Volume 12 Number 1 Winter 2017

Respiratory Therapy™

The Journal of Pulmonary Technique

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*Source: Batchelder, P.B., Fingertip Pulse Oximeter Performance in Dyspnea and Low Perfusion During Hypoxic Events. Clinimark Laboratories, Boulder, Colorado. 2016. White Paper.

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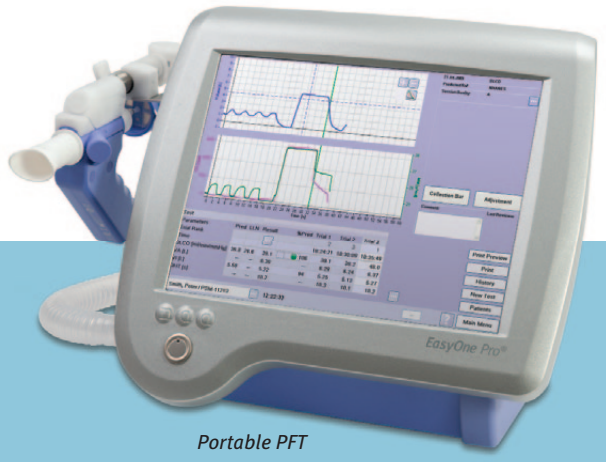

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News

■ Winter 2017

VAP Rates Have Not Declined, Say Data

Contrary to previously reported numbers from the Centers for Disease Control and Prevention (CDC), ventilator-assisted pneumonia (VAP) rates have not declined, but have remained near 10% since 2005, according to data from the Medicare Patient Safety Monitoring System (MPSMS). MPSMS-measured VAP incidence, based on a review of hospital charts of elderly patients in intensive care units, was 10.8% (95% confidence interval, 7.4% - 14.4%) during 2005 to 2006 and 9.7% (95% confidence interval, 5.1% - 14.9%) during 2012 to 2013, report Mark L. Metersky, MD, a professor of medicine and director of the Center for Bronchiectasis Care at UConn Health Pulmonary/Critical Care in Farmington, Connecticut. In contrast, data from the CDC's National Healthcare Safety Network (NHSN) have shown declines in VAP rates of 71% and 62% in medical and surgical intensive care units, respectively, between 2006 and 2012.

Dräger Donates 19 Ventilators to Respiratory Therapy Schools

Dräger has donated 11 Savina 300 and eight Evita Infinity V500 ventilators to US respiratory therapy (RT) schools at this year's American Association for Respiratory Care (AARC) International Congress. Providing the latest mechanical ventilation technology, Dräger is helping to foster a greater learning experience for RT students – professionals critical to the future of healthcare. RT schools are on the frontlines of training the next-generation of respiratory professionals – a role that will become even more important as the healthcare industry prepares for the demands of an aging population. The donation of Dräger ventilators gives RT students the invaluable experience of training with modern-day equipment in a simulated lab setting. "Finding funding for capital budgets in educational programs can be exceptionally difficult, and many students are benefiting from the equipment donated by Dräger," said Shawna Strickland, PhD, RRT-NPS, RRT-ACCS, AE-C, FAARC and Associate Executive Director-Education at AARC. "We appreciate the extra efforts of Dräger to improve respiratory care education and maximize positive patient outcomes."

New Eagle Has Landed

Hans Rudolph, Inc. has unveiled its New Eagle Disposable Masks for Non-Invasive Ventilation(NIV) & administration of Oxygen and other breathing gases. New disposable interface concept allowing one mask to stay with patient from emergency accident site EMS to transport vent, emergency room vent, acute care, surgery, sub-acute care, to hospital room Respiratory support NIV procedures. Features include: 3 Color coded sizes (S,M,L); chin cup; low deadspace, lightweight, built-in 22mm ID (female) port.

Propeller Device Takes Off

Propeller Health, the leading digital solution for respiratory medicine, announced US Food and Drug Administration 510(k) clearance to market its Propeller platform for use with GSK's Ellipta inhaler, the pharmaceutical company's innovative, patented, dry powder inhaler (DPI). The sensor for the Ellipta inhaler was built and cleared as part of a development agreement and R&D collaboration between Propeller and GSK that was announced in 2015. This FDA clearance follows CE

Respiratory Care

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Mark and Health Canada registration for the device and system earlier this year. Propeller is FDA-cleared to help patients and their physicians better understand asthma and COPD, and help to improve the symptoms and outcomes of these chronic respiratory diseases. With proprietary sensor technology, software, and services, Propeller's digitally-guided therapy platform integrates information from multiple sources, including connected medications, then uses machine intelligence to help individuals manage their condition.

'A New Standard'

ResMed introduced the AirFit N20 nasal mask and AirFit F20 full face mask for positive airway pressure (PAP) treatment of sleep apnea. Loaded with innovations designed to improve mask fit, comfort and ease of use, the new-generation ResMed masks are the result of more than three years of research and development. The AirFit N20 and AirFit F20 feature ResMed's innovative new InfinitySeal silicone cushion that adapts to the unique facial contours of each patient to increase comfort, improve fit and reduce leakage for maximum treatment efficacy. Hard-to-fit masks affect sleep specialists and patients alike, so with the new AirFit 20 series, ResMed has taken one of its most popular mask features—magnetic clips, which make the headgear easier to get on and off—and introduced them on its full face model. Testing shows the AirFit N20 fit an astonishing 99 percent of patients tested, and the AirFit F20 fit an impressive 97 percent—regardless of facial structure, gender or age. "These new masks address two of the biggest catalysts for effective sleep apnea treatment: fit and comfort," said ResMed CEO Mick Farrell. "Patients rate mask comfort as the number one reason that can help them stay on therapy. Not only are the F20 and N20 our most comfortable masks ever, they're easier and faster for clinicians to fit on patients the first time, helping more people suffering from sleep apnea adhere to this life-changing therapy." The masks are part of ResMed's Air Solutions connected care portfolio, complementing its best-selling, cloud-enabled Air10 flow generator devices and myAir and AirView monitoring tools that are proven to help improve patients' CPAP use.

Two Options Offered

Device maker Vortran has announced there will be two options for its new Manometer: One with a Tee Connector and the other with a Vertical Connector. The Manometer is made with new copper beryllium springs, making it MRI Conditional and does not cause artifacts in the picture. Manometer is a single patient use, airway pressure indicating device for the purpose of monitoring patient's ventilation conditions with devices such as the Automatic Resuscitator or other similar resuscitators/ventilators. Manometer will indicate airway pressure like any other pressure manometer with an indicator needle that shows PIP (Peak Inspiratory Pressure) and PEEP (Positive End Expiratory Pressure) in cm-H2O.

PneuView Updated

Michigan Instruments, makers of the original "Michigan Lung" Training & Test Lung Simulation products, continue to innovate and identify helpful applications for users. They have just announced the release of PneuView 3.1 Software. This is an upgrade of the PneuView 3 software which is used with the PneuView 3 Lung Simulation System, first released in early 2015. Version 3.1 software offers several new capabilities, along with improvements to the user interface. James Maatman, Michigan Instrument President says, "Many users of the PV3 software have provided feedback and suggested improvements to the product. We realize that our products serve an exceptional user base of educators, researchers, and quality control professionals. We continue to adapt our lung simulation products to better serve them." Updates to the PneuView 3.1 include: Improved accuracy of flow parameters, new recording mode and snapshot mode, recording mode allows recording of live ventilation data for replay and analysis, snapshot mode allows users to grab a set of numeric data on the screen and saves them to a .csv or .xls table format.

Respiratory Information System Unveiled

Iris, the first and only Integrated Respiratory Information System (IRIS), brings relevant respiratory data together in one place, empowering physicians to efficiently analyze and optimally diagnose, stage, and manage respiratory disease. Iris lets you quickly and easily share real-time information and updates with key members of a patient's care team, enabling the most informed clinical decisions, leading to enhanced outcomes and lower costs. Iris Decision is a modular respiratory care workstation designed to provide actionable, streamlined information to physicians and department managers in order to better care for their patients. The Interpretation Module is the first released component. The Iris Decision Interpretation Module uses the power of Iris to present all relevant clinical and diagnostic respiratory data together in one place for enhanced interpretations with high confidence of accuracy. View relevant data from multiple sources including PFT, Spirometry, pre/post test questionnaires, and test results from other respiratory devices to provide an interpretation based on the complete picture of your patient's health. Interpretation workflow is simplified, allowing you to quickly review, interpret, digitally

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New Study Highlights Monaghan Medical's Drug-Free Aerobika Device

Monaghan Medical Corporation (MMC) announced that a new study presented to the American College of Chest Physicians (CHEST) shows MMC's Aerobika device is effective in reducing drug use for treatment of Chronic Obstructive Pulmonary Disease (COPD). COPD is a major source of morbidity and mortality in the United States. The Center for Disease Control estimates that COPD medical visits, hospital admissions and lost time costs 36 billion dollars annually. The recommended course of treatment for acute COPD exacerbations includes antibiotics and oral corticosteroids (OCS). The study results were revealed at the CHEST Annual Meeting in Los Angeles, show that those study patients who used the Aerobika device experienced a significant reduction (57% and 89% reduction, respectively) in the use of antibiotics and OCS in the hospital setting compared to those study patients who did not use the Aerobika device in addition to the regular COPD medication treatment. These findings are part of a larger 6-month retrospective study that demonstrated a 28% reduction in exacerbations in as little as 30 days of treatment, when used as an add-on to usual COPD medications. COPD exacerbations can be caused by viral or bacterial infections, in fact pulmonary infections are associated with 50% of COPD hospital admissions and higher mortality rates. Overproduction of mucous leads to increased rates of infection and inflammation contributing significantly to morbidity and mortality in COPD. This study showed for patients in the Aerobika device cohort, antibiotics were used 57% less and oral corticosteroids were used 89% less than for the cohort without the Aerobika device within 6 months' post-exacerbation. The decreased need for short-term drug therapies including antibiotics and OCS, may have reflected better disease control with those patients who used the non-drug device. Additionally, patients in the Aerobika device cohort exhibited significantly lower costs throughout the study period with an average reduction of $6,347 USD and $9,936 USD per patient at 30 days and 6 months respectively for all in-patient and out-patient hospital costs. The projected cost of COPD in the US by 2020 has been calculated at $49 billion. Since COPD exacerbations account for the greatest proportion of burden on healthcare systems, and readmissions are unwanted and expensive, the simplest way to reduce hospital admissions for COPD is to reduce exacerbations.

New Vitalograph Micro Spirometer Off to Flying Start

At the recent AARC conference in San Antonio, Vitalograph successfully introduced its new handheld spirometer perfect for bedside testing by respiratory therapists. Never before has there been a full function spirometer with Vitalograph's legendary quality at under $900. The response from the attendees was very positive for this device, as there has not been very good alternatives in this price and quality category in the past. The Micro provides spirometry made simple, reliable, ultra-quick and affordable. This handheld spirometer is packed with a host of features including full color touch screen, icon driven menu and highly accurate and robust pneumotachometer flow sensor technology. There is an optional remote flowhead tubing kit which allows the patient to hold only the flowhead, keeping the touchscreen more easily visible to the therapist while maintaining eye contact with the patient for better coaching. It comes complete with Vitalograph Reports 2 software for FAST PDF REPORTS that can easily be imported into your electronic health record.

Company Invests in New Personalized Product Line

Electromed announced the expansion of its SmartVest SQL Airway Clearance System product line to include new SmartVest garment and SQL generator colors, offering patients with chronic impaired airway clearance more opportunities to personalize their HFCWO therapy experience. The expanded SmartVest garment and SQL generator colors made their debut at the North American Cystic Fibrosis Conference in Orlando, Florida. For the SmartVest garment, the company unveiled seven designs, including green camouflage, pink camouflage, and black. The SmartVest features Velcro-like closures, soft-touch fabric, and a single-hose design to make treatment easy and comfortable. As for the SmartVest SQL generator, it's considered the lightest HFCWO generator on the market, and is now available in four unique colors to fit a patient's personal style: blue, red, bright blue, and gray. With the expansion to seven garment colors and four generator enclosure colors, patients receive a greater opportunity to uniquely customize their SmartVest system. Higher personalization can positively influence satisfaction with therapy and may improve adherence, along with the SmartVest's ease of use, ergonomic comfort, and lifestyle convenience. The new color selection is marketed for domestic homecare use only. The SmartVest system is designed to promote airway clearance and enhance bronchial drainage through high frequency chest wall oscillation (HFCWO), a proven clinical therapy that helps clear the lungs of excess secretions, reducing the risk of respiratory infections and hospitalizations. Airway clearance therapies must be consistently followed to have their intended benefit, and as with any treatment, poor adherence can compromise its effectiveness.

Bad News for Sleep Apnea Patients

Patients with obstructive sleep apnea (OSA) and asthma are 14 times as likely to have severe asthma exacerbations compared to asthma patients without OSA, new research shows. "Inattention to OSA evaluations in these patients may lead to diagnostic and treatment delays and to increases in the frequency of severe acute exacerbations," Dr Ke Hu of Renmin Hospital in Wuhan, China, and colleagues note in their report. "Thus, we hope that the findings from our study encourage practitioners to consider screening for OSA and to consider the clinical outcomes." The findings were published online in Sleep Medicine. Epidemiological studies have found that people with asthma are more likely to have OSA, and vice versa, Dr Hu and his team write. "However, it remains unclear whether OSA affects severe exacerbations in patients with asthma," they add. To investigate, they had 146 patients with asthma and 157 controls undergo full-night polysomnography, and recorded severe asthma exacerbations among the patients over a four-year period. Twenty-eight asthma patients and 15 controls had

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** The VisiVest™ System transmits data about vest usage. It does not make care decision recommendations.*
*** The VisiVest™ System is intended to provide airway clearance therapy when external manipulation of the thorax is your choice of treatment.*

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OSA. The relative risk of OSA in patients with asthma was 2.25. Asthma patients with OSA also had more severe exacerbations, with a relative risk of 14.23. Apnea hypoxia index correlated significantly with the number of severe exacerbations. Repeated episodes of hypoxia and re-oxygenation that occur in OSA may lead to systemic inflammation that affects the airway and aggravates asthma, the researchers suggest. "It remains unclear whether OSA alters pulmonary function, which is a risk factor for acute exacerbations," they add. "Further studies are needed to determine whether the observed increase in acute exacerbations arose as a consequence of differing incidences of OSA in asthma patients or whether OSA reduces lung function in asthma patients."

Nonin Medical Launches Next Generation

Nonin Medical, Inc., the inventor of finger pulse oximetry and a leader in noninvasive medical monitoring, announced it has launched the next generation of end-tidal CO_2monitors in the LifeSense II capnograph/pulse oximeter and RespSense II capnograph. The Nonin LifeSense II and RespSense II are value-priced monitors that are ideal for a wide range of medical monitoring applications where a stand-alone capnograph is desirable, including resuscitation, procedural sedation, pain management, post-anesthesia monitoring and sleep testing. With both devices, clinicians have first-breath detection of respiratory rate and end-tidal CO_2 ($EtCO_2$). In addition, the LifeSense II adds Nonin's proven PureSAT SpO_2 technology which utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements. They offer key benefits over first-generation LifeSense and RespSense products with a larger display, internal memory with USB and multiple settings options, among many others.

New Research Shows Benefits of Nasal High Flow Therapy

Fisher & Paykel Healthcare welcomes new research on the benefits of its Optiflow nasal high flow therapy. This research was presented at the American Association of Respiratory Care (AARC) Congress in San Antonio, Texas. Earlier in October, the prestigious Journal of the American Medical Association (JAMA) published another study led by Associate Professor Hernández MD, which investigated the use of nasal high flow (NHF) therapy in comparison to non-invasive ventilation (NIV) for patients at high-risk of reintubation. The randomised clinical trial was conducted across three intensive care units and used Fisher & Paykel Healthcare's Optiflow nasal cannula. The research showed that among high-risk adults who had undergone extubation, NHF was not inferior to NIV for preventing reintubation and post-extubation respiratory failure. The multicentre randomised non-inferiority clinical trial, involving 604 adults in three intensive care units in Spain, found that the proportion requiring reintubation was 22.8% with NHF therapy vs 19.1% with NIV, and post-extubation respiratory failure was observed in 26.9% with NHF vs 39.8% with NIV, reaching the non-inferiority threshold. As secondary outcomes, median time to reintubation was not significantly different in the two groups but median ICU length of stay after randomisation was lower in the NHF group: 3 days vs 4 days. In addition, adverse effects requiring withdrawal of the therapy were observed in none of the patients in the NHF group vs 42.9% of patients in the NIV group. This research follows on from an earlier study in 2016 by Assoc. Prof Hernández and colleagues, which found that the use of Optiflow NHF therapy reduced the risk of escalation for extubated patientswithin 72 hours when compared to conventional oxygen therapy. The much better comfort and tolerance of NHF compared with NIV, permitting nearly 24 hours of daily use, are significant advantages and together, these two studies published by Assoc. Prof Hernández comprise compelling clinical evidence of the benefits of Optiflow NHF therapy.

Intelligent Humidification Presented

As a manufacturer of Intelligent Ventilation solutions, Hamilton Medical provides caregivers with technologies that allow them to focus on the important aspects of patient care. To expand the Intelligent Ventilation concepts to devices directly involved in critical care ventilation was the next logical step. "Humidification is an important part of respiratory care. When we developed the HAMILTON-H900 humidifier, we talked to many clinicians to understand what they would improve in conventional humidification," explains Jens Hallek, President of Hamilton Medical. Easier handling of circuits, cables and connections, an improved user interface, reduction of rain-out, and increased safety were the most requested enhancements. The HAMILTON-H900 aims at improving humidification in exactly these areas. The HAMILTON-H900 comprises only two components, which are delivered pre-assembled and ready to use: The wall-heated breathing set including the new all-in- one connectors, integrated temperature probe, water refill tube, Y-piece, and water chamber, and the humidifier base with the user interface and the heating plate. This saves time, increases efficiency, and facilitates the handling of the humidifier, as well as reducing the risk of contamination. With no need to worry about extra cables to connect or disconnect anymore, the caregiver only needs to slide the water chamber into the humidifier and connect the breathing circuit to the patient. The breathing circuits for the HAMILTON-H900 integrate the heater wires into the circuit wall. This eliminates the cold interface between heated breathing gas and ambient temperatures, and leads to significantly reduced condensation and rain-out effects in the breathing circuit. To perfectly adapt the humidification therapy to the individual patient and environmental conditions, the HAMILTON-H900 humidifier allows for manual adjustment of the chamber temperature and temperature gradient. Having too much condensation in the tubing can, therefore, be avoided by adjusting the temperature gradient. By reducing the need to open the circuit to drain condensate, the HAMILTON-H900 minimizes the potential for the spread of pathogens associated with the development of ventilator-associated pneumonia (VAP). Due to the ergonomic design, the user interface can be easily seen and operated from a standing position, and provides all the information the caregiver needs at a glance. The large, high-contrast LC display provides excellent readability, even in direct sunlight. Alarms are displayed with self-explanatory icons on the LC display, and can be heard and seen from afar thanks to the bright alarm lamps and audible alarm.

Investment Drives Forward for Companies

Clayton, Dubilier & Rice ("CD&R") announced an agreement under which CD&R-managed funds will make a significant equity investment alongside existing management in Drive DeVilbiss Healthcare ("Drive"), a global manufacturer of medical products. Terms of the transaction were not disclosed. Formed in 2000, Drive has become a leading manufacturer of medical products with a strong and consistent track record of growth achieved both organically and through acquisitions. The company's high-quality, diverse product portfolio, channel footprint and global operating scale were strategically built by its executive

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An estimated 8 million COPD patients may have Bronchiectasis,
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If you have COPD/Respiratory patients that have had:

✓ A productive cough for 6 continuous months in the last year.

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AND

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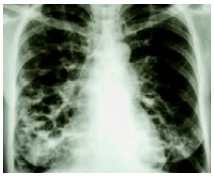
These patients may have bronchiectasis and, if confirmed via a CT scan, are eligible for the AffloVest through Medicare, Medicaid or private insurance.*



An X-ray of Bronchiectasis.

The AffloVest is the first truly portable, battery operated, fully mobile during use, High Frequency Chest Wall Oscillation (HFCWO) vest. The AffloVest promotes airway clearance and lung secretion mobilization in physician prescribed treatment of respiratory diseases like **Bronchiectasis, Cystic Fibrosis, MS, MD, ALS, and other neuromuscular diseases.***

- The AffloVest incorporates 21st century technology utilizing the latest in oscillation therapy, portability and mobility during use
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- 9 setting variations for individualized treatment
- 7 sizes available
- Quiet and lightweight

Patents Pending – USA & Worldwide

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* AffloVest requires a doctor's prescription for treatment by High Frequency Chest Wall Oscillation (HFCWO). The AffloVest has received the FDA's 510k clearance for U.S. market availability, and is approved for Medicare and private health insurance reimbursement under the Healthcare Common Procedure Coding System (HCPCS) code E0483 – High Frequency Chest Wall Oscillation.

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leadership team to take advantage of favorable underlying demographic and industry trends. Drive's products include a full suite of mobility, respiratory, sleep, bath and personal care, specialty beds, pressure prevention, rehabilitation and other related products, and are sold into the homecare, long-term care, retail and e-commerce channels. Drive serves a customer base of more than 15,000 dealers, home healthcare providers, healthcare distributors, retailers and e-commerce companies and sells its branded products in more than 80 countries around the world.

Nasal Pillow Mask Unveiled

3B Medical has announced the introduction of the Rio Nasal Pillow Mask, the newest mask in 3B's line up of premium, soft, comfortable and light weight interfaces. The Rio stands apart from other masks weighing in at only 2.6 ounces, headgear included, making it the lightest mask on the market. One-piece cushion construction makes it ideally suited for resupply with very simple cushion replacement. Its unique rotating ball in socket swivel offer true freedom of movement.

Device Maker Finds Way to Adapt

Passy-Muir, the leading manufacturer of the No Leak speaking valve, is introducing two adapters to provide clinicians with a way to easily connect the Passy-Muir Valve inline while the patient is mechanically ventilated. The adapters are designed to provide a secure connection between the Passy-Muir Valve and a tracheostomy tube, ventilator tubing, closed suction systems, or other adapters. Each adapter is latex free, color coded for easy identification, and provided in re-sealable, multiple unit packaging. The PMV-AD1522 is a step-down adapter to connect the PMV 007 (Aqua Color) to a T-piece type closed suction system. The flexible, PMV-AD22 adapter is designed to be used with the PMV 2001 (Purple Color). All Passy-Muir's products are proudly made in the USA. Both adapters will be available for purchase through Passy-Muir. In other company news, Passy-Muir recently released a new user-friendly app for iPhone and iPad designed to facilitate patient communication, provide valuable information regarding tracheostomy and foster patient participation in care. The app includes a number of useful features including: Pre-recorded responses & phrases which enable communication at a touch of a button, user-defined male or female voice, child voice option, attractive and intuitive menu, and custom phrase record option. Clinicians attending the 2015 ASHA conference may have caught a glimpse of some exciting revisions to the Toby Tracheasaurus pediatric program. The enhancements include new dinosaur cartoon characters, new therapeutic activity cards, and a clinically improved Toby Tracheasaurus Coloring & Activity Book that is sure to appeal to tracheostomized children, their caregivers and clinicians. Each Toby Tracheasaurus pediatric program kit comes with a draw-string backpack containing a Toby Tracheasaurus Plush Toy, the Toby Tracheasaurus Coloring & Activity Book with crayons, and a Toby Tote with an assortment of therapeutic toys. Featuring a pediatric tracheostomy tube and Passy-Muir Valve for the purpose of demonstration and education, the Toby Tracheasaurus Plush Toy provides therapists with a lighthearted method to introduce children to tracheostomy and the Passy-Muir Valve, while facilitating vocalization and enhancing therapeutic activities.

Landmark Study Results In

Inspire Medical Systems, Inc., announced the results of a landmark long-term clinical study for its Inspire Upper Airway Stimulation (UAS) System, the first FDA-approved implantable neurostimulation treatment for people diagnosed with Obstructive Sleep Apnea (OSA). OSA affects more than 18 million Americans and can have devastating effects on heart and brain health, impair quality of life and increase accident risk. Inspire therapy is for some people diagnosed with moderate to severe OSA who are unable to tolerate or get relief from Continuous Positive Airway Pressure (CPAP). In contrast to CPAP, Inspire therapy works inside the body and with a patient's natural breathing process. Controlled by the patient sleep remote, the system includes a breathing sensor and a stimulation lead powered by a small battery. During sleep, the system senses breathing patterns and delivers mild stimulation to the tongue and other soft tissues of the throat to keep the airway open. Inspire therapy is currently available at more than 60 leading medical centers across the United States and Europe. The Stimulation Therapy for Apnea Reduction (STAR) trial was conducted at 22 leading sleep medicine centers across the United States and Europe. One-year STAR trial outcome measures, published in the New England Journal of Medicine, showed that sleep apnea patients receiving Inspire therapy experienced significant reductions in sleep apnea events and significant improvements in quality of life measures. The new long-term study outcomes showed that the improvements observed at one-year were sustained at the three-year follow up mark. The outcomes include a 78 percent reduction in apnea-hypopnea index (AHI) from baseline, an 80 percent reduction in oxygen desaturation events from baseline, 80 percent of bed partners reported soft or no snoring as compared to 17 percent of bed partners at baseline, quality of life measures, including daytime sleepiness and functioning, showed clinically meaningful improvements and a return to normal levels over baseline. The biggest challenge for OSA patients is that many are unable to tolerate or get relief from CPAP. Published studies show that CPAP adherence rates are less than 50 percent. In contrast, new data from the STAR Trial demonstrate that more than 80 percent of the patients with Inspire therapy report nightly use after three years of being prescribed the therapy.

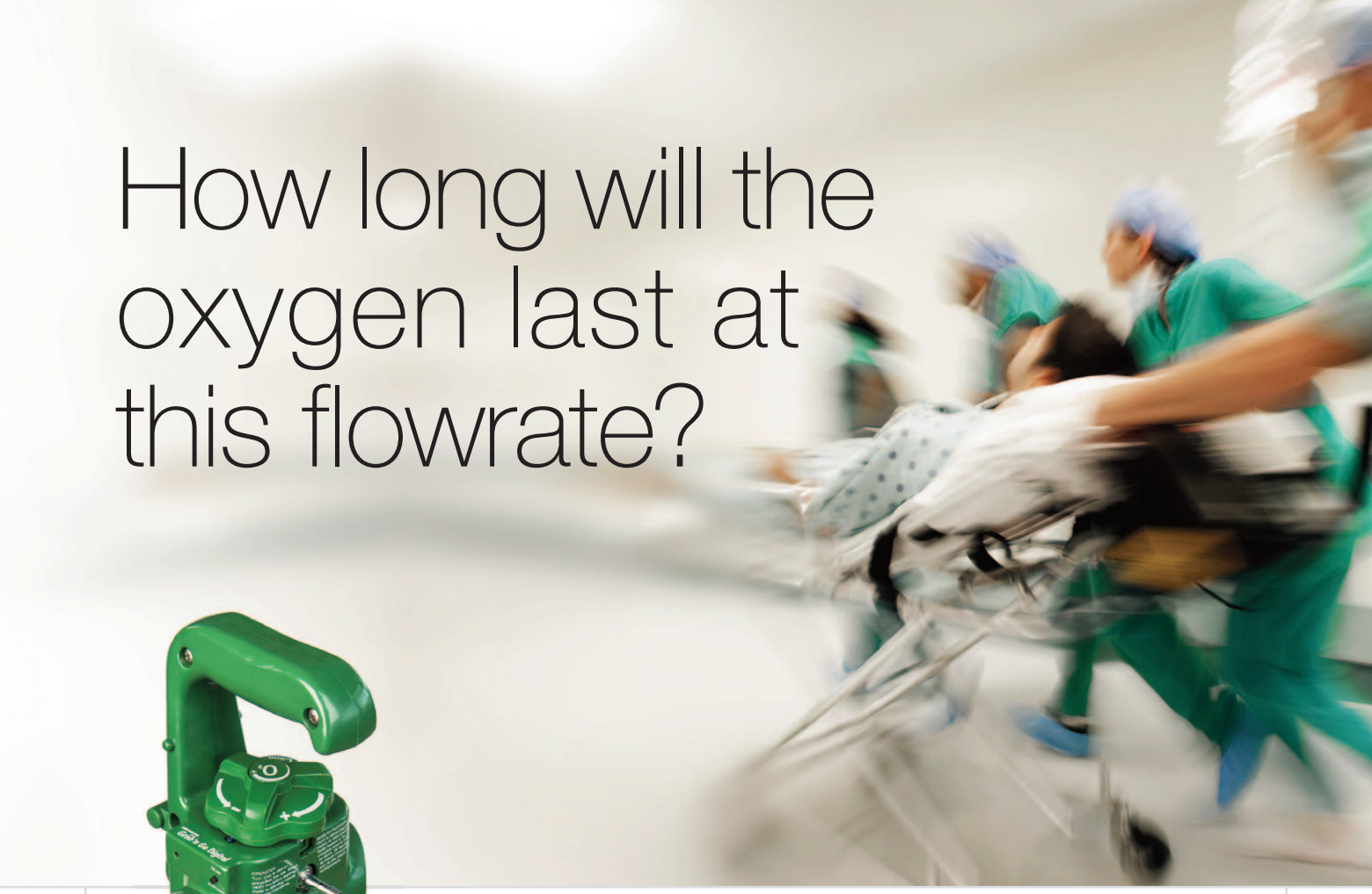
System Offers Better Suction

Ciel Medical, a medical device start-up focusing on unmet needs of those caring for the intubated patient, has announced the launch of the Sherpa Suction System, a tool to give nurses and respiratory therapists greater confidence in suctioning secretions pooling above the endotracheal tube's inflated cuff. Caregivers want to remove these mucus secretions to avoid aspiration into the lungs and the subsequent risk of acquiring ventilator associated pneumonia (VAP). The Sherpa Suction System is a single-patient product and includes the Sherpa Suction Guide and Suction Line. The Guide is a single molded unit that includes a locking feature, handle, soft tip and compatible with ETT sizes from 7.0 to 8.5 mm. Sherpa Suction Guide is easily clipped to the underside of the endotracheal tube and advanced until the handle is at the patient's teeth. The integrated Suction Line easily threads through the Guide, is advanced through the opening in the handle and guided to the optimal position for removal of secretions. The Sherpa Suction System allows for selective and cost-effective use of above-the-cuff suctioning in targeted patients.

Measuring Lung Function at Home

Using ndd Medical Technologies' EasyOne spirometer, Chronic Obstructive Pulmonary Disease (COPD) patients enrolled in the WISDOM study were as adept in monitoring lung function at home as the professionals who performed their baseline

How long will the oxygen last at this flowrate?



Praxair's *Grab 'n Go® Digital* portable medical oxygen system now features an easy-to-read "time remaining" display, with audible and visual alerts. These alerts are designed to activate if the cylinder pressure drops below 300 psig. With no need to estimate oxygen supply, transports can be more efficient with reduced human error.

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measurements in the clinic when the trial began. Results of the 2,161-patient clinical trial were recently presented in a poster at the American Thoracic Society meeting in Denver. Previous WISDOM (Withdrawal of Inhaled Steroids During Optimized Bronchodilator Management) study results were published in the New England Journal of Medicine (NEJM). Most patients in the study had severe or very severe COPD. The EasyOne spirometers used in the WISDOM and other clinical trials are portable spirometers employing advanced TrueFlow ultrasonic technology. There are no moving parts, no codes to enter, no screens to catch sputum, and no disposables to calibrate. The ultrasonic flow measurement is independent of gas composition, pressure, temperature, and humidity thus eliminating errors due to these variables.ndd Medical also manufactures the mobile EasyOne Pro and EasyOne Pro LAB, which perform most functions of a hospital-based PFT lab and have been found to be as accurate.

Early Warnings Go Wireless

SensiumVitals is a revolutionary new wireless early warning system that enables early intervention by continuously and accurately monitoring vital signs of heart rate, respiration rate and axillary temperature every two minutes, and alerting the nursing staff when pre-set thresholds are exceeded. The system is based on a disposable, single-use, wearable patch that monitors patients. By notifying clinicians of changes in patients' vital signs, SensiumVitals brings the nurse to the deteriorating patient, allowing intervention before the condition worsens, resulting in improved patient outcomes, shorter hospital stays, and lower treatment costs. It is currently in trials in two leading National Health Service (NHS) hospitals at St. James's University Hospital in Leeds and Queen Elizabeth Hospital in Birmingham. An abnormal respiration rate is a strong indicator of serious underlying illness. SensiumVitals measures respiration rate using the technique of Impedance Pneumography (IP), which involves the direct measurement of thoracic impedance changes associated with respiration. The respiration rate algorithm used in SensiumVitals also ensures that irregular measurements caused by motion, eating, talking, sneezing, and so forth are not reported, reducing the occurrence of false alarms. The SensiumVitals digital patch is an FDA-cleared, lightweight (weighing only ½ ounce), energy-efficient, battery-powered device that uses a proprietary digital radio chip to monitor a patients' vital signs. It is designed for in-hospital use, particularly in general care, post-surgical areas, and emergency rooms, and can be easily attached to the patient's chest by means of two self-adhesive conventional ECG electrodes. The SensiumVitals patch has unique roaming capabilities, which means that patients' vital signs can be transmitted as they move around, helping patients recover more quickly.

Ventilation Device Addresses Transporting Neonates

The HAMILTON-T1 with neonatal option is a high-end transport ventilator that provides the best possible ventilation therapy for your smallest and most vulnerable patients. During transport, the HAMILTON-T1 delivers the same performance as a fully featured NICU ventilator at the bedside. Its unique features make it one of the best transport ventilators for neonates. Hamilton Medical has specially adapted the HAMILTON-T1 hardware and software to optimally meet the needs of ventilated neonates. Supporting tidal volumes of just 2 ml, the HAMILTON-T1 allows for effective, safe, and lung- protective ventilation for even the smallest preemies. The reliable and robust neonatal flow sensor accurately measures pressure, volume, and flow proximal to the patient. This guarantees the required sensitivity and response time, and prevents dead space ventilation. Therefore, the patient is better synchronized and the work of breathing (WOB) is reduced. The new neonatal expiratory valve can balance even the smallest differences in pressure and offers the neonate the possibility to breathe spontaneously in each phase of a controlled breathing cycle. In addition to all modern neonatal ventilation modes, the HAMILTON-T1 offers a new generation of nCPAP. In the new nCPAP-PC (pressure control) mode, you only define the desired CPAP target value for your patient and the ventilator automatically and continuously adapts the required flow to the patient's condition and possible leaks. Thanks to the demand flow technology, your patient will receive only as much flow as is necessary to obtain the set CPAP target. This reduces WOB, reduces the need for user interventions and ensures optimal leak compensation. You will also require less oxygen for transport and noise caused by the ventilator decreases distinctively. With approvals and certificates for most types of transport and situations the HAMILTON-T1 is an ideal escort for your tiniest patients, reliable everywhere, both inside and outside the hospital, in the air as well as on the ground. The built-in high-performance turbine makes it completely independent of compressed air, gas cylinders or compressors. This saves weight and space and even noninvasively ventilated neonates can be transported over long distances. The combination of a built-in and an optional hot-swappable battery provides a battery operation of more than 9 hours. This can be extended indefinitely with additional hot-swappable batteries.

Ventilator Circuit Stabilizer Launched

As many ventilator patients have become more mobile, both in long-term care centers and at home, increased safety has become an issue. One of the areas that is most important is to secure the patients ventilator circuitry and prevent accidental dislodgement. A more mobile patient, moving from bed to wheelchair and through everyday life, presents a unique challenge in not only providing proper ventilation but also in providing a safe method in securing the life sustaining ventilator tubing. In these critical moments of movement, the tubing and circuitry may easily find itself ensnared in bed sheets, on wheelchair railings or other hazards, which can result in serious injury or death from ventilator disconnections. Pepper Medical has introduced two products that will eliminate this issue and provide a safer environment for these patients. The first is the 701VCS (ventilator circuit stabilizer). The 701VCS is a harness style belt made of soft cotton laminate that fits comfortably around a patient's waist. Incorporated into the harness is a tubing securement strap that reliably secures the ventilator tubing getting it out of harms way and positioned close the patient's chest. The second product is the 701VCS/NG offering the same circuitry securement but also adds a second strap used to secure a nasal gastric (or oral gastric) tube keeping it secure and avoiding decannulation thereby reducing these difficult reinsertions. Find out more at www.peppermedical.com.

FDA grants priority review of Rapamune

The FDA has accepted a supplemental new drug application for priority review of Rapamune for the treatment of lymphangioleiomyomatosis, according to a press release. "If approved, Rapamune would be the first FDA-approved treatment option for patients living with (lymphangioleiomyomatosis [LAM])," Steve Romano, MD, senior vice president of Global Medicines Development at Pfizer, said in a press release. The application acceptance was based on results from the

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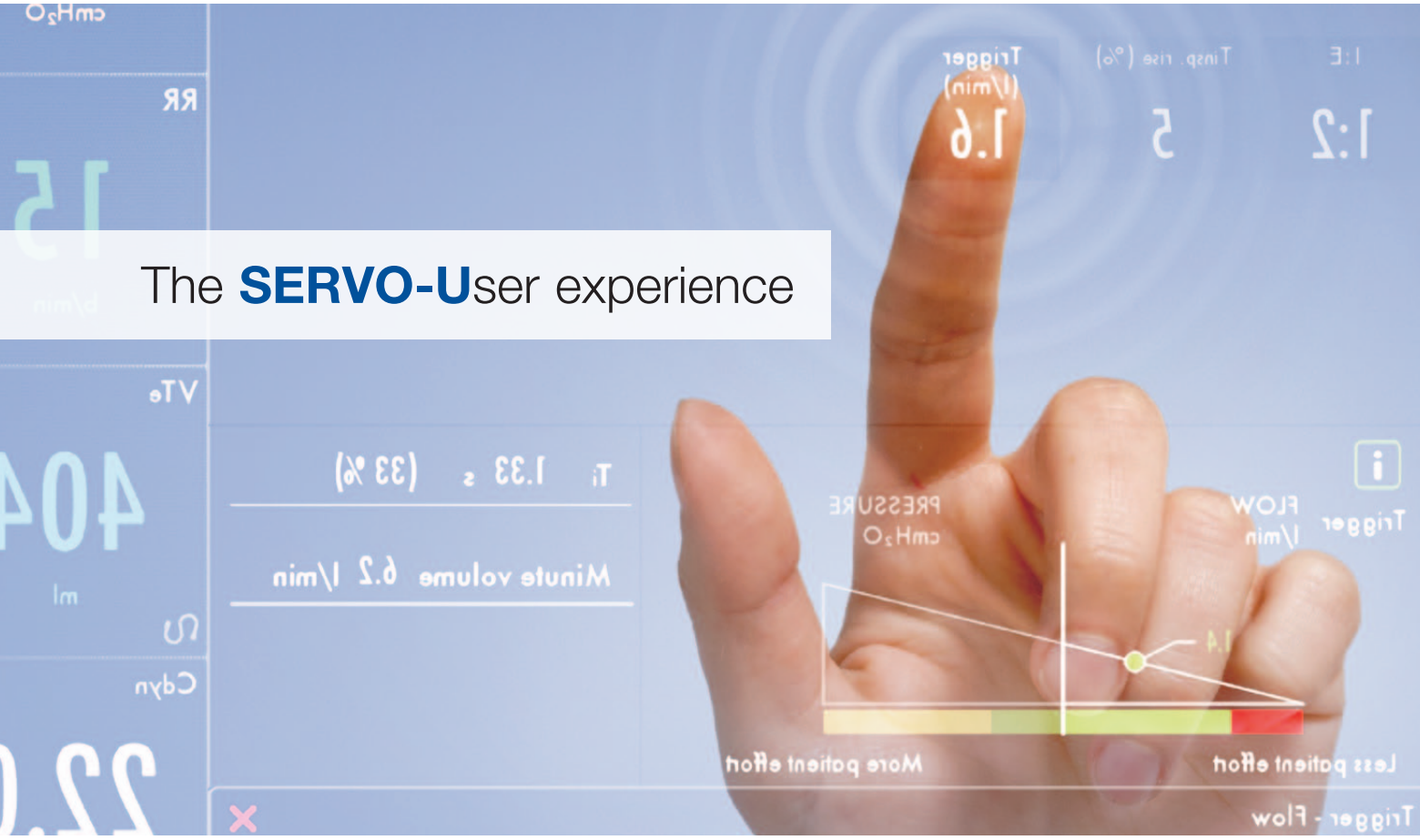

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Multicenter International Lymphangioleiomyomatosis Efficacy and Safety of Sirolimus (MILES) trial. LAM is a rare, progressive lung disease occurring in women of childbearing age that often is fatal. The trial involved 89 patients with LAM who had moderate lung impairment and were randomized to receive sirolimus or placebo for 12 months, followed by an additional 12-month observational period. Patients treated with sirolimus for 1 year experienced stabilization of lung function as measured by forced expiratory volume in 1 second. "The results of the MILES trial demonstrated that Rapamune has the potential to stabilize lung decline in patients suffering from LAM," Francis X. McCormack, MD, director of pulmonary, critical care and sleep medicine at the University of Cincinnati School of Medicine, said in the release.

Use of 3D Printed Splints for Infants

Three infants with an often-fatal airway disease have been treated by implanting a 3D printed medical device that improves breathing and changes shape as the children grow, the researchers reported. All three custom airway splint devices were designed to fit the anatomy of each child, researchers at the University of Michigan and colleagues reported in the journal Science Translational Medicine. The splints were hollow, porous tubes that could be stitched over the affected airways, forming a scaffolding that helped support the weakened structures. They were made with a "bioabsorbable" material known as polycaprolactone that dissolves in the body over time. Researchers at the University of Michigan made the devices using 3D printing, in which materials are added in layers to create custom products. Such printers are already used in medicine to create a number of custom implants, creating new jaws, hips and hearing devices, for example.

Looking at GERD

Gastroesophageal reflux disease (GERD), being female, and certain scores on the St. George's Respiratory Questionnaire (SGRQ) were associated with exacerbations of chronic obstructive pulmonary disease (COPD) in subjects using long-acting controller medication, according to a study presented at the 2015 American Thoracic Society International Conference. "Knowing these factors can help clinicians identify subjects at risk for acute exacerbations of their COPD," said Robert Busch, MD, Brigham and Women's Hospital, Boston. Although inhaled medications can decrease the risk for exacerbations, some COPD patients still experience them, Dr. Busch said. Researchers aimed to determine the prospective risk factors for acute exacerbations (AE) of COPD among subjects in the COPDGene study, which focuses on genetic factors relating to COPD. A total of 2489 adults with COPD on tiotropium (TIO), long-acting beta-agonist inhaled corticosteroids (LABA/ICS), and/or short-acting bronchodilators (SAB) alone or in combination were studied using retrospective data from the COPDGene study and prospective data from the telephone and web-based biannual Longitudinal Follow-Up program. Researchers divided subjects according to medication use groups (TIO/LABA/ICS, TIO, LABA/ICS, and SAB); exacerbators and nonexacerbators were identified by the frequency of AECOPD (one or more AECOPD a year compared with zero AECOPD for nonexacerbators). In multiple medication groups, the presence of GERD, female gender, and higher total SGRQ scores were significant predictors of exacerbator status, according to the researchers. Subjects in the LABA/ICS or TIO groups had similar characteristics, such as forced expiratory volume in one second, 6-minute walk distance, percent emphysema by CT scan, and pack-years of smoking. There was a trend toward significantly lower rates of exacerbations in subjects taking TIO compared with those taking the LABA/ICS combination. This was especially true in subjects who did not have a doctor's diagnosis of asthma.

The Benefits of Pulmonary Rehabilitation

Pulmonary rehabilitation (PR) treatment could be a valuable addition to comprehensive therapy in patients with obstructive sleep apnea (OSA) syndrome, according to a new study. The study was presented at the American Thoracic Society International Conference. "In our study with 40 newly diagnosed OSA patients and a control group, pulmonary rehabilitation helped reduce body mass index, certain body circumferences, and improve pulmonary function," said researcher Katerina Neumannova, MSc, PhD, Palacky University, Faculty of Physical Culture, Olomouc, Czech Republic. The classic treatment for patients with OSA is continuous positive airway pressure, often called CPAP or CPAP therapy. Treatment via PR, which is used for conditions such as chronic obstructive pulmonary disease (COPD), has not been thoroughly studied in OSA, even though patients with OSA often have respiratory symptoms associated with a decreased health-related quality of life and a diminished functional capacity. The study included 40 patients with OSA who were randomly assigned to either the PR group (n=20) or the control group (n=20). All patients involved in the study received CPAP therapy as their apnea/hypopnea index (AHI) was higher than 15. The PR group had 6 weeks of 60-minute individual rehabilitation sessions twice a week. The sessions consisted of education, exercise training, breathing retraining, respiratory muscle training, and oropharyngeal exercises. At baseline and then after 6 weeks of CPAP-only use or CPAP with the PR, researchers tracked a number of parameters, including pulmonary function, AHI, body mass index (BMI), percentage of body fat; and neck, waist, and hip circumferences. The final study included 15 patients in the PR group and 20 in the control group, as 5 patients did not complete PR. Although OSA severity was significantly decreased in both groups after the treatment, significant reduction of BMI, neck, waist and hip circumferences was confirmed only in the PR group. That same group also had an improvement in pulmonary function. Patients in both groups had decreased body fat, although body fat loss was higher in the PR group. "Patients with OSA can benefit from pulmonary rehabilitation treatment," Dr. Neumannova said. "We can determine on a patient-by-patient basis which patients would benefit most from pulmonary rehabilitation based on their individual disease and clinical judgment."

COPD Worse in Rural, Poor Areas

Living in a rural area and being poor are risk factors for chronic obstructive pulmonary disease (COPD), said Sarath Raju, MD, MPH, Johns Hopkins School of Medicine, Baltimore, Maryland, lead author of a study presented at the 2015 American Thoracic Society International Conference. The researchers used a nationally representative sample to pinpoint COPD risk factors. "We wanted to identify the prevalence of COPD in urban and rural areas in the US and determine how residence, region, poverty, race and ethnicity, and other factors influence COPD rates," Dr. Raju said. Using data from the National Health Interview Survey, the US Census, and the National Center for Health Statistics Urban-Rural Classification Scheme, the 87,701 participants included a population-based sample of adults older than age 40. The study's main outcome was the prevalence of COPD, defined as self-reported emphysema or chronic bronchitis. The researchers looked at both community-based and

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individual-based factors that are potential predictors of COPD, such as region, census level poverty, urban/rural residence, fuel sources, age, sex, race/ethnicity, smoking years, household income, home ownership, and education status. The prevalence of COPD in the study was 7.2%. However, in small metro/rural-poor communities, the prevalence was 11.9%. Rural residence, southern residence, and community poverty were all associated with a greater prevalence of COPD. When the researchers added individual income to the model, community poverty was no longer significant. Researchers found an association between biomass fuels and COPD in the South, but there was no association in an overall multivariate model. "Findings suggest regional differences and the need for future disparities research to understand the potential contribution of occupational exposures, fuel sources, and indoor air pollutants to COPD prevalence in poor, rural areas," the researchers concluded.

More News continued on page 51…

VENTILATION ROUNDTABLE

ResMed

What ventilation products does your company offer?
ResMed's life-support ventilators include the Astral 100 and Astral 150, which are lightweight, portable and easy to use, while providing an extended battery life of up to 24 hours. Astral is used for a range of respiratory conditions, including chronic obstructive pulmonary disease (COPD), restrictive thoracic disorder and neuromuscular diseases (NMD), as well as for some pediatric disorders.

What are the new features?
In May 2016, Astral became the world's first cellular, cloud-connected ventilator. It can connect thousands of Astral users to ResMed's remote monitoring platform, AirView, enabling physicians and home medical equipment providers to remotely access key patient data and better manage their therapy. AirView already helps clinicians remotely monitor a world-leading 3 million patients with sleep apnea. In June 2016, ResMed announced FDA clearance of Astral's intelligent Volume-Assured Pressure Support (iVAPS) therapy mode. iVAPS offers a unique minute ventilation algorithm that provides a volume guarantee, while providing patients the flexibility of using a standard leak circuit and vented mask.

Tell us about your company's current or recent R&D efforts.
At ResMed, we continually dedicate 7% of our revenue toward R&D and support research that has practice-changing potential. For example, ResMed supported a trial known as HOT-HMV, which was presented at the 2016 European Respiratory Society International Congress in September 2016. The study showed that home NIV therapy may significantly reduce the risk of re-hospitalization and death in patients with COPD. Those who received home NIV in addition to oxygen therapy had a 51% decreased risk in re-hospitalization or death compared to those who received oxygen therapy alone [HR=0.49, 95% CI=(0.31, 0.77) p=0.002].

Discuss the training and support services you offer.
ResMed offers its partners in-person, webinar and digital training via the ResMed Academy Online at no cost. The Academy offers online courses for continuing education credits (CEUs) as well as non-credit courses and product tutorials. Through the ResMed Academy Online, users can learn more about ResMed products, how to create workflow efficiencies and ways to improve patient outcomes.

We've recently released two new CEU courses related to the care of respiratory patients:

- **NIV for COPD.** COPD is the third-leading cause of death in the world. This CEU covers COPD's common symptoms, and how NIV therapy can reduce both hospital readmissions, and the risk of death in these patients.
- **Oxygen therapy.** This course dives into the history of oxygen therapy and its current market status. It also covers the pros and cons of each type of oxygen therapy and how to tell the difference between oxygen delivery systems.

Where are your products used? (ie, hospital, home, etc.)
All of ResMed's sleep and ventilation devices are designed for easy use in both the home and hospital. Astral allows for greater portability, which makes it a great fit for both home and hospital. In the home, patients can experience greater mobility, knowing they have the reliability of an 8-hour internal battery in a 7-pound device. Daytime activities can be scheduled with confidence. Astral is also a great device for intra-facility transports. Its size and weight allow it to be used during transfer and mobilization of patients in sub-acute areas, and to promote the pulmonary rehabilitation process.

What developments do you foresee for ventilation products and applications?
For healthcare systems to reach their greatest potential, their care networks need to connect to one another. Connectivity not only increases workflow efficiencies, but also offers tools to provide better patient care. We are seeing an increasing number of manufacturers working on ventilation data capabilities. Developments are focused on EMR integrations, cloud-based patient management applications, solutions to manage patients by exception, and automated patient coaching tools. These capabilities will likely become standard of care for ventilation devices.

SPOTLIGHT ON SPIROMETRY

Respiratory Information System
nSpire Health is a global respiratory information systems software developer and medical device manufacturing company, and the exclusive provider and developer of Iris, the world's first Integrated Respiratory Information System; and KoKo pulmonary function testing, diagnostic spirometry, and respiratory home monitoring devices. Together, its expert, scalable software solutions and sophisticated data collection products empower healthcare providers to advance respiratory diagnostic processes, and improve patient outcomes while meeting the demanding clinical and business objectives of thought leaders in respiratory care. Iris, the first and only Integrated Respiratory Information System (IRIS), brings relevant respiratory data together in one place, empowering physicians to efficiently analyze and optimally diagnose, stage, and manage respiratory disease. Iris lets you quickly and easily share real-time information and updates with key members of a patient's care team, enabling the most informed clinical decisions, leading to

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Workshop Highlights Multi-breath Nitrogen Washout Testing

ndd Medical Technologies held a practical workshop on performing multi-breath nitrogen washout (MLB) testing to facilitate diagnosis of small airways diseases at the ERS International Congress 2016 in London, England. The workshop, on the utility of the Lung Clearance Index (LCI) in a standard clinical environment, was led by Prof Dr Monika Gappa, Chief of Pediatrics at the Marien-Hospital in Wesel and twice voted among Germany's top doctors. LCI is already used worldwide to monitor patients with cystic fibrosis (CF). The workshop helped physicians interested in introducing LCI to their practice. Studies have found the LCI to be as good as high-resolution computed tomography (CT) and more sensitive than FEV1 in measuring changes in lung function. There can be significant changes in LCI without notable changes in FEV1, alerting physicians to the need for earlier intervention. Research also shows that the LCI, derived from multiple-breath nitrogen washout tests, is useful with other respiratory diseases, including non-CF bronchiectasis. The test is easier to perform in children than conventional lung function testing. Multi-breath nitrogen washout testing is simplified with the mobile, ultrasound-based EasyOne Pro LAB, which in addition performs the full range of pulmonary function tests including DLCO and FEV1. The single breath diffusing capacity of the lungs (DLCO), measuring the ability of the lungs to transfer oxygen from inhaled air to the red blood cells in pulmonary capillaries, is considered to be one of the most clinically valuable tests of lung function. Known for its accurate, reproducible results and ease of use, ndd Medical's point-of-service ultrasound technology—requiring no calibration, no altitude adjustment, no maintenance and no disposables other than spirettes and bariettes—makes the EasyOne line of PFT devices ideal for researchers and clinicians. "Our EasyOne Plus has achieved 40 percent market-leading share in spirometry for these reasons, and our EasyOne Pro and EasyOne Pro LAB make full PFT testing available wherever the patient is—in the office, clinic, lab, hospital or at a mobile screening event," said Georg Harnoncourt, CEO of ndd Medical Technologies. With 40 percent of the US spirometry market share, ndd Medical Technologies offers innovative, easy-to-use pulmonary function testing instruments that help clinicians diagnose lung disease with greater precision for optimal treatment. Its EasyOne and EasyOne Pro portable instruments take up just 12 inches of space to take lung function testing wherever it is needed, measuring DLCO, FRC, LCI and FVC. Ndd's patented Ultrasonic TrueFlow technology, which requires no calibration, eliminates problems associated with traditional methods of flow measurement, making testing fast, reliable and error free. To learn more, visit www.nddmed.com.

Flying Start

At the recent AARC conference in San Antonio, Vitalograph successfully introduced its new handheld spirometer perfect for bedside testing by respiratory therapists. Never before has there been a full function spirometer with Vitalograph's legendary quality at under $900. The response from the attendees was very positive for this device, as there has not been very good alternatives in this price and quality category in the past. The Micro provides spirometry made simple, reliable, ultra-quick and affordable. This handheld spirometer is packed with a host of features including full color touch screen, icon driven menu and highly accurate and robust pneumotachometer flow sensor technology. There is an optional remote flowhead tubing kit which allows the patient to hold only the flowhead, keeping the touchscreen more easily visible to the therapist while maintaining eye contact with the patient for better coaching. It comes complete with Vitalograph Reports 2 software for FAST PDF REPORTS that can easily be imported into your electronic health record. Contact Vitalograph, Inc. (800) 255-6626. Or https://vitalograph.com/product/162436/micro.

Oxygen Conserving Device (OCD) Technologies: Variability and the Potential Effect on Clinical Applications and Health & Economic Outcomes

Vernon R. Pertelle

Background

Long-term oxygen therapy (LTOT) has become one of the major treatments for patients with chronic obstructive pulmonary disease (COPD) who are hypoxemic.[1] The methods used for LTOT can be divided into three categories: ***oxygen source*** (concentrators, cylinders and liquid oxygen), ***oxygen delivery*** (nasal cannula, masks, trans-tracheal and oxygen conservers) and ***supplemental equipment*** (humidifiers and methods to carry oxygen).[2] Few studies have evaluated and compared the performance of the different oxygen sources; and the majority of clinical trials focus on ambulatory oxygen sources.

There are four types of oxygen sources used for ambulatory oxygen: liquid, concentrator-filled portable cylinder, conventional portable cylinder (various sizes), and portable oxygen concentrator (POC).[2] The oxygen source selected should depend upon the patient's specific clinical need and environment of care. Oxygen delivery falls into two main categories: (1) nasal cannula, face masks, Trans-tracheal catheter (rarely used for LTOT) and (2) oxygen conserving device (OCD) technologies.[2]

The patient's breathing pattern, respiratory rate, stage of disease, hypoxemia and activity should guide the technology selected for therapy. A small, non-randomized trial showed that the percent of oxygen delivered with nasal cannula at 2 LPM (liters per minute) continuous flow (CF) can be highly variable, with individual inspired oxygen concentrations varying between 24% and 35%.[3] High flow oxygen delivery via standard nasal cannula for LTOT is not appropriate. High flow oxygen delivery devices, such as venturi masks are designed to deliver accurate concentrations of oxygen with high flow rates; although are not typically used for ambulatory oxygen.[3] Trans-tracheal oxygen (TTO) delivery via a catheter surgically inserted between the second and third tracheal rings, is a low flow solution that may be used in place of delivery via nasal cannula; although rarely used for ambulatory oxygen delivery.

OCD technologies deliver oxygen during inspiration; eliminate oxygen waste during expiration, and enable gas and battery powered sources to last longer in contrast to CF delivery. Use of OCD technologies can reduce costs associated with home oxygen therapy.[2,4] Studies have shown that OCD technologies can reduce oxygen gas (cylinder or liquid source) usage by as much as 64%.[5,6,7,8]

There is a high degree of performance variability between OCD technologies. Patients should be evaluated before being provided a particular technology;[2] because OCD technologies vary in their ability to maintain a patient's oxygen saturation (SpO2) level during activity.[9] Continuous flow (CF) oxygen delivery when compared with delivery via OCD technologies showed no clinical difference.[2,10]

Oxygen Conserving Device (OCD) Technologies

OCD technologies have been commonly referred to in the literature as demand oxygen delivery (DOD)[11,12] intermittent flow (IF)[13,14] and pulsed-dose oxygen delivery (PDOD) technologies.[15,16] The terms that describe OCD technologies vary as do the technologies themselves. Modern OCD technologies are typically electronic or mechanical (pneumatic) and operate on demand, responding to a pressure drop triggered by the patient's inspiratory effort and then delivers a predetermined bolus of oxygen. Key performance characteristics of OCD technologies include: triggering sensitivity, trigger response time, flow waveforms, pulse flowrates, and pulse/bolus volumes. The fraction of inspired oxygen (FiO2) with OCD technologies can be objectively studied using standardized breathing models and bench test fixtures. The results allows for comparisons of various OCD technologies with each other and CF at different breath rates. OCD technologies operate using a fixed minute volume or fixed bolus volume methodology, with relatively fast response and bolus delivery.

- OCD technologies, that are designed to provide a fixed-minute volume of oxygen per setting, deliver less net oxygen per breath in response to increased breathing rates, while maintaining a steady minute-volume of oxygen
- Conversely, conventional fixed-bolus technology will deliver more net oxygen per breath during increased breath rates, which results in a higher net minute volume of oxygen
- A breath-responsive, variable-bolus volume device that uses algorithms to adjust the bolus size in response to different breath rates (sometimes referred to as auto-adjusting) will deliver more net oxygen per breath in response to increased breath rates, which results in a higher net minute-volume of oxygen compared to both fixed minute volume and traditional fixed bolus volume devices

Oxygen delivery capabilities are important to understand in order to ensure the appropriate technology to maintain

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adequate oxygen saturation (SpO2) for patients. Understanding the performance characteristics can help identify the right technology that meets the therapeutic needs of a patient who requires LTOT.

Key Points

- Continuous Flow (CF) oxygen delivery, long considered the standard of care for the delivery of Long Term Oxygen Therapy (LTOT) is limited in adapting to changing breathing patterns. CF oxygen delivery is inefficient and wastes large amounts of oxygen. CF delivery is not practical nor more of an advantage than OCD technologies for use with ambulatory oxygen sources in the home environment
- OCD Technologies can efficiently and effectively deliver oxygen therapy; and are incorporated into nearly all modern ambulatory oxygen sources. Due to differences in engineering design and manufacturers' specifications, technologies will perform and deliver oxygen differently
- Understanding OCD technology performance capabilities will help to improve clinical applications and achieve expected outcomes of patients who use LTOT
- The breath-responsive, variable-bolus OCD technology delivers more oxygen per breath in the face of variable breathing patterns and rates when compared to other OCD technologies and CF delivery. This may translate clinically to improved patient oxygenation and improved health and economic outcomes
- Delivery of the appropriate FiO2 to maintain SpO2 may promote increased patient activity and exercise leading to an overall improved health related quality of life, patient satisfaction and O2 prescription adherence leading to better health and economic outcomes
- Effective home LTOT can reduce exacerbations and hospitalizations, reducing the overall cost of care for patients with COPD who require LTOT

Testing Objective

To compare OCD technologies with each other and with continuous flow (CF) oxygen delivery to determine the performance capabilities based on manufacturer specifications. Compare results using pre-determined performance characteristics in a bench test environment to draw conclusions regarding the potential effect on clinical applications and health and economic outcomes in patients who require long-term oxygen therapy (LTOT).

Test Strategy

Testing was conducted by Valley Inspired Products (VIP) using pre-determined protocols to support the objective evaluation of OCD technologies using industry established and validated methodology.

Selection Criteria

Device selection was based on commonly used OCD technologies intended for use with patients requiring LTOT in the home. OCD technologies that are not well established commercially or novel delivery technologies were given lesser consideration and not used for the purposes of this technology assessment.

Main Results

Bench tests of four commercially available oxygen conserving device (OCD) technologies and CF technology demonstrated wide variability in the key performance specifications tested.

Abbreviations and Acronyms

ADLs	Activities of Daily Living
COPD	Chronic Obstructive Pulmonary Disease
CF	Continuous Flow
DOD	Demand Oxygen Delivery
FDA	Food and Drug Administration
FiO2	Fraction of Inspired Oxygen
IF	Intermittent Flow
LPM	Liters per Minute
LTOT	Long-Term Oxygen Therapy
NOTT	Nocturnal Oxygen Therapy Trial
O2	Oxygen
OCD	Oxygen Conserving Device
PDOD	Pulsed-Dose Oxygen Delivery
POC	Portable Oxygen Concentrator
SaO2	Arterial O2 Saturation-Blood Gas
QOL	Quality of Life
SpO2	Peripheral O2 Saturation-Oximetry
TTO	Trans-Tracheal Oxygen
VIP	Valley Inspired Products
VT	Tidal Volume

Disclaimer: The technology assessment and bench test, was supported by an unrestricted educational grant by Drive Medical, Inc. Healthcare providers must use clinical judgement, knowledge and expertise for the management of patients. The conclusions cited here are a guide and may not be appropriate for use in all situations. The guidance provided does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their caregiver.

Although this technology assessment cannot represent all commercially available OCD technologies; the design, oxygen delivery methods and performance specifications are similar in all OCD technologies. This is important, as OCD technology is incorporated into nearly all ambulatory oxygen sources, including cylinders, portable liquid and portable oxygen concentrators (POCs). All patients should be evaluated and titrated to their specific OCD for each activity of daily living.

Author Conclusions and Comments

The OCD technologies tested were highly variable and may limit activities of daily living if not appropriately selected and assessed on a specific patient. While OCD technologies have equivalent technical features this does not result in equivalent therapeutic functionality when used for oxygen delivery.

Clinical evaluation of OCD technologies is not mandated by the Food and Drug Administration (FDA) before granting approval to the manufacturer for marketing. Consequently, the individual or comparative therapeutic effectiveness while in use by patients is unknown. Because standard home oxygen (O2) sources deliver O2 at fixed rates, they are not designed to ensure optimal oxygen delivery based on physiologic need.

These findings may translate clinically into variable oxygen delivery during periods of activity associated with changes in breathing patterns and rates.

These data suggest the breath-responsive, variable-bolus OCD technology (SmartDose®), which utilizes biometric inputs from the patient's breathing pattern and rate to adjust the oxygen

bolus volume; delivers a more consistent and predictable FiO2, without the need for the patient or caregiver to adjust the setting. (Graph 1) The technology provided a fixed-dose of oxygen, and increased or decreased oxygen dose as the breath rate changed (increased or decreased) in dynamic breathing conditions.

For patients who are active and/or require high- flow oxygen, the breath-responsive, variable- bolus OCD technology (SmartDose) will maintain or even increase FiO2 levels with activity; without the need to manually change the setting. This is consistent with the manufacturer's performance specifications.

While these results support the benefits of a breath-responsive, variable-bolus OCD technology (SmartDose) and its potential effect on positive health (optimal FiO2 with adequate oxygen saturation) and economic (oxygen source savings) outcomes in a bench test environment; the objective evaluation when used by patients is required to further validate the effectiveness of the breath-responsive, variable-bolus (SmartDose) OCD technology.

OCD technologies are integrated with the vast majority of ambulatory oxygen sources used in the home. However, this trend has evolved with little clinical research.

As such, physicians and respiratory therapists need to assess patients on each device, at each activity level the patient is capable of performing in the home environment; in order to ensure the appropriate OCD technology is used to provide therapeutic health benefits for the patient.

The economic benefits associated with reduced delivery of oxygen sources by oxygen providers and resultant savings is apparent.

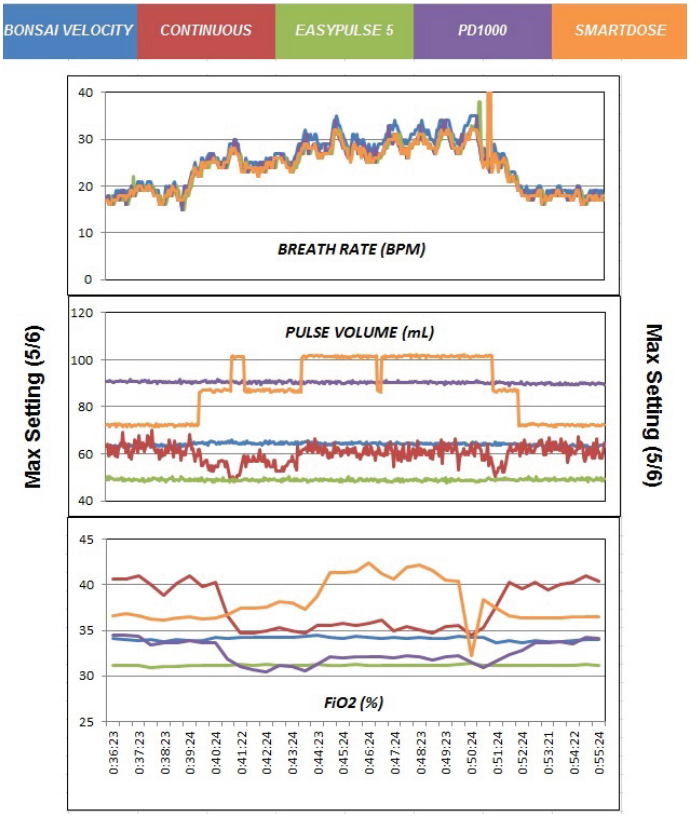
Clinicians and patients must be thoroughly familiar with the oxygen source and oxygen delivery method they use and must understand the capabilities and limitations.

More research is required to evaluate the application and effectiveness of OCD technologies used in LTOT because of the differences between the delivery methods; and effectiveness when used on patients has great variability.

Introduction

Long Term Oxygen Therapy (LTOT) is intended to correct hypoxemia caused by disease progression in patients with chronic obstructive pulmonary disease (COPD).[17] Ambulation and activity are important considerations in the treatment and management of patients with COPD, as patients with low activity levels experience higher disease related morbidity and mortality.[18] LTOT can be delivered from cylinders, concentrators or as liquid oxygen. Each source can be stationary or ambulatory, and the specific source selected for a particular patient is dependent upon the clinical condition of the patient, and cost to supply the oxygen source as determined by the oxygen provider.[2]

There are few published studies from peer-reviewed medical journals, which compare the various delivery technologies with regards to different clinical conditions.[2] Some studies have compared similar OCD technologies however, few are recent and newer technology has superseded them.[2] An ideal LTOT source and delivery method must meet the therapeutic needs of patients with COPD during activities of daily living (ADL); at rest, exercise, and while asleep. In addition, patient adherence



Graph 1

to LTOT may be dependent upon the oxygen source and delivery being easy to use. An ambulatory oxygen source should be small, lightweight and easy to transport. In short, an ideal LTOT source must meet the patient's clinical and lifestyle needs.

Continuous Flow Oxygen

Continuous Flow (CF) oxygen has long been considered the gold standard in oxygen therapy because it has been used effectively in institutional environments of care (hospitals, post-acute centers, clinics, etc.). Most clinicians are familiar with the CF oxygen delivery in institutional environments of care. Conversely, many are often unfamiliar with oxygen sources and delivery technologies used in the home environments of care.

Typically, patients who are discharged from institutional environments of care for ongoing treatment and management in the home environments of care; are prescribed oxygen at 2 liters

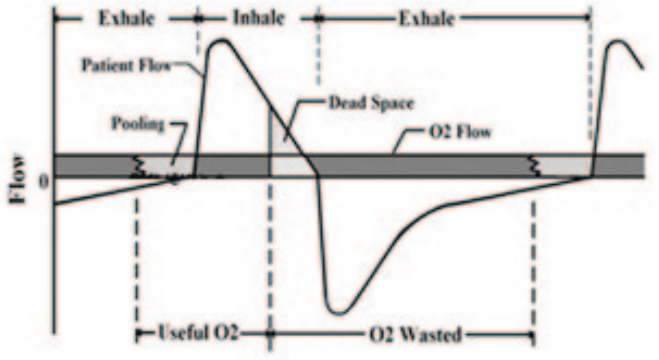


Figure 1. During continuous flow (CF) oxygen therapy, as a patient's breath rate increases their inspiratory time decreases, decreasing the amount of useful O2.

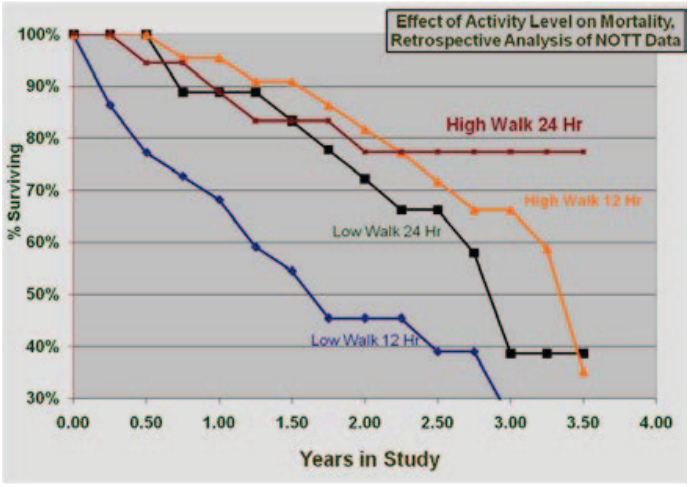


Figure 2. This figure displays the survival rate of four types of oxygen patients as classified in the NOTT study revisited: High Walkers on 24hrs CF O2, Low Walkers on 24hrs CF O2, High Walkers on 12hrs CF O2 and Low Walkers on 12hrs CF O2. High Walkers (i.e. active patients) on 12 and 24hr CF O2 had higher survival rates after 1-1/2 years on supplemental oxygen.

per minute (LPM) via nasal cannula; often without consideration of the type of LTOT technology selected, and the relationship to the patient's clinical or lifestyle needs. Continuous flow is the most basic form of oxygen delivery and requires regulated pressure and flow.

Oxygen is delivered throughout the breath cycle, while the patient inhales and exhales, which not only creates waste of cylinder and liquid oxygen but more importantly does not provide consistent therapeutic benefit to the patient despite the continuous flow. (Figure 1) This is due in large part to the patients varying needs with activities of daily living (ADLs), or exercise.

Bulk oxygen provided in an institutional environment of care is relatively inexpensive so does not typically incentivize organizations and clinicians to reduce oxygen waste. However, oxygen provided to the patient at home can be costly, thus creating a financial incentive for home oxygen providers to utilize efficient oxygen sources and delivery technologies.

This often results in the "oxygen technology disconnect" between institutional environments of care, prescriber, home oxygen provider and most importantly, the patient in the home environment of care.

Continuous flow (CF) oxygen therapy has various technical and clinical limitations and as a result, may not provide the intended therapeutic benefits for many patients. The patient's breathing pattern, which includes rate, tidal volume and I:E ratio are key variables that can alter the clinical effectiveness of CF oxygen therapy.

As a patient breathes faster, which typically occurs during increased activity or exercise, inspiratory time (I time) will shorten and a smaller inhaled "dose of oxygen" is delivered, even though the flow setting has not been altered.

In other words, during CF, the amount of oxygen delivered over time—such as in one minute—will not change significantly, even though the patient's breathing rate changes.

However, the amount of oxygen actually inhaled by the patient will decrease as their breath rate increases. This effect may be compounded with patients that have more advance stages of COPD and prolonged exhalation. This fixed minute volume method of oxygen delivery is the primary limitation of CF oxygen delivery, and is why many patients require both a 'resting' and an 'active' flow rate oxygen prescription.

Mobility Issues with Oxygen

Portable oxygen is intended to allow patients to effectively perform activities of daily living (ADLs), while being adequately oxygenated. Early portable oxygen systems were typically "E" cylinders with CF regulators, often weighing more than 20 pounds.

Many clinicians argued such systems often discouraged ambulation and activity by patients. Patients nowadays are often very active and seek clinically effective ambulatory oxygen sources that are lightweight, durable and have long durations of use.

The well-known Nocturnal Oxygen Therapy Trial (NOTT) study,[19] along with the British, Medical Research Council (MRC) study,[20] documented the clinical benefits and improved survival associated with the use of long term oxygen therapy in severely hypoxemic patients with COPD (Figure 2).

The NOTT study also served as the basis for reimbursement for LTOT equipment from the Centers for Medicare and Medicaid Services (CMS). Data from the work of Petty and Bliss that revisited the findings of the NOTT study further documented benefits of regular ambulation/activity on the survival of LTOT patients.[18]

OCD Technology Capabilities and Limitations

Continuous flow oxygen therapy is typically understood by most clinicians. Unfortunately many clinicians are not familiar with the specifications and performance characteristics of OCD technologies. A lack of technical understanding with a specific technology may create the perception that all OCD technologies are equivalent in functional capabilities and effects on patients; however they are not all the same. Prescribing clinicians must become educated on the differences of OCD technologies. While OCD technologies do vary; many OCDs may provide equal or better oxygenation over CF, and can help to improve the patient's ability to perform activities of daily living (ADLs) and exercise.

Although oxygen therapy prescriptions are generally written in liters per minute (LPM), OCD technologies are developed to actually deliver a volume of oxygen to the patient. The volume of oxygen delivered is simply a result of the fixed flow of the gas over time. The net volume of the inspired oxygen delivered to a patient over the course of a minute is a product of the oxygen flowrate, patient's breath rate, inspiratory time and the tidal volume (V_T) minus anatomical deadspace (V_{Dant}).

Modern OCD technologies are typically electronic or mechanical (pneumatic) and operate on demand, responding to a pressure drop triggered by the patient's inspiratory effort and then delivers a predetermined bolus of oxygen. The clinical basis of pulsed-dose oxygen delivery (PDOD) relies on the assumption that inspired oxygen enters the airways quickly, during the first two-thirds of the inspiratory cycle.

Oxygen flowing at the end of inspiration, during exhalation and during the pause prior to the next inspiration cycle; is wasted, since it plays no role in gas exchange. Approximately one-third of a person's inspiration is gas that remains in the V_{Dant} thus is considered waste.

There are a few key elements associated with efficient OCD technology, including bolus size, sensitivity, and bolus speed/delivery. A common assumption with OCD technologies, promotes the theory that the earlier the oxygen bolus is delivered into the inspiratory cycle, the more clinically efficient the oxygen delivery will be. Oxygen boluses delivered late in inspiration may be less effective in improving blood oxygen levels, as portions of the bolus may fall into the anatomical deadspace.

Early work by Tiep and Lewis noted that the efficiency of pulsed oxygen therapy can be improved by focusing the oxygen delivery during early inspiration.[21]

Recent OCD technologies operate using a fixed minute volume or fixed bolus volume methodology, with relatively fast response and bolus delivery.

- ***Conventional fixed-minute volume*** devices actually perform in a manner that mimics CF when faced with increased breathing rates. To maintain a steady minute volume, these devices decrease the bolus size with each breath as the rate increases
- ***Conventional fixed-bolus*** devices deliver the same volume of oxygen per breath, regardless of breathing rate; similar to the way a mechanical ventilator delivers a preset tidal volume with each assisted breath. The faster the breathing rate, the higher the minute volume of oxygen delivered.
- ***Breath-responsive, variable-bolus volume*** systems use algorithms to adjust the bolus size in response to different breathing patterns and rates (sometimes referred to as auto-adjusting). This method will deliver more net oxygen per breath in the face of increased breathing frequencies, which results in a higher minute-volume of oxygen as compared to both fixed minute volume and traditional fixed bolus volume devices

A common point of confusion with OCD technologies are settings. Each device has a number range (ie, 1-5) on the delivery dial, which are commonly assumed to be "equivalent" to continuous flow oxygen – liters per minute (lpm). Since the dose-volume per setting is predetermined in the design, and generally a mathematical derivative of the nasal cannula FiO2 equation. The dose per setting can vary greatly between OCD technologies based on mathematical assumptions and algorithms developed by the respective manufacturers.

As such, one-size does not fit all because design characteristics vary widely. As a result, the settings are more of a reference point vs. precise flow equivalent, which is why various consensus statements, publications and clinical practice guidelines suggest titrating all OCD technologies to the patient need at rest and during ADLs.[10,22]

Recommendations for Evaluating OCD Technology for Potential Application and Benefit on Patients

Current research focuses on the benefits of exercise and activity for patients with COPD. LTOT sources must be capable of meeting the patient's physiologic need for oxygen during various activity levels. As previously reviewed, all oxygen sources, including continuous flow, delivers oxygen differently in the face of changing breath patterns and rates.

Bench testing of CF and OCD technologies (Images 1-5) using breathing simulation models is an objective and practical approach to measuring the different technical and performance specifications. Such testing and evaluation can serve as tool in predicting how these technologies will perform when used by patients.

Testing Methods

Selected OCD and CF Technologies

Note: Three units of each device were tested. All products were new, fresh-out-of-the-box units.

Image 1. Drive Medical SmartDose®

Image 2. CHAD® Bonsai® Velocity

Image 3. CHAD® O2 Regulator 4808-L: Continuous flow (CF) device selected to compare with OCD Technologies

Image 4. DeVilbiss® Healthcare PD1000

Image 5. Precision Medical EasyPulse 5

Test Equipment

- Series 1101 Breathing Simulator – Hans Rudolph, Inc.
- 570A Oxygen Analyzer – Servomex
- BTC-II Miniature Diaphragm Pump – Hargraves Technology
- Corp. (not shown)
- Model 24PC Pressure Sensor – Honeywell Model 4140 Mass Flowmeter – TSI, Inc. Ref. 1104 Nasal Cannula – Hudson RCI Artificial Nose – Valley Inspired Products
- Breathing Simulator Expansion Interface – Valley Inspired
- Products
- Clinical Oxygen Dose Recorder – Inovo

Test Lung and Data Acquisition Settings

For tests conducted in this evaluation, the following breathing patterns (Chart 1) were utilized by the breathing simulator to simulate a patient:

Pattern	Resistance	Compliance	Rate*	Amplitude*	Slope	% Inhale	VT
1	20	30	10	18.1	40	34	~500
2	20	30	15	20	40	34	~500
3	20	30	20	22.5	40	34	~500
4	20	30	25	26	40	34	~500
5	20	30	30	29.5	40	34	~500
6	20	30	35	33	40	34	~500
7	20	30	40	37	40	34	~500

Chart 1

Note: The only adjusted parameters were Breath Rate and Amplitude. Amplitude could be further adjusted from shown values to ensure ~500mL V_t. Resistance and Compliance settings resulted in restrictive lung conditions. Slope setting of 40 created a square inhalation curve to ensure device triggering. The percent [%] Inhale setting yielded a 1:2 I:E ratio. The breathing simulator was set to record data at 50 Hz (20ms intervals). Data acquisition channels were set to record simulated patient volume flow, ambient temperature and pressure dry (ATPD), oxygen flow (as read from the flowmeter via expansion interface), and nasal cavity pressure (as read from the external pressure sensor via expansion interface).

Tests for Pulse Flow Characteristics

The artificial nose (Image 7) was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. The 4140 flowmeter was placed in line with the nasal cannula; one inch below the cannula wye so that delivered oxygen from the device under test went through the flowmeter before being delivered into the nasal cavity. Pulse flow characteristics were recorded at each of the device's integer settings over six consecutive breaths in each of the seven test patterns.

Pulse Volumes

Pulse volumes were calculated by integrating the raw oxygen flow data recorded from the flowmeter during the inhalation phase.

Flow Waveforms

Waveforms were created from the raw oxygen flow data.

Pulse Delivery Times

Delivery times were calculated by using the raw oxygen flow data to determine the time differential between the onset and cessation of oxygen flow from the device.

Oxygen Minute Volume

Oxygen minute volume was calculated by multiplying the respective pulse volume by the tested breath rate. **Note:** For continuous flow results, this method resulted in a lower minute volume value as volume delivered during exhalation was not considered.

Delivered FiO2%

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. A diaphragm pump was set up to pull an air sample from the breathing simulator lung bellows and directly into the oxygen analyzer during the simulation. Delivered FiO2% was recorded at each of the device's integer settings in each of seven test patterns, with up to five minutes allowed to pass for FiO2 to stabilize.

Triggering Sensitivity

The artificial nose was attached to the breathing simulator port and a nasal cannula was inserted into the nasal cavity. The external pressure sensor was connected to the pressure sampling port of the artificial nose. The simulator settings were adjusted to match "Pattern 3", except Slope was set to 10 and % Inhale was set to 50%, creating a moderately shallow breath simulation. Amplitude values were adjusted (in integer increments) until the device did not consistently trigger breath-to-breath.

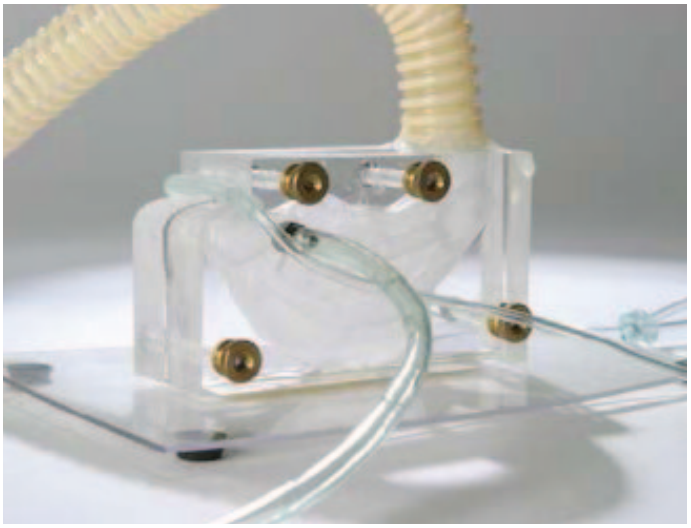


Image 7

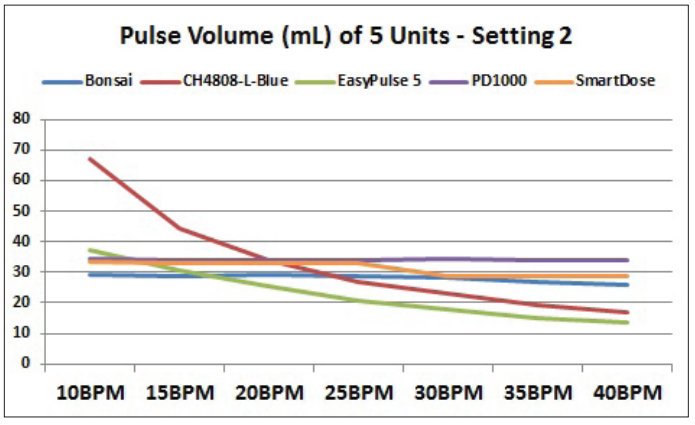
Amplitude was then set to the last setting prior to noting inconsistent triggering, and the simulation was allowed to stabilize. The nasal cavity pressure profile was recorded and the negative pressure in the nose at the onset of oxygen delivery was determined from the raw data file. Triggering sensitivity data was recorded at each of the device's integer settings over six consecutive breaths. If the device had multiple sensitivity settings, data was recorded for each trigger setting.

Dynamic Breath Rate Testing

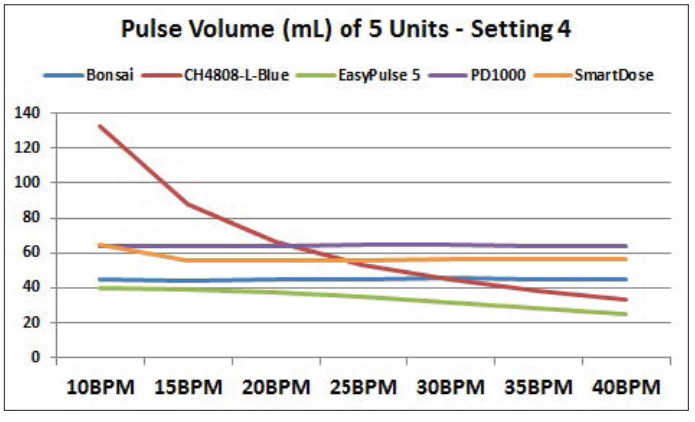
Test setup was a combination of the pulse delivery and FiO2 test setups, with the Clinical Oxygen Dose Recorder (CODR) placed in-line instead of the TSI flowmeter. A computer running the CODR software package was used for data collection. The breathing simulator was programmed to run a script based on breath rate data taken from an actual oxygen patient, where the patient was resting with a 1:2 I:E ratio, then active (1:1 I:E), then resting again (1:2 I:E). Using the breath rate data and adjusting the amplitude setting to maintain a static tidal volume throughout the test; the simulator script ran for a total duration of 19 minutes, with FiO2% data taken every 30 seconds. The CODR and software recorded breath rate and pulse volume delivery on a breath-by- breath basis. Each unit was tested at their 2, 4, and max (5/6) setting. FiO2%, pulse volume, and breath rate data were synchronized and plotted after test completion. (Graphs 3-8)

Selected Performance Characteristics

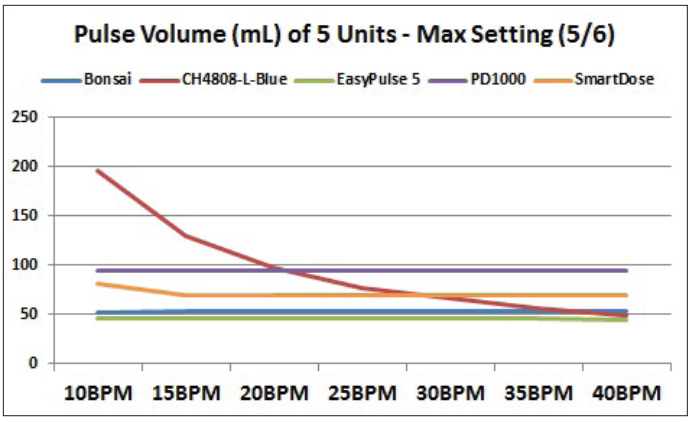
Pulse Volume in 100% of Inspiratory Time and in 60% of Inspiratory Time



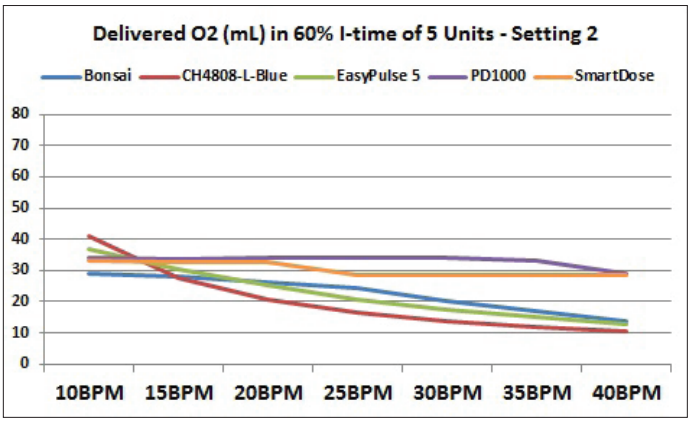
Graph 3



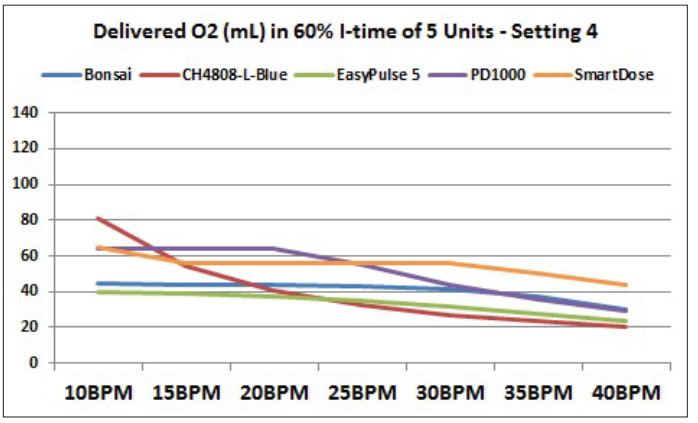
Graph 4



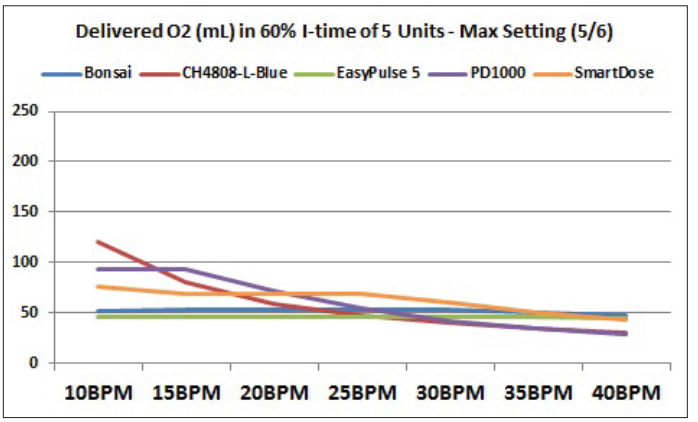
Graph 5



Graph 6



Graph 7



Graph 8

Pulse volume is a determinant in the amount of oxygen that will supplement tidal volume during a patient's inspiration. This volume of oxygen is blended with the gas in the inspired breath that comes from room air — which contains 21% fraction of inspired oxygen (FiO2) value.

Note: In the graphs 3-8; in CF (from the CH-4808 regulator) the 'pulse' volume decreases as breath rate rises. CF system is a fixed minute volume system.

The EasyPulse 5, which has characteristics of a fixed-minute volume system, at lower settings, also demonstrates this decrease in bolus volume as the breath rate rises. The PD1000 and Bonsai® Velocity, fixed-bolus devices, maintain the same pulse volume at a given setting, regardless of breath rate. The SmartDose has breath responsive, fixed-bolus volumes; determined by initial device setting and the patient's breathing rate.

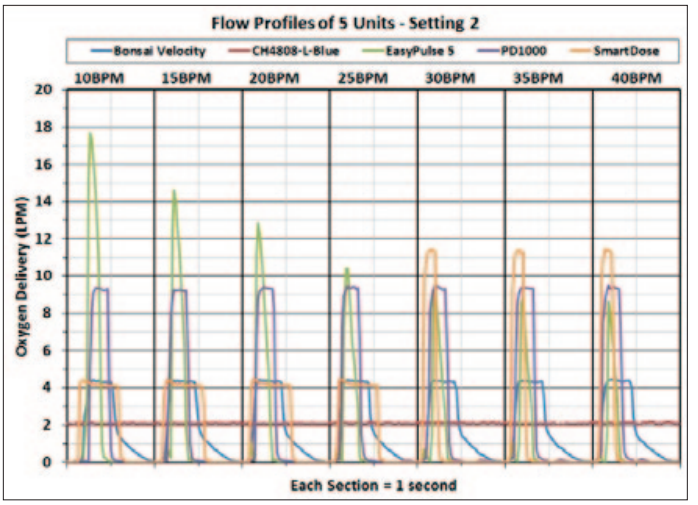
A common and accepted theory is that, oxygen delivered within the first 60% of inhalation is considered therapeutic, as any remaining oxygen will likely reside in the anatomic dead space. It is for this reason that many PDOD devices feature a short bolus time with a high peak flow, which is intended to deliver the entire bolus in the first 60% of the inspiration. Some devices may promote a large bolus but without an effective peak flow, and the entire volume may not be delivered within the first 60% of inhalation. Oxygen delivered in the anatomic deadspace does not participate in gas exchange and is therefore not clinically relevant.

In the graphs 3-8; CF flow (CH4808-L-Blue) shows that the volume delivered within 60% of the inspiratory cycle is less than that delivered in 100% of the same cycle at all rates. This is due to the 'continuous' nature of CF delivery. Oxygen delivery from the EasyPulse 5 device showed no such decreases in volume delivered between 100% and 60% of inhalation, indicating that in all test conditions the entire dose was delivered within 60% of the inhalation cycle. On the other tested devices, the data showed that the higher the breath rate and higher the setting, the greater likelihood the entire bolus of oxygen was not being delivered within 60%. At the max setting 6; on the PD1000, at rates of 20BPM and greater, some of the oxygen volume was delivered after the 60% threshold.

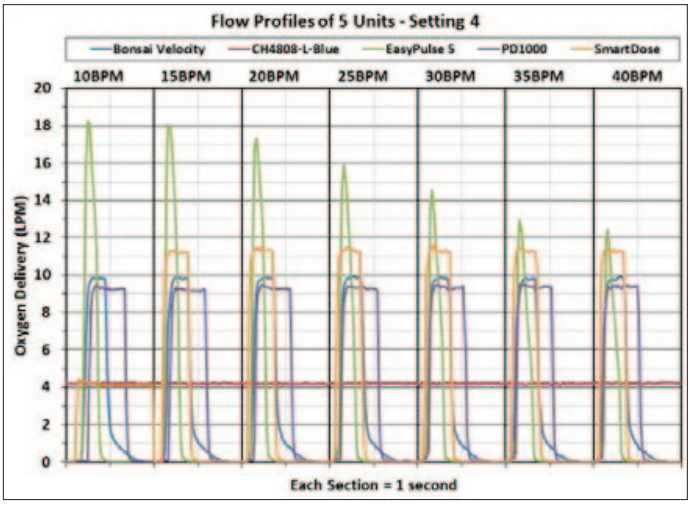
Key point: Early delivery of a full bolus (dose) of oxygen during inhalation provides the best potential to increase the FiO2 and improve oxygenation.

Flow Profiles

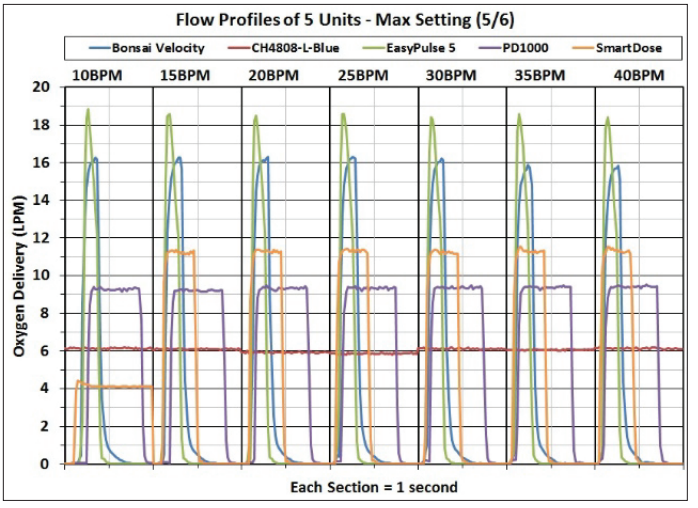
Flow profiles provide a visual representation of how OCD technologies deliver the bolus of oxygen at various settings and breathing rates. The area under each curve is used to calculate delivered volume. (Graphs 9-11)



Graph 9



Graph 10



Graph 11

Note the fixed-bolus nature of the Bonsai Velocity and PD1000, where the delivery profile (waveform) of a given setting does not change as the rate increases. These devices do not track breath rate or inspiratory time, and thus are not capable of making adjustments as the patient breathes faster. Conversely, the SmartDose, which monitors breath rate (breath-responsive), is able to adjust the oxygen delivery (bolus) when certain breathing patterns and rate thresholds are surpassed.

As breath rates increase for the EasyPulse 5 (settings <5), the peak flow decreases, shrinking the bolus-volume, which is consistent with the design of a fixed-minute volume system.

Dose setting has a direct impact on the flow profile by design and influences the amount of oxygen a technology delivers per breath.

The graph here highlights areas where inspiratory time has exceeded 60% of the inhalation cycle and as the rate increases; oxygen delivered by the device may not reach the lungs.

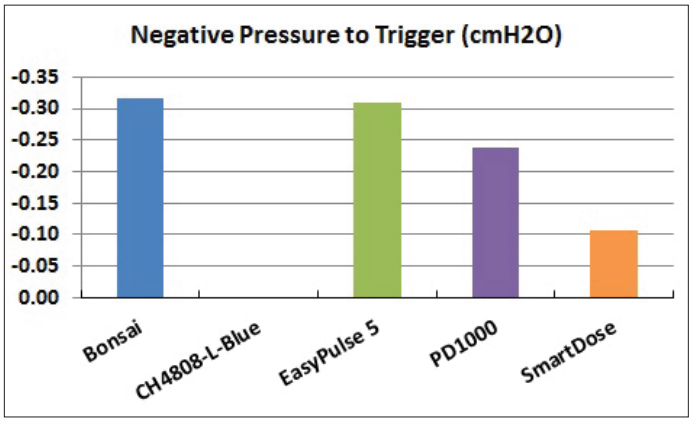
Key point: How oxygen is delivered to the patient is a determining factor on the capabilities of an OCD technology. It is important to know how a device operates to determine if lack of oxygenation with a patient is the result of a devices' inability to meet the therapeutic need (device performance should be considered first); or the patient's disease process.

Triggering Sensitivity

Adequate triggering sensitivity (Graph 12) is important, as a patient must be able to trigger the OCD technology for oxygen to be delivered. Triggering is not an issue in CF since oxygen is being delivered throughout the breath cycle.

Awake and active patients generally have strong inspiratory effort and can effectively trigger most OCDs. A sedentary or sleeping patient may have small tidal volumes, with low inspiratory flows and pressures. As a result, under such circumstances, some patients may not routinely trigger a specific OCD technology.

By design, pneumatic devices tend to be less sensitive, due to the mechanical nature of the valves. Electronic devices tend to be more sensitive because of the electronic pressure sensors and valves inherent in the design. This tendency is demonstrated in the test results; the pneumatic Bonsai Velocity and EasyPulse 5 units are not as sensitive as the electronic PD1000 and SmartDose devices. Although there is no recognized sensitivity standard; lower trigger thresholds (more sensitivity) increases the likelihood that a breath will trigger oxygen delivery, even with the shallowest breathing.

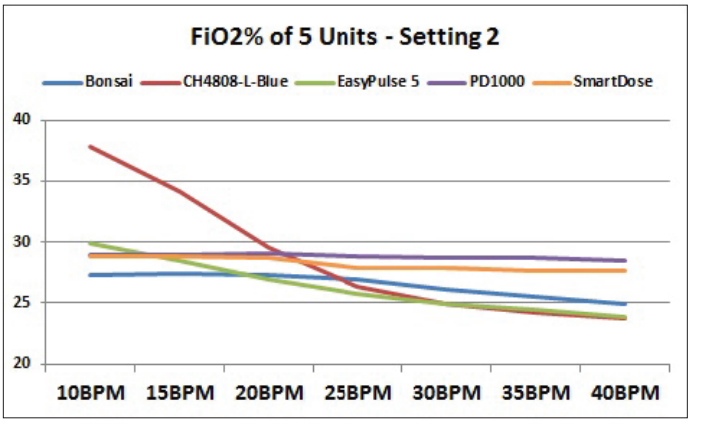


Graph 12

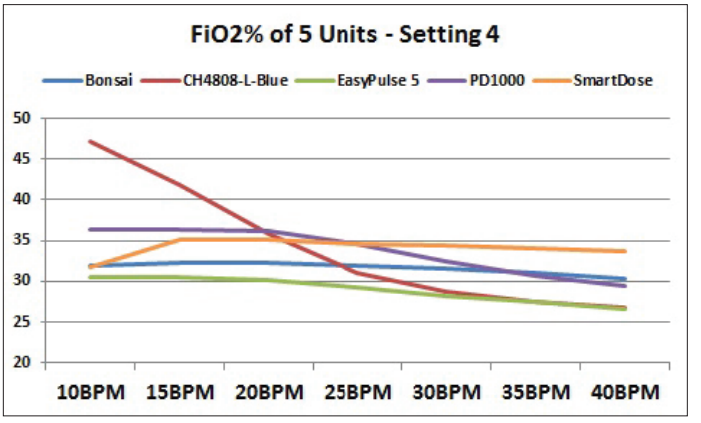
Key point: Knowing the triggering sensitivity of OCD technologies is important to help determine if the patient will be able to trigger the device at different breathing patterns (sleep, rest, and exercise).

FiO2

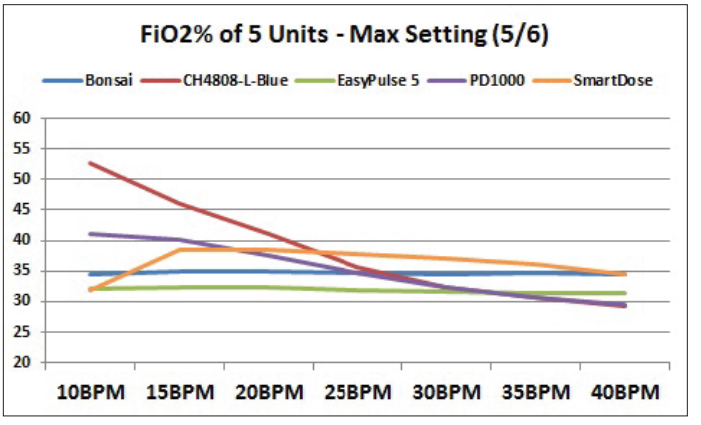
FiO2 is the determining factor in effective oxygenation. An adequate oxygen source and delivery technology should have the capability to provide enough supplemental oxygen to meet the therapeutic need and maintain oxygen saturation above 90% at all activity levels. (Graphs 13-15)



Graph 13



Graph 14



Graph 15

FiO2 can be dependent on a combination of factors, including characteristics such as the volume of oxygen inspired per breath, the timing of the oxygen delivery, triggering sensitivity, and breath rate. Graphs 13-15 show the effect that various static breath rates have on FiO2 for each device tested.

Low flow oxygen delivery, which includes both CF and OCD technologies, need to be adjusted to meet the patient's physiologic needs. In this model, CF shows the greatest

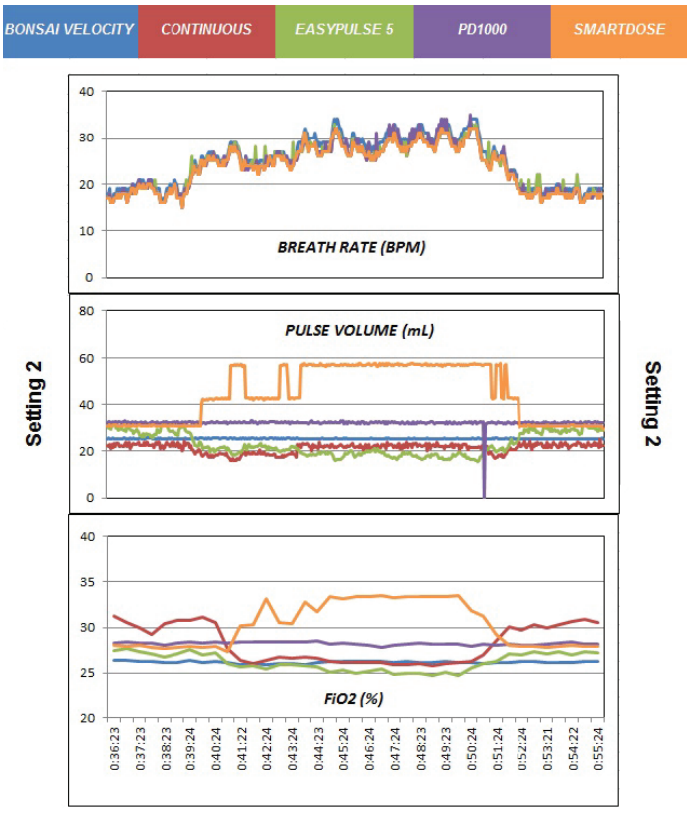
decrease in FiO2 as the breath rate increases. Some clinicians and more importantly, patients recognize this phenomenon and may increase the setting with activity to stay oxygenated. Unfortunately, many clinicians and patients do not understand this and as a result, experience desaturation during activity. This is a common problem with both CF and OCD technologies.

As the data in graphs 16-18 shows; even with fixed-bolus devices, FiO2 can still decrease at high breath rates. Note the decline in FiO2 on the Bonsai Velocity at setting 2 and PD1000 at the max setting 6, at the highest breathing rates: 35-40. As shown in the graphs, oxygen delivery exceeded the 60% inhalation threshold at those settings, so the oxygen was wasted and did not contribute to the FiO2. In the case of the PD1000 at setting 6, if a patient was not oxygenating with activity, another device with more efficient delivery and/or higher flow rates would need to be considered.

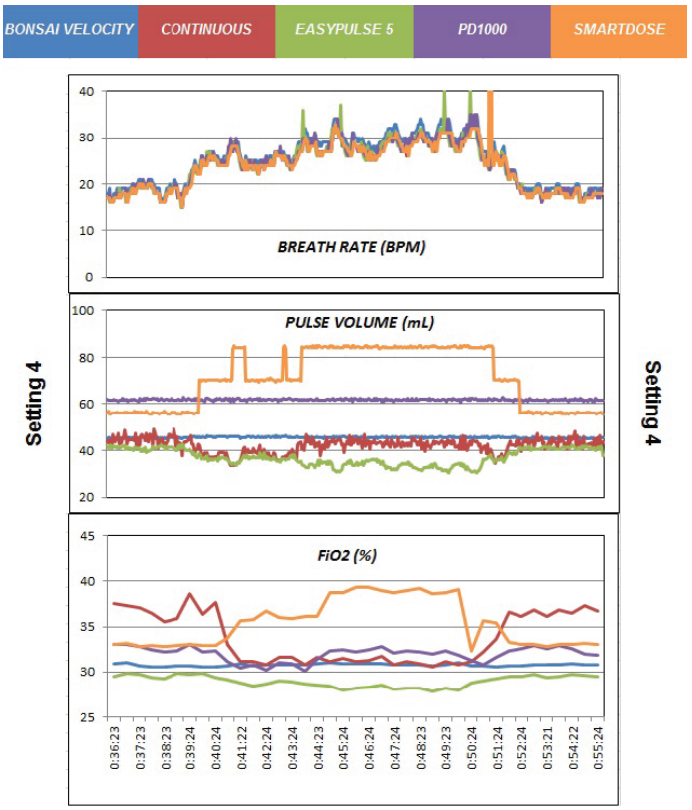
Key Point: If FiO2 drops with increased breath rate, the setting should be increased to meet the patient's oxygen needs. If the device is at its maximum setting and is not meeting the patients' needs, another device must be considered.

Dynamic Breath Rate Testing

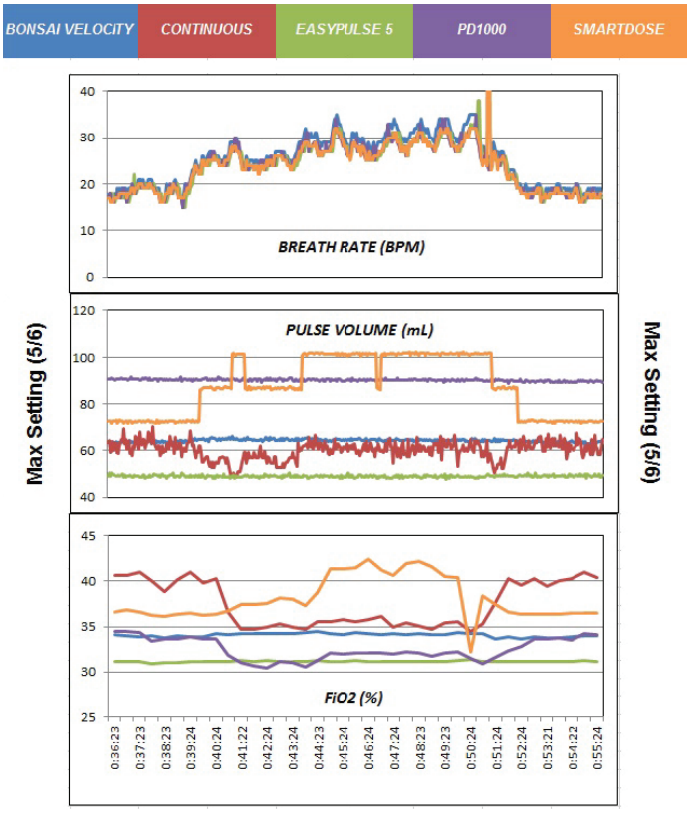
The graphics shown in graphs 16-18 demonstrate that when presented with a dynamic breath pattern; simulating a patient going from rest to activity/ambulation back to rest, the FiO2 results over time from the five tested devices set to the same setting varied considerably.



Graph 16



Graph 17



Graph 18

As shown earlier, with CF, increasing the breath rate without increasing the liter flow will result in a drop in FiO2. This is demonstrated in the data shown in graphs 16-18. The FiO2 is

noticeably lower during active breathing (>25 BPM) compared to the baseline breath rate.

On the Bonsai Velocity, a fixed-bolus device, FiO2 remained relatively stable at each of the settings tested, demonstrating effective oxygen delivery. However, on the PD1000, also a fixed bolus device, FiO2 decreased during activity despite being set at 6. This demonstrates that bolus size is not the sole determinant of FiO2.

As previously discussed, oxygen delivery in the first 60% of the inspiration is required to deliver FiO2. In the case of the PD1000 facing high breath rates, some volume of oxygen is lost to the deadspace, causing the drop in FiO2.

The SmartDose OCD technology is unique in that it will increase the bolus volume as the patient's breathing pattern changes and the rate rises.

The SmartDose then reduces the bolus volume as the pattern and rate return to the baseline. This algorithm is demonstrated in the pulse volume graphs shown, where there is a sharp increase (or decrease) in delivered volume when a notable change in the breath pattern and rate occurs.

As a result, during high frequency breathing (25 BPM and above) FiO2 actually increased, meaning more usable oxygen was delivered than at the baseline rate.

The SmartDose technology is currently the only breath-responsive, variable-bolus OCD technology available; that will respond to breathing patterns and deliver the appropriate therapeutic dose of oxygen.

Discussion

The data shown compares five types of oxygen delivery; one continuous flow and 4 OCD technologies. All delivery methods, including continuous flow demonstrated variability. This variability is generally by design, as there are no current performance standards for OCD technologies and each manufacturer develops devices based on various clinical, proprietary engineering technical specifications and assumptions. As a result, one must assume that regardless of design and delivery methodology, OCD technologies may perform differently during bench testing and clinical applications.

1. **CH4808-L** standard CF oxygen regulator, delivered CF flow and all delivery characteristics were consistent with what is known about CF oxygen therapy; lower inspired oxygen volumes as breath rates increase lead to lower FiO2 in the same conditions.
2. **EasyPulse 5** delivered a fixed-minute volume of oxygen at settings 1-4. The EasyPulse 5 setting 5 appears to perform as a fixed-bolus volume. As a result, the EasyPulse 5 delivered the lowest minute volume of oxygen at the higher breath rates, which is consistent with the design.
3. **Bonsai Velocity** provided a fixed bolus volume of oxygen per breath and generally maintained a constant bolus volume and FiO2 per breath as breath rate increased. This is consistent with the design and performance specifications.
4. **PD1000** provided a fixed bolus of oxygen per breath but had prolonged pulse volumes observed at the higher breath rates. As the breathing rates increased (>30), the FiO2 per breath declined due to the bolus delivery time exceeding the 60% inhalation threshold. This suggests the bolus flowrate is too slow at the higher rates and oxygen volume is lost to the anatomic deadspace.
5. **SmartDose** provided a fixed-dose of oxygen, and also increased and/or decreased oxygen delivery as the breath pattern and rate changed in dynamic breathing conditions. The SmartDose demonstrated the potential to maintain and increase FiO2 levels with simulated changes in breathing patterns and rates; without the need to manually change the dose setting with each change. This is consistent with the manufacturer's algorithm and performance specifications.

As shown in this report, continuous flow and OCD technologies respond differently to variable breathing patterns and will have limitations in oxygen delivery based on the engineering and design of each technology. As a result, the FiO2 will vary with the technology's oxygen dosing characteristics, in response to changes in breathing patterns and rates. The net volume of inhaled oxygen, and the FiO2 will increase or decrease based on the OCD technology's performance specifications and capabilities.

OCD technology that can automatically increase or decrease the dose (bolus volume) of oxygen based on breathing patterns and rates have the capability to automatically respond to a patient's changing need for oxygen, whereas standard technology may need to be adjusted manually to maintain appropriate oxygenation; which is not likely to occur consistently.

Oxygen is the fuel that supports metabolism, so as metabolic needs increase, oxygen demand will increase. Providing necessary oxygen therapy with activity promotes conditioning and improved health related quality of life. Oxygen delivery technologies, should be used with informed knowledge of the product's performance specifications and abilities. An oxygen delivery technology that adequately supports most, if not all oxygenation needs; should be used to promote physical activity, reduce exacerbations, prevent co-morbidities due to hypoxemia, and generally improve the patients overall health related quality of life.

Conclusion

Bench tests of five commercially available oxygen delivery technologies demonstrated wide variability in the key performance specifications tested, which is consistent with prior published research. Although this technology assessment cannot represent all commercially available OCD technologies; the design, oxygen delivery methods and performance specifications are similar in all OCD technologies. This is important, as OCD technology is incorporated into nearly all ambulatory oxygen sources, including cylinders, portable liquid and portable oxygen concentrators (POCs). This also reinforces findings and recommendations from prior studies and clinical practice guidelines that all patients be evaluated and titrated to their specific OCD technology for each activity of daily living. Based on the results shown is this report, the breath-responsive, variable-bolus OCD technology, which utilizes biometric inputs from the patient's breathing pattern and rate to make adjustments to the oxygen bolus volume to deliver a more consistent and predictable FiO2; may mitigate the need for ongoing titration. Although further research is required when used on patients to determine if this is possible.

Comments

OCD technology specifications and performance are highly variable and may limit activities of daily living if not appropriately selected and assessed on each specific patient. While OCD technologies may have similar technical features, this does not necessarily result in equivalent therapeutic functionality during use with individual patients.

Clinical studies, such as randomized controlled trials, are not required by the Food and Drug Administration (FDA) as part of the FDA 510(k) process to clear most medical devices for marketing, which includes FDA Class II devices, such as OCD technologies. Consequently, the evidence demonstrating individual or comparative therapeutic effectiveness of OCD technologies while in use by patients is sparse. Objective bench testing and smaller clinical studies are important resources for understanding the technical and clinical performance of such technologies.

Because standard home oxygen (O2) sources, deliver O2 at fixed rates, these sources are not designed to ensure optimal oxygen delivery based on changing physiologic need. These findings may translate clinically into variable oxygen delivery during periods of activity associated with changes in breathing patterns and rates. These data suggest breath-responsive, variable-bolus OCD technology, which utilizes biometric inputs from the patient's breathing pattern and rate to make adjustments to the oxygen bolus volume may deliver a more consistent and predictable FiO2, without the need for the patient or caregiver to adjust the setting. The technology provided a fixed-dose of oxygen, and increased or decreased oxygen delivery as the breath rate increased or decreased during dynamic breathing conditions.

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Transition of Care from Hospital to Home: A Wearable Ventilator's Role in the Coordinated Care Plan of a Patient with Idiopathic Pulmonary HTN and BOS

Robert Gregory

The focus of this case study is a twenty-four-year-old, Caucasian, female diagnosed with Idiopathic Pulmonary Hypertension (IPHTN), type II Diabetes Mellitus, asthma, migraines, and severe protein malnutrition. The patient had proceeded with surgical treatment for IPHTN—a progressive and debilitating disease, via a bilateral cadaveric transplant more than six years before at a pediatric transplant center. Unfortunately, her post-transplant trajectory was complicated by an unforeseen need to temporarily halt the usage of her anti-rejection medications. The temporary hiatus from her transplant medications resulted in an irreversible condition known as Bronchiolitis Obliterans Syndrome (BOS). This life-threatening pathology led her to seek medical consultation at another adult regional transplant center located in Philadelphia.

On April 8, 2016, the patient was transferred from that regional transplant center to Kindred Hospital of South Philadelphia for physical rehabilitation and nutritional support in the hope of re-qualifying her for yet another exploration into lung re-transplantation. Upon transfer to our facility, the patient was evaluated and presented as cachexic, anxious, and notably dyspneic. Our goal was to ramp up the patient's physical conditioning and address her muscle-wasting syndrome.

The elevation in oxygen consumption related to patients with profound lung pathology has a deleterious effect on the body's ability to retain muscle mass. In addition, the associative physiologic finding of an increased Respiratory Quotient (RQ)—spending a significant amount of energy on respiratory effort—prevents these patients from actively participating in physical rehabilitation. Fortunately, new advances in ventilation technology provide hope for many patients that were once delegated to a sedentary and isolated lifestyle. Breathe Technologies, Inc. offered just that solution for our patient to participate in a trial with their proprietary Non-Invasive Open Ventilation (NIOV) System to decrease her overall work of breathing (WOB) and RQ. The results were nothing less than remarkable. The patient's former intractable BMI of 13.70 and weight of 72.70 pounds was improved notably to a BMI of 16.90 and a weight of 89.60 pounds, a gain of 16.9 pounds, within a three week time period. Another benefit gained from using the NIOV System was the significant improvement in her endurance tolerance. Prior to her transfer and using the NIOV System, the patient was walking less than 200 feet with notable oxygen desaturations into the mid-70 percentages. Now, while using the NIOV System, the patient was energized to complete a six-minute walk achieving more than 1,250 feet without any notable desaturations.

These milestone accomplishments are compelling predictors of successful lung transplantation in the first post operative year. Clinical research has shown that being underweight is an independent risk factor in morbidity after lung transplantation.[1] In addition, the improved functional ability of this patient's six minute walk distance may represent a positive impactful factor in diminishing post-operative risk factors.

The NIOV System afforded this young woman with new found opportunities to pursue activities of daily living that we all too often take for granted. Using the NIOV System throughout the day renewed her confidence and determination to successfully cope with physical endurance challenges ahead. Supported by Breathe Technologies, this young woman was able to transition back to her home, which was more than one hundred miles from our hospital. Now she is surrounded by her loved ones with a sense of hope that her next visit to the hospital will be to receive her new lungs.

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Aerogen Reduces ED Admissions by 32%

Significant impacts also found to discharge rates and median length of stay.

Aerogen, the global leader in aerosol drug delivery, recently announced the results of a groundbreaking study which showed a 32% reduction in the number of patients admitted to the hospital when treated with Aerogen® Solo vibrating mesh technology.[1] This breakthrough study demonstrates the impact of a high-performance aerosol drug delivery system on patient care in the Emergency Department at St John's Medical Center (Detroit, Michigan) and was presented simultaneously at both the American Association of Respiratory Care (San Antonio) and the American College of Emergency Physicians (Las Vegas).

The findings come at a time when Emergency Departments across the country are experiencing a sharp increase in the number of patients presenting with respiratory disorders such as COPD, asthma and influenza, which have more frequent exacerbations over the winter season.[2] The result is pressure on hospitals to increase the number of patients going through the Emergency Department.

"Reducing a patient's need to be admitted means a couple of things. First, it means that patient feels a lot better and is ready to go home, which is great for the patient, but second, it also means one less person who may be waiting for a bed and spending some time in the hospital" noted principal investigator and study co-author Robert Dunne, MD, Vice Chair of Emergency Medicine at St. John Medical Center.

The study looked at 1,576 patients over two sequential 30-day periods in a busy, urban emergency department. It compared the impact of bronchodilator medication administered with Aerogen® Solo vibrating mesh technology to treatments administered with a traditional small volume nebulizer. The research found that Aerogen technology was statistically associated with 32% fewer admissions to the hospital, a 75% reduction in the amount of medication administered and a 37-minute median reduction in the length of a patient's stay in the Emergency Department.

"This large clinical study demonstrates the impact Aerogen technology can have in the Emergency Department and is further evidence of the outstanding clinical results we've seen when Aerogen technology is used in critical medical units all over the world," noted John Power, Managing Director and CEO of Aerogen. "When patients feel better and can go home faster, without an extended hospital stay, it benefits everyone. This is truly great news for patients, clinicians and hospital administrators alike."

This article was submitted by www.aerogen.com.

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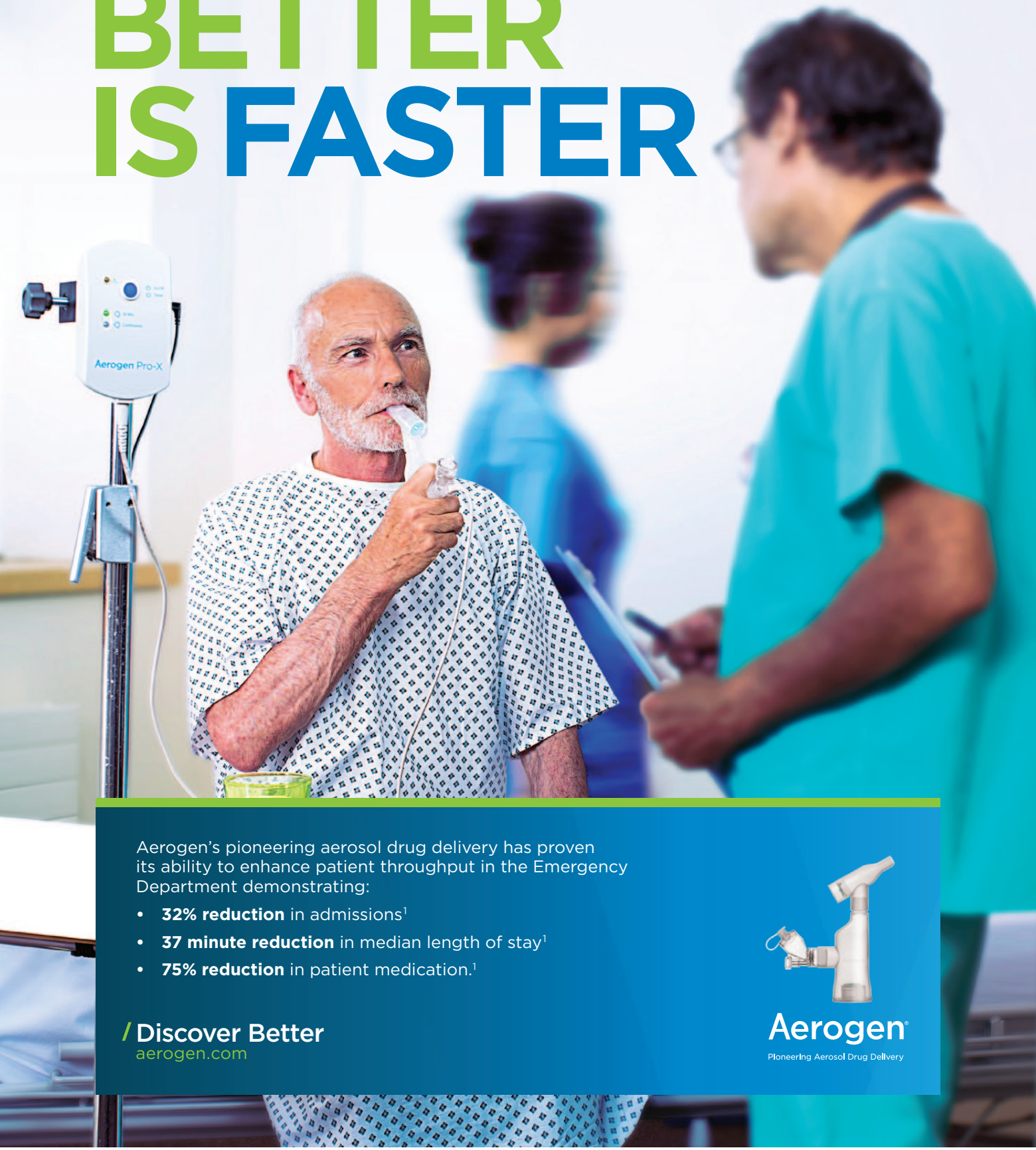

Aerogen's pioneering aerosol drug delivery has proven its ability to enhance patient throughput in the Emergency Department demonstrating:

- **32% reduction** in admissions[1]
- **37 minute reduction** in median length of stay[1]
- **75% reduction** in patient medication.[1]

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1 Dunne R et al. Aerosol dose matters in the Emergency Department: A comparison of impact of bronchodilator administration with two nebulizer systems. Poster at the American Association for Respiratory Care. 2016

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PM315

The Benefits of Using Apneic Oxygenation to Prolong the Period of Safe Apnea: A Literature Review

Chris Campbell

When it comes to the field of anesthesiology, a major concern is the issue of maintaining oxygenation during airway management. Anesthesia providers often have to deal with the serious challenges posed by a difficult intubation.

A documented 17% of the most "damaging events" in the American Society of Anesthesiologists (ASA) closed-claims database from 1990 to 2007 are from adverse respiratory events, and 31.8% of the claims in the American Association of Nurse Anesthetists (AANA) database from 2003 to 2012.

The definition of "damaging events" is listed as negative outcomes that lead to punishing malpractice claims.

According to a report published in the October 2016 issue of the AANA Journal, "even with advances in respiratory monitoring technology and practice guidelines for managing the difficult airway, difficult airway management accounted for 27% of all adverse respiratory events in the ASA closed-claims database: 67% on induction and 12% on extubation."[1,2]

And out of that 27%, 93% are "unanticipated," according to the report, written by Matt Pratt and Ann B. Miller, both from Florida Gulf Coast University. (The authors also said there is no single predictor of a difficult intubation).[3]

"Safe airway management requires a proper and thorough preoperative airway evaluation and a plan to secure the airway, with alternate plans available when the initial plan fails. Pediatric, obese, and obstetric patients undergoing general anesthesia with endotracheal intubation are considered to be at risk of rapid desaturation."

Pratt and Miller's report says that to support conventional preoxygenation techniques, continuous oxygen administration during the apneic period-termed apneic oxygenation (AO)—"assists in the maintenance of oxygenation when tracheal intubation is attempted."

The authors found, however, that the application of AO—despite its benefits—is currently "not standard practice in the United States."

To challenge that status quo in the U.S., Pratt and Miller conducted a literature review in an effort to pull together relevant research on AO. Nine articles were selected for appraisal in the review, including 6 randomized control trials, 2 prospective studies, and 1 retrospective study.

The literature they reviewed studied multiple apneic oxygenation techniques, including nasopharyngeal catheter, nasal prongs, endotracheal tube, intratracheal catheter, and high-flow transnasal humidified oxygen.

What was clear from the articles the team reviewed was that AO "demonstrated effectiveness at delaying the onset of hypoxemia during the apnea period.

Prolonging the apneic window changes the nature of airway management in patients at high risk of desaturation and when an unanticipated difficult airway arises."

At-Risk Patients

The risk feared by anesthesia providers involves rapid desaturation, particularly when it comes to pediatric, obese, and obstetric patients undergoing general anesthesia. Increased O2 consumption and reduced functional residual capacity (FRC) hastens the development of hypoxemia.[16,18,19]

Infant patients are especially vulnerable, according to the authors, as they desaturate more quickly because they have a higher metabolic rate and greater O2 consumption.[12,17]

"Multiple attempts with direct laryngoscopy increase the risk of pharyngeal and laryngeal trauma. Subsequently, the resulting trauma may increase the difficulty of successful face-mask ventilation and successful intubation via repeated laryngoscopy."

The goal is to prolong the safe apnea period, defined as the time between the onset of apnea and when the SpO2 concentration reaches 90% or less, increasing the margin of safety with tracheal intubation.[19] Doing this may reduce the negative impact of a stop-start situation during laryngoscopy.

According to the authors, "as evidenced by clinical research, AO provides acceptable O2 saturations. Frumin et al[9] and Cook et al[12] suggest saturations greater than 95% for 45 minutes in the nonobese adult patient and 10 minutes in the pediatric patient, respectively."

AO Endorsements

While not a standard in the US, in 2013, the Canadian Airway

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Focus Group[4] endorsed continuous oxygen (O2) administration during the apneic period (AO), when tracheal intubation is attempted.

"Research demonstrates that AO can safely prolong the duration of apnea without desaturation, maintaining an oxygen saturation measured by pulse oximetry (SpO2) at or above 90%.[5-14]"

In the United Kingdom, the Difficult Airway Society and the Obstetric Anaesthetists' Association updated its guidelines for management of the unanticipated difficult airway and management of the difficult airway in obstetrics. "Emphasis was placed on AO in patients who are considered at high risk of desaturation after the induction of anesthesia.[15,16]"

More recently, an analysis was conducted on the Pediatric Difficult Intubation (PeDI) registry in the United States, and based on adult studies and anecdotal reports, PeDI "investigators speculate that AO would delay the onset of hypoxemia in children and reduce the number of tracheal intubation attempts.[17]"

"Considering that pediatric patients have a smaller apneic period for establishing a definitive airway, anesthesia providers should incorporate AO into their airway management plan," the authors wrote.

The authors found that AO was implemented using various methods. For example, four studies[5,7,10,14] examined the efficacy of AO using a nasopharyngeal catheter and found it was "more efficacious in prolonging the apneic period compared with preoxygenation alone. After preoxygenation and induction, a nasopharyngeal catheter was placed and O2 was insufflated at 3 L/min or 5 L/min. Study end-point times were 6 minutes and 10 minutes or until the SpO2 concentration fell to 92% or 95%, whichever occurred first.[5,7,10,14] In 3 studies[5,10,14] all patients in the AO groups maintained their SpO2 concentration at 97% or higher for the duration of the apneic period.

"Conversely, all patients in the control groups desaturated to 92% or 95% before the study cutoff time; mean apnea times were 3.65 minutes,[5] 4.04 minutes,[14] and 6.8 minutes.[10]"

Conclusions

The authors wrote that after finishing their review of the literature on the AO techniques that are clinically available, they concluded that, "all are shown to be more effective at prolonging the safe apnea period compared with preoxygenation alone… Although there are currently no available consensus guidelines for the clinical use of AO, clinicians should consider the potential patient safety applications of the technique.

Given the vital nature of ensuring oxygenation and ventilation in rendering safe patient care, AO, although often unconsidered, may provide a potentially valuable clinical technique in selected patient scenarios."

The authors added that while doing their research, they discovered there are additional studies being conducted around the world on AO,[20] with several focused on infants—something they encourage.

"As research evolves in the area of AO, these techniques provide a potentially lifesaving tool to be used by anesthesia professionals when critical time is needed to establish a definitive airway."

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Accurate Non-intubated Capnography Highly Dependent on a Quality Sampling Line

Greg Spratt, BS RRT CPFT

A key to obtaining an accurate $etCO_2$ measurement and quality waveforms with any capnograph is the sampling line. With sidestream capnography commonly used for non-intubated $etCO_2$, measurement technology can only report what is being delivered to the measurement chamber; so if the sampling line is not providing a representative CO_2 sample from the breath, the accuracy of the reading is impacted.

Keys to Accurate Sampling

The design of various exhaled CO_2 sampling lines varies significantly. A common design is to split sampling and oxygen delivery between the two nares (Figure 1), delivering oxygen to one nostril while sampling CO_2 from the other. This design may be limited in sampling and/or oxygen delivery in cases where one or both nares are blocked (eg, deviated septum, sinus congestion, NG tubes, etc). In addition, a little-known phenomenon called 'nasal cycling' exists, leading to alternating congestion (ie, increased airway resistance) and decongestion (ie, decreased airway resistance) of the opposing nasal passages causing the predominance of nasal airflow to shift back and forth intermittently between the two nares.[1] It has been estimated that this phenomenon exists in 72-80% of the population.[2,3] Thus, sampling from both nares is ideal for consistent and accurate results.

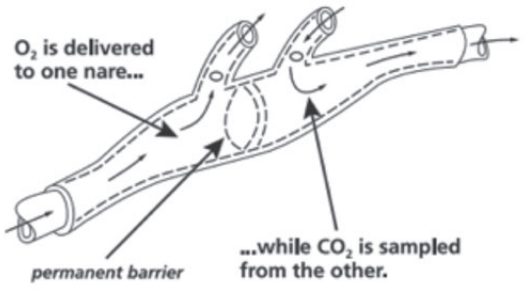

Figure 1. Split sampling and oxygen delivery

In addition to proper nasal sampling, oral sampling methodologies vary significantly. Many designs are nasal-sampling only which could lead to obvious problems when the patient is predominantly mouth-breathing. Mouth breathing is common when patients are in respiratory distress or while under sedation, two common scenarios for monitoring $etCO_2$. Most CO_2 sampling lines with oral sampling are designed with a thin small tube that extends over the mouth. One design provides an oral scoop to obtain a broader sampling area for exhaled gas from the mouth while simultaneously sampling from both nares, (Figure 2).[4]

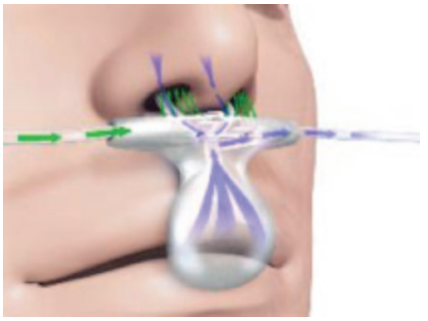

Figure 2. Oral Scoop Design

Testing on 29 healthy patients with 3 different sample lines, one being the scoop and the other two employing oral tubes, was compared for accuracy during oral breathing. All three were designed for oral/nasal sampling. The mean $etCO_2$ measurements across all participants during mouth breathing while on room air and on oxygen at 2 l/m are shown below (Figure 3).[5]

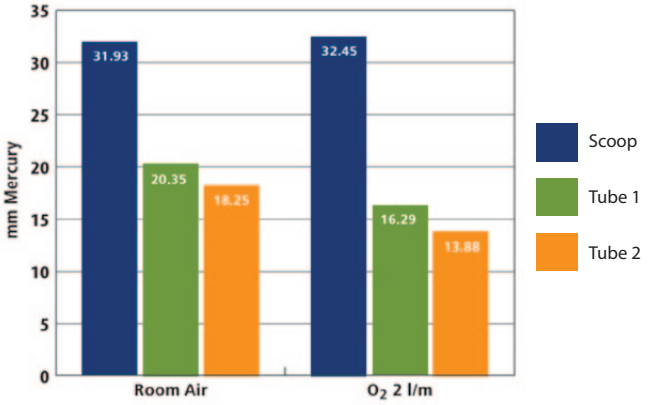

Figure 3. Oral sampling with 3 designs.[5]

While each of the devices showed statistically equivalent values during nasal breathing, two designs showed dramatically lower measurements during mouth breathing. Comparing Hodges-Lehmann interval to the equivalence bounds for each of the three oral-nasal devices demonstrates that only the scoop design showed equivalent mouth to nose breathing results at equivalence bounds of Δ=15%. For the other designs, equivalence could not be demonstrated even at equivalence bounds of Δ= 20%, both having far lower mouth- versus nose-breathing values.

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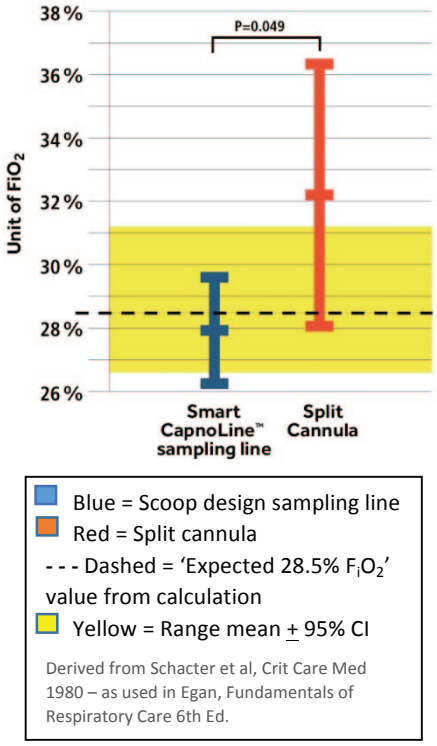

Figure 4. FiO2 percentage/consistency during O_2 delivery at 2.5 lpm[6]

Oxygen Delivery

Similarly, oxygen delivery methodologies vary significantly. The scoop sample line is designed to deliver oxygen to both nares and orally by producing an "oxygen cloud" in front of the nose and mouth. This is achieved with a series of small holes at the base of the nasal prongs and oral scoop that deliver oxygen. This design is also intended to minimize attenuation of the CO_2 sample by oxygen dilution. Other designs employ one of two methodologies: 1) delivering oxygen on one side of the nose while sampling on the other as discussed earlier 2) splitting each nasal sampling line down the middle so that oxygen is delivered on one side of the split and CO_2 is sampled via the other side.

In a study comparing two oxygen delivery designs, subjects were studied using oxygen delivery at 2.5 l/m.[6] The fraction of inspired oxygen (FiO_2) in the posterior pharynx was monitored. The results showed that the pharyngeal FiO_2 of the scoop sampling line is not different from the anticipated F_iO_2 predicted from standard reference values for a nasal cannula (yellow bar). The delivery of oxygen via the scoop design provided a more consistent FiO_2 and was significantly different, as compared to a traditional split design at 2.5 l/m (Figure 4).

Summary

When monitoring $etCO_2$, there are significant differences in the performance of different designs, both in CO_2 sampling and oxygen delivery. It is important to ensure that the sample line being used provides a quality sample of exhaled gas and delivers a consistent and predictable level of oxygen.

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Clinician's Data Analysis: Lung Function Improvement Maintained Over 16 To 24 Months With Use Of AffloVest™ HFCWO Vest By International Biophysics

Michael Cooper, RT

Lung function improvement was observed in a previous evidence-based study on 5 cystic fibrosis patients.[1] Current data from the same five patients shows that their lung function scores improved and were maintained over a period of usage of 16 to 24 months.

In the previous paper[1] five adolescent patients used the AffloVest by International Biophysics for 3-5 months each and saw increased Pulmonary Function Test (PFT) scores. The PFT routinely measures airflow, lung volumes, gas exchange, response to bronchodilators, and respiratory muscle function. All patient care was provided at a major US hospital actively treating cystic fibrosis. The five patients involved in the study ranged in age at the time between 14 and 18 years of age. All patients were using an air bladder HFCWO vest for their prescribed treatment plan, before switching to the AffloVest. The objective of the study was to measure lung function scores before and after use to determine efficacy. The data in this first analysis observed that the AffloVest improved breathing scores in the five patients over a 3 to 5 month period:

Average FVC: 0.308L, 09.5% Increase
Average FEV1: 0.312L, 11.5% Increase
Average FEF 25-75%: 0.744L, 21.3% Increase

The ongoing data collected for this clinician paper was collected from the same five patients after 16 to 24 months of treatment using the AffloVest. The data collected on the five AffloVest patients shows that lung improvement overall was maintained over that total time period.

Patient Data Summary Table (16 to 24 months)

	Initial Pre-AffloVest Use Value (Mean)	Final Value (Mean)	% Change Final vs. Initial
FVC (L)	3.23	3.77	+ 16.80%
FEV1 (L)	2.72	3.16	+ 16.02%
FEF 25% - 75% (L/sec)	3.49	4.02	+ 15.30%

The data described in this paper were collected independently by the clinician author and not at the direction of International Biophysics Corporation (IBC). All patients independently obtained an AffloVest by prescription from their physicians via their own insurance or private pay for their own personal use. Results were documented during routine clinical visits. At the conclusion of data collection and collation, the author contacted IBC and shared the findings. Following review of the findings, IBC provided modest financial and editorial support to the author in connection with the preparation of this clinician paper. MKT0029 Rev A.

For these 5 patients, the data observations have shown that patient lung function scores improved and are being maintained over time with use of the AffloVest.

Improvement in lung function scores along with AffloVest use had also previously been observed in a 25 patient clinician paper by Michelle W. Tackett, RRT and Vivian P. Henderson, RRT, Knoxville, Tennessee.[2]

In this paper, a total of 25 patients were set up on the Afflovest. The data presented in this clinician paper was from twelve patients (48%) who experienced increases in their lung function scores after adopting AffloVest technology into their Airway Clearance Treatment (ACT) regimen. The remaining 13 patients (52%) saw no significant increase, and no decrease, in their lung function. All patients had the benefit of increased mobility, convenience and ACT therapy with the Afflovest.

The 12 patients in the Tackett analysis ranged in age from 11 to 18 years old and they all used the AffloVest for periods ranging from less than a month to almost a full year. Eleven (11) of the 12 had been using air bladder style vests previously. One patient had previously used no ACT until adopting the AffloVest. The lung function scores collected were FVC, FEV1, and FEF 25-75%. Average FVC, FEV1, and FEF 25-75% increased 15.22%, 17.41%, and 11.21% respectively with the AffloVest. These patient data analysis reviews are observing positive lung improvement scores that improve and that are maintained over time with patients that are adopting the AffloVest in their treatment plan.

In a study[3] conducted at the UAB Gregory Fleming James Cystic Fibrosis Research Center no significant relationship was found between adherence to High Frequency Chest Wall Oscillation (HFCWO) Airway Clearance Therapy (ACT) and lung function. The HFCWO vests referred to in this study were all air bladder style vests.

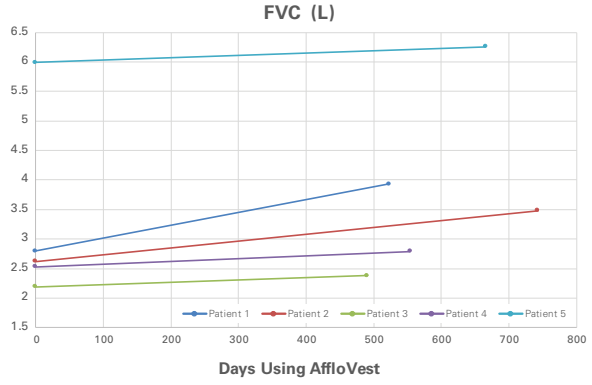
Conclusion

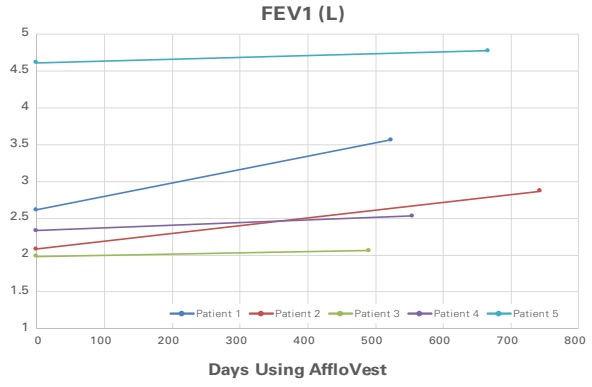
In conclusion, the data in this analysis observed improved breathing scores in the five patients using the AffloVest and that the improvement was maintained over 16 to 24 months.

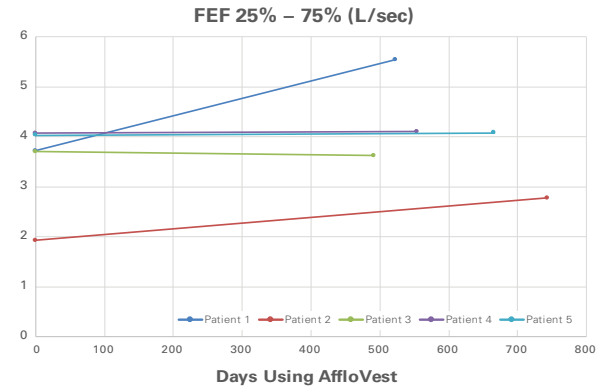
Average FVC: + 16.80% Increase
Average FEV1: + 16.02% Increase
Average FEF 25-75%: + 15.30% Increase

The overall usage time between the first and last test was 16 months to 2 years. The clinician performing this study concluded that the AffloVest patients showed improvement in each patient's condition. The average patient used the AffloVest 2-3 times a day, and the average settings were 8 minutes at medium (13Hz) and 16 minutes at intense (20Hz) for total treatment time of 24 minutes. Based on this data analysis, other CF programs may want to consider undertaking their own PFT data analysis with patients switching to or incorporating the AffloVest in their patient's therapy regimen.

AffloVest Patient Graphs







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AffloVest Patient Data

Patient 1
Age: 15 Gender: Male
Days using AffloVest: 523

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 17 Months	%Change Final vs. Initial
FVC(L)	3.33	2.80	3.93	+ 40.36%
FEV1(L)	3.06	2.61	3.56	+ 36.40%
FEF 25%-75% (L/sec)	3.44	3.72	5.54	+ 48.92%

Patient 2
Age: 15 Gender: Male
Days using AffloVest: 743

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 24 Months	%Change Final vs. Initial
FVC(L)	3.33	2.62	3.48	+ 32.82%
FEV1(L)	3.06	2.08	2.87	+ 37.98%
FEF 25%-75% (L/sec)	3.44	1.93	2.78	+ 44.04%

Patient 3
Age: 16 Gender: Female
Days using AffloVest: 491

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 16 Months	%Change Final vs. Initial
FVC(L)	3.07	2.19	2.38	+ 8.68%
FEV1(L)	2.92	1.98	2.06	+ 4.04%
FEF 25%-75% (L/sec)	3.31	3.70	3.62	- 2.16%

Patient 4
Age: 19 Gender: Female
Days using AffloVest: 554

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 18 Months	%Change Final vs. Initial
FVC(L)	3.13	2.53	2.79	+ 10.28%
FEV1(L)	2.98	2.33	2.53	+ 8.58%
FEF 25%-75% (L/sec)	3.36	4.07	4.1	+ 0.74%

Patient 5
Age: 19 Gender: Male
Days using AffloVest: 667

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 22 Months	%Change Final vs. Initial
FVC(L)	4.08	5.99	6.26	+ 4.51%
FEV1(L)	3.76	4.61	4.77	+ 3.47%
FEF 25%-75% (L/sec)	4.14	4.03	4.08	+ 1.24%

Cost-Effective Analysis of Using High Frequency Chest Wall Oscillation (HFCWO) in Patients with Non-Cystic Fibrosis Bronchiectasis

Chet E. Sievert, BS[1] and Caroline A. Beaner, CRT[1]

Abstract

Purpose: Bronchiectasis is a chronic progressive disease characterized by irreversible pathological dilation of pulmonary bronchi. Treatments for bronchiectasis are aimed at mobilizing airway secretions, reducing inflammation, preventing respiratory infections, enhancing ventilation, minimizing the number of exacerbations, and improving a person's quality of life. High frequency chest wall oscillation (HFCWO) is an airway clearance treatment currently used for a number of chronic airway compromising diseases including non-cystic fibrosis bronchiectasis. This study evaluated the economic impact of HFCWO treatment delivered by the SmartVest® Airway Clearance System on bronchiectasis-related healthcare utilization and cost.

Methods: The results of a previously published case review outcome-based clinical study by the authors provided the basis for this cost effectiveness analysis. Bronchiectasis-related exacerbations including the number of hospitalizations, emergency department (ED) visits and frequency of antibiotic prescriptions were recorded for each patient for a one year period prior to SmartVest use (standard of care control) and for a one year period after starting SmartVest use. The exacerbation rates for one year pre-SmartVest and one year post-SmartVest were compared. Exacerbations were verified from both the patient's medical records and by phone interview. Antibiotic costs were determined using "on-line discount pharmacy pricing" whereas hospitalization and ED costs were determined using the Healthcare Cost and Utilization Project (HCUP) Statistical Brief #146 and the HCUP National Inpatient Sample (NIS) 2013 database.

Results: The previously published clinical outcomes of fifty-nine SmartVest patients with non-cystic fibrosis bronchiectasis served as the basis for this analysis. When the outcome data were analyzed, SmartVest use, compared to the standard of care control, was associated with statistically significant results; a 58% decrease in antibiotic cost, a 63% decrease in ED visit cost and a 60% decrease in hospitalization cost. In total, the cost analysis resulted in an annual savings of $3,045 per patient per year of SmartVest use.

Conclusions: The clinical effectiveness of using SmartVest as a treatment for non-cystic fibrosis bronchiectasis patients was previously verified by a significant reduction in bronchiectasis-related exacerbations, which directly translates into a significant 60% overall reduction in healthcare utilization and cost in this population. Furthermore, secondary benefits such as the potential to reduce hospital readmissions and the potential to impact in deterring antibiotic resistance may have even greater benefits than decreasing cost.

Keywords: SmartVest, high frequency chest wall oscillation, HFCWO, bronchiectasis, cost

Introduction

Bronchiectasis is a chronic and etiologically heterogeneous disease. Common characteristics of bronchiectasis are shortness of breath, frequent exacerbations, chronic cough, hemoptysis, and excessive sputum production. The disease is typically characterized by cycles of impaired mucociliary clearance, bronchial infection, and inflammation resulting in structural damage to the airways with permanent and abnormal dilation.[1] Bronchiectasis can be the outcome from a diverse array of respiratory and systemic diseases, including cystic fibrosis, dyskinetic ciliary syndromes, inhalation/aspiration injuries, primary and acquired immunodeficiency states, and a number of rheumatic and inflammatory conditions.[2] Bronchiectasis is observed in 7% to 52% of patients with asthma or chronic obstructive pulmonary disease (COPD).[3,4,37]

Seitz, et al, analyzed a 5% sample of the Medicare outpatient claims database for bronchiectasis among beneficiaries aged ≥65 years from 2000 to 2007. [6] The database contains claims-level information from non-institutional outpatient healthcare providers. Bronchiectasis was identified by the database using the International Classification of Diseases, Ninth Revision, Clinical Modification codes (ICD-9-CM) codes. The study population included >2 million unique individuals enrolled in Medicare Part B for at least one month from 2000 to 2007. The study determined the prevalence of bronchiectasis in the overall population to be 1,106 cases per 100,000 people over the eight-year review period. The study also found that the prevalence of bronchiectasis in Medicare beneficiaries increased by 8.7% between 2000 and 2007 and the hospitalization rate for bronchiectasis increased annually at a rate of 2.4% among men and 3.0% among women.

The overall burden of advanced lung disease is rising, and where data exist, the costs related to the morbidity and mortality of these diseases appear significant.[2] This might, in part, be

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a reflection of the increasing aging population with chronic lung disease which has a disproportionate rise in health-care costs; the rate of hospitalization due to chronic lung disease markedly increases above the age of 50 years, and particularly in older women.[2,7] Using discharge records from between 1997-2010, it was estimated the mean hospital cost for inpatient care in patients with a pneumonia exacerbation was $9,300.[28] In 2001, it was also estimated that the annual medical cost of care for persons in the United States with bronchiectasis was $13,244, which is greater than the annual cost for many other chronic diseases, such as heart disease ($12,000) and COPD ($11,000).[38] A 2005 study found that patients with non-cystic fibrosis bronchiectasis averaged 2.0 additional days per year in the hospital, had 6.1 additional outpatient encounters and 27.2 more days of antibiotic therapy compared with patients without the disease.[9] In 2005, the treatment costs for non-cystic fibrosis bronchiectasis was $630 million annually.[5]

Patients with non-cystic fibrosis bronchiectasis can have difficulty clearing airway secretions and can significantly benefit from airway clearance therapy.[2] The aims of treatment for bronchiectasis are to mobilize airway secretions so as to reduce inflammation, prevent respiratory infections, enhance ventilation, minimize the number of exacerbations, and improve a patient's quality of life.[10-12] A number of therapeutic methods are currently used to clear airway secretions in patients with pulmonary disease, respiratory mucus clearance impairment, or who are at risk of developing either one of those conditions.[8] These methods generally aim to promote secretion clearance by reducing mucus viscosity and using shear forces to release the mucus from the lung wall to facilitate mobilization for ease of expectoration. Standard of care involves combination therapy with mucolytic and mucokinetic agents, bronchodilators, anti-inflammatory therapy, and some form of physical/mechanical airway clearance therapy.[2] Airway clearance therapy plays a critical role as it helps to avoid retention of pathogen-laden mucus which is the underlying origin of recurrent infection that causes progressive pulmonary deterioration.[2,13,14] Airway clearance methods play a critical role in maintaining respiratory health throughout the life-time of the patient.

A number of airway clearance methods are available including chest physiotherapy, positive end-expiratory pressure masks, oral-high frequency devices, and high frequency chest wall oscillation (HFCWO).[2] Positive end-expiratory pressure masks and oral-high frequency devices require active effort, mastery of the technique, and/or physical agility which can limit their use.[2]

HFCWO is used for airway clearance in patients with a wide range of airway compromising diseases and conditions, including genetic and immunological disorders, neuromuscular diseases, and obstructive pulmonary conditions, such as asthma and COPD.[15-18] In contrast to some other methods, HFCWO requires minimal activity from the user and is not dependent on a Healthcare Provider's technique to be effective.[2] Clinical studies, primarily in patients with cystic fibrosis, have shown HFCWO to be safe and effective.[2,15,19-22] HFCWO delivers compression pulses to the chest wall through an inflatable vest connected to an air pulse generator.[2] The generator produces an alternating flow of air into, and out of, the vest that rapidly compresses and releases the chest wall within a range of selectable frequencies and pressures. The oscillatory compression imparted to the chest wall has been reported to thin viscous mucus, disconnect mucus from the lung's wall, and propel mucus from the minor airways of the lungs toward the major airways where it can be expectorated or suctioned away.[2,23,24] HFCWO can lead to significant improvement in lung volume of 15 to 57mL and in flow up to 1.6L/sec.[22]

A prior case review study evaluated the clinical outcomes of SmartVest® Airway Clearance System therapy on exacerbation-related healthcare utilization and medication use in subjects with non-cystic fibrosis bronchiectasis.[25] The study found that the use of SmartVest resulted in a statistically significant 60% reduction in bronchiectasis-related exacerbations including antibiotic use, emergency department (ED) visits and hospitalizations. The current study is designed to assess the economic impact of SmartVest therapy on bronchiectasis-related healthcare and antibiotic costs.

Methods

A recent SmartVest (Electromed, Inc., New Prague, MN, USA) case review outcome-based clinical study served as the basis for this analysis.[25] The study recorded all bronchiectasis-related exacerbations to include the number of hospitalizations, ED visits and antibiotic use for a one year period prior to SmartVest use (standard of care control) and, for comparison, for a one year period after the start of SmartVest use (treatment). The study included only those subjects with a diagnosis of non-cystic fibrosis bronchiectasis who had been using SmartVest for at least one year, and whose medical records were available for one year prior to initiation of SmartVest therapy. Patients were excluded if they had not been compliant with their prescribed SmartVest therapy regimen, were unable to be contacted by phone, or had expired. All data collected prior to SmartVest use were captured via the patient's medical records.

Patient's medical records were reviewed for all bronchiectasis-related exacerbations that occurred during a one year period prior to starting SmartVest therapy. Subjects were contacted and interviewed by phone to collect bronchiectasis-related exacerbations for the one year period after starting SmartVest therapy. The questionnaire for the phone survey was developed for the exclusive purpose of the study. During the phone interview, the subject was asked specific questions regarding respiratory-related antibiotic use, ED visits and hospitalizations. The interview also inquired whether the patient was using SmartVest according to the physician's prescription regimen.

Antibiotic costs were determined using "on-line discount pharmacy pricing" however, the cost of office visits and physician fees were not included. Hospitalization and ED costs were determined using the weighted national estimates from Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS), 2013, Agency for Healthcare Research and Quality (AHRQ), based on data collected by individual States and provided to AHRQ by the States.[26] NIS database includes a stratified probability sample of hospitals from State Inpatient Databases that include hospitalizations by patients with Medicare, Medicaid, private insurance, and the uninsured.[27] The NIS contains data from 5 to 8 million hospital stays from about 1000 hospitals. It is designated to approximate a 20% sample of the US nonfederal, short-term hospitals as defined by the American Medical Association. The NIS is drawn from states participating in the Healthcare Cost and Utilization Project. The NIS contains uniform inpatient stay data from hospital discharge databases maintained by state agencies, hospital associations, and other private

organizations. Total number of weighted discharges in the US based on HCUP NIS was 35,597,792.[28]

Results

Review of HCUP and Medicare databases revealed associated healthcare costs for a bronchiectasis-related exacerbation to be $450 (2012) for an ED visit and $9,300 (2010) for a hospitalization with pneumonia. Extended hospital stays based on complications or comorbidities were not calculated. Using on line discount pharmacy pricing calculations, the cost of a standard antibiotic regimen for pneumonia was $290 (2016). Physician fees for an office visit and subsequent prescription were not available for calculation.

Of the 104 bronchiectasis SmartVest patients identified, fifty-nine patients met the inclusion/exclusion criteria.[25] In the study population, the average number of antibiotic prescriptions per year was 58% less for SmartVest (0.6/yr) compared to standard of care control (1.4/yr) (see Table 1). SmartVest use also significantly reduced ED visits by 63% (0.08/yr verses 0.03/yr) and hospitalizations by 60% (0.5/yr verses 0.2/yr). The annual per patient costs for antibiotics for patients treated with SmartVest were about $233 lower compared to those treated with standard of care (see Table 1). Hospitalizations, after one-year of SmartVest use, were also significantly reduced by $2,790 per patient per year. In total, the overall results revealed an annual savings of $3,045 per patient per year of SmartVest use.

Table 1. Summary of cost analysis of SmartVest versus standard of care control

Bronchiectasis-Related Exacerbations*	Standard of Care Control	SmartVest Treatment	Percent Reduction
Antibiotic Rxs (per yr)	1.4	0.6	58%
ED Visits (per yr)	0.08	0.03	63%
Hospitalizations (per yr)	0.5	0.2	60%
Cost Comparison Analysis			
Antibiotic Rxs (per yr)	$406	$174	58%
ED Visits (per yr)	$36	$13	63%
Hospitalizations (per yr)	$4,650	$1,860	60%
Total Cost per Year	$5,092	$2,047	60%

*Sievert CE, Beaner CA, Sievert CP. Using High Frequency Chest Wall Oscillation in a Bronchiectasis Patient Population: An Outcomes-Based Case Review. Respiratory Therapy Journal 2016;11(4):34-38.

The analysis did not account for any physician/office fees incurred to obtain an antibiotic prescription without hospitalization. Also, the analysis did not account for an office visit for a potential exacerbation that did not result in a prescription or hospitalization. In addition, the analysis did not account for added expense if the exacerbation was an antibiotic resistant bacterial strain pneumonia which reportedly can cost more than $15,000 for each episode.

Discussion

The purpose of the analysis was to evaluate the economic impact of SmartVest use on bronchiectasis-associated medical costs compared to a standard of care control. To our knowledge, this is the first study to assess the healthcare costs of treating non-cystic fibrosis bronchiectasis patients with HFCWO. Overall cost included the cost of antibiotics, ED visits, and hospitalizations related to exacerbations associated with non-cystic fibrosis bronchiectasis. The study demonstrated a significant reduction in healthcare utilization and its associated cost when bronchiectasis patients were treated with SmartVest for one-year. The overall cost was reduced by 60% which translates into a savings of $3,045 per patient per year.

A recent study that evaluated hospital discharges, readmissions, and ED visits for COPD or bronchiectasis in adults in the United States found from 2001 to 2012 the number of hospital discharges rose by 88,000.[31] The study also found that about 7% of patients with COPD or bronchiectasis were readmitted within 30 days with COPD or bronchiectasis as the principle diagnosis.[31] In contrast, the rate of discharge decreased for other diseases.[31] The reason for the significant rise in COPD and bronchiectasis hospital and ED visits is not clear as a significant decline in rates of smoking have been observed. However, it may reflect the potential under diagnosis of the disease and the long-term nature of COPD and bronchiectasis in an aging population.[31]

A previous case review outcome-based study reported that SmartVest use reduced hospitalizations by 1.5 fold,[25] indicating the cost benefit of HFCWO on reducing healthcare utilization burden. Other studies have also evaluated factors (both system and patient) that may lower readmission in patients with COPD, and are, at least in part, relevant to patients with bronchiectasis. These factors include continuity with the patients' primary care provided or pulmonologist, discharges coordinator intervention, and the extent or type of respiratory therapy.[32-34]

Reduction in the number of bronchiectasis-related exacerbations can also impact a patient's quality of life.[35,36] In a population of patients with COPD, the use of SmartVest was associated with significant improvement in the five-symptom score P=0.002 (rating of sputum, wheeze, cough, shortness of breath, and exercise tolerance).[36] SmartVest treatment also demonstrated a significant improvement in the St. George's Respiratory Questionnaire (SGRQ) P=0.02, while no improvement was observed in patients treated with conventional treatment.[36] Similarly, our prior case review outcome-based study found that 68% of the subjects indicated during the phone call interview that the use of SmartVest had significantly improved their quality of life.[25]

Several limitations to the study design should be considered when interpreting the results. The patient size of the study was small, and the hospitalizations, ED visits, and antibiotic use data after initiation of SmartVest therapy was obtained primarily through patient interview. The study may be considered conservative due to no costing added for physician's fees associated an office visit resulting in an antibiotic prescription or, no costing added for an office visit that did not result in an antibiotic prescription. In addition, Reliance on HCUP, NIS and AHRQ data bases, which depend on the diagnoses entered on claims, may be coded incorrectly or not coded at all, thereby potentially introducing measurement error with respect to ICD-9-CM-based variables.

Reducing healthcare utilization cost such as antibiotic use, ED visits and hospitalizations are prioritized objectives of recent healthcare directives such as the Affordable Care Act (ACA). For example, the ACA has established the Hospital Readmissions Reduction Program (HRRP), which has directed CMS to penalize hospitals by reducing reimbursement payments for excess patient readmissions for the same condition. HRRP originally identified the top three "applicable conditions" for focused readmission measurement to include acute myocardial infarction, heart failure and pneumonia. In addition, CMS

recently finalized the expansion of additional applicable conditions beginning with the fiscal year 2015 program to include patients readmitted for an acute exacerbation of COPD. The significant reduction in healthcare utilization and hospitalizations for non-cystic bronchiectasis patients using SmartVest, as demonstrated in this study and others, may play a critical role in helping hospitals reduce readmissions and thus not be penalized.

For patients who have airway infections resistant to oral antibiotics, the burden is much greater and more serious. Intravenous antibiotics complicate care greatly because hospitalization or home monitoring is required. Treatment for these patients includes placement of a central venous catheter, coordination of the doses of drugs that often must be given multiple times per day, regular blood tests to monitor for side effects, and measurement of blood levels of the antibiotic for many days, steps that become expensive and disrupt patients' lives.

The World Health Organization (WHO) has declared that microbial resistance to antibiotics poses a "major global threat with devastating implications to public health." Antimicrobial resistance threatens the effective prevention and treatment of an ever-increasing range of infections caused by not only bacteria but viruses and fungi as well. The US Centers for Disease Control and Prevention (CDC) considers antimicrobial resistance one of their top concerns and priorities. In the US alone, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of those infections.[39] In response to the worldwide concern, the US Centers for Medicare & Medicaid Services (CMS) recently released a proposed rule change to its Conditions of Participation which would, among other changes, require hospitals to implement antibiotic stewardship programs in order to participate in Medicare and Medicaid programs. Antibiotic stewardship includes improvement of patient outcomes by adoption of processes and procedures that reduces the incidence of infections with particular attention to pneumonia such as preventative treatment care. As a secondary benefit to the cost benefit results of this study, a significant reduction in the need for antibiotics in bronchiectasis patients by the use of SmartVest may have even greater benefits than decreasing cost. An available treatment that could significantly reduce respiratory infections and thus the need for antibiotics fits well within hospital's infection control programs.

In summary, the clinical effectiveness of HFCWO airway clearance demonstrated by SmartVest in patients with COPD[36] and those with bronchiectasis,[25] and the significant reduction in antibiotic, ED and hospitalization costs observed in this study supports the cost benefit of SmartVest use and argues for insurance coverage of SmartVest by payers. Furthermore, secondary benefits such as the potential to reduce hospital readmissions and the potential to impact in deterring antibiotic resistance may have even greater benefits than decreasing cost.

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University of Cincinnati's Online Program in Respiratory Therapy: Helping Students Increase Employability

Shane Keene

To advance the profession, the respiratory therapy profession recently began encouraging students to earn bachelor's degrees, instead of associate's degrees. However, students seeking to earn those four-year degrees were faced with a lack of available programs.

In the 2014–2015 academic year, there were 374 associate's degree programs in respiratory therapy, but only 61 bachelor's programs. In fact, in several states there were no four-year respiratory therapy degree programs. At University of Cincinnati, we decided to create an online bachelor of science in respiratory therapy program (http://respiratorytherapy.uc.edu/) to extend the opportunity to earn this degree to students around the country.

We chose to partner with Pearson, which provides online program management services, to launch and support the online bachelor of science in respiratory therapy program. The first students enrolled in the program in the spring of 2013. The online program was aimed at mid-level professional respiratory therapists who wanted to enhance their employability by earning a bachelor's degree, as well as recent graduates of associate's degree programs who want to continue their education.

To secure a steady stream of students, we collaborated with Pearson to develop articulation agreements with 32 community colleges nationwide that offered an associate's degree in respiratory therapy. Students had to become credentialed as registered respiratory therapists to enter the capstone phase of the program and graduate. We offered support to help students through the credentialing process, providing a home study guide to prepare for the exam and paying for the two-part exam as well.

The structure of the online program was designed to meet the scheduling needs of students, many of whom are enrolled part-time and have careers and family. Students took two consecutive 7-week courses and one fourteen-week course per semester.

To address student concerns about degree completion times and cost, we developed an accelerated curriculum, which required students to complete 50, instead of 60, credits. That way, students could complete the online program in five semesters (20 months), instead of two to four years.

Dr Shane Keene is associate dean, College of Allied Health Sciences, at the University of Cincinnati. He developed the university's accelerated 100-percent online bachelor's completion program specifically for working respiratory therapists.

Our goal was to prepare students to become managers, educators, or researchers or to enter graduate school. When developing the accelerated curriculum, we made sure the courses aligned with learning outcomes that would help students progress along their career paths.

To further increase students' employability, we ensured the program emphasized the development of written and oral communication skills. Writing in the American Psychological Association (APA) format and speaking in front of groups are two requirements for becoming a leader. What separated our program from a lot of other programs available today was the incorporation of learning the APA style into all the coursework.

Another component that made our undergraduate program unique was the emphasis on research for an undergraduate program, including an introductory research course, an advanced research course and a capstone project, designed to prepare students for graduate studies.

In the course of three years, from the spring of 2013 to the fall of 2015, the number of students in the bachelor of science program steadily rose from three to 144.

Our online program management solution not only helped the college increase enrollment in the program, it also helped to retain students. The students, for the most part, were invested. They were working professionals who realized the importance of the degree. But we were able to figure out ways to make our program work for students despite the challenges that may come up in their lives.

For example, the program has found ways to accommodate deployed members of the military. Instead of letting students drop out, we give them "incompletes" and let them start their studies when they get stateside. Working with the military was key to our program because many members of the military enroll in respiratory therapy programs.

Pearson student advisors check in regularly with students from the start of the first class until graduation, providing information, guidance and encouragement. This support allows us to be proactive before a student drops out.

Graduates have expressed satisfaction with the online program, writing letters to thank program staff and to share stories about how the program enhanced their employability. One graduate,

Brittany Jernigan, wrote, "Getting my B.S. in respiratory therapy from the University of Cincinnati was challenging, but the staff made everything outside of learning and course work easy. All of the professors are highly qualified, and I learned so much from each one."

Building on the success of our undergraduate program, we are currently in the process of developing an online master's in respiratory therapy program to meet the market's evolving needs. In the future, we hope to take the best practices for online learning used in the respiratory therapy program and apply them in other departments at the college.

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Length of Mechanical Ventilation Poses Risks

Critically ill patients who have been mechanically ventilated for more than seven days are at greatly increased risk for functional impairment and mortality at one year following discharge from the intensive care unit (ICU), according to a new study presented at the 2015 American Thoracic Society International Conference. "Prolonged mechanical ventilation has a significant impact on the long-term well-being of patients," said lead author Margaret Herridge. MD, MPH. of the University of Toronto. "In our study of nearly 400 ICU patients, we were able to identify a number of characteristics that predicted subsequent disability. Knowing these risk factors can help guide their rehabilitation needs." The study involved 391 patients who had undergone at least one week of mechanical ventilation. Median ventilation time was 16 days, mean length of stay in the ICU was 22 days, and mean length of stay in the hospital was 29 days. Assessment included the Functional Independence Measure (FIM), an indicator of disability level, along with measures of physical capacity, neuropsychological status, quality of life, healthcare utilization, and mortality. FIM score at seven days post post-ICU discharge was associated with patient age and length of stay in the ICU. The oldest patients with the longest ICU stays had the worst outcomes, with 40% of those patients aged 46-66 years with an ICU length of stay of 14 days or more dying within the first year of follow-up, 29% being readmitted to ICU, and most exhibiting severe impairments in daily activities, including bathing, dressing and climbing stairs. In contrast, patients younger than 42 years of age with an ICU length of stay of less than two weeks had the best functional outcomes. The rate of hospital readmission was high for all patients, ranging from 36% to 43% for different age and length of stay patient groups. FIM score, Charlson score (a measure of comorbidities), and age independently predicted mortality at one year. "A combination of FIM score at 7 days after ICU discharge, length of stay in the ICU, and patient age can be used to predict subsequent impairment in mechanically ventilated patients," said Dr. Herridge. "Earlier intervention based on these predictions may improve outcomes for these high-risk patients."

AR and Central Sleep Apnea Linked: Researchers

Central sleep apnea and Cheyne Stokes respiration are linked to increased odds of atrial fibrillation, particularly in men aged 76 years and older, according to a prospective cohort study from University Hospitals Case Medical Center in Cleveland, Ohio, and colleagues. The researchers prospectively followed a population cohort of 843 older men without atrial fibrillation at baseline for a mean of 6.5 years. The men underwent assessments for their apnea-hypopnea index, presence of central or obstructive sleep apnea, presence of Cheyne Stokes respiration, and proportion of sleep time with greater than 90% oxygen saturation. In calculating the men's odds of developing incident atrial fibrillation, the authors adjusted for age, race, body mass index, cardiopulmonary disease, alcohol use, pacemaker, cholesterol, cardiac medications, and apnea type (obstructive or central). Men with central sleep apnea had 2.58 greater odds of atrial fibrillation than men without it (odds ratio [OR], 2.58; 95% confidence interval, 1.18 - 5.66), and men with central sleep apnea–Cheyne Stokes respiration had a similar increased risk (OR, 2.27; 95% CI, 1.13 - 4.56; $P < .05$ for both). Men with obstructive sleep apnea or hypoxemia, however, had no increased odds of atrial fibrillation. The greater risk for atrial fibrillation among older participants may represent a multiplicative effect from advanced age and sleep-disordered breathing, the authors suggest.

COPD Outcomes Show Improvement

For patients with moderate to severe chronic obstructive pulmonary disease (COPD), the dual bronchodilator combination of tiotropium plus olodaterol improves quality of life better than either therapy alone, according to an analysis of data from the Tiotropium+Olodaterol Fixed Dose Combination (FDC) Versus Tiotropium and Olodaterol in Chronic Obstructive Pulmonary Disease (COPD) (TONADO) studies. The global assessment rate was significantly better with the combination than with monotherapy. The secondary analysis of data from the phase 3 TONADO 1 and TONADO 2 studies was presented during a late-breaking session here at CHEST 2015: American College of Chest Physicians Meeting. The subanalysis involved 3100 patients with COPD: 1033 were randomly assigned to once-daily tiotropium 5 µg, 1038 to olodaterol 5 µg, and 1029 to a combination of both drugs for 52 weeks.

Get Off Their CHEST

The treatment of central sleep apnea in heart failure patients was debated at CHEST 2015, as experts discussed whether or not to reject the use of adaptive servo ventilation in this patient population in light of recent findings from the SERVE-HF trial. In that trial, all-cause mortality was 28% higher in the ventilation group than in the placebo group, and cardiovascular mortality was 34% higher. The current recommendation from the American Academy of Sleep Medicine (AASM) is to "not start anybody on adaptive servo ventilation who would have qualified for this trial."

Risks Reduced

For infants with acute bronchiolitis, nebulized hypertonic saline (HS) can reduce the risk for hospitalization in outpatients and reduce the length of hospital stay among inpatients, a new study suggests from Federal University of Rio Grande, Brazil, and colleagues. published the results of their systematic review and meta-analysis online September 28 and in the October issue ofPediatrics. "[T]his new systematic review shows that nebulized HS is associated with a mean reduction of 0.45 days (~11 hours) in [length of stay (LOS)] among infants admitted for acute bronchiolitis and a mean reduction of 20% in the risk of hospitalization among outpatients," the authors write. "This review also suggests that nebulized HS is a safe treatment in infants with bronchiolitis, especially when administered in conjunction with a bronchodilator." Acute bronchiolitis is the most frequent lower respiratory tract infection and the leading cause of hospitalization in children younger than 2 years. It is usually caused by a viral infection, most commonly resulting from respiratory syncytial virus. ■

Analysis of Three Oscillating Positive Expiratory Pressure Devices During Simulated Breathing

Doug Pursley, MEd, RRT-ACCS, FAARC

Introduction

Previous studies reporting performance characteristics of Oscillating Positive Expiratory Pressure (OPEP) devices have gathered data using a constant flow source at various ranges of flow.[1,2] Other than the standard measured parameters of frequency and mean expiratory pressure, the parameter that seems to get the most attention is pressure amplitude. However, it is actually short bursts of increased expiratory air flow that help move secretions up the airway.[3] Just as in a forced cough, peak expiratory flow is a major factor in improving secretion clearance with OPEP devices.

Therefore the primary purpose of this study is to analyze maximum expiratory flow during OPEP therapy by comparing flow-volume loops generated by the vPEP (D R Burton Healthcare, Farmville, NC), the Aerobika (Monaghan Medical, Plattsburg, NY), and the Acapella (DHD Healthcare, Wampsville, NY) during simulated, spontaneous breathing. Frequency, mean expiratory pressure, maximum inspiratory flow, mean pressure amplitude, and mean flow amplitude were also measured. The hypothesis for this evaluation is that the three devices will produce similar values at five different volumes.

L to R: vPEP (D R Burton Healthcare), Acapella (DHD Healthcare), and Aerobika (Monaghan Medical)

Doug Pursley is affiliated with Ozarks Technical Community College, Springfield, MO; D R Burton Healthcare, Farmville, NC; and Ohio Medical, Gurnee, IL.

Method

An Ingmar Medical ASL 5000, v.3.5 (Pittsburgh, PA) was used in the data acquisition and analysis. The simulator was adjusted to mimic a two second inspiration with a two second breath hold for all measurements. Up to 5.8 seconds was allowed for expiration. Actual expiratory time varied depending on the set volume, the resistance setting, and the mechanical properties of the device.

Data was collected at five different volumes centered around an inspiratory volume of 1200 ml (400 ml, 800 ml, 1200 ml, 1600 ml, and 2000 ml). The rationale for choosing a median volume of 1200 ml is founded in a longitudinal study of 5,992 COPD patients where the mean inspiratory capacity was 2.03 liters.[4] A previous study of forty-two healthy volunteers by this author found that the average subject achieved approximately 65% of their inspiratory capacity when asked to take a deeper breath than normal during OPEP therapy.[5] Therefore, applying this value and adjusting for disease process, it seems reasonable that the average COPD patient should be able to achieve a volume of approximately 1200 ml while performing OPEP therapy. Low and high targets were arbitrarily set at 400 ml and 800 ml above and below this value to reflect a larger patient population.

The devices were placed in the horizontal position at the inlet of the simulator using 22 mm O.D. and I.D. adaptors. Measurements were taken at lowest and highest resistance settings and no measurement was taken until the volume reached a steady state (±5 ml of target). After reaching the target volume, the simulator was allowed to run an additional five minutes before recording any data. Three separate measurements were taken at each volume to get a mean value.

Frequency was measured and recorded as the total number of oscillations seen on the flow-time scalar divided by the total oscillatory time for a given breath. Maximum inspiratory and maximum expiratory flows were measured and recorded from a scrolled reading on the flow-volume loop while mean expiratory pressure was recorded as a digital reading from real time analysis on the ASL 5000. Peak-to-peak oscillatory amplitudes were measured and recorded from a scrolled reading at 25%, 50%, and 75% of expiratory volume on the flow-volume or pressure-volume loop. The values were then averaged to get a mean value. The difference between maximum expiratory flow and maximum inspiratory flow was also calculated and recorded. Statistical analysis was performed using SPSS software (Chicago, IL).

Results

Maximum Expiratory Flow

Maximum expiratory flowrates increased progressively with increases in volume in all three devices. Increasing the resistance from low to high had a negative effect on expiratory flow. In 29 of 30 data points, maximum expiratory flow decreased as resistance was increased. Charts 1 and 2 show the mean values for maximum expiratory flow at the low and high resistance settings for the three devices.

Chart 1. Maximum expiratory flow at the lowest resistance setting.

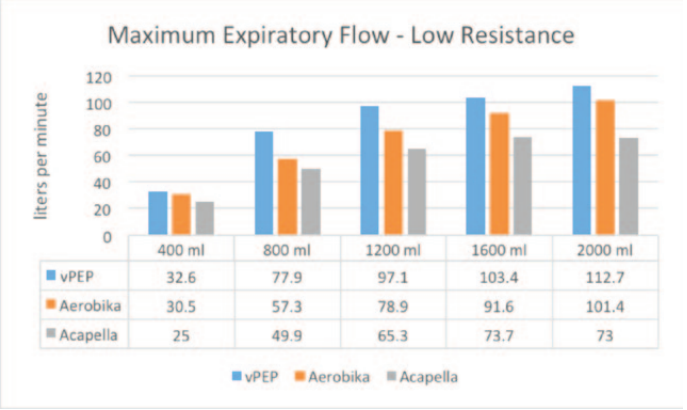
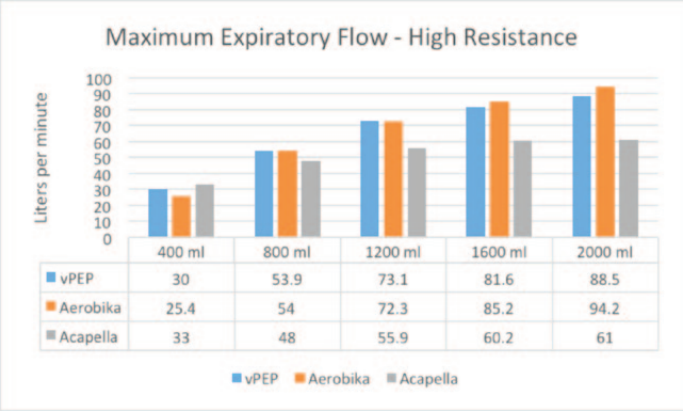


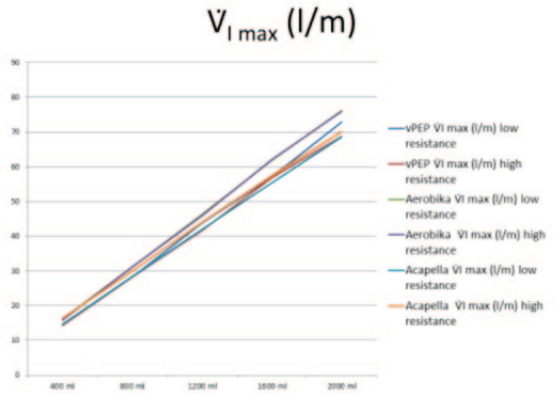
Chart 2. Maximum expiratory flow at the highest resistance setting.



Maximum Inspiratory Flow

Maximum inspiratory flows also increased progressively with increases in volume on all three devices. As one would expect, increasing the resistance had little to no effect on inspiratory flow. Chart 3 shows the maximum inspiratory flow across five inspiratory volumes for the three devices.

Chart 3. Maximum inspiratory flow at low and high resistance settings.



Statistical Analysis — Maximum Expiratory and Maximum Inspiratory Flow

Resistance had a significant effect on expiratory flow (P = < .001), but not on inspiratory flow (P = .648). There was a significant difference in expiratory flow between all three devices when compared to each other (all three P = < .001).

There was a significant difference in inspiratory flows between the vPEP and Aerobika (P = < .001) and the Acapella and Aerobika (P = <.001), however, there was no difference in inspiratory flows between the vPEP and Acapella (P = .51).

Flow vs Pressure Amplitude

Peak-to-peak flow oscillatory amplitude tended to increase progressively or increase and plateau with increases in volume. Peak-to-peak pressure oscillatory amplitude was less predictable and more consistent across the five inspiratory volumes. Charts 4, 5, and 6 compare pressure amplitude to flow amplitude when averaged for both high and low resistance readings.

Chart 4. Pressure amplitude and flow amplitude comparisons on the vPEP

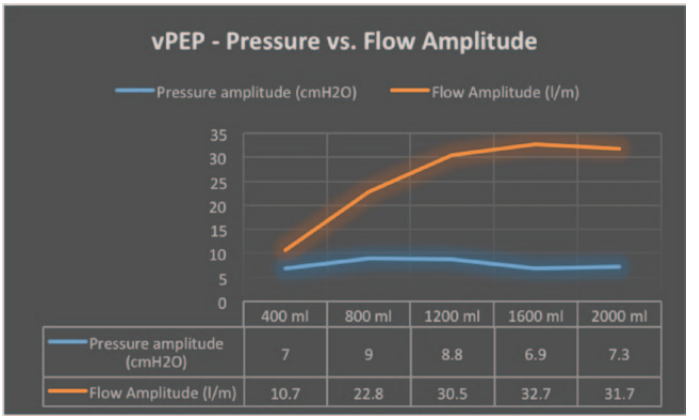


Table 1. Summary of results and standard deviations averaged across five volumes for both high and low resistance.

	V̇E max (l/m)	V̇I max (l/m)	V̇E – V̇I difference (l/m)	flow amplitude (l/m)	pressure amplitude (cmH2O)	frequency (hertz)	expiratory MAP (cmH2O)
vPEP	75.1 ± 28.3	42.6 ± 21.1	32.5 ± 13.9	25.7 ± 10.8	7.8 ± 2.1	18.3 ± 1.9	4.7 ± 2.4
Aerobika	69.1 ± 26.5	46.2 ± 22.5	22.9 ± 7.0	24.9 ± 12.0	8.8 ± 3.1	11.6 ± 2.2	4.1 ± 2.5
Acapella	54.5 ± 16.0	42.7 ± 20.1	11.8 ± 10.1	24.7 ± 7.9	7.8 ± 2.2	15.0 ± 3.7	7.0 ± 3.8

Chart 5. Pressure amplitude and flow amplitude comparisons on the Aerobika

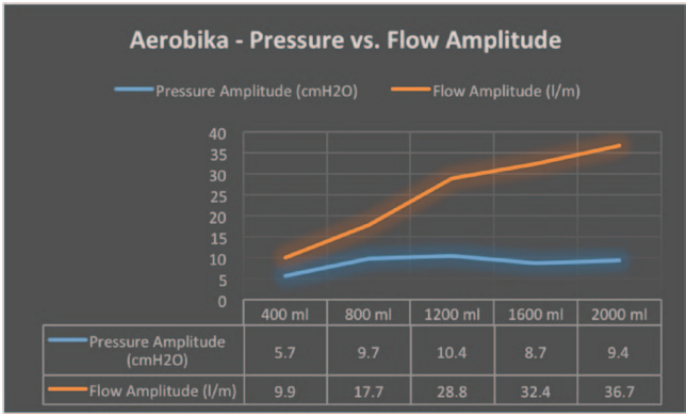
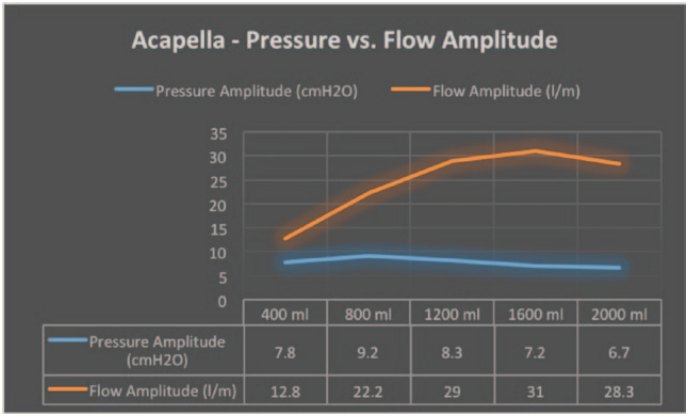


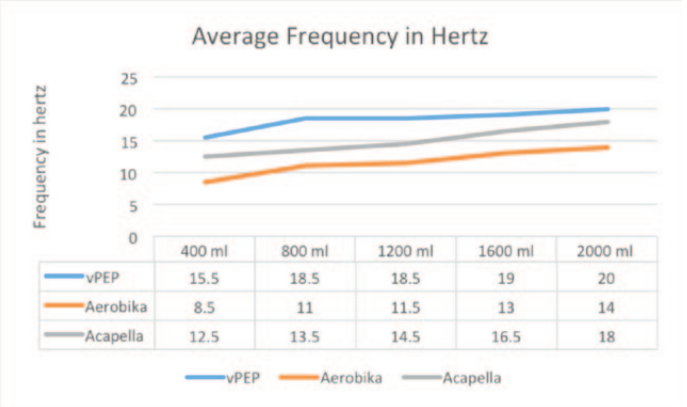
Chart 6. Pressure amplitude and flow amplitude comparisons on the Acapella



Frequency

There was a direct relationship between frequency and inspiratory volume. The higher the inspiratory volume, the higher the frequency in hertz. Changing the resistance from low to high had minimal impact on frequency for the vPEP and Aerobika but was more significant on the Acapella. When switching from low to high resistance across five inspiratory volumes, the frequency increased an average of 1.4 hz on the vPEP, 1.2 hz on the Aerobika, and 5.6 hz on the Acapella. Chart 7 shows frequency comparisons for the three devices. The values reflect an average of the high and low resistance settings.

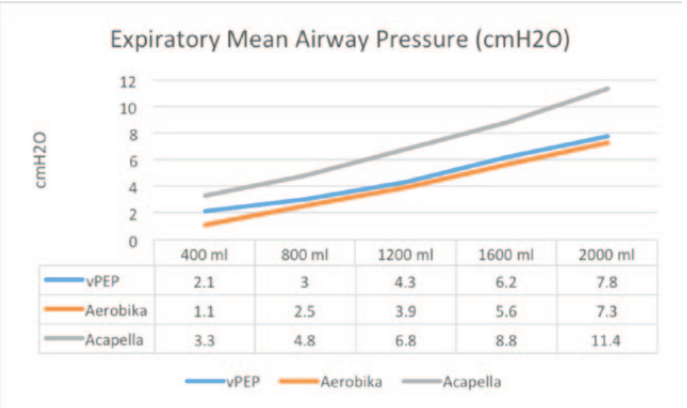
Chart 7. Average frequency in hertz for the three devices.



Expiratory Mean Airway Pressure

There was a direct relationship between expiratory mean airway pressure and inspiratory volume. The higher the inspiratory volume, the higher the expiratory mean airway pressure. This held true on both low and high resistance settings on all three devices. As one would expect, increasing the resistance increased the expiratory mean airway pressure across all five volumes on all three devices with the most profound effect seen on the Acapella. When changing the resistance setting from low to high, the expiratory mean airway pressure increased an average of 1.7 cmH2O on the vPEP, 1.7 cmH2O on the Aerobika, and 4.4 cmH2O on the Acapella. Chart 8 shows expiratory mean airway pressure for the three devices. The values reflect an average of the low and high resistance settings.

Chart 8. Expiratory mean airway pressure expressed as an average of low and high resistance settings



Discussion

Effect of Increasing Resistance

Although it is common practice to increase the resistance on an OPEP device to allow the patient to exhale longer, practitioners

should be aware of the fact that increasing resistance will decrease the maximum expiratory flowrate (Poiseuille's Law). As stated earlier, maximum expiratory flow is a major factor in determining mucous clearance.

Figures 1,2, and 3 show side-by-side flow volume loops at lowest and highest resistance settings. Note the effect of increased resistance on maximum expiratory flow in all three devices.

Figure 1. vPEP flow-volume loops at 1200 ml – low vs. high resistance

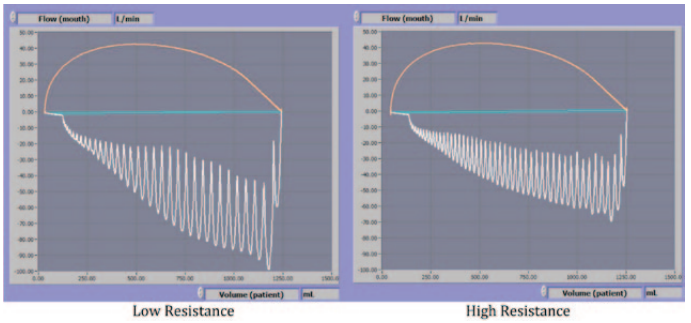


Figure 2. Aerobika flow-volume loops at 1200 ml – low vs. high resistance

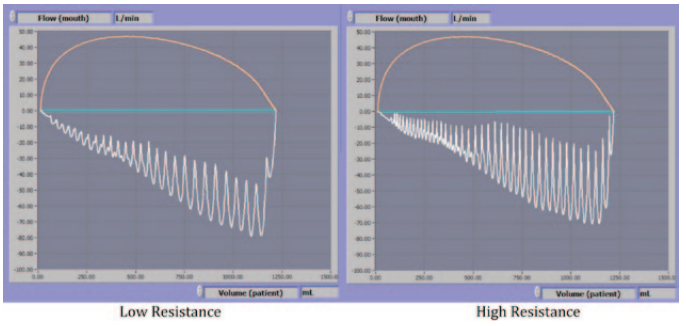
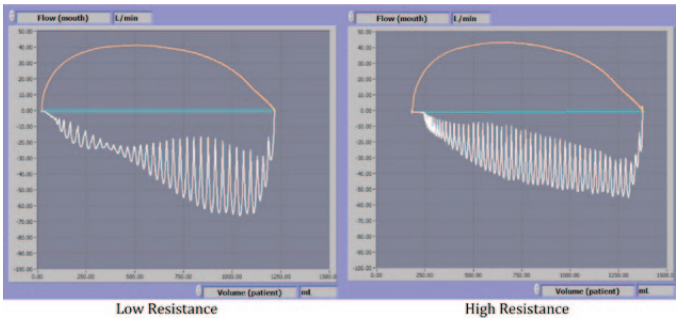


Figure 3. Acapella flow-volume loops at 1200 ml – low vs. high resistance



Oscillatory Clearance Index

Another major factor in determining mucus clearance is the ratio or difference between maximum expiratory flow and maximum inspiratory flow. That is, in order to move mucus cephalad, peak expiratory flow should be greater than peak inspiratory flow creating an expiratory flow bias.[6]

The oscillatory clearance index (OCI) was developed to find optimal airway and chest wall oscillation settings for mucus transport.[7] However, it seems reasonable to apply the same formula to OPEP therapy. The OCI states that the higher the expiratory flow, the lower the inspiratory flow, higher the frequency, and the greater the oscillatory I:E ratio, the higher the OCI.

In other words, at a given frequency and oscillatory I:E ratio, mucus clearance increases when maximum expiratory flow exceeds maximum inspiratory flow. The OCI will be zero if the oscillatory I:E ratio is 1:1 AND if the inspiratory and expiratory flows are the same. The full formula is written as:

$$OCI = f \times (T_I \div T_E) \times (\dot{V}_{E\,max} \div \dot{V}_{I\,max}) - f$$

Considering the importance of the relationship of maximum expiratory and inspiratory flowrate, the maximum expiratory — maximum inspiratory difference was calculated at the low and high resistance settings for the three devices (shown in Charts 9 and 10.)

Chart 9. Maximum expiratory — maximum inspiratory flowrate difference at the lowest resistance setting.

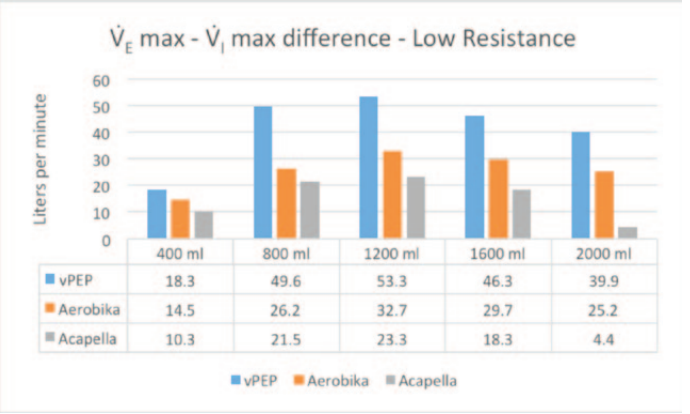
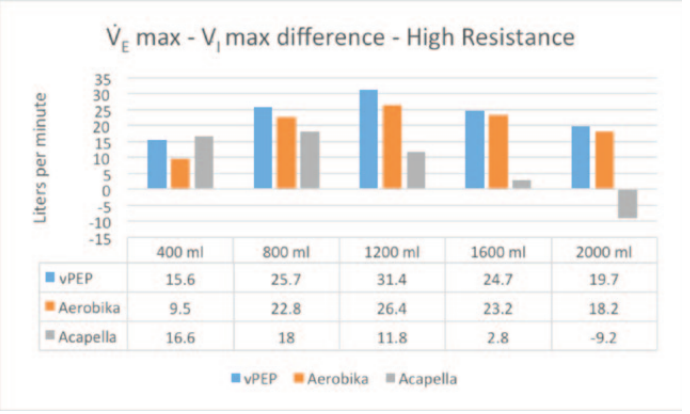


Chart 10. Maximum expiratory — maximum inspiratory flowrate difference at the highest resistance setting.



Inspiratory Time, Inspiratory Flow, and the OCI

In the study of 42 healthy volunteers mentioned earlier, the mean inspiratory time during OPEP therapy (excluding the breath hold) was 2.02 seconds ± 0.49. In spite of all subjects receiving the same instructions, the range was 1.13 – 3.52 seconds. Subjects in the lower range tended to have higher peak inspiratory flows and possibly lower V̇E max/V̇I max ratios. This could be seen in patients as well. Therefore, in order for an OPEP device to produce the highest V̇E max/V̇I max ratio possible, coaching the patient to perform a slow inspiration is of paramount importance. It is the one aspect of OPEP therapy that the practitioner can modify to result in a more therapeutic treatment and a potentially higher OCI.

Flow vs Pressure Oscillatory Amplitude

One incidental finding of the study is the lack of a direct relationship between pressure and flow when using a simulated breathing model. In all three devices, there was a steady increase in mean flow amplitude as the inspiratory volume was increased in 400 ml increments from 400 ml to 1600 ml. On the other hand, although mean pressure amplitude increased initially, it decreased from at least one previous value across the same range of volume in all three devices.

In contrast, when one evaluates an OPEP device using a constant flow source, there is a direct relationship between pressure and flow — but this is not how the device is used. Simulated breathing produces a more realistic, decelerating flow pattern during exhalation instead of the square wave flow that would be produced from testing a device using continuous flow. The fact that pressure amplitude is less predictable and non-linear in a spontaneous breathing model can be explained by the differences in flow waveforms.

Comparative Summary

When averaged across five volumes for both high and low resistance, there were similarities in flow and pressure amplitudes. However, there were differences between at least two out of the three devices for maximum inspiratory flow, maximum expiratory flow, $\dot{V}E - \dot{V}I$ difference, frequency, and expiratory mean airway pressure. The overall results followed by standard deviations are summarized in Table 1.

Conclusion

The three OPEP devices tested each employ a unique operating principle to create positive pressure oscillations. The different mechanisms, including the manner in which resistance is created, cause different outputs in terms of flow, pressure, and frequency.

The importance of expiratory flow cannot be overstated. As detailed earlier, the higher the maximum expiratory flow in relation to the maximum inspiratory flow, the greater the expiratory flow bias and presumably the greater the secretion clearance.

Oscillatory positive expiratory pressure devices are indicated to help patients mobilize secretions and promote the movement of mucus cephalad. In order to achieve this goal and assuming a steady exhalation, the oscillatory clearance index will be maximized when the practitioner adjusts the resistance on the lowest setting and instructs the patient to take the slowest inspiration possible.

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High Frequency Chest Wall Oscillation: Airflow Bias and Secretion Clearance

Jane Braverman, PhD

Abstract

High frequency chest wall oscillation (HFCWO) mobilizes pulmonary secretions principally via air-liquid interaction. During HFCWO, chest compression-induced oscillations create rapid air movement in and out of the lungs. Vibrations to the chest wall cause transient increases in airflow in the lungs that enhance gas-liquid interactions and mucus mobility. Flow bias (inspiratory vs expiratory) determines whether secretions move upstream or downstream. Maximum clearance occurs when high expiratory bias airflow velocities are generated. Laboratory and clinical studies confirm that the synchronized effects of flow bias and oscillations frequency (cycles/second) correlate strongly with significant mucus clearance. Effects were seen in both peripheral and central lung regions. Their magnitude may be measured at the mouth as mean oscillated volume. Currently, there are several commercially available HFCWO devices. Theoretically, all such devices operate upon the same principles and are assumed to provide comparable therapy. However, comparative studies to confirm this assumption are lacking. Given the critical importance of the HFCWO-induced airflow effects on the effectiveness of mucus transport, intra-device studies comparing mean oscillated volumes at the mouth are needed to better understand differences that may exist.

Pulmonary Defense

Lung health depends upon effective mechanisms to clear pulmonary secretions and inhaled debris from the airways. Larger particles are cleared from the upper airways by coughing, swallowing or other expectoration. Smaller particles are entrapped in mucus lining the lower airways and are removed by a combination of the unidirectional "escalator" effect of the mucociliary clearance (MCC) system and airflow. Effective MCC depends upon synchronistic ciliary motion and, critically, airflow moving away from peripheral lung regions and directed towards the head (cephalad).

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Airflow Bias and Secretion Clearance

Cephalad airflow bias regulates the movement of airway mucus during normal breathing.[1,2] In healthy individuals, airway diameters increase on inspiration and decrease on expiration. During normal (tidal) breathing, airway narrowing during exhalation results in increased airflow velocity and shearing forces that induce a cephalad airflow bias. This airflow bias is greatly amplified during coughing or sneezing because increased transmural pressure causes the airways to constrict.[3] Cough generates a burst of airflow creating shear stress at the air-mucus interface and resulting in accelerated mucus flow.[4,5]

Impaired Airflow and Diminished Secretion Clearance

MCC function may be impaired by several factors that arrest or delay mobilization of mucus from distal lung regions to central airways. These include 1) increased mucus production; 2) abnormal mucus rheology; 3) abnormal ciliary activity and; 4) loss of ciliated cells.[6] Most patients with acute or chronic respiratory conditions present with some degree of one or more of these anomalies. Measurements of tracheal mucus velocity (TMV) in diverse patient populations demonstrate rates markedly below that of healthy control subjects.[7-9] In acute airway diseases leading to ciliary dysfunction and/ or mucus hypersecretion, including respiratory infections or severe asthma attacks, cough is the main mechanism for clearing secretions from central airways while the role of cephalad airflow bias in mobilizing secretions from peripheral airways is increased.[3] In chronic airway diseases characterized by mucus hypersecretion, including cystic fibrosis (CF), bronchiectasis and chronic bronchitis, both cough and cephalad airflow bias are critical to airway patency.[3]

Impaired MCC and Therapeutic Interventions

Airway Clearance Therapy (ACT): When MCC is impaired, a variety of therapeutic interventions, including nebulized medications, antibiotics and ACT interventions are used to enhance secretion clearance. The goal of ACT is to prevent mucus retention which helps maintain airway patency and maximize gas exchange. Among the large array of ACT modalities in current use, theoretical foundations and mechanisms of action vary greatly.[3,10]

High Frequency Chest Wall Oscillation (HFCWO)/Chest Physiotherapy (CPT)

HFCWO technology was first developed in the 1980's as an alternative to traditional chest physiotherapy (CPT). CPT relies upon manual percussion of successive lung segments to loosen secretions from the airways alternating with postural positioning. The viscosity of mucus is such that, in the absence of effective MCC mechanisms, it resists cephalad flow.[3] High Frequency Chest Wall Oscillation devices are designed to provide expiratory bias in airflow required for effective mucus propulsion.[11,12]

HFCWO Operation and Action

HFCWO therapy is administered via a vest-like garment that generates airflow oscillations sufficient to produce cough- like shear forces which may decrease secretion viscosity.[13,14,21] These effects assist patients in mobilizing secretions from smaller to larger airways where they can be more easily removed by expectoration or coughing. On inflation, pressure is exerted on the thorax, forcing the chest wall to compress and generate a short burst of expiratory flow. Pressure pulses are superimposed on a small positive pressure baseline. On deflation, the chest wall recoils to its resting position, causing inspiratory flow. HFCWO can generate volume changes and produce 300 to 1500 staccato coughs per minute.[3,20] Repetitive cough induces significantly more mucus clearance than a single cough, and even more clearance with an increased frequency of repetitive cough or airflow oscillations.[14] HFCWO induces rapid air movement that mimics cough which enhances mucus mobility.[14]

High Frequency Chest Wall Oscillation (HFCWO)

Studies of the effects of airflow on mucus mobility and velocity have elucidated several likely mechanisms of action. Among key findings, HFCWO has been shown to: 1) generate an airflow bias that accelerates TMV and propels mucus flow from peripheral towards central airways;[12,13,15-18] 2) produce mucus-airflow interactions that may favorably reduce mucus physical characteristics including viscosity;[19,21] and 3) create shear forces at the air-mucus interface that promote mucus clearance.[12,22] HFCWO mechanisms enhance secretion clearance by mimicking the mucolytic and mucokinetic effects of normal mucocilliary clearance (MCC).

Airflow Effects

Studies in in vitro and animal models: The relationship between nonsymmetrical airflow and mucus mobilization has been evaluated over several decades by numerous research teams. They found, among other effects, that during HFCWO therapy, chest compression - induced oscillations create rapid air movement in and out of the lungs and that the magnitude of these effects may be measured at the mouth as mean oscillated volume. Increased mean oscillated volume increases mucus clearance from the peripheral and central airways in a cephalad direction.[14,22,23] HFCWO generates peak expiratory airflows sufficiently greater than peak inspiratory flows (VE/V1 > 1) resulting in mucus transport toward the airway opening. The increase in expiratory airflow bias is similar to that which occurs during a cough.[23]

Airflow Bias and Tracheal Mucus Clearance Rates

Among techniques used to measure MCC, most are based on two basic principles: 1) direct measurement of the transport rate of deposited particles in an anatomically defined airway[7,8,22,24] or; 2) measurement of the rate of elimination on inhaled aerosols from the tracheobronchial tree.[25,26] HFCWO studies have utilized both methods. Under experimental conditions, HFCWO has been shown to dramatically accelerate tracheal mucus clearance rates (TMCR).[12,13,15-18] In three studies by King, et al, HFCWO was shown, under varying conditions, to increase TMCR up to 340%, 240% and again 240% of spontaneously breathing controls.[12,15,16] Rubin et al demonstrated comparable effects.[17] The magnitude of TMCR was found to be frequency-dependent. Key studies and conclusions are cited below:

- King, et al. (1990) Found that TMCR during HFCWO 240% greater than control ($p = < 0.001$) and in line with previous results.[16]
- Chang, et al. (1988) Via an experimental model using mucus gel simulants, suggests that non-symmetrical airflow at the air-mucus interface significantly enhances mucus clearance during HFCWO.[13]
- Warwick. (1991) Using a Fleish pneumotach to measure inspiratory and expiratory airflows during HFCWO, showed that the passive staccato coughs produced result in the expulsion of generally greater volumes of air from the lungs than with forced expiration, thus supporting the hypothesis that HFCWO effectiveness relies, in part, on the 300-1500 staccato coughs produced per minute.[18]
- King, et al. (1983) Studied tracheal mucus clearance (TMC) by direct observation of the rate of displacement of a charcoal particle spot by means of a fiberoptic bronchoscope and found that mucus clearance was most pronounced in the range of 11 to 15 Hz, reaching a peak value of 340% of control at 13 Hz.[15]

Airflow Bias and Peripheral Lung Mucus Clearance

Some patients have excessively thick, sticky mucus that tends to plug the airways. In such patients, the effect of HFCWO may be stronger in the lung periphery than in the central airways, and more effective than conventional CPT at mucus clearance.[12,14,17,22] An important early four-year retrospective-prospective clinical study comparing CPT with HFCWO showed unprecedented, sustained improvement in several pulmonary function parameters using HFCWO.[27] Carbon particles and radioactive tracers permit visualization of HFCWO effects in the peripheral airways.[12,17,22] Studies of HFCWO-enhanced sputum induction demonstrate significantly higher yields of cells likely derived from peripheral lung regions (alveolar macrophages) with High Frequency Chest Wall Oscillation than without.[28,29]

- Gross, et al (1985) investigated the effect of high frequency chest compression (HFCWO) on clearance of secretions from peripheral lung regions. Technetium -99 labelled sulfur colloid aerosol generated by nebulizer was used to assess regional clearance. Overall, HFCWO enhanced both central and peripheral mucus clearance in normal dogs.[22]
- Hansen, et al (1990) Administered HFCWO for one year to a 48 year-old CF patient with Pseudomonas aeruginosa and a two-year history of declining pulmonary function test (PFT) scores. After 12 months, PFTs returned to levels measured five years before initiation of the therapy. A baseline technetium aerosol scan showed absence of ventilation in the upper lobes, but after 8 months of HFCC, a repeat test showed that ventilation was restored in these regions.[23]
- Agostinis, et al (1995) Assessed the sputum-induction efficacy of a thirty-minute treatment with high-frequency chest compression (HFCWO) combined with hypertonic saline (HS) solution and found a significantly higher percentage of cells probably derived from peripheral lung regions as suggested by a greater percentage of macrophages.[28]
- McKinnon, et al (1996) Found that inhaled nebulized water

+ high frequency chest compression (NW+ HFCWO) yielded superior sputum specimens in 52 heavy smokers compared to nebulized water alone. Specimen adequacy, determined by presence of alveolar macrophages, showed significantly greater proportions of these diagnostically important cells.[29]

Airflow Bias and Mucolytic Effects

Mucus transport can be altered by changes in the physical properties of mucus. Among those properties, viscosity, elasticity, and spinability (capacity to form threads under traction) may be affected. Reductions in mucus spinability and viscoelasticity correlate with accelerated transport. Several studies demonstrate oscillation airflow — induced mucolytic effects. These changes occur as airflow reduces cross-linkages, viscoelasticity and spinability resulting in improving mucus transport.[4,14,15,19,21]

- Tomkiewicz, et al (1994) Measured oscillatory air flow — induced rheological variables, including spinability and viscoelasticity, in mucus gel simulants. Data showed that both mucus spinability and viscoelasticity decreased significantly, suggesting that oscillating air flow may act as a physical "mucolytic," which may enhance cough clearability.[21]
- App, et al (1998) Results of this study evaluating the effects of high-frequency oscillations on the breakdown of mucus viscoelasticity in cystic fibrosis (CF) sputum samples suggest that such oscillations can break down DNA.[19]

Summary

Abundant studies demonstrate the effects of chest- compression-induced increased mucus clearance in part due to cephalad airflow bias. Currently, there are several commercially available devices marketed to deliverer HFCWO therapy. Devices vary significantly in terms of pressure and frequency settings, as well as in delivery systems and garment construction. Given the apparent importance of airflow effects on the magnitude of mucus transport, intra-device assessments comparing cephalad airflow bias are needed to understand differences that may exist.

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ARDS: Treatment or Prevention?

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Background

Acute Respiratory Distress Syndrome (ARDS) is reported to have a mortality rate of approximately 40%.[1]

The definition of ARDS has undergone several revisions based on research and a better understanding of the pathophysiology of the syndrome. In 1994, the American-European Consensus Conference (AECC) defined ARDS by establishing four key parameters which are: 1) acute onset, 2) P/F ratio of<300, 3) no demonstrable left heart failure, and 4) presence of bilateral infiltrates.[2] Then again in 2012, the Berlin definition included sub-stratifications to define the severity of ARDS; those being mild, moderate, and severe.[3]

Current Practices

It is now known that improper mechanical ventilation can exacerbate ARDS-induced lung injury leading to a secondary ventilator induced lung injury (VILI), which can significantly increase mortality. In 2000 the standard of care changed dramatically when the ARMA trial demonstrated that when limited tidal volumes to 6cc/Kg-ibw, as compared to previous tidal volume standards, there was a marked improvement of 9% in survival rates.[4] However, recent analysis suggests that the absolute size of the the tidal volume is not the mechanism driving VILI but rather it has been shown that minimizing the driving pressure is the key to reducing ARDS mortality [Amatoi MBP NEJM 2016;372]. Also we remain without a consensus regarding the methodology of defining the optimal level of PEEP necessary to maintain lung volume during expiration and prevent alveolar collapse and reopening with each breath. The current understanding of an optimal lung protective strategy necessary to minimize VILI is to open the lung and keep it open. A collaboration between Dr's Jesus Villar and Arthur Slutsky concluded that "ARDS is no longer a syndrome that must be treated, but is a syndrome that should be prevented."[5]

Airway Pressure Release Ventilation (APRV)

APRV was first described in 1987 and defined as continuous positive airway pressure (CPAP) with a brief release period while allowing the patient to spontaneously breathe throughout the respiratory cycle. APRV may be an ideal mode for the "open lung" strategy; the extended time at inspiration (ie CPAP) would continually recruit the lung, while minimal release time would prevent lung collapse during expiration. Unfortunately, the settings that constitutes a APRV breath have been inconsistently defined and significant variations in both clinical practice and laboratory experiments render any conclusions of APRV efficacy difficult. Variations in APRV strategies revolves around modifying the CPAP and release time durations; however, the most significant evolution of APRV has been the development of the ability to personalize the expiratory duration to precisely meet the needs of the patient's changing lung physiology.[6] This personalization is accomplished by analyzing the expiratory flow curve with each breath and adjusting expiratory duration accordingly [Jain S. Intensive Care Med Exp 2016;4:11]. Since the initial concepts of APRV in 1987, there has been a major paradigm shift in the way in which APRV is set. Initially, settings that determined inspiratory and expiratory termination were fixed and not adjusted to an individual patient's lung compliance. In 2005, Dr Habashi published a novel method of setting expiratory duration based on expiratory mechanics of the slope of the expiratory flow curve.[7]

In humans, Putensen et al showed that APRV with spontaneous breathing increased oxygenation, cardiac index, and pulmonary compliance with reduced sedation requirements as compared with conventional positive pressure ventilation.[8] Our understanding of ventilatorinduced lung injury is an evolution from a normal homogenously ventilated lung to that of a heterogeneously ventilated lung that is characterized by collapse and edema-filled alveoli. This heterogeneity results in stress concentrators and recurrent alveolar collapse. Thus a ventilation strategy that restores or maintains homogeneity would minimize VILI and obstruct the progression of acute lung injury.[9,10,11]

> The most significant evolution of APRV has been the development of the ability to personalize the expiratory duration to precisely meet the needs of the patient's changing lung physiology.[6]

Personalized APRV: Alveolar Stress And Strain

As mentioned earlier, the most significant evolution of APRV is the understanding to personalize the mechanical breath which recruits alveoli resulting in homogenous inflation of the lung, coupled with a brief release phase based on lung mechanics (expiratory curve of the flow-time waveform). The prevention of alveolar collapse and cyclical opening and closing of the alveoli prevents dynamic tissue strain.[12,13] Kollish-Singule et al conducted three micro-anatomic studies that demonstrated

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reduced alveolar and conducting airway micro-strain as well as increased alveolar homogeneity using a personalized APRV approach where the Tlow was set to maintain an end-expiratory flow/peak expiratory flow (EEF/PEF) ratio of 75%. Extending the EEF/PEF ratio to 10% resulted in alveolar collapse and instability.[14]

> Initiating and maintaining both invasive and non-invasive mechanical ventilation is a complex process.

Clinical Implications of APRV & Current Stat

In a meta-analysis, Andrews et al. demonstrated a tenfold decrease in the incidence of ARDS as well as a threefold decrease in mortality when compared to trauma patients with similar injuries that were treated with standard of care ventilation in fifteen trauma units.[15]

It is clear from the initial days of Dr.s Stock and Downs and current reviews that the application and principle behind APRV have evolved over nearly thirty years. Although the acronym remains as "APRV" the mechanical properties of the breath are vastly different. The "personalized APRV breath approach" appears to be an exciting and novel approach to reduce the incidence of ARDS, morbidity and mortality of established ARDS.

Controversy Remains

Despite recent animal laboratory studies and retrospective analysis of trauma sites, there is a lack of human trials that utilize a personalized APRV approach. This appropriately leads to questions which must be answered before a wide-spread change of clinical practice can be considered.

A pro-con discussion had been conducted at a Respiratory Care Journal Conference discussing the role of APRV. The authors and the panel participants did not reference many of the contemporary research works that are enumerated in this whitepaper.[16] The published pro-con discussion focused on the technical characteristics of "fixed-APRV" which as discussed can render a mechanical breath either protective or harmful based on current understandings of "personalizing" the mechanical breath. APRV can not simply be considered inverse ratio ventilation, the brief release phase (Tlow) must be set appropriately to prevent alveolar collapse. The pro/con discussion added that different manufacturer's devices operate differently; to this there is no disagreement and that understanding these differences when using APRV clinically are of paramount importance. A White Paper from the AARC and UHC Respiratory Care Network provides guidance on best practices to define competency, training, and an interdisciplinary approach necessary for patient safety and improving outcomes.[17]

Lessons Learned

The published pro/con debate also pointed out that for APRV to perform as intended and obtain the desired therapeutic goals, clinicians must set the device appropriately. However, optimal settings are critical for APRV to be lung protective and the ability to set these optimal settings vary amongst different manufacturer's devices.[16] This is very true, initiating and maintaining both invasive and non-invasive mechanical ventilation is a complex process. The licensed clinician must differentiate among various manufacturers, ventilator models, available modes, and breath types to determine which is appropriate for each individual patient.[17] The suggestion of an evidence-based protocol or management strategy is valid, as is potentially the need to have an established nomenclature.

> Generally speaking, the ventilator management of ARDS should take into consideration the patient's specific physiologic parameters with the objective of providing the greatest benefit with the least risk of complications.

More Study and Education Efforts Required

Generally speaking, the ventilator management of ARDS should take into consideration the patient's specific physiologic parameters with the objective of providing the greatest benefit with the least risk of complications. Although low tidal volume and high PEEP has led to improved outcome in ARDS, mortality remains high. To date, APRV remains a "tool in the toolbox" for clinicians. Further clinical trials will be required before it will be considered a main-stream line of treatment in the future. Promising animal studies and retrospective reviews will continue to advance our understanding of the mechanical breath profile. Additionally, clinicians must be educated in the personalized breath approach to APRV to ensure effectiveness when the clinical decision is made to utilize this mode.

Questions?

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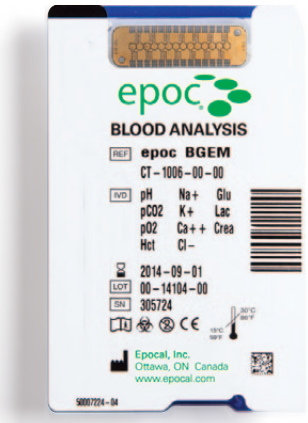

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