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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. 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 (etCO₂). 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. etCO₂ ≤ 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.³ By comparison of ROC curves, etCO₂ had a higher discriminatory power to predict sepsis, severe sepsis, and mortality than the other variables collected in the study.¹ When all patients were considered, the area under the ROC curve predicting sepsis was 0.99 for etCO₂. Low etCO₂ 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

News

Fall 2016
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, Sevara 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

For more information contact us at: info@flosuretechnologies.com, or 914-909-6577
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Visit us at AARC booth #1206 in San Antonio!
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, Université 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.
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.

Visit us at AARC booth #803 in San Antonio!
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 comorbidities 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’ SpO2 readings in real time. Clinicians and patients can easily save or share their SpO2 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 SpO2 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 $800 million. BD’s Respiratory Solutions facilities will transfer to the new company,
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including locations in Yorba Linda, Calif.; Palm Springs, Calif.; Plymouth, Minn.; Mexicali, Mexico; Cotia, Brazil; Hoechberg, Germany and Shenzhen, 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 breathe 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 EtCO2 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 EtCO2,” EtCO2 measurements in non-intubated patients are unreliable so clinicians resort to using the respiratory rate (RR) measurements from the capnograph. Normal EtCO2 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 breaths/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 GHR. • “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.

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(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...
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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.

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The MiniMe® is a non-invasive ventilation mask for infants and children. Dräger will present the SmartVest® 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 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.

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What speakers or papers will you be featuring? 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.
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
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?

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 improved 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
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Phone: (800) 446-3908 or Email: ExperienceOptiflow@fphcare.com
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, LRCF, 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.

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Booth 801

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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.

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 PPT 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.
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.

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AEROSOL TREATMENT IN CHILDREN HAS NEVER BEEN MORE EFFICIENT

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.
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.

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.

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.

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

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 than a nasal cannula; as it doesn’t inhabit the nares or sit on the skin.

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 Cannula, Lumix Tx (a therapy device for hospital that includes all modes of ventilation) and our new Portable Oxygen Concentrator.
OxyMask™
Advancing Oxygen Therapy for Better Patient Care

An open oxygen mask ...
Learn more at: the better oxygen mask.com

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 input 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.
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Designed to win more than awards

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.

Please visit Getinge Group at AARC booth #412
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. 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. 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%. 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.

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. A current meta-analysis of 17 studies including 3369 patients noted a 0.58 relative risk for VAP using subglottic suction. 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.

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

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. 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.

The practical problems with subglottic suctioning became evident when looking closely at a randomized controlled SSD study conducted in France. 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. 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…”

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.
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]."

**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.

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

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 amounts 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. 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


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. 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. The overall prevalence of non-cystic fibrosis bronchiectasis is about 52 per 100,000 adults and the mean age at diagnosis is 61 years. The incidence of hospitalization due to non-cystic fibrosis bronchiectasis is rising and is markedly increased for patients 50 years of age or older. Bronchiectasis patients annually averaged: 6 more outpatient encounters, 27 more days of antibiotic treatments, and 2 more days in the hospital. In 2005, the estimated cost for non-cystic fibrosis bronchiectasis was $630 million annually in the United States.

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. Patients with non-cystic fibrosis bronchiectasis can have difficulty clearing airway secretions, and can benefit from airway clearance therapy. 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. 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. These methods generally aim to promote secretion clearance by...
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.

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

<table>
<thead>
<tr>
<th>Number of Hospitalizations</th>
<th>60% decrease in ER visits</th>
<th>6× reduction in steroid use</th>
<th>57% fewer antibiotic prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>per study sample (N=59)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One year pre-SmartVest</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One year post-SmartVest</td>
<td>12</td>
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</table>

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

“SmartVest” is a registered trademark of 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, 1 of 17 subjects (6%) 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 did not require a readmission for an exacerbation.

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>
<thead>
<tr>
<th>Table 1. Summary of outcomes for one year prior and one year after initiating the use of SmartVest for bronchiectasis (N=59)</th>
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<tbody>
<tr>
<td><strong>Hospitalizations</strong></td>
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<tr>
<td>Number hospitalized, n (%)</td>
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<tr>
<td>Total number of hospitalizations, n</td>
</tr>
<tr>
<td>Average hospitalizations per subject (n=17)</td>
</tr>
<tr>
<td>Average number of hospitalizations per study population (n=59)</td>
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<table>
<thead>
<tr>
<th><strong>Hospital readmissions</strong></th>
<th><strong>ER visits, n (%)</strong></th>
<th><strong>Antibiotic use, n (%)</strong></th>
<th><strong>Total number of prescriptions, n</strong></th>
<th><strong>Average number of prescriptions per subject (n=44)</strong></th>
<th><strong>Average number of prescriptions per study population (n=59)</strong></th>
<th><strong>Steroid use, n (%)</strong></th>
<th><strong>Post-SmartVest Use</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ER visits, n (%)</td>
<td>NA</td>
<td>5 (8%)</td>
<td>44 (74%)</td>
<td>1.9</td>
<td>1.4</td>
<td>11 (19%)</td>
<td>10 (17%)</td>
</tr>
<tr>
<td>Number hospitalized, n (%)</td>
<td>17</td>
<td>10</td>
<td>26 (44%)</td>
<td>1.2</td>
<td>0.6</td>
<td>2 (3%)</td>
<td></td>
</tr>
<tr>
<td>Total number of prescriptions, n</td>
<td>83</td>
<td>36</td>
<td>83</td>
<td>1.3</td>
<td>1.4</td>
<td>11 (19%)</td>
<td></td>
</tr>
<tr>
<td>Average number of prescriptions per study population (n=59)</td>
<td>0.5</td>
<td>0.2</td>
<td>0.5</td>
<td>0.6</td>
<td>11 (19%)</td>
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</table>

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). 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 HFCW0 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). 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. In contrast, there was no change in the self-reported symptom or SGRQ scores in patients who received conventional treatment. 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 (e.g., 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). The same study found that the annual age-adjusted hospitalizations rate was 16.5 hospitalizations per 100,000 population. 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. 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).

In conclusion, this study found that SmartVest significantly reduced bronchiectasis-related healthcare utilization and antibiotic 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.

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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 ECMO 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 rationale 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 H₂O. 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...
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 25cmH₂O or less, PEEP of 10cmH₂O 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 decreased.

Transpulmonary Monitoring

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 differentiate 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 27cmH₂O for VILI risk-reduction. Esophageal balloon monitoring is contra-indicated in patients with esophageal surgical procedures, GI bleeding, and other upper GI disease etiologies. Balloon
Airway Pressure Release Ventilation
Clinicians advocate for airway pressure release ventilation (APRV) as a ventilatory 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 (CO₂). Airway pressure release ventilation, unlike CPAP, facilitates both oxygenation and CO₂ clearance and originally was described as an improved method of ventilatory support in the presence of ALI and inadequate CO₂ 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 CO₂ 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 breathe 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 demonstrated 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 than 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. Accidental 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 cycler 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 CO₂ 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/H₂O.

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 (Kuniguyama & 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 CO₂ 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 term 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 (Kunigiyama & 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

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 al² and Oermann et al³ 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, Illinois¹ 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 clinician 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

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

### 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

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.
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• 9 setting variations for individualized treatment
• 7 sizes available
• Quiet and lightweight
• Medicare, Medicaid and Private Insurance reimbursed*

* Patients must qualify to meet eligibility requirements.
** Cooper, Michael, RT. An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest By International Biophysics contributed to improved lung function scores. Chicago, IL.
Taskett, 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

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** 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

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Predicted Value</th>
<th>Initial Pre-AffloVest Use Value</th>
<th>Interim Value Day 1</th>
<th>Final Value Day 315</th>
<th>%Change Final vs. Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>4.14</td>
<td>3.80</td>
<td>4.25</td>
<td>4.36</td>
<td>+ 14.74%</td>
</tr>
<tr>
<td>FEV1</td>
<td>3.52</td>
<td>3.02</td>
<td>3.47</td>
<td>3.50</td>
<td>+ 15.89%</td>
</tr>
<tr>
<td>FEF 25-75%</td>
<td>4.10</td>
<td>2.79</td>
<td>3.2</td>
<td>3.27</td>
<td>+ 17.20%</td>
</tr>
</tbody>
</table>

### Patient 2
**Age:** 12  **Gender:** Female  **Days using AffloVest:** 95

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

### Patient 3
**Age:** 17  **Gender:** Female  **Days using AffloVest:** 140

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

### Patient 4
**Age:** 12  **Gender:** Female  **Days using AffloVest:** 107

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

*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

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

### Patient 6
**Age:** 17  **Gender:** Male  **Days using AffloVest:** 74

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Predicted Value</th>
<th>Initial Pre-AffloVest Use Value</th>
<th>Interim Value Day 74</th>
<th>Final Value Day 74</th>
<th>%Change Final vs. Initial</th>
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<tbody>
<tr>
<td>FVC</td>
<td>3.81</td>
<td>2.65</td>
<td>NA</td>
<td>2.84</td>
<td>+ 21.79%</td>
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<tr>
<td>FEV1</td>
<td>3.34</td>
<td>1.51</td>
<td>NA</td>
<td>1.75</td>
<td>+ 15.89%</td>
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<tr>
<td>FEF 25-75%</td>
<td>3.93</td>
<td>0.74</td>
<td>NA</td>
<td>0.91</td>
<td>+ 22.97%</td>
</tr>
</tbody>
</table>

### Patient 7
**Age:** 17  **Gender:** Male  **Days using AffloVest:** 182

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

### Patient 8
**Age:** 13  **Gender:** Female  **Days using AffloVest:** 31

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Predicted Value</th>
<th>Initial Pre-AffloVest Use Value</th>
<th>Interim Value Day 16</th>
<th>Final Value Day 31</th>
<th>%Change Final vs. Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>2.94</td>
<td>2.1</td>
<td>2.89</td>
<td>3.06</td>
<td>+ 45.71%</td>
</tr>
<tr>
<td>FEV1</td>
<td>2.77</td>
<td>1.44</td>
<td>2.11</td>
<td>2.61</td>
<td>+ 11.25%</td>
</tr>
<tr>
<td>FEF 25-75%</td>
<td>3.43</td>
<td>* 0.87</td>
<td>1.67</td>
<td>2.48</td>
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</table>

*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

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Predicted Value</th>
<th>Initial Pre-AffloVest Use Value</th>
<th>Interim Value Day 12</th>
<th>Final Value Day 112</th>
<th>%Change Final vs. Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>2.06</td>
<td>2.31</td>
<td>NA</td>
<td>2.49</td>
<td>+ 7.79%</td>
</tr>
<tr>
<td>FEV1</td>
<td>1.88</td>
<td>1.68</td>
<td>NA</td>
<td>1.96</td>
<td>+ 16.67%</td>
</tr>
<tr>
<td>FEF 25-75%</td>
<td>2.28</td>
<td>1.33</td>
<td>NA</td>
<td>1.73</td>
<td>+ 30.08%</td>
</tr>
</tbody>
</table>

### Patient 10
**Age:** 15  **Gender:** Female  **Days using AffloVest:** 177

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Predicted Value</th>
<th>Initial Pre-AffloVest Use Value</th>
<th>Interim Value Day 28</th>
<th>Final Value Day 177</th>
<th>%Change Final vs. Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>3.09</td>
<td>2.09</td>
<td>2.38</td>
<td>2.77</td>
<td>+ 32.54%</td>
</tr>
<tr>
<td>FEV1</td>
<td>2.79</td>
<td>1.41</td>
<td>1.77</td>
<td>1.84</td>
<td>+ 30.50%</td>
</tr>
<tr>
<td>FEF 25-75%</td>
<td>3.46</td>
<td>0.91</td>
<td>1.38</td>
<td>1.01</td>
<td>+ 10.99%</td>
</tr>
</tbody>
</table>

### Patient 11
**Age:** 12  **Gender:** Female  **Days using AffloVest:** 98

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

### Patient 12
**Age:** 18  **Gender:** Male  **Days using AffloVest:** 28

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


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, PhD2

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 patient-ventilator 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.6,11 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...
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).

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 differences (Table 2).
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 1—Sedative Units Determined for Each Drug

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (boluses)</th>
<th>Dose (infusion)</th>
<th>Sedative unit¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam</td>
<td>0.1 mg/kg</td>
<td>0.1–0.4 mg/kg/hr</td>
<td>0.1 mg/kg</td>
</tr>
<tr>
<td>Diazepam</td>
<td>0.1–0.2 mg/kg</td>
<td>None</td>
<td>0.133 mg/kg</td>
</tr>
<tr>
<td>Propofol</td>
<td>1–3 mg/kg</td>
<td>1–4 mg/kg/hr</td>
<td>1.0 mg/kg</td>
</tr>
<tr>
<td>S-Ketamine</td>
<td>1–2 mg/kg</td>
<td>0.5–3.5 mg/kg/hr</td>
<td>0.875 mg/kg</td>
</tr>
<tr>
<td>Thiopental</td>
<td>3–7 mg/kg</td>
<td>1–5 mg/kg/hr</td>
<td>1.5 mg/kg</td>
</tr>
<tr>
<td>Dexmedetomidine</td>
<td>0.5–1 µg/kg</td>
<td>0.2–0.8 µg/kg/hr</td>
<td>0.5 µg/kg</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Loading 20 mg/kg maintenance 3–6 mg/kg/d</td>
<td>None</td>
<td>4 mg/kg</td>
</tr>
</tbody>
</table>

¹A 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.

### TABLE 2—Patient Characteristics and Indications for Invasive Ventilation

<table>
<thead>
<tr>
<th></th>
<th>NAVA</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Males n (%)</td>
<td>51 (60)</td>
<td>51 (60)</td>
</tr>
<tr>
<td>Age (months) Mean (SD)</td>
<td>50.0 (63.4)</td>
<td>39.4 (61.4)</td>
</tr>
<tr>
<td>Weight (kg) Mean (SD)</td>
<td>17.4 (17.0)</td>
<td>15.5 (19.5)</td>
</tr>
<tr>
<td>Height (cm) Mean (SD)</td>
<td>93.0 (39.2)</td>
<td>82.4 (37.8)</td>
</tr>
<tr>
<td>Treatment indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative care n (%)</td>
<td>66 (77.6)</td>
<td>65 (76.5)</td>
</tr>
<tr>
<td>Craniosurgery</td>
<td>12 (14.1)</td>
<td>10 (11.8)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>8 (9.4)</td>
<td>6 (7.1)</td>
</tr>
<tr>
<td>Palato-/velopharyngoplasty</td>
<td>16 (18.8)</td>
<td>13 (15.3)</td>
</tr>
<tr>
<td>Orthopedic surgery</td>
<td>14 (16.5)</td>
<td>13 (15.3)</td>
</tr>
<tr>
<td>Gastrointestinal surgery</td>
<td>7 (8.2)</td>
<td>10 (11.8)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (10.6)</td>
<td>13 (15.3)</td>
</tr>
<tr>
<td>Respiratory infection n (%)</td>
<td>8 (9.5)</td>
<td>6 (7.1)</td>
</tr>
<tr>
<td>Neonatal sepsis n (%)</td>
<td>1 (1.2)</td>
<td>3 (3.5)</td>
</tr>
<tr>
<td>Neonatal RDS n (%)</td>
<td>3 (3.5)</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>Meconium aspiration n (%)</td>
<td>3 (3.5)</td>
<td>4 (4.8)</td>
</tr>
<tr>
<td>Near drowning/suffocation n (%)</td>
<td>1 (1.2)</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>Trauma n (%)</td>
<td>1 (1.2)</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Others¹ n (%)</td>
<td>2 (2.4)</td>
<td>2 (2.4)</td>
</tr>
</tbody>
</table>

¹Varicella Zoster meningoencephalitis/ADEM and SSRI side effects in a newborn infant in the NAVA group, and cardiac failure and hemoptysis in the control group.
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. 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, and it has also been shown that the better synchrony provided by NAVA improves patient comfort. 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

<table>
<thead>
<tr>
<th></th>
<th>NAVA mean (SD)</th>
<th>Control mean (SD)</th>
<th>Difference of the means</th>
<th>95% CI</th>
<th>P-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedation units per hour</td>
<td>1.42 (1.76)</td>
<td>1.81 (2.16)</td>
<td>-0.39</td>
<td>-1.00 to 0.21</td>
<td>0.20</td>
</tr>
<tr>
<td>Amount of opiates per hour²</td>
<td>0.048 (0.061)</td>
<td>0.057 (0.079)</td>
<td>-0.009</td>
<td>-0.031 to 0.012</td>
<td>0.39</td>
</tr>
<tr>
<td>Postoperative patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedation units per hour</td>
<td>1.58 (1.85)</td>
<td>1.68 (2.03)</td>
<td>-0.10</td>
<td>-0.78 to 0.58</td>
<td>0.77</td>
</tr>
<tr>
<td>Amount of opiates per hour²</td>
<td>0.052 (0.067)</td>
<td>0.065 (0.088)</td>
<td>-0.013</td>
<td>-0.040 to 0.015</td>
<td>0.36</td>
</tr>
<tr>
<td>Postoperative patients excluded</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedation units per hour</td>
<td>0.80 (1.16)</td>
<td>2.23 (2.54)</td>
<td>-1.43</td>
<td>-2.79 to -0.07</td>
<td>0.03</td>
</tr>
<tr>
<td>Amount of opiates per hour²</td>
<td>0.030 (0.022)</td>
<td>0.032 (0.030)</td>
<td>-0.002</td>
<td>-0.020 to 0.015</td>
<td>0.78</td>
</tr>
</tbody>
</table>

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

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**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.
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
Introducing The VisiVest™ System

Enhancing Teamwork.
Enhancing Care.
Enhancing Life.

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.

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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.5 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.6 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.

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.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.9 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

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.
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.2 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**


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

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. Evidence has shown that the deployment of specialized teams, although it may take longer, results in increased patient safety and improved patient outcomes.

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.

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 and has been shown to improve oxygenation in neonates and children being transferred to an ECMO center. 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.

References


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
Capnography can be a cost-effective way to monitor real-time carbon dioxide (CO₂) 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 (etCO₂ or PetCO₂), the maximal concentration of CO₂ during exhalation
- Fraction of inspired CO₂ (FiCO₂) which should generally be zero as inhaled air contains minute amounts of CO₂
- Capnogram (aka, capnograph, etCO₂ waveform) which is a graphic representation of the CO₂ 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, 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. In addition to its value in confirming proper ETT placement, capnography may also be useful for trending CO₂ 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.

Capnography is measured using two primary methods. Mainstream capnography measures CO₂ by placing a sensor chamber directly in the breathing circuit, attached at the ETT and provides a graph of the CO₂ concentration against volume. Sidestream capnography measures CO₂ by drawing a sample of the breath from the breathing circuit to the sensor within the monitor and plots a CO₂-time capnogram. Each offers advantages which are summarized in Table 1. Microstream technology is an innovation of sidestream technology which uses a CO₂-specific IR wavelength that is unaffected by the presence other gases (ie O₂, N₂O, He or inhaled anesthetics). 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.

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<thead>
<tr>
<th>Mainstream</th>
<th>Sidestream</th>
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<tr>
<td>Advantages:</td>
<td>Advantages:</td>
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<tr>
<td>1. Some devices provide estimates of dead space (Vd/Vt)</td>
<td>1. Less weight/obstruction on the end of the ETT which may reduce the potential for kinking and migration/extubations and improve patient comfort</td>
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<tr>
<td>2. No removal of air from Vt to sample for measurement</td>
<td>2. No external exposure of expensive sensor to damage/replacement</td>
</tr>
<tr>
<td>3. Easy to use with intubated and non-intubated applications</td>
<td>3. Easy to use with intubated and non-intubated applications</td>
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Capnography in Intubated Infants

In patients with normal ventilation to perfusion (V/Q) matching, the etCO₂ is generally 2-5 mmHg less than the arterial CO₂ (PₐCO₂). 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 etCO₂ to PₐCO₂ remained strong at all ranges of increasing dead space. McSwain states, “In patients with a Vd/Vt ≤ 0.40 there was an excellent correlation (p=0.95) between PetCO₂ and PaCO₂. 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, PetCO₂ appears to be a useful indicator of PaCO₂ even in patients with substantial lung disease, provided that the expected increase in the PetCO₂-PaCO₂ 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 etCO₂ and PaCO₂. However, this correlation was stronger in the groups with no underlying lung disease. Naidu concluded that while etCO₂ cannot replace ABGs, it can be used as a valuable trending tool understanding the impact of gradient.

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premature infants with a median gestational age of 26.5 weeks were ventilated with HFV. Analysis included 195 measurements and the correlation of carinal etCO2 with PaCO2 ($r = 0.68, P < 0.0001$) and the agreement (bias ± precision: $-2.0 ± 10.7 \text{mmHg}$) were adequate. They concluded that continuous integrated etCO2 measured at the carina is feasible in HFV, has adequate correlation and agreement with PaCO2 and can be helpful for trends and alarm for unsafe levels of PaCO2 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 CO2 with ABG was excellent ($r^2 = 0.907$). 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 CO2 to ABG.

In a retrospective study, Moses et al investigated the correlation and level of agreement between end-tidal carbon dioxide and venous CO2 ($PvCO_2$) in non-intubated pediatric patients with moderate to severe respiratory distress. EtCO2 was correlated highly with $PvCO_2$ 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, etCO2 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 CO2. 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

**References**


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**etCO2 Sampling at the Carina**

Kugelman et al explored an innovative method of sampling etCO2 at the carina through the use of an endotracheal tube (ETT) with a monitoring lumen (Figures 1 and 2), which may be less affected by the ventilator circuit flow and leaks around the uncuffed ETTS, thus improving the correlation with PaCO2. 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 etCO2 and PaCO2 for most infants; etCO2 is typically two to five millimeters of mercury lower than PaCO2 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 CO2 at the carina and ETT connector respectively, carinal end-tidal CO2 had a better correlation with PaCO2 and a better agreement with PaCO2 than etCO2 sampled at the ETT connector. In patients with significant lung disease ($P_{O_2}/P_{O_2}$ ratio < 0.3), the gradient between carinal etCO2 and PaCO2 increased, but the bias remained < 5 mm Hg. The average agreement with $PvCO_2$ was $–1.5\text{mmHg}$.

More recently, Kugelman used this same sampling method in infants using high-frequency ventilation (HFV). Sixteen
Integrated O₂ 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 O₂ system, this study demonstrated a reduced need for non-invasive ventilation by approximately 80%, less episodes of O₂ 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.

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.

**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):

<table>
<thead>
<tr>
<th>Extubation To Simple Oxygen Therapy/Cold Aerosol Mask Or Trach Collar</th>
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<tbody>
<tr>
<td>Cost of complete stand-alone setup (Aerosol generator, tubing, mask or trach collar)</td>
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<tr>
<td>Cost of Aerosol mask alone (using existing circuit from ventilator)</td>
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<tr>
<td><strong>Cost Savings Using V500/VN500 O₂ Therapy option</strong></td>
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<tr>
<th>Extubation To High-Flow Nasal Cannula</th>
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<tr>
<td>Cost of complete stand-alone setup (HF cannula, proprietary circuit)</td>
</tr>
<tr>
<td>Cost of high-flow cannula alone (using existing circuit from ventilator)</td>
</tr>
<tr>
<td><strong>Cost Savings Using V500/VN500 O₂ Therapy option (excluding device and maintenance costs)</strong></td>
</tr>
</tbody>
</table>

**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 O₂ therapy option as FI₂ 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.
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 O₂ Therapy option provides a cost-effective alternative to providing high-flow nasal O₂ 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.

References
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
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
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.
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