really does tell you a lot. On the left-hand side of your screen is actually an X-ray image of what we call the large bore nasogastric orogastric Salem Sump feeding tube and again, designed as a drain.

You'll note that there's a radiopaque stripe that runs the length of the tube and I'm going to use my little... Oops, I'm sorry, going the wrong way, my little arrow to show you that in that radiopaque stripe, you'll see that all of a sudden, there's a little break. And the little break in the radiopaque stripe is right in the middle of the side hole of that feeding tube. Now, why is this important? Again, just to help you guys understand, this tube is designed as a drain and so we want to make sure that the drainage holes for this tube are all within the stomach. That is the area of the anatomy that we want to be draining. And so when we are looking at these tubes on radiographic view, we want to be sure that the side hole is below the level of the diaphragm because that tells us the tube in its entirety is safely in the patient's stomach.

If the side hole is above the level of the diaphragm, that portion of the tube is still in the esophagus. And then if we start using this tube as a feeding device, we run the risk of aspiration because that side hole is still within the esophageal anatomy. It's not safely down in the stomach below the GE junction, below that lower esophageal sphincter where the risk of aspiration is going to be lower. So very, very important when you look at imaging that you're looking at the tube in its entirety and making sure that those side holes are all below the level of the diaphragm.

You'll note on the right-hand side of your screen the small bore nasal enteric feeding tube. Here, the entire tube is radio opaque. So you can see the entire tube show up on the X-ray. So you see the passage of the tube from just below the esophagus where it enters the stomach, makes a loop through the stomach, drops down into the duodenum, and then the tip of the tube in this particular image is actually located in the proximal jejunum.

So you can see that whole tube shows up on X-ray versus on the large ball where you just see that very thin little radio-opaque stripe that runs the length of the tubing. Now, it is very important that imaging includes always, the tip of the feeding tube. If the film is clipped up too high and you can't see where the tube terminates, then it truly is advisable to repeat the X-ray to make sure that the entire pathway of the tube through the GI anatomy can be visualized on the X-ray film so that we can say with certainty where the tip of the tube lies within the GI anatomy.

So let's do a quick anatomical review. Nasal enteric feeding tubes pass through the naris, in the nose, into the oropharynx and into the esophagus. From there, the tubes may terminate or end in either the stomach and we would refer to that as a nasogastric tube. And nasogastric tube, if you're looking at your anatomical mile markers, usually, the measurements that we are looking at for the stomach 55 to 65 centimeters thereabouts, usually in the average size adult, indicates the tube is usually within the gastric anatomy and that is indicated by the number one on the image in front of you. The tube can then move from the stomach through the pylorus and into the duodenum and we would refer to this as a nasal duodenal tube and usually, the nasal duodenal tube, anatomical mile markers anywhere between 70 to 85 centimeters and that is shown here by the number two on the image in front of you.

And then beyond that and beyond the ligament of Treitz, we're looking at the tube tip terminating in the jejunum, which is that second portion of the small bowel. And we would refer to this as a nasojejunal feeding tube and usually, beyond 85 to 95

centimeters thereabouts. If we're placing this tube at the bedside, we're looking at a nasojejunal placement depicted there by the number three on your screen. So very important to note the anatomy of the patient. Very important to do H&P review of your patients prior to placing the nasal feeding tube so that you can anticipate any variations in the norm from anatomy, especially if they've got surgically altered GI anatomy.

Okay. So outside of the GI anatomy, also very important to include a review of the anatomy that we use to secure the feeding tube. So once the tube is in place, it really does need to be adequately secured in place to prevent incidental dislodgement of the feeding tube. We really only have one or two anatomical choices in this case and we use the nose to externally anchor the tube in place using a tape securement device. There are some challenges with taping the feeding tube in place and we will speak a little bit more to that a little later in my presentation. And then our second option for anchoring the tube is with more of an internal anatomical anchoring structure and we can anchor the tube behind the vomer bone.

And so this is internal nasal anatomy as depicted by the image on the right-hand side of your screen. The vomer bone is shown in green on this particular image and right behind the vomer bone, there is a natural little anatomical space where the two nostrils communicate with one another. And using this natural anatomical space, we can anchor the feeding tube very securely in place. The vomer bone is very strong, it ossifies at birth and can withstand up to about 35 pounds of breaking pressure. And so you really have to tug on a feeding tube pretty hard in order to do damage to those structures in the back of that space. It's usually also a very sensitive area. And so if you think about yourself, if you've ever taken a bump to the nose where suddenly, it's very painful and your eyes start to water, kind of the same sensation if a patient tugs on a feeding tube and it's anchored behind the vomer bone, uncomfortable. And so the tendency is to let the tube go. So, it is a little bit of a deterrent to patients pulling on their feeding tubes when they're securely anchored behind the vomer bone.

All right. So let's think about some clinical indications for enteral feeding. Historically, many, many years ago when oral intake was not possible or adequate, wooden or glass tubes were actually used to feed patients and administer liquids. This method clearly was very unsafe. You can just imagine a glass tube or a wooden tube going into the GI anatomy, not something that I would like to volunteer for, that's for sure. It was extremely unsafe, extremely difficult and was truly considered a last result. In the 18th and 19th centuries, equipment remained quite primitive and our nutrition options were limited, really, to broth, milk and wine, so nothing like administering wine through the feeding tube, but options were limited. And then later in the 19th century, it was actually believed that the majority of nutrition was absorbed in the colon. And so rectal feeding was actually fairly common.

Fortunately today, medical technology advancement now affords the opportunity for us to select from a variety of access devices and different formulas for feeding. So, some of our indications for enteral feeding, first of all, oral intake is always going to be optimal, but it's not always going to be an option, for some of the following reasons. Sometimes oral intake is impossible. Think of those patients in the ICU that are intubated. They have large ET tubes in the oral cavity, they're oftentimes sedated. Oral intake would not be possible for these patients and neither would it be safe.

Second of all, sometimes oral intake is just inadequate. We have poor appetite associated with either acute or chronic medical conditions or treatments for medical conditions. And oftentimes, and we're all guilty of this, prolonged NPO status while the patient is in the hospital. And then third is, sometimes oral intake is unsafe. So patients with dysphasia, patients that have had some form of neurological insult, be it stroke, traumatic brain injury, brain surgeries, even sometimes, an anterior approach to cervical spine surgeries, those patients can develop pretty significant dysphasia, which makes oral intake unsafe because of the risk of aspiration.

And then for some folks, oral intake is not an option because of intractable nausea and vomiting. And then for other patients, there is just such a major, major protein and energy requirement that it is almost physiologically impossible to keep up with the demands, the metabolic demands required for healing or navigating those certain illnesses like burns, massive burns, huge amount of protein loss, major trauma, significant wounds where we require a lot of healing. And then sometimes, just in critical illness. If you think of our patients, again, in the hospital setting, just a huge, huge metabolic demand on the body when we're in a state of critical illness. And it makes keeping up with the protein and energy requirements during those times a full-time job. Oftentimes, patients just can't do it. And so in these cases, enteral nutrition is truly preferred over intravenous or parenteral nutrition, but only in patients with a functional GI tract. So the focus of this discussion really is patients that are amenable to enteral feeding because they have a functional GI tract.

So some of the considerations that we do need to take into place and some things we need to take into consideration when we're talking about placing a nasal enteric feeding tube and starting patients on feeding through a nasal tube are the clinical and nutritional status of the patient, diagnosis and prognosis, the risks and benefits for the patient, quality of life considerations. Are there any ethical considerations? Patient and family must be included. Shared decision making is really, really required, especially if patients are going to be going home with enteric feeding tubes. And, of course, cost and reimbursement.

Baseline assessment really needs to include a very detailed diet history and the risk assessment for refeeding syndrome. And we will talk a little bit more about refeeding syndrome a little further on in my presentation. We must consider the underlying pathology. What is driving the need for the supplemental enteral nutrition and what is the prognosis for resumption of oral intake if we see this patient through this period where they need supplemental feeding through the tube? What are the risks and what are the benefits related to enteral feeding for this patient? And of course, quality of life is a huge consideration. Nasal enteric feeding tubes are visible. You look more sick when you have a tube coming out of your nose. How active is this patient? Once they're through with their hospital course, what do they like to do when they're at home? Do they work? Do they operate heavy machinery? Is there the risk of this tube snagging on something that would prohibit them from going back to work and doing their job and earning an income?

Are they in a skilled facility and is the staff at the skilled facility adequately trained to manage the nasal enteric tube? And

are the patients going home? And if they are, are they able to independently manage a nasal tube or do they have a family member to support them through the use of this feeding tube? Does the patient have an underlying condition that maybe we need to take some ethical considerations into account where mental status is waxing and waning is certainly one where feeding through the tube can be very, very tricky and also plays into cost and reimbursement. There are some certain conditions that are excluded from reimbursement from some of our payers related to the underlying diagnosis. Dementia and waxing and waning mental status is one of those. And so if this is something that's going to be cost prohibitive to a patient or a family because there's a fixed income, that really does need to be taken into consideration.

And then, of course, we must consider our contraindications. Does this patient have an accessible GI tract or is it inaccessible because there's a tumor, stricture, paraesophageal hernia? Is this a non-operative mechanical obstruction in the upper GI tract? A circumferential esophageal tumor for example, that would prohibit the passage of the tube down into the GI tract? Is there hemodynamic instability? And is this patient at risk for an ischemic bowel if we do start feeding them through an enteral feeding tube? Do they have severe short bowels at less than 100 centimeters of small bowel remaining where absorption is really not going to be possible or optimal for this patient? And would we rather consider parental nutrition? Do they have severe coagulopathies or active GI bleeding which would not be conducive to us placing a nasal enteric tube? And is there an anterior breach to the base of skull which would make passage of the tube through the nasal anatomy unsafe? These all contraindications that we must, must, must take into consideration when placing a nasal feeding tube.

So what are our options for nasal enteric feeding tube placement? There are several, and I'm going to just briefly give you an overview of each. Blind placement is the placement of a nasal enteric feeding tube through the nose into the GI anatomy without the use of any navigation system or guided technology to show us the passage of the tube through the GI anatomy during the placement procedure. Blind placement of the tube is associated with increased incidence of tube dislodgement into the respiratory anatomy. And if you have a look at the X-ray image showed on the left-hand side of your screen, here, you can see that the feeding tube has been placed into the patient's right lung. So blind placement really is risky for our patients. And when we do see incidental airway placement of the feeding tube, it is most often associated with blind placement of the tube.

Guided placement of a feeding tube refers to the use of technology or use of a feeding tube navigation system, which provides image guidance of the pathway of the tube through the GI anatomy during the actual placement procedure. So you actually get to visualize the pathway of the tube and visualize whether it is deviating into the airway very early in the procedure. And if it is, you have the option right at that time to abort, to pull the tube back before any harm comes to the patient. And then to try and reinsert the tube into the esophageal anatomy.

Guided placement really does optimize and reduce risk of airway placement of the feeding tube, optimizes your successful placement into the GI tract and does really assist in post-pyloric placement because you can visualize the tube moving through the stomach anatomy and into the small bowel. And so if you have a look at the image in the middle of your screen, here, you can see this is actually one of my images from a patient that I placed a feeding tube on and you can see that the tube has safely passed down the esophagus through the stomach, dropped down into the duodenum of the small bowel right at the pylorus and then terminates at the ligament of Treitz. So guided placement is much preferred of a blind placement because of the patient safety aspect.

And then there's direct visualization of the feeding tube. This includes the use of endoscopic placement of the feeding tube where the endoscope can be used to guide the tube through the GI anatomy or they can place a guide wire through the pylorus, way down into the small bowel and then the tube gets passed over the guide wire and into the small bowel anatomy. Direct visualization is helpful for patients that have some very tricky anatomy, oftentimes, patients with surgically altered anatomy where we just can't get the tube into the correct anatomical location without the use of direct visualization. But again, it's a last result. This is a procedure for a patient. It includes sedation which is not without risk. And so ideally, if we can avoid having to place the tube using EGD, that's preferred. Preferred to use guided placement, but in some circumstances, guided placement is just not going to work. And then we need to know our limits and know when to reach out to our GI colleagues and refer the patient for EGD placement.

One other option is to use what we call a two-step process where you can place the feeding tube up to about 30 centimeters into the esophagus, get an X-ray, and if it's determined that the tube is safely in the esophagus and is not deviating left or right into the airway, you can then continue with your placement, advance the tube through the stomach and hopefully, into the small bowel, and then get another film at the end of the procedure procedure to verify that the tube is in fact way down in the GI anatomy. This is, at least, one way of a step better than doing blind placement I would say, but it does require a lot of coordination of resources. You have to have your X-ray tech at the bedside, patients getting more radiation exposure, two X-rays that would need to be taken versus just one. So all those things do need to be taken into consideration when choosing a method of placement that's going to be safest for the patient.

There are a lot of technological devices out there for the guided placement of feeding tubes. I'm not going to go into detail. There's a variety of them that are listed on the screen in front of you. I encourage all of you to check with your organization, see if you are using guided placement technology, what are you using, do some research on the device and just know that there are others out there. Cotrak, Envue, and IRIS, those systems are all used for placement of feeding tubes into the stomach and into the small bowel. Nasotrak and Entarik. Those are used for placement of feeding tube into the stomach only, not quite for post [inaudible 00:29:10] placement at this time. But again, I encourage you to go ahead and review these devices for yourself. I will say that the feeding tubes for these devices are not interchangeable, which means that each system comes with its own feeding tube. So if your organization is using Cotrak, you'll see your patients with Cotrak feeding tubes. If they're using Envue, you would see the Envue feeding tubes and so on. Not interchangeable between devices.

Okay. Let's shift gears to the location of the tube tip and why is it so important? So knowing the anatomical location of the tube tip is very important and really should be included as an element of patient assessment and does need to be included in the documentation of the feeding tube within the patient's medical record. The tube tip can either end in the stomach or the gastric anatomy, and that could be the gastric fundus, the gastric body or the gastric antrum. The tube can be post-pyloric, so beyond the pylorus of the stomach into the duodenum and the duodenum is broken up into four areas, D-1 through D-4. And then the last portion that the nasal enteric feeding tube usually terminates in would be the proximal jejunum, just beyond the ligament of Treitz. We really do need to know where the tube tip is and it's really, really, really important because it determines a lot of things for the patient moving forward as well as your understanding of what can and cannot be done through nasal enteric tube because of the location of the tube tip. We'll talk a little bit more about that.

So what's this look like from the inside for the patient? Again, I love to look at imaging. I think it tells us so much about our patients, what a privilege we get to see our patients from a view that they will never get to see themselves sometimes. And so if you have imaging available, learn to interpret it, look at it, it tells you so much. And so on the left-hand side of your screen, you see a gastric feeding tube. This tube is placed down into the gastric antrum. If you're looking at a review of normal anatomical mile markers in most patients, anything from 50 centimeters to about 75 centimeters is from the GE junction where the esophagus joins the stomach to where the pylorus creates an entrance into the small bowel. So that really is just looking at your gastric anatomy.

The image in the middle shows you a nasal duodenal tube and in this case the tube has come through the duodenal sweep down into D-2. You can see how the tube drops down when it gets to the small bowel. And so the tube travels through the gastric anatomy. You would see it follows the greater curvature of the stomach very nicely here and then it takes a downward sweep. And that's because right at the level of the pylorus, the duodenum drops away and travels a little posteriorly before it makes a turn back across midline. And so on imaging, we know that the tube is in the small bowel because we appreciate that drop on the image as the tube drops into the small bowel. And then on the far right-hand side of your screen, you see that the tube has come all the way through that duodenal sweep. It's come back up towards the diaphragm where the ligament of Treitz, that suspensory ligament pulls the small intestines up in the abdominal cavity and then drops back down into the proximal jejunum.

And so, the feeding tip for that patient is way down in the proximal jejunum. And so really, really important to note, where the tip of the feeding tube is in the anatomy of the patient. In most adults, our anatomical mile markers are approximately the same. In pediatrics, the mile markers are slightly different and so you need to make those adjustments if you work in the pediatric world. And then of course, patients with surgically altered anatomy will have different anatomical mile markers. And so again, HMP review is just so important prior to feeding tube placement or even prior to ordering a feeding tube for your patients, just so that we know what to anticipate. Some of the surgically altered anatomies that we encounter are the Roux-en-Y gastric bypass anatomies, gastric sleeve. A patient may have had a gastric sleeve and you'll see slightly different anatomical mile markers in those patients.

Patients that have had a Whipple procedure where the duodenum is completely removed, you're not going to see your tube drop into the duodenum among those patients. It's going to go from the gastric anatomy straight down into the jejunum. And then some patients may have had a gastrectomy, partial gastrectomy with a pull-through where the gastric anatomy is pulled almost up into the thoracic cavity and then joined to the small bowel, depending on how much of a surgical resection has occurred. So again, knowing the location of the tip is important and knowing the patient's anatomy is incredibly important to optimize success for feeding tube placement.

Now, why does it matter so, so much? So if the stomach can stall and break down food, by doing that, we mean by secreting the acids and the enzymes that are required for food breakdown and mechanically distributed, which means we require gastric motility, and distributed in the right direction, that means moving it in the direction of the pylorus for digestion, we should truly use the stomach. But if we're not able to use the stomach because there is a malfunction either with storage of food, breakdown of food or the passage of food, the motility of food from the stomach towards the small bowel, we can bypass the stomach and use the small intestine. There are many physiological benefits to using the stomach and using the GI tract for feeding. It maintains GI integrity while supporting the body's natural immune system. Remember, about 80% of our body's immune cells are produced by the healthy bacteria that colonize the GI tract, more specifically, the small intestines.

And so everyone loves a good anatomy review. So, if you consider the importance of the gallbladder and the pancreas and the digestive process and think back to when you learned about anatomy and you remember that term, the sphincter of Oddi and everyone wonders where on earth is the sphincter of Oddi? Well, it's located in the second duodenum and this is where, as you can see in the picture here, bile from the gallbladder and pancreatic enzymes from the pancreas are emptied into the second duodenum right there in D-2. And the hormones that are responsible for contracting the gallbladder and the secretion of the enzymes from the pancreas are stimulated by the presence of those macronutrients in the gut. And so the passage of food through the duodenum helps stimulate some of those hormones to make the gallbladder contract and for the pancreas to secrete the pancreatic enzymes. And these are all things that are incredibly important for the digestion of carbohydrates, fats, and proteins.

So again, if we can use the GI tract, we really do end up with preservation of the entire tract and all the organs that go with it. If we're not using the stomach, we're going to see gastric atrophy. If we're not stimulating the gallbladder and the pancreas, those things start to slow down and that's when we could start to see feeding intolerance in some of our patients. Now, on the converse of that, is if we want that biliary tree and that pancreas to really rest, then we don't want to feed the stomach. We want the feeding tube to go way beyond the stomach and maybe for the tip of the feeding tube to be in the proximal jejunum so that we can allow the pancreas to rest.

So, think of your patients with acute necrotizing pancreatitis or we don't really want all that of that pancreatic acid secretion.

Those patients are better served when the tube tip location is way down beyond the sphincter of Oddi and in the small bowel. So this is why it's so important to know where the tube tip is for your patients. Another reason it's so important is that we need to think about the determination for the plan for feeding this patient, right? Is this somebody we are going to bolus feed a couple of times a day, giving them a large volume at one time as if they were having several meals a day? Or is this somebody that can't tolerate large volume because of the tip of the feeding tube is not in an area where the anatomy can accommodate large volume and they'd be better served by continuous feeding at a lower volume through a pump?

So I want you to think of the stomach as a reservoir. Stomach is a reservoir, it's able to expand, it's able to hold volume and therefore, the stomach can accommodate bolus feeding. So just as if you were eating a meal several times a day, you could bolus feed a patient a respectable volume, several times a day and they would probably do okay, if the tube tip is in the gastric anatomy. So the tip of the feeding tube must be in the stomach for them to really tolerate the bolus feeding. The small bowel is not a reservoir. I want you to think of the small bowel as a highway as shown here on the right-hand side of your screen. It's a small lumen. It's about 2.5 to three centimeters in diameter, which is maybe just a little bit bigger than your index finger. So it is not an area of the anatomy that does well accommodating a large volume.

And so, we don't want to really be bolus feeding large volumes into the small bowel. It can create a lot of discomfort, bloating, cramping, diarrhea, and what we would call feeding intolerance for our patients. If the tip of the feeding tube is way down in the small bowel, in the duodenum or the proximal jejunum, those folks are best suited to continuous feeding at a lower volume, maybe 45 cc's an hour via feeding pump for an expanded time. So maybe 45 cc's an hour over 24 hours via feeding pump trickling into that area. It's a highway, it's designed to move things along and absorb along the way. It's not designed as a reservoir to hold volume. So this is another reason why it's incredibly important to know the location of the tube tip. It helps you bring the whole plan for the patient together. Is this somebody going home on bolus feeding or is this somebody that is going home on continuous feeding through a feeding pump?

Verification of the feeding tube tip location is very important. And to do this, we have several different options. We can use a navigation device such as the Cotrak, the IRIS, the Envue, the Entarik, any of those. These are FDA approved devices. They are FDA approved as confirmation devices. Radiographic confirmation is truly the gold standard by ASPEN guidelines for determining the tube tip location and that would be X-ray imaging. We can use pH testing. A pH of less than or equal to five is proposed as safe for gastric verification. We can use the Whoosh test, although this research has demonstrated that this is not a reliable method for verification of tube tip location, this involves air insufflation, listening for that whoosh of air over the epigastrium as you do that. Truly not a safe method and preferably should not be used.

Ultrasound can be used to visualize the tube within the GI anatomy. Just a side note, you can visualize the tubes in the esophagus and the stomach, the injection of a little bit of aero saline. You can sometimes visualize those bubbles just to confirm placement. So it does require a trained technician or trained staff to use ultrasound at the bedside. And body habitus can certainly affect sensitivity and accuracy. So that must be taken into account. And then capnography, high CO_2 levels when the tube is at about 30 centimeters could indicate a lung placement. And we spoke about direct visualization using EGD guidance to verify tube tip location.

Nasal enteric feeding tube securement. Again, our options here are to tape the tube to the nose or to the cheek. Being very mindful that complications related to pressure injuries can occur. And so if we are taping the tube, then the tape needs to be removed. And the naris inspected for breakdown of the nasal mucosa. The bridle I spoke about earlier here in the middle of your screen involves the placement of that very biocompatible thin blue tubing in the space behind the vomer bone, anchors the tube in place, clips to the tube in front and really does exponentially reduce the chance of dislodgement. And then if neither of those two things are an option, the tube may be sutured to the nose. In my organization, we see this sometimes with our patients that have had major head and neck surgeries, bridling may not be a possibility and so we will suture the tube in place to keep it secure.

The role of a nutrition support team and nasal enteric tube placement, incredibly important. This is a dedicated team of APPs, RNs or dietitians. They have a very high level of competence and confidence in placing nasal enteric feeding tubes. They have troubleshooting expertise. The use of the team significantly reduces the incidence of blind placement and its associated complications, definitely associated with increased patient satisfaction and safety and successful placement in the desired tube to location on the very first attempt. At our organization, we do have a dedicated nutrition support team comprised of five nurses who are highly skilled and trained, and then myself, as the clinical expert who is more involved with the high-risk placements and as clinical support for the team.

Some complications of feeding tubes include mispositioning of the tube, epistaxis or nasal bleeding during insertion. Aspiration can still occur with the nasal enteric tube, esophageal perforation, which is very rare, I will say and respiratory compromise. And then post-insertion. Unfortunately we see clogging of the device. Device-related pressure injuries, displacement or dislodgement of the tubes. And then tube malfunction which can include cracking, kinking and rupture of the tube and of course, re-feeding syndrome, which I'll discuss in a little more detail on the next slide. So what do these look like for the patients? These are some of the complications we see. Some images of some clogs on the left-hand side.

In the middle of your screen, that X-ray image actually shows a fractured feeding tube, which is the consequence of aggressive flushing of a medication clog of a feeding tube. Tube migration if it's not anchored in place correctly. Lung placement. And there are some pictures of pressure injuries when our tubes are not secured properly. And then just to remind you that mispositioning of the tube can occur in both the respiratory anatomy and in the neuroanatomy. If there's an anterior breach in the base of skull, it is possible for the tube to go through that breach and through the [inaudible 00:45:38], to the spinal cord and sometimes into the brain. So something we'd obviously like to avoid for our patients.

But look at complications on paper. It's one thing to look at

them, see what they look like for a patient, is another. So how do we manage our complications for misposition tubes? Use a navigation system, avoid blind placement. For epistaxis, H&P review, look at your COEX for your patients. The use of an Afrin-type nasal spray prior to placing the tube can help. If your INR is incredibly high, if your patient's on anticoagulants, you want to bear those things in mind. Aspirations, set yourself up for success. Make sure you have suction ready and handy when you're placing the feeding tube. If your patient does have an aspiration event, clear the airway as quickly as you can. Make sure the patients are sitting upright. Make sure you have adequate help at hand as well in the event of an aspiration event.

Like I said, esophageal perforation, very rare. H&P review important here. If your patient's had profound radiation and could have radiation necrosis, stop and think, is this the right thing to be doing for the patient? For clogging, what you really, really want to do is make sure that your medication administration technique is very sound. Medications need to be administered by crushing them one at a time, diluting them with warm water, using a 60 cc syringe to administer the medications through the tube. Don't use excessive force and don't allow medications and formula to mix because you don't want a nutrient interaction that could cause clumping, clogging or precipitation.

Device-related pressure injuries. Very careful assessment of the nasal anatomy for these patients. Offload pressure, patients tend to tuck the tubes behind their ears. They got to change that every two hours just like you would offload pressure anywhere else. And then kinking, cracking and rupture of the tube. Again, avoided by good tube maintenance, good tube hygiene, flushing the tube, avoiding medication clogs. Refeeding syndrome is a talk for another day. It's a very complex metabolic process, but it is a complication of any feeding tube. And in this case, starting somebody on feeding, going from a starved state to a fed state can lead to severe metabolic derangement. And so assessing for the risk of refeeding syndrome before starting the enteral feeding is probably the number one complication management in that regard.

Enteral misconnections are very serious. This is when we connect feeding tubes to devices that are not intended for feeding. So for example, connecting a feeding device to an intravenous device. And unfortunately, this has been a lingering safety issue for a number of years. And so, to mitigate this, back in 2012, ISO, which is our International Standardization Organization, the FDA and GEDSA, which is our Global Enteral Device Safety Association, came up with a mandate that we need to create enteral devices that are only able to be connected with other enteral devices. This is a global patient safety initiative intended to eliminate misconnections between devices intended for enteral feeding or other medical devices. This is known as ENFit or enteral fit. And it is a standard that mandates that small bore connections have a very unique connectivity between enteral tubes feeding sets and syringes, which makes them incompatible with intravenous or other devices and so exponentially decreasing the risk for enteral misconnections.

And what they've actually done, if you have a look on the right-hand side of your screen, you see the old style, what we would call the legacy connection style feeding tube where we used a friction fit and we could force things together. On the left-hand side of your screen, you see what we call ENFit, which is a very unique threaded connection style for enteral feeding tubes, which makes them compatible only with enteral access devices. And so you cannot use these with intravenous devices, intravenous syringes or force a fit between devices that are not intended for enteral use.

ENFIT implementation at an organization is a monumental undertaking. If your organization is converted to ENFit. Congratulations. If you have not yet, I encourage everybody to please, please do so in the name of patient safety. It requires a buy-in at an organizational level. It's an interdisciplinary team between pharmacy, physicians, nurses, supply chain management, dietitians. It is an ongoing journey. You have to go to where the work is done to truly see what the devices are that are in use and what is the ENFit interchangeable device and how do we get those items stocked in the areas where the work is being done.

Requires ongoing socialization. It's not a one and done. You have to keep re-socializing the ENFit concept staff turnover. There are 101 different ways that devices are ordered and stocked and supplied in the OR, in the ED, in the nursing units, in the pharmacies, the DME companies that are sending these supplies home to patients. Really requires that all these key stakeholders are involved in an ENFit transition. At our organization, we created a lot of videos and used a lot of visual tools to promote success of the adoption of ENFit technology. And we used super users to get the work done in all of the areas. We're a large, large organization, it's impossible for one team of people to do this. And so, super users were really key in helping us roll out for success.

So, in summary, enteral nutrition is a life-sustaining therapy. Nasal enteric tubes provide short-term access in individuals with a functional GI tract. Tube-securement devices exponentially reduce incidental dislodgement of feeding tubes. Safety is an absolute priority and so guided placement of nasal enteric feeding tubes is preferred as is the transition to ENFit to avoid enteral misconnections. Tubes are not without risk of complication and unfortunately, we don't have a lot of quality metrics that drive quality related to enteral nutrition and enteral feeding. So we need to move the needle in that respect. And risk mitigation and complication management must be included in the plan of care for every patient, for safe enteral access and for the delivery of safe enteral nutrition. And with that, I conclude my presentation and I'm going to turn it back over to Linda Lord, my contact details are on the screen and I'm happy to take any questions.

Linda Lord: Thank you, Lauren. That was a very informative session. Now, I would like to let our viewers know how to obtain CEs for this session. This activity has been approved for one contact hour. You can obtain these continuing education credits by logging on to www.saxetesting.com/p. You will need to register on the test site and complete the evaluation form. Upon successful submission, you'll be able to print your certificate of completion. And for the dietitians, once you have completed the online CE process and have received a certificate, we will email you a CDR conforming certificate. Again, this activity is supported by an education grant from Dale Medical Products Incorporated.

An archive on demand version will be available on www.perspectivesinnursing.org and you'll be getting an email related

to that. The on-demand version will be accredited for Continuing Education credits. And I think we'll be able to go on to the question and answer period now. So there have been a few questions that have come in. Let's see. One of the first ones for you, Lauren, is why would a provider choose to do blind placement if guided placement is applicable?

Lauren Bruwer: Great question. And so guided placement of feeding tubes is obviously preferable. I know that not everybody's trained to use the technology. So the technology is only useful when you've actually been trained to use it and you have it readily accessible. And so you may see somebody choosing to do blind placement A, if they haven't been trained to use the navigation system and don't know how to use the technology and don't know how to interpret the imaging that they see on the technology. That can be just as dangerous as placing a tube blindly. If you don't know what you're looking at when you're placing it, you get that false sense of security. So are they trained and are they competent?

The other thing is do they have access to a navigation system or is it locked away somewhere in a unit and they don't have access to it and the patient needs access? Is this somebody who's coming to the emergency room on a Saturday morning and doesn't necessarily require admission to the hospital but the feeding tube is clogged, the patient just wants to go home, they just want the feeding tube replaced and the feeding tube to go home. A provider may elect to do a blind placement in that circumstance. And so number of factors can play into that. Is there a team available to place the feeding tube? What are the hours that that team works? Is it three in the morning? A lot of these factors drive into making the decision to say, "I'll just quickly drop the tube blindly. It'll be okay." And unfortunately, sometimes, it works out and oftentimes, it does not.

Linda Lord: I think also what helps with that is if you have someone who already has a feeding tube in and you know the length of tubing it takes to get, let's say into their stomach and it clogs and they're able to swallow water while the tube is going down, sometimes people will elect to do blind placement under those conditions.

Lauren Bruwer: Yeah.

Linda Lord: Okay. And then another question have is during tube placement, what tips do you have to get a small bore feeding tube to pass through the tight junction in the pylorus to get a small bowel tube placement?

Lauren Bruwer: Great question. Patients of the pylorus is number one. That's the one thing I say. The pylorus opens every 40 to 60 seconds in a healthy individual with a functional GI tract. Patients that are sick, that's going to be a bit slower. Patients that haven't eaten for a while, the pylorus gets lazy, it doesn't want to open, it hasn't had to open for a week or two because eating hasn't been optimal and the gut hasn't been used. It's going to slow down. It's going to not function as it usually would. So A, you've sometimes just got to be patient. Two, you can trick the pylorus. When you know your tube is safely down using a navigation system and you're right at that pylorus, you feel that little bit of resistance, flush the tube with about 20 cc's of water, splash that up against the pylorus. Oftentimes, that makes it think something good's coming and it'll open up and allow the passage of the tube.

Right-sided rotation is very helpful if you can get gravity on your side. Rotate the patient to their right side, keeping constant pressure at that point, and then just wait for that pylorus to open and watch your tube drop down into the duodenum. The other thing is if your tube has a guide wire, pulling the guide wire back out of the tube to soften up the tip of the feeding tube often helps you, we call that a floppy tip will often help you get through the pylorus a little bit easier. And the last thing that you can try is the use of prokinetics. So sometimes, five milligrams of intravenous Reglan administered at that point, wait a couple of minutes holding pressure at the pylorus and within 10 minutes or so, oftentimes, it'll open up and just suck that tube right in with peristalsis if you use a prokinetic. So those are a lot of the tips and tricks that I use to get post-pyloric placement.

Linda Lord: Yeah. And one of the things I'd like to mention back in the early 1990s, we did some investigation on prokinetics and we used 10 milligrams of IV [inaudible 00:58:33] and we found that it worked over 90% well with transpyloric intubation, with unweighted tubes, but didn't make any difference with the weighted tube. So that was just one study, but even the tube type you have, you might want to investigate that with the process that you're using.

I think we're actually getting close to one o'clock. So we did have a few more questions, but maybe you can email Lauren. So I want to thank you, Lauren for this, and I would like to turn this presentation over to Tracy now for some concluding remarks.

Tracy Cook: Thank you, Linda, and thank you, Lauren for such a great presentation. We'd like to thank everyone for attending today's webinar. Immediately upon the conclusion of the webinar, you'll be presented with an online survey. Please keep your web browser open and we appreciate your feedback. In one hour following the conclusion of this webinar, you will receive an email with instructions and this link to obtain your CE credits. That's www.saxetesting.com/p. And with that, this concludes today's webinar. We hope everyone has a great rest of their day. Thank you.

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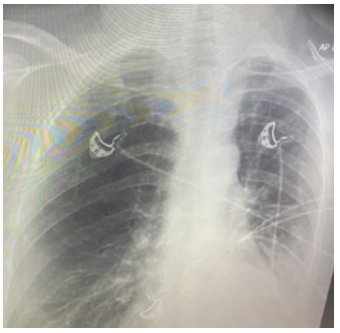
The Use of Volara System Oscillation and Lung Expansion (OLE) Therapy to Aid a Patient With COPD and Bronchiectasis

Overview
Report of a 73 year-old female admitted for pneumonia and COPD exacerbation with complaints of thick sputum and inability to expectorate.

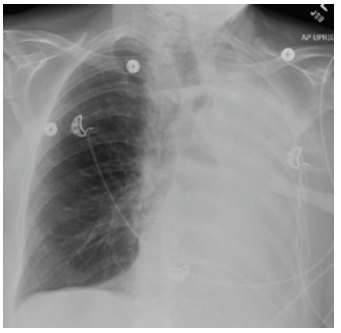
History
Comorbidities include COPD and Bronchiectasis, on 3L O2 at home. Has had multiple hospital admissions in the last several months for COPD exacerbations and pneumonia, requiring bronchoscopy for mucus plugging.

Following Admittance
Initiated on heated high-flow nasal cannula (HFNC) and started on PEP device.

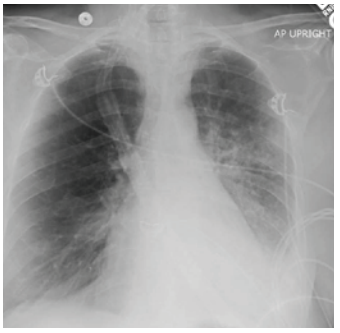
Evidence



Intake CXR: Pre-PEP or Volara System use.



Day 4: Post-PEP device (3.5 days of treatment), Pre-Volara System OLE Therapy.



Day 6: Post-Volara System OLE Therapy (2.5 days of treatment).

Patient Timeline
Below is the progression of the patient's status over the week:

	O2 Requirement	PAO2	Therapy/Modality
Day 1	40L/70%	94 mmHg	PEP device
Day 2	40L/70%		PEP device
Day 3	40L/85%	59 mmHg	PEP device
Day 4	55L/85%	61 mmHg	PEP used until 1200, when **Volara** System started Q4
Day 5	40L/60%	87 mmHg	**Volara** System Q4
Day 6	35L/45% to 4L NC		**Volara** System Q4 , changed to QID with transfer from ICU to floor

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References
1. Data on file at Baxter International Inc.
2. Compared to The Vest System Model 105.

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Assessment of Oscillatory Pressure and Flow Waveforms with the Biwaze® Clear System

Robert DiBlasi RRT-NPS, FAARC Niko Kontoudios RRT Hattie KenKnight, BS

Introduction

Airway clearance is critical in maintaining respiratory health, especially for chronic and acute lung diseases. Common conditions associated with mucostasis include cystic fibrosis, bronchiectasis, bronchitis, and pneumonia, where ineffective cough or mucociliary dysfunction prevents the removal of airway secretions.[1] Left unresolved, mucostasis can result in the accumulation, impaction, and obstruction of mucus in the bronchioles, which can partially or fully collapse the lungs, impair lung function, promote morbidity, and prolong hospitalization.[1]

Oscillating lung expansion (OLE) therapy airway clearance systems, like the BiWaze Clear, combine lung expansion, secretion clearance, aerosol, and oxygen into a single therapy. High- frequency oscillation (HFO) applies distending pressure during the respiratory cycle to maintain airway patency, recruit collapsed airways and alveoli and improve lung volumes and gas exchange. The rapid pulses of oscillating flow shear the mucus from the airway lining and assist in mobilizing secretions from peripheral airways to larger conducting airways, which can then be removed via airway suctioning or coughing.[2]

A critical aspect of effective mucus mobilization is the expiratory flow bias (EFB), which occurs when peak expiratory flow (PEF) exceeds peak inspiratory flow (PIF). This dynamic, reflected in the PIF/PEF ratio, ensures that airflow directs secretions out of the lungs rather than deeper into the airways. A PIF/ PEF ratio below 0.9 is considered optimal for airway clearance therapy.[2,6,9,10,11,12,20]

The therapeutic benefits and clinical efficacy of high-frequency oscillation are not well known with existing OLE airway clearance systems. However, several mechanisms are thought to contribute to secretion clearance and lung expansion, which include:

1. Applying higher inspiratory and expiratory flow in the airways increases the transairway pressure gradient, gas flow velocity, turbulence, mechanical stress, and differential shear forces. These factors contribute to a reduction in the stability of mucus viscosity at the air-mucus interface, thereby preventing the adhesion of secretions on the mucus layer of the airway lining.[3]
2. Changes in the kinetic energy between the expiratory and inspiratory flows create differences in airflow velocities during the oscillatory phases. During the expiratory phase of the oscillation, the higher airflow velocities can induce a reduction in airway diameter, which, combined with the velocity differences between expiratory and inspiratory phases, may help prevent mucus from moving deeper into the lung periphery and instead facilitate its clearance toward the central airways.[4]
3. The pressure gradient within the airway needs to be high enough to dilate the airway, get the air behind (distal to) the mucus, and accelerate the expiratory flow leading to the expulsion of mucus from deep within the peripheral airways (aka “mini coughs”).[5]
4. The effectiveness of endobronchial secretion mobilization from the bronchioles to the central airways is optimized by the airway pressure oscillations that produce an EFB.[2,6,9,10,11,20]

The overall effectiveness of HFO on secretion mobilization may be highly dependent on the expiratory flow bias but also the frequency and magnitude of the airway pressure oscillations and the attenuation through the airways, as well as the impact of pressure and flow related to the underlying lung mechanics (pulmonary pathophysiology) and mucus viscosity.

Moreover, the effects of superimposed airway pressure oscillations on flow, tidal volume (V_T), mean airway pressure (P), and end-expiratory lung pressure (PEEP) during spontaneous breathing during HFO are important factors to consider for maintaining airway patency, expansion, recruitment, and lung protection during airway clearance therapy.

We conducted descriptive studies in vitro to characterize the pressure-flow relationship during HFO produced with the BiWaze® Clear system. We analyzed the effect of HFO in spontaneously breathing pediatric and adult patients having normal, obstructed, and restricted lung mechanics. HFO pressure and waveforms were also analyzed to quantify the mechanical forces and flow bias that could promote secretion clearance and lung expansion during HFO. The findings from these experiments will be used to corroborate the outcomes related to the efficiency of mucus transport and compare it with another OLE airway clearance therapy device, the Volara® System (Baxter Hillrom, Deerfield, IL).

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Table 1. Study Model Parameters

	Lung Condition	Respiratory Rate (breaths/min)	Ti (s)	~I:E	Tidal Volume (mL)	Compliance (mL/cm H_2O)	Resistance (cm H_2O/L/s)	Pleural Pressure (cm H_2O)
ADULT (70 kg)	Normal	15	1.3	1:2	520	100	4	8
	Obstructed	14	0.85	1:4	600	100	20	31
	Restricted	25	0.8	1:2	420	35	9	17
PEDIATRIC (25 kg)	Normal	25	0.8	1:2	145	55	25	12
	Obstructed	22	0.68	1:3	140	42	50	21
	Restricted	38	0.52	1:2	100	30	15	7

Study Method

Device Descriptions

The BiWaze® Clear features a dual-blower design with each blower dedicated to inhaled and exhaled airflows and oscillatory pressures independently. The filtered coaxial breathing circuit has separated inspiratory and expiratory gas flow pathways and a sealed (aka 'closed') handset. In contrast, the Volara® System features a single-blower design and utilizes a filtered single-limb breathing circuit. The Volara breathing circuit includes an integrated fixed-leakage port, referred to as the "expiratory valve," on the open handset to flush out exhaled carbon dioxide. In both systems, internal oscillations are delivered directly to the patient airway.

Experimental Setup

A digitally controlled, high-fidelity lung simulator (ASL 5000; Ingmar Medical, Pittsburgh, PA) was used to replicate realistic breathing patterns for both pediatric (25 kg) and adult (70 kg) subjects.

The simulator was configured to model normal, obstructive, and resistive lung mechanics and breathing parameters. Utilizing a screw-drive-controlled piston and advanced mathematical modeling, the system enabled precise simulation of tidal breathing while measuring flow, pressure, and volume with high accuracy. The model parameters are shown in Table 1.[13,14,15,16,17,18,19]

A realistic 3D-printed pediatric[7] and adult[8] anatomic upper airway model was attached to the simulator during spontaneous breathing. Baseline spontaneous breathing measurements (without HFO) were obtained for each patient model and disease state to determine the effects of HFO on the flow bias, tidal volume, and pressure. Following baseline measurements, HFO was applied via a sealed mouthpiece attached to the oral opening of the 3D printed anatomic airway model, using HFO setting of 20 and 30 cm H_2O with medium frequency (4 Hz).

The raw airway pressure and flow signals from the internal lung chamber of the simulator were recorded at 500 Hz using the ASL software and later used to reconstruct waveforms and calculate different breathing parameters. In addition, the raw pressure and flow recording data were acquired with a low-resistance flow pneumotachometer and pressure transducer placed in series with the distal trachea of each airway model. The voltage signals were acquired and processed in real-time (1000 Hz) with an analog-to- digital converter (PowerLab, ADInstruments, Colorado Springs, CO) and later used to characterize the tracheal oscillations in pressure and flow across all the different experimental conditions. Each test lasted 2 minutes.

Measured Parameters-Data Analysis and Results

After completing the experimental runs, the tracheal measurement data recorded for each condition was analyzed to calculate the change in airway pressure (ΔP) between the

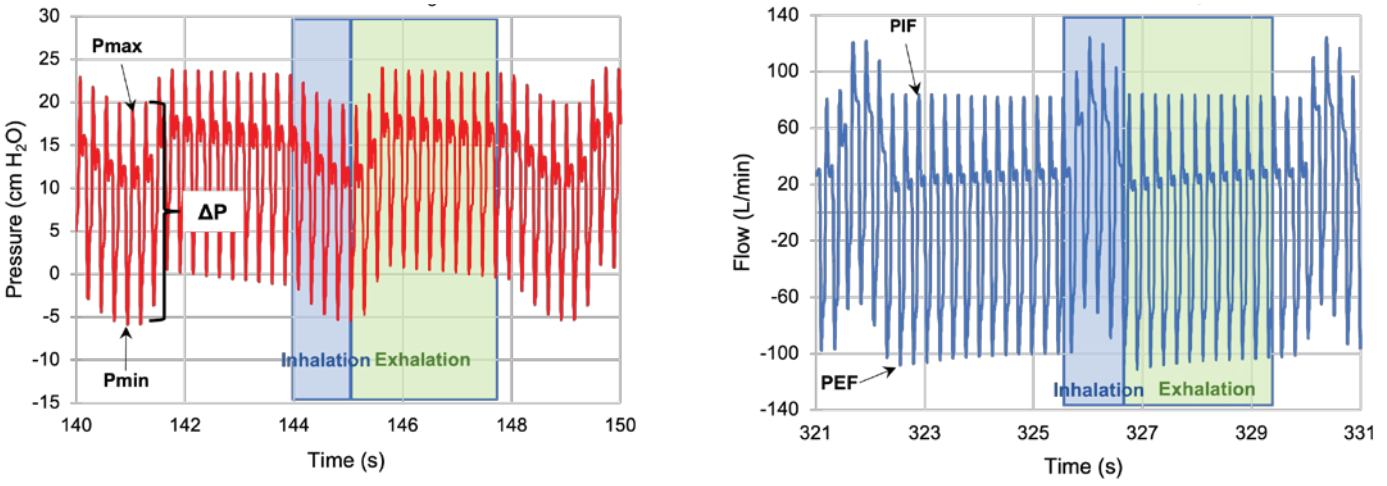

Figure 1. Tracheal and Lung Simulator Model Measurements

minimum (Pmin) and maximum (Pmax) values. The resulting peak inspiratory flow (PIF) and peak expiratory flow (PEF) generated by the therapy pressure oscillations were also determined. As previously noted, sufficient driving pressure (ΔP or trans airway pressure gradient) is required to transport gas past the mucus obstructions, generating enough kinetic force to shear secretions from the airway lining and accelerating expiratory flow to effectively mobilize secretions from the lungs.

Oscillatory flow values were used to calculate the expiratory flow bias (EFB) by subtracting the peak inspiratory flow (PIF) from the peak expiratory flow (PEF). A negative EFB indicates a tendency to drive secretions further into the distal airways, while a positive EFB supports improved mucus mobilization toward the proximal airways. The PIF/PEF ratio was also calculated to compare the relative differences between baseline spontaneous breathing and HFO therapy conditions, evaluating whether the therapy improved or hindered secretion mobilization.

PIF/PEF ratio changes were categorized based on their impact on flow bias. Ratios decreasing from baseline (e.g., PIF/PEF decreasing from 1.0 to 0.6) were associated with a positive EFB, improving mucus mobilization. Conversely, ratios increasing from baseline (e.g., PIF/PEF increasing from 1.0 to 1.5) were associated with a negative EFB, which is unfavorable to mucus mobilization (aka inspiratory flow bias).[20] A PIF/PEF ratio of less than 0.9 is generally considered optimal for mobilizing mucus to the larger airways.[6,2] Additional calculations were performed using the breath-by-breath data acquired from within the ASL 5000 to evaluate the cumulative effect of superimposed airway pressure oscillations on the peak inspiratory pressure (PIP), PEEP, (P), and V_T during spontaneous breathing (see Figure 1).

Results

Adult Model

In the spontaneously breathing adult model with normal lung mechanics, the tracheal oscillatory ΔP increased from baseline (no therapy) with both systems (Table 2A). The BiWaze Clear generated nearly two-fold higher ΔP pressures than Volara, resulting in higher PEF during HFO. The PEF was 2 to 3-fold greater with BiWaze Clear compared to the baseline, whereas the PEF measured with Volara was less than the baseline. This resulted in a significantly improved EFB and PIF/PEF ratio (0.69) with BiWaze Clear. Conversely, Volara demonstrated a 7 to 9-fold reduction in the EFB compared to baseline, resulting in an inspiratory flow bias, which is an unfavorable flow pattern that may drive mucus deeper into the lungs (see Table 2A). Increasing the HFO pressure settings from 20 to 30 cm H_2O did not result in further improvement in flow bias for either system.

Overall, the measured tracheal oscillatory pressures with BiWaze Clear were more consistent with the set pressure and exhibited lower variability (SD) than Volara, which underdelivered oscillatory pressure by approximately 50% of the set pressure during HFO. The additive effects of superimposed oscillations on spontaneous breaths resulted in intrinsic reductions in the delivered V_T (~50%) to the lung model with both systems (Table 2B). However, V_T increased as the set pressure was raised from 20 to 30 cm H_2O in BiWaze Clear but decreased in Volara under the same conditions. Additionally, higher PIP, PEEP, (P) and flows were observed in the lung model with BiWaze Clear compared to Volara, attributed to the relatively higher oscillatory ΔP generated by BiWaze Clear (Table 2A).

Normal Adult Model

In the Normal Adult Model Oscillatory pressure and flow wave forms show that BiWaze® Clear consistently delivered higher tracheal oscillatory pressures (ΔP) that were closer to the set pressures, demonstrated lower variability, and achieved lower Pmin values compared to Volara. The peak expiratory flow (PEF) generated with BiWaze Clear was 2-3 times greater than baseline, resulting in a significantly improved expiratory flow bias (EFB) and an optimal PIF/PEF ratio below 1. In contrast, Volara exhibited lower PEF than baseline, leading to a negative EFB and unfavourable PIF/PEF ratios.

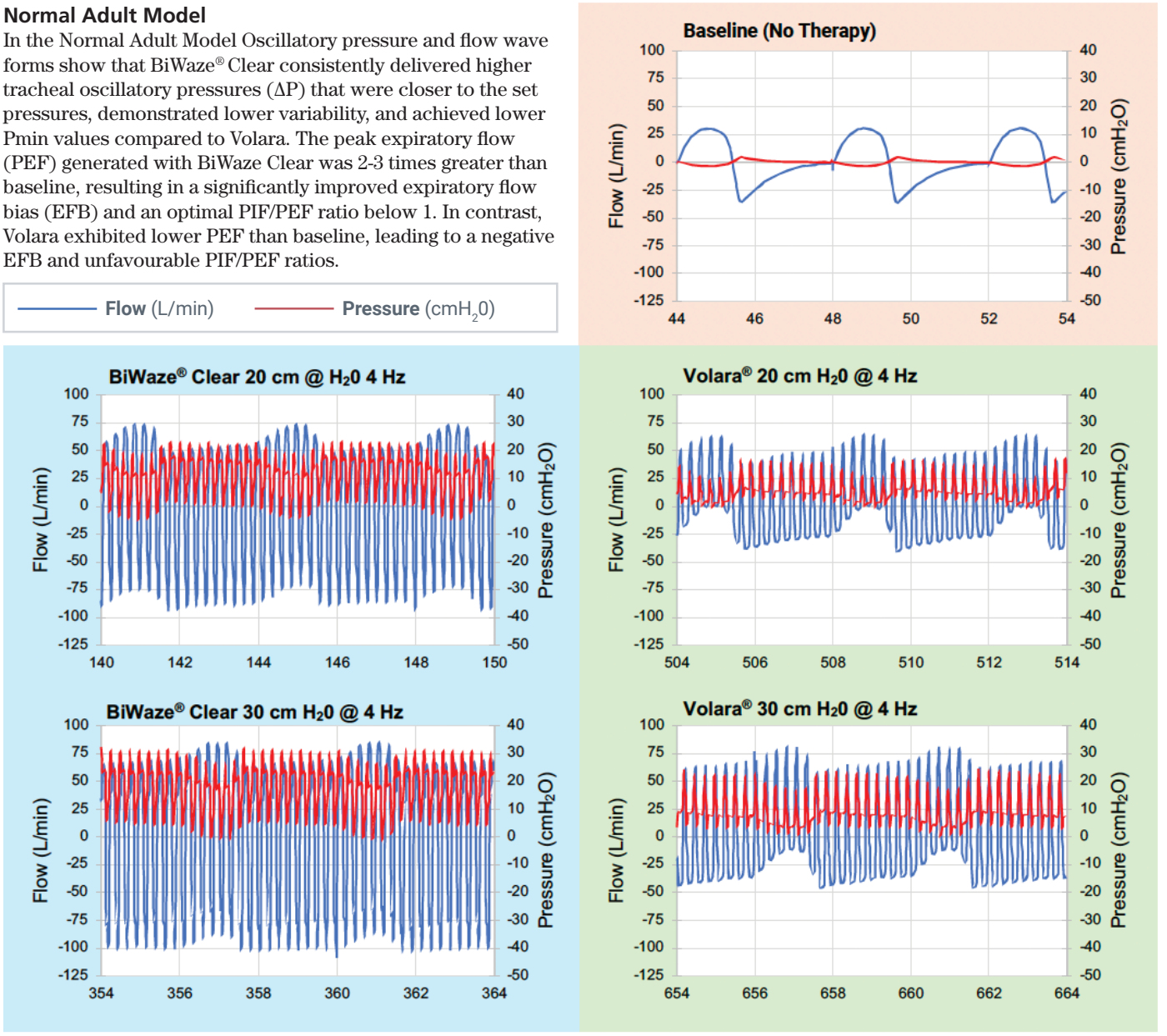

Figure 2. Pressure and Flow Waveforms - normal adult model

Table 2A. Tracheal Measurements – Spontaneously Breathing Normal Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	3.34 (0.14)	21.00 (0.57)	11.64 (1.00)	26.08 (0.71)	16.41 (1.17)
PIF (L/min)	29.64 (0.27)	65.82 (8. 92)	61.65 (8.27)	80.48 (8.92)	83.17 (7.68)
PEF (L/min)	35.24 (0.56)	(98.24 (7.53)	29.47 (12.19)	117.94 (6.21)	35.15 (13.23)
EFB (L/min)	5.60 (0.62)	32.42 (11.67)	-32.84 (14.73)	37.46 (10.82)	-48.02 (15.03)
PIF/PEF (L/min)	0.84 (0.02)	0.67 (0.10)	2.09 (0.91)	0.68 (0.08)	2.37 (0.92)

Table 2B. Lung Simulator Measurements – Spontaneously Breathing Normal Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	525.04 (2.15)	250.79 (16.52)	232.76 (24.44)	273.30 (17.35)	228.64 120.89)
PIP (cm H_2O)	0.13 (0.01)	24.75 (0.14)	19.46 (0.32)	33.32 (0.68)	26.24 (0.31)
PEEP (cm H_2O)	0.05 (0.04)	12.90 (0.31)	6.67 (0.21)	18.85 (0.64)	10.11 (0.28)
Pmean (cm H_2O)	0.01 (0.02)	11.79 (0.17)	6.02 (0.14)	17.43 (0.53)	9.29 (0.15)
PIF (L/min)	30.60 (0.21)	77.34 (0.45)	68.68 (1.00)	88.72 (0.96)	87.19 (0.96)
PEF (L/min)	36.38 (0.40)	93.47 (1.26)	36.96 (1.10)	108.52 (3.34)	45.83 (0.92)

Obstructed Adult Model

In the Obstructed Adult Model, the BiWaze® Clear achieved higher tracheal oscillatory pressures (ΔP), closer to set pressures, with lower variability compared to Volara. BiWaze Clear also demonstrated higher peak expiratory flow (PEF) and a notable improvement in expiratory flow bias (EFB) compared to baseline, while Volara showed lower EFB than baseline. Increasing the pressure to 30 cm H_2O did not have any further positive impact on both the parameters in both systems.

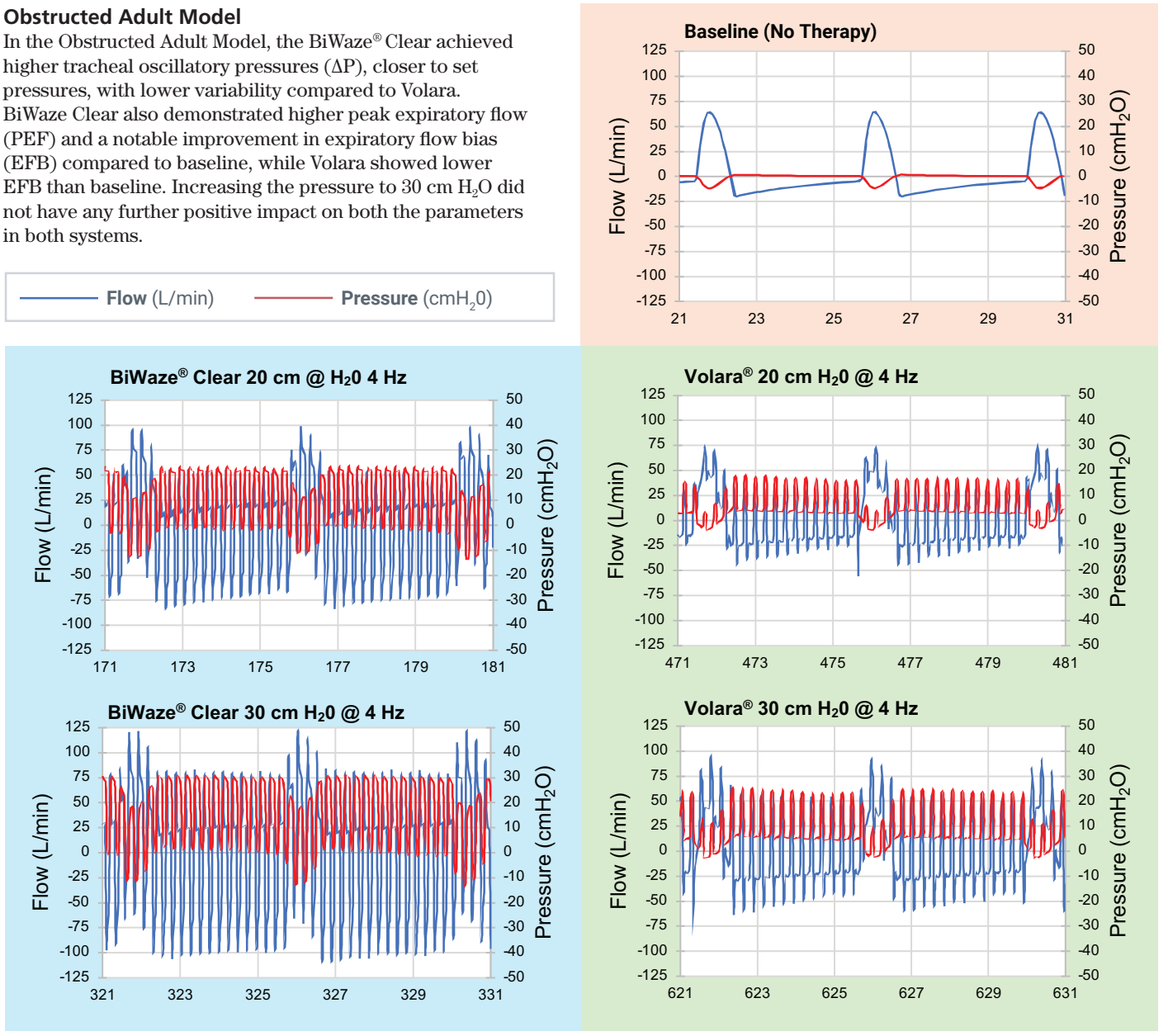

Figure 3. Pressure and Flow Waveforms – Obstructed Adult Model

Table 3A. Tracheal Measurements – Spontaneously Breathing Obstructive Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	6.10 (0.01)	23.48 (2.27)	17.09 (3.32)	33.95 (2.09)	22.88 (2.35)
PIF (L/min)	63.41 (0.03)	44.65 (13.9)	45.99 (20.74)	61.74 (14.60)	59.42 (15.38)
PEF (L/min)	19.48 (0.08)	59.34 (9.40)	32.34 (5.35)	74.69 (10.73)	39.23 (13.43)
EFB (L/min)	-43.93 (0.08)	14.69 (16.78)	-13.65 (21.42)	12.95 (18.12)	-20.19 (20.42)
PIF/PEF (L/min)	3.25 (0.01)	0.75 (0.26)	1.42 (0.68)	0.83 (0.23)	1.52 (0.65)

Table 3B. Lung Simulator Measurements – Spontaneously Breathing Obstructive Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	610.02 (11.93)	388.33 (51.70)	533.22 (18.13)	419.24 (41.70)	471.32 (43.59)
PIP (cm H_2O)	0.12 (0.01)	24.54 (0.08)	18.27 (0.36)	31.31 (0.62)	26.24 (0.40)
PEEP (cm H_2O)	0.12 (0.11)	13.97 (0.27)	8.37 (0.12)	19.47 (1.54)	11.95 (0.21)
Pmean (cm H_2O)	0.0 (0.01)	11.15 (0.19)	6.03 (0.12)	16.50 (1.11)	9.45 (0.20)
PIF (L/min)	64.61 (12.61)	106.19 (1.22)	82.65 (1.60)	131.01 (2.71)	103.64 (1.82)
PEF (L/min)	19.77 (12.17)	89.29 (3.18)	50.24 (2.28)	117.00 (4.62)	74.07 (4.41)

Restrictive Adult Model

In the Restrictive Adult Model, BiWaze® Clear achieved higher tracheal oscillatory pressures (ΔP) that were closer to set pressures with lower variability compared to Volara. BiWaze Clear improved expiratory flow bias (EFB) and PIF/PEF ratio over baseline, while Volara reduced the EFB and PIF/PEF ratio from baseline. Increasing the pressure to 30 cm H_2O had marginal positive impact with BiWaze Clear while impact was negative with Volara.

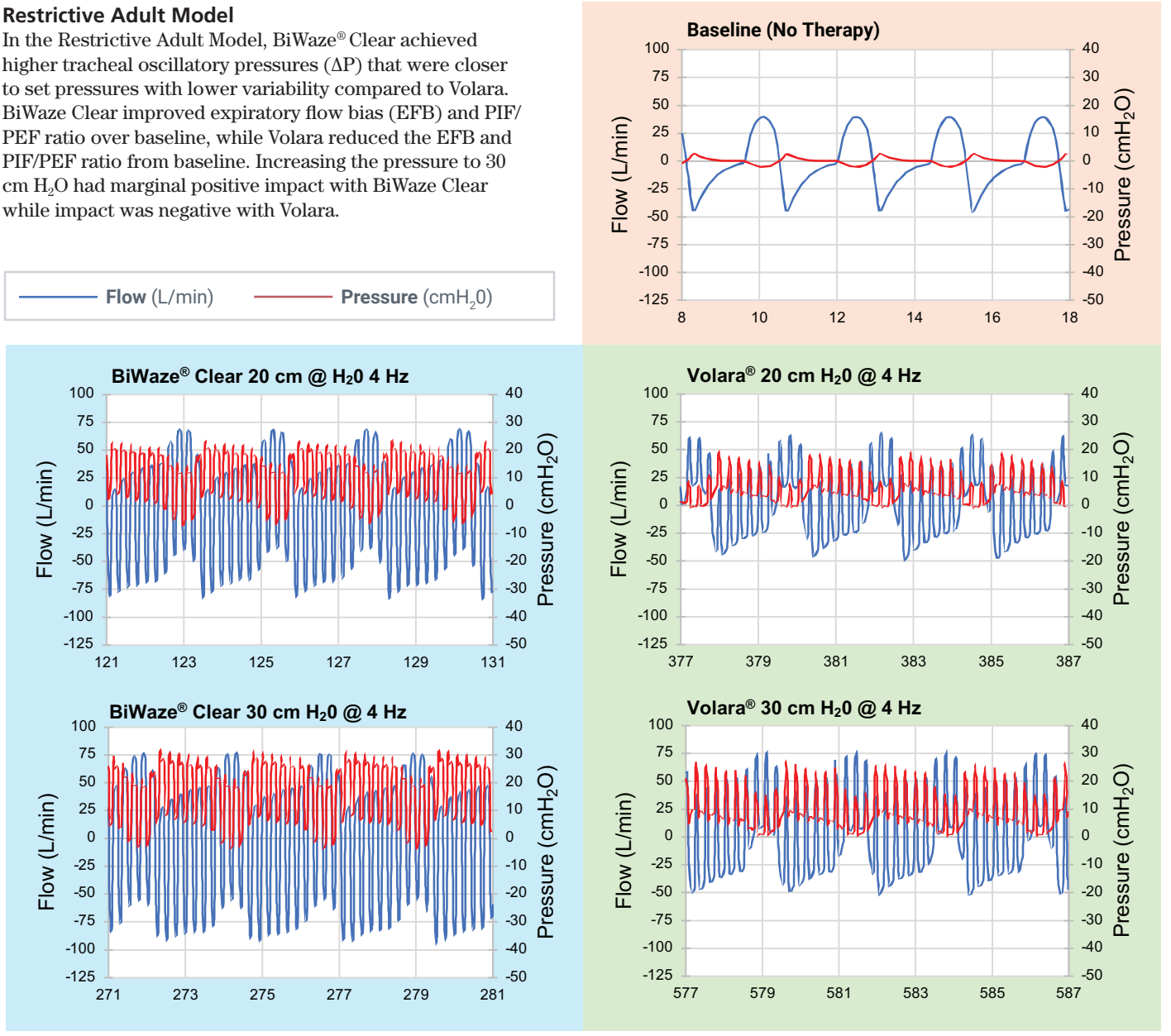

Figure 4. Pressure and Flow Waveforms – Restrictive Adult Model

Table 4A. Tracheal Measurements – Spontaneously Breathing Restrictive Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	4.98 (0.02)	22.27 (2.76)	15.16 (3.28)	26.92 (2.42)	18.31 (2.17)
PIF (L/min)	38.80 (0.07)	54.36 (16.60)	56.24 (15.31)	64.08 (15.13)	71.32 (12.52)
PEF (L/min)	45.20 (0.16)	71.10 (14.28)	41.60(12.40)	88.92 (13.15)	33.51 (19.16)
EFB (L/min)	6.40 (0.17)	16.74 (21.9)	-14.64 (19.7)	24.84 (20.05)	-37.81 (22.89)
PIF/PEF (L/min)	0.86 (0.00)	0.77 (0.28)	1.36 (0.56)	0.72 (0.20)	2.13 (1.27)

Table 4B. Lung Simulator Measurements – Spontaneously Breathing Restrictive Adult Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	421.20 (0.08)	244.27 (27.36)	351.64 (21.29)	266.35 (27.38)	315.59 (21.63)
PIP (cm H_2O)	0.15 (0.01)	24.48 (0.18)	21.81 (0.47)	33.14 (0.33)	29.43 (0.70)
PEEP (cm H_2O)	0.03 (0.01)	12.91 (0.74)	7.22 (0.45)	18.93 (0.85)	10.85 (0.61)
Pmean (cm H_2O)	0.10 (0.01)	10.92 (0.17)	6.09 (0.12)	16.56 (0.26)	9.41 (0.13)
PIF (L/min)	39.66 (0.03)	70.71 (0.64)	64.39 (0.86)	79.59 (0.58)	79.34 (0.80)
PEF (L/min)	46.06 (0.04)	77.05 (1.69)	41.35 (2.61)	92.55 (1.36)	47.84 (2.13)

In the spontaneously breathing adult model with obstructive lung mechanics, the ΔP increased from baseline with both pressure settings, showing similar trends in the transtracheal pressure delivery similar to those observed in the normal model. However, ΔP was comparatively higher in the obstructive model due to the higher lung resistance and turbulence in the central airways (Table 3A). The oscillatory PIF decreased from baseline while the PEF was improved with both systems, with BiWaze Clear showing the highest improvement in EFB and P/F from baseline. While BiWaze Clear showed a PIF/PEF ratio of less than 0.9 in both settings, the ratio did not improve, though it increased slightly with a pressure increase to 30 cm H_2O. Volara, on the other hand, showed a higher PIF/PEF ratio greater than 1 across the settings. Overall, BiWaze Clear delivered tracheal oscillatory pressures *(Pmax*, Figure 3*)* closer to set pressures and with less variability (SD) compared to Volara, which underdelivered the oscillatory pressure by up to 25% of the set pressure during HFO (Table 3A).

The addition of superimposed oscillations on spontaneous breaths resulted in lower VT in the lung model with both HFO systems when compared to baseline with the lowest VT observed with BiWaze Clear (Table 3B). While V_T increased when the pressure setting was increased from 20 to 30 cm H_2O with BiWaze Clear, it decreased with the Volara. Additionally, BiWaze Clear demonstrated higher PIP, PEEP, (P) and flows in the lung model compared to Volara due to the relatively higher oscillatory pressures generated with the BiWaze Clear (Table 3A).

The waveforms shown in Figure 3 show the oscillatory pressure and flow profiles generated at baseline and HFO at various pressure settings in the obstructive adult model during spontaneous breathing with both systems. Increasing the HFO pressure setting resulted in a notable increase in Pmax and ΔP and significant improvements in the PEF and EFB with BiWaze Clear. In contrast, Volara showed only marginal improvements in PEF and EFB compared to the baseline.

In the spontaneously breathing adult model with restrictive lung mechanics, intratracheal oscillatory ΔP and PIF increased from baseline, with both HFO settings for BiWaze Clear and Volara (Table 4A). While BiWaze Clear at the HFO pressure of 20 improved PEF and EBF compared to baseline, the PIF/PEF ratio improved slightly from 0.86 to 0.77. In contrast, Volara at HFO of 20 demonstrated reduced PEF and EFB, leading to a worsened PIF/PEF ratio from baseline (0.86 to 1.36). Increasing the HFO pressure to 30 cm H_2O resulted in nearly double the PIF and PEF and a four-fold greater EFB compared to baseline, while optimizing the PIF/PEF ratio (0.72).

The tidal breathing parameters in the restrictive adult model showed similar trends between baseline and HFO settings as observed in the normal and obstructive lung models, though with reduced V_T and flows, due to the lower compliance used in this model (see Table 4B and Figure 4).

Pediatric Model

The intratracheal pressure, flow oscillation measurements, and tidal breathing parameters for the normal, obstructive, and restrictive pediatric models are shown in Tables 5, 6, and 7, with corresponding waveforms in Figures 5, 6, and 7, respectively.

In all pediatric lung models, both BiWaze Clear and Volara demonstrated increased ΔP compared to baseline breathing, with BiWaze Clear consistently delivering the highest pressures and significant improvements in PEF and EFB. Notably, BiWaze Clear was the only HFO system to consistently achieve substantially lower PIF/PEF ratios than baseline or HFO settings with Volara. Across all testing conditions, BiWaze Clear maintained PIF/PEF ratios below 1 in the pediatric models, indicating optimized expiratory flow dynamics. Additionally, BiWaze Clear demonstrated higher V_T, PIP, PEEP, and P) than Volara. These factors highlight BiWaze Clear's superior ability to maintain effective ventilation, improve secretion clearance, and provide consistent and predictable therapy outcomes, making it a more favorable option for pediatric respiratory therapy.

Normal Pediatric Model

In the Normal Pediatric Model, BiWaze® Clear consistently delivered higher tracheal oscillatory pressures (ΔP) closer to set pressures and achieved significantly higher peak expiratory flow (PEF) and expiratory flow bias (EFB) compared to Volara. BiWaze Clear maintained optimal PIF/PEF ratios below 1 across all pressure settings, indicating superior mucus mobilization. In contrast, Volara exhibited lower PEF and higher PIF/PEF ratios, reflecting less effective expiratory flow dynamics.

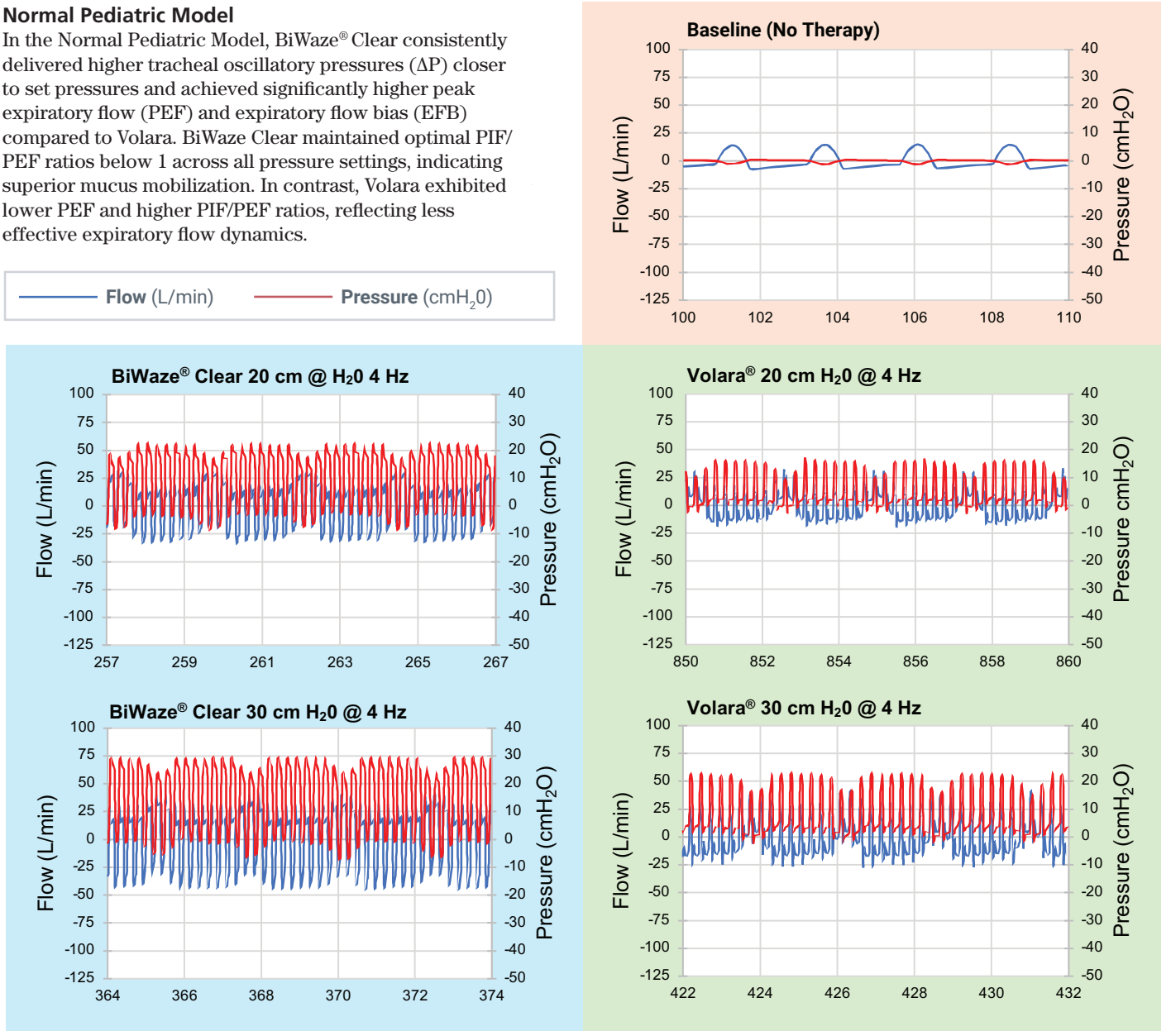

Figure 5. Pressure and Flow Waveforms – Normal Pediatric Model

Table 5A. Tracheal Measurements – Spontaneously Breathing Normal Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	2.36 (0.00)	24.69 (1.00)	15.17 (4.32)	33.91 (1.03)	22.65 (1.01)
PIF (L/min)	17.58 (0.06)	28.17 (4.79)	29.05 (4.91)	35.70 (4.24)	39.49 (4.15)
PEF (L/min)	8.50 (0.12)	34.99 (4.49)	18.78 (7.27)	44.23 (4.00)	27.77 (6.25)
EFB (L/min)	-9.08 (0.12)	6.82 (6.57)	-10.27 (8.77)	8.53 (5.83)	-11.71 (7.5)
PIF/PEF (L/min)	2.07 (0.03)	0.80 (0.17)	1.55 (0.65)	0.81 (0.12)	1.42 (0.35)

Table 5B. Lung Simulator Measurements – Spontaneously Breathing Normal Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	149.02 (6.24)	82.90 (15.06)	107.28 (26.06)	104.85 (12.07)	72.87 (18.64)
PIP (cm H_2O)	0.08 (0.01)	23.50 (0.68)	17.15 (0.12)	30.62 (0.60)	24.32 (0.22)
PEEP (cm H_2O)	0.17 (0.08)	12.06 (0.67)	6.97 (0.13)	17.44 (0.66)	9.77 (0.16)
Pmean (cm H_2O)	0.14 (0.12)	9.84 (0.54)	5.02 (0.20)	15.05 (0.52)	7.72 (0.14)
PIF (L/min)	17.34 (6.79)	36.86 (1.07)	32.31 (1.28)	47.36 (1.22)	41.89 (1.43)
PEF (L/min)	8.19 (5.91)	36.50 (2.19)	17.12 (1.33)	49.16 (2.11)	25.90 (1.03)

Obstructive Pediatric Model

In the Pediatric Obstructive Model, BiWaze® Clear achieved higher tracheal oscillatory pressures (ΔP) and demonstrated significantly higher peak expiratory flow (PEF) and expiratory flow bias (EFB) compared to Volara. Increasing pressure settings further to 30 cm H_2O enhanced EFB and PIF/PEF ratio with BiWaze Clear, while Volara showed reduction in both parameters.

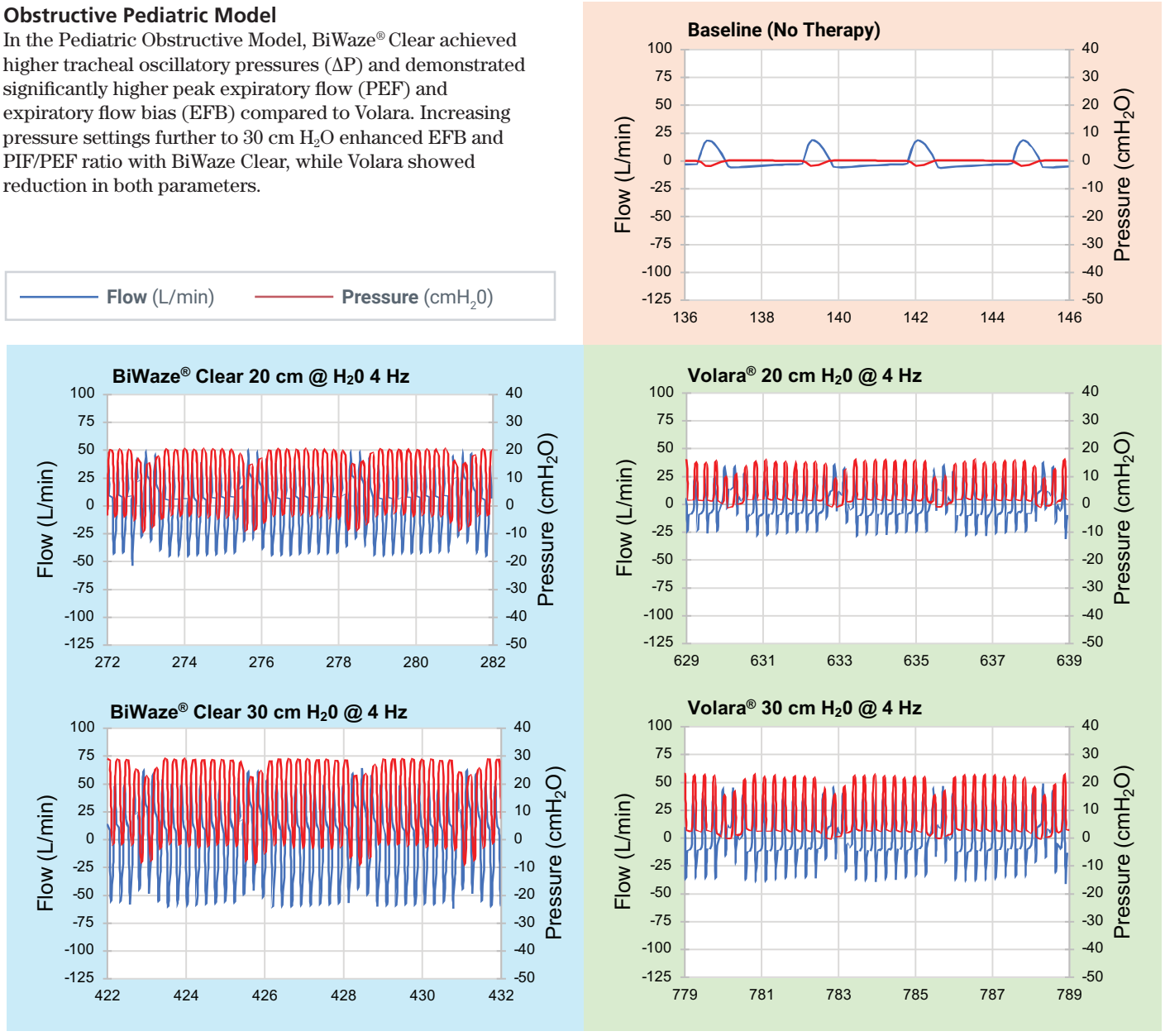

Figure 6. Pressure and Flow Waveforms – Obstructive Pediatric Model

Table 6A. Tracheal Measurements – Spontaneously Breathing Obstructive Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	2.38 (0.03)	24.20 (1.10)	15.90 (0.78)	33.93 (1.25)	22.06 (0.93)
PIF (L/min)	18.46 (0.06)	34.67 (4.95)	30.71 (4.67)	41.88 (4.48)	40.90 (3.93)
PEF (L/min)	6.38 (0.06)	38.06 (4.36)	25.18 (6.75)	48.29 (3.83)	34.56 (6.08)
EFB (L/min)	-12.08 (0.08)	3.39 (6.6)	-5.53 (8.2)	6.41 (5.89)	-6.34 (7.24)
PIF/PEF (L/min)	2.89 (0.03)	0.91 (0.17)	1.22 (0.38)	0.87 (0.12)	1.18 (0.24)

Table 6B. Lung Simulator Measurements – Spontaneously Breathing Obstructive Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	140.27 (5.04)	106.49 (15.95)	85.67 (22.74)	133.67 (14.53)	99.96 (20.14)
PIP (cm H_2O)	0.05 (0.01)	21.10 (0.08)	16.61 (0.16)	29.35 (0.36)	23.95 (0.31)
PEEP (cm H_2O)	0.08 (0.01)	12.45 (0.34)	7.66 (0.19)	18.19 (0.52)	10.42 (0.23)
Pmean (cm H_2O)	0.15 (0.03)	9.59 (0.23)	5.02 (0.18)	15.13 (0.33)	7.72 (0.18)
PIF (L/min)	18.60 (6.77)	55.87 (0.73)	40.40 (1.57)	67.27 (0.79)	52.74 (1.49)
PEF (L/min)	6.06 (5.84)	50.20 (1.05)	34.30 (2.37)	65.09 (3.03)	46.88 (2.94)

Restrictive Pediatric Model

In the Pediatric Restrictive Model, BiWaze® Clear delivered higher tracheal oscillatory pressures (ΔP) closer to set pressures and achieved significantly higher peak expiratory flow (PEF) and expiratory flow bias (EFB) compared to Volara. BiWaze Clear consistently maintained optimal PIF/PEF ratios below 1, while Volara exhibited higher PIF/PEF ratios, reflecting less effective expiratory flow bias.

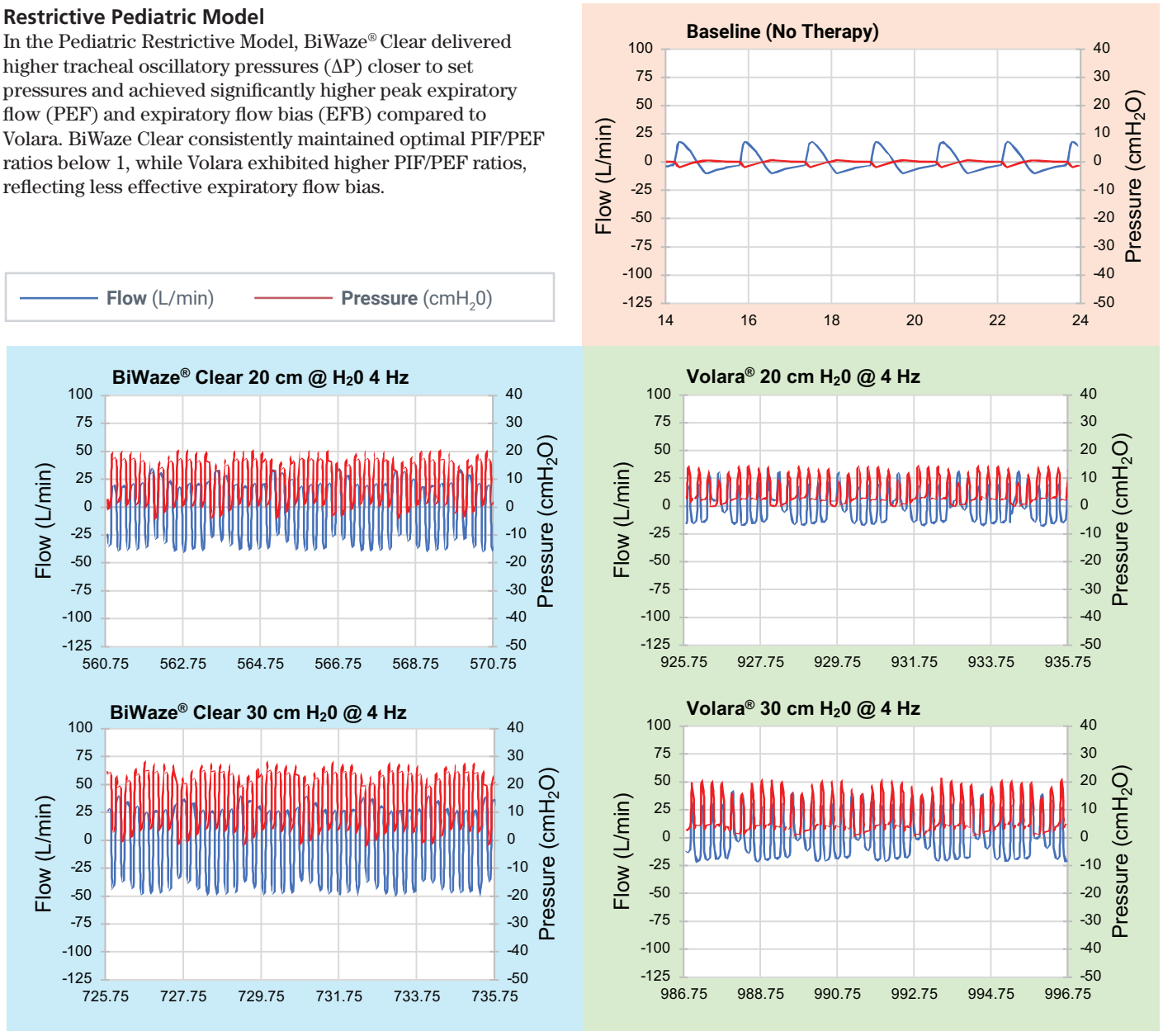

Figure 7. Pressure and Flow Waveforms – Restrictive Pediatric Model

Table 7A. Tracheal Measurements – Spontaneously Breathing Restrictive Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
ΔP (cm H_2O)	2.78 (0.03)	20.48 (1.22)	12.20 (0.7)	25.17 (1.28)	16.55 (0.74)
PIF (L/min)	18.65 (0.09)	32.68 (5.50)	32.15 (5.12)	39.03 (4.92)	43.88 (4.41)
PEF (L/min)	10.10 (0.14)	42.38 (4.67)	14.23 (6.29)	52.45 (4.41)	19.50 (6.24)
EFB (L/min)	-8.55 (0.17)	9.70 (7.22)	-17.92 (8.11)	13.42 (6.61)	-24.38 (7.64)
PIF/PEF (L/min)	1.85 (0.03)	0.77 (0.16)	2.26 (1.06)	0.74 (0.11)	2.25 (0.75)

Table 7B. Lung Simulator Measurements – Spontaneously Breathing Restrictive Pediatric Model

	Baseline	20 cm H_2O @ 4 Hz		30 cm H_2O @ 4 Hz	
Measurements	No Therapy	BiWaze® Clear	Volara®	BiWaze® Clear	Volara®
Tidal Volume (mL)	98.13 (2.01)	78.07 (10.69)	69.69 (34.60)	104.44 (8.70)	58.05 (11.09)
PIP (cm H_2O)	0.06 (0.01)	21.81 (0.14)	16.45 (0.26)	28.73 (0.67)	22.38 (0.22)
PEEP (cm H_2O)	0.11 (0.01)	11.59 (0.48)	5.98 (0.26)	17.13 (0.85)	8.55 (0.38)
Pmean (cm H_2O)	0.10 (0.01)	9.98 (0.26)	4.75 (0.16)	15.32 (0.61)	7.19 (0.11)
PIF (L/min)	18.03 (3.80)	32.76 (1.49)	31.25 (3.00)	36.93 (1.02)	40.08 (1.30)
PEF (L/min)	10.06 (1.20)	40.58 (0.58)	16.35 (0.87)	49.71 (1.54)	20.94 (0.78)

Discussion

The findings from our in vitro study highlight the superior performance of BiWaze® Clear in generating HFO waveforms that could be useful for lung expansion and secretion mobilization during OLE therapy. BiWaze Clear consistently delivered higher tracheal airway pressures that were closely aligned with the set pressures, outperforming Volara, which underdelivered pressure relative to the set pressure. These findings suggest that BiWaze Clear's ability to maintain higher PEEP and improved EFB can enhance alveolar recruitment, reduce atelectasis, and promote better mucus mobilization.

Decreasing atelectasis through improved alveolar recruitment and enhanced collateral channel ventilation can lead to a reduction in recurrent lower respiratory tract infections, airway wall destruction, and the development of bronchiectasis. This may translate into fewer respiratory complications, reduced need for mechanical ventilation, and improved patient comfort. Additionally, optimized PIF/PEF ratios (<0.9) indicate more effective secretion clearance, which could lead to shorter hospital stays and faster recovery times for patients with chronic respiratory conditions such as cystic fibrosis or bronchiectasis. The higher driving pressures and (P), enhance the ability of BiWaze Clear to distribute gas flow effectively through mucus-impacted airways or collateral channels, assisting with alveolar and distal airway expansion and reducing the risk of atelectasis.

BiWaze Clear's dual blower design delivers HFO pressures with an active pressure release mechanism to maintain an expiratory flow bias, which is critical for effective mucus mobilization and to avoid airway collapse, especially for distal airways. Additionally, the closed breathing circuit and sealed handset prevent flow leakage, ensuring that pressures are preserved within in the system. These features optimize the beneficial effects of HFO, optimizing mucus mobilization.

In contrast, Volara's single-blower and single-limb circuit designs appear to contribute to pressure attenuation and variability. These limitations may reduce the therapy's effectiveness and inhibit Volara's ability to achieve expiratory flow bias (EFB) (PEF), which is important for effective secretion clearance. Clinically, this could result in suboptimal mucus mobilization, increased risk of airway obstruction, and potentially longer recovery times for patients.

Our findings suggest that BiWaze Clear could provide superior pressure delivery and lung recruitment, which are essential for enhancing airway clearance, preventing atelectasis, and supporting efficient gas exchange.

The oscillatory pressure and flow profiles at baseline and during HFO highlight differences between the two systems under various pressure settings during spontaneous breathing in the normal adult model. BiWaze Clear consistently delivered higher Pmax values closer to the set pressures and achieved lower Pmin values than Volara.

Mobilization of mucus requires asymmetric airway oscillations with a positive EFB. Symmetric flow profiles when PIF equals PEF or when the PIF exceeds the PEF, creating an inspiratory flow bias or negative EFB, impede mucus mobilization, causing secretions to pool in the lung or are propelled further down into the peripheral airways. BiWaze Clear reliably delivered greater intratracheal flow oscillations, greater PEF, improved EFB, and optimal PIF/PEF ratios (<0.9) across the lung models.[2,6,9,10,11,20] Conversely, Volara showed suboptimal PIF/PEF ratios (>1), which could result in less effective mucus mobilization than baseline spontaneous breathing.

The observed limitations with Volara, lower driving pressure compared to set and inspiratory flow bias, may be attributed to the compressor design, single-limb circuit turbulence, or leakage through its integrated valve. These factors likely attenuate the pressure transmission and reduce oscillator flow performance, particularly under high-resistance or low-compliance conditions.

This study highlights the utility of using of multiple lung models to reveal distinct differences in EFB and pressure dynamics, providing insights into the conditions needed for optimal lung recruitment and mucus mobilization. While promising, the results should be interpreted cautiously, as in vitro findings may not fully predict in vivo outcomes. Future studies have been planned to evaluate the clinical efficacy of HFO on physiologic improvements related to this form of airway clearance. Additionally, the HFO delivered by BiWaze Clear warrants further investigation to understand the potential impact on gas trapping, secretion mobilization, and overall patient outcomes.

Conclusion

This study provides a comprehensive evaluation of the performance of BiWaze Clear and Volara systems during high-frequency oscillation (HFO) therapy with different pressure settings using multiple in vitro lung models, including normal, obstructive, and restrictive adult and pediatric conditions.

The findings demonstrate that BiWaze Clear consistently outperforms Volara in delivering precise and effective mechanical high-frequency oscillations, which is crucial for airway clearance therapy. By improving key parameters such as PEEP, EFB, and PIF/PEF ratios, BiWaze Clear has the potential to significantly enhance patient outcomes. These improvements could lead to better secretion clearance, reduced lung inflammation, and faster recovery, ultimately improving quality of life and reducing the burden on healthcare resources.

BiWaze Clear exhibited higher intratracheal pressures and flow oscillations that closely aligned with set pressures, achieving superior peak expiratory flow (PEF), expiratory flow bias (EFB), and optimal PIF/PEF ratios (<0.9). These results indicate that BiWaze Clear could enhance mucus mobilization and airway stability, supporting effective secretion clearance and reducing the risk of atelectasis. By contrast, Volara frequently underdelivered pressure showed suboptimal EFB and often displayed PIF/PEF ratios exceeding 1, which could impair secretion mobilization and clearance.

Key design features of BiWaze Clear, such as its dual-blower system, active pressure release mechanism, and sealed breathing circuit, were instrumental in maintaining reliable pressure delivery and optimizing airflow dynamics.

These features provide significant advantages in maintaining expiratory flow bias and minimizing leakage, particularly under high-resistance or low-compliance conditions.

The study also highlights the challenges of achieving EFB and flow performance with Volara, potentially due to pressure attenuation caused by its single-limb circuit and integrated leak

valve. These limitations were more pronounced in restrictive and obstructive lung models, emphasizing the need for precise pressure control in airway clearance therapy.

While the results suggest that BiWaze Clear may provide superior therapeutic benefits, further clinical studies are needed to evaluate its impact on physiologic outcomes, including secretion clearance and lung expansion. This in vitro study is a foundational step in understanding the mechanisms and potential clinical advantages of HFO, particularly with systems like BiWaze Clear that deliver consistent and effective oscillatory pressures.

These findings underscore the importance of advanced design and precise pressure control in optimizing airway clearance therapy, offering valuable insights for respiratory therapists and healthcare professionals seeking effective solutions for managing mucus mobilization and airway stability in diverse patient populations.

Key Findings Summary

- **Enhanced Mucus Mobilization**
  BiWaze® Clear demonstrated consistent positive expiratory flow bias (EFB) and optimal PIF/PEF ratios (<0.9), critical for effective secretion clearance.
- **Superior Pressure Delivery**
  BiWaze® Clear delivered higher and more consistent tracheal pressures (ΔP) which closely aligned with set values while maintaining precision and reducing variability.
- **Effective Airway Clearance Across Models**
  Waveform analysis shows potential for high clinical efficacy of BiWaze® Clear in normal, obstructive, and restrictive lung conditions for adult and pediatric models.
- **Dual-Blower Design Advantages**
  BiWaze Clear's dual-blower system provided superior control of inspiratory and expiratory flows, reducing leakage and optimizing pressure dynamics.
- **Potential for Improved Clinical Outcomes**
  BiWaze® Clear showed a potential to reduce atelectasis, enhance lung recruitment and secretion mobilization through precise and reliable airway clearance therapy.

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Filtration: Added Protection for Both Pediatric and Adult Patients With Tracheostomies

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Tracheostomy

Why would a patient with a tracheostomy be more at risk for disease exposure? Not only does the patient with a tracheostomy have co-morbidities that increase their risk of contracting disease, but they also have a higher risk of spreading viral and bacterial contagions because the open airway is often a forgotten source. A physiologic consequence of a tracheostomy is a change in the direction of airflow for the patient. Since the tracheostomy tube is placed in the trachea and provides an access point for airflow to the lower respiratory system at that point of entry, this placement bypasses the natural mechanisms of filtration, ciliary clearance, warming, and humidification of the air that are usually provided by the nose and oral cavity. Thus, a patient, adult or pediatric, with a tracheostomy may experience increased cough, pulmonary infections, and drying of pulmonary secretions. Respiratory gases inhaled through a tracheostomy bypass a patient's nasal passage, thus entering and exiting the upper airway and lungs in an unfiltered state. As a result, patients with tracheostomies have an increased risk of exposure to bacterial, viral, and particulate matter and are more likely to contaminate others. Personal protective equipment (PPE) may be used with these patients to protect them from these exposures.

Disease Exposure

Considering that COVID-19 became a pandemic worldwide and still exists, the current influenza season already has approximately 35 million cases per the CDC, whooping cough and similar respiratory diseases are on the rise, and even the common cold (rhinoviruses and enteroviruses) is on the rise, understanding what the risks are for patients with tracheostomies and how to protect their respiratory system is essential.[1-3] A range of 3% to 17% of patients who contract COVID-19 develop Acute Respiratory Distress Syndrome (ARDS); however, most remain mild and manage their illness at home.[4] Among all patients who develop the severe classification of the COVID-19 disease, the average time to dyspnea (shortness of breath) is 5 to 8 days and to develop ARDS is a median of 8 to 12.[5] Concurrent risk factors for developing ARDS also include respiratory viral infections, such as influenza and cold viruses.

Why is this significant? Well, when a patient progresses to ARDS, this level of disease often requires intubation and may lead to a tracheostomy. If the patient already has a tracheostomy and the severity of the disease increases, or they contract a new disease, their potential recovery and progress may be negatively impacted. Pre-existing conditions influence the severity of illnesses, and patients with tracheostomies have the significant factor of an already compromised respiratory system. Adding a viral or bacterial infection raises the risk significantly with some reporting a mortality rate of 31% in critically ill patients who contract COVID-19.[6]

Another consideration that moved to the forefront of medical care during COVID-19 is the recognition that producing droplets through cough and throat clear during a procedure is then an aerosol-generating procedure (AGP). If a patient has a tracheostomy, airflow from the tracheostomy site or nose and mouth during an AGP increases the risk. Covering the mouth and nose is typically managed with a face mask; however, the patient with a tracheostomy has the added area of the tracheostomy site – an opening into the airway that is both a risk for inhaling viral and bacterial loads and exhaling them during breathing, coughing, sneezing, and more. Because of the risk with AGPs and the potential spread of COVID-19 or other viruses, in general, patients with tracheostomies have additional risks for exposure to any virus around them or to others. With the use of proper personal protective equipment (PPE), the risk for and from these patients is reduced.

Personal Protective Equipment

In the earlier phases of COVID-19, the use of PPE changed. David, Russell, El-Sayed, and Russell (2020) reported on the use of both contact and airborne precaution-level PPE for patients with tracheostomies.[7] Viral load and reduction were managed with a time-based strategy instead of PPE, such as extended intubation times and staff limitations, to limit viral shedding. During this time, PPE for staff often included a gown, N95 mask, gloves, goggles, shoe covers, and at times, a powered air purifying respirator (PAPR). Currently, many of these precautions are still in place, especially during APGs. For patients, they are often isolated in their rooms when in a facility. If at home, they are confined to a bedroom or designated space to limit others from being exposed.

With 25 years of experience in medical, academic, and industry settings, Dr King brings a unique perspective of medical speech pathology. Her research, publications, and teachings focus on traumatic brain injury, swallowing disorders, and critical care (tracheostomy and mechanical ventilation) for both pediatric and adult patient populations. She has been an invited speaker both domestically and internationally and has published in peer-reviewed journals. Currently, Dr King is the Vice President of Clinical Education and Research for Passy-Muir, Inc.

The use of PPE is for the protection of both healthcare professionals and patients. However, for a patient with a tracheostomy proper protection is limited. This patient population breathes through the tracheostomy site, limiting the options for providing filtration to either placing a face mask over the tracheostomy site or using an off-label device, such as placing a filter made for mechanical ventilation onto the tracheostomy tube hub. These are usually large and have some weight as they are not designed for direct patient placement, not for use off the ventilator.

Figure 1. Patient using a face mask for PPE but with an open tracheostomy tube.

Filters

Previously, available filters have been intended for use with ventilators, anesthesia machines, and open-flow systems where filtration of inspired and/or expired gases is desired. The open flow system terminology indicates a breathing system that does not control the inhaled or exhaled gases of a patient. The bacterial and viral filter used for anesthesia machines has been shown to reduce the risk of viral and bacterial cross-contamination between patients or between staff and patients, even when used for non-ventilated patients.[8] These filters are often developed in combination with a heat moisture exchanger (HME) component to allow the provision of both filtering and humidification for patients on mechanical ventilation. However, it is a large device that is not designed or intended for placement directly on a tracheostomy tube hub. And, while heat moisture exchanger (HME) devices are designed for placement on the hub, this design is for humidification and has little to no filtration capability.

However, the *Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)* is a filter available for use directly on tracheostomy tube hubs and intended for both pediatric and adult patients. This electrostatic filter uses a polypropylene media with a pleated design to increase surface area without increasing size. This media is used to improve safety, effectiveness, and efficiency as compared to paper or foam. The PM-APF15 maintains an open flow system via the tracheostomy tube, allowing the patient to continue inhaling and exhaling at the site of the tracheostomy tube. This device has a bacterial filtration efficiency of >99.9%, viral filtration efficiency of >99.9%, and other particulate matter at a filtration efficiency of > 99.0%. It is intended to fit onto the 15mm hub of a tracheostomy tube and is easy to apply and remove with a gentle twist motion. This filter provides much-needed protection for patients with tracheostomies for both inspiratory and expiratory risks.

Having a high viral filtration efficiency provides a superior filtration performance and protection factor for patients. Meister et al. (2020) reviewed safety recommendations following tracheostomy in the presence of COVID-19 (or other viral and bacterial matter) and also addressed that a primary concern is transporting patients and the need for a viral filter to lower transmission risk during transport.[9] The PM-APF15 can be used during transport.

A filter also should be used to prevent irritation of the airways, due to dust or harmful substances contained in the air as a patient breathes. Another component of tracheostomy care is to have proper humidification and suctioning as these are essential to reduce the risk of crusting, mucus plugs, and tube blockage due to dryness.[10] While HMEs (heat moisture exchangers) may be used to assist with humidification and secretion management,[11] none of the current ones on the market are rated with a filtering capacity for viral and bacterial particulates.

Figure 2. Patient using a face mask and a PM-APF filter to protect from viruses, bacteria, and particulate matter during inspiratory and expiratory airflow at the site of the tracheostomy tube.

Filter Placement

The PM-APF15 filter is designed with a standard conical connector, fitting on the 15 mm hub of a tracheostomy tube. This design is consistent with current HMEs and speaking valves which are placed and used independently by patients. The PM-APF15 filter is designed to be used in the same manner for placement and removal. The ability of a patient to independently place and remove accessories to the tracheostomy tube has quality of life and safety implications to enhance patient care.

Martin et al. (2021) reported on patient independence with speaking valve use and found that patients could independently manage their speaking valves without safety concerns.[12] Research also has reported that patients' independence for the use of speaking valves and care significantly improves their psychological state and quality of life.[13] It is common practice to

teach patients independence in the care of their tracheostomy, including removal and insertion of the tracheostomy tube, and placement and removal of accessories, such as HMEs, speaking valves, suction lines, and more. Having a patient trained for independence increases care and safety. Placement and removal of a filter by the patient would be a standard of care that is currently observed with other accessories that have 15 mm connectors. The process for placement and removal of HMEs, speaking valves, and the PM-APF15 filter would be the same. Russell et al. (2022) reviewed tracheostomy care in a community setting and reported that the aim of teaching independence is to "enhance patient and carer confidence, and thereby promote independence, safety, and quality of life."[14]

Summary

Meister et al. (2020) conducted a State-of-the-Art review for safety recommendations following tracheostomy in the presence of COVID-19 (and other viral and bacterial matter).[9] The authors found that having a heightened awareness of protective equipment and care protocols with patients increased safety and mitigated transmission risks, including the use of a filter that would be specific to viral and bacterial matter.[9] Providing a patient who has a tracheostomy with access to a filter that has a high filtration efficiency not only protects the patient but also offers caregivers and healthcare professionals lower risks of exposure. In a patient population with an already compromised respiratory system, reducing the risk and co-morbidities by providing appropriate personal protective equipment enhances the quality of life and may lower the risks of mortality.

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Bridging the Gap: Addressing Barriers to Pulmonary Hypertension in Medical Care Deserts

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Introduction

Pulmonary arterial hypertension (PAH) is a rare but progressive condition that, when left undiagnosed and untreated, leads to significant morbidity and mortality. The disease is characterized by elevated pulmonary arterial pressures, leading to right ventricular failure and ultimately death. Pre-capillary pulmonary hypertension (PH) is defined as hemodynamic measurements showing a mean pulmonary arterial pressure (mPAP) >20 mmHg, the elevation of pulmonary vascular resistance (PVR) > 2 Wood Units (WU) and pulmonary arterial wedge pressure (PAWP) ≤15 mmHg (Kovacs et al., 2024). In PAH patients, the right atrium experiences an increased workload due to pressure overload from right ventricular diastolic stiffness and volume overload caused by tricuspid regurgitation and vena cava backflow (Hemnes et al., 2024). Health-related quality of life (HRQoL), as assessed through patient-reported outcome measures, highlights the significant negative effects of pulmonary hypertension on both physical functioning and psychological well-being (Ford et al., 2024). Early diagnosis and access to specialized care are paramount in improving outcomes for patients with PAH. However, the geographic isolation of certain regions in the United States, particularly medical care deserts like Central Appalachia, presents a significant barrier to timely and effective care. This article examines how generalizable symptoms, delayed diagnoses, and geographical barriers impede optimal PAH management and explores potential strategies to bridge these gaps.

The Challenge of Early PAH Diagnosis

One of the most significant challenges in managing PAH is its delayed diagnosis. Early symptoms of PAH, such as dyspnea on exertion, fatigue, and occasional dizziness, are non-specific and overlap with a range of common conditions, including asthma, chronic obstructive pulmonary disease (COPD), and anxiety disorders (Frost et al., 2019). These symptoms often lead to initial misdiagnosis, delaying referral to a PH specialist.

A study by Small et al. (2024) looking at patient reported data found that time from symptom onset to a confirmed PAH diagnosis is approximately 17 months and initial misdiagnoses occur in over 40% of patients. During this time, misdiagnosed patients may be prescribed treatments which do not address the underlying pathology. This delay is particularly concerning given that disease progression is rapid in the early stages of PAH.

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Geographic Isolation and Medical Care Deserts

Geographic barriers to pulmonary hypertension (PH) care further complicate timely diagnosis and treatment. Accredited PH care centers, recognized by the Pulmonary Hypertension Association (PHA), provide specialized multidisciplinary care, including advanced diagnostics, individualized treatment plans, and access to clinical trials (PHA, 2024). However, these centers are unevenly distributed across the United States, leaving vast rural regions without nearby access.

For example, residents of southern West Virginia, part of Central Appalachia, must often travel several hours to reach the nearest PH center and often out of state. This distance presents a significant challenge, particularly for patients with limited transportation options or those facing financial constraints. The lack of public transit infrastructure in rural areas compounds this issue, leaving many patients without feasible means to access care. This is just one example as there are several other medical care deserts throughout the United States and globally (Ford et al., 2024).

The Impact of Delayed Diagnosis and Limited Access

Patients in medical care deserts experience poorer outcomes due to delayed diagnosis and inadequate access to specialized care. Humbert et al. (2010) emphasized that early intervention with PAH-specific therapies significantly improves survival and quality of life. However, such therapies are often initiated after a confirmed diagnosis, which can be delayed in geographically isolated regions. Right heart catheterization (RHC) is widely regarded as the gold standard for diagnosing pulmonary arterial hypertension (Kovacs et al., 2024). This invasive procedure directly measures pulmonary arterial pressures, cardiac output, and pulmonary vascular resistance, providing definitive confirmation of PAH and its severity (Simonneau et al., 2019). Unlike non-invasive tests such as echocardiography, which can suggest the likelihood of PAH, RHC allows for precise hemodynamic assessment and exclusion of other conditions that may mimic PAH, such as left heart disease or chronic thromboembolic pulmonary hypertension. Noninvasive methodology lacks sufficient precision to accurately assess and validate hemodynamics for a PAH diagnosis (Kovacs et al., 2024).

However, access to RHC is often limited in rural areas,

where specialized centers with experienced interventional cardiologists or pulmonologists are scarce. This lack of availability poses a significant barrier to accurate diagnosis and timely initiation of treatment. Rural hospitals may not have the resources or trained personnel to perform RHC, leading to delays in referrals and increased reliance on less definitive diagnostic tools.

Additionally, the logistical challenges of traveling long distances for care contribute to higher rates of missed appointments, decreased adherence to follow-ups, and lower opportunities for enrollment in clinical trials. These disparities disproportionately affect socioeconomically disadvantaged populations, further widening health inequities.

Case Example: Central Appalachia

Central Appalachia is a stark example of how medical care deserts impact PAH care. This region has one of the highest burdens of respiratory diseases in the United States due to high smoking rates, occupational exposure to coal dust, and limited access to preventive care (Blackley et al., 2018). In rural southern West Virginia, the nearest PH care centers are often hundreds of miles away, requiring extensive travel. For patients experiencing severe dyspnea or advanced disease, such travel is not only inconvenient but also physically taxing. Figure 1 illustrates the vast geographical isolation from PH Care Centers for a case example city of Bluefield, WV followed by distances required by patients for care to an accredited PH treatment center in Table 1.

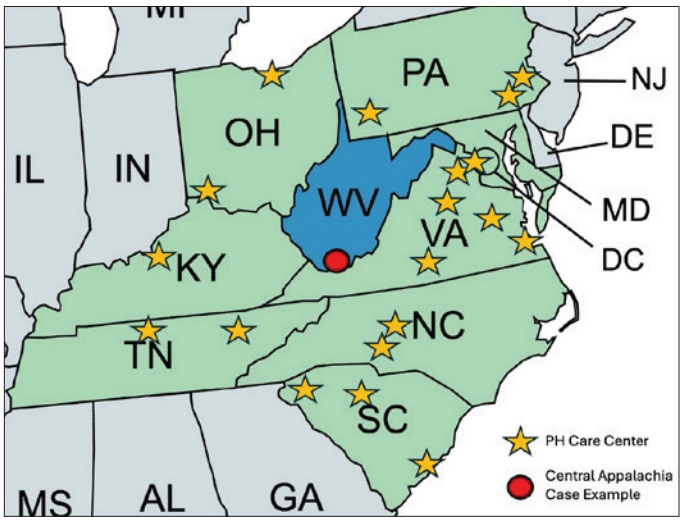

Figure 1. Distances to PH Care Centers from Central Appalachia Case City Example.

PHA Accredited Care Centers	Distance (Miles)	Duration (Driving)
Lynchburg, VA	163	2 hr 50 min
Charlottesville, VA	218	3 hr 18 min
Falls Church, VA	330	5 hr 0 min
Washington, D.C.	338	5 hr 28 min
Pittsburgh, PA	290	5 hr 0 min
Philadelphia, PA	476	8 hr 0 min
Cincinnati, OH	302	5 hr 22 min
Cleveland, OH	356	5 hr 35 min
Louisville, KY	353	5 hr 42 min
Knoxville, TN	216	3 hr 15 min
Nashville, TN	396	6 hr 4 min
Anderson, SC	293	4 hr 58 min
Columbia, SC	262	4 hr 20 min
Charleston, SC	377	6 hr 12 min
Chapel Hill, NC	200	3 hr 0 min
Durham, NC	200	3 hr 0 min

Table 1. Distances from Case Example to PH Care Centers.

Potential Solutions to Address Barriers

Education of the early signs of PAH can potentially improve referrals to specialized centers. Training programs and awareness campaigns tailored to rural healthcare providers could potentially help reduce misdiagnoses. Telehealth services could potentially connect patients in rural areas to PH specialists, reducing travel needs. Online platforms and eHealth tools offer PH patients access to reliable medical information, shared experiences, and lifestyle advice, fostering global support through forums, social media, and informal online communities (Ford et al., 2024).

Mobile units equipped with echocardiography and pulmonary function testing can provide preliminary diagnostics and identify high-risk patients for referral until RHC confirmation testing can be performed. Establishing satellite clinics staffed by rotating specialists from accredited PH centers could bring specialized care closer to underserved regions. This model has gained promise in improving access to care for chronic diseases (Senior & Chambers, 2006).

Expanding funding for rural health programs and incentivizing specialists to practice in underserved areas can address long-term access issues. Policies that subsidize transportation for medical care could also alleviate travel-related barriers.

Conclusion

Overcoming the barriers posed by medical care deserts is essential to improving outcomes for patients with PAH. Early screening, timely diagnosis, and access to specialized care are the cornerstones of effective disease management. By leveraging innovative solutions such as telemedicine, mobile screening, and enhanced education, we can potentially bridge the gap and help ensure equitable access to PH care. Addressing these challenges is not only a matter of healthcare delivery but also of health equity, ensuring that all patients, regardless of geography, have the opportunity to receive life-saving treatment.

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Etiometry Closes the Gap in ARDS/PARDS Detection

Chris Campbell

Acute respiratory distress syndrome (ARDS) affects more than 200,000 US patients each year, causing nearly 75,000 deaths. But even with clear diagnosis and treatment guidelines,[1] ARDS is often missed by clinicians, preventing timely interventions.

One reason is because ARDS is challenging to recognize in a timely matter; patients may meet diagnostic criteria without clinicians being aware. In addition, fear of subjecting patients to ventilator-induced lung injury (VILI) can have a negative impact on adherence to lung protective ventilation (LPV) measures, which are essential for treating patients with ARDS.

Etiometry's clinical pathway automation can help by quickly flagging patients who meet the criteria for ARDS or PARDS (Pediatric Acute Respiratory Distress Syndrome) and giving clinicians confidence that they are delivering the correct treatment, says Jo'el Barr, RN, BSN, CCRN, clinical development specialist at Etiometry.

"What we want to communicate is that there are in fact clear guidelines for treating ARDS," he says. "Etiometry can help guide clinicians in managing a patient's care by monitoring compliance with established protocols like ARDSnet or the PALICC guidelines, including tidal volumes, plateau pressures, PEEP, FiO2, and PaCO2 along with keeping them within physiological targets as well."

Currently, diagnosing ARDS/PARDS is a labor-intensive process that requires clinicians to manually calculate PaO2/FiO2, or SaO2/FiO2 ratios / OI, or OSI using lengthy, complex equations. Because these calculations are so time consuming, they tend to be performed infrequently in the ICU, leading to late detection.

While ARDS can also be diagnosed radiologically, scans are subject to physician interpretation, and studies have found a high rate of diagnostic disagreement, Barr notes.

Etiometry works by automatically aggregating patient vital signs and laboratory results directly from the patient monitor, ventilator, laboratory information systems, and standalone devices and visualizing it in a way that makes it easy to act upon. The platform's automated clinical pathway then automatically calculates SF/PF or OI/OSI ratios and is able to flag patients who meet the criteria for ARDS/PARDS.

"Etiometry's pathways give providers confidence to see that their patient is within the defined guidelines, and it helps eliminate the fear that maybe they're contributing to ventilator induced injury," Barr says.

Etiometry also has two proprietary, FDA-approved algorithms that can be used to enhance insights for the care team's diagnosis and improve care, he adds, including the IVCO2 Index™, which calculates the likelihood a patient is experiencing inadequate ventilation of carbon dioxide, and secondly, the IDO2 Index™, which calculates the likelihood a patient is experiencing inadequate delivery of oxygen.

Barr notes that research has found that Etiometry's IVCO2 Index outperformed end tidal CO2 monitoring, the previous gold standard for detecting CO2 levels during ventilation,[2] giving clinicians further confidence when they are administering treatment appropriately, he says.

This fall, the Etiometry team deployed PARDS pathways in two of the top US children's hospitals to support care teams in the management and treatment of ARDS/PARDS.

Barr notes that in addition to supporting individual patient management, Etiometry can also be used for practice tracking to improve standardization of care.

"Our platform's quality improvement app can be employed to generate reports on ventilation compliance, thus closing the gap between current hospital policies around ARDS management and their adoption by the clinical staff," he says.

Etiometry can also be used to generate reports like the number of patients being flagged for ARDS, severity, ventilation usage, and outcomes—helping administrators track a unit's performance over time.

The bottom line is about improving patient care, Barr says. "There's a huge need for making sure these patients don't go under-recognized and under-treated," he said. "Our clinical pathway automation is bridging that gap."

Chris Campbell is the Senior Editor of Respiratory Therapy.

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Guideline.
2 Etiometry User Manual (See: Discriminatory accuracy Comparison: IVCO2 vs EtCO2)

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lightweight, non-invasive wearable can be seamlessly integrated into daily life, providing continuous data collection without disrupting activities. It features advanced sensor technology and wireless connectivity, enabling data to be easily transmitted to healthcare providers for ongoing assessment and management. Dr Panagis Galiatsatos, MD, MHS, Associate Professor of Medicine in the Division of Pulmonary & Critical Care Medicine at Johns Hopkins University Hospital, stated, "This device will save lives; both in the sense of picking up low oxygen levels, and ensuring the quality of life that so many patients lose when they need to measure their oxygen level is preserved. For me, as a physician, recommending OxiWear will be a game changer for my patients, and watching them enjoy life as they measure their oxygen levels confidently and responsibly, reaffirms my passion in medicine and doctoring." The FDA clearance paves the way for OxiWear to expand its market share for its innovative technology. The company is committed to continuing its research and development efforts to expand the capabilities of its platform and address a broader range of health monitoring needs.

MGC Diagnostics Corporation Receives 510K Substantial Equivalence Determination for Ascent Cardiorespiratory Diagnostic Software

MGC Diagnostics Corporation, a global medical technology company dedicated to cardiorespiratory diagnostic solutions, is pleased to announce that it has received notification of 510K Substantial Equivalence Determination from the US Food and Drug Administration (FDA) for its Ascent cardiorespiratory

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Transforming COPD Care: The Power of Value-Based Approaches

Heather Patterson, RRT

Chronic Obstructive Pulmonary Disease (COPD) is a major public health challenge, affecting millions of people worldwide. According to Ford et al. (2013), COPD is a leading cause of morbidity and mortality, with a significant burden on healthcare systems.[1] The Global Initiative for Chronic Obstructive Lung Disease (GOLD) reports that COPD is responsible for a substantial proportion of hospital admissions and readmissions, placing a significant strain on healthcare resources.[2]

In response to these challenges, value-based care has gained significant attention in recent years, particularly in the management of chronic diseases like COPD. This approach involves a shift from traditional fee-for-service models to a payment system that rewards healthcare providers for delivering high-quality, patient-centered care that improves outcomes and reduces costs. Apria Healthcare is at the forefront of this shift, offering innovative solutions and personalized respiratory care plans that aim to reduce hospital admissions and enhance patient outcomes. Read along as we discuss how leveraging value-based COPD care can transform patient care and healthcare systems.

The Need for Value-Based Care in COPD Management

Value-based care is built on the principles of delivering high-value healthcare, which is defined as the best possible health outcomes achieved at the lowest possible cost.[3] In the context of COPD management, value-based care involves a multidisciplinary approach that focuses on preventing hospitalizations, improving patient outcomes, and reducing healthcare costs.[4]

Current COPD care models have several limitations, including fragmented care, inadequate patient education, and lack of coordination between healthcare providers.[4] All too often, these limitations mean people experience inconsistent healthcare, are readmitted to hospitals, and end up with an increase in medical bills and overall poor outcomes. Value-based care inspires healthcare providers to prioritize patient-centered care, where the whole person—not just their COPD symptoms—gets attention and support.

The Burden of COPD on Healthcare Systems

COPD is a significant burden on healthcare systems, with high rates of hospitalizations and frequent readmissions. According to the GOLD reports, COPD is responsible for a substantial proportion of hospital admissions and readmissions, placing a significant strain on healthcare resources.[5] The economic burden of COPD is also significant, with estimates suggesting that COPD accounts for over $32 billion in annual costs for the US healthcare system.[5]

The estimated direct costs of COPD are ***$32 billion*** and the indirect costs are ***$20.4 billion***

(Løkke et al., 2021).[5]

Reducing Hospital Readmissions: The Role of Value-Based Care

Frequent hospitalizations are a major concern for COPD patients, leading to poor health outcomes, increased healthcare costs, and a decreased quality of life.[6] With some of the highest hospital readmission rates globally, the US has a major issue on its hands. Enter value-based care models—powerful tools for revamping the way we approach healthcare. By paying providers based on outcomes rather than services, models like bundled payments and accountable care organizations promote collaborative, sustainable care that helps patients avoid the turmoil of hospital revisit.

Moreover, proactive care from providers like Apria Healthcare and post-discharge follow-ups can reduce hospital readmissions by identifying and addressing potential complications early, reducing the need for hospitalization.

Approximately 20% of patients discharged following an exacerbation of COPD are readmitted for any reason within 30 days, making it the third leading cause of readmissions in the United States

(Press et al., 2020).[7]

How Apria Facilitates Value-Based Care

Apria Healthcare plays a crucial role in facilitating value-based care by providing comprehensive post-discharge support and home-based healthcare solutions. Their proactive approach includes regular follow-ups, patient education, and the use of advanced technologies to monitor patient health. This ensures

Heather Patterson is the Director of Respiratory Solutions at Apria.

ASPECT	TRADITIONAL COPD CARE	VALUE-BASED COPD CARE
Care Model	Fragmented care with multiple, non-coordinated providers	Integrated, coordinated care across providers
Patient Education	Often inadequate, leading to poor self-management	Comprehensive education to empower patients in managing their condition
Provider Incentives	Fee-for-service, incentivizing volume of services	Incentives based on patient outcomes and quality of care
Care Approach	Reactive, treating symptoms as they arise	Proactive, focusing on prevention and management of chronic conditions
Health Outcomes	Generally poorer, with higher rates of complications and hospital readmissions	Improved outcomes with reduced hospital readmissions and complications
Healthcare Costs	Higher due to frequent hospitalizations and emergency care	Potential to lower overall costs through efficient, preventive care
Patient-Centeredness	Limited focus on individual patient needs and preferences	High focus on personalized care tailored to individual patient needs and preferences
Coordination Between Providers	Often lacking, leading to gaps in care and communication	Strong coordination, ensuring seamless transitions and comprehensive care

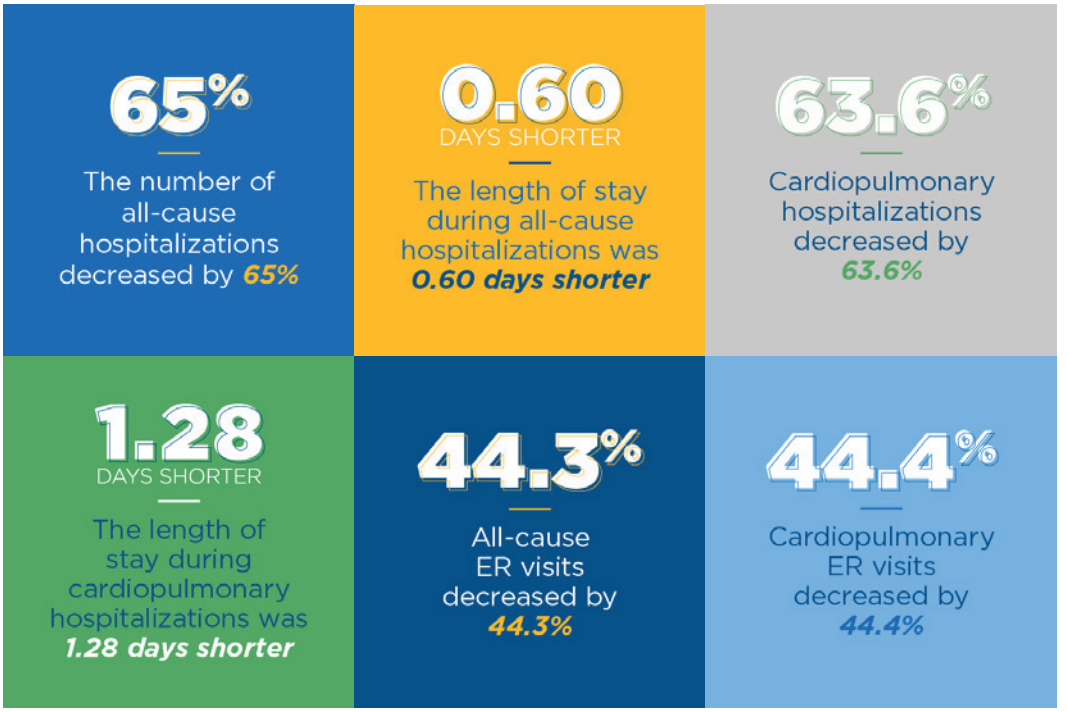
Table 1. Traditional vs Value-Based COPD Care

that potential complications are identified and managed early, significantly reducing the likelihood of hospital readmissions. By focusing on patient outcomes and continuous care, Apria helps to lower healthcare costs and improve the quality of life for COPD patients.

The Role of Non-Invasive Ventilation (NIV) at Home

A key component of Apria's value-based care approach is the integration of non-invasive ventilation (NIV) for COPD patients, particularly those with severe disease. NIV has been shown to improve patient outcomes, reduce hospitalizations, and improve survival rates.[8] Early adoption of home-based NIV can also decrease healthcare costs.

Clinical evidence supports the efficacy of NIV in improving lung function, reducing the work of breathing, and improving gas exchange, which is crucial for patients with acute hypercapnic respiratory failure.[9, 10] Additionally, the use of NIV in acute care settings has been associated with shorter hospital stays and lower mortality rates.[11] These benefits highlight the importance of integrating NIV into COPD management plans to optimize health outcomes and reduce the overall burden on healthcare systems.



Improving Patient Adherence to COPD Treatments

Medication and device adherence are critical components of COPD management, but patients often face challenges in adhering to treatment regimens. Healthcare providers play a crucial role in enhancing adherence through education, follow-up, and digital health tools.[12] Personalized care plans and remote patient monitoring can also encourage adherence to therapies, improving patient outcomes and reducing healthcare costs.

The Importance of Personalized Care Plans

Personalized care plans are critical to improving patient outcomes in COPD management. When healthcare providers customize care to meet the unique needs of each patient, they can boost patient involvement, lower the chances of hospital readmissions, and improve overall health outcomes. Creating individualized care plans also aids in spotting high-risk patients early, allowing for timely interventions and preventing potential complications.

The Role of Remote Patient Monitoring (RPM) in COPD Care

Remote patient monitoring (RPM) is a promising solution to improving patient outcomes in COPD care. RPM can identify potential complications early, reducing the need for hospitalization and improving patient outcomes. A study by Harris et al. (2024) concluded that RPM was associated with reductions in post-hospitalization mortality and hospital readmissions for COPD patients.[14]

In fact, another study found that RPM was associated with a significantly lower rate of unplanned hospitalizations per patient per year.[13] This reduction in unplanned hospitalizations can, in turn, reduce the burden on healthcare facilities and staff, leading to enhanced patient satisfaction.

A study by Polsky et al. (2023) on the use of RPM for patients with COPD showed that of the patients who had at least one hospital admission pre-initiation of RPM, **79.4%** experienced a reduction in hospitalizations, 10.8% had the same number, and 9.8% experienced an increase.[13]

A study by Polsky et al. (2023) found that remote patient monitoring (RPM) significantly reduced the rate of unplanned hospitalizations per patient per year, highlighting its potential to improve long-term COPD management.

Apria's Role in the Care Continuum

Apria Healthcare is committed to supporting patients from the first diagnosis by offering vital education and early intervention resources. Recognizing the importance of early intervention and COPD management, Apria's programs are tailored to equip patients with the knowledge they need, provide essential equipment, and emphasize the significance of treatment adherence for better outcomes.

Continuous support is fundamental to Apria's approach. Respiratory therapists and healthcare professionals provide personalized care and collaborate with physicians to adjust treatment plans as needed. Through regular home visits, telehealth services for remote consultations, advanced remote patient monitoring devices to track utilization and other therapy triggers, and trending other diagnostic testing metrics like oxygen saturation and CO2 levels, Apria's team ensures timely reporting to physicians and care teams. They also provide patients with the self-administered COPD Assessment Test (CAT) and track changes over time to assess signs of effective therapy or identify persistent symptoms that need early intervention strategies. By communicating symptoms timely, patients can collaborate with their physician and healthcare provider to discuss other innovative treatment options when appropriate,

such as BiPAP devices, non-invasive ventilation, and HFCWO therapy.

Future Directions in COPD Value-Based Care

Emerging trends, such as telehealth, remote patient monitoring, and artificial intelligence, offer promising solutions to improving COPD care. Telemedicine, for example, can improve patient engagement, reduce hospital readmissions, and enhance patient outcomes by allowing the patient to engage with their clinician more often without the burden of traveling to a care center.[15] Artificial intelligence can also play a critical role in COPD care, enabling data-driven interventions that improve patient outcomes and potentially reduce healthcare burdens.[16]

Conclusion

Value-based care offers a promising solution to the challenges of COPD management, particularly in reducing hospital readmissions, improving patient outcomes, and reducing healthcare costs. By leveraging non-invasive ventilation, improving patient adherence, and adopting innovative models of care, healthcare providers can revolutionize COPD management and improve patient outcomes.

At Apria, we are committed to supporting these value-based strategies. Our comprehensive respiratory care services are designed to enhance patient-centered care, leveraging the latest evidence and emerging trends to improve COPD management and reduce the burden of this debilitating disease. We address gaps in care through our follow-up programs, ensuring continuous communication with providers. Additionally, our use of remote patient monitoring helps track patient progress and adherence, fitting seamlessly into system-wide value-based care models.

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Heparin-Binding Protein in Lower Airway Samples as a Biomarker for Pneumonia

Magnus Paulsson,[1,2,3] Louise Thelaus,[2] Kristian Riesbeck,[3] Ingemar Qvarfordt,[4] Margaretha E Smith,[4] Anders Lindén[5,6] and Adam Linder[1,2]

Abstract

Objectives: Ventilator-associated pneumonia (VAP) is difficult to diagnose using clinical criteria and no biomarkers have yet been proved to be sufficiently accurate. The use of the neutrophil-derived Heparin-binding protein (HBP) as a biomarker for pneumonia was investigated in this exploratory case-control study in two intensive care units at a tertiary referral hospital.

Methods: Patients with clinical signs of pneumonia were recruited and bronchoalveolar lavage fluid (BALF) or bronchial wash (BW) samples were collected. Mechanically ventilated and lung healthy subjects were recruited as controls. HBP was measured with enzyme-linked immunosorbent assay.

Results: BALF was collected from 14 patients with pneumonia and 14 healthy controls. Median HBP in BALF pneumonia samples was 14,690 ng/ml and controls 16.2 ng/ml ($p < 0.0001$). BW was collected from 10 pneumonia patients and 10 mechanically ventilated controls. Median HBP in BW pneumonia was 9002 ng/ml and controls 7.6 ng/ml ($p < 0.0001$).

Conclusions: These data indicate that HBP concentrations is significantly higher in lower airway samples from patients with pneumonia than control subjects and is a potentially useful biomarker for diagnosis of VAP.

Introduction

Ventilator-associated pneumonia (VAP), hospital-acquired pneumonia (HAP) and community-acquired pneumonia are conditions diagnosed based on clinical criteria and cultures from lower airway samples (LAS).[1] The addition of biomarkers in plasma or bronchoalvolar lavage fluid (BALF) have not yet been proved to add substantial clinical value and poor biomarkers increase the risk of incorrect diagnosis, leading to unnecessary antibiotic treatment or increased time to correct diagnosis. The ATS/IDSA do not recommend biomarker-guided HAP/VAP diagnosis as the sensitivity and specificity in published reports failed to exceed 90%.[1] Still, semi-quantitative cultures on respiratory samples constitute gold-standard but these cultures are time consuming and can be biased by previous antibiotic treatment or presence of unculturable pathogens. Since VAP significantly increases mortality, a biomarker that accurately identifies VAP would be highly valuable.[2]

Heparin-binding protein (HBP) is present in azurophilic granules and secretory vesicles of neutrophils and is released by activated neutrophils. Its known properties include antimicrobial effects, monocyte and macrophage activation, and particularly induction of vascular leakage.[3] Several studies have successfully evaluated plasma HBP as a biomarker for prognosticating organ dysfunction in sepsis and septic shock and there is evidence that HBP in BALF from patients with lung allografts can detect pulmonary infection with a cut-off value of 150 ng/mL.[4] In addition, the severity of bronchiectasis as well as exacerbations of cystic fibrosis correlate with sputum HBP.[5,6] In this exploratory study, we evaluated the biomarker potential of HBP in LAS from patients with pneumonia.

Materials and methods

Patients displaying clinical symptoms of pneumonia (temperature > 38 °C or < 36 °C, purulent tracheal aspirate or decreased oxygen saturation) and radiological signs (new infiltrate on Chest X-ray) were recruited at the Departments of Infectious Diseases or Anesthesiology and Intensive Care at Skåne University Hospital (Malmö, Sweden) from 2015 to 2017. BALF (3 × 50 ml sterile phosphate-buffered saline, PBS) was collected from the first 14 recruited patients ("Pneumonia 2016"), while BW (2 × 10 ml PBS) was collected from the following 10 patients ("Pneumonia 2017"). In both patient groups, the most affected lung segment was identified based on appearance at the time of bronchoscopy and chosen for sampling, as described.[7] Mechanically ventilated and endotracheally intubated control subjects for BW ($n = 10$, "BW control") were recruited to avoid the potentially confounding influence of mechanical ventilation on HBP concentrations. These control subjects were orthopedic patients without pulmonary disorders being planned for back surgery. To establish appropriate control samples for BALF, we utilized samples from unexposed healthy volunteers ($n = 14$), who were recruited to the Section of Respiratory Medicine, Sahlgrenska University Hospital (Gothenburg, Sweden) for a

Author details can be found at the end of this article.

Table 1 Baseline characteristics of all included subjects

Variable	Study group			
	BALF "Pneumonia 2016"	BALF control	BW "Pneumonia 2017"	BW control
Number of subjects	14	14	10	10
Males	8 (57.1)	7 (50.0)	8 (80.0)	4 (40.0)
Age (years)	74 (60.8–82.0)	23.5 (22–24)	66 (58.5–68.8)	55 (39–59)
Current smoker	0 (0.0)	0 (0.0)	2 (20.0)	0 (0.0)
COPD	4 (28.6)	0 (0.0)	3 (30.0)	0 (0.0)
Other pulmonary diseases	1 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	4 (28.6)	0 (0.0)	1 (10.0)	1 (10.0)
Cardiovascular disease	5 (35.7)	0 (0.0)	3 (30.0)	2 (20.0)
Non-pulmonary malignancy	5 (35.7)	0 (0.0)	2 (20.0)	0 (0.0)
Radiographic lung infiltrate	11 (78.6)	NA	6 (60.0)	0 (0.0)
Purulent sputum	8 (57.1)	0 (0.0)	3 (30.0)	0 (0.0)
Temp > 38 °C within the last 24 h	12 (85.7)	0 (0.0)	6 (60.0)	0 (0.0)
Days with ventilator	5 (4.0–6.0)	NA	2.5 (1.8–6.5)	0.5 (0–1.0)
Arterial oxygen saturation (%)	93.5 (92.0–94.0)	98 (98.0–99.0)	95.5 (93.3–98.0)	97 (96–98)
Plasma CRP (mg/l)	69.5 (23.5–142.8)	NA	89.5 (53.3–188.0)	3.1 (1.3–10.9)
Blood leukocytes (10^9 cells/l)	10.6 (9.0–15.0)	6.4 (5.4–7.8)	10.3 (7.4–16.7)	6.9 (5.7–8.7)
Blood neutrophils (10^9 cells/l)	9.1 (8.7–13.2)	3.5 (2.7–4.0)	5.7 (5.6–9.9)	3.4 (3.3–5.8)
Gram-positive PPM	5 (35.7)	NA	3 (30.0)	0 (0.0)
Gram-negative PPM	7 (50.0)	NA	6 (60.0)	0 (0.0)
Viral PMM	1 (7.1)	NA	0 (0.0)	0 (0.0)
Fungal PMM	1 (7.1)	NA	0 (0.0)	0 (0.0)
Antibiotic treatment	14 (100.0)	0 (0.0)	10 (100.0)	6 (60.0)
Systemic steroid treatment (= > 10 mg prednisolon)	3 (21.4)	0 (0.0)	2 (20.0)	0 (0.0)
Inhalation steroid treatment	3 (21.4)	0 (0.0)	6 (60.0)	0 (0.0)
Other immunosuppression	1 (7.1)	0 (0.0)	1 (10.0)	0 (0.0)

Data are presented as median (interquartile range) or *n* (%), unless otherwise stated. *BW* bronchial wash, *BALF* bronchoalveolar lavage fluid, *COPD* chronic obstructive pulmonary disease, *CRP* C-reactive protein, *PPM* potentially pathogenic microorganism;

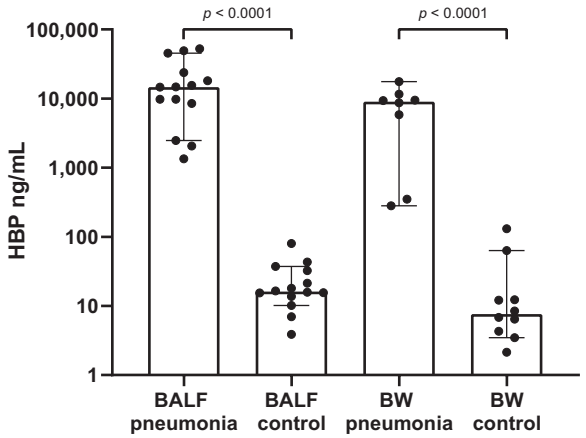

Fig. 1 Concentrations of Heparin-binding protein (HBP) were measured in bronchoalveolar lavage fluid (BALF) and bronchial wash (BW) samples from patients with pneumonia and from healthy control subjects. The median HBP in BALF "Pneumonia 2016" samples was 14,690 ng/ml and BALF control 16.2 ng/ml ($p < 0.0001$). The median HBP in BW "Pneumonia 2017" samples was 9,002 ng/ml and BW control median was 7.6 ng/ml ($p < 0.0001$). Bar graph show median values and 95% confidence intervals. Each dot represents one study subject. Statistical evaluations were made with Mann–Whitney test. *P*-values are indicated on the graph

previously published study on the local effects of endotoxin exposure.[8] Baseline data of all included study subjects are summarized in Table 1.

We quantified HBP in BALF or bronchial wash (BW) from patients with pneumonia (n = 24) and from control subjects (n = 24) using a commercial ELISA kit (Axis-Shield Diagnostics, Dundee, United Kingdom) in accordance to the manufacturer's instructions.

Statistical analysis was made using Prism software (Graphpad v8.4.3, San Diego, CA). Two-tailed p-values were calculated using Mann–Whitney's test. A receiver-operating characteristic (ROC) curve was calculated with 95% confidence interval (CI).

Results

The concentration of HBP was significantly increased in samples from patients with pneumonia compared those from control subjects, whether collected as BALF or as BW (Fig. 1). Two "Pneumonia 2017" subjects were excluded from further analysis because of negative cultures, all other samples contained bacterial pathogens. All control subjects had HBP concentrations below the previously proposed cut-off of 150 ng/ml and all pneumonia patients displayed concentrations above 150 ng/ml. The two excluded subjects both had HBP values below

150 ng/ml. We observed no statistically significant difference in HBP concentrations between BALF and BW samples. Given this, a ROC curve was calculated using pooled samples from both pneumonia patients and control subjects. Best diagnostic accuracy was achieved using a cut-off of 206 ng/ml, that yielded a sensitivity to detect pneumonia of 100% (95% CI = 85.1 – 100%) and a specificity of 100% (95% CI = 86.2 – 100%).

Discussion

The usefulness of HBP as biomarker for pneumonia depends on its accuracy in differentiating pneumonia from other diagnoses, ease of sample collection and time from sampling to results. Importantly, HBP can be analyzed using a point-of-care device in less than 30 min, a fact that enables HBP in LAS to influence the decision to start antibiotic therapy. The recent VAPrapid2 trial investigated if IL-1β and IL-8 in BALF were useful in an antibiotic stewardship design.[9] However, antibiotic prescription remained unchanged, which was partly attributed to reluctance for collecting BALF in critically ill patients. In view of this, we included a BW cohort and found no significant difference in HBP concentrations between BALF and BW. Although not as accessible as blood samples, BW samples are specific for the conditions in the lungs and the smaller lavage volumes of BW are less likely to cause adverse effects than BAL and may be more tolerable for the clinician. In addition, the BW control group was mechanically ventilated and better matched to the pneumonia patients in terms of age. Yet, the HBP values in the BW control group were similar to those in the BALF control group and indicated no increase in HBP related to mechanical ventilation.

We did not normalize HBP concentrations to urea or return volume, because normalization may confound the results and omitting normalization is in line with current recommendations and imitates the clinical setting.[10] Instead, our sampling protocol was standardized with BALF collected using 3 × 50 ml lavage fluid and BW collected with 2 × 10 ml. Yet, we obtained very clear-cut results. The latter and the fact that we explored a limited study sample, supports the idea that HBP possesses substantial potential as a robust biomarker for clinical use. Nevertheless, a larger study sample would allow independent ROC analysis of each material, so larger and prospective cohort studies in critically ill patients are warranted in the near future to verify the diagnostic accuracy and the optimal positive test cut-off.

Conclusions

In conclusion, this exploratory study forward evidence that the median HBP concentration in LAS is enhanced around a 1000-fold in patients with pneumonia. This indicates that HBP in LAS is a potential biomarker that may be added to current diagnostic tools for VAP.

Abbreviations

BALF: Bronchoalveolar lavage fluid; BW: Bronchial wash; COPD: Chronic obstructive pulmonary disease; CRP: C-reactive protein; HAP: Hospital-acquired pneumonia; HBP: Heparin-binding protein; LAS: Lower airway samples; PBS: Phosphate-buffered saline; PPM: Potentially pathogenic microorganism; ROC: Receiver-operating characteristic; VAP: Ventilator-associated pneumonia.

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Authors' contributions

MP, AnL and AdL conceived and designed the work. MP, IQ, MS, KR and AnL provided samples. MP and LT analyzed the samples and MP drafted the work. All authors were involved in data interpretation, revised the manuscript for important intellectual content, approved of the version to be published and agree to be accountable for all aspects of the work. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

All parts of this study have been reviewed and approved by the Regional Ethical Review Boards in Gothenburg (Dnr S618-02; T065-04; T683-07) or Lund (Dnr 2014/529; 2016/523) and conforms to the guidelines by the World Medical Association (the Declaration of Helsinki).

Competing interests

M.P. reports personal fees from MSD for participation in expert input forums, outside the submitted work; All other authors report nothing to disclose.

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Enhancing Tracheostomy Care: An Interview with the Lead Investigator on HME Adoption and Utilization

Ann Kearney, CScD, CCC-SLP, BCS-S and Carmin Bartow, MS, CCC-SLP

Introduction

The use of Heat and Moisture Exchangers (HMEs) in tracheostomy care has gained considerable attention. The Fall 2024 issue of *Respiratory Therapy* featured an article titled "TrachPhone HME: A Comprehensive Approach to Tracheostomy Humidification," which highlighted research on the advantages of HMEs over conventional external humidification systems. To explore this critical topic further, an interview with the primary investigator of the study "Adoption and Utilization of Heat and Moisture Exchangers (HMEs) in the Tracheostomy Patient" was conducted. The conversation delved into the study's motivations, key findings, and potential impact on clinical practices.

Background

A tracheostomy results in the loss of upper airway humidification, which can compromise pulmonary health by causing thicker secretions, mucus plugging, tracheal mucosa irritation, and respiratory distress. The standard practice to address humidification deficits following a tracheostomy has been the use of a conventional external humidification system (CEHS). However, these systems have several disadvantages, such as cost, reduced patient mobility, noise, reduced patient compliance, and delays in discharge due to issues obtaining CEHS equipment for home use. To address these issues, Stanford Medical Center conducted a Quality Improvement (QI) project to evaluate HME use in patients with a tracheostomy. The TrachPhone HME was chosen for the project due to its multiple features, including a speaking function, suction port, oxygen connector, and hygroscopic foam for optimal heat and moisture retention.

Below is the interview conducted by Carmin Bartow, MS, CCC-SLP, with Ann Kearney, CScD, CCC-SLP, BCS-S, the lead investigator of the Stanford Medical Center HME study.

What was the primary gap in clinical practice that made this study necessary?

In our medical center, we had made a change from CEHS to HMEs in our laryngectomy population. This switch was a huge success with patients, nursing staff, and discharge planning. The results indicated that improved patient and staff outcomes seen with HME use with laryngectomy patients could be applied to our tracheostomy patients as well. So, we decided to explore HME vs CEHS for our tracheostomy population.

Why do you think this gap in research or knowledge existed and needed to be addressed?

Despite the disadvantages, CEHS has been the standard of care for tracheostomy humidification for a very long time, especially for nursing care and protocols. The use of HMEs for patients with tracheostomy is not well-known to providers. Changing long-held practices can be challenging.

Can you briefly describe your key findings?

97% of patients in our study tolerated TrachPhone HME immediately post-op without exhibiting respiratory distress. Nurses preferred the TrachPhone HME over CEHS due to improved patient mobility, decreased noise in the patient's room, ease of set-up, decreased maintenance, increased patient communication, less training for patients and caregivers, and decreased suction requirements. Case management found reductions in discharge planning time because of reduced DME requirements. A cost analysis found significant cost-savings for our institution. By switching from CEHS to HME, the projected annual cost reduction was $68,000.

Were there any difficulties or barriers that you encountered during your study?

There was initial hesitation from some of our healthcare providers, but with education about HMEs as well as the study design, they were on-board and interested in the potential improvements in patient care.

What were the key criteria for selecting the patient population in your study, and how might different selection criteria affect the outcomes?

Our out-patient ENT clinic had been successfully using HMEs for years but were unaware of the Trachphone. When we first learned about the Trachphone, we immediately recognized its potential to benefit our postoperative patients in the inpatient setting; therefore, we started on the ENT subspeciality unit in the hospital. We started with all ENT patients, except for free flaps per wishes of our H&N surgeons (who are now using). There may be a diagnosis that cannot tolerate the resistance that is inherent in the HME. For most, that resistance is actually a positive for pulmonary health, but patients with advanced ALS or other advanced neurologic diagnoses may not tolerate the HME.

Ann Kearney has a Clinical Science Doctorate and has been an SLP for 35 years. She has spent the majority of her career at academic medical centers including Stanford, Brigham and Women's, Tufts and UCSF.
Carmin Bartow has over 20 years of clinical experience treating patients with tracheostomy in acute care. She is currently a tracheostomy clinical educator with Atos Medical.

Were there any adverse effects or complications observed during the study that were not highlighted in the article?
No. Only 3% of patients (2/71) enrolled in our study did not tolerate the HME due to elevated tracheostomy suctioning needs. Of the 97% who tolerated the TrachPhone HME, none developed respiratory distress, air trapping, or mucus plugs.

How do your findings contribute to the current understanding of the artificial humidification needs for patients with tracheostomy?
It is well-known that artificial humidification is necessary to restore the lost functions of the upper airway and to optimize pulmonary health in health in patients with a tracheostomy. It is also known that CEHS has disadvantages. Our article emphasizes that HMEs are an excellent option for humidification in the tracheostomy patient population. Similar to the extensive research on laryngectomy care, further clinical studies are likely to reveal improvements in respiratory health through the use of closed humidification systems provided by HMEs.

How do you see your findings influencing clinical decision-making for the specific condition or treatment you researched?
The use of HMEs in our facility has grown substantially, and they are now standard care for all patients with tracheotomies. I am confident this practice will be embraced by many other institutions in the future.

Can you discuss the significance of the study's sample size and how it may have influenced the reliability of the results?
We had a robust sample size of 71 patients. Our results should encourage people to further study and consider the use of HMEs.

Can you provide more details on the statistical analysis methods used?
We used proportion and relative frequency to report our statistics.

What do you believe will be the most significant impact of your article on clinical practice or future research in this field?
We just received notification from the publisher, Wiley, that our article has reached over 1,000 downloads. Healthcare providers are becoming more interested in this topic and I predict external humidification systems will become obsolete or used in only a small subset of patients/diagnoses in the future.

What additional research would you like to see conducted to further build on your findings?
Additional studies which investigate the outcomes of HME use for patients with tracheostomy are necessary. There is a growing body of research in this area, but more studies which examine outcomes such as pulmonary health, secretion management and suctioning needs, time to decannulation, ease of communication, and swallowing ability would help make an impact.

Do any barriers exist that would impede additional research being conducted?
Some HCPs are unfamiliar with the benefits of HMEs so that may result in resistance. However, with education about the benefits of HMEs for patients with tracheostomy much of the resistance can be overcome. HCPs buy-in, especially with RTs and nurses, is critical.

What kind of feedback have you received after your study was published?
HCPs around the world have shown great interest in these findings, with many clinicians reaching out to learn more about challenging the standard method of humidification. I'm always delighted to share our positive outcomes and insights!

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diagnostic software. Asceny is now available for both Pulmonary Function Testing (PFT) and Cardiopulmonary Exercise Testing (CPET). Ascent is a comprehensive software platform designed to streamline cardiorespiratory diagnostic testing and interpretation workflow. The software seamlessly integrates with MGC Diagnostic systems, providing real-time data capture and analysis. Ascent offers a wide range of advanced features, including: Intuitive user interface: The software features a modern and intuitive interface that is easy to learn, use, and customize. Comprehensive reporting: Ascent generates comprehensive reports that can be tailored to meet the specific needs of each organization. Advanced analysis tools: The software includes a variety of advanced analysis tools, such as the ATS/ ERS grading scorecards, automated PFT and CPET interpretation, and exercise prescription. "We are thrilled to receive the notification of substantial equivalence determination for Ascent," said Todd M. Austin, President at MGC Diagnostics Corporation. "This software platform was designed from the ground up and represents a significant advancement in cardiorespiratory diagnostics. Offering a single, integrated solution for both PFT and CPET enables MGCD to provide our customers with a modern and more efficient way to assess patient respiratory and cardiovascular function."

Older Patients With COPD at Increased Risk for PE-Associated Death

Patients with chronic obstructive pulmonary disease (COPD) are at an increased risk for fatal pulmonary embolism (PE) and may require personalized, targeted thromboprophylaxis. Those are the conclusions of investigators who analyzed public health data and found that patients with COPD have a markedly increased risk for PE-related death, particularly among those aged 65-85 years. The data suggest that "maybe we should start thinking about if we are admitting a patient with COPD in that specific age group, higher thromboprophylaxis for PE," said Marwa Oudah, MD, a pulmonary hypertension fellow at the University of Pennsylvania in Philadelphia. She presented her group's findings in a rapid-fire oral abstract session at the American College of Chest Physicians (CHEST) 2024 Annual Meeting. COPD is a known risk factor for PE. To estimate how the obstructive lung disease may contribute to PE-related deaths among patients of varying ages, Oudah and colleagues drew data on deaths due to an underlying cause of PE from 1999 through 2020 from the Centers for Disease Control and Prevention's WONDER database. They stratified the patients into two groups — those with or without COPD — whose data were included in the Multiple Causes of Death dataset, according to age groups ranging from 35 years to over 100 years. The investigators calculated proportional mortality ratios in the non-COPD group and applied these to the COPD-positive group among different age ranges to estimate the observed vs expected number of deaths. A total of 10,434 persons who died from PE and had COPD listed among causes of death were identified. The sample was evenly divided by sex. The peak range of deaths was among those aged 75-84 years. The authors saw an increase in PE-related mortality among patients with COPD aged 65-85 years ($P < .001$). The ratios of observed-to-expected deaths among patients in this age range were "substantially greater than 1" Oudah said, with patients aged 75-79 years at highest risk for PE-related death, with an observed-to-expected ratio of 1.443. In contrast, the rate of observed deaths among patients aged 85-89 years was similar to the expected rate, suggesting that the COPD-PE interaction may wane among older patients, she said. Among patients aged 35-64 years, the risk for death from PE was not significantly higher for any of the 5-year age categories. The investigators emphasized that "given the observed trend, individualized patient assessments are imperative to optimize preventable measures against PE in the aging COPD population."

Vitalograph acquires Morgan Scientific to meet growing global demand for respiratory diagnostic solutions

Vitalograph has announced the acquisition of Massachusetts-based Morgan Scientific, a long-term partner of the respiratory diagnostics leader, strengthening its US commercial footprint and enabling it to meet the growing global demand for its innovative solutions, particularly in advanced pulmonary function testing solutions. Speaking of the acquisition, Frank Keane, CEO of Vitalograph said: "We have a long and successful relationship with Morgan Scientific. This agreement is the natural progression for both companies as our combined expertise allows us to focus on delivering the best possible diagnostic solutions that can enable a better understanding of lung health." Morgan Scientific is an expert in customer-facing software for advanced PFT systems. ComPAS2, the company's flagship software powers Vitalograph's innovative range of advanced PFT solutions, the VitaloPFT Series. Morgan Scientific is also a key distributor for Vitalograph's pulmonary function testing solutions in the US. Speaking of their collaboration to date, Mr Keane said: "The recent creation of the VitaloPFT Series has given us valuable experience in working as a team and built mutual respect for our individual expertise. Morgan Scientific is a natural complement to the Vitalograph brand, and this development brings incredible value to our customers all over the world. This acquisition paves the way for us to develop our comprehensive PFT range further." He continued: "Vitalograph is a family-owned company and recognises the pioneering drive of the Morgan family to create a business founded on people, integrity, quality, and innovation. These values are at the heart of Vitalograph and are instilled in every part of our business today." Gareth Morgan, son of the founder of Morgan Scientific said: "There is no other company in the world that we trust to uphold our legacy of innovation and to continue to put the needs of customers at the forefront of every decision. Joining a globally present and renowned brand such as Vitalograph will enable us to concentrate our efforts on building the business through what we know best — excellence in innovation and customer service." The acquisition of Morgan Scientific is a key milestone in Vitalograph's plan to develop its respiratory diagnostics business globally, furthering its goal of providing comprehensive testing solutions that enable the best possible respiratory healthcare. The company is in the middle of an ambitious growth strategy and is on track to treble its respiratory diagnostics business in the four years leading to 2026. The acquisition coincides with Vitalograph's 50th anniversary of operating and growing in Ennis, Ireland.

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