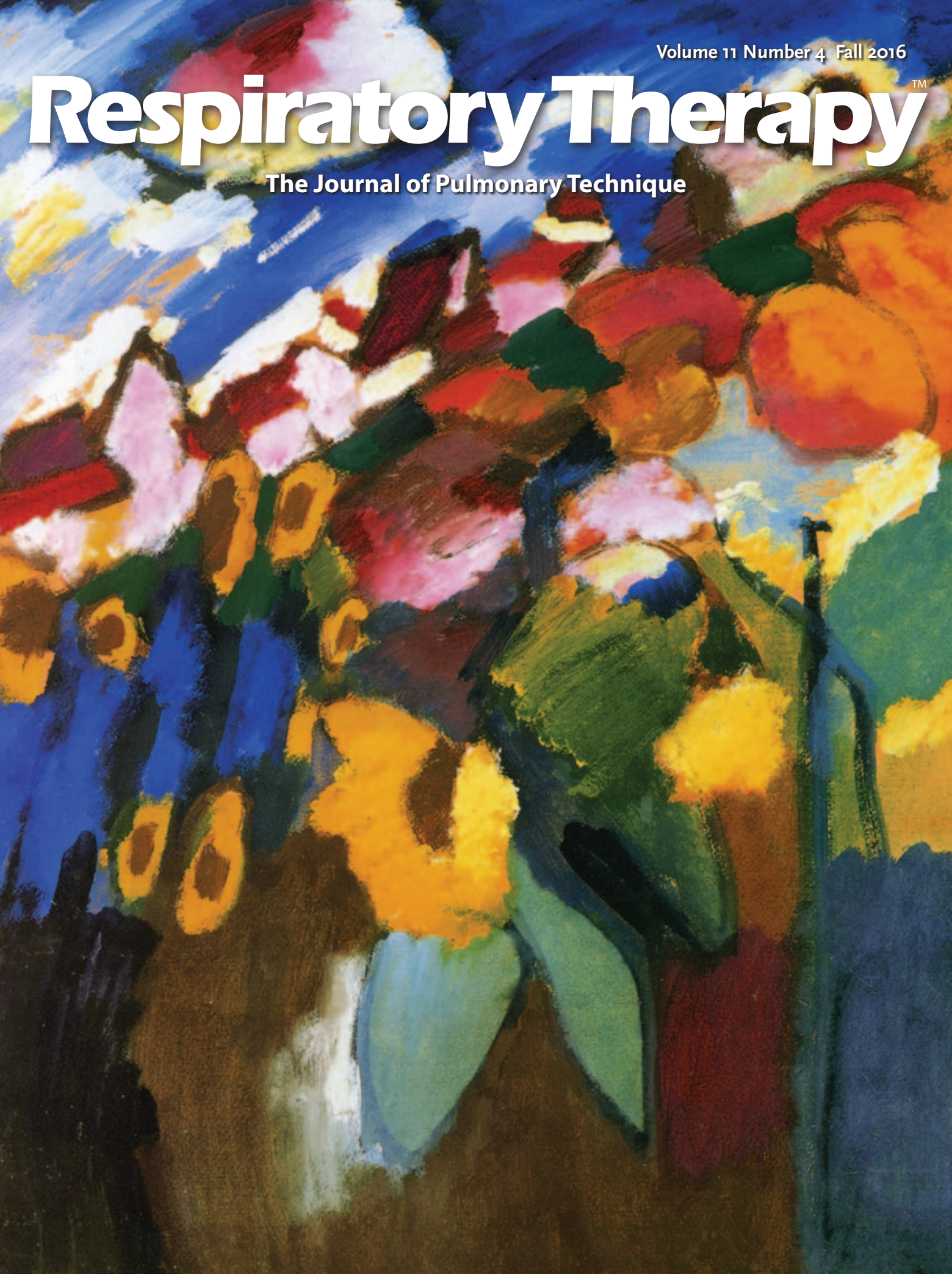
Volume 11 Number 4 Fall 2016

Respiratory Therapy™

The Journal of Pulmonary Technique



AcuCare™ HFNC
High flow nasal cannula

Speed, Stability and Success in HFOT

Ensure success in high flow oxygen therapy with the AcuCare™ high flow nasal cannula (HFNC) by ResMed. The AcuCare HFNC is fast and intuitive to fit, engineered to stay in place and designed to be soft and comfortable on the patient's skin.

- Fits in seconds. The intuitive AcuCare HFNC draws on technology used in ResMed's premium patient interfaces.
- Stays in place. The advanced headgear-to-frame combination is engineered to create a stable platform suiting a wide range of facial profiles.
- Built-in success. With innovation built into ResMed's AcuCare HFNC, you can simply fit it and trust it to provide quality care to your patients.

CareFusion

Distributed by CareFusion, booth #1012

ResMed

Learn more at ResMed booth #923

MICROSTREAM™ CAPNOGRAPHY MATTERS.

FROM NEONATE TO ADULT, YOUR PATIENTS COUNT ON YOU.

Microstream capnography monitoring helps you detect subtle, but clinically significant variations in your patient's breathing. This means if your patient shows signs of respiratory compromise, you can respond faster and provide earlier intervention.

- Intubated and non-intubated CO_2 continuous monitoring
- 50ml/min sample size for measurement of CO_2 partial pressure
- CO_2-specific algorithm for enhanced accuracy
- Ability to accurately detect up to 150bpm for CO_2 qualified respiration rate
- Smart alarm management technology

Visit our website to learn more about respiratory compromise:

www.covidien.com/rms/clinical-solutions/respiratory-compromise

Medtronic
Further, Together

Respiratory Therapy
The Journal of Pulmonary Technique

ISSN 2152-355X
Published six times each year by
Goldstein and Associates, Inc.
10940 Wilshire Blvd., Suite 600
Los Angeles, CA 90024 USA
Tel: 310-443-4109 · Fax: 310-443-4110
E-mail: s.gold4@verizon.net
Website: www.respiratorytherapy.ca

Publisher/Editor in Chief
Steve Goldstein
Managing Editor Christopher Hiscox
Senior Editor Chris Campbell
News Editor Vincent Terrier
Associate Editor Jordana Hammeke
Associate Editor Susan Goldstein
Assistant Editor Laszlo Sandor

Circulation, Coverage, Advertising Rates: Complete details regarding circulation, coverage, advertising rates, space sizes, and similar information are available to prospective advertisers. Closing date is 45 days preceding date of issue.

Change of Address: Notices should be sent promptly to Circulation Department. Provide old mailing label as well as new address. Allow two months for change.

Editorial Contributions will be handled with reasonable care. However, publishers assume no responsibility for the safety of artwork, photographs or manuscripts. All submissions may be emailed to s.gold4@verizon.net. Every precaution is taken to ensure accuracy, but the publishers cannot accept responsibility for the correctness or accuracy of information supplied herein or for any opinion expressed. Editorial closing date is the first day of the month preceding month of issue.

Editorial Advisory Board

Spot the Toby Tracheasaurus™

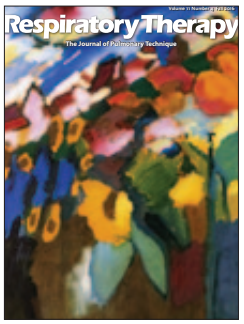
Thanks to the Passy Muir® Valve, Hazel cannot only pose like her favorite furry friend, she can roar like a dinosaur too.

To find out how the Passy Muir Valve can help restore your patient's voice, enhance swallowing and reduce aspiration, or to find out more about the Passy Muir Toby program, visit

www.passy-muir.com

Passy Muir®
Millions of Voices, ONE VALVE™

Now Available: 2 New Adapters from Passy Muir
Visit www.passy-muir/adapters for more information



Respiratory Therapy™
The Journal of Pulmonary Technique

Vol. 11 No. 4
Fall 2016

Table of Contents

DEPARTMENTS

ARTICLES

News

■ Fall 2016

Addendum to Capnography: A Screening Tool for Sepsis?

Greg Spratt BS, RRT, CPFT – Director of Clinical Marketing – Medtronic Patient Monitoring

In follow up to the article "Capnography: A Screening Tool for Sepsis?" which appeared in the Winter 2016 issue of Respiratory Therapy, Hunter et al recently published another article seeking to answer this question in the prehospital environment.[1] In a prospective cohort study, researchers sought to determine the utility of a prehospital sepsis screening protocol utilizing systemic inflammatory response syndrome (SIRS) criteria and end-tidal carbon dioxide ($etCO_2$). Sepsis alerts (Table 1) were activated by EMS for a 12-month period after the initiation of a sepsis protocol.

Table 1. Sepsis Alert was instituted for patients meeting the following 3 criteria:

1. Suspected infection AND
2. $etCO_2 \leq 25$ mmHg AND
3. Two or more of the following:
   a. Temperature > 38°C (100.4°F) OR < 36°C (96.8°F)
   b. Respiratory Rate > 20 breaths/min
   c. Heart Rate > 90 beats/min

The purpose of a Sepsis Alert is to provide pre-arrival Emergency Department notification in order to facilitate rapid identification and intervention in suspected sepsis patients as this has been shown to improve outcomes and mortality in these patients.[2,3]

By comparison of ROC curves, $etCO_2$ had a higher discriminatory power to predict sepsis, severe sepsis, and mortality than the other variables collected in the study.[i] When all patients were considered, the area under the ROC curve predicting sepsis was 0.99 for $etCO_2$. Low $etCO_2$ correlated with elevated lactate levels and predicted sepsis, severe sepsis, and mortality, suggesting that it serves as a rapid, continuous objective measure for hypoperfusion.

References

1 Hunter CL, Silvestri S, Ralls G, Stone A, Walker A, Papa L. A prehospital screening tool utilizing end-tidal carbon dioxide predicts sepsis and severe sepsis. Am J Emerg Med (2016), http://dx.doi.org/10.1016/j.ajem.2016.01.017
2 Levy MM, Dellinger RP, Townsend SR, et al; Surviving Sepsis Campaign: The Surviving Sepsis Campaign: Results of an international guideline-based performance improvement program targeting severe sepsis. Crit Care Med 2010; 38:367–374
3 Jones AE, Shapiro NI, Trzeciak S, et al; Emergency Medicine Shock Research Network (EMShockNet) investigators: Lactate clearance vs central venous oxygen saturation as goals of early sepsis therapy: A randomized clinical trial. JAMA 2010; 303:739–746.

A **NEW** Direction for **Subglottic Secretion** Management

The ***SIMEX*** Subglottic Aspiration System, available as ***cuff*** M and ***cuff*** S, is the most advanced solution for the aspiration of subglottic secretions, and features the all new, state of the art, ***automated intermittent*** mode of therapy.

- Automated and fully customizable
- Significant increases in volumes of secretions collected
- Reduced need for bronchial aspiration
- Reduced risk of injury to the tracheal mucosa
- More RT control over the aspiration procedure
- Increased patient comfort/virtually silent operation
- Self-contained system prevents cross contamination

"Using syringe or other conventional suction sources for SSD proved impractical and ineffective in our institution. An 8-month trial of 10 patients using the SIMEX automated subglottic aspiration system resulted in significant increases in volumes of secretions collected, significant decreases in maceration and soiling, and there were no incidents of VAE or VAC."

Jerry Gentile, BSRT, BSHA, MBA, EdD(c), RT, RRT
Partner, Severa Health, LLC
Director of Respiratory Care Services
Eastchester Rehabilitation & Healthcare Center
Bronx, New York

The SIMEX *cuff* M and *cuff* S are the only suction pumps designed and indicated for intermittent aspiration of subglottic secretions.

Patent Pending

FloSure™
www.flosuretechnologies.com

For more information contact us at: info@flosuretechnologies.com, or 914-909-6577

Visit us at AARC booth #1206 in San Antonio!

SF-436-02/16

Symposium Planned on Nasal High Flow

A Clinical Breakfast Symposium is being organized for the AARC congress on Optiflow Nasal High Flow Across the care continuum. The event is on October 15 from 6:30 to 8:15 am At the Grand Hyatt Hotel in San Antonio, Texas. The presenter is Prof Jean-Damien Ricard, Universitie Paris Diderot, and Hopitaux de Paris, and Dr Gonzalo Hernandez, from the Hospital Virgen de la Salud in Madrid, Spain. At the end of the session, people will be able to identify the current evidence for Nasal High Flow therapy, including mechanisms of action, evaluate the emerging and clinically significant applications for NHF therapy, and discuss the evidence regarding the use of NHF. CRCE credits will be available. For more details, contact your Fisher & Paykel Healthcare rep. Call (800) 446-3908 or email nasalhighflowevents@fphcare.com.

Dräger Donates Ventilators to Respiratory Therapy Schools

Dräger announced that it donated four Savina 300 ventilators to US respiratory therapy schools during the American Association for Respiratory Care (AARC) Summer Forum. Providing the latest mechanical ventilation technology, Dräger is helping to foster a greater learning experience for respiratory therapy (RT) students — professionals critical to the future of healthcare. Hospitals face enormous challenges attracting qualified RTs to meet the increasing demands of an aging population and an evolving healthcare marketplace. Institutions of higher learning that offer respiratory-care education are on the frontlines of training the next generation of dedicated respiratory professionals. Training on modern-day mechanical ventilators within a simulated lab setting is essential to ensuring RT graduates are prepared to enter the workforce. RT students at Florida State College, SUNY-Sullivan County, Seward County Community College and University of Texas-San Antonio can now train on modern Dräger Savina 300 ventilators. Around the world, Savina ventilators have logged more than 400 million hours of therapy time, setting the standard for industry quality and reliability. "As a corporate partner of AARC, and a company dedicated to life-saving technologies, Dräger takes pride in its corporate and social responsibilities," said Ed Coombs, MA, RRT-NPS, ACCS, FAARC, Director of Marketing for Intensive Care at Dräger. "By providing leading innovations in respiratory care to the next generation of RT professionals, we hope to play a part in improving patient outcomes while maintaining cost effectiveness."

New Instrumentation System Released

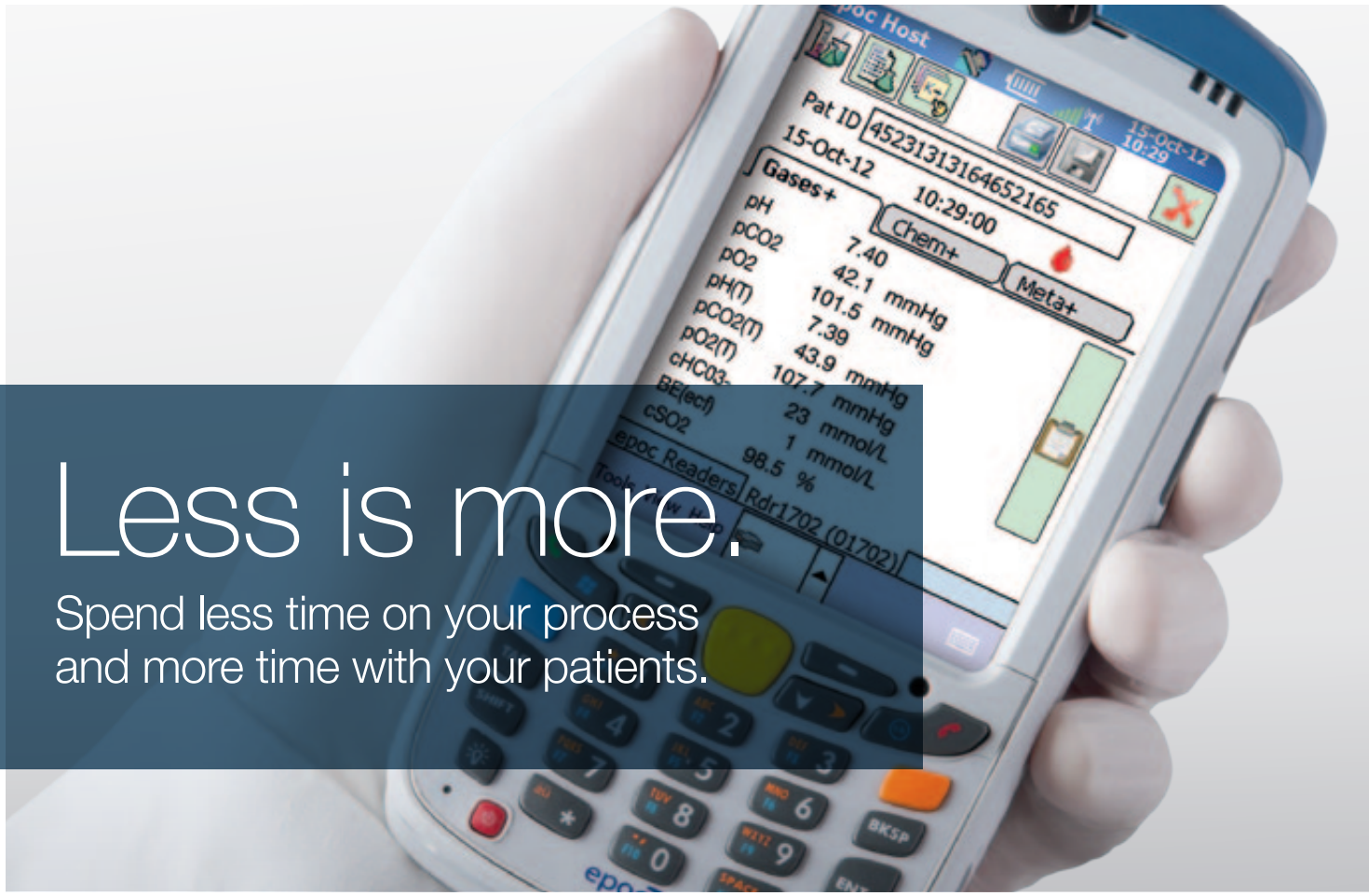
The Hans Rudolph, Inc SmartLab Instrumentation System with Insight Software is a flexible system for measurement and analysis of respiratory signals in research applications. The base module can accept up to four sensor modules for measuring flow from pneumotachs and airway or other pressures or a voltage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

Mercury Medical Expands Team

Mercury Enterprises has announced that John Gargaro MD has joined the Corporate Board of Directors and Douglas Smith has joined the company as Vice President of Sales and Marketing. Dr Gargaro is currently a board certified orthopedic surgeon and graduate of Harvard University and the University of Michigan Medical School. He is currently Chief of the Department of Orthopedic Surgery at Kaiser Permanente Colorado, former Chairman of the Department of Orthopedic Surgery and former Treasurer of the Medical staff at St Joseph Hospital, Denver, CO. Industry experience includes consulting positions with Wright Medical and Johnson & Johnson/DePuy, as well as clinical research and speaker panel positions for Sanofi-Synthelabo Inc. and Organon Labs. Douglas Smith's background includes 20+ years of sales and marketing experience with GE Healthcare, Dräger, Maquet Medical Systems USA and Siemens Medical Solutions USA, Inc. Mercury Medical, a veteran-owned medical products manufacturing and marketing organization, focused on airway management and anesthesia, is recognized by the industry as a leading provider of innovative airway management devices.

World's First Connected Airway Clearance System

Hill-Rom Holdings, Inc., a leading global medical technology company, announced the introduction of the VisiVest System, a connected therapeutic solution for patients in need of airway clearance therapy. The world's first solution combining industry-leading high-frequency chest-wall oscillation (HFCWO) technology with wireless connectivity powered by Qualcomm Life, Inc, a subsidiary of Qualcomm Incorporated, the VisiVest System provides therapy adherence data that may help inform decisions caregivers make for their patients, resulting in reduced risk of respiratory infections, hospitalizations, and medical costs. Patients' usage data from the VisiVest System is remotely and securely transmitted to the VisiView Health Portal via Qualcomm Life's 2net Hub enabling highly secure, medical-grade connectivity and effortless user experience. The VisiView Health Portal, developed by Razorfish, a leading application development company, then displays data trends in an easy-to-use dashboard format. This connectivity fosters a closer partnership between patients and health care teams, so treatment decisions by caregivers can be more tailored and responsive, which may result in better therapy adherence. "In healthcare, the ability to make decisions based on accurate, timely information is essential," said Alton Shader, president, Front Line Care at Hill-Rom. "The VisiVest System and Qualcomm Life's 2net connectivity solution bring care teams and patients closer, helping to better manage patients' illness and improve their quality of life." In a pilot study conducted over the past few months, 160 patients from seven cystic fibrosis clinics have adopted The VisiVest System. Patients and care teams have responded with great enthusiasm and excitement for the technology. "What I like most about the VisiVest System is being able to see my patients' session data and trends," said Tom Newton, pulmonary therapist, Miller Children's Hospital, Long Beach, CA. "Now I'm not just telling my patients the more adherent they are to their therapy, the higher their pulmonary function numbers are likely to be. We can actually look at their adherence score together and have a more comprehensive conversation about their numbers." Connected health solutions will continue to strengthen Hill-Rom's leadership role in the respiratory care industry. Hill-Rom's VisiVest garment provides airway clearance by inflating and deflating rapidly, applying gentle pressure to the chest wall. This works to loosen and dislodge mucus from the bronchial walls and move it to larger airways where it can be cleared by coughing or suctioning. If not removed, retained secretions may contribute to increased rates of respiratory infection, hospitalization and reduced lung function.

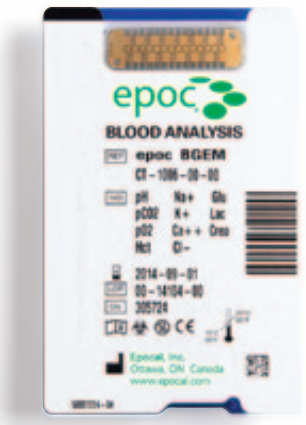


Less is more.

Spend less time on your process and more time with your patients.

You have a department to run with a staff that needs to concentrate on patient care. The epoc® System is the tool to help you improve your blood gas and electrolyte testing process. With features such as positive patient identification, wireless communication and SmartCard technology, your staff can do everything they need to do standing at the patient's side.

To see how "Less is more," contact your Alere representative for a demonstration and a discussion about how the epoc® System can improve your process. 1.877.441.7440 or visit alere-epoc.com.



epoc® BGEM Test Card

Visit us at AARC booth #803 in San Antonio!

Alere™ Knowing now matters.™

Smart Wireless Finger Pulse Oximeter Unveiled

Nonin Medical, Inc, the inventor of finger pulse oximetry and a leader in noninvasive medical monitoring, today announced it has globally launched the NoninConnect Elite Model 3240 Bluetooth Smart wireless finger pulse oximeter for clinicians and their patients. The NoninConnect Elite measures arterial blood oxygen saturation and pulse rate and features Nonin's clinically proven PureSAT pulse oximetry technology. The device is designed to help clinicians and their patients with challenging respiratory conditions like COPD to proactively identify issues for early intervention and avoid re-hospitalization. (An oximeter prescription is required for patients in the US) "Making the right decision for patients who have COPD and complicating co-morbidities such as CHF often depends on getting an accurate oxygen saturation reading," said Rick Eagle, vice president of sales for Nonin Medical. "We've known for some time that not all FDA-cleared pulse oximeters perform alike on all patients," he added. "However, a new independent hypoxia lab study on humans, which simulated COPD patient conditions, demonstrates that Nonin's PureSAT pulse oximetry technology captures and reports worsening patient conditions better than other FDA-cleared oximeter brands," Eagle said. "These findings are significant for clinicians who want a pulse oximeter that is going to be accurate, reliable and cost effective for all patients, including very sick patients like those with COPD," Eagle said. The NoninConnect Elite uses state-of-the-art Bluetooth Smart (low energy) wireless technology to allow clinicians to remotely (up to 10m/32 ft) view their patients' SpO_2 readings in real time. Clinicians and patients can easily save or share their SpO_2 history via e-mail, using the NoninConnect iOS mobile app on their compatible Apple device. Patients are able to share spot-check readings via Apple's Health app. Compatible devices with the NoninConnect Elite and NoninConnect app include: iPhone 4S and newer, iPad 3 and newer, all iPad Air and iPad Minis, and the iPod Touch 5th edition and newer (with Apple iOS 8.1 or newer installed). Provides SpO_2 and pulse rate readings from small to large fingers, good to poor perfusion and dark to light skin tones. Provides simplified pairing for vital information exchange over a secure wireless connection. Long battery life: Up to 2,200 spot checks on two AAA batteries

Life Support Ventilators Get Clearance

ResMed announced US Food and Drug Administration (FDA) clearance of the iVAPS (intelligent Volume-Assured Pressure Support) therapy mode for its Astral life support ventilators. ResMed's award-winning, cloud-connected Astral ventilators are used for a range of respiratory conditions including chronic obstructive pulmonary disease (COPD), neuromuscular disease and restrictive thoracic disorder. iVAPS intelligently and automatically adapts to patients' changing needs by constantly monitoring their actual ventilation and respiratory rate in relation to their target ventilation and respiratory rate, and automatically adjusting pressure support as needed to accommodate each patient's unique needs, even as their disease progresses. "The iVAPS therapy mode has been one of the most requested enhancements to the platform," said Luke Maguire, president of ResMed's Cardio-Respiratory Care Global Business Unit. "Its introduction dramatically increases Astral's capabilities and gives pulmonologists, home medical equipment (HME) providers and others more flexibility." iVAPS is one of two key technologies within ResMed's IntelligentAir suite in the United States. The other is Intelligent Backup Rate (iBR), which provides backup breaths only when needed to give patients a chance to spontaneously trigger the ventilator.

New Study on Pulse Oximetry

Nonin Medical, Inc, has announced the results of a new independent hypoxia lab study in humans that demonstrates that Nonin's PureSAT pulse oximetry technology captures and reports worsening patient conditions better than other Food and Drug Administration (FDA)-cleared oximeter brands. Nonin made the results available in a white paper at the American Thoracic Society (ATS) and American Telemedicine Association (ATA) conferences. In the study, conducted independently by Clinimark Laboratories in Boulder, Colo., three finger pulse oximeters were tested; one from Nonin Medical and two from large, private-labeled manufacturers. All oximeters had FDA 510(k) clearance as "medical devices," but two of them did not provide the clinical accuracy required to track desaturations in patients with low blood circulation and labored breathing. Only the Nonin Medical oximeter was able to accurately track the desaturation events as compared to an independent hospital tabletop oximeter control device. "Over the years, a number of inexpensive, imported FDA-cleared oximeters have flooded the market, all claiming to be accurate," said Jim Russell, vice president of quality, regulatory and clinical affairs for Nonin Medical. "This study dispels the myth that all pulse oximeters perform alike, especially on challenging patients such as those with chronic obstructive pulmonary disease (COPD)."

Respected Educator Joins Passy Muir

Passy-Muir, Inc, the industry leader in tracheostomy education and manufacturer of the patented no-leak Passy-Muir Valve is honored to announce the appointment of Kristin King, PhD, CCC-SLP to the position of Vice President of Clinical Education & Research. Dr King comes to Passy Muir from the University of Tennessee Knoxville, where she was professor of Audiology and Speech Pathology. Her expertise is in cognitive-communication and swallowing disorders with medically complex patients of all ages, particularly those with needs secondary to traumatic brain injury (TBI), tracheostomy/ventilator, and pre-term birth. She has trained SLPs in FEES and VFSS and developed a program for SLPs in the management of patients on ventilators and the use of Passy-Muir Valves at a level-one trauma hospital. Dr King has published several peer-reviewed articles regarding evaluation and treatment of TBI, and regularly speaks to domestic and international audiences on the benefits and use of speaking valves, evaluation and treatment following TBI, and swallowing disorders. Dr King earned her PhD in Communication Sciences and Disorders from East Carolina University in 2008, and brings extensive experience as a college professor, published clinical researcher, and international speaker to her new position at Passy Muir. As a part of her responsibilities, Dr King will Chair Passy Muir's Centers of Excellence program, will act as Editor in Chief for Talk-Muir, will coordinate product related research, and work with the company's clinical education team to design and develop instructional programs and materials.

BD, Apax Partners to Form Joint Venture

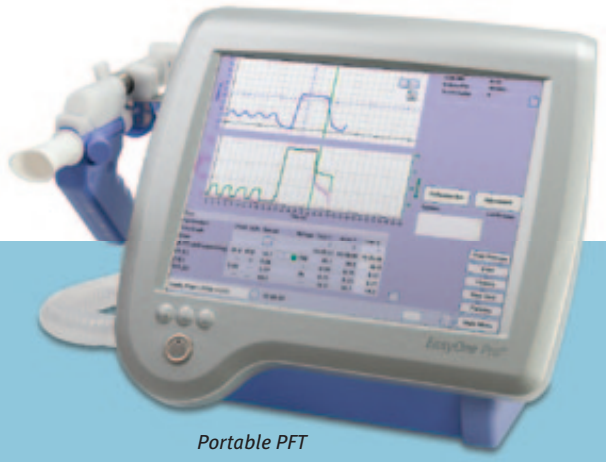
BD (Becton, Dickinson and Company), a leading global medical technology company, today announced a definitive agreement to sell 50.1 percent of its Respiratory Solutions business to funds advised by Apax Partners, a leading global private equity firm, and form a joint venture that will operate as a new, independent company. The new company will include all business lines within BD's Respiratory Solutions business including Ventilation, Respiratory Diagnostics, Vital Signs and AirLife, and have estimated annual revenue of approximately $900 million. BD's Respiratory Solutions facilities will transfer to the new company,

How are You Managing COPD? Your Choice is an EasyOne®

ndd products are easy-to-use, accurate and reliable for testing anytime, anywhere. With the EasyOne Pro, spirometry, DLCO and lung volumes can be obtained in just 20 minutes. Automatic calibration, outstanding worldwide service along with a maintenance free design makes your choice for lung function an EasyOne.

Office spirometry

PC spirometry



Portable PFT

For more information go to www.nddmed.com

including locations in Yorba Linda, Calif.; Palm Springs, Calif.; Plymouth, Minn.; Mexicali, Mexico; Cotia, Brazil; Hoechberg, Germany and Shenzen, China. The new company will employ more than 5,000 associates around the world. BD will retain 49.9 percent of the company as a significant but non-controlling minority owner. "We have been proactively targeting the industry for respiratory devices and have been impressed with the continued progress the company has made over the past few years," said Steven Dyson, partner at Apax Partners. "We are pleased to have the opportunity to work with the entire team in further developing Respiratory Solutions' position as a focused and leading global player. In order to take advantage of this opportunity, we are highly supportive of an investment program to further strengthen the business's existing platform, both organically and through acquisitions." The transaction values the entire business today at nearly $500 million. The structure of the transaction reflects the completion of a thorough strategic review process and BD's determination that the business is non-core to its long-term strategy. By maintaining a significant but non-controlling minority ownership position, BD intends to maximize value by participating in future earnings and the anticipated appreciation in valuation. The transaction is expected to close in late fiscal year 2016 or early fiscal year 2017. Due to the proximity to the end of its fiscal year 2016, BD expects an immaterial impact to its fiscal year 2016 guidance. BD plans to use net proceeds for share repurchases, subject to market conditions. In fiscal year 2017, due to the limited profitability of the business today, BD anticipates earnings dilution of approximately $0.10 to $0.14. The company expects to record a material tax loss on the transaction at the time of closing. The completion of the transaction is subject to pending regulatory approval, consultations with employee representative bodies in Europe and customary closing conditions.

Japanese Approval Put in Motion

Respiratory Motion, Inc, in conjunction with their exclusive distribution partner, IMI Co, Ltd, Japan, received Japanese regulatory approval for their new ExSpiron 1Xi Minute Ventilation Monitor. Respiratory Motion, Inc. developer of ExSpiron, is the only patient monitor measuring non-invasive Minute Ventilation, critical for early identification of potentially life-threatening respiratory depression. Respiratory Motion's ExSpiron 1Xi was launched by IMI Co, Ltd at the Japanese Society of Intensive Care Medicine at the February 11th – 14th conference. The Japanese Society of Intensive Care Medicine (JSICM) was founded in 1974. Physicians joining the JSICM have specialized in intensive care with past experiences as anesthesiologists, emergency physicians, cardiologists, and pediatricians. The ExSpiron patient monitor provides non-invasive monitoring for Minute Ventilation, Tidal Volume and Respiratory Rate. Knowing a patient's minute ventilation, how much air they breath in one-minute, is essential to knowing their respiratory status. ExSpiron is the ONLY respiratory device to provide this comprehensive information for non-intubated patients enabling a more complete and quantifiable patient assessment throughout the care continuum. ExSpiron technology was first introduced to the Japanese market in 2015 in lectures given at several conferences by prominent physicians. Clinical research presented at JSICM overwhelmingly confirms that current respiratory monitoring using Respiratory Rate or $EtCO_2$ is insufficient with potentially over 80% of Respiratory Depression events going undetected. Highlights of some of these six significant presentation include: "Risk Stratification Using a Respiratory Volume Monitor" Late detection of respiratory depression (RD) in non-intubated patients compromises patients safety. Respiratory Volume Monitoring (RVM) can detect patients at risk for opioid-induced RD and/or experiencing post-operative apnea. "Ventilation is a Better Assessment of Respiratory Status than $EtCO_2$" $EtCO_2$ measurements in non-intubated patients are unreliable so clinicians resort to using the respiratory rate (RR) measurements from the capnograph. Normal $EtCO_2$ coincided with adequate RR just 24.9% of the time. Data demonstrated that relying on capnography to capture the respiratory status in non-intubated patients is lacking. "Respiratory Rate is a Poor Assessment of Respiratory Status During and After Upper Endoscopy Procedures." Despite the use of capnography monitoring, incidence of low MV during routine endoscopic procedures was significant. Over 80% of all low MV episodes would not have triggered a low RR alarm. Conventional RR monitoring alone would fail to capture more than 80% of all low MV episodes. "Assessing Ventilation in Patients Receiving Opioids" Monitoring respiratory rates as low as 6 breadths/min would still miss nearly 90% of Low MV episodes. "Identifying Patients at Risk for Respiratory Depression" RVM can identify and quantify respiratory compromise in the PACU, ICU, or GHF. • "Respiratory Volume Monitoring Reduces False Alarms". Respiratory depression poses a significant threat to the safety of patients in Japan, where aging population and economic pressures have pushed hospital systems to embrace novel technology to eliminate preventable adverse events and contain cost. As in the United States, health care providers in Japan seek ways to identify patient risk before it becomes life-threatening. Repeated studies show the ExSpiron Patient Monitor is more effective than other technologies for identifying subtle changes in respiration that foreshadow life-threatening respiratory depression.

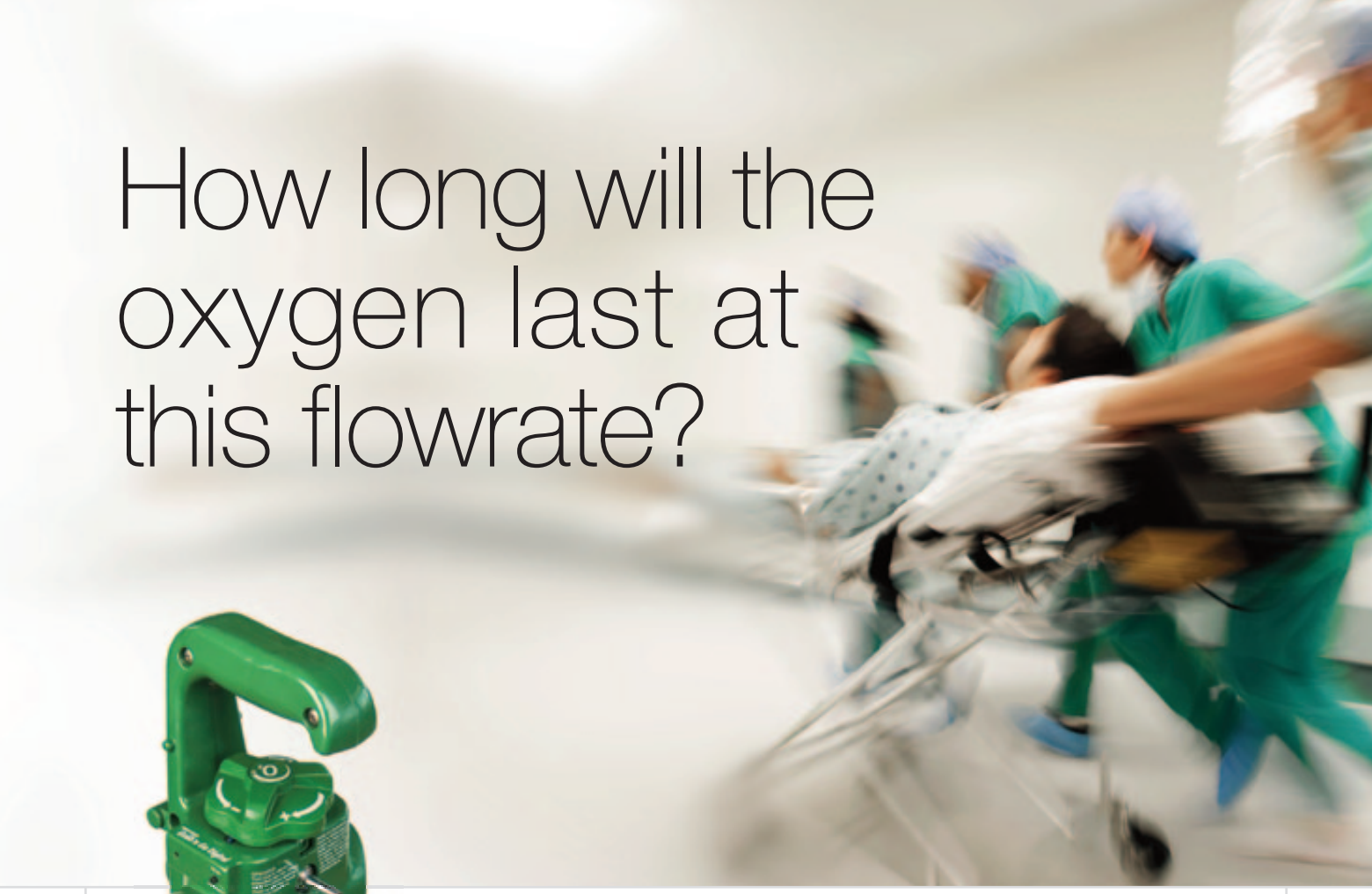
Spirometer Interface Announced

nSpire Health Inc and Meditab Software Inc have announced a new standardized HL7 interface providing pre-configured interoperability between AllergyEHR electronic health record and KoKo spirometers. This flexible solution interface offers many advantages to AllergyEHR and KoKo users. A spirometry order is created from the IMS Visit. The order with full patient demographics is available from any KoKo testing station. All of the available KoKo spirometry tests can be performed, including FVC pre- and post-bronchodilator, challenge, and SVC testing. Test results are automatically returned to the IMS Visit Note with a formatted text report, configurable PDF graphical report, and interpretation notes. "In the Allergy, Asthma, and Immunology specialty, AllergyEHR has been rated the #1 EHR vendor by Black Book year after year. Partnering with KoKo enables us to keep delivering innovative solutions to our clients to meet the demanding and changing needs of their medical practice," says Manish Amin, Director of Product Development at Meditab. "This partnership helps our common customers make the most of their EHR and spirometry systems." Mary Burrell, Vice President of Global Sales at nSpire Health added, "There is an enormous demand for interoperability between our systems. We are coordinating the implementation efforts to ensure a seamless and quick customer implementation."

Sunovion Makes Application

Sunovion announced that it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for SUN-101/eFlow, an investigational treatment for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease

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.

No guesswork. No maintenance. Everything you need is built into the new *Grab 'n Go® Digital system* and maintained by Praxair.

Call Praxair to Schedule an Evaluation of Your Cylinder Needs Today at 1.800.PRAXAIR

PRAXAIR
HEALTHCARE SERVICES

(COPD). The submission is based on the positive results of the GOLDEN (Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer) clinical trials program, which evaluated the efficacy and safety of SUN-101 (glycopyrrolate), a nebulized long-acting muscarinic antagonist (LAMA) delivered via an innovative investigational eFlow nebulizer system (SUN-101/eFlow). The GOLDEN program included three Phase 3 clinical trials. GOLDEN-3 and GOLDEN-4 were Phase 3, 12-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter efficacy and safety trials comparing SUN-101/eFlow with placebo in patients with moderate-to-very severe COPD. GOLDEN-5 was a Phase 3, 48-week, randomized, open-label, active-controlled, parallel-group, multicenter safety trial designed to evaluate the long term safety and tolerability of SUN-101/eFlow® in patients with moderate-to-very severe COPD. "Patients are at the heart of everything we do at Sunovion," said Antony Loebel, MD, Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "This is an important milestone for us and the larger respiratory community, as we continue our mission of pioneering innovative treatments and therapies for COPD patients, their caregivers and healthcare providers."

New Entry Into Oxygen Product Space

3B Medical announced their entry into the oxygen product space with the launch of their 5 Liter stationary concentrator, the Cirrus 5. The Cirrus 5 was carefully designed with performance and reliability in mind including unique features such as an innovative cooling system to protect the sieve beds and an oxygen purity monitor. "We are very excited about our newest product introduction", said Joe Toth, Vice President of Sales and Marketing at 3B Medical. "The Cirrus 5 will continue to demonstrate our commitment to the homecare market by delivering a high quality product that also delivers a solution to today's business challenges. Once you remove the back panel and explore the internal design, it is easy to see that it was designed for performance, low maintenance and will set a new standard for durability", said Toth. For further information, email info@3Bproducts.com.

Two-in-One Drug Succeeds in Lung Disease Test

AstraZeneca has announced that its experimental drug PT003 for chronic obstructive pulmonary disease (COPD) proved successful in two final-stage Phase III trials, boosting hopes for the company's respiratory pipeline. PT003 is a twice-daily fixed-dose combination of glycopyrronium, a long-acting muscarinic antagonist (LAMA) and formoterol fumarate, a long-acting beta-2 agonist (LABA). The development program also included assessment of the individual components of PT003 - glycopyrronium pMDI (PT001) and formoterol fumarate (PT005) pMDI. PT003 demonstrated statistically significant improvements in trough FEV1 versus PT001, PT005 and placebo. Both PT001 and PT005 also demonstrated statistically significant improvements in trough FEV1 compared to placebo, the company reported.

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 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

Vitalograph Pneumotrac

for the highest quality spirometry with Spirotrac V software

Mention this ad for a free box of filters

Wouldn't your patients benefit from having the highest quality spirometry with Spirotrac V software backed by the only company with over 50 years of spirometry experience?

No question!

A variety of portable and desktop spirometers are available — all connectable to the Spirotrac V network

Vitalograph®

Your cardio-respiratory partner

1-800-255-6626 • www.vitalograph.com

email: vitcs@vitalograph.com

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 2015 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."

Bronchial Nerves Targeted by COPD Therapy

A therapy in development through the University of Groningen Medical Center in the Netherlands called "targeted lung denervation" (TLD) may be a future treatment option for patients with chronic obstructive pulmonary disease (COPD) if results from a first-in-human study are duplicated and validated. TLD is a bronchoscopic therapy based on ablation of parasympathetic pulmonary nerves that release acetylcholine, which, in turn, leads to smooth muscle constriction in the bronchi. TLD, delivered through a dual-cooled radiofrequency (RF) catheter, is designed to ablate targeted tissue "at depth with minimal heating and damage of the inner surface of the airway," researchers wrote. Researchers conducted a one-year trial involving 22 COPD patients, 12 who received ablation at 20 watts and 10 who received ablation at 15 watts. The researchers performed a series of pretreatment procedures, including starting patients on tiotropium bromide in a minimum eight-day run-in period, and conducting a pretreatment visual bronchoscopic inspection of the airwaves. During rigid bronchoscopy under general anesthesia, researchers placed and activated an electrode in up to eight rotational positions per bronchus to complete a circumference. The researchers used bronchoscopic and fluoroscopic visualization to guide electrode positioning throughout treatment. "TLD has the potential to overcome many of the limitations of inhaled drugs for the treatment of COPD," the researchers wrote. They cited four potentials: TLD may eliminate inhaler compliance issues; TLD would not be subject to peak and trough variations; TLD may eliminate variable regional drug delivery and deposition by ablating the nerves that travel the bronchial tree; and TLD, in combination with inhaled anticholinergic drugs, may reduce airway obstruction and mucus production and inhibit local airway inflammation.

EXECUTIVE PREVIEWS OF THE AARC

B&B

Booth 906

What products will you be presenting at AARC?
B&B's endotracheal tube holders, tracheostomy anti-disconnect devices, nebulizers for adult and pediatric patients, and bubble CPAP valves.

Are there any new products you wish to emphasize?
B&B Bubbler 12.5 cm H2O Pressure Relief Manifold. Prevents bubble CPAP system pressure build up from exceeding the preset level.

Why should AARC participants visit your display?
Receive a free sample of the B&B Bubbler and/or the new 12.5 cm H2O Pressure Relief Manifold or other products upon request.

Bunnell

Booth 1029

What products will you be presenting at AARC?
The New LifePulse High-Frequency Ventilator (HFV) will be introduced at the AARC Congress in San Antonio, TX. This new model of the LifePulse is small and light with a built-in battery for improved mobility. The user interface is simple and the alarms are prioritized for easy operation.

Are there any new products you wish to emphasize?
The New LifePulse delivers the same uniquely effective high-frequency jet ventilation as the pioneering technology released 30 years ago. The LifePulse has passed the test of time with over 100,000 patients treated at more than 300 hospitals.

Discuss educational/training materials you'll be offering.
The Bunnell Website features clinical and technical information on the LifePulse in pdf and video formats.

Lectures are available by leading physicians on specific clinical applications of the LifePulse. Bunnell is committed to the ongoing education and training of its customers over the life of the ventilator.

What speakers or papers will you be featuring?
Bunnell has a library of research articles and clinical abstracts on HFV. Call our Clinical Services department to identify and access topics of interest, 800.800.4358 ext 124.

Why should AARC participants visit your display?
Clinicians need to see the New LifePulse to appreciate the improvements we made in HFV technology. Simple and easy with the same effective, reliable therapy Bunnell has offered for the last 30 years.

Dräger

Booth 401

What products will you be presenting at AARC?
Dräger will be featuring the following ventilation products: Babylog VN500, Evita Infinity V500, Savina 300. Additionally we will be highlighting Draeger's ventilation consumables. Special emphasis will be on our newly released Babyflow plus system. There is now a system that enables the complete customization of non-invasive respiratory support based on the size of the patient. Babyflow plus includes not only individually sized masks and nasal prongs but also hoses in three sizes that enable optimal positioning of the patient supporting the ventilation as well as developmental needs of the patient.

Are there any new products you wish to emphasize?
Our newly released Babyflow plus system for neonates and infants. Also, we will be featuring the MiniMe® 2 by Sleepnet is a non-invasive ventilation mask for infants and children. The MiniMe® 2 is a non-invasive ventilation mask for children between the ages of 2 and 12 years-old. Dräger is one of the few vendors that can offer non-invasive ventilation consumable solutions for all its patients neonate to adult!

Discuss educational/training materials you'll be offering.
We will be sponsoring the AARC Pre-Congress Symposium titled Lung Protection, VILI, & Alveolar Stability: The Good, The Bad, & The Better, on Friday, October 14th from 12:30-4:30 PM. This event will feature presenters Gary Niemann, BA, Michaela Kollisch-Singule, MD, Nader Habashi, MD, and Penny Andrews, RN. Should you miss the Pre-Congress Symposium, you can view these presentations daily in the Dräger Corporate Partner's Meeting Room from 12:30-4:30 PM.

What speakers or papers will you be featuring?
Gary Niemann, BA: A Personalized Breath to Reduce the Incidence of ARDS, Michaela Kollisch-Singule, MD: Alveolar Stress & Microstrain, Nader Habashi, MD: Preemptive Use of APRV to Prevent ARDS, and Penny Andrews, RN: Myths & Misconceptions of APRV.

Why should AARC participants visit your display?
Visit booth 401 to receive Dräger's free giveaway — a CPR mask keychain. Stop by our reception desk to pick up this life-saving keychain!

Electromed

Booth 300

What products will you be presenting at AARC?
Electromed will present the SmartVest® SQL® Airway Clearance System at AARC congress 2016. The SmartVest system uses high frequency chest wall oscillation (HFCWO), a proven clinical therapy prescribed for people with impaired airway clearance, that helps clear the lungs of excess mucus, reducing the risk of respiratory infections and hospitalizations. The SmartVest system consists of an inflatable garment connected to a programmable air pulse generator. During therapy, the SmartVest garment delivers a rapidly repeating pulse of air, alternately squeezing and releasing the upper body. Each squeeze simulates a "mini cough," which acts to loosen, thin and propel mucus toward major airways, where it can be more readily expectorated or suctioned away.

Are there any new products you wish to emphasize?
In 2013, Electromed introduced the next generation SmartVest system, model SQL. The SmartVest SQL was designed to stand apart among HFCWO devices with features that Electromed patients and clinicians requested to promote therapy adherence. In a third-party study, the SmartVest system consistently delivered the lowest oscillatory trough pressure and greatest average decompression, which may lead to a more comfortable treatment. In addition to optimizing comfort, the SmartVest system is designed with an array of unique features to promote therapy adherence, including a single-hose design, easily programmable SQL generator, and a SmartVest garment with Velcro-like closures to make treatment easy, every time.

What speakers or papers will you be featuring?
In this edition of Respiratory Therapy, Electromed presents meaningful clinical outcome data on the health benefits of using its SmartVest SQL system. Look for the title, "Using High Frequency Chest Wall Oscillation in a Bronchiectasis Patient Population: An Outcomes-Based Case Review." The study found that SmartVest use significantly reduced bronchiectasis-related healthcare utilization cost and antibiotic and steroid use which is consistent with the clinical utility of SmartVest: improving airway clearance and bronchial drainage. Importantly, the study found patients reporting a significant improvement in their quality of life after SmartVest use.

Why should AARC participants visit your display?
Participants will learn firsthand what makes the SmartVest system a preferred choice for HFCWO therapy through hands-on demonstration of the SmartVest SQL. In today's healthcare environment, there is a comprehensive focus to reduce hospital readmission penalties associated with the Affordable Care Act. Solutions like the SmartVest System help patients with impaired airway clearance improve bronchial drainage, reducing the likelihood of future lung infections and other health risks and complications. Electromed is the only HFCWO device company to earn Home Care Accreditation from The Joint Commission, a symbol of quality and commitment to meeting performance standards for in-home patient therapy and service.

FloSure Technologies, LLC

Booth 1206

What products will you be presenting at AARC?
The Simex Subglottic Secretion Aspiration System is available as cuff S and cuff M. The system is the only fully automated, intermittent device cleared by the FDA specifically for the aspiration of subglottic secretions which pool above the ballooned cuff in mechanically ventilated patients and can enter the lower airways, causing pneumonia, and a greatly increased risk of mortality.

Are there any new products you wish to emphasize?
A recently completed randomized, controlled trial of the Simex automated subglottic aspiration system, demonstrates the combined potential of using the device along with tracheal tubes with integrated suction ports. The volume of secretions removed with the system are up to 10-fold those previously removed via traditional suction methods. The Simex Subglottic Secretion Aspiration System has been used for over 5 years and in over 1000 patients in both ICU and long-term care settings.

F&P Bubble CPAP

Used on over a quarter of a million babies globally.

The F&P Bubble CPAP System is designed to help babies make the transition to unassisted breathing. Not only is it non-invasive, it is also designed to protect the infant's lungs through world-leading humidification technology.

www.fphcare.com

Fisher & Paykel HEALTHCARE

Discuss educational/training materials you'll be offering.
Booth attendees can meet Jerry Gentile, the chief investigator, to ask questions and learn more about his clinical experience with the Simex system and the results of his RCT. Demonstrations of the product and copies of published articles will be available.

What speakers or papers will you be featuring?
Jerry Gentile, BSRT, BSHA, MBA, MPH, EdD(c), RT, RRT, Director of Respiratory Care Services at the Eastchester Rehabilitation and Healthcare Center, Bronx, New York, and lead investigator of a randomized controlled trial will share his clinical experience and findings. Gentile will be available to discuss his work, both at the booth, as well as speaking to the general audience as Long Term Care Spotlight speaker for Management of the Upper Airway, Sunday Oct 16, 1:45- 2:20 PM.

Why should AARC participants visit your display?
The benefits of subglottic secretion drainage (SSD) are well documented, but until recently, SSD has proved impractical to implement adequately. Booth attendees will gain a clear understanding of how use of the automated system can make SSD a practical protocol and standard of care. The Simex system reduces patient risk, improves patient comfort, allows for more rapid weaning from mechanical ventilation, and for faster restoration of the ability to swallow, and to speak. It effectively reduces staff burden and provides overall cost benefits to the institution.

Hill-Rom

Booth 1113

What products will you be presenting at AARC?
The MetaNeb® System, The Vest® System for Acute and Home, The VitalCough System.

Are there any new products you wish to emphasize?
The first Airway Clearance System with Bluetooth® connectivity, The VisiVest™ Airway Clearance System is the next generation of The Vest® System, the most widely used and trusted system today. Recently launched new garment color — cute camo and new size — our 16" garment.

Discuss educational/training materials you'll be offering.
Whitepaper on the importance of Airway Clearance and Adherence. MetaNeb protocol and impact tracker. In booth demonstrations & hands on experience.

What speakers or papers will you be featuring?
Whitepaper on the importance of Airway Clearance; Whitepaper on Therapy Adherence; The Impact of High-Frequency Chest Wall Oscillation on Healthcare Use in Patients with Neuromuscular Disease.

Why should AARC participants visit your display?
Learn what is new and products available for the continuum of care and reducing readmission rates.

International Biophysics Corp.

Booth 937 & 939

What products will you be presenting at AARC?
We will have the AffloVest at the show. The AffloVest is the first truly portable High Frequency Chest Wall Oscillation (HFCWO) vest that promotes airway clearance and lung secretion mobilization prescribed in the treatment of respiratory diseases like Bronchiectasis, Cystic Fibrosis, MS, ALS, and other neuromuscular diseases.*

Are there any new products you wish to emphasize?
The AffloVest has been on the market for about 3 years now. The newest version of the AffloVest that came out this year incorporates new features and more sizes based on feedback from patients and clinicians.

Discuss educational/training materials you will be offering.
We will have collateral and training materials available in our booth. The International Biophysics booth staff can provide product demos and answer any questions about the product and its indications.

Why should AARC participants visit your display?
AARC participants should visit our display to see and learn about the AffloVest, a product that can help improve their patient's clinical outcomes. We will have copies of 2 clinician papers that show imptroved lung function after adoption of the AffloVest in their ACT therapy.

MGC Diagnostics

Booth 901

What products will you be presenting at AARC?
MGC Diagnostics® will display recent product developments and technology advancements, including systems for pulmonary function testing and gas exchange testing. Pulmonary Function Testing systems include: The Platinum Elite™ body plethysmograph and the repackaged Ultima Series™ cardiorespiratory diagnostic systems. Both have RTD™ real time diffusion technology which delivers clinically significant graphic data and immediate results. Gas Exchange Testing systems include: The Ultima CPX™ metabolic stress testing system, CCM Express® indirect calorimeter and the Ultima™ CardiO2® gas exchange analysis system with integrated ECG. Our latest version of BreezeSuite™ cardiorespiratory diagnostic software incorporates the latest HIPAA — HITECH Security Safeguards to protect your patient's Identifiable Health Information. We will also be showcasing the CPFS/D™ USB spirometer — a full function, portable spirometer and Resmon™ PRO FULL FOT (Forced Oscillation Technique) device.

Are there any new products you wish to emphasize?
MGC Diagnostics will be highlighting the Resmon™ PRO FULL FOT which recently received FDA 510K clearance to market. The FOT is designed to provide medical professionals the ability to measure the mechanical properties of the respiratory system during normal tidal breathing, providing a simple, effort-independent assessment for patients age 4 and up. The FOT helps to determine the degree of obstruction, the delta in inspiratory and expiratory reactance, heterogeneity, and bronchial reversibility with no forced maneuvers.

Discuss educational/training materials you'll be offering.
Managing the MGC Diagnostics® exhibit will be our best in class clinical, sales and support staff available to answer not only

Have you experienced Optiflow™?

Visit Booth 323 at AARC Congress 2016
Phone: (800) 446-3908 or Email:
ExperienceOptiflow@fphcare.com

AARC
CONGRESS 2016

VISIT US

BOOTH 323

F&P Optiflow™ F&P 850™ System F&P Evaqua 2™ F&P AIRVO™

www.fphcare.com

IMPROVING CARE AND OUTCOMES
THROUGH INSPIRED AND WORLD-LEADING
HEALTHCARE SOLUTIONS

Fisher & Paykel HEALTHCARE

your product questions, but provide expert consultation for your clinical application and cardiorespiratory business needs.

Why should AARC participants visit your display?
MGC Diagnostics® delivers diagnostic solutions for detection, classification and management of cardiorespiratory patients worldwide. This singular focus guides our strategy and defines our commitment to customers, employees and shareholders. These attributes make us uniquely qualified to solve today's challenges and uncover solutions for tomorrow's opportunities.

Nonin

Booth 801

What products will you be presenting at AARC?
NoninConnect 3240 finger pulse oximeter, Onyx Vantage 9590 finger pulse oximeter, WristOx2 3150 wrist-worn pulse oximeter, PalmSAT 2500 hand-held pulse oximeter, Model 7500FO fiber-optic table-top pulse oximeter, RespSense capnograph, LifeSense capnograph/pulse oximeter, and compatible Nonin Medical pulse oximetry sensors.

Are there any new products you wish to emphasize?
The RespSense II capnograph and LifeSense II capnograph/pulse oximeter.

Discuss educational/training materials you'll be offering.
Nonin Medical's COPD STEP Readmission Reduction Plan: Nonin Medical's STEP Plan for hospitals, pulmonary rehab centers and other providers offers a practical, affordable, proven solution to the problem of comprehensive COPD treatment and management. The plan outlines a seamless transitional care plan while teaching patients how to manage their condition and reduce the chance for re-hospitalization.

What speakers or papers will you be featuring?
Nonin Medical's new PureSAT competitive fingertip pulse oximetry white paper: Fingertip Pulse Oximeter Performance in Dyspnea and Low Perfusion During Hypoxic Events, PB Batchelder, RRT, LRCP, Clinimark Laboratories, Boulder, CO.

The data from this important new study shows that during an oximeter comparison test of healthy subjects in an independent hypoxia lab, which simulated the symptoms of COPD patients, not all FDA-cleared pulse oximeters perform alike. Oximeters from three manufacturers were tested to see which ones could track hypoxic events consistently and accurately. Only the Nonin Medical oximeter with proprietary Nonin PureSAT technology was able to accurately track desaturation in humans with low pulse strength and labored breathing.

Why should AARC participants visit your display?
Get more information about Nonin Medical's COPD STEP Readmission Reduction Plan, which may help reduce hospital admissions for improved patient care. And, learn more about the Nonin Medical WristOx2 Model 3150, the most advanced wrist-worn pulse oximeter available. Ideal for overnight sleep apnea (OSA) studies and daily activity monitoring, Nonin's WristOx2 is simple and easy to use — providing patients with increased independence during continuous monitoring applications.

Nspire

Booth 507

What products will you be presenting at AARC?
Collect more, accurate, and reliable respiratory data. KoKo® pulmonary function testing devices are designed with the patient and user experience in mind, making them easier to use, faster and more reliable, all while providing the lowest total cost per test. All KoKo testing devices seamlessly integrate with IrisTM Respiratory Information System delivering unparalleled workflow and EMR interoperability.

Are there any new products you wish to emphasize?
KoKo Px, our new generation of comprehensive pulmonary function testing devices, combines industry leading PFT performance with patient reported data, interpretive analytics, comprehensive reporting, verifiable quality, and workflow automation to ensure the highest quality test results are delivered to physicians efficiently and cost effectively. New features include:

- Quality Control
- eForms (patient reported data, QoL, symptom scores, etc)
- Attach 3rd Party PDF Reports
- Global Lung Initiative (GLI) Predicted Equations
- Photo-realistic Incentive Graphics
- Compact, Ergonomic Cart
- Dedicated Physician Workstation
- Professional Services

Why should AARC participants visit your display?
Come to booth 507 for the unique opportunity to provide your insights on monitoring device & test quality and business productivity, learn how a Respiratory Information System can improve lab quality & efficiency, interact with our new generation of PFT systems, and learn how together we can drive innovation to improve the management and treatment of patients with respiratory diseases.

Passy Muir

Booth 207

What products will you be presenting at AARC?
New Adapters from Passy Muir
Passy Muir (Irvine CA), the manufacturer of the No Leak speaking valve now offers two adapters to provide clinicians with easier access to connecting the Passy-Muir® Valve inline while the patient is mechanically ventilated. The PMV-AD1522™ is a step-down adapter designed to connect the PMV 007 (Aqua Color™) within a ventilator circuit, and the flexible, PMV-AD22™ adapter is designed for use with the PMV 2001 (Purple Color™). All Passy Muir products are proudly made in the USA.

TRACHTOOLS™ Communication App
Passy Muir released a new user-friendly app for iPhone, iPad, and Androids, designed to facilitate patient communication and education, provide valuable information regarding tracheostomy, and foster patient participation in care. For communication, the app includes pre-recorded phrases which enable communication at a touch of a button, user-defined male, female, or child voice, attractive and intuitive menu, and custom phrase record option. For education, the app includes patient videos, a cleaning and care guide, and easy access to patient and clinician resources. Available free from the App Store or Google Play.

Aerogen®

Pioneering Aerosol Drug Delivery

NEW

AARC ZENITH AWARD 2015

AEROSOL TREATMENT IN CHILDREN HAS NEVER BEEN MORE EFFICIENT

Aerogen is the winning choice for respiratory patient care in the PICU

Up to 9 times higher drug dose than a traditional standard small volume nebulizer during mechanical ventilation.[1]

Discover a better way to treat your pediatric patients.

See our award winning technology in action.
www.aerogen.com

Aerogen® / Discover Better

1. BERLINSKI, A. & WILLIS, J. R. 2013. Albuterol delivery by 4 different nebulizers placed in 4 different positions in a pediatric ventilator in vitro model. Respir Care, 58, 1124-33.

PM254

Exciting updates to the Toby Tracheasaurus™ Pediatric Program
Passy Muir has unveiled new updates to its popular Toby Tracheasaurus™ Pediatric program. The enhancements include a clinically improved Toby Tracheasaurus Coloring & Activity Book, with new dinosaur cartoon characters, that are 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.

Are there any new products you wish to emphasize?
New Adapters, conveniently available at the same place as our valves
Two new adapters offered by Passy Muir are now available wherever you purchase other Passy Muir products. 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 resealable, multiple unit packaging. The PMV-AD1522™ is a step-down adapter designed to connect the PMV 007 (Aqua Color™) to a T-piece type closed suction system. The flexible, PMV-AD22™ adapter is designed for use with the PMV 2001 (Purple Color™). All Passy Muir products are proudly made in the USA.

Discuss education/training materials you'll be offering:
Passy-Muir, Inc is committed to improving the quality of life for tracheostomized and ventilator-dependent patients. To meet this mission, we provide free education through on-line self-study webinars and onsite inservices tailored to meet the needs of your facility. These educational opportunities are free and offer CEUs for respiratory therapy, speech pathology, and nursing. Go to www.passy-muir.com/education for more information. We also offer a national seminar at a nominal cost of $75 which provides 8 CEUs, food for the day (including lunch), and delivers state-of-the-art education through didactic lecture with patient videos from both an RRT and SLP, hands-on instruction, specialized training in ventilator application and dysphagia management, and case studies to synthesize all the information. Do not miss out on the 2016 opportunities that are still available: October 4th in Nashville, TN and October 22nd in Sleepy Hollow, NJ. Stay tuned for a 2017 seminar near you — with dates and places to be announced soon.

Why should AARC participants visit your display?
Visiting our display gives you an opportunity to participate in interesting hands-on activities, check out our new adapters, explore the TRACHTOOLS app, and learn about our exciting new seminars and educational offerings.

ResMed
Booth 923

What products will you be presenting at AARC?
We will be showing all of our Sleep and Respiratory Care devices, from CPAP/APAP to Astral life support ventilators. We also have hospital masks, a new High Flow Nasal Canula, Lumix Tx (a therapy device for hospital that includes all modes of ventilation) and our new Portable Oxygen Concentrator.

Are there any new products you wish to emphasize?
Our Astral life support ventilator is now connected! This new solution enables the automatic transfer of patient vent data to ResMed's Airview software each day. This launch will represent the first ventilator in the market with the ability to pull data daily and visualize patient therapy report. We will also be showing our newly acquired portable oxygen concentrator, Activox.

Discuss educational/training materials you'll be offering.
ResMed will be participating in new product demonstrations and offering hands-on training support for all of our devices on the floor.

What speakers or papers will you be featuring?
We will have clinical representatives at our ResMed booth offering clinical/education presentations as well as access to educational papers and materials.

Why should AARC participants visit your display?
ResMed will be highlighting the latest in medical device technology capabilities, demonstrating the ability to access life support ventilation data and how to evaluate and troubleshoot data from daily downloads.

COMPANY PROFILE

Southmedic

Describe your product(s) and its unique features.
OxyMask is a highly efficient 'open' mask system that eliminates the need for a closed design, valves and reservoirs.

OxyMask incorporates an innovative Pin and Diffuser technology designed to concentrate and redirect the flow of oxygen. The mushroom-shaped Pin redirects the flow of oxygen, forming an organized pattern of vortices and a cloud of concentrated oxygen molecules. The triangular directional Diffuser refines the shape of the oxygen vortices and directs the flow towards the patient's nose and mouth.

During the patient's inhalation, oxygen flow is mixed with room air drawn in through the mask openings. Respiratory mechanics and breathing patterns determine how room air combines with the delivered oxygen. The concentration of oxygen received during the breath is a function of the oxygen flow compared to the patient's inspiratory flow and tidal volume. This results in the prescribed concentration of oxygen being delivered to the patient.

During exhalation, the mask openings allow expired carbon dioxide to escape.

The open design of OxyMask allows for easier communication, access for oral and nasal care, reduces the risk of rebreathing or aspiration of emesis, and there is no build up of humidity under the mask. Patients find that OxyMask is more comfortable then a nasal cannula; as it doesn't inhabit the nares or sit on the skin

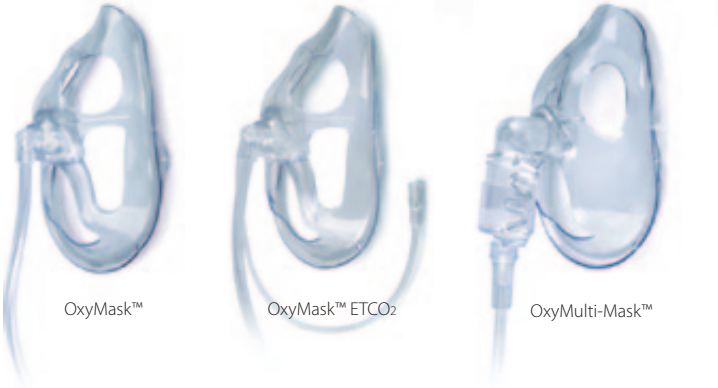
OxyMask™

Advancing Oxygen Therapy for Better Patient Care

OxyMask™

An open oxygen mask ...

Learn more at: the**better**oxygen**mask**.com



OxyMask™ | OxyMask™ $ETCO_2$ | OxyMulti-Mask™

Southmedic

Manufactured by:
Southmedic Inc., 50 Alliance Blvd., Barrie, ON L4M 5K3 contactus@southmedic.com 1-800-463-7146 Toll free in North America

under the nose. All-in-all, OxyMask is the one mask for patient safety, patient comport, and oxygen therapy compliance.

Tell us about the latest advances in the area your product serves.
Southmedic has three distinct OxyMask products that have created advancement in several areas; the OxyMask, OxyMulti-Mask, and OxyMask ETCO2.

OxyMask delivers O2 and is used in numerous acute care facilities. OxyMask is an ideal replacement for traditional oxygen therapy interfaces. Among its numerous benefits, the OxyMask delivers 24% to 90% FiO2. This allows the OxyMask to replace multiple devices that provide a limited range of FiO2. For instance, a simple mask offers 35-50% FiO2, a partial rebreathing mask offers 40-70%, and a non-rebreathing mask offers 60-80%. Early adaptors are realizing the reduced inventory, medical waste and clinician time that one OxyMask offers.

OxyMulti-Masks can be used for heated aerosol, medicated aerosols, or oxygen delivery on its own. OxyMulti-Mask is often used in acute care facilities and is gaining popularity with EMS/Fire Services. OxyMulti-Mask allows paramedics the ability to deliver a medicated aerosol hands-free without changing masks. Additionally, with the open design, there is no need to run high flows of oxygen to flush out the patient's CO2 as with a NRB. With this, the consumption of oxygen is greatly reduced, which is a significant benefit for EMS as they use tank oxygen. It also helps EMS staff meet the requirement for CPR to titrate oxygen saturation to 94%. OxyMulti-Masks are the ideal choice for disaster preparedness, mass casualty and pandemic events.

OxyMask ETCO2 delivers O2 therapy and captures ETCO2 tracings. OxyMask ETCO2 is gaining popularity in endoscopy, bronchoscopy and interventional radiology. The open design is perfect for access of scopes and the additional oxygen flow to the nares and mouth helps patients who need more flow than what a divided cannula can provide. The pin and diffuser technology along with the sampling line delivers oxygen and monitors ETCO2 even when the patient has an occluded nare or is a mouth breather. In addition the mask can be used for conscious sedation, cath labs, MRI or cat scan where increased oxygenation and monitoring, patient comfort, and patient safety is needed.

Discuss your R&D process, including clinical user input.
Southmedic's R&D process is on-going. Clinician's imput and suggestions from the field are continuously being directed back to marketing, sales, engineering and manufacturing. For example, as a result of meeting with RN's and Clinical Managers, OxyMask ETCO2 is available with a 14' sampling and oxygen line to fit 11' cath lab tables, and to assure there is enough length for an MRI or cat scan. That not only makes for a less expense and easier set up for staff, it reduces the potential of tubing becoming disconnected.

Discuss the educational services you offer for use of your product.
The available educational services for OxyMask are comprehensive. In addition to educational information being posted on our website such as videos, handouts and quizzes, individual training is available. Individual training is utilized for product introductions and/or when a hospital is transitioning to an OxyMask product. This training is performed by a Canadian sales representative, a Southmedic RT product specialist or a member of a local distributors' sales team.

What new technology do you see as having the greatest impact on your area of expertise?
The great thing about our technology is that it is never stagnant. The OxyMask technology advances oxygen therapy for better patient care, and that axiom will continue to drive how the OxyMask product evolves. As the industry standard of oxygen therapy progresses, OxyMask will continue to change along with it.

Recently, monitoring ETCO2 has become increasingly mandatory in more medical scenarios. The OxyMask ETCO2 products features and benefits make it an ideal go-to O2 / ETCO2 delivery device.

Currently, we are seeing a growing need for heated aerosol systems especially at home as a nasal interface is not always an option. We've seen more involvement with EMS/Fire, especially for rotary, fixed wing, and ground response for oxygen delivery. Unfortunately, disasters, mass casualty and pandemic events are not going to go away, but we do offer a solution that is currently not available.

GETINGE GROUP

Passion for life

The SERVO-U® ventilator

Designed to win more than awards

MAQUET

GETINGE GROUP

Designed with clinicians, for clinicians, SERVO-U continues our legacy of trusted mechanical ventilation innovation.

SERVO-U combines protective ventilation capabilities, using easily accessible comprehensive support tools, with award-winning functional innovation. The full touch-screen design and flexible configuration solutions enable you to easily tailor SERVO-U to the unique needs of your patients across all levels of respiratory support.

Winning design awards is gratifying—supporting you and your patients is **everything**.

reddot design award winner 2015

Medical Design Excellence Awards

design for experience awards

Please visit Getinge Group at AARC booth #412

www.getingegroup.com

The Role of Subglottic Secretion Drainage in VAP Prevention: ICU Experience with an Automated Intermittent Subglottic Secretion Drainage System

Dr med Markus Wolf

Abstract

The most difficult and challenging cases in the ICU involve long periods of mechanical ventilation which are associated with a high risk of ventilator-associated pneumonia (VAP). Patients with VAP face prolonged hospital stays and significantly increased risk of mortality. Efforts to prevent VAP have included selective oral decontamination (SOD), elevation of head rest and subglottic suctioning of secretions.

This paper describes a new approach that combines the use of tracheal and endotracheal tubes containing ballooned cuffs and integrated suction ports, with the use of an automated intermittent subglottic secretion aspiration system, in an 18-bed ICU in Hamburg, Germany. The author provides an overview of the cases of 16 patients on the automated devices visited during a single day on unit rounds, as well as a description of an additional, and particularly challenging, paradigmatic case. The cases are intended as a "snapshot" of clinical experience gained with the system in over 4 years and in approximately 500 patients.

Keywords: Ventilators, Mechanical, Pneumonia, Respiratory Tract Infections, Ventilator Associated Pneumonia (VAP), Ventilator Associated Events (VAE), Subglottic Secretion Drainage (SSD), Automated Intermittent Subglottic Aspiration

Introduction

Ventilator-associated pneumonia (VAP) is the most common and serious type of hospital-acquired infection (HAI) in the ICU. The reported incidence varies in different studies on the subject which is in part due to complexity, and differences in the applied criteria such as epidemiological variables, diagnostic tests, use of antimicrobials, and other management strategies. A large current observational study in 27 ICUs of 9 European countries found 18.3 episodes of VAP per 1000 ventilator-days and an increase in mortality of 6% as well as an increase of duration of ventilation and length of stay.[1] VAP continues to be a serious problem, despite progress in the understanding of its origins, and improvements in treatment protocols.

The 18-bed ICU unit at Asklepios Klinik Barmbek in Hamburg specializes in weaning long-term ventilated patients from the ventilator. The patients treated are almost exclusively referrals from mainly surgical ICUs in the Hamburg area and at the time of transfer in general have been ventilated for about 20 days. The average length of stay is 34 days and at any time point about 90% are invasively ventilated, and 90% of those have a tracheal cannula. This specialized weaning unit was created in 2008 and expanded thereafter. Subglottic suctioning and selective oral decontamination (SOD) were not practiced until 2012 when the decision was made to implement a VAP prevention bundle, based on several observations in this cohort of long-term ventilated patients. In about half of the patients we saw what was described as "hypersalivation." These patients always had a lot of saliva in the mouth, and the tissue surrounding the tracheostoma was always wet and patients required a higher frequency of endotracheal (bronchial) suctioning. In addition, some of these patients had subfebrile temperatures that we could not find a reason for, and the rate of purulent bronchial secretions was deemed elevated. Further observations of these patients for several minutes revealed that swallowing was not present. We therefore concluded that their problem was a deficit in swallowing rather than hypersalivation.

We looked at the published evidence for measures to reduce VAP and found that all proven interventions had something to do with reducing the likelihood of pathogens passing from the upper gastrointestinal tract to the lung, first noting a more than 50% reduction in VAP when postpyloric feeding was compared with the conventional gastric feeding.[2] We also noted that at the gastric level, avoiding the use of proton pump inhibitors, which elevate the gastric pH and thus favor bacterial survival, can reduce VAP by more than 50%.[3] Looking at the next level in the supposed pathway, the oropharynx, we reviewed a large meta-analysis showing a 44% reduction of VAP when using selective oral decontamination.[4]

We then turned to evidence involving the last step in the pathway, which is the prevention of oropharyngeal and subglottic secretions from entering the lower respiratory tract via the outside of the cuff. A study comparing intermittent vs. continuous control of ballooned cuff pressure showed a 44% VAP reduction when continuous cuff pressure was used.[5] A current meta-analysis of 17 studies including 3369 patients noted a 0.58 relative risk for VAP using subglottic suction.[6] Looking on these results together it seems obvious that there is a common mechanism as all these interventions hinder the ascension of pathogens from the gastrointestinal tract to the lung. This is in accordance with the observation that the rate of VAP is not reduced when a closed suction system is used.[7]

Dr Markus Wolf is Senior Physician Weaning Station, Department of Pneumology and Intensive Care, Asklepios Klinik Barmbek, Hamburg, Germany.

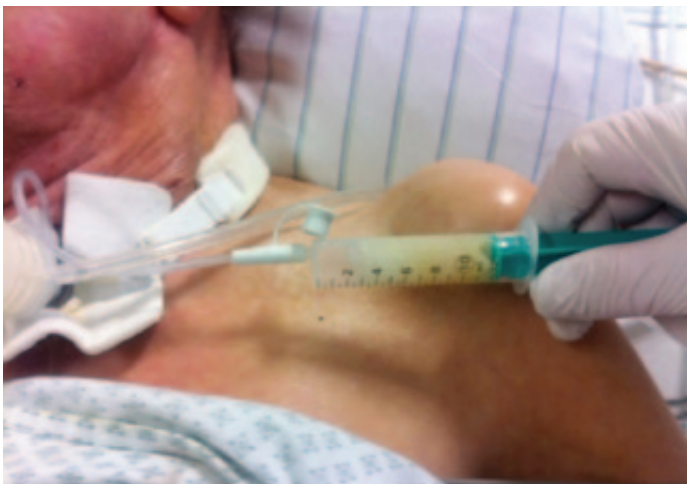
The hypothesis of VAP being a consequence of the movement of pathogens from the gastrointestinal tract to the lung is strengthened by a study from Johannesburg published in 1999.[8] Researchers in the Johannesburg study looked for the time course of the appearance of pathogens in the oropharynx, stomach, lower respiratory tract, and inside the endotracheal tube, every 6 hours after intubation. After the first 12 hours following intubation, gram positive pathogens, especially Staphylococcus, appeared in the pharynx. After about 1.5 days, gram negative pathogens, for example Klebsiella, Pseudomonas, E. coli, Proteus, Enterobacter, and Enterococcus appeared about simultaneously in the stomach and in the oropharynx. After about 3 days, they appeared in the lower respiratory tract, and only after that appeared on the inside of the cannula. This sequence of events strengthens the hypothesis that the pathogens that cause VAP reach the lung traveling with contaminated oral secretions via the outside of the cannula passing the cuff of the endotracheal tube rather than being introduced by the staff through the lumen of the tube.

Based on our review of the evidence, we decided that our VAP prevention bundle should include:

- a preference for postpyloric feeding and PEG/PEJ thus avoiding nasogastric tubes
- systematic use of SOD
- continuous cuff pressure control, and
- subglottic suctioning

The introduction of SOD did not pose any problems while the introduction of continuous cuff pressure control was not possible for economic reasons.

Figure 1. Manual suctioning using a syringe. Similar to that used in the French study protocol[9] for SSD.



The practical problems with subglottic suctioning became evident when looking closely at a randomized controlled SSD study conducted in France.[9] The study included 333 adult patients in 4 centers and yielded similar results as the above cited meta-analysis, reducing the relative risk of VAP to 0.55. The protocol called for manual suctioning hourly with a 10 ml syringe, and called for the recording of the amount of secretions removed. Actual suctioning took place at approximately 90-minute intervals. The volume of secretions on average was 14 ml per day with a span of 8-22 ml, with a minimal value of 0 and a maximum value of 197 ml. The suctioning of every patient at least every 90 minutes consumes a lot of manpower and represents a great challenge to ICU staff. With only 6 nurses per shift on our 18-bed unit, hourly manual suctioning would not have been possible (see Fig 1).

In reviews of the SSD literature, both wall suction regulators and manual syringes had been shown to exert more force on the airways than recommended by guidelines.[10] In addition, prior experience on our own unit where various brands of wall suction had been evaluated for use in SSD, the wall suction proved insufficient for controlling negative pressures and suction time intervals, and unsuitable for removing the different types and volumes of secretions among our patients. Therefore we began using an automated subglottic secretion drainage device immediately when we introduced our VAP prevention bundle.

> "…prior experience on our own unit where various brands of wall suction had been evaluated for use in SSD, the wall suction proved insufficient for controlling negative pressures and suction time intervals, and unsuitable for removing different types and volumes of secretions…"

Figure 2. Automated Intermittent Subglottic Secretion Aspiration System.

October 2014 Unit Rounds Snapshot

During a single day in October of 2014, each patient on our 18-bed unit was visited during rounds, with the goal of creating a snapshot of our challenging patient population to serve as a basis for discussing the lessons learned in our efforts to prevent VAP using the automated aspiration system. On that day, 16 devices were available and utilized in the treatment of the patients described in Table 1.

Table 1 shows the patient characteristics (where captured and recorded) for all 16 patients on the automated aspiration device. The cases are typical of cases on the unit at any given time. Disease categories documented included cardiovascular, respiratory, neurologic, gastrointestinal, metabolic, and oncologic. Sepsis, organ failure, and severe CIP were noted. The pathogens documented, many drug resistant, are those frequently associated with VAP. Large amounts of secretions, of varying viscosities, were removed daily. Dysphagia was noted in the majority of the patients.

Table 1. Automated Subglottic Aspiration System Patients

Pt	M/F	Age	Condition	Pathogen(s)	Secretion/Daily	Other Observations
01	M	63	Coronary artery bypass OP. Cerebeller infarction	Morganella morgagnii	100 ml mucopurulent (fecal smell)	Delirium Dysphagia
02	M	85	Valve replacement. CHF. Diabetes	E.coli. Morganella morgagnii. Stenotrophomonas	150-250 mucopurulent	Delirium Dysphagia
03	M	67	55 day post esophagectomy for cancer. COPD		400 ml watery	Gastric regurgitation
04	M	74	Coronary artery bypass OP with aortic valve replacement. Acute persistent renal failure. Severe critical illness polyneuropathy. Slow recovery due to axonal type		150 ml mucopurulent. 1400 ml total collected within a few days	Dysphagia Depression
05	M	83	29 days post emergency coronary artery bypass OP. Severe critical illness polyneuropathy		250-350 ml mucopurulent	
06	F	79	48 hours post intubation for AECOPD	Stenotrophomonas maltohilia	50 ml mucopurulent. 600 ml total collected within a few days	Dysphagia Anxiety disorder
07	F	63	Intubated for pneumonia. MS for 20 years		400-600 ml watery	Dysphagia
08	M	75	AECOPD	Enterobacter. Serratia	50-100 ml Mucoid, hemorrhagic secretions	Delirium Dysphagia
09	M	75	AECOPD. ICU weakness. CIP. CIM.	E.coli. Pseudomonas. Klebsiella. Multi resistant against 3-4 major antibiotic classes.	500-1000 ml watery	Severe dysphagia
10	M	71	92 days post ARDS, following spondylodiscitis with sepsis and fibrotic lung	Enterococcus resistant to 4 major antibiotic classes		De-cannulated but later died not wanting further treatment
11	M	66	37 days post pneumonia. Sepsis. Multiple organ failure. Severe weakness		50-100 ml mucopurulent	Delirium Dysphagia
12	F	82	Valve replacement for endocarditis. ICU acquired weakness	Multi-resistant Klebsiella and E. coli	50 ml Mucoid, hemorrhagic secretions	Delirium
13	F	73	32 days post op for aortic dissection	Stenotrophomonas in sputum. Non-invasive ventilation		
14	F	69	AECOPD. Extreme weakness	Very resistant MRSA and Enterococcus	50-150 ml mucopurulent	Dysphagia
15	F	48	123 days post pulmonary embolism. Slightly obese	Klebsiella in sputum on non-invasive ventilation		
16	M	67	26 days intubated for pneumonia and AECOPD	Klebsiella oxytoca	500 ml watery	Dysphagia Delirium

Two Patient Populations

From clinical experience we make a distinction between two patient populations. Group 1 has massive aspiration of a saliva-type fluid. From the subglottic port we remove 400-1000 ml of secretions per day and we adjust the settings of the automated aspiration device to a rather low pressure because the fluid is not very viscous. We also use a very short interval of 5 minutes because the watery fluid can microaspirate and pass the ballooned cuff quickly. You can appreciate the practical impossibility of using manual suction when such frequent suctioning is needed. Group 2 patients have a small-to-medium amount of thick, mucopurulent secretions, in the range of 20-200 ml per day. We adjust the parameters of the automated device differently, using higher negative pressures because the secretions are viscous, with longer intervals to allow accumulation of the secretions on top of the ballooned cuff. This approach facilitates the suctioning of the fluids, while avoiding inadvertent suctioning of the tracheal wall.

Secretions in Group 2 seem to develop primarily in the space between the vocal cords and the cuff. This space is around 20 ml and in normal life it is ventilated all the time, passing some 15 liters of air every minute. When a cuff is in place, this space is no longer ventilated but the mucous membranes continue to produce mucus that then accumulates on top of the cuff. There is no effective barrier to oropharynx pathogens passing into this space and inoculating the above mentioned mucus.

> "Group 1 [patient population] has massive aspiration of saliva-type fluid [400-1000 ml per day]....Group 2 patients have a small-to-medium amount of thick, mucopurulent secretions [20-200 ml per day]."

As the temperature in this space is 37°C, and because there is no ventilation, conditions are very favorable for bacterial growth. The mucus then turns to a purulent and highly infectious material. It is of critical importance to prevent this from entering the lung. Regular suctioning above the cuff is therefore warranted.

Negative pressure settings for the automated intermittent aspiration system range from -60 to -300 mbar (-45 to -225 mmHg). Suction interval settings range from 10-60 seconds (ON), and from 3-60 minutes (OFF). SSD guidelines from the AARC recommend the use of negatives pressures from -80 to -150mmHg.[11]

A Paradigmatic Case

A 58-year-old man was initially admitted to another hospital with decompensated heart failure. He was known to have insufficiency of the aortic and mitral valves. On holiday, he had hiked in the mountains and overstressed his capacity. They tried to recompensate him medically, but after that failed, an emergency double valve replacement was done and the patient's condition further deteriorated and remained critical. He had severe shock (cardiogenic or septic), and developed renal failure and subileus. A pneumothorax occurred. Nonetheless, he began to improve soon after the operation.

He was extubated on Day 6 post op and put on non-invasive ventilation. Dysphagia became apparent on Day 6 post-extubation, and on the 10th day post-extubation the patient was reintubated. On the 12th day they performed a tracheotomy. A pericardial effusion was drained. He had atrial fibrillation and a catheter-associated infection with E. faecium.

When we first saw the patient on our unit he had a very reduced vigilance and an extremely pronounced muscle weakness such that he was almost tetraplegic. He appeared to be hyperventilating. He had a fever and his CIP was very strong. As the tracheotomy was performed only a few days prior to his transfer to our unit and the cannula used had no port for subglottic suctioning for the first 4 days of his stay we could not perform subglottic suctioning. In this period we had to suction frequently endotracheally and from the mouth as there were large amounts of saliva type secretions. These procedures were very unpleasant to this patient.

On his 4th day on our unit, we successfully put in a tracheal cannula with a subglottic port, and using the automated device suctioned a large amount of secretions. The frequency of endobronchial suctioning and suctioning from the mouth required was immediately reduced. Almost 900 ml of secretions per day were being removed subglottically. Very little endobronchial secretions remained. By the 5th day we could already start with short intervals of spontaneous breathing and by Day 6 the use of a speaking valve was possible. Day 7 there was still a large amount of subglottic secretions, and some dysphagia persisted, but he no longer required ventilation. By Day 14, only 50 ml a day were being removed subglottically. On Day 18, we were able to remove the tracheal cannula and discharge him.

The case is typical in that patients frequently respond very positively after having large volumes of secretions removed by the device that previously would have descended into the lungs. The case seemed special, and somewhat atypical, from

Figure 3. Example of watery secretions collected (400-600ml daily) – Pat. # 7 in Table 1.

Figure 4. Example of watery secretions collected (500-1000ml daily) – Pat. # 9 in Table 1.

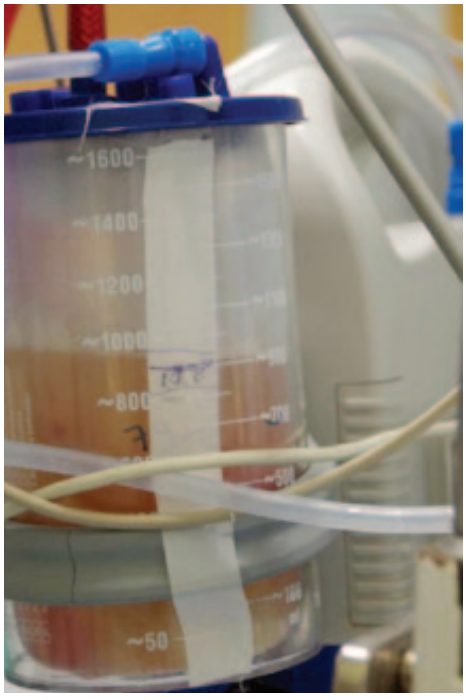


Figure 5. Example of mucopurulent secretions collected (150-250ml daily) – Pat. # 2 in Table 1.

the standpoint of the dramatically short time that was required for the patient to recover from his serious and threatening conditions. His problem, and the reason why he could not be weaned before we started subglottic suctioning was the huge amount of secretions that were passing to his lungs due to a severe dysphagia caused by his critical illness polyneuropathy.

The Practical Application of Subglottic Secretion Drainage

Since 2012 we have used a bundle of measures for the prevention of VAP. When patients are admitted, we change as soon as possible to a cannula with a subglottic port and start automated intermittent suctioning. We do selective oral decontamination (SOD) on all patients using polyhexanide.

We do FEES (fiberoptic endoscopic evaluation of swallowing) on all patients before oral feeding. If we find a relevant amount of dysphagia, we insert a PEG (percutaneous endoscopic gastrostomy tube) and if there is regurgitation we proceed to postpyloric feeding. We start training with a speaking valve early when the patients are still dependent on the ventilator. Even if we know a patient is dysphagic, we start to put him on the speaking valve for periods of 15 minutes to re-ventilate the subglottic space which helps to reconstitute its sensitivity and the swallowing reflex. All patients receive specialized logopedic training and repeat FEES evaluations to see if the training is working. When we start feeding, we color the food with methylene blue in order to see whether there is still aspiration. We also engage head-of-bed elevation, and emphasize early mobilization. We do not use PPI treatment because it has been shown that reducing the acidity of the stomach allows gastrointestinal pathogens to pass into the oropharynx.

As a common initial setting for the automated device, we frequently use -200 mbar (-150 mmHg), with a suction time of 20 seconds and a pause between suctioning of 5 minutes. Manual aspiration has to be done every 8 hours because the machine cannot replace the nurse or doctor or the respiratory therapist—it is a means to help in their work. The responsibility is still with the human being.

Discussion

Our experience with the benefits of subglottic suctioning are in accordance with the large body of evidence for its use that has prompted the German commission for hospital hygiene and infection prevention at the Robert Koch Institute, an organization with similarities to the US CDC, to recommend its use. The KRINKO[12] recommendations issued in 2013 call for the use of an endotracheal tube with a subglottic port for suctioning if the time of ventilation is expected to be greater than 72 hours. In addition, consideration of the exchange of a conventional endotracheal tube to one with an integrated subglottic suctioning port is recommended if the benefits are deemed to outweigh the risks of the procedure. The category of the recommendation is 1A, the highest possible.[12]

Even though the benefits of SSD for patients are undisputable, its use is not as widespread as it should be. It is our belief that this stems from the practical problems with instituting its use in a hospital environment where nursing time is an issue. With the use of an automated system this problem has been overcome in our institution. Our guidelines call for manual suctioning only every 8 hours which proved to be practical. An observation in our unit is that the amount of secretions we are able to suction subglottically using an automated system substantially exceed the amount of secretions collected cited in publications. Our explanation is that in the intervals of 90 minutes and more for manual suctioning a substantial amount of these secretions bypass the cuff while the automated system is able to suction every five minutes when necessary to collect the secretions. An additional benefit of the automated subglottic aspiration system is that it is less traumatic to the tracheal wall. Syringes have been shown to create a vacuum equal to a negative of 1000 mbar (-750 mmHg), while the negative pressure created by the automated pump is strictly limited to -300 mbar (-225 mmHg). Automated subglottic aspiration results in less manipulation of infectious material because the material is contained, and greatly reduces the amount of manpower that was previously devoted to suctioning. In an era of growing concern with antibiotic resistant bacterial infections in hospitals, subglottic suctioning provides a means to reduce bacterial infections in a very vulnerable patient population. A recent study showed that subglottic secretion drainage and continuous control of ballooned cuff pressure, implemented together, save health care costs. Thus, the costs of the interventions should no longer be an issue.[13] Looking on VAP as an evitable hazard to our patients, we should consider all efforts to prevent VAP an obligation to all medical institutions.

"An observation in our unit is that the amount of secretions we are able to suction subglottically using an automated system substantially exceed the amounts of secretions collected cited in publications."

From our experience we therefore strongly recommend the use of subglottic suctioning at least in the here-reported population of long-term ventilated patients. We believe automated intermittent subglottic aspiration offers the means to overcome the practical problems associated with implementing subglottic suctioning.

"Thus, the costs of the interventions should no longer be an issue. Looking on VAP as an evitable hazard to our patients, we should consider all efforts to prevent VAP an obligation to all medical institutions."

Conclusion

Automated intermittent subglottic suctioning in our experience offers a lower rate of VAP than manual and other methods, less endotracheal (bronchial) suctioning, less atelectasis, easier use of a speaking valve, shortened ICU stays, and lowers staff burden. Further studies and clinical evaluation of automated SSD are warranted.

References

1 Koulenti D, Tsigou E, Rello J. Nosocomial pneumonia in 27 ICUs in Europe: Perspectives from the EU-VAP/CAP study. Eur J Clin Microbiol Infect Dis. 2016; Jun 10 Epub ahead of print.

2 Hsu CW, Sun SF, et al. Duodenal versus gastric feeding in medical intensive care unit patients: A prospective, randomized, clinical study. Crit Care Med. 2009;37:6:1866-1872.

3 Khorvash F, Abbasi S, Meidani M, Dehdashti F, et al. The comparison between proton pump inhibitors and sucralfate in incidence of ventilator associated pneumonia in critically ill patients. Adv Biomed Research (PPI) Adv Biomed Res. 2014;Jan 27:3:52.

4 Chan EY, Ruest A, Meade MO, Cook DJ. Oral decontamination for prevention of pneumonia in mechanically ventilated adults: systematic review and meta-analysis. BMJ. 2007;Apr 28:8:334(7599):889.

5 Lorente L, Lecuona M, Jemenez A, Lorenzo, L, et al. Continuous endotracheal tube cuff pressure control system protects against ventilator-associated pneumonia. Critical Care. 2014;Apr 21:18:R77.

6 Caroff DA, Li L, Muscedere J, Klompas M. Subglottic secretion drainage and objective outcomes: A systematic review and meta-analysis. Crit Care Med. 2016;Apr;44:4:830-840.

7 Siempos II, Vardakas ME, Falagas ME. Closed tracheal suction systems for prevention of ventilator-associated pneumonia. Br J Anaesth. 2008;100:3:299-306.

8 Feldman C, Kassel M, Cantrell J, Kaka S, Debbat K, et al. The presence and sequence of endotracheal tube colonization in patients undergoing mechanical ventilation. Eur Respir J. 1999;13:546-551.

9 Lacherade JC, De Jonghe B, Guezennec P, et al. Intermittent subglottic secretion drainage and ventilator-associated pneumonia: A multicenter trial. Am J Resp Crit Care Med. 2010;182:910-917.

10 Gentile G, Fendler H. Advances in subglottic secretion drainage. Resp Ther. 2016;Spring:11:2:39-47.

11 AARC Clinical Practice Guidelines, Respiratory Care. 2010;55:6:758-762.

12 Prevention of nosocomial ventilator-associated pneumonia. The Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2013;Nov:11:1578-1590.

13 Lorente L, Lecuona M, Jiménez A, Cabrera J, et al. Subglottic secretion drainage and continuous control of cuff pressure used together save health care costs. Am J Infect Control. 2014;Oct:42:10:1101-1105.

Using High Frequency Chest Wall Oscillation in a Bronchiectasis Patient Population: An Outcomes-Based Case Review

Chet E Sievert, BS[1] Caroline A Beaner, CRT[1] and Carson P Sievert, MS[2]

Abstract

Introduction: The goals of bronchiectasis treatment are to mobilize airway secretions to reduce pulmonary infections, minimize the number of respiratory exacerbations, enhance ventilation, and improve a person's quality of life. High frequency chest wall oscillation (HFCWO) is widely used for improving airway clearance in patients with a range of diseases and conditions that clinically benefit from increased bronchial drainage. However, only a limited number of studies have evaluated the use of HFCWO in patients with non-cystic fibrosis bronchiectasis. This case review study was designed to assess the clinical outcomes of the SmartVest® Airway Clearance System (Electromed, Inc, New Prague, MN, USA) on exacerbation-related healthcare utilization and medication in subjects with non-cystic fibrosis bronchiectasis.

Methods: Subjects (N=59) with confirmed 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 were included. Subjects were also contacted and interviewed by phone to collect information regarding exacerbation-related healthcare utilization and medication needs during the first year after the start of SmartVest therapy. The frequency of hospitalizations, total number of hospital and emergency room (ER) visits, and antibiotic and steroid use for one year before and after initiation of SmartVest therapy were determined. Compliance to treatment, as prescribed by the subject's physician, was also determined. To provide statistical evidence that SmartVest therapy significantly decreased these frequencies, a paired t-test was used.

Results: The number of subjects hospitalized for a bronchiectasis related exacerbation was approximately 1.5 fold lower (P=0.007) after using the SmartVest for one year (10 of 59 or 17%) compared to the year before SmartVest use (17 of 59 or 29%). In addition, 11 of the 17 subjects (65%) who reported a hospital admission prior to SmartVest use did not require a hospital readmission for an exacerbation after SmartVest use. The number of ER visits decreased 63% (from 8% to 3%, p=0.083) with the use of SmartVest. The percentage of subjects using antibiotics decreased from 74% in the year prior to SmartVest therapy to 44% in the year following initiation of therapy (P=0.0000047). The number of antibiotic prescriptions per subject declined with SmartVest use (from 1.9 to 1.3 per subject) as well as the prescriptions per the entire study population (from 1.4 to 0.6 per population). SmartVest therapy was also associated with a greater than six fold decrease (19% vs. 3%) in steroid use (P=0.0020). Although not included in the phone interview call protocol, 40 of the 59 subjects (68%) interviewed reported a significant improvement in their quality of life.

Conclusion: This outcomes-based case review of SmartVest use demonstrated a statistically significant reduction in bronchiectasis-related healthcare utilization and antibiotic and steroid use. The results validate and are consistent with the SmartVest's clinical utility of improving pulmonary mucus clearance and bronchial drainage and decreasing respiratory related exacerbations in non-cystic fibrosis bronchiectasis patients.

Introduction

Bronchiectasis is defined as an irreversible dilation and destruction of the bronchi with significantly reduced clearance of pulmonary secretions.[1,2] The disease is associated with recurrent lower respiratory infections, inflammation, reduction in pulmonary function, impaired respiratory secretion clearance, increased hospitalizations and medication use, and increased morbidity and mortality.[3-5] The overall prevalence of non-cystic fibrosis bronchiectasis is about 52 per 100,000 adults and the mean age at diagnosis is 61 years.[6] The incidence of hospitalization due to non-cystic fibrosis bronchiectasis is rising and is markedly increased for patients 50 years of age or older.[5,6] Bronchiectasis patients annually averaged: 6 more outpatient encounters, 27 more days of antibiotic treatments, and 2 more days in the hospital.[6,7] In 2005, the estimated cost for non-cystic fibrosis bronchiectasis was $630 million annually in the United States.[6,7]

The goals of bronchiectasis treatment are to mobilize airway secretions to reduce respiratory infections, minimize the number of exacerbations, enhance ventilation, and improve a person's quality of life.[8,9] Patients with non-cystic fibrosis bronchiectasis can have difficulty clearing airway secretions, and can benefit from airway clearance therapy.[6] Efficient removal of retained respiratory secretions, in addition to the use of antibiotics and other medications can lessen episodes of acute illness and slow the rate of progressive deterioration.[6,10] A number of therapeutic methods are currently used to clear airway secretions in patients with pulmonary disease, respiratory mucus impairment, or who are at risk of developing either one of those conditions.[8] These methods generally aim to promote secretion clearance by

[1]Electromed Inc., 500 6th Ave NW, New Prague, MN. [2]Department of Statistics at Iowa State University, Ames, IA.

Outsmart the Cycle of Chronic Lung Infection

Managing Bronchiectasis with the SmartVest® Airway Clearance System

The clinical efficacy of an HFCWO (high frequency chest wall oscillation) system can be measured by comparing clinical outcomes before and after consistent use.

An outcomes-based case review assessed the clinical efficacy of the SmartVest® Airway Clearance System on exacerbation-related healthcare utilization and medication in patients with non-cystic fibrosis bronchiectasis.

This case review study supported the clinical utility of the SmartVest system by improving airway clearance and bronchial drainage for patients with non-cystic fibrosis bronchiectasis.

Engineered and Built in Minnesota.

The SmartVest system was associated with a significant reduction in bronchiectasis-related healthcare utilization.

One year pre-SmartVest

One year post-SmartVest

Number of Hospitalizations
per study sample (N=59)

60%
decrease in ER visits

6×
reduction in steroid use

57%
fewer antibiotic prescriptions

68% of interview subjects unreservedly reported a significant improvement in quality of life, although not included in the phone interview protocol.

Learn more about managing bronchiectasis with the SmartVest® Airway Clearance System.

Visit www.smartvest.com or contact Electromed at 800.462.1045.

smartvest®
AIRWAY CLEARANCE SYSTEM
BY ELECTROMED, INC.

reducing mucus viscosity and using shear forces to release the mucus from the lung wall.

High frequency chest wall oscillation (HFCWO) is used for airway clearance in patients with a range of diseases and conditions, including genetic and immunological disorders, neuromuscular diseases, and obstructive pulmonary conditions such as asthma and chronic obstructive pulmonary disease (COPD).[11-14] A number of clinical studies have demonstrated the safety and efficacy of HFCWO, primarily in patients with cystic fibrosis.[6,11,15-17] Typically, HFCWO delivers compression pulses to the chest wall through an inflatable vest (or wrap) connected to an air pulse generator.[6] The generator produces an alternating flow of air into the vest that rapidly compresses and releases the chest wall at a variety of selectable frequencies and pressures, resulting in an oscillation in airflow within the airways that act to loosen, thin, and propel mucus toward the major airways where it can be expectorated or suctioned away.[18,19] During HFCWO, all segments of the lungs are treated simultaneously.[6] HFCWO can lead to changes in lung volume of 15 to 57 mL and in flow up to 1.6 L/s, which generate effective coughing to mobilize secretions.[20] The therapy requires minimal activity from the user and is technique independent.[6]

Although HFCWO is well tolerated and has shown efficacy in improving mucociliary clearance in patients with cystic fibrosis, there is currently very little evidence of usage or benefit in adults with non-cystic fibrosis bronchiectasis.[20] Knowing the clinical utility and efficacy of a given device are of considerable clinical importance and also impacts patient accesses to this technology. Clinical efficacy is one of the considerations used by Medicare, Medicaid, and private insurers to make coverage and reimbursement decisions. The objective of this outcomes-based case review study was to determine whether that SmartVest Airway Clearance System (Electromed, Inc., New Prague, MN, USA) was associated with a reduction in exacerbation-related healthcare utilization and medication use in patients with non-cystic fibrosis bronchiectasis.

Methods

The study was performed in accordance with the declaration of Helsinki. The Western Institutional Review Board waved the necessity of the protocol being reviewed by an Institutional Review Board, and the requirement for obtaining written informed consent from subjects, as all subjects had signed a HIPAA privacy agreement prior to the release of their medical records to the study's sponsor.

Study Subjects

Patients 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 were eligible for study recruitment. Subjects, who had not been compliant with SmartVest therapy as prescribed by their physician, had died, or who were unable to be contacted by phone were excluded from the study. Compliance was determined by patient follow-up via phone interview, returned compliance report or recorded clock hours in the generator.

Study Design

The Electromed patient database, which includes patient medical records, was screened for potential subjects who met the inclusion/exclusion criteria. Patient medical records were reviewed for all bronchiectasis-related exacerbations that occurred within one year of starting SmartVest therapy, and the number hospitalizations, ER visits, and antibiotic and/or steroid use exclusively related to the subject's existing respiratory condition were also recorded. All prior use of any alternative airway clearance devices prior to using the SmartVest was also recorded. Subjects were contacted and interviewed by phone to collect the same information for the one year following initiation of SmartVest therapy. All phone interviews were performed by the same licensed respiratory therapist (C Beaner).

The questionnaire was developed by Electromed for the exclusive purpose of this study. During the phone interview, the subject was asked the following questions:

1. Are you still using the SmartVest according to your Doctor's prescription? If no, when did you stop using it?
2. Since you began using the SmartVest, have you required treatment with antibiotics or prednisone to treat a respiratory infection?
3. Since you began using the SmartVest, have you required hospitalization related to your respiratory condition? If yes, where?
4. Since you began using the SmartVest, have you required a visit to the emergency room related to your respiratory condition? If yes, where?

All data was summarized descriptively. To provide evidence that SmartVest therapy significantly decreased these frequencies, a paired t-test was used.

Results

Of the 104 bronchiectasis subjects identified from the Patient Database who met the inclusion/exclusion criteria, two were found to be deceased per data base review. Of the remaining 102 subjects, all received a phone call attempt. Fifty-nine subjects met the inclusion/exclusion criteria required to be included in the study. The other 43 subjects were not included in the study for several reasons: eight were not able to be contacted due to incorrect contact information, 2 were reported to be deceased by the caregiver, 1 subject was incoherent, 25 subjects did not respond to calls and/or multiple voicemail messages, and seven subjects were found to be noncompliant with SmartVest treatment as prescribed by their physician.

SmartVest treatment was associated with reduced bronchiectasis-related healthcare utilization (Table 1). The number of subjects hospitalized for a bronchiectasis related exacerbation was approximately 1.5 fold higher (P=0.007) during the year prior to SmartVest use (17 of 59 or 29%) compared to one year after its use (10 of 59 or 17%). Of those hospitalized, 11 of 17 subjects (65%) who reported an admission prior to SmartVest use did not require a readmission for an exacerbation after one year of SmartVest use. The number of ER visits decreased from 8% to 3% (63% decrease) with the use of the SmartVest. The subjects that had ER visits prior to SmartVest use of were not the same subjects who visited the ER after starting therapy.

The use of SmartVest was associated with a statistically significant decrease in the use of antibiotics and steroids for treating a bronchiectasis related exacerbation (P=0.000004 and P=0.002 respectively). The percentage of subjects using antibiotics decreased from 74% prior to SmartVest use to 44% after one year of SmartVest therapy. The number of prescriptions

also decreased per subject who used an antibiotic (from 1.9 to 1.3 per subject) as well as the prescriptions per the entire study population (from 1.4 to 0.6 per population). SmartVest therapy was also associated with a greater than six fold decrease (19% vs. 3%) in steroid use (P=0.0020).

Although not included in the phone interview protocol, 40 of the 59 subjects (68%) interviewed unreservedly reported a significant improvement in their quality of life.

Table 1. Summary of outcomes for one year prior and one year after initiating the use of SmartVest for bronchiectasis (N=59)

	Pre-SmartVest Use	Post-SmartVest Use
Hospitalizations		
Number hospitalized, n (%)	17 (29%)	10 (17%)
Total number of hospitalizations, n	29	12
Average hospitalizations per subject (n=17)	1.7	1.2
Average number of hospitalizations per study population (n=59)	0.5	0.2
Hospital readmissions ER visits, n (%)	NA 5 (8%)	4 of 17 2 (3%)
Antibiotic use, n (%)	44 (74%)	26 (44%)
Total number of prescriptions, n	83	36
Average number of prescriptions per subject (n=44)	1.9	1.3
Average number of prescriptions per study population (n=59)	1.4	0.6
Steroid use, n (%)	11 (19%)	2 (3%)

Discussion

Non-cystic fibrosis bronchiectasis is a serious progressive condition related to permanent and abnormal widening of the airways which may require extensive medical care including medications and hospitalizations. Currently, there is limited information regarding the efficacy of treating non-cystic fibrosis bronchiectasis with HFCWO, and no prior study has evaluated the use of SmartVest in this patient population. This case review outcome study was designed to gain insight into the efficacy of the SmartVest system in treating non-cystic fibrosis bronchiectasis by evaluating changes in bronchiectasis-related healthcare utilization and medication use due to a related exacerbation following one year of SmartVest treatment. We found that SmartVest was associated with a significant reduction in hospitalizations both per patient and per study population. It also resulted in a significant reduction of associated medication use, including a reduced number of antibiotic prescriptions and steroid use both per subject and per study population.

Our findings are consistent with SmartVest's clinical utility of improving airway clearance and bronchial drainage in patients with a range of diseases and conditions. The improvement in airway clearance and sputum production is reported by a prior study that evaluated SmartVest in the treatment of subjects with moderate chronic obstructive pulmonary disease (COPD) (N=22).[21] Subjects received four weeks of SmartVest therapy. Use of SmartVest was associated with a decline in sputum production, although this did not reach statistical significance compared with conventional treatment; the mean change in sputum volume was –2.6 mL (range –53 to +27 mL) for SmartVest, and +6 mL (range –70 to +40 mL) for conventional treatment (P=0.06). The degree of sputum volume decrease was related to baseline sputum production (P=0.02). The HFCWO modality delivered by the SmartVest system was well tolerated in patients who often had significant disability including shortness of breath at rest. No subjects dropped out due to intolerance of the device.

Chakravorty, et. al., (2011) also found that there was clinically improvement in patient reported quality of life with SmartVest therapy. Subjects reported improvement in the five-symptom score (rating of cough, sputum, wheeze, shortness of breath, and exercise tolerance) (P=0.02).[21] SmartVest therapy significantly improved the symptom dimension of the St. George's Respiratory Questionnaire (SGRQ) (P=0.02), an instrument that evaluates health-related quality of life.[21] In contrast, there was no change in the self-reported symptom or SGRQ scores in patients who received conventional treatment.[21] Although, we did not prospectively plan to collect quality of life information during our study, 68% of the subjects during the phone interview commented that the use of SmartVest had appreciably improved their quality of life.

Medicare, Medicaid and other insurance policies for coverage and reimbursement of HFCWO therapies tend to be similar. Medicare will cover HFCWO for bronchiectasis if the patient has a confirmed diagnosis, has a history of more than two exacerbations per year requiring antibiotics or documentation of a daily productive cough for at least 6 continuous months, and well-documented failure of standard treatment devices (eg, positive expiratory pressure (PEP)) to adequately mobilize secretions. The efficacy in airway clearance demonstrated by HFCWO in different populations, use of SmartVest in patients with COPD, and now by this bronchiectasis outcomes-based study supports the argument for insurance coverage by payers. Importantly, the use of SmartVest significantly decreased the number of hospitalizations and antibiotic/steroid use in this study. The reduction of hospitalizations, including readmissions, would be expected to significantly impact healthcare costs, as the cost of inpatient care is high; a study performed in 2009 found that median cost of inpatient care from 1993 to 2006 for non-cystic fibrosis bronchiectasis was $7,837 (USD).[5] The same study found that the annual age-adjusted hospitalizations rate was 16.5 hospitalizations per 100,000 population.[5] This is particularly important in older patients as the rate of hospitalization markedly increases above the age of 50 years, and particularly in older women.[5] A 2005 study found that patients with non-cystic fibrosis bronchiectasis averaged 2.0 additional days in the hospital, had 6.1 additional outpatient encounters, 27.2 more days of antibiotic therapy, and total excess medical expenditure of $5681 (USD).[6,7]

In conclusion, this study found that SmartVest significantly reduced bronchiectasis-related healthcare utilization and antibiotic and steroid use which is consistent with SmartVest's clinical utility of improving airway clearance and bronchial drainage. Larger studies are planned to further evaluate the efficacy and cost-benefit of SmartVest in treating bronchiectasis patients.

References

1. Barker AF. Bronchiectasis. N Engl J Med. 2002;346(18):1383-1393. 10.1056/NEJMra012519
2. Habesoglu MA, Ugurlu AO, Eyuboglu FO. Clinical, radiologic, and functional evaluation of 304 patients with bronchiectasis. Ann Thorac Med. 2011;6(3):131-136. 10.4103/1817-1737.82443

3. King PT, Holdsworth SR, Freezer NJ, Villanueva E, Gallagher M, Holmes PW. Outcome in adult bronchiectasis. COPD. 2005;2(1):27-34.
4. Alzeer AH, Masood M, Basha SJ, Shaik SA. Survival of bronchiectatic patients with respiratory failure in ICU. BMC Pulm Med. 2007;7:17. 10.1186/1471-2466-7-17
5. Seitz AE, Olivier KN, Steiner CA, Montes de Oca R, Holland SM, Prevots DR. Trends and burden of bronchiectasis-associated hospitalizations in the United States, 1993-2006. Chest. 2010;138(4):944-949. 10.1378/chest.10-0099
6. Braverman J, Miller H. High-frequency chest compression: a practical therapy for patients with bronchiectasis. Respiratory Therapy. 2008;3(1):22-26.
7. Weycker D, Edelsberg J, Oster G, Tino G. Prevalence and economic burden of bronchiectasis. Clinical Pulmonary Medicine. 2005;12:205-209.
8. Fibrosis. AoCPiC. Standards of care and good clinical practice for the physiotherapy management of cystic fibrosis 2011 [cited 2016 January 4]. Available from: https://www.cysticfibrosis.org.uk/media/82076/CD_Standards_of_Care_Physio_Jun_11.pdf.
9. O'Donnell AE. Bronchiectasis. Chest. 2008;134(4):815-823. 10.1378/chest.08-0776
10. McShane PJ, Naureckas ET, Tino G, Strek ME. Non-cystic fibrosis bronchiectasis. Am J Respir Crit Care Med. 2013;188(6):647-656. 10.1164/rccm.201303-0411CI
11. Arens R, Gozal D, Omlin KJ, et al. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. Am J Respir Crit Care Med. 1994;150(4):1154-1157. 10.1164/ajrccm.150.4.7921452
12. Fink JB, Mahlmeister MJ. High-frequency oscillation of the airway and chest wall. Respir Care. 2002;47(7):797-807.
13. Hansen LG, Warwick WJ. High-frequency chest compression system to aid in clearance of mucus from the lung. Biomed Instrum Technol. 1990;24(4):289-294.
14. Lange DJ, Lechtzin N, Davey C, et al. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. Neurology. 2006;67(6):991-997. 10.1212/01.wnl.0000237439.78935.46
15. Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. Pediatr Pulmonol. 1991;11(3):265-271.
16. Kluft J, Beker L, Castagnino M, Gaiser J, Chaney H, Fink RJ. A comparison of bronchial drainage treatments in cystic fibrosis. Pediatr Pulmonol. 1996;22(4):271-274. 10.1002/(SICI)1099-0496(199610)22:4<271::AID-PPUL7>3.0.CO;2-P
17. Scherer TA, Barandun J, Martinez E, Wanner A, Rubin EM. Effect of high-frequency oral airway and chest wall oscillation and conventional chest physical therapy on expectoration in patients with stable cystic fibrosis. Chest. 1998;113(4):1019-1027.
18. Osman LP, Roughton M, Hodson ME, Pryor JA. Short-term comparative study of high frequency chest wall oscillation and European airway clearance techniques in patients with cystic fibrosis. Thorax. 2010;65(3):196-200. 10.1136/thx.2008.111492.
19. Chatburn RL. High-frequency assisted airway clearance. Respir Care. 2007;52(9):1224-1235; discussion 1235-1227.
20. Nicolini A, Cardini F, Landucci N, Lanata S, Ferrari-Bravo M, Barlascini C. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. BMC Pulm Med. 2013;13:21. 10.1186/1471-2466-13-21
21. Chakravorty I, Chahal K, Austin G. A pilot study of the impact of high-frequency chest wall oscillation in chronic obstructive pulmonary disease patients with mucus hypersecretion. Int J Chron Obstruct Pulmon Dis. 2011;6:693-699. 10.2147/COPD.S22896

Using Extracorporeal Membrane Oxygenation (ECMO) to Prevent Lung Injury in the Mechanically Ventilated Patients with Acute Respiratory Distress Syndrome (ARDS): Is there a Best Strategy?

Kenneth Miller MEd, MSRT, RRT-ACCS, NPS, AE-C, FAARC

Abstract

Acute respiratory distress syndrome (ARDS) is a common complication of critical illness. Mortality is high, and survivors often have long-term complications. Although mechanical ventilation is life-sustaining for patients with ARDS, it can perpetuate lung injury. Clinical and laboratory research suggest that repetitive overstretching or collapse of lung units with each respiratory cycle can generate local and systemic inflammation, contributing to multi-organ failure and death. Recently, the utilization of extracorporeal membrane oxygenation (ECMO) has been advocated to "rest and protect the lung" during ARDS. The clinical rationale for this intervention is to allow the ECMO device to maintain gas exchange and while utilizing the ventilator to gently ventilate the lungs, maintain lung inflation and minimize any additional lung injury.

Using Extracorporeal Membrane Oxygenation (ECMO) to Prevent Lung Injury in the Mechanically Ventilated Patient with Acute Respiratory Distress Syndrome (ARDS): Is there a Best Strategy?

Advances in medical care and technology created the need for progressive and creative approaches to health care delivery practices and processes. The number of chronic and complex medical conditions present in the American population continues to increase generating the escalation in acute care costs and demand for services. Frequently conventional mechanical ventilation strategies are insufficient for treating a critical care patient's declining pulmonary condition. Emergence of the use of extracorporeal membrane oxygenation (ECMO) for patients in acute respiratory distress syndrome (ARDS) shifts the pathophysiologic process of oxygenation from an internal process within the body to an external process occurring through a machine. Despite the improved oxygenation EMCO facilitates, respiratory care providers must use various strategies to ensure optimal, sustained ventilation of the lungs while preventing additional lung injury. The purpose of this paper is to discuss various lung protective strategies used during ECMO therapy and describe the rational for use to achieve optimal patient outcomes.

Pathophysiology of ARDS

Acute respiratory distress syndrome, previously known as respiratory distress syndrome, or shock lung, is a severe, life-threatening medical condition characterized by widespread inflammation in the lungs. This condition may be triggered by various clinical insults such as trauma, pneumonia and sepsis that precipitate acute lung injury characterized by rapidly progressive hypoxic respiratory failure (Collins & Blank, 2010). ARDS is a disease of the alveoli, the microscopic air sacs of the lungs, leading to decreased exchange of oxygen and carbon dioxide resulting in arterial blood gas anomalies. Pulmonary pathologic changes associated with ARDS include the release of inflammatory chemicals, breakdown of the cells lining in the pulmonary vessels, surfactant loss creating increased surface tension, fluid accumulation, and excessive scarring. Diffuse alveolar damage results in acute inflammation of the alveolar walls with hyaline membranes is consistently present in ARDS patients. Often the alveoli are heterogeneous in configuration generating an increased propensity of ventilator induced trauma by hyper-inflation of healthy or less sick alveoli and hypo-inflation of sick or ill alveoli (Collins & Blank, 2010). The mortality rate with ARDS varies widely based on disease severity, the patient's age, and the presence of other underlying medical conditions but had a general mortality rate of between 20-50 percent (Amato et al, 2015).

Mechanical Ventilation Effects of ARDS

Mechanical ventilation support is the one of the cardinal clinical interventions in the treatment of acute respiratory distress syndrome. Its purpose is to provide adequate gas exchange and maintain lung inflation. Unfortunately, based on the pathophysiology associated with ARDS, mechanical ventilation can be responsible for producing significant lung injury (Litell, Gong, Talmor, & Gajic, 2011). In ARDS, lung units may have heterogeneous configuration producing some lung units that are fully injured, some partially injured, and others without injury at all. This heterogeneity creates unequal gas distribution of the mechanically ventilated breath causing ventilator-induced lung injury (VILI). Further over-inflation results precipitating injury to healthy normal lung units and the lack of gas inflation to the sick or injured lung units (Beitler, Schoenfeld, & Thompson, 2014). Ventilator induced lung injury is the result of various types of lung trauma.

Barotrauma is one type of trauma that occurs when lung units are exposed to ventilator airway pressures greater than 35cm/H_2O. These high airway pressures, often referred to as alveolar distending pressures, can cause mechanical trauma of the alveoli and promote capillary leakage resulting in a congested or collapsed lung unit. If the high airway pressures

Kenneth Miller is a Clinical Educator, Dean of Wellness, Respiratory Care Services, Lehigh Valley Health Network, Allentown, Pa.

Figure 1. Example of the Pressure/Volume tool on the HAMILTON-G5 ventilator. Note the lower inflection point (setting of PEEP) is approximately 20-22cm/H_2O for this ARDS patient.

Figure 2. Transpulmonary monitoring indicating correct PEEP setting denoted by Ptrans E 1.3cm.

are transmitted to severely injured alveoli, alveolar rupture and a potential pneumothorax may occur. One gold standard target of lung protective ventilation is to maintain an alveolar distending pressure below 35cm/H_2O to minimize the chance of VILI (ARDS Definition Task Force, 2012).

A second form of VILI is volutrauma. This occurs when the ARDS lung is exposed to large distending tidal volumes. Alveolar distention can result in a self-perpetuating cascade of alveolar-capillary facture and pulmonary inflammation leading to worsen alveolar diffusion capacity resulting in significant gas exchange impairment (Brower et al, 2004). High tidal volume delivery above 12cc/kilogram of the patient's ideal body weight (IBW) along with distending pressures above 35cm/H_2O can result in alveolar injury and actually mimic the ARDS pathology that is being treated. During mechanical ventilation of ARDS all efforts should be aimed at the delivery of tidal volumes of 12cc/kg/IBW with the focused target delivery of between 6-8cc/kg/IBW to maximize lung protective ventilation. A reduction in ARDS mortality and morbidity was noted by 22% when mechanical ventilation was provided with lower tidal volumes and distending pressures (Acute Respiratory Distress Syndrome [ARDS] Network, 2001).

The third form of VILI is shear trauma also referred to as atelectasis collapse trauma or rapid alveolar collapse. Lung units inflated at high volumes and/or pressures coupled with inadequate amount of pressure or volume remaining in the unit promotes unit collapse. The next ventilated breath will require a higher opening pressure to expand the unit. If this cascade of open and collapsing continues, alveolar stain will result, leading to a fractured lung unit incapable of participating in gas exchange. The collapse of the alveolus can also result in surfactant inactivation progressing into more alveolar de-recruitment requiring a higher distending pressure to re-expand the inured lung unit. To prevent this phenomenon, it is imperative to maintain an expiratory pressure above the critical closing pressure. Application of an adequate and consistent amount of positive end expiratory pressure reduces the amount of lung collapse. This is critical if high distending pressures and high tidal volume delivery are required to maintain adequate gas exchange (Schmidt et al, 2014).

Bio-trauma is another consequence of ventilator induced trauma. Bio-trauma is the result of an inflammatory response of the body as the result of lung injury. Cytokine release occurs with any type of barotrauma, volutrauma or shear trauma generating a systemic inflammatory response. This response further accelerates distal organ failure escalating the morbidity and mortality of the ARDS patient.

Mortality increased by 18-20% with every additional organ that fails. The majority of ARDS patients die as a result from multi-system organ failure rather than hypoxemic failure (Amato et al, 2015). Based on the clinical experience and research, preventing ventilator-induced trauma during the management of ARDS is paramount in optimizing outcomes. The goal of mechanical ventilation is to facilitate gas exchange, lung inflation, and minimize the chance of causing VILI. Respiratory care practitioners must identifying effective strategies that will maintain that fine balance between adequate ventilation and iatrogenic lung injury production in the current acute care environment.

Extracorporeal Membrane Oxygenation

Extracorporeal membrane oxygenation (ECMO) is a clinical intervention that minimizes the reliance of mechanical ventilation, thereby reducing the chance of VILI. According to the Extracorporeal Life Support Organization, ECMO is "the use of mechanical devices to temporarily support heart or lung functions during cardiopulmonary failure, leading to organ recovery or replacement." Treatment with ECMO is indicated for patients with severe heart or lung failure who are at a high mortality risk despite optimal conventional therapy. During ECMO therapy, blood is circulated away from the patient's body by a mechanical pump; oxygen and carbon dioxide are exchanged in an oxygenator; blood is then pumped back into the body through the use of large cannula. Percutaneous cannulation is possible for both methods in up to 90% of adults (Franco, Enders, Wilson, Gajic, & Pannu, 2016).

ECMO can be configured as venovenous (V-V) or venoarterial (V-A), depending on the need for pulmonary or cardiopulmonary support. Carbon dioxide removal is accomplished by the sweeping of gas by a set liter flow. In both methods, blood is

removed from the inferior and/or superior vena cava. The type of ECMO determines the location for the return of oxygenated blood. In V-V ECMO therapy, oxygenated blood is returned to the right atrium. This method relies on the patient's adequately functioning heart to circulate the newly oxygenated blood but allows the lungs to rest without the need for high oxygen concentrations or ventilation pressures that might exacerbate the underlying cause of ARDS. ECMO therapy is the most commonly used method to treat patients with ARDS, provided patients show no evidence of cardiac compromise (Betit, 2009).

V-V ECMO therapy may be done using two cannulation sites. In this approach, blood is typically removed from the inferior vena cava via femoral vein cannulation and oxygenated blood is reinfused into the right atrium, most commonly via the right internal jugular vein. This type of ECMO therapy may also be performed via a single-access site using a dual lumen cannula (Avalon) inserted into the right internal jugular vein. This carefully placed cannula allows deoxygenated blood to be removed through single lumen of the catheter via ports located in the superior and inferior vena cava, and the oxygenated blood is then returned to the right atrium via a second lumen of the same catheter (Betit, 2009).

During ECMO utilization, the primary goal is to allow oxygenation and carbon dioxide removal to be accomplished using the external ECMO oxygenator and sweep liter flow. The role of mechanical ventilation is to provide lung inflation, airway patency, and back-up of gas exchange in any patient that the ECMO parameters have been maximized or if ECMO circuit failure occurs. The patient is generally placed on "rest ventilator parameters" to minimize the chance of VILI. Typically, the goal is maintain an alveolar distending pressure (plateau pressure) of 25cm/H_2O or less, PEEP of 10cm/H_2O or less and tidal volume delivery of 6cc/kg/IBW or less. By adhering to this ventilator strategy, the chance of alveolar stretch and strain should be maintained at a safe level. However, if ventilator parameters are set to conservatively, the lungs may become under-inflated and become difficult to re-inflate post ECMO (Schmidt et al, 2014).

During ECMO all other aspects of ventilator management and patient care need to be addressed and maintained. Providing airway patency, secretion removal, treatment of bronchospasm, promoting spontaneous breathing, frequency repositioning, and adequate sedation are very important to insure a smooth transition from ECMO decannulation to ventilator liberation. Recently, the "rested lung" concept has been debated as the best strategy during ECMO cannulation (Beitler et al, 2014). There has been debate among respiratory and medical clinicians that the lungs during ECMO could be maintained safety with other ventilator strategies and interventions (Schmidt et al, 2014).

ARDS Treatment Strategies

Historically, the ARDS treatment goal is supportive in nature and aims at minimizing additional iatrogenic lung injury by utilizing a wide array of clinical interventions (Beitler et al, 2014). Although the ARDS treatment goal is clear, the strategies used to attain the goal remain vast and have inconsistent and disappointing results (Litell et al, 2011). Individual patient condition determines the necessary strategy selection to optimize the patient's lung function for decannulation. V-V ECMO, low tidal volume delivery, transpulmonary monitoring, airway pressure release ventilation, inhaled pulmonary vasodilator medications, prone positioning, intravenous administration of neuromuscular blocking agents, and high frequency percussive ventilation are all appropriate strategies for maintaining lung function during the "resting" period of V-V ECMO therapy.

Low Tidal Volume Delivery

Different lung protective approaches during ECMO implementation have been postulated. The primary and most commonly supported strategy is the use of a lung protective approach during mechanical ventilation. Setting a low tidal volume, minimizing airway pressures, and employing an adequate amount of PEEP appears to be a sound recommendation (Armato et al, 2015). Since the main goal of ECMO utilization is to minimize lung injury and this strategy meets that objective. However, if the patient's ventilatory needs are unmet, the PEEP applied is incorrectly set, and the ventilator pressure is not reflective of the true transpulmonary pressure, lung protection may fail. Often ventilator settings are based on a protocol which reflects a generalized strategy to ventilator management during ECMO. This generic prescription can be markedly unsatisfactory in patients that are morbidly obese, fluid overloaded, exhibit high work of breathing requirements, and have mixed respiratory etiologies.

Identifying the appropriate PEEP setting may be best accomplished by the utilization of a pressure-volume tool that systematically inflates and deflates the lung to determine the lower and upper inflation points. This can be beneficial in patients with high chest or abdominal impedance requiring additional splitting to maintain adequate lung inflation. Also the insertion of an esophageal balloon can help differentiate ventilator pressures from transpulmonary pressures and thus help guide the determination of optimal ventilator delivery volumes and pressures. The need for meeting the patient ventilator demand is vital for improved clinical conditions. If the ventilator is set a rest setting and patient is requiring high work of breathing setting the transpulmonary pressure swing may be as detrimental as shear trauma itself (Collins & Blank, 2010). Therefore setting the ventilator at rest setting is not a monolithic strategy that fits all ECMO patients.

Transpulmonary Monitoring

One of the cardinal features of VILI is high distending pressures. However, in many ARDS patients it difficult to rely solely on ventilator delivery pressures to determine if the patient is at risk for VILI. Patients with high chest wall impedance, that are morbid obese, and/or fluid overloaded often do not receive the bulk of delivered pressure via the ventilator (Rodriguez, Bonelli, Sletter, & Attie, 2013). Much of the delivered pressure is attenuated and does not reach the alveolar level for inflation and to participate in gas exchange. These patients are at risk of experiencing under-inflation and developing alveolar collapse on exhalation. The insertion on an esophageal balloon can help differentiae ventilator delivered pressures from true lung pressures. Calculation of transpulmonary pressure (peak airway-esophageal pressure) allows the bedside to safely increase ventilator pressure without risk of VILI in this patient population who develops ARDS (Talmor et al, 2008). Transpulmonary monitoring can also be helpful in assessing the patient lung mechanics when clinical interventions such as diuresis and fluid resuscitation are performed. The goal is to maintain a transpulmonary pressure greater than or equal to 27cm/H_2O for VILI risk-reduction. Esophageal balloon monitoring is contraindicated in patients with esophageal surgical procedures, GI bleeding, and other upper GI disease etiologies. Balloon

placement can be difficult at times and obtaining accurate measurements can be challenging in spontaneously breathing patients further expanding the potential use complications.

Airway Pressure Release Ventilation

Clinicians advocate for airway pressure release ventilation (APRV) as ventilator strategy to provide lung protective ventilation during ECMO utilization (Collins & Blank, 2010). APRV Airway pressure release ventilation has been described as continuous positive airway pressure (CPAP) with regular, brief, intermittent releases in airway pressure. The release phase results in alveolar ventilation and removal of carbon dioxide (CO_2). Airway pressure release ventilation, unlike CPAP, facilitates both oxygenation and CO_2 clearance and originally was described as an improved method of ventilatory support in the presence of ALI and inadequate CO_2 ventilation. This strategy can either augment alveolar ventilation in the spontaneously breathing patient or accomplish complete ventilation in the apneic patient (Fan & Stewart, 2006). The CPAP level drives oxygenation, while the timed releases aid in CO_2 clearance.

Technically, APRV is a time-triggered, pressure-limited, time-cycled mode of mechanical ventilation. In addition, it allows unrestricted, spontaneous breathing throughout the entire ventilatory cycle. Advantages of APRV include significantly lower peak/plateau airway pressures for a given tidal volume, ability to superimpose spontaneous breathing throughout the ventilatory cycle, decreased sedation requirements, and near elimination of neuromuscular blockade administration (Putensen, Theuerkauf, Zinserling, Wriggle, & Pelosi, 2009). The ability of the patient to breath spontaneously during APRV facilitates diaphragmatic activity which in turn results in dorsal dependent lung recruitment not seen with time-cycle volume or pressure target modes. However, theoretical concerns about APRV include the occurrence on intrinsic PEEP if time in at the time low is to brief, and the potential for large tidal volume releases which may result in large pleural-pressure swings. Both of these factors could enhance rather than prevent VILI. Also, the increase in the pleural pressure may be transmitted to the thoracic vasculature and impair venous return and reduce cardiac output, thus resulting in poor tissue oxygenation (Collins & Blank, 2010).

Inhaled Pulmonary Vasodilators

An additional strategy to provide lung protection during ECMO is the administration of pulmonary vasodilators. Inhaled vasodilators such as inhaled nitric oxide (INO) or nebulized Flolan, selectively vasodilates the pulmonary vasculature in ventilated, patent alveoli. This improves ventilation-perfusion matching and hypoxemia while lowering pulmonary arterial pressure. Since these drugs are delivery by the pulmonary route, systemic side effects such as hypotension are often minimized (Collins & Blank, 2010). By reducing the arterial pulmonary pressure, the formation of edema can be stunted and right ventricular load be reduced. Hyper-perfusion of patent alveoli results in a reduction in venous admixture occurs (Collins & Blank, 2010). Both of these mechanisms may improve oxygenation without any increase in ventilator parameters and thus provide a form of lung protection during ECMO (Raoof, Goulet, Esan, Hess, & Sessler, 2011).

Both INO and inhaled prostacyclins have demonstration transient improvement in oxygenation, but currently no study has shown improvement or reduction in mechanical ventilation days (Raoof et al, 2011). INO is very expensive and administration of high levels can result in methemoglobinemia which extends tissue hypoxemia. Prostacyclins are less expensive that INO, but are subject to inconsistent dose delivery and may cause ventilator dysfunction by clogging the expiratory value and thus resulting in airway obstruction (Lui et al, 2010).

Prone Position

Utilization of the prone position has been postulated to reduce VILI during ECMO secondary to the ability to lower ventilator parameters (Culbreth & Goodfellow, 2016). In prone positioning, patients with ARDS are placed on their abdomens for a portion of the day. The concept has been advocated in the literature since 1974 as a way to expand the dependent lung areas (Culbreth & Goodfellow, 2016). In theory, positioning the patient prone promotes expansion of the dependent lung areas opening collapsed alveoli, increasing ventilation capacity, and improving oxygenation. Work of breathing can also be reduced with prone positioning because it reduces the pressure on the lungs from the cardiac structures and abdominal organs. Reducing work of breathing saves vital energy that the patient can use for healing and recovery.

Prone positioning is a generally simple, safe, and noninvasive technique aimed at oxygenation improvement while preventing further pulmonary injury caused by high PEEP, volutrauma, and oxygen toxicity. Oxygen toxicity, or exposure to prolonged or high concentrations of oxygen, can damage the alveolar epithelium, inactivate surfactant, and lead to increased intra-alveolar edema, all of which contribute to increased pulmonary fibrosis (Sud et al, 2010). Prone positioning should be used for a minimum of 16 to 20 hours a day to achieve maximum benefits (Culbreth & Goodfellow, 2016). Sedation administration is required to minimize patient discomfort or anxiety.

Prone positioning can be accomplished manually with a team of clinicians, or mechanically by placing the patient in a specialty bed with pronation capabilities. No published studies advocate one proning method over the other. Clinical studies have demonstrated improvement in oxygenation and survival of ARDS patients when oxygenation is poor despite high ventilator support (Franco et al, 2016). However, prone position is not without its complications. Accident endotracheal dislodgement, facial edema, pressure ulcers, the inability to gain patient access, and clinically assessment are some of the problems that may arise during prone positioning. In summary, prone positioning is not indicated as a routine strategy in ARDS management but may be indicated in patients with severe refractory hypoxemia (Litell et al, 2011).

Administration of Neuromuscular Blockade Drugs

The intravenous administration of neuromuscular blockade, or paralytic, drugs is another clinical intervention that can be used during ECMO management. Patients with ARDS have a high work of breathing secondary to alveolar collapse and re-expansion. This cyclic open and collapsing of the lung unit can be analogous to an individual attempting to inflating 300 million tiny balloons (Hraiech, Forel, & Papazian, 2012). High minute ventilation requires are necessary to eliminate CO_2 adequately secondary to the amount of dead-space ventilation that results from ARDS. High minute ventilation requirement also causes difficulty with ventilator-patient synchrony maintenance. Often large transpulmonary shifts result from

the patient inhaling a high negative pressure topped by a high positive pressure breath delivered by the ventilator. VILI results when the transpulmonary pressure exceeds 30cm/H_2O.

A brief period of chemical paralysis from neuromuscular blocking agents may facilitate lung protective mechanical ventilation by improving patient–ventilator synchrony and allowing for the accurate adjustment of tidal volume and pressure levels (Hraiech et al, 2012). This limits the risk of both asynchrony related alveolar collapse and regional alveolar pressure increases with over distention. Recent data suggests that administration of neuromuscular blocking agents within the first forty-eight hours of disease diagnosis may improve ARDS survival rates (Hraiech et al, 2012). Unfortunately, use of these medications is not without negative consequences. Long-term skeletal muscle weakness, reduced gastrointestinal motility, hemodynamic stress, histamine release, and the loss of neurological assessment are a few of the undesirable events associated with the long term administration of neuromuscular blocking agents.

High Frequency Percussive Ventilation

High frequency percussive ventilation (HFPV) is a ventilatory strategy the employs both sub-tidal volumes (a percussive rate) and the delivery of bulk gas (a pressure-limited breath). HFPV incrementally inflates the lung to a selected level in lung volume before entering an oscillatory equilibrium that ventilates the lung with continuously programmed percussive sub tidal breaths. A unique feature of HFPV is the presence of a phasitron. This piston mechanism situated at the end of the endotracheal tube acts as a sliding venturi and produces a dynamic airway interface through which pulsatile flow is delivered into the lungs. Percussive frequency, inspiratory (I) and expiratory (E) times, plateau, PEEP, and I/E ratio are determinants of mean airway pressure determination. Alone or in combination, these factors modify gas exchange (Chang et al, 2013).

HFPV generates intrabronchial vibrations, airway turbulence and higher airflow, all of which may enhance mobilization and clearance of airway debris and secretions creating additional benefits for its use. This ventilatory pattern helps insure that all alveoli get their share of inspired gas by creating an oscillatory plateau instead of only those that are patent or have quick time filling constants (Kunugiyama & Schulman, 2012). This is a critical factor in ARDS since often the lungs are heterogeneous in disease, having a plethora of different filling times and characteristics. The sub-tidal volumes breaths can stent the airways and provide an endobronchial wedging to facilitate the delivery of the inspired gas and promote lung recruitment.

Providing airway patency allows secretions along with CO_2 can be eliminated from the lungs. This can be beneficial in patients with retained secretions or fluid overloaded. Gas exchange can be regulated by adjustments of either the bulk gas or percussive rate. Negative consequences of HFPV include requirements for chemical paralysis of the patient during utilization, the chance of mucus plugging secondary to movement of distal secretions to more proximal areas, lack of pulmonary assessment secondary to nature of the device, and a lack of true clinical understanding of the ventilator strategy (Chang et al, 2013). Requirement of neuromuscular blocking agents compounds the potential negative side effects of HFPV ventilation as outlined in the previous section.

Discussion

The primary goal of ECMO is to provide gas exchange for patient at risk for ventilator induced injury. So it would be logical to provide a management strategy that provides adequate lung inflation reducing risk of VILI. Respiratory clinicians continue to search for the single strategy that meets the goal and minimizes the risks. Currently, only low-tidal volume, low pressure ventilation has demonstrated a mortality reduction in the treatment of ARDS (ARDS Network, 2001). All other management interventions including ECMO have not resulted in increased survival rates for these critically ill patients. However, recently ECMO has shown promise in improving survival rates in H1N1 flu patients and patients with severe refractory hypoxemia (Schmidt et al, 2014). All other strategies have demonstrated outcome improvements in isolated cases or in a niche patient population (Franco et al, 2016).

APRV could be seen as a lung protective strategy by providing ventilation above the lower inflection point and maintaining gas inflation for several seconds to optimize an equal distribution of gas (Fan & Stewart, 2006). However, critics argue that large release volumes of greater than 12cc/kg/IBW could be lung injurious and counterproductive in attempting lung protective ventilation. Also by increasing the intrathoracic pressures hemodynamic stability and ECMO flow can be compromised. APRV is an appropriate therapy to employ in patients on ECMO with large positive fluid balances and those with high abdominal and thoracic impedance (Putensen et al, 2009).

The administration of inhaled pulmonary vasodilators has demonstrated improvement in oxygenation and reduction of pulmonary hypertension secondary to right ventricular strain. The administration of these drugs cause on apparent to lung tissue and may decrease the need for vasopressors (Lui et al, 2010). However, these drugs fail to maintain lung inflation or provide lung protection. These agents are costly and can cause ventilator malfunction and tissue hypoxia. At best they may improve oxygenation but not long term survival. They can be utilized with ECMO to enhance gas exchange, but do not provide long tern lung protection.

Prone position improves outcomes in patient with severe refractory hypoxemia (Sud et al, 2010). Considering ARDS is a dorsal dependent disease process patients' response to prone position positioning is often positive. By shunting the bulk of perfusion to apical lung units, oxygenation should improve and ventilator parameters could be reduced. But prone positioning is associated with many potential problems that outweigh its positive effects. Accidental extubation, pressure ulceration, and loss of reliable monitoring are consequences that may greatly impede its use. Also the threat of ECMO cannula dislodgement or occlusion could result in a life threatening crisis (Chang et al, 2013). Prone positioning appears to be an alternative or precursor to ECMO instead of a concurrent intervention.

The utilization of neuromuscular blockade medications should be considered as a first line management strategy during ECMO. The combination of attempting to minimize oxygen consumption secondary to a high work of breathing and reducing the possibility of VILI from ventilator asynchrony makes sound judgment (Hraiech et al, 2012). Ideally, these drug administrations should occur only for the first forty-eight hours after ECMO implementation to insure desired patient control. Daily paralytic holidays should be conducted periodically to

perform neurological assessments and decrease the long-term effects of these medications.

HFPV provides both the delivery of percussive and bulk gas breaths. The percussive breaths create an endobronchial wedge and the bulk gas maintains an oscillatory equilibrium (Kunugiyama & Schulman, 2012). The combination of these two mechanisms should provide a lung protective strategy during ECMO by insuring an equal distribution of gas delivery and minimizing VILI. The percussive breaths can help facilitate secretion removal in patients with retained secretion who are requiring frequent bronchoscopies adding another level of effectiveness (Chang et al, 2013). Unfortunately, the inability to measure exhaled gas, assess pulmonary mechanics, and the requirement of paralytic administration during ventilation makes HFPV less that optimal for all patients requiring ECMO. However, it should be considered for ECMO patients with retained secretions, when ECMO oxygenation and sweep parameters are maximized, and when lung compliance remains poor despite high PEEP.

Monitoring transpulmonary pressure can help differentiate thoracic impedance from pulmonary elastic and be reflective of what pressure the lung is being subject to. Using this strategy in conjunction with an open lung tool can help the clinical team set the PEEP above the lower inflection point to help facilitate lung expansion and keep the airway pressure below a value that could cause VILI (Chang et al, 2013). Recommendations outline that these two strategies should be part of any ECMO ventilator regime (Schmidt et al, 2014). All other strategies discussed would be classified as additional rescue or adjunct interventions.

Based on the evidence, the most effective lung protective strategy is a ventilator strategy that maintains gas inflation above the lower inflection while limiting airway pressures above the upper inflection point (Beitler et al, 2014). The utilization of a pressure-volume measurement that assists the clinician to determine the pressure required to inflate and maintain the lung along with identification of the lung over inflation point should be employed on all patients at risk for VILI. Currently the majority of fifth generation ventilators have some "open-lung" tool to obtain these measurements. The procedure usually require a setting of a beginning and end PEEP setting of zero and a pressure high setting 3 to 5cm over the current plateau pressure. This maneuver can be completed in less than thirty minutes. One caveat to performing this measure is that the patient needs to be either highly sedated or chemically paralyzed. There is an additional risk of hemodynamic embarrassment in patients who are hypotensive or vascularly volume depleted. The use of an esophageal monitoring balloon that reflects lung pressures is another method that assists clinicians to determine the true pressure the lung is receiving.

Summary

Providing lung protective ventilation during extracorporeal membrane oxygenation during ARDS management is critical for optimizing survival rates. Insuring that ventilator induced injury is minimized during ECMO management continues to be a consistent primarily goal. It would appear that providing a ventilator strategy that allow for ventilation above the lower infection point, preventing the lung from collapsing, and preventing pressures or volumes above the upper inflection point would be desired end-point. Combined utilization of a pressure/volume tool and transpulmonary monitoring appears to be two adjunctive interventions that can help determine safe ventilator pressures.

HFPV is indicated for patients that are maximized on ECMO parameters and have retained secretions (Collins & Blank, 2010). There is an arsenal of strategies that exist to help achieve these end-points. However, consensus and evidence lacks the best and safest option to utilize during ECMO. Many of strategies have demonstrated oxygenation improvement but not survival benefit. Although advances in medical technology and knowledge have broadened the ARDS treatment methods, effective outcomes require adaptability for respiratory clinicians to change strategies quickly to achieve that intricate balance between patient effectiveness and consequence. Choices between these options are currently based upon clinician familiarity, resource availability, and cost considerations. Changes in patient status will drive the need for an individualized mechanical ventilation strategy to achieve optimal outcomes. More clinical trials need to be conducted to gleam recommendations of a specific best strategy to be utilized during ECMO intervention. Treatment options discussed in this paper all have value in caring for the ECMO patient with ARDS, yet the gold standard promoting the best outcomes is yet to be determined in the published literature or clinical practice.

References

- Acute Respiratory Distress Syndrome Network. (2001). Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. The New England Journal of Medicine, 342, 1301-1308.
- Amato, M., Meade, M., Slutsky, A., Brochard, L., Costa, E., Schoenfeld, D., Stewart, T., Briel, M., Talmor, D., Mercat, A., Richard, J., Carvalho, C., & Brower, R. (2015). Driving pressure and survival in acute respiratory distress syndrome. The New England Journal of Medicine, 372(8), 747-755. doi: 10/1056/NEJMsa1410639
- ARDS Definition Task Force. (2012). Acute respiratory distress syndrome: The Berlin definition. Journal of the American Medical Association, 307(23), 2526-2533. doi: 10.1001/jama.2012.5669
- Beitler, J., Schoenfield, D., & Thompson, B. (2014). Preventing ARDS. Progress, promise, and pitfalls. Chest 146(4), 1102-1113. doi: 10.1378/chest.14-0555
- Betit, P. (2009). Extracorporeal membrane oxygenation: quo vadis? Respiratory Care 54(7), 948-957.
- Brower, R., Lanken, P., MacIntyre, N., Matthay, M., Morris, A., Ancukiewicz, M., Schoenfeld, D., & Thompson, B. (2004). Higher versus lower positive end-expiratory pressures in patients with the acute respiratory distress syndrome. The New England Journal of Medicine, 351(4), 327-336.
- Chang, S., Dabbagh, O., Gajic, O., Patrawalla, A., Elie, M., Talmor, D., Malhotra, A., Adesanya, A., Anderson, H., Blum, J., Park, P., Gong, M. (2013). Contemprorary ventilator management in patients with and at risk of ALI/ARDS. Respiratory Care, 58(4), 578-588.
- Collins, S., & Blank, R. (2010). Approaches to refractory hypoxemia in acute respiratory distress syndrome: Current understanding, evidence, and debate. Respiratory Care 56(10), 1573-1582. doi: 10.4187/respcare.01366
- Culbreth, R., & Goodfellow, L. (2016). Complications of prone positioning during extracorporeal membrane oxygenation for respiratory failure: A systematic review. Respiratory Care, 61(2), 249-254. doi: 10.4187/respcare.03882

- Fan, E., & Stewart, T. (2006). New modalities of mechanical ventilation: high frequency oscillatory ventilation and airway release ventilation. Clinical Chest Medicine, 27(4), 615-625.
- Franco, P., Ender, F., Wilson, G., Grajic, O., & Pannu, S. (2016). A comparative effectiveness study of rescue strategies in 1,000 subjects with severe hypoxemic respiratory failure. Respiratory Care, 61(2), 127-133. doi: 10.4187/respcare.04162
- Hraiech, S., Forel, J., & Papazian, L. (2012). The role of neuromuscular blockers in ARDS: benefits and risks. Current Opinions in Critical Care, 18(5), 495-502. doi: 10.1097/MCC.0b013e328357efe1
- Litell, L., Gong M., Taalmor, D., & Gajic O. (2011). Acute lung injury: Prevention may be the best medicine. Respiratory Care, 56(10), 1546-1554. doi: 10.4187/respcare.01361
- Lui, L., Aldich, M., Shimabukuro, D., Sullivan, Taylor, B., Thorton, K., & Gropper, M. (2010). Rescue therapies for acute hypoxemic failure. Anesthesia & Analgesia, 111(3), 693-702. doi: 10.1213/ANE.0b013e3181e9c356
- Kunugiyama, S., & Schulman, C. (2012). High-frequency percussive ventilation using the VDR-4 ventilator: An effective strategy for patients with refractory hypoxemia. Advances in Critical Care, 23(4), 370-80.
- Putensen, C., Theuerkauf, N., Zinserling, J., Wriggle, H., & Pelosi, P. (2009). Meta-analysis: ventilation strategies and outcome of the acute respiratory distress syndrome and acute lung injury. Annals of Internal Medicine, 151(8), 566-576.
- Raoof ,S., Goulet, K., Esan, A., Hess, D., & Sessler, C. (2011). Severe hypoxemic respiratory failure. Seminars in Respiratory Critical Care Medicine, 32(5), 607-625.
- Rodriguez, P., Bonelli, I., Sletter, M., & Attie, S. (2013). Tranpulmonary pressure and gas exchange during incremental PEEP titration in ARDS patients. Respiratory Care, 58(5), 754-763.
- Schmidt, M., Pellegrino, V., Combe, A., Scheinkestel, C., Cooper, J., & Hodgon, C. (2014). Mechanical ventilation during extracorporeal membrane oxygenation. Critical Care, 18(1), 203-213.
- Sud, S., Friedrich, J., Taccone, P., Polli, F., Adhikari, N., Latini, R., Pesenti, A., Guérin, C., Mancebo, J., Curley, M., Fernandez, R., Chan, M., Beuret, P., Voggenreiter, G., Sud, M., Tognoni, G., Gattinoni, L. (2010). Prone ventilation reduces morality in patients with acute respiratory failure and severe hypoxemia: a systematic review and meta-analysis. Intensive Care Medicine, 36(4), 585-599. doi: 10.1007/s00134-009-1748-1
- Talmor, D.,Sarge, T., Malhotras, A., O'Donnell, C., Ritz, R., Lisbon, A., Novack, V., & Loring, S. (2008). Mechanical ventilation guided by esophageal pressure in ARDS. The New England Journal of Medicine, 359(20), 2095-2114. doi: 10.1056/NEJMoa0708638

Lung Function Improvement With AffloVest® HFCWO Use: A Clinician's Perspective On PFT Score Data From 25 Patients With Cystic Fibrosis

Michelle W Tackett, RRT and Vivian P Henderson, RRT, Knoxville, Tennessee

Chronic pulmonary, respiratory, and neurological diseases and disorders such as cystic fibrosis, bronchiectasis, MD, ALS and others are often complex, life-long conditions that affect the pulmonary, digestive, and other body systems. Patients can have difficulty clearing mucus and pathogens from the lungs which can lead to chronic infections and inflammation. Maintaining airway clearance is critical. Traditionally, treatment has been by Chest Physical Therapy, comprised of postural drainage and/or percussion and/or High Frequency Chest Wall Oscillation (HFCWO) vests utilizing air bladder style technology.

Previous studies, Tecklin, Jan et al[2] and Oermann et al[3] demonstrated improvement, efficacy and patient satisfaction with HFCWO treatment in general. In a previous five-patient study in 2015 conducted by Michael Cooper, RT, Chicago, Illinois[1] treatment with the AffloVest contributed to improved lung function scores compared to previous scores. Average FVC, FEV1, and FEF 25-75% increased 9.5%, 11.5%, and 21.3% respectively with the AffloVest.

The AffloVest technology, which does not utilize an air bladder, is a battery-operated, portable HFCWO device providing patient mobility during treatment. Eight oscillating motors sewn into the vest generate 8 individual oscillation waveforms helping to mobilize secretions in the patient's lungs. These oscillation motors target the different areas of the lungs (upper and lower lobes, front and back). The digital, programmable controller offers 3 oscillation treatments (percussion, vibration, and drainage) and 3 treatment levels (soft/5Hz, medium/13Hz and intense/20Hz). Prescribing clinicians can program customized treatment plans for their patients. The fact that the AffloVest is quiet and truly portable allows the patient to perform normal daily activities during treatment. This may lead to increased patient use of device as stated by the clinicians and patients in this article.

A total of 25 patients were set up on the Afflovest. The data presented in this clincian paper is 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, ACT therapy and comfort of the AffloVest. The 12 patients 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. Patient 6 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.

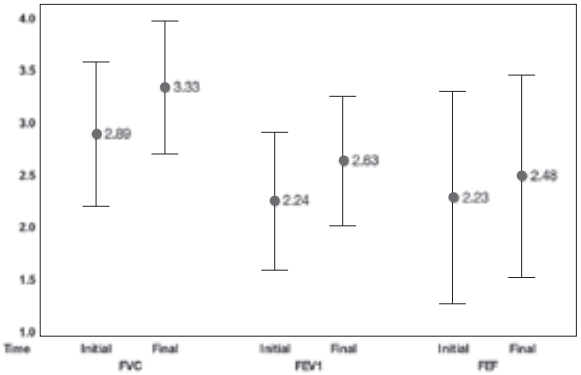
Mean PFT scores and percent increase

	Initial Pre-AffloVest Use Value (Mean)	Final Value (Mean)	% Change Final vs. Initial
FVC (L)	2.89	3.33	+15.22%
FEV1 (L)	2.24	2.63	+17.41%
FEF 25% - 75% (L/sec)	2.23	2.48	+11.21%

Summary

The data collected from these patients show that PFT scores improved in the 12 patients after adopting the AffloVest into their Airway Clearance Treatment (ACT) regimen.

Average FVC increase: 0.45L, +15.22% increase
Average FEV1 increase: 0.39L, +17.41% increase
Average FEF 25-75% increase: 0.26L, +11.21% increase



PFT score means - Final vs. Initial

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 report.

Made In the U.S.A.

Battery operated, portable HFCWO therapy.

AffloVest®
by International Biophysics

Breathe Better. Be Free.

- The AffloVest is the latest in HFCWO technology
- Freedom of movement without external air hoses or bulky generators
- 9 setting variations for individualized treatment
- 7 sizes available
- Quiet and lightweight
- Medicare, Medicaid and Private Insurance reimbursed*

The proof is in the data.

Two clinician papers have demonstrated quantitative improvements in patient lung function through the use of AffloVest**

Download the papers at:
www.afflovest.com/lungfunctionimprovement

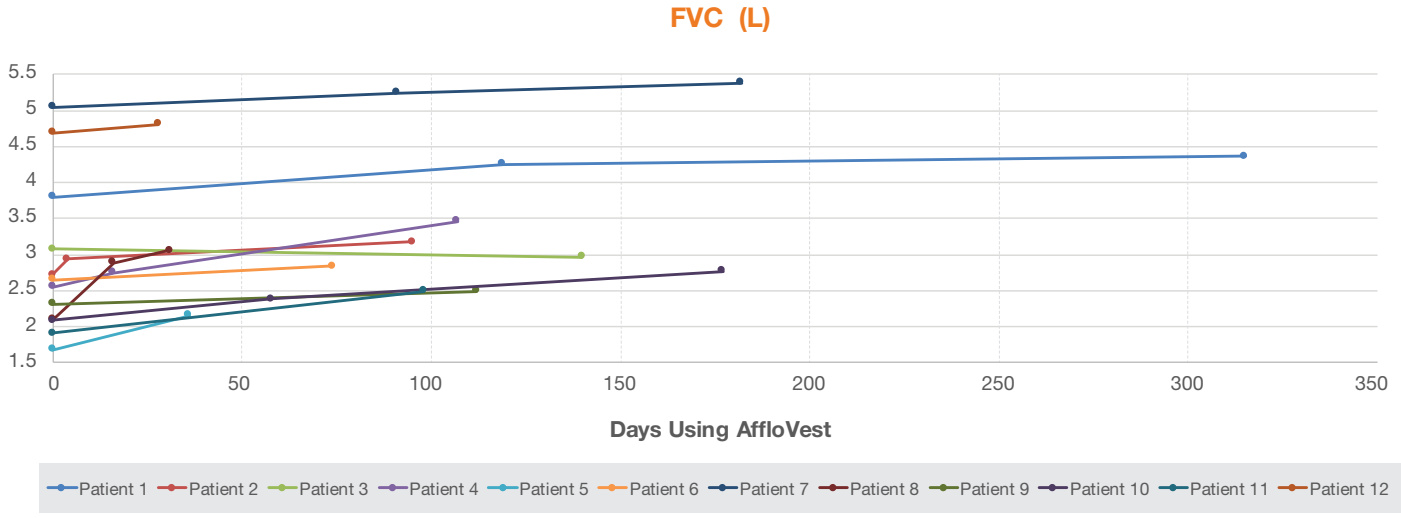
Patents Pending – USA & Worldwide

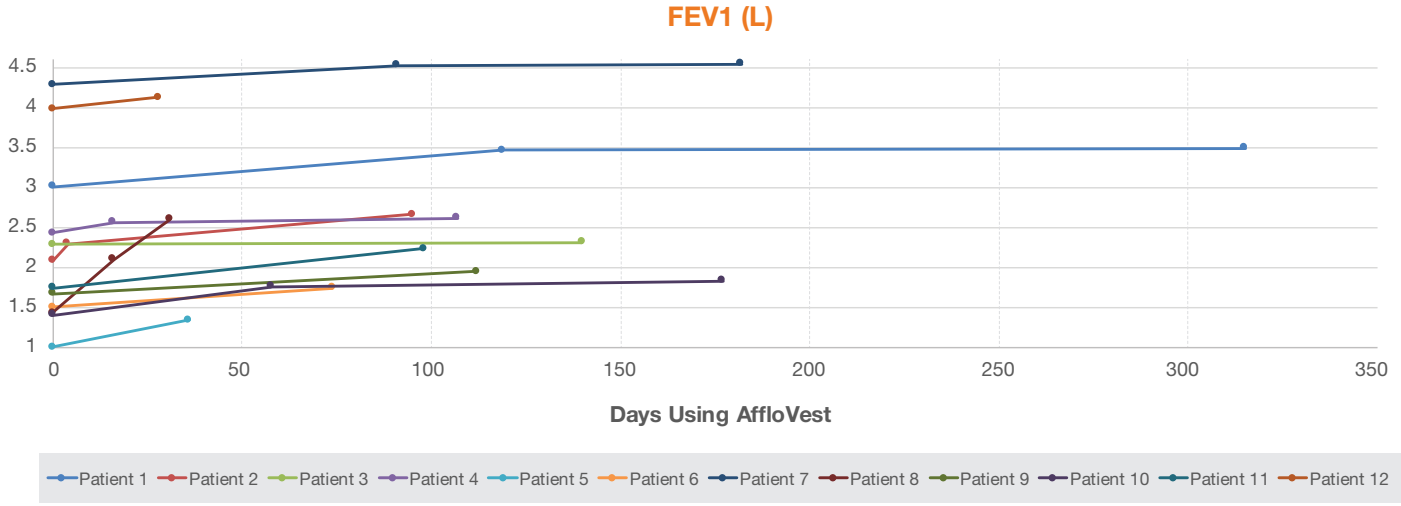
* Patients must qualify to meet eligibility requirements.

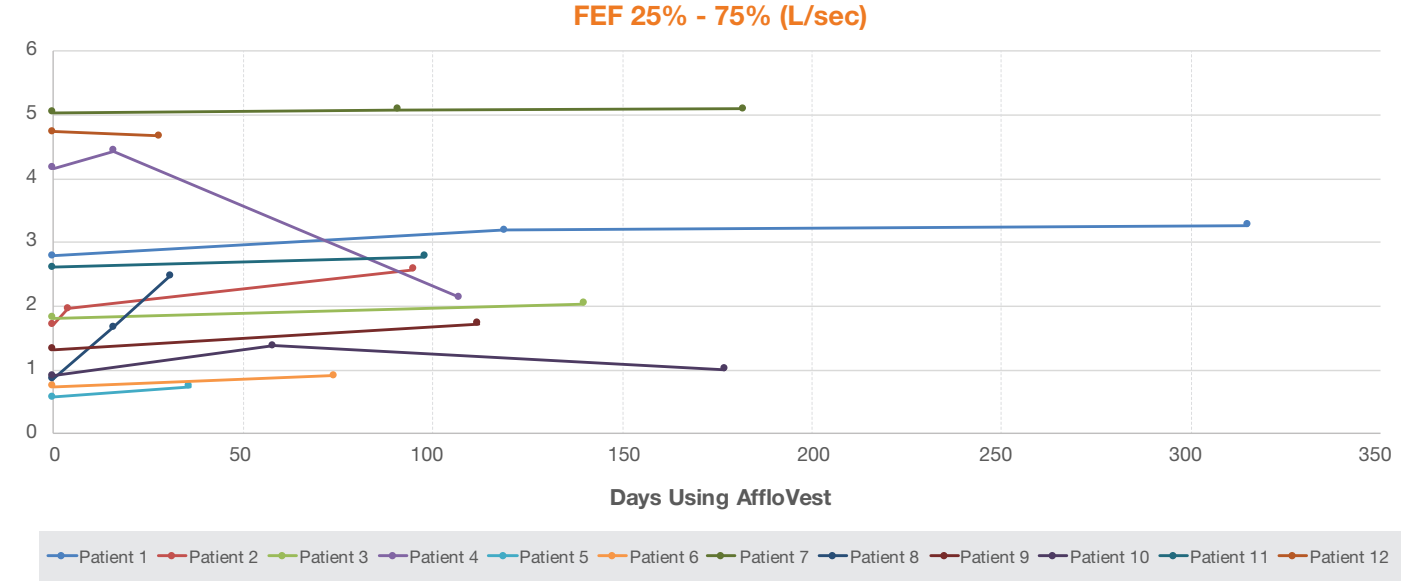
** Cooper,Michael, RT. An evidence-based study of adolescents with cystic fi brosis demonstrated that AffloVest By International Biophysics contributed to improved lung function scores. Chicago, IL. Tackett, Michelle, RRT, Henderson, Vivian, RRT. Lung function improvement with AffloVest HFCWO use: a clinician's perspective on PFT score data from 25 patients with cystic fibrosis. Knoxville, TN.

Learn more at **afflovest.com**, or call us at **888-711-1145**

Hear what AffloVest users are saying at **ibcafflovest** and **afflovest**







*** Both patients 4 and 8 had invalid test results due to erroneous spirometry output data. The erroneous data were not included in scoring calculations.*

Patient 1

Age: 14 Gender: Male Days using AffloVest: 315

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 119	Final Value Day 315	%Change Final vs. Initial
FVC	4.14	3.80	4.25	4.36	+ 14.74%
FEV1	3.52	3.02	3.47	3.50	+ 15.89%
FEF 25-75%	4.10	2.79	3.2	3.27	+ 17.20%

Patient 2

Age: 12 Gender: Female Days using AffloVest: 95

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 4	Final Value Day 95	%Change Final vs. Initial
FVC	3.09	2.72	2.94	3.18	+ 16.91%
FEV1	2.58	2.09	2.3	2.67	+ 27.75%
FEF 25-75%	2.69	1.72	1.96	2.58	+ 50.00%

Patient 3

Age: 17 Gender: Female Days using AffloVest: 140

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 140	%Change Final vs. Initial
FVC	3.46	3.08	NA	2.97	- 3.57%
FEV1	3.06	2.29	NA	2.32	+ 1.31%
FEF 25-75%	3.75	1.82	NA	2.04	+ 12.09%

Patient 4

Age: 12 Gender: Female Days using AffloVest: 107

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 16	Final Value Day 107	%Change Final vs. Initial
FVC	2.90	2.55	2.75	3.46	+ 35.69%
FEV1	2.44	2.44	2.57	2.62	+ 7.38%
FEF 25-75%	2.59	4.17	4.44	*2.14	

*Patient 4 test reading suggests an erroneous test result based on spirometry profile. This data point is omitted from all calculations.

Patient 5

Age: 13 Gender: Male Days using AffloVest: 36

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 36	%Change Final vs. Initial
FVC	3.32	1.68	NA	2.16	+ 28.57%
FEV1	2.97	1.01	NA	1.35	+ 33.66%
FEF 25-75%	3.37	0.58	NA	0.74	+ 27.59%

Patient 6

Age: 17 Gender: Male Days using AffloVest: 74

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 74	%Change Final vs. Initial
FVC	3.8	2.65	NA	2.84	+ 7.17%
FEV1	3.34	1.51	NA	1.75	+ 15.89%
FEF 25-75%	3.93	0.74	NA	0.91	+ 22.97%

Patient 7

Age: 17 Gender: Male Days using AffloVest: 182

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 91	Final Value Day 182	%Change Final vs. Initial
FVC	5.20	5.05	5.24	5.38	+ 6.53%
FEV1	4.53	4.29	4.53	4.55	+ 6.06%
FEF 25-75%	4.96	5.04	5.09	5.1	+ 1.19%

Patient 8

Age: 13 Gender: Female Days using AffloVest: 31

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 16	Final Value Day 31	%Change Final vs. Initial
FVC	2.94	2.1	2.89	3.06	+ 45.71%
FEV1	2.77	1.44	2.11	2.61	+ 81.25%
FEF 25-75%	3.43	* 0.87	1.67	2.48	

*Patient 8 test reading suggests an erroneous test result based on spirometry profile. This data point is omitted from all calculations.

Patient 9

Age: 11 Gender: Male Days using AffloVest: 112

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 112	%Change Final vs. Initial
FVC	2.06	2.31	NA	2.49	+ 7.79%
FEV1	1.88	1.68	NA	1.96	+ 16.67%
FEF 25-75%	2.28	1.33	NA	1.73	+ 30.08%

Patient 10

Age: 15 Gender: Female Days using AffloVest: 177

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 58	Final Value Day 177	%Change Final vs. Initial
FVC	3.09	2.09	2.38	2.77	+ 32.54%
FEV1	2.79	1.41	1.77	1.84	+ 30.50%
FEF 25-75%	3.46	0.91	1.38	1.01	+ 10.99%

Patient 11

Age: 12 Gender: Female Days using AffloVest: 98

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 98	%Change Final vs. Initial
FVC	2.82	1.91	NA	2.49	+ 30.37%
FEV1	2.60	1.75	NA	2.24	+ 28.00%
FEF 25-75%	3.24	2.61	NA	2.78	+ 6.51%

Patient 12

Age: 18 Gender: Male Days using AffloVest: 28

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 28	%Change Final vs. Initial
FVC	5.19	4.69	NA	4.81	+ 2.56%
FEV1	4.46	3.99	NA	4.13	+ 3.51%
FEF 25-75%	4.92	4.74	NA	4.67	- 1.48%

The usage between tests averaged 78 days, and the duration of use ranged from 28 days to 315 days. The AffloVest was prescribed to these patients hoping to increase frequency of use and pulmonary function test scores. Patients with the most FEV1 score improvements appear to be those who reported little or no compliance using their air bladder vests, and that the AffloVest's technology and portability coupled with ease of use helped increase the frequency of patient use. The majority of the patients who demonstrated pulmonary function test improvements after adopting the AffloVest into their ACT regimen remained improved over time and continued to improve over time.

In addition to the improvement in lung function scores, patients elaborated on their experience with the AffloVest:

- Patients liked having the ability to read, write, watch TV, play games and work on their computer during treatment.
- Parents said their children were more likely to use the AffloVest because of its mobility/portability and were able to carry on with normal activities.
- The AffloVest is easier to carry and travel.

For more information visit www.afflovest.com or call 888.711.1145.

References

1 Cooper, Michael. An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest by International Biophysics contributed to improved lung function scores.

2 Tecklin, Clayton, and Scanlin. High frequency chest wall oscillation vs. traditional chest physical therapy in CF – a large, one-year, controlled study. Pediatr Pulmonol 2000; (suppl 20):459.

3 Oermann, Retsch-Bogart, Quittner, et al. An 18-month study of the safety and efficacy of repeated courses of inhaled aztreonam lysine in cystic fibrosis. Pediatr Pulmonol 2010; 45: 1121-1134.

Neurally Adjusted Ventilatory Assist (NAVA) in Pediatric Intensive Care — A Randomized Controlled Trial

Merja Kallio, MD,[1] Outi Peltoniemi, MD, PhD,[1] Eija Anttila, MD,[1] Tytti Pokka, MSc,[1] and Tero Kontiokari, MD, PhD[2]

Background: Neurally adjusted ventilatory assist (NAVA) has been shown to improve patient-ventilator synchrony during invasive ventilation. The aim of this trial was to study NAVA as a primary ventilation mode in pediatric intensive care and to compare it with current standard ventilation modes.

Methods: One hundred seventy pediatric intensive care patients were randomized to conventional ventilation or NAVA. The primary endpoints were time on the ventilator and the amount of sedation needed. To enable comparison between sedative agents, a "sedative unit" was defined for each drug.

Results: The median time on the ventilator was 3.3 hr in the NAVA group and 6.6 hr in the control group (P=0.17), and the length of stay in the PICU 49.5 hr in the NAVA group and 72.8 hr in the control group (P=0.10, per protocol P=0.03). The amount of sedation needed in the total patient population did not differ between the groups (P=0.20), but when postoperative patients were excluded (19 vs 20 patients), the amount was significantly lower in the NAVA group (0.80 vs 2.23 units/hr, P=0.03). Lower peak inspiratory pressure and a lower inspired oxygen fraction were found in the NAVA group (P=0.001 for both). Arterial blood CO2 tensions were slightly higher in the NAVA group up to 32 hr of treatment (P=0.008). There were no significant differences in the other ventilatory or vital parameters, arterial blood gas values or complications.

Conclusions: We found NAVA to be a safe and feasible primary ventilation mode for use with children. It outscored standard ventilation in some aspects, as it was able to enhance oxygenation even at lower airway pressures and led to reduced use of sedatives during longer periods of treatment. Pediatr Pulmonol. 2015;50:55–62.

Introduction

Neurally adjusted ventilatory assist (NAVA) is an invasive ventilation mode which provides ventilatory support proportional to the electrical activity of the diaphragm (Edi).[1] It enables physiological variations in tidal volume and inspiratory time from breath to breath. Several small clinical trials and patient series reported in recent years have shown NAVA to improve patientventilator synchrony in neonatal and pediatric populations,[2-6] and lower peak inspiratory pressures (PIP) and less need for inspired oxygen have been reported relative to standard conventional ventilation.[5,7] Sedation is commonly used in pediatric intensive care units (PICUs) to reduce a patient's discomfort and facilitate invasive ventilation. Adequate use of sedative agents and regular assessment of the sedation level are essential in order to avoid adverse events such as agitation, pain, over-sedation, accidental extubation, or withdrawal syndrome.[8-11] The Edi signal that indicates the strength of the patient's spontaneous breathing is one measure that may be used to assess the sedation level. The risk of treatment complications associated with either the mechanical ventilation itself or the sedation could be reduced by shortening the time on the ventilator.[10,12]

The aim of this randomized controlled trial was to evaluate NAVA as an initial ventilation mode and compare it with current standard conventional ventilation in terms of the duration of mechanical ventilation and the amount of sedation needed. We speculated that the better patient-ventilator synchrony achieved during NAVA could lead to lower sedation requirements and even a shorter total time on the ventilator.

Materials and Methods

All pediatric patients from full-term newborns to adolescents aged 16 years who were expected to need invasive ventilation for at least 30 min were eligible for this trial, but critically ill patients with a severe respiratory, hemodynamic or bleeding disorder, and patients needing high frequency oscillatory ventilation (HFOV) were excluded. If invasive ventilation had lasted over 24 hr prior to the assessment the patient was not considered eligible. Children with a known defect of the diaphragm and those for whom the positioning of a nasogastric or orogastric tube was not possible were also left out. The patients were enrolled at the PICU of Oulu University Hospital, Finland, from September 2009 to May 2012.

Retrospective data on the duration of invasive ventilation at the PICU were used to estimate the sample size. The mean duration of ventilation was 13.0 hr (SD 13.4 hr), and a reduction of 6 hr was considered clinically significant. With α=0.05 and a power of 0.8, the calculated sample size was 160 (80 patients/group). To ensure this number in the final analysis, 170 patients were recruited. The randomization, treatment and follow-up stages in the trial are shown in Figure 1.

The Ethical Committee of the Northern Ostrobothnia Health Care District approved the protocol, and written informed consent was obtained from a parent or legal guardian before

[1]Department of Pediatrics, Oulu University Hospital, Oulu, Finland.
[2]University of Oulu, Oulu, Finland.

performing any procedures related to the study. The children were randomly allocated into the NAVA or control group for invasive ventilation. Computerized random-number generator and opaque envelopes were used in the randomization.

All the patients were ventilated by means of a Servo-i ventilator, versions 4.0–6.1 (Maquet Nordic, Solna, Sweden). An Edi catheter was inserted as soon as possible for the patients randomized to the NAVA group. For postoperative patients this was done in the operating room whenever possible, before transfer to the PICU. The correct position of the catheter was checked as instructed by the manufacturer. The ventilation mode was changed to NAVA as soon as a regular Edi signal was obtained. The NAVA level was estimated to reach the same PIP as in the previous ventilation mode. If NAVA was being used before any other mode, an initial NAVA level of 1.0 cmH2O/mV was chosen and adjusted during treatment as needed, aiming at a peak Edi of 5–15mV. Peak pressure limit 35 cmH2O and 10 sec apnea time were used. The control group received patient-triggered timecycled and either pressure-limited or volume-limited ventilation (PC for neonates and PRVC for older children). These patients were ventilated following the lung protective strategy and current treatment practices in the PICU, without any strict ventilation protocol related to this trial. The clinician responsible for the treatment was allowed to change the ventilation mode if and when this was considered clinically relevant. The time on NAVA was calculated with reference to the active switching of the ventilation mode to or from NAVA. Any time when the Edi signal was too weak to guide ventilation and the ventilator automatically switched to the pressure support or back-up mode was counted as a part of the NAVA ventilation period. The extubation criteria in both groups were: normothermia, stable hemodynamics and oxygenation, and sufficient spontaneous breathing (ie, frequency >15/min and tidal volume 5 ml/kg despite reduction in the level of support).

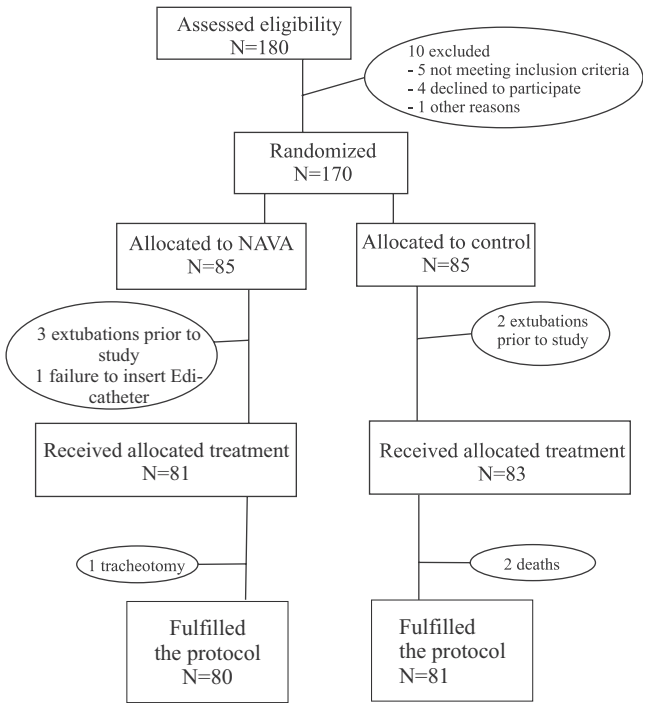


Fig. 1. Randomization, treatment and follow-up. All 170 patients (85 vs 85) were included in the intention-to-treat analysis and the patients who fulfilled the protocol were included in the per protocol analysis (80 vs 81).

Sedation was aimed at level four (calm and cooperative) on the Sedation Agitation Scale (SAS), with a continuous Edi signal in the NAVA cases.[13] The primary sedative agents used were morphine (0.01–0.04 mg/kg/ hr), midazolam (0.03–0.4 mg/kg/hr) and S-ketamine (0.5–3.5 mg/kg/hr), with additional boluses as needed. Other sedatives were used when considered relevant by the responsible clinicians. To enable comparison between the sedative agents, a "sedative unit" was determined for each drug (Table 1). Opiate doses were rendered comparable by converting them to morphine equianalgesic doses.[14]

The primary endpoints of the study were the duration of invasive ventilation and the amount of sedation needed. Secondary endpoints were the length of stay in the PICU, sedation level, ventilator parameters (inspired oxygen fraction, tidal volume, airway pressures, and respiratory rate), vital parameters (heart rate, blood pressure, and oxygen saturation), arterial blood gas (ABG) values and complications (pneumonia, atelectasis, air leak, reintubation within 24 hr). Data collection were started on arrival in the PICU in the case of postoperative patients and otherwise as soon as written informed consent had been obtained from a parent or legal guardian and the Edi catheter could be inserted. The parameters were recorded at the start, after 15 min (all except ABG analysis), 30 min, 1 and 2 hr, then every other hour up to 12 hr of treatment and from then on every 4 hr until extubation and 1 hr after that. The amount of each sedative agent was recorded from the Centricity Critical Care Clinisoft monitoring database and a special data collection sheet was used for the other parameters.

The data were analyzed on an intention-to-treat basis, Student's t-test being used to compare group means for the amount of sedation and the chi-square test to compare the numbers of complications. Kaplan–Meier curves were plotted for the time on the ventilator and the length of stay in the PICU, and the Log Rank test was used to evaluate the survival distributions between the groups (both intention-to-treat and per protocol analyses were performed, Fig. 1). In the case of repeated measurements a split-plot design was used to evaluate the effect of the intervention on the ventilatory and vital parameters.[15] The ventilation method was considered to represent the whole plot intervention, and the subject within the whole plot was used as a replication term for testing the effects of the intervention methods. As the anesthesia used during surgery may affect the need for further sedation, the postoperative and other patients were also analyzed separately. The data analyses were performed with IBM SPSS Statistics version 20.

Results

The patients showed a wide variation in age, size, and clinical diagnosis (Table 2), but there were no significant differences between the two groups in these respects. The reason for invasive ventilation was postoperative care in 77% of cases (Table 2). Five patients dropped out due to early extubation in the operation room or immediately on arrival in the PICU. Edi catheter positioning failed once in a patient in postoperative care after velopharyngoplasty, and one patient in the NAVA group underwent tracheotomy after 2 weeks of invasive ventilation and her length of stay in PICU was 67 days. Two patients in the control group died, the first at 13 hr and the second at 6 days of treatment (Fig. 1). The median duration of invasive ventilation after inclusion in the trial was 3.3 hr in the NAVA group and 6.6 hr in the control group. Cumulative extubation rates calculated by the Kaplan–Meier method showed no statistically significant

TABLE 1— Sedative Units Determined for Each Drug

Drug	Dose (boluses)	Dose (infusion)	Sedative unit[1]
Midazolam	0.1 mg/kg	0.1–0.4 mg/kg/hr	0.1 mg/kg
Diazepam	0.1–0.2 mg/kg	None	0.133 mg/kg
Propofol	1–3 mg/kg	1–4 mg/kg/hr	1.0 mg/kg
S-Ketamine	1–2 mg/kg	0.5–3.5 mg/kg/hr	0.875 mg/kg
Thiopental	3–7 mg/kg	1–5 mg/kg/hr	1.5 mg/kg
Dexmedetomidine	0.5–1 μg/kg	0.2–0.8 μg/kg/hr	0.5 μg/kg
Phenobarbital	Loading 20 mg/kg maintenance 3–6 mg/kg/d	None	4 mg/kg

[1]A sedative unit was calculated to correspond to one-fourth of the maximal infusion dose per hour. For drugs in which this size of unit differed clearly from the bolus instructions (thiopental and dexmedetomidine), the size of the unit was adjusted upwards.
The sedative unit of diazepam was determined to be equivalent to that of midazolam, and that of phenobarbital corresponded to a typical daily dose used during maintenance treatment.

difference in the time on the ventilator (P=0.17; Fig. 2). The time on NAVA varied from 0 to 294 hr (mean 14.6 hr, SD 35.6 hr), and this accounted for 80% of the total duration of invasive ventilation among the NAVA patients.

The median time from the beginning of data collection to the commencement of NAVA ventilation was 9 min. The duration of invasive ventilation prior to inclusion in the trial did not differ between the groups (5.2 hr in the controls vs 4.7 hr in the NAVA group, P=0.56). The length of stay in the PICU was 49.5 hr in the NAVA group and 72.8 hr in the control group (P=0.10; Fig. 2). Per protocol analysis showed the length of stay in the PICU to have been significantly shorter in the NAVA group (P=0.03).

The amount of sedation used in the NAVA group was 1.42 units/hr, compared with 1.81 units/hr in the control group (P=0.20; Table 3). The three most commonly used sedatives apart from opiates were midazolam, S-ketamine and dexmedetomidine. Comparisons between these drugs showed no statistically significant differences (P=0.18, 0.21, and 0.55, respectively), but a tendency toward lower doses in the NAVA patients was seen. When the postoperative patients were excluded, the amount of sedation needed was significantly lower in the NAVA group (0.80 vs 2.23 units/hr, P=0.03), but there were no significant differences between the groups in the use of opiates (Table 3). The level of sedation as assessed with SAS was similar for the two groups (P=0.188; Fig. 3).

Lower PIPs and a lower inspired oxygen fraction were found in the NAVA group (P=0.001 for both; Fig. 3), and there was also a tendency toward lower mean airway pressures, but without reaching statistical significance (P=0.065). The oxygenation index was significantly lower in the NAVA group (P=0.002). A statistically significant difference was found in arterial blood CO2 tension (kPaCO2), with higher levels in the NAVA group at the beginning of treatment and lower levels after 32 hr of treatment (Fig. 3). No significant differences were found in positive end expiratory pressure (PEEP), breathing frequencies, tidal volumes, vital parameters, or any other blood gas values.

The number of treatment complications was 14 in the NAVA group and 19 in the control group, so that they did not differ significantly (P=0.35). Thorax X-rays showed 10 minor treatment complications (small atelectasis or air leaks) in the NAVA group and 11 in the control group, but none of these required any separate procedures. Two patients in the control group accidentally received more sedative medication than planned, whereas there were no dosage errors in the NAVA group.

TABLE 2— Patient Characteristics and Indications for Invasive Ventilation

		NAVA	Control
Number of patients	N	85	85
Males	n (%)	51 (60)	51 (60)
Age (months)	Mean (SD)	50.0 (63.4)	39.4 (61.4)
Weight (kg)	Mean (SD)	17.4 (17.0)	15.5 (19.5)
Height (cm)	Mean (SD)	93.0 (39.2)	82.4 (37.8)
Treatment indication			
Postoperative care	n (%)	66 (77.6)	65 (76.5)
Cranioplasty		12 (14.1)	10 (11.8)
Neurosurgery		8 (9.4)	6 (7.1)
Palato-/velopharyngoplasty		16 (18.8)	13 (15.3)
Orthopedic surgery		14 (16.5)	13 (15.3)
Gastrointestinal surgery		7 (8.2)	10 (11.8)
Other		9 (10.6)	13 (15.3)
Respiratory infection	n (%)	8 (9.5)	6 (7.1)
Neonatal sepsis	n (%)	1 (1.2)	3 (3.5)
Neonatal RDS	n (%)	3 (3.5)	2 (2.4)
Meconium aspiration	n (%)	3 (3.5)	4 (4.8)
Near drowning/suffocation	n (%)	1 (1.2)	2 (2.4)
Trauma	n (%)	1 (1.2)	1 (1.2)
Others[1]	n (%)	2 (2.4)	2 (2.4)

[1]Varicella Zoster meningoencephalitis/ADEM and SSRI side effects in a newborn infant in the NAVA group, and cardiac failure and hemoptysis in the control group.

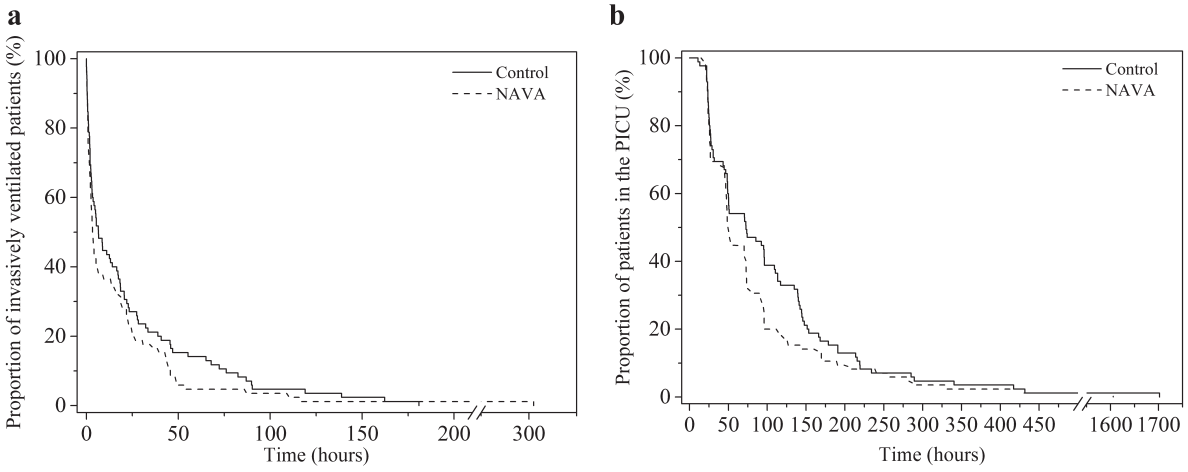


Fig. 2. (a) Effect of ventilation mode on the proportion of invasively ventilated patients over time. Time on the ventilator after inclusion in the trial is presented. Log Rank P=0.17 (per protocol P=0.07). (b) Length of stay in the PICU. Log Rank P=0.10 (per protocol P=0.03).

Accidental extubation occurred once in the NAVA group and twice in the control group, and three patients in the former and four in the latter required reintubation within 24 hr of extubation, for uncontrollable pain, apnea and respiratory insufficiency (non-postoperative) in the NAVA patients and respiratory insufficiency (four postoperative patients) in the control group. One patient in the NAVA group required deeper sedation and controlled ventilation due to increasing intracranial pressure and was switched to PRVC after 6 hr of NAVA treatment.

Discussion

NAVA proved to be a safe and feasible primary ventilation mode for most general PICU patients. The time spent on the ventilator did not differ between the groups. Patients recovering from surgery and needing ventilatory support for only a short time formed the main part of the series, representing a typical PICU population.[16] This is seen in the Kaplan–Meier curves, where nearly half of the patients were extubated within a few hours and the curves remain close together. The time of extubation in these children was evidently determined by the clearance of the sedatives given during the operation and the type of ventilation probably played no more than a minor role in this timing. The Kaplan–Meier curves seem to separate out more in the course of time, however, and one may speculate that those remaining on the ventilator for longer might benefit from NAVA, but this needs further research.

The children in the NAVA group left the PICU almost 1 day earlier than the controls, a difference that was statistically significant in the per protocol analysis. On an intention-to-treat basis, however, the total time in the PICU did not differ significantly between the groups. As the time of extubation is the main determinant of patient transfer from the PICU, even a small reduction in time on the ventilator may shorten the total time spent in the PICU and thus reduce costs.

The level of sedation was similar between the groups when assessed on the sedation-agitation scale, and the amount of sedative required to reach SAS 3–4 did not differ significantly between them, nor were any differences found in the comparisons of individual sedatives, although there was a tendency toward smaller amounts in the NAVA group. Among the children without any preceding surgical anesthesia, however, the amount of sedatives used was 2.2 units/hr in the control group but only 0.8 units/hr in the NAVA group, which is clearly a significant difference. We have shown earlier that the patient and ventilator are more closely synchronized functionally during NAVA than in standard modes,[5] and it has also been shown that the better synchrony provided by NAVA improves patient comfort.[17] Postoperative patients will have been given a load of analgesics and sedatives during the operation and most of them will have some sedation and pain relief protocol after surgery. For these reasons, we believe that patients without any surgical reason for ventilation better represent the true effect of the ventilation mode on the need for sedation.

The key to the lower and—as we think—more accurate dosage of sedatives among the non-surgical cases was the Edi signal.

TABLE 3— Amounts of Sedation Used During the Trial

		NAVA mean (SD)	Control mean (SD)	Difference of the means	95% CI	*P*-value[1]
All Patients	N	85	85			
Sedation units per hour		1.42 (1.76)	1.81 (2.16)	−0.39	−1.00 to 0.21	0.20
Amount of opiates per hour[2]		0.048 (0.061)	0.057 (0.079)	−0.009	−0.031 to 0.012	0.39
Postoperative patients	n	66	65			
Sedation units per hour		1.58 (1.85)	1.68 (2.03)	−0.10	−0.78 to 0.58	0.77
Amount of opiates per hour[2]		0.052 (0.067)	0.065 (0.088)	−0.013	−0.040 to 0.015	0.36
Postoperative patients excluded	n	19	20			
Sedation units per hour		0.80 (1.16)	2.23 (2.54)	−1.43	−2.79 to −0.07	0.03
Amount of opiates per hour[2]		0.030 (0.022)	0.032 (0.030)	−0.002	−0.020 to 0.015	0.78

[1]Independent-samples *t*-test.
[2]Morphine equianalgesic dose (mg) per weight (kg).

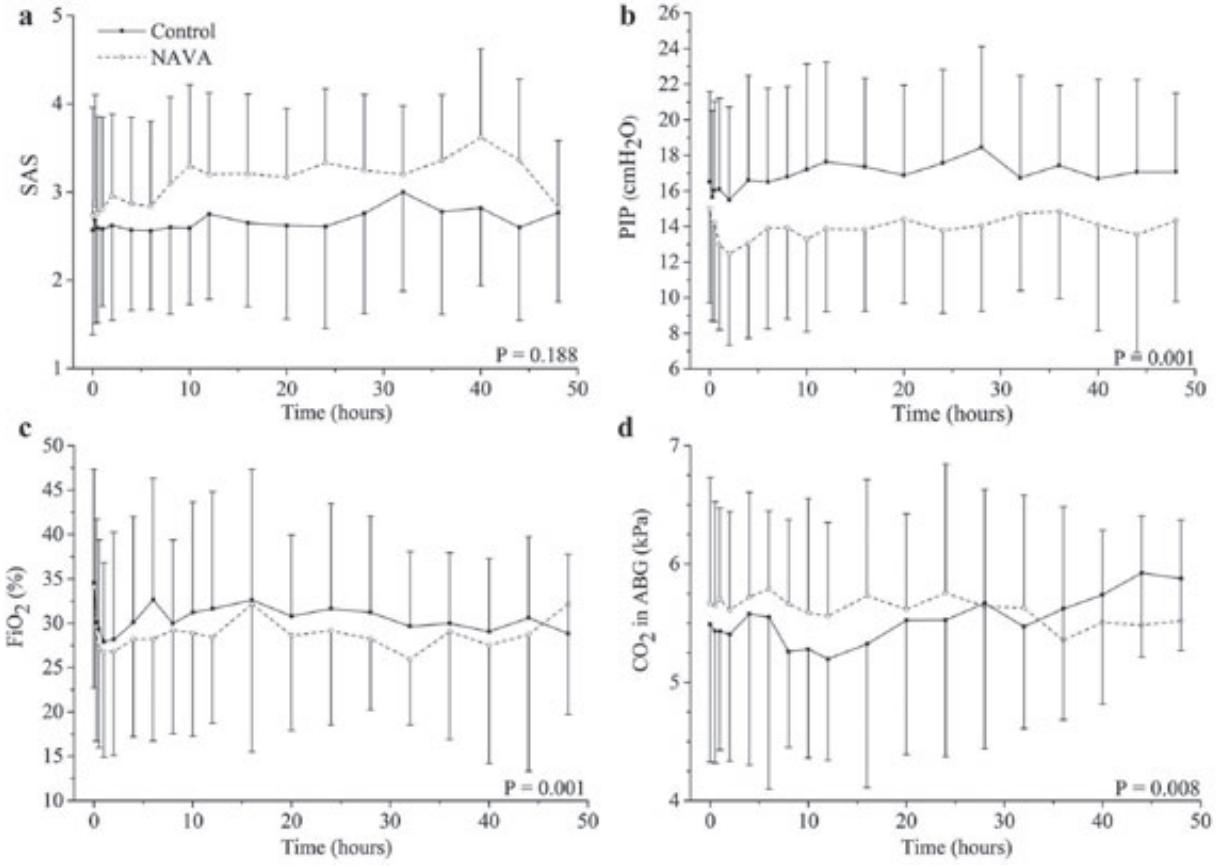


Fig. 3. Comparison of sedation level (a), peak inspiratory pressure (b), inspired oxygen fraction (c) and arterial blood CO2 tension (d) between the groups. Data are shown up to 48 hr.

The target sedation level was set at SAS 4, but the levels observed were deeper, down to SAS 3. No clinical judgement or scoring system can provide a complete assessment of the sedation level in children, and although BIS scoring has recently helped to resolve this problem, it is far from a perfect tool, as it works only with selected drugs, requires its own machinery, is timeconsuming and is at best only an indirect measure of breathing insufficiency.[18-22] Thus, as Edi is a direct measure of the patient's own breathing drive, it may become a valuable tool for assessing the level of sedation, too. When the Edi signal was maintained with a relatively low dose of sedatives, the children were still no more agitated than otherwise, as demonstrated by their similar SAS scoring. The risk of an overdose of sedative may in fact be reduced, as was observed in this trial, as there were two such events in the control group but none in the NAVA group.

We found NAVA ventilation to result in a lower PIP and inspired oxygen fraction with an improved oxygenation index and no significant differences in oxygen saturation. Thus the NAVA children were equally able to transfer oxygen to their tissues, while their lungs were less stressed. These findings are in line with earlier publications based on selected small patient groups of various ages.[3-5,7,23,24] The slightly higher levels of arterial blood CO2 tension among the NAVA patients up to 32 hr of treatment indicate a lower risk of hypocapnia, which is still surprisingly common in pediatric ventilatory care.[16] The ventilation in both of the groups followed the lung protection ideology, aiming at small tidal volumes and low airway pressures without compromising tissue oxygenation. In the light of our results, we succeeded in achieving that goal better with NAVA than with conventional modes.

We observed a similar number of treatment complications in both groups and there were no complications compromising the treatment. The two deaths in the control group were associated with a severe primary disease, that is, tuberosis sclerosis with hemoptysis and neonatal ornithine transcarbamylase (OTC) deficiency—neither of which had been diagnosed prior to recruitment for the trial, and obviously neither could be attributed to the choice of ventilation mode. None of the other safety indicators, that is, heart rate, systolic and diastolic blood pressures, and ABG values, differed between the groups.

There were some limitations to our trial. First, the nonblinded nature of this randomized protocol could have led to decisions favoring the initial hypothesis, that is, a shortening of the time on the ventilator and a lowering of the dose of sedatives in the NAVA group. It is obvious that blinding was not an option in the current case since concealing the patient's breathing patterns and ventilatory settings from the responsible physician would be a serious danger for the patient. The differences in airway pressures and the timing of ventilatory support clearly cause NAVA to stand out from other support techniques. We believe, however, that the lack of blinding has not affected the main results to any marked extent, as there were equal low numbers of reintubations in both groups, indicating the correct timing of extubation.We also observed equal SAS scores, indicating that the sedation level was similarly correct in both groups. Secondly, the desire to assess the total amount of sedation led us to define a "sedative unit." One may argue that the chosen doses are not unequivocal as dosing recommendations vary between units and each drug has its own distinctive pharmacodynamics. Anyhow, since sedation is often administered using more than one drug and no drug is superior in all respects, we had to

accept the use of different sedatives during this trial, so that the only means of measuring and comparing the cumulative amount of sedatives used during each treatment episode was by creating a sedative unit. Thirdly, we wanted to study the feasibility of NAVA in a general PICU population and ended up with a very heterogeneous series of patients, which might have partly obscured possible differences between the ventilation modes. Nevertheless, this is typical of the patient population that pediatric intensivists usually face, and we thus believe that our results are well applicable to most general PICU situations.

In conclusion, neurally adjusted ventilatory assist is a safe and feasible primary ventilation mode for use in pediatric intensive care. It improves oxygenation even with lower airway pressures and reduces the need for sedation in patients requiring longer periods of invasive ventilation. The continuous information on spontaneous breathing provided by the Edi signal enables more accurate adjustment of sedation and thus improves patient safety.

Acknowledgments

We thank Professor Matti Uhari for his valuable guidance in statistical matters and his constructive comments on the manuscript. We also thank the Alma and KA Snellman Foundation, Oulu, Finland, for financial support granted to Dr Kallio and the Foundation for Pediatric Research, Finland, for project support.

References

1 Sinderby C, Navalesi P, Beck J, Skrobik Y, Comtois N, Friberg S, Gottfried SB, Lindstrom L. Neural control of mechanical ventilation in respiratory failure. Nat Med 1999;5: 1433–1436.

2 Beck J, Reilly M, Grasselli G, Mirabella L, Slutsky AS, Dunn MS, Sinderby C. Patient-ventilator interaction during neurally adjusted ventilatory assist on low birth weight infants. Pediatr Res 2009; 65:663–668.

3 Breatnach C, Conion NP, Stack M, Healy M, O'Hare BP. A prospective crossover comparison of neurally adjusted ventilatory assist and pressure support ventilation in a pediatric and neonatal intensive care unit population. Pediatr Crit Care Med 2010;11: 7–11.

4 Bengtsson JA, Edberg KE. Neurally adjusted ventilatory assist in children: an observational study. Pediatr Crit Care Med 2010; 11:253–257.

5 Alander M, Peltoniemi O, Pokka T, Kontiokari T. Comparison of pressure- flow- and NAVA-triggering in pediatric and neonatal ventilatory care. Pediatr Pulmonol 2012;47:76–83.

6 Bordessoule A, Emeriaud G, Morneau S, Jouvet P, Beck J. Neurally adjusted ventilatory assist (NAVA) improves patientventilator interaction in infants compared to conventional ventilation. Pediatr Res 2012;72:194–202.

7 Stein H, Howard D. Neurally adjusted ventilatory assist in neonates weighing <1500 g: a retrospective analysis. J Pediatr 2012;160:786–789.

8 Hartman ME, McCrory DC, Schulman SR. Efficacy of sedation regimens to facilitate mechanical ventilation in the pediatric intensive care unit: a systematic review. Pediatr Crit Care Med 2009;10:246–255.

9 Grant MJ, Scoppettuolo LA, Wypij D, Curley MA. Prospective evaluation of sedation-related adverse events in pediatric patients ventilated for acute respiratory failure. Crit Care Med 2012;40: 1317–1323.

10 Fernandez-Carrion F, Gaboli M, Gonzalez-Celador R, Gomez deQuero-Masia P, Fernandez-de Miguel S, Murga-Herrera V, Serrano-Ayestaran O, Sanchez-Granados JM, Payo-Perez R. Withdrawal syndrome in pediatric intensive care unit. Incidence and risk factors. Med Intensiva 2013;37:67–74.

11 Ng E, Taddio A, Ohlsson A. Intravenous midazolam infusion for sedation of infants in the neonatal intensive care unit. Cochrane Database Syst Rev 2012;6: CD002052.

12 Caironi P, Langer T, Carlesso E, Protti A, Gattinoni L. Time to generate ventilator induced lung injury among mammals with healthy lungs: a unifying hypothesis. Intensive Care Med 2011;37: 1913–1920.

13 Riker RR, Picard JT, Fraser GL. Prospective evaluation of the Sedation-Agitation Scale for adult critically ill patients. Crit Care Med 1999;27:1325–1329.

14 Eastern Metropolitan Region Palliative Care Consortium (Victoria). Opioid conversion ratios—guide to practice 2010. (Accessed September 19, 2012, at http://www.emrpcc.org.au _Uploadlibrary_ 405204312EMRPCCOpioidConversion2010 (Final)).

15 Jones B, Nachtshiem C. Split-plot designs what, why, and how. J Qual Technol 2009;41:340–3361.

16 Alander M, Peltoniemi O, Saarela T, Anttila E, Pokka T, Kontiokari T. Current trends in pediatric and neonatal ventilatory care—a nationwide survey. Acta Paediatr 2013;102:123–128.

17 de la Oliva P, Schu¨ffelmann C, Gomez-Zamora A, Villar J, Kacmarek RM. Asynchrony, neural drive, ventilatory variability and COMFORT: NAVA versus pressure support in pediatric patients. A non-randomized cross-over trial. Intensive Care Med 2012; 838–846.

18 Amigoni A, Mozzo E, Brugnaro L, Gentilomo C, Stritoni V, Michelin E, Pettenazzo A. Assessing sedation in pediatric intensive care unit using Comfort Behavioural Scale and Bispectral index: these tools are different. Minerva Anestesiol 2012;78:322–329.

19 Sammartino M, Volpe B, Sbaraglia F, Garra R, D'Addessi A. Capnography and the Bispectral Index—their role in pediatric sedation: a brief review. Int J Pediatr 2010;2010:828347. doi: 10.1155/2010/828347

20 Agrawal D, Feldman HA, Krauss B, Waltzman ML. Bispectral index monitoring quantifies depth of sedation during emergency department procedural sedation and analgesia in children. Ann Emerg Med 2004;43:247–255.

21 McDermott NB, VanSickle T, Motas D, Friesen RH. Validation of the bispectral index monitor during conscious and deep sedation in children. Anesth Analg 2003;97:39–43.

22 Overly FL, Wright RO, Connor FA Jr, Fontaine B, Jay G, Linakis JG. Bispectral analysis during pediatric procedural sedation. Pediatr Emerg Care 2005;21:6–11.

23 Lee J, Han-Suk K, Sohn JA, Lee JA, Choi CW, Kim EK, Kim BI, Choi JH. Randomized crossover study of neurally adjusted ventilatory assist in preterm infants. J Pediatr 2012;161:808–813.

24 Coisel Y, Chanques G, Jung B, Constantin JM, Capdevila X, Matecki S, Grasso S, Jaber S. Neurally adjusted ventilatory assist in critically ill postoperative patients: a crossover randomized study. Anesthesiology 2010;113:925–935.

Introducing The VisiVest™ System

Enhancing Teamwork. Enhancing Care. Enhancing Life.

VISIVEST™
Airway Clearance System

Your patients are not alone on their journey with chronic lung disease.

You – and the rest of the care team – are there for your patients, through good days and bad, helping them manage their illness and live their best life. So it makes sense to do as much as possible to help everybody work better as a team.

That's the idea behind the new Bluetooth®-enabled VisiVest™ Airway Clearance System. It connects the care team with the patient, sending data about therapy sessions so you can collaborate in making tailored care decisions.*

The first Airway Clearance System with Bluetooth® connectivity, The VisiVest™ Airway Clearance System is the next generation of The Vest® System, the most widely used and trusted system today.

Provides prompt treatment feedback through The VisiView™ Health Portal, to help your patients stay motivated with their therapy and to allow you to see usage information and trends over time.

For further information about this product or a service, please contact your local Hill-Rom representative or visit **www.hill-rom.com**.

** 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.*

198601 rev 1 12-JUL-2016 ENG – US

Enhancing outcomes for patients and their caregivers.

Hill-Rom

Treatment Adherence and Clinical Outcomes: Closing the Gap with Technology-Mediated Interventions

Jane Braverman, PhD

Introduction

Prescribed therapies are generally based upon clinical trials and experience showing that specific treatments may improve patients' clinical status and prevent deterioration and/or delay disease progression. It is assumed that benefit is realized in proportion to a patient's treatment adherence (TA) and that poor adherence may result in clinical deterioration. Poor TA affects far more than the health and well-being of individual patients. Negative consequences extend to patient's families, healthcare teams, healthcare delivery systems, third-party payers and drug and device manufacturers. Given the rapidly rising costs of healthcare and possibly preventable poor outcomes, new approaches are needed to close the gap between non-adherence and suboptimal outcomes. Technology-mediated interventions (TMI), although still evolving, show great potential to impact the TA/outcomes gap.

Treatment non-adherence: A persistent challenge

Non-adherence to prescribed treatments is a worldwide phenomenon that has been widely recognized for more than 50 years.[1,2] Adherence denotes the ability or willingness of a patient to correctly perform prescribed therapies. Although opinions vary, non-adherence is generally defined as taking medications or performing treatments less than 80% of the time.[3,4] Despite major efforts to mitigate this problem, TA rates remain stubbornly variable and persistently low.[3] Poor TA may be responsible for the considerable discrepancy between current treatment success rates and those thought to be achievable. High levels of non-adherence have immense effects on individual and population-level health outcomes and costs.[5] Ineffective treatment attributed to deficient TA is associated with increased morbidity, disease related complications, hospitalizations, and health care expenditures.[6] Estimates suggest that non-adherence costs the US health care system around $100 billion annually.[7,8] Benefits resulting from improved self-management of chronic diseases could produce a dramatic cost savings.

Jane Braverman is an independent consultant for Hill-Rom. She has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. Jane has 40 years' experience in healthcare and medical education including 10 years as a basic research and clinical laboratory technologist, 15 years as an assistant professor at the University of Minnesota Medical School and 15 years as a medical device industry professional.

Barriers to TA

Exhaustive literature reviews have been undertaken to identify the causes of poor TA. Reasons for non-adherence are complex and highly individual. Barriers may be classified broadly as real or perceived obstacles arising from psychosocial, technical, health and socioeconomic factors.[3,4,9-15] In self-reported interviews and questionnaires, most patients and/or families report barriers and disincentives drawn from several of these categories. In a recent study to understand obstacles to adherence among adolescents with CF, Sawicki et al recruited 20 patient/parent pairs to participate in a one-time interview session. Barriers cited included time pressures, awareness of disease trajectory, competing priorities, privacy issues, and lack of perceived consequences. These findings are consistent with those identified in previous studies. Based upon analysis of interview data, several facilitators for improvement emerged:

- Understanding the importance of treatment components
- Building strong relationships with health care teams
- Establishing structured treatment routines
- Strengthening skills to promote independent self-care

Successful approaches include:

- Programs tailored to minimize incompatibilities between treatment requirements and lifestyle
- Flexibility and compromise
- Respect for patient preferences and health beliefs
- Mutual patient/family and healthcare team commitment
- Shared planning and decision-making

Treatment Adherence: Impact on health outcomes

Adherence to prescribed treatments is associated with measureable health and economic outcomes in numerous acute and chronic conditions.[5] Highly adherent patients are shown to have less disease-related morbidity, fewer symptoms, less functional impairment, lower rates of healthcare utilization, reduced need for rescue medications and, importantly, better quality of life (QOL).[16-18] In a first-of-its kind study designed to link TA with quantitative health outcomes, Eakin et al followed 95 CF patients for 12 months while estimating TA based on medication refill data.[17] They found that TA is a significant predictor of declining lung function and pulmonary exacerbation (PE):

- Patients with TA at or above 80% maintained baseline pulmonary function and had no pulmonary exacerbations, defined as need for IV antibiotic therapy, over the study period.
- Patients with moderate (50-80%) and poor (< 50%) TA had

declining trends in their baseline lung function.
- Patients with moderate or poor TA had PE episodes at a rate of 1-2 (23.2%) and 3 or more (16.8%).

Traditional TA Interventions

While it is clear that TA leads to better outcomes, it is also clear that common strategies and interventions to improve adherence have yielded generally disappointing results.[3] Available TA data is notoriously untrustworthy.[2,12,18,19] Traditional methods to capture adherence data, including patient, caregiver or doctor/healthcare team or insurance questionnaires, telephone or in-clinic interviews, are both subjective and difficult to interpret. In particular, in self-reported information, the prevalence of deliberate or inadvertent false reporting is considerable.[19] When self-reported data is compared to direct measures of TA, such as biomarkers of medication blood levels, significant disparities are commonly detected. Such objective measures show that patients who report non-adherence are likely to have responded accurately. However, those who exaggerate or falsify information are identified by contradictory lab results.[14] Poor adherence has serious health and economic consequences. This problem must be resolved before outcomes can be significantly improved.

Technology-Mediated Interventions (TMI)

Recent systematic reviews of the adherence of CF patients to their home treatment programs have noted that TA data captured via electronic monitoring is significantly and consistently lower than self-reported information.[3,14] Currently, a variety of electronic monitoring technologies and telecommunication systems are in stages of research, development and beta-testing. Some have been successfully integrated into management of chronic diseases.[2] The creation of such systems, classified generically as technology-mediated interventions (TMI), demonstrates great potential to mitigate the persistent challenges of poor TA. Technology that promotes active patient participation involving real-time feedback can motivate TA, support timely care plan modifications, improve clinical outcomes and reduce overall healthcare costs.[21-24] Three basic varieties of TMI are described in the literature.[2] These include programs focusing upon education and/or counseling, self-monitoring and/or feedback and electronic reminders. In a study by Cox, et al, use of an internet-based program to graphically represent participation in physical activity among recently hospitalized CF patients demonstrated both feasibility and acceptability.[20] TMI is still in early stages of clinical use and deficiencies in study design and implementation, as well as equipment-related technological problems, have weakened the quality of published studies. However, many of these studies demonstrated encouraging outcome trends.

TMI Linked to Improved TA and/or Clinical Outcomes

A number of recent studies show that the use of targeted TMI programs can produce significant improvements in TA. Fourteen of thirty-eight TMI studies evaluated by Mistry, et al showed improvements in both TA and clinical outcomes.[2] Examples include:

- Antonicelli, et al (2008) studied the effects of home telemonitoring in 57 elderly patients with congestive heart failure (CHF) by comparison with a randomized group receiving usual care. After 12 months of participation, home telemonitoring was associated with improvements in the composite endpoint of mortality or rate of hospitalizations (P = 0.006), a better compliance with therapy, more frequent use of beta-blockers and statins, lower total cholesterol level and better reported health perception.[21]
- Lester, et al (2010) used mobile phone communication between health-care workers and patients starting antiretroviral therapy in Kenya led to improvement in drug adherence and suppression of plasma HIV-1 RNA load. After 12 months, patients who received and responded to SMS support had significantly improved ART adherence and rates of viral suppression compared with the control.[22]
- El Miedany, et al (2012) performed a double blind randomized controlled study to evaluate the feasibility and effect of visual feedback (VF) on TA in patients with early inflammatory arthritis (EA). At 6 months, the VF group showed significantly greater adherence to medication and positive effect on pain score and disease activity.[23]

Although none of the studies showing improved TA followed by better outcomes discuss reduced healthcare costs, such savings may be cautiously inferred. Study limitations, including technical difficulties with TMI platforms, provide guidance for designing more rigorous future studies.

Summary

TMI strategies to improve TA remain in early stages of development. Thus far, their utility and cost-effectiveness cannot be fairly assessed. High quality studies are needed to better assess feasibility and outcomes. However, the preponderance of early evidence supports the potential for TMI to strengthen TA and improve the gap between prescribed therapies and clinical and economic outcomes. Despite limitations, these studies suggest that when important technical and methodological problems are solved, greater treatment adherence may be possible.

References

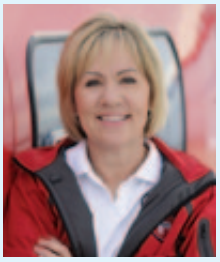
1 Naderi SH, Bestwick JP and Wald DS, Adherence to drugs that prevent cardiovascular disease: meta-analysis on 376,162 patients. Am J Med, 2012. 125(9): p. 882-7 e1.
2 Mistry N, et al. Technology-mediated interventions for enhancing medication adherence. J Am Med Inform Assoc, 2015. 22(e1): p. e177-93.
3 Nieuwlatt R, WN, Navarro E, et al. Interventions for enhancing medication adherence. 2014, Cochrane DB Syst Rev.
4 Haynes RB, et al. Interventions for enhancing medication adherence. Cochrane Database Syst Rev, 2008(2): p. CD000011.
5 Viswanathan M, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med, 2012. 157(11): p. 785-95.
6 Ansell BJ, Not getting to goal: the clinical costs of noncompliance. J Manag Care Pharm, 2008. 14(6 Suppl B): p. 9-15.
7 Berg JS, Dischler J, Wagner DJ, Raia JJ, Palmer-Shevlin N, Medication compliance: a healthcare problem. Ann Pharmacother 1993;27:Suppl 9:S1-S24.
8 IMS Institute for Healthcare Informatics. (2013). Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly. Parsippany, N.J.
9 Demonceau J, et al. Identification and assessment of adherence-enhancing interventions in studies assessing medication adherence through electronically compiled drug dosing histories: a systematic literature review and meta-analysis. Drugs, 2013. 73(6): p. 545-62.

10 Kardas P, Lewek P and Matyjaszczyk M, Determinants of patient adherence: a review of systematic reviews. Front Pharmacol, 2013. 4: p. 91.
11 McCullough A, et al. Interventions for enhancing adherence to treatment in adults with bronchiectasis. Cochrane Database Syst Rev, 2015. 11: p. CD011023.
12 Bregnballe V, et al. Barriers to adherence in adolescents and young adults with cystic fibrosis: a questionnaire study in young patients and their parents. Patient Prefer Adherence, 2011. 5: p. 507-15.
13 Lang AR, et al. Medical device design for adolescent adherence and developmental goals: a case study of a cystic fibrosis physiotherapy device. Patient Prefer Adherence, 2014. 8: p. 301-9.
14 O'Donohoe R and Fullen BM, Adherence of subjects with cystic fibrosis to their home program: a systematic review. Respir Care, 2014. 59(11): p. 1731-46.
15 Sawicki GS, et al. Motivating adherence among adolescents with cystic fibrosis: youth and parent perspectives. Pediatr Pulmonol, 2015. 50(2): p. 127-36.
16 Agh T, et al. Relationship Between Medication Adherence and Health-Related Quality of Life in Subjects With COPD: A Systematic Review. Respir Care, 2015. 60(2): p. 297-303.
17 Eakin MN, et al. Longitudinal association between medication adherence and lung health in people with cystic fibrosis. J Cyst Fibros, 2011. 10(4): p. 258-64.
18 Milgrom H, et al. Noncompliance and treatment failure in children with asthma. J Allergy Clin Immunol, 1996. 98(6 Pt 1): p. 1051-7.
19 Rubin BK and Fink JB, Optimizing aerosol delivery by pressurized metered-dose inhalers. Respir Care, 2005. 50(9): p. 1191-200.
20 Cox NS, et al. Telehealth in cystic fibrosis: a systematic review. J Telemed Telecare, 2012. 18(2): p. 72-8.
21 Antonicelli R, et al. Impact of telemonitoring at home on the management of elderly patients with congestive heart failure. J Telemed Telecare, 2008. 14(6): p. 300-5.
22 Lester RT, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet, 2010. 376(9755): p. 1838-45.
23 El Miedany Y, El Gaafary M and Palmer D, Assessment of the utility of visual feedback in the treatment of early rheumatoid arthritis patients: a pilot study. Rheumatol Int, 2012. 32(10): p. 3061-8.
24 Yang MC, et al. Beneficial Effects of Long-Term CPAP Treatment on Sleep Quality and Blood Pressure in Adherent Subjects With Obstructive Sleep Apnea. Respir Care, 2015. 60(12): p. 1810-8.

ICU Care For Children And Neonates During Emergency Transport

The combination of specialized teams and customized technology has meant that many emergency services are now capable of bringing critical care to their patients prior to reaching the hospital.

Intermountain Life Flight Children's Services in Utah transport patients aged between 0 and 18 years in a five-state referral area. Of the some 1,700 patients transported each year, around 25% are in need of respiratory support. In order to meet the needs of such a broad age group, the team operates with the HAMILTON-T1 transport ventilator that features ICU capabilities and also accommodates settings specific to neonates and children.



"Not all ventilators have all the capabilities we need. With the HAMILTON-T1 we can transport invasively or noninvasively, so we don't need to intubate patients that are sitting on the edge. Depending on the patient, we can do nasal CPAP or DuoPAP instead."

– Trisha Degoyer, Neonatal Flight Nurse

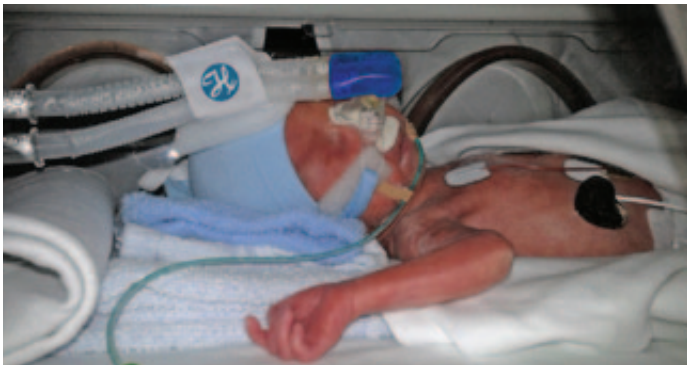
With just one device the team is prepared for a multitude of different scenarios, including patients with severe asthma or ARDS, critically ill neonates requiring inhaled nitric oxide, or babies needing respiratory assistance whom they would prefer not to intubate.

Regardless of which therapy is the most appropriate, the team is equipped to provide the same, very high level of expert care as the patient will receive at the hospital.

"The HAMILTON-T1 gives us the ability to take whatever comes at us and effectively and safely ventilate the whole spectrum of patients. This really does allow us to be an extension of the Primary Children's Hospital."

– Lori McBride, Pediatric Flight Nurse

Nasal CPAP with pressure control
The nCPAP-PC mode with demand flow technology only requires you to set the desired CPAP target value. The ventilator then automatically adjusts the flow according to the patient's condition and possible leaks, ensuring the patient only receives sufficient flow to reach the target. This demand flow technology prevents unintended peak pressures, reduces WOB, ensures optimal leak compensation and lowers oxygen consumption.



While data on the specific benefits of transport ventilators for children and newborns is still quite sparse, it is now recognized that timely delivery of the appropriate therapy may play a more important role than the speed of transport to the ICU.[1] Evidence has shown that the deployment of specialized teams, although it may take longer, results in increased patient safety and improved patient outcomes.[2,3]

This article was submitted by Hamilton Medical.

Equipped with the necessary expertise and advanced technology, these teams are able to initiate specialized therapies earlier, provide improved patient monitoring and sustain the positive effect of therapy during transport.

"For some of our very sick ARDS patients, the ability to add nitric oxide to our circuit has increased the success of their transport."

– Laurie Merrick, Pediatric Flight Nurse

iNO therapy during transport

Inhaled nitric oxide therapy may be used safely on patients during air transport[4] and has been shown to improve oxygenation in neonates and children being transferred to an ECMO center.[5] For patients already on iNO, the sudden discontinuation of therapy prior to transport can have severe consequences. The ability to continue providing iNO between facilities may therefore be vital to ensure its safe, effective application and keep the patient stable.[6]

Particularly with air transport, the complexity of managing critically ill patients is compounded by additional factors such as space limitations, excessive movement and noise. Despite these challenging conditions, today's specialized transport teams are increasingly able to bring ICU care to young patients in a pre- or inter-hospital environment.

"If you have a single ventilator that works for multiple different patient types and multiple different age groups, it frees up more space for us to work in. And if you use the same ventilator for every ventilated patient, it makes you an expert in using that ventilator."

– Parker Scrafford, Pediatric Flight Nurse

HAMILTON-T1 transport ventilator

The optional neonatal function allows the HAMILTON-T1 to deliver the same performance as a fully featured NICU ventilator at the bedside.

- Specially adapted hardware and software to meet the needs of neonates
- Tidal volumes as low as 2 ml to ensure lung-protective ventilation even for preemies
- Neonatal flow sensor measures pressure, volume and flow proximal to the patient
- Neonatal expiratory valve can balance even the smallest difference in pressure
- Modern neonatal ventilation modes including nasal CPAP with pressure control

References

1. Stroud MH, Prodhan P, Moss MM, Anand KJ. Redefining the golden hour in pediatric transport. Pediatr Crit Care Med. 2008 Jul;9(4):435-7
2. Orr RA, Felmet KA, Han Y, McCloskey KA, Dragotta MA, Bills DM, Kuch BA, Watson RS. Pediatric specialized transport teams are associated with improved outcomes. Pediatrics. 2009 Jul;124(1):40-48
3. Ajizian SJ, Nakagawa TA. Interfacility transport of the critically ill pediatric patient. Chest. 2007 Oct;132(4):1361-7
4. Lutman D, Petros A. Inhaled nitric oxide in neonatal and paediatric transport. Early Hum Dev. 2008 Nov;84(11):725-9
5. Westrope C, Roberts N, Nichani S, Hunt C, Peek GJ, Firmin R. Experience with mobile inhaled nitric oxide during transport of neonates and children with respiratory insufficiency to an extracorporeal membrane oxygenation center. Pediatr Crit Care Med. 2004 Nov;5(6):542-6
6. Kinsella JP, Griebel J, Schmidt JM, Abman SH. Use of inhaled nitric oxide during interhospital transport of newborns with hypoxemic respiratory failure. Pediatrics. 2002 Jan;109(1):158-61.

Value of Capnography in Infants

Greg Spratt BS RRT CPFT

Capnography can be a cost-effective way to monitor real-time carbon dioxide (CO_2) levels and trends in intubated and non-intubated infants and neonates. Recent innovations in capnography sampling and measurement are directed at ease of use and accuracy. Capnography provides the continuous measurement of partial pressure of carbon dioxide in the breath during inhalation and exhalation and displays:

- The partial pressure of end-tidal carbon dioxide ($etCO_2$ or $PetCO_2$), the maximal concentration of CO_2 during exhalation
- Fraction of inspired CO_2 (F_iCO_2) which should generally be zero as inhaled air contains minute amounts of CO_2
- Capnogram (aka, capnograph, $etCO_2$ waveform) which is a graphic representation of the CO_2 waveform
- Respiratory rate derived from the waveform
- Trends of these readings

Capnography is the standard of care for continuously monitoring adequacy of ventilation for intubated patients during general anesthesia in the operating room,[1] and is recommended by the American Heart Association and American Association for Respiratory Care to confirm and monitor endotracheal tube (ETT) placement as well as monitoring for effective chest compressions and return of spontaneous circulation during CPR[2,3,4] In addition to its value in confirming proper ETT placement, capnography may also be useful for trending CO_2 levels during ventilator management.

With the advent of newer technology which allows for improved sampling in non-intubated patients including neonates, capnography is rapidly growing in use in many non-intubated applications where adequacy of ventilation may be compromised. These applications include use during procedural sedation, monitoring of patients on opioids or other respiratory depressants, and monitoring for respiratory compromise in patients both within and outside the hospital setting.[5]

Capnography is measured using two primary methods. Mainstream capnography measures CO_2 by placing a sensor chamber directly in the breathing circuit, attached at the ETT and provides a graph of the CO_2 concentration against volume. Sidestream capnography measures CO_2 by drawing a sample of the breath from the breathing circuit to the sensor within the monitor and plots a CO_2-time capnogram. Each offers advantages which are summarized in Table 1. Microstream technology[6] is an innovation of sidestream technology which uses a CO_2 -specific IR wavelength that is unaffected by the presence other gases (ie O_2, N_2O, He or inhaled anesthetics).[7] Other capnography technology requires correction for these gases or may report inaccurate results. Additionally, Microstream permits the use of a very low sample flow rate (50 ml/min), minimizing removal of tidal volume (Vt) which is important in neonates.

Mainstream	Sidestream
Advantages: 1. Some devices provide estimates of dead space (Vd/Vt) 2. No removal of air from Vt to sample for measurement	**Advantages:** 1. Less weight/obtrusion on the end of the ETT which may reduce the potential for kinking and migration/extubations[8] and improve patient comfort 2. No external exposure of expensive sensor to damage/ replacement 3. Easy to use with intubated and non-intubated applications

Capnography in Intubated Infants

In patients with normal ventilation to perfusion (V/Q) matching, the $etCO_2$ is generally 2-5 mmHg less than the arterial CO_2 (P_aCO_2). When V/Q mismatching occurs secondary to changes in dead space or perfusion, this gradient widens; however, McSwain et al found that the correlation of $etCO_2$ to P_aCO_2 remained strong at all ranges of increasing dead space.[9] McSwain states, "In patients with a $Vd/Vt \leq 0.40$ there was an excellent correlation ($p=0.95$) between $PetCO_2$ and $PaCO_2$. Though the strength of the association diminishes slightly as Vd/Vt increases, the correlation remains strong ($p=0.86$) even at Vd/Vt of 0.56-0.70, and moderately strong ($p=0.78$) at $Vd/Vt > 0.7$. Thus, $PetCO_2$ appears to be a useful indicator of $PaCO_2$, even in patients with substantial lung disease, provided that the expected increase in the $PetCO_2$-$PaCO_2$ difference is taken into consideration."

In a review of publications to explore the value of end-tidal carbon dioxide in ventilated neonates, Naidu found that all the studies in this review showed that a correlation exists between $etCO_2$ and $PaCO_2$.[10] However, this correlation was stronger in the groups with no underlying lung disease. Naidu concluded that while $etCO_2$ cannot replace ABGs, it can be used as a valuable trending tool understanding the impact of gradient.

Greg Spratt BS RRT CPFT is the Director of Clinical Marketing in Patient Monitoring Market Development at Medtronic. Correspondence can be sent to gregory.k.spratt@medtronic.com.

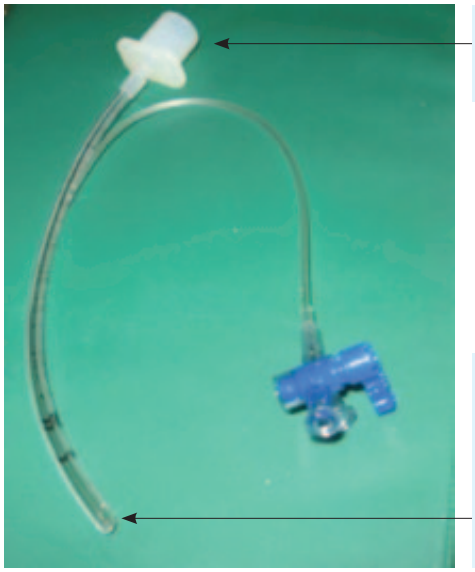


Figure 1. ETT with monitoring lumen[11] permitting sampling at the distal end of the ETT (at carina).

From a cost savings perspective, this can have a significant impact. In a retrospective review comparing the utilization of blood gases before and after the implementation of continuous capnography in a pediatric ICU, Rowan et al found the average number of blood gases per encounter decreased from 20.8 and 21.6 in the two years pre-implementation to 13.8 post intervention. The total charge savings over a 6-month period was $880,496.[8]

$etCO_2$ Sampling at the Carina

Kugelman et al explored an innovative method of sampling $etCO_2$ at the carina through the use of an endotracheal tube (ETT) with a monitoring lumen (Figures 1 and 2),[11] which may be less affected by the ventilator circuit flow and leaks around the uncuffed ETTs, thus improving the correlation with $PaCO_2$.[12,13] Kugelman states "Since 2008 and even before, we have used the double lumen ET tube and Microstream capnography monitoring as a routine in our unit. We continue to use it routinely for other studies and during routine care within the department and in the delivery room. I would say that in 80 to 90% of the infants we use Microstream capnography monitoring via the double lumen tube. We have good agreement between $etCO_2$ and $PaCO_2$ for most infants; $etCO_2$ is typically two to five millimeters of mercury lower than $PaCO_2$ for most babies. For infants where the gradient is higher, such as those with higher ventilation/perfusion mismatch, we get an idea of the agreement and as there may be fluctuations as the baby's condition changes, we still periodically check the blood gas to ensure the gradient is staying relatively consistent"

In their study of 27 infants which included analysis of 222 and 212 measurements of end-tidal CO_2 at the carina and ETT connector respectively, carinal end-tidal CO_2 had a better correlation with $PaCO_2$ and a better agreement with $PaCO_2$ than $etCO_2$ sampled at the ETT connector. In patients with significant lung disease (P_aO_2/P_AO_2 ratio < 0.3), the gradient between carinal $etCO_2$ and $PaCO_2$ increased, but the bias remained < 5 mm Hg. The average agreement with P_aCO_2 was –1.5mmHg.

More recently, Kugelman used this same sampling method in infants using high-frequency ventilation (HFV).[14] Sixteen

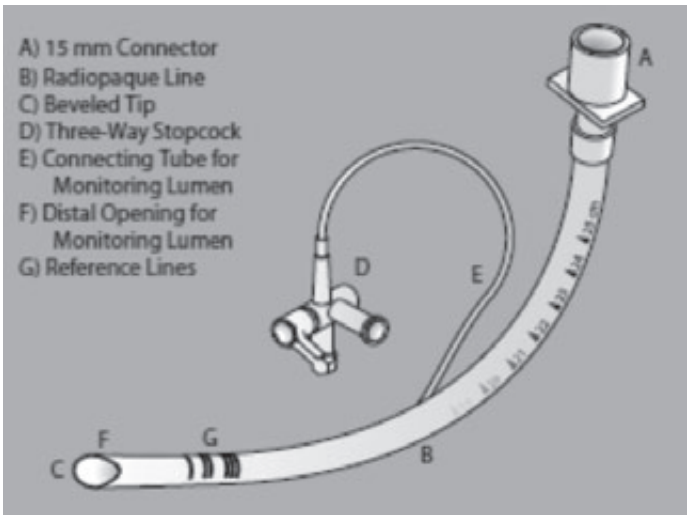


Figure 2. Detail on ETT with monitoring lumen[11]

premature infants with a median gestational age of 26.5 weeks were ventilated with HFV. Analysis included 195 measurements and the correlation of carinal $etCO_2$ with $PaCO_2$ ($r = 0.68$, $P < 0.0001$) and the agreement (bias ± precision: -2.0 ± 10.7 mmHg) were adequate. They concluded that continuous integrated $etCO_2$ measured at the carina is feasible in HFV, has adequate correlation and agreement with $PaCO_2$ and can be helpful for trends and alarm for unsafe levels of $PaCO_2$ in premature infants ventilated with HFV.

Capnography in Non-Intubated Infants

In a study of the performance of capnography in non-intubated infants by Coates et al, the correlation of sidestream CO_2 with ABG was excellent ($r^2 = 0.907$).[15] Results were not significantly altered when weight and respiratory rate were added as independent variables. Bland-Altman analysis revealed a bias of –2.7 with a precision of ±6.5 when comparing sidestream CO_2 to ABG.

In a retrospective study, Moses et al investigated the correlation and level of agreement between end-tidal carbon dioxide and venous CO_2 (P_vCO_2) in non-intubated children with moderate to severe respiratory distress.[16] $EtCO_2$ was correlated highly with P_vCO_2 in non-intubated pediatric patients with moderate to severe respiratory distress across respiratory illnesses. They concluded that although the level of agreement between the two methods precludes the overall replacement of blood gas evaluation, $etCO_2$ monitoring remains a useful, continuous, non-invasive measure in the management of non-intubated children with moderate to severe respiratory distress.

Summary

Capnography can play an important role in the management of both intubated and non-intubated infants in providing a continuous trend of CO_2. Sampling at the carina may play a role in improving the correlation of end-tidal and arterial CO_2. It is important for the clinician to clearly understand the benefits and limitations in the use of the technology, as well as factors that impact the gradient between end-tidal and arterial CO_2.

References

1 American Society of Anesthesiologists Policy Statements on Practice Parameters: Standards for Basic Anesthetic Monitoring http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/standards-for-basic-

anesthetic-monitoring.pdf Accessed April 12, 2016
2 Link MS, Berkow LC, Kudenchuk PJ, Halperin HR, Hess EP, Moitra VK, Neumar RW, O'Neil BJ, Paxton JH, Silvers SM, White RD, Yannopoulos D, Donnino MW. Part 7: adult advanced cardiovascular life support: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015; 132(suppl 2):S444–S464
3 Walsh BK, Crotwell DN, Restrepo RD. Capnography/ Capnometry During Mechanical Ventilation: Respiratory Care 2011; 56(4):503-509.
4 de Caen AR, Berg MD, Chameides L, Gooden CK, Hickey RW, Scott HF, Sutton RM, Tijssen JA, Topjian A, van der Jagt E, Schexnayder SM, Samson RA. Part 12: Pediatric Advanced Life Support: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation 2015; 132(suppl 2):S526–S542.
5 Restrepo RD, Nuccio P, Spratt G, Waugh J. Current applications of capnography in non-intubated patients. Expert Rev. Respir. Med. Early online, 1–11 (2014). http://www.ncbi.nlm.nih.gov/pubmed/25020234 Accessed April 12, 2016
6 Microstream Technology– Medtronic Website http://www.covidien.com/rms/brands/microstream Accessed April 12, 2016
7 Microstream Technology– Medtronic Website http://solutionscontent.covidien.com/uploads/11/11292-14PM0020_SS_MicrostreamTechnologyAdvantageFINAL020314-1392132899.pdf Accessed April 12, 2016
8 Rowan CM, Speicher RH, Hedlund T, Ahmeda SS, Swigonskid NL.Implementation of Continuous Capnography Is Associated With a Decreased Utilization of Blood Gases. J Clin Med Res. 2015;7(2):71-75
9 McSwain SD, Hame DS, Smith PB, et al. End-tidal and arterial carbon dioxide measurements correlate across all levels of physiologic dead space. Respir Care 2010;55(3):288-293
10 Naidu S. Is ETCO2 a predictor of PaCO2 in ventilated neonates on the Neonatal Intensive Care Unit? Working Papers in Health Sciences 1:1 ISSN 2051-6266 / 20120005 http://www.southampton.ac.uk/assets/centresresearch/documents/wphs/Is%20ETCO2%20a%20predictor%20of%20PaCO2%20in%20ventilated%20neonates%20on%20the%20Neonatal%20Intensive%20Care%20Unit.pdf. Accessed May 3, 2016.
11 Mallinckrodt Oral/Nasal Tracheal Tube - Cuffless w/ Monitoring Lumen - http://aemprod.covidien.com/covidien/products/intubation/mallinckrodt-oral-nasal-endotracheal-tube-cuffless-monitoring-lumen
12 Kugelman A. Capnography Use in the NICU. Neonatal Intensive Care 2015; 28 (4):21-23
13 Kugelman A, Zeiger-Aginsky D, Bader D, Shoris I, Riskin A. A Novel Method of Distal End-Tidal CO2 Capnography in Intubated Infants: Comparison With Arterial CO2 and With Proximal Mainstream End-Tidal CO2. Pediatrics 2008; 122:1219-1224
14 Kugelman A, Riskin A, Shoris I, Ronen M, Stein IS, Bader D. Continuous Integrated Distal Capnography in Infants Ventilated With High Frequency Ventilation. Pediatr Pulmonol. 2012; 47(9):876-83.
15 Coates BM, Chaize R, Goodman DM, Rozenfeld RA. Performance of capnometry in non-intubated infants in the pediatric intensive care unit. BMC Pediatrics 2014, 14:163 doi:10.1186/1471-2431-14-163
16 Moses JM1, Alexander JL, Agus MS. The correlation and level of agreement between end-tidal and blood gas pCO2 in children with respiratory distress: a retrospective analysis. BMC Pediatr. 2009 Mar 12;9:20. doi: 10.1186/1471-2431-9-20.

Integrated O_2 Therapy Option for Respiratory Care Patient Outcomes – Cost Savings – Workflow Improvement Tangible Benefits for Today's Hospitals

Edwin Coombs, MA RRT-NPS, ACCS, FAARC

Background

This paper examines the recent trends in the use of high-flow oxygen therapy that has shown benefits in improved oxygenation post extubation, improved lung volumes, and patient comfort and tolerance.

An example of a typical hospital's potential for cost-savings when using a device-integrated oxygen therapy option as compared to other commercially available stand-alone devices.

The discussion will conclude with a brief summary of other potential tangible benefits to the workflow and delivery of patient care.

Patient Outcomes

A comparison of high-flow nasal oxygen delivery vs Venturi mask oxygen therapy has shown improvements in oxygenation, comfort, and clinical outcomes. When using a high-flow nasal O_2 system, this study demonstrated a reduced need for non-invasive ventilation by approximately 80%, less episodes of O_2 desaturation by an estimated 66%, less need for reintubation by approximately 80%, and a reduced length of stay in the ICU by an approximate average of 1.3 days.[1]

When studying post-cardiac surgical patients where alveolar collapse and post-op atelectasis is a common complication, use of high-flow oxygen therapy demonstrated significant improvements in end-expiratory lung volumes (hence FRC). This was determined by the use of electrical impedance tomography EELI values. This was explained by the low-level positive airway pressure generated when using a high flow nasal cannula.[2]

Cost Savings/Consumables

While local expenses will vary based on contractual obligations or purchasing agreements, a typical comparison of the cost to extubate a patient to both a simple aerosol oxygen mask and a high-flow nasal cannula system can be extrapolated. Theoretically, the following cost savings are possible (however there is no guarantee that any individual hospital will realize similar savings):

Extubation To Simple Oxygen Therapy/Cold Aerosol Mask Or Trach Collar	
Cost of complete stand-alone setup (Aerosol generator, tubing, mask or trach collar)	$10.00 USD per patient
Cost of Aerosol mask alone (using existing circuit from ventilator)	$6.00 USD per patient
Cost Savings Using V500/VN500 O_2 Therapy option	**$4.00 USD per patient**
Extubation To High-Flow Nasal Cannula	
Cost of complete stand-alone setup (HF cannula, proprietary circuit)	$80.00 USD per patient
Cost of high-flow cannula alone (using existing circuit from ventilator)	$20.00 USD per patient
Cost Savings Using V500/VN500 O_2 Therapy option (excluding device and maintenance costs)	**$60.00 USD per patient**
Calculated Annual Savings	
3 patients per week (52 weeks/annually) extubated to simple O_2 mask/collar	$624.00 annually
3 patients per week (52 weeks/annually extubated to high-flow cannula	$9,360.00 annually

Work Flow Improvement

Time management for the caregiver is streamlined as one device can remain at the bedside to support all oxygenation and ventilation requirements of the patient simply by changing the patient-circuit interface. No longer is a second device required which also saves space in the ICU room itself reducing clutter and in some cases noise levels.

A reduction in devices will reduce the biomedical requirements and expense of maintaining a multitude of different devices with respect to spare parts, preventative maintenance, and asset tracking.

Data management and EMR charting is facilitated using the V500/VN500 O_2 therapy option as FiO_2 concentration and flow rate values can be electronically transferred via the medibus protocol. These data points can be trended over time to analyze the patient's changing status over a few hours to several days.

Impact

A randomized clinical trial comparing post-extubation high-flow nasal cannula vs conventional oxygen therapy showed that reintubation rates was lower in the high-flow group (13 patients/4.9%) vs the conventional oxygen therapy group

Edwin Coombs, MA RRT-NPS, ACCS, FAARC, Director of Marketing, Intensive Care Dräger. This article was provided by Dräger.

(32 patients/12.2%).[3] As a result of this evidence, the trend is becoming to utilize high-flow oxygen therapy. As market pressures continue to press hospitals to improve the quality of care while decreasing costs, the V500/VN500 O_2 Therapy option provides a cost-effective alternative to providing high-flow nasal O_2 therapy. Dräger will continue to work with customers to bring technology and comprehensive solutions to support these mutual objectives to improve our delivery of health care.

As a result of this evidence, the trend is becoming to utilize high-flow oxygen therapy.

References

1 SM. Maggiore, FA. Idone, R. Vaschetto, et al. "Nasal High-Flow vs Venturi Mask Oxygen Therapy after Extubation: Effects on Oxygenation, Comfort, and Clinical Outcome", American Journal of Respiratory & Critical Care Medicine, 2014: 190(3), 282-8.

2 A. Corley, LP. Caruana, AG. Barnett, O. Tronstad, JF. Fraser. "Oxygen Delivery through High-Flow Nasal Cannulae Increase End-Expiratory Lung Volume and Reduce Respiratory Rate in Post-Cardiac Surgical Patients", British Journal of Anesthesia 107 (6): 998-1004, (2011)

3 Hernandez, G. Conception, V. et al. "Effect of Post-Extubation: High-Flow Nasal Cannula vs Conventional Oxygen Therapy on Reintubation in Low Risk Patients", JAMA, April 5, 2016: 315(13), 1354-1361.

Improved Respiratory Outcomes and Decrease in Pain Medication Dependence in a Patient with a Collapsed Diaphragm Using a Wearable Ventilator

Thomas Brennan, RRT; David M Serlin, MD

Introduction

Pneumococcal pneumonia, a serious infection of the lungs, affects an estimated 900,000 individuals in the US yearly with a 5-7 percent overall mortality rate.[1] Approximately 400,000 hospitalizations are caused each year in the US.[2] Pneumonia may be bacterial or viral in origin, with the majority of cases caused by bacterial infection. In these cases, antibiotics are typically used to treat the infection, with symptomatic improvement typically seen within 1-3 days. Though the condition is commonly eradicated quickly, certain cases require hospitalization and have long-term effects.

Patient Background

Erin, a 58-year-old female from the Northeastern United States was seen in November 2014 presenting with a paralyzed diaphragm stemming from a severe case of pneumonia 12 years prior. Initially, she received nocturnal Bi-level Positive Airway Pressure (Bi-level) treatment that was insufficient and resulted in headaches and marked shortness of breath. Bi-level therapy was augmented to a regimen of 18-20 hours per day. While she was able to ambulate for short periods of time, she was severely restricted in her movement and required daily naps of 2-3 hours and the use of a cane or wheelchair.

Erin was also affected by severe muscle spasms and chronic chest pain from overuse of intercostal and accessory muscles, and had become dependent on narcotic painkillers to manage her symptoms. In addition to pain and movement limitations, Erin was unable to generate sufficient airflow to enable phonation and had been almost completely without a voice for 13 years. At one point, her condition seriously deteriorated after developing influenza with pneumonia, and she became completely dependent on Bi-level therapy 24/7 for several months, only pausing treatment for long enough to eat. Following Erin's marked decline, the initial assessment was that she needed tracheostomy and invasive ventilation.

Treatment Recommendation

After conducting a more comprehensive health assessment, we recommended that Erin begin therapy with the Non-Invasive Open Ventilation (NIOV) System, developed by Breathe Technologies, Inc, prior to trying a more intrusive option. This FDA-cleared, one-pound, palm-sized wearable ventilator delivers a high mixture of oxygen and air through an unobtrusive nasal pillows interface, working to augment an individual's spontaneous breath. The NIOV System can be used by oxygen dependent patients and has also received FDA clearance for use with a compressed air supply for non-oxygen dependent patients with neuromuscular diseases.

The system also unloads respiratory muscles by providing positive pressure and augmenting patient's tidal volume.[3] Published data that support the efficacy of the Breathe NIOV System demonstrate that the device reduces dyspnea (shortness of breath), increases oxygenation, enhances exercise endurance, and unloads respiratory muscle activity.

Outcomes Following Discharge

Following the commencement of her treatment with NIOV, which she uses during the day, Erin has made remarkable improvements from her baseline evaluation. She is now able to walk 400 feet unassisted (compared to only 20 steps using her previous regimen). She has regained her ability to speak and has decreased her use of pain medicines by approximately 80 percent.

In addition to significant improvements in overall endurance and mobility, Erin was also able to resume driving, something she had not been able to do for approximately one year due to exhaustion and pain. She was able to also run routine errands, perform basic daily chores and participate more fully in everyday life.

Reflecting on how rapid the change has been, Erin remarked, "The most common comment I receive is not only how much better I look, but how I am more like my old self. I have a more normal life because I am able to go without needing assistance. NIOV, quite frankly, has been life changing."

With the approval of her doctor, in April 2015 Erin was able to travel with her husband to Florida to watch their daughter perform with her high school musical group at Disney World. She coordinated with a local Orlando-based scuba shop to get a supply of compressed air and her tanks were filled throughout her trip.

"We had the medical air tanks on the back of my wheelchair and I was able to go out every day at Disney, including to see my

Thomas Brennan, RRT is Senior Manager, Sales Development – Eastern Region, Breathe Technologies, Inc. David M Serlin, MD specializes in critical care medicine, pulmonology and allergy & immunology. He practices at Pioneer Valley Respiratory Associates in Northhampton, Mass. and is on staff at Cooley Dickinson Hospital.

daughter perform, which brought me to tears. Before NIOV, there was no way I would have been able to go because I needed to be on the Bi-level for so many hours and could not travel due to pain. Now that I was being properly ventilated, we went full tilt! Seeing my daughter perform at Disney was a once in a lifetime experience."

References

1 Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012.

2 Huang SS, Johnson KM, Ray GT, et al. Healthcare utilization and cost of pneumococcal disease in the United States. Vaccine 2011;29(18):3398-412.

3 Porszasz J, et al. Physiologic effects of an ambulatory ventilation system in COPD. Am J Respir Crit Care Med Vol 188, Iss. 3, pp 334–342, Aug 1, 2013.

The Use Of Continuous High Frequency Oscillation To Reverse Atelectasis Post-Abdominal Aortic Aneurysm Repair Surgery

Tina M Lovings, BSRT, RRT-ACCS, RCP; Mike Sweet, CRT, RCP

Among lung expansion (LE) devices, intrapulmonary percussive ventilation (IPV) devices have been in use for more than 25 years and are used widely in the acute care, post-surgical, and homecare settings. The MetaNeb System is a lung expansion modality that incorporates all the physiological effects of IPV while providing additional therapeutic advantages intended primarily to more effectively treat and/or prevent pulmonary atelectasis. Equipment consists of a pneumatic compressor that delivers continuous high-frequency oscillation (CHFO) and continuous positive expiratory pressure (CPEP) to facilitate clearance of mucous from the lungs; provide lung expansion therapy; and enhance the delivery of aerosol therapy.

A 75-year-old male with a history of Diabetes mellitus (type 2), obstructive sleep apnea (home CPAP), chronic kidney disease, hypertension, and previous abdominal aortic aneurysm (AAA) repair, in 1996, presented to emergency department with abdominal pain and underwent abdominal aortic aneurysm repair surgery. On Post-op Day 2 the patient developed acute renal failure and by Day 6 he developed worsening respiratory status, including acute desaturation overnight.

Day 6 Chest X-ray (CXR) at 2030 revealed a large collapse of the left lung with volume loss and leftward mediastinal shift, consistent with atelectasis and likely secondary to mucous plugging. He was positioned with his poor lung up and treated with MetaNeb Therapy via in-line ventilator circuit using 0.9% normal saline for 10 minutes x 3 treatments at 2100, 2200, and 2300. Day 6 CXR at 2345 showed markedly improved aeration of the left lung and complete resolution of the collapse, only 3 hours after the initiation of MetaNeb Therapy.

By Day 7 the ventilator settings were weaned to pressure support mode. In addition, he was saturating well and hemodynamically stable while on Levophed. The MetaNeb Therapy was found to be an effective airway clearance strategy in this patient with left lung collapse post-surgery. MetaNeb Therapy may play an important role in this patient population although further studies are needed.

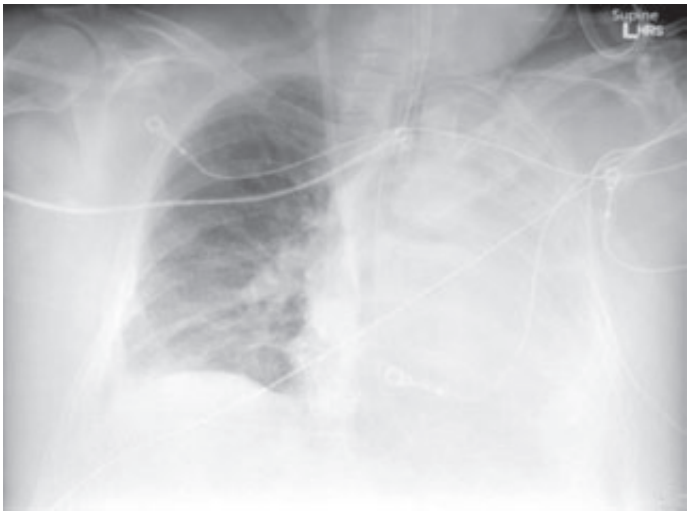


Figure 1. Post-Op Day 6 CXR at 2030, Pre-MetaNeb Therapy.

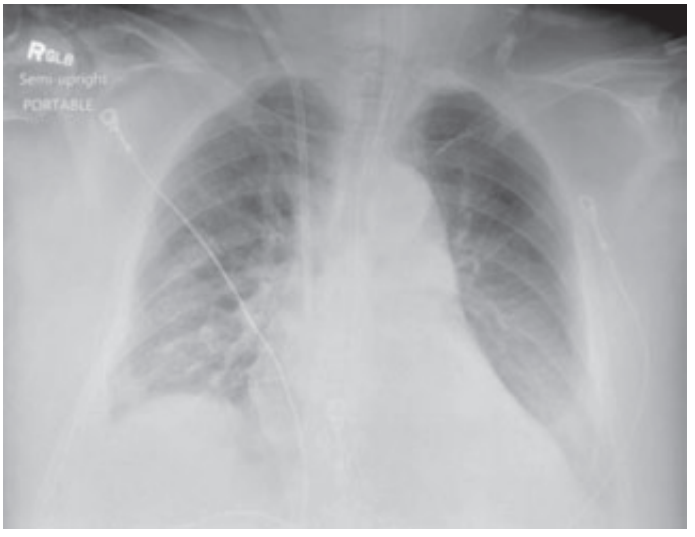


Figure 2. Post-Op Day 6 CXR at 2345, Post-MetaNeb Therapy (3 treatments).

Tina is Director, Respiratory Care Services for Wake Forest Baptist Medical Center, Winston-Salem, NC.

WHEN IT COMES TO
RESPIRATORY CARE

think
of the ramifications

THERE'S NO ROOM FOR COMPROMISE.

PATIENT SATISFACTION IS OUR HIGHEST PRIORITY AND WE KNOW IT IS YOURS TOO. THAT'S WHY EVERY DALE PRODUCT HAS BEEN DESIGNED AND MANUFACTURED TO DELIVER PERFORMANCE YOU CAN TRUST.

THE DALE TRACHEOSTOMY TUBE HOLDERS
DESIGNED TO PROVIDE SECURE POSITIONING AND TO MINIMIZE MOVEMENT OF THE TRACHEOSTOMY TUBE. WILL ALLOW YOU TO ELIMINATE THE FRUSTRATIONS ASSOCIATED WITH TWILL TIES AND OTHER HOLDERS WHILE MINIMIZING SECONDARY COMPLICATIONS AT THE SAME TIME. THE MOISTURE WICKING LINING ON THE 2-PIECE, ADJUSTABLE NECKBAND LEAVES THE SKIN DRY, REDUCING THE RISK OF SKIN BREAKDOWN. SECURE AND EASY TO USE FASTENER TABS FIT ANY SIZE TRACH PLATE.

DALE® ENDOTRACHEAL TUBE HOLDER
STABILOCK SECURES ENDOTRACHEAL TUBES QUICKLY AND EASILY TO HELP PREVENT ACCIDENTAL EXTUBATION. THE DALE STABILOCK PROVIDES EASY ACCESS TO THE PATIENT'S MOUTH ALLOWING THE CLINICIAN TO PERFORM ORAL CARE WHICH STUDIES SHOW CAN REDUCE THE RISK OF VAP. THE PRODUCT ALLOWS THE TUBE TO BE REPOSITIONED IN THE PATIENT'S MOUTH TO REDUCE RISK OF INJURY TO LIPS AND UNDERLYING TISSUES.

MINIMIZE COMPLICATIONS.
MAXIMIZE QUALITY CARE. THINK DALE.

THINK DALE®

ThinkRamifications.com
800-343-3980

Not all FDA-Cleared Finger Pulse Oximeters Perform Alike

Nonin Medical's SpO_2 technology is proven more accurate in patients with challenging conditions, like COPD*

Nonin Medical...when getting accurate SpO_2 values matter

Nonin Medical invented finger pulse oximeters, and we continue to be the most trusted brand of finger oximeters on the market.

Respiratory patients often have complex conditions with co-morbidities. Your ability to make the right decision is often dependent on getting an accurate SpO_2 reading. Nonin has more than 25 years of clinical usage experience. Our oximeters are superior for pediatric through adult patients and under challenging conditions, including labored breathing, dark skin tones, motion and low blood circulation.

"Does your oximeter work for *all* of your patients?"

Download the new study/white paper at **onyxvantage.com**

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

Visit us at **onyxvantage.com** or call **800.356.8874**

NONIN®
Leaders in *Nonin*vasive Medical Monitoring