

Volume 10 Number 4 Fall 2015

Respiratory Therapy™

The Journal of Pulmonary Technique



ONLY ONE

LiteSaver™

a disposable, color-coded manometer
with integrated timing light

Any time a patient is being manually ventilated, managing ventilation rates, volumes and pressure is extremely important.

Having a manometer with timing light integrated with a BVM (CPR bag) is critical for validating delivered pressures and helps clinicians in delivering proper ventilation rates.

- Easy-to-Use Timing Light with Pull Tab for activation
- Light blinks every 6 seconds/10 breaths per minute
- Assists in Reduced Risk of Aspiration
- Assists in Reduced Stacking of Breaths
- Variety of BVM configurations

Delivering safer ventilation results in sufficient expiration time avoiding breath stacking.

Visit the Mercury Medical Booth #1023
AARC Congress 2015
American Association for Respiratory Care
Tampa Convention Center - Tampa, Florida
November 7 - 10, 2015

Patent # US 5,557,049 B1, # US 8,522,618 B1, Other Patents Pending

mercurymed.com
800.2376418

Mercury Medical®

50+
YEARS

Your Need . . . Our Innovation®

Pull
to
Activate
Timing Light



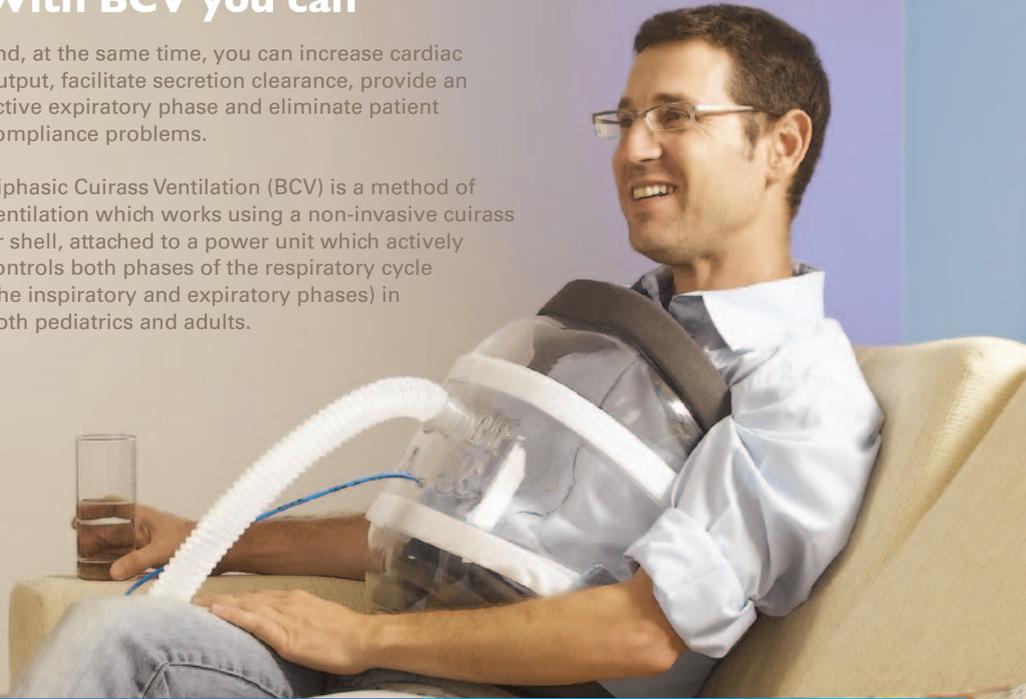
What if you could ventilate...

- without a facemask?
- without sedation?
- without the risk of barotrauma?
- without the risk of infection?

With BCV you can

and, at the same time, you can increase cardiac output, facilitate secretion clearance, provide an active expiratory phase and eliminate patient compliance problems.

Biphasic Cuirass Ventilation (BCV) is a method of ventilation which works using a non-invasive cuirass or shell, attached to a power unit which actively controls both phases of the respiratory cycle (the inspiratory and expiratory phases) in both pediatrics and adults.



Key Benefits of BCV:

- A real **non-invasive alternative** to invasive ventilation
- Provides **complete ventilation** non-invasively without the need for a mask
- Has **over 200 citations** to demonstrate safety and efficacy
- Proven to **increase cardiac output** - and reduce CO₂ levels
- Is a **super potent secretion clearance** tool
- The only method of ventilation that has **no known side effects**
- Treatment can be administered either in the **hospital or the home**
- **More comfortable**, for most, than a mask or endotracheal tube

Patient Groups:

- Acute respiratory failure
- Chronic Obstructive Pulmonary Disease
- Neuromuscular
- Cystic fibrosis
- Difficult to wean patients
- AIDS related lung disease
- Head and spinal injuries
- Ventilation post-operation
- Influenza pandemic
- ...and many more



You can use BCV in almost any circumstance you would use non-invasive ventilation, and in most cases where you would use invasive ventilation too. To find out more visit: <http://www.unitedhayek.com/bcv>

ISSN 2152-355X

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

Publisher/Editor in Chief

Steve Goldstein

Managing Editor Christopher Hiscox

Senior Editor Chris Campbell

News Editor Vincent Terrier

Associate Editor Jordana Hammeke

Associate Editor Susan Goldstein

Assistant Editor Laszlo Sandor

Circulation, Coverage, Advertising

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

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

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

©2015 by Goldstein & Associates, Inc. All rights reserved. Reproduction in whole or in part without written permission is strictly prohibited.

Editorial Advisory Board

Mohammed Al Ahmari, PhD, MSc, RRT
AARC Intl Fellow
Director, Respiratory Care Program
King Fahd Military Medical Complex &
Prince Sultan College of Health Sciences
Al-Khobar, Saudi Arabia

Prof. Nicolino Ambrosino, Head,
Pulmonary Unit, Cardio-Thoracic
Department
University Hospital, Pisa; Head,
Pulmonary Rehabilitation and
Weaning Unit
Auxilium Vitae, Volterra, Italy

Muhammad Aslam, MD
Associate Professor of Pediatrics
University of California Irvine
Neonatologist
UCI Medical Center
California, USA

Eliezer Be'eri, MD
Director, Respiratory Rehabilitation Unit
Alyn Hospital
Founder and CSO
Innovent Medical Systems
Jerusalem, Israel

Melissa K. Brown, BS, RRT-NPS, RCP
Faculty, Respiratory Therapy Program
Grossmont College
El Cajon, CA

Prof. Andrea Calkovksa, MD, PhD
Department of Physiology, Jessenius
Faculty of Medicine
Comenius University
Mala Hora, Slovakia

Prof. Enrico M. Clini
Clinica di Malattie Apparato
Respiratorio
Dipartimento di Oncologia
Ematologia e Pneumologia
Universita Studi di Modena e
Reggio, Italy

Larry H. Conway, BS, RRT Chief,
Director of Respiratory Care
VA Medical Center
Washington, DC

Ed Coombs, MA RRT-NPS, ACCS, FAARC
Marketing Director — Intensive Care
Key Application Field Manager —
Respiratory Care
North America
Draeger Medical
Telford, PA

Prof. Caglar Cuhadaroglu, MD
Pulmonology Department and
Sleep Center
Maslak Hospital, Faculty of Medicine
University of Acibadem
Istanbul, Turkey

Antonio Esquinas, MD, PhD, FCCP
Director, International School of
Noninvasive Mechanical Ventilation
Catholic University-San Antonio
Murcia, Spain

Dr. Javier Fernandez
Director of Clinical Affairs & Education
Respiratory Division Latin America
Miami, FL

Gerardo N. Ferrero, PT
Clinical Specialist, Latin America
Buenos Aires, Argentina

Louis Fuentes, RRT
Marketing Manager — Ventilation
Maquet Medical Systems, USA
Wayne, NJ

Dr. Miguel Goncalves
Pulmonology Department and ICU and
Emergency Department
University Hospital of S. João School
Faculty of Medicine
University of Porto, Portugal

Joshua F. Gonzales, MHA, RRT-NPS,
RRT-SDS, RCP
Associate Professor
Department of Respiratory Care
Texas State University
San Marcos, TX

Rik Goselink, PT, PhD
Professor, Rehabilitation Sciences
Dean, Faculty of Kinesiology and
Rehabilitation Sciences
Universitaire Ziekenhuizen Leuven/
Katholieke Universiteit Leuven, Belgium

Charles J. Gutierrez, PhD, RRT, FAARC
Assistant Chief
Neurorespiratory Care Program —
Spinal Cord Injury Center
James A. Haley Veterans Hospital
Tampa, FL

Ken D. Hargett, MHA, RRT, RCP, FAARC,
FCCM
Director, Respiratory Care Services,
Pulmonary Diagnostic Laboratory,
Digestive Disease Endoscopy
The Methodist Hospital
Houston, TX

Surinder K. Jindal, MD
Postgraduate Institute of Medical
Education & Research
Chandigarh, India

Brent D. Kenney, BSRT, RRT, RCP, FAARC
Supervisor of Care Coordinators,
Respiratory Care Department
Mercy Hospital
Springfield, MO

Prof. Dr. Naomi Kondo Nakagawa
Department of Physiotherapy,
Communication Science and Disorders
and Occupational Therapy
Faculdade de Medicina da Universidade
de Sao Paulo, Brazil

Scott E. Leonard, MBA, BA, RRT
Director of Respiratory Therapy, EEG,
Neurophysiology
George Washington University Hospital
Washington, DC

Rebecca A. Mabry, BS
Senior VP, Marketing and Sales
Breathe Technologies, Inc.
Irvine, CA

Paul Mathews, PhD, RRT, FCCM,
FCCP, FAARC, Associate Professor,
Respiratory Care Education, University
of Kansas Medical Center
Kansas City, KS

Benan Mayrakci, MD
Assistant Professor of Pediatrics
Director of Pediatric
Intensive Care Unit
Hacettepe University School of
Medicine, Ankara, Turkey

Timothy R. McConnell, PhD
Chair, Department of Exercise Science
Bloomsburg University
Pennsylvania USA

Bob Messenger, BS, RRT, CPFT
Manager, Respiratory Clinical Education
Invacare Corporation
Elyria, OH

Kenneth Miller, Med, RRT-NPS, AE-C
Clinical Educator, Dean of Wellness,
Respiratory Care Services
Lehigh Valley Health Network
Allentown, PA

Nawal M. Mofarreh
MBBS, Arab Board-Internal
Medicine I, Cardiac Center-
Al-Thawra General Modern Hospital,
CPR Instructor & Co-Ordinator
Saudi Heart Association in affiliation
with American Heart Association, CPR
Center, Al-Thawra Hospital
Sana'a-Yemen

Richard J. Morishige, MS, RRT, RCP,
RAC
Director, Clinical Affairs
Breathe Technologies, Inc.,
Irvine, CA

Pavlos M. Myrianthefs, MD, PhD
Assistant Professor
Athens University
Critical Care Department
KAT Hospital
Athens

Cheryl Needham, BA, RRT
Sr. Clinical Marketing Manager
Global Channel Marketing
Philips Home Healthcare Solutions
Murrysville, PA

Paul Nuccio, MS, RRT, FAARC
Director of Pulmonary Services
Brigham and Women's Hospital &
Dana-Farber Cancer Institute
Boston, MA

Lisa Pappas, RRT, BS
Respiratory Clinical Coordinator, NICU
University of Utah Hospital
Salt Lake City, UT

Hossein Razavi, MD, FCCP
Pulmonary, Critical Care &
Sleep Medicine
St. Helena, CA

Dr. John H. Riggs, PhD, RCP, FAARC
Director of Respiratory Services
Mission Hospitals
Asheville, NC

Daniel D. Rowley, MSc, RRT-ACCS, NPS,
RPFT, FAARC
Clinical Coordinator
Pulmonary Diagnostics & Respiratory
Therapy Services
University of Virginia Medical Center
Charlottesville, VA

J. Kyle Schwab, MD
Medical Director
Louisiana Sleep Foundation
Baton Rouge, LA

Tushar A. Shah, MD, MPH, FAAP
Division of Neonatology
Cincinnati Children's Hospital
Medical Center
Cincinnati, OH

Chet Sivert Jr, BS
Director of Regulatory and
Clinical Affairs
Electromed, Inc.
New Prague, MN

Dave Swift, RRT
Ottawa Hospital — Civic Site; Campus
Coordinator (Professional Practice) &
Special Care Nursery Charge Therapist;
Respiratory Therapy Team Lead;
National Office of the Health Care
Emergency Response Team (NOHERT);
Subject Matter Expert, Health Canada



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

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



For more information go to www.nddmed.com

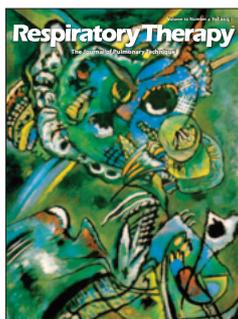


Table of Contents

DEPARTMENTS

- 6 News
- 18 Executive Preview AARC

ARTICLES

- 27 Automated Intermittent Subglottic Secretion Drainage
- 29 Improving Oxygen Supply Safety
- 31 Benefits of Vibrating Mesh with Valved Adapter
- 32 Improving Lung Function Scores
- 37 Optimizing Gas Exchange
- 41 Testing Blood Gas and Electrolyte Analyzers
- 42 Interview
- 46 Learning By Simulation
- 49 Assessing the H.R. 2619 RT Initiative Act
- 51 COPD and the Quality of Spirometry of Patients
- 53 Diagnosis of Acute Respiratory Distress Syndrome
- 61 Role of Sedation for Agitated Patients

News

■ Fall 2015

GOLD Diagnostic Measures 'Don't Work'

Current chronic obstructive pulmonary disease (COPD) management programs and guidelines overdiagnose elderly patients and underdiagnose young ones, according to an analysis that details the problem and calls for the adoption of lower limits of normal (LLN) criteria for airflow obstruction that are specific for different populations. Martin R. Miller, MD, from the University of Birmingham in the United Kingdom, and Mark L. Levy, MBChB, from the Harrow Clinical Commissioning Group in London, United Kingdom, wrote their article as part of a series in the journal on overdiagnosis. The Global Initiative for Obstructive Lung Disease (GOLD) strategy documents were introduced in 2001 and were intended to create a new and simple threshold for airway obstruction. A diagnosis of COPD is thus based entirely on an assessment of airway obstruction as measured by the ratio of forced expiratory volume in 1 second (FEV1) divided by the forced vital capacity (FVC). Although the GOLD guidelines are based on consensus expert opinion, they do not effectively diagnose COPD, Dr Miller and Dr Levy contend. Yet, the GOLD criteria have been adopted by the UK National Institute for Health and Care Excellence and are used extensively throughout the United States, Europe, and Australasia. In their analysis, Dr Miller and Dr Levy propose that the GOLD criteria be refined by the addition of LLN criteria. At a minimum, they suggest, the LLN should be incorporated into future studies of COPD. The authors explain that when the GOLD definition is applied to England and Wales, 22% of individuals older than 40 years meet the criteria for COPD. In contrast, the LLN criteria would diagnose 13% of individuals older than 40 years as having COPD, suggesting the current system results in a great deal of overdiagnosis.

Telehealth Partnership for COPD Remote Patient Monitoring

Nonin Medical, Inc., the inventor of

finger pulse oximetry and a leader in noninvasive medical monitoring, today announced it has partnered with IDEAL Life, a Toronto-based leader in remote health management solutions. IDEAL Life will integrate the Nonin Model 3230 Bluetooth Smart wireless finger pulse oximeter into its latest telehealth platform. The IDEAL Life system remotely monitors the oxygen saturation and other vital signs of chronic illness patients at home, then transmits the data to the hospital or clinic. Model 3230 advantages include: Bluetooth Smart (low energy) wireless technology, which provides long battery life and simplified pairing with quality systems like IDEAL Life; Nonin's clinically proven PureSAT pulse oximetry technology, which utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements—even in the presence of motion, low perfusion or other challenging conditions Nonin's CorrectCheck technology, which provides digital feedback when the patient's finger is placed incorrectly in the device; Nonin's SmartPoint capture algorithm that automatically determines when a high quality measurement is ready to be wirelessly transmitted to help improve accuracy. The Nonin Model 3230 Bluetooth Smart Pulse Oximeter won the Bluetooth Breakthrough Award in 2014.

Instrumentation System Offers Flexibility

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

A *NEW* Direction for Subglottic Secretion Management

The **SIMEX** Subglottic Aspiration System, *cuff M* and *cuff S* are the most advanced solution for the aspiration of subglottic secretion, featuring an all-new, state-of-the-art, *automated intermittent* mode of therapy.

- Reduced risk of injury due to drying of the mucous membrane
- Fully customizable
- Increased patient comfort/ virtually silent operation
- Respiratory Therapist has significantly more control over the aspiration procedure
- Self-contained system prevents cross contamination

“In our experience, the amount of material drained increases by up to 10 times over what we were seeing with manual suctioning by our staff. It has saved time for our staff and reduced our contact with infectious material. And it has been beneficial to our patients, with less force put on the tracheal wall and no trauma from repeated endotracheal suctioning. To date, we have successfully treated over 300 patients using the SIMEX automated intermittent system.”

Dr. med Marcus Wolf
Senior Physician Weaning Station, Department
of Pneumology and Intensive Care
Askepolis Klinik Bambeck, Hamburg, Germany

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

FloSure™

www.flosuretechnologies.com

For more information contact us at: info@flosuretechnologies.com, or 914-909-6577
©2015 FloSure Technologies' LLC, all rights reserved.

SF-434-09/15

Electromed Invests in Smart Airway Technology

Electromed has announced the US market launch of its next generation SmartVest Airway Clearance System for acute care high frequency chest wall oscillation (HFCWO), the model SQL-I. The SmartVest SQL-I is designed to promote airway clearance, improve bronchial drainage and enhance mucus transport for patients with a wide range of pulmonary-related health conditions. The SmartVest SQL-I builds on Electromed's successful launch of the SQL System for homecare use in January 2014, by offering a device that is significantly smaller, quieter and lighter than previous versions. The system features enhanced generator programmability and adjustable RAMP, allowing clinicians greater flexibility to program patient specific HFCWO therapy protocols. The system also features a patented single-hose design, which eliminates multiple connection points, allows the patient greater freedom of motion and eliminates additional maintenance associated with hose cleaning. "The SmartVest SQL-I System represents Electromed's commitment to innovation by delivering market-driven HFCWO therapy solutions to physicians and their patients," said Kathleen Skarvan, Chief Executive Officer. "We designed the SmartVest SQL-I with unique features that set us apart from other HFCWO devices — plus innovations to help hospital staff provide the ultimate in therapeutically effective airway clearance therapy for adults and children." Additionally, the SmartVest SQL-I System features active inflate-active deflate and an open system design, which provides a more comfortable therapy experience by allowing patients to take deep breaths and breathe more easily without feeling restricted. The SmartVest System is sold into the homecare market for people with chronic lung issues, including bronchiectasis, cystic fibrosis and neuromuscular disease, and

into the acute care setting for patients suffering from impaired airway clearance.

Companies Locked in Battle

3B Medical, maker of products used in the treatment of obstructive sleep apnea, has filed a legal action in the US District Court for the Middle District of Florida, alleging antitrust violations by ResMed – specifically alleging that ResMed is “choosing winners and losers in the CMS competitive bidding process by preferential pricing,” and has “created an environment of fear and bullying among customers,” and “intentionally interfered in 3B Medical’s business relationships.” In a statement from ResMed’s Global General Counsel, David Pendarvis, the company responded to 3B Medical’s allegations against ResMed: “There is no substance to the claims in the case. ResMed conducts business in an ethical and lawful manner. Physicians, customers, and patients prefer our products because they are better. We expect to win this case if it is brought to trial. We recently filed – and won – a case for patent infringement against 3B and its Chinese-based manufacturer, BMC Medical Co. The International Trade Commission agreed with us and found that BMC and 3B had infringed ResMed’s mask patents. In their complaint, 3B concedes they have had very limited success in the marketplace. Our business creates better lives for patients by designing, making, and selling high quality products that provide value for patients, customers, and healthcare systems. We maintain our focus on changing 20 million lives by 2020.”

Acquisition Completed

Becton, Dickinson and Company has announced that it completed its acquisition of CareFusion Corporation.



Find the **perfect FIT** for your patients
with **CAIRE POCs.**



- Ensure patients are saturated at ALL times at any activity level
- Treat all disease states from early to severe with our market-leading selection of POCs
- Unlimited Ambulation with POCs give the highest quality of life compared to tanks
- The most clinical features to ensure the highest level of treatment



Early
Mild
Moderate
Severe

Available Concentrator	Weight	Flow Settings	Oxygen Output	Features
AirSep Focus	1.75 lb	Pulse: 2	332.5 mL/min	<ul style="list-style-type: none"> • Wearable • UltraSense technology* • Simple 1-Touch Operation
AirSep FreeStyle	4.4 lbs	Pulse: 1 - 3	500 mL/min	
AirSep FreeStyle 5	6.2 lbs	Pulse: 1 - 5	1000 mL/min	
SeQual eQuinox	14.0 lbs	Pulse: 1 – 9 Cont.: 0.5 – 3.0 LPM	Bolus Size 16 mL – 192 mL	<ul style="list-style-type: none"> • Transportable • 24/7 Capability • autoSAT Technology** • Adjustable Rise Time • Adjustable Sensitivity • Voice Module available on eQuinox
SeQual Eclipse	18.4 lbs			

*UltraSense Technology

- -0.054 to -0.1 cm H₂O sensitivity is the most sensitive trigger of any concentrator
- Prevents skipped breaths and provides maximum patient comfort
- Ensures delivery in first 1/3 of inhalation

**autoSAT Technology

- Servo-controlled compressor adjusts speed based on patient's breathing rate
- Keeps saturation levels up as activity increases
- Ensures fixed bolus size is always delivered with every breath
- Ensures accurate and timely delivery of pulse dose

For more information, please contact our CAIRE Customer Support Team: **800.482.2473** www.chartindustries.com/Respiratory-Healthcare

The F&P Infant Respiratory Care Continuum™



Toby's Journey to Health

Follow Toby around our Care Continuum to see his journey from birth to home. **We're there every step of the way.**



To learn more about Toby's journey and our therapy solutions along the F&P Infant Respiratory Care Continuum™ visit www.fphcare.com
 Fisher & Paykel Healthcare 15365 Barranca Parkway, Irvine, CA 92618 USA.
 Tel + 800 446 3908 or +1 949 453 4000 Fax +1 949-585-9803

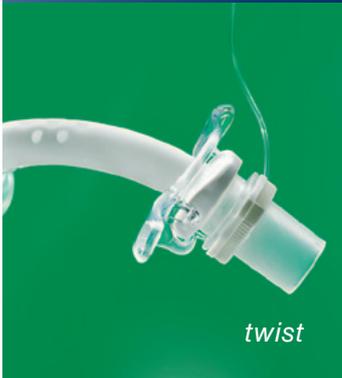


TRACOE®



comfort

a Trach Tube is not just a Trach Tube



twist

- Improved airflow
- Less breathing resistance
- Patient comfort



vario

TRACOE medical GmbH
Germany

Quality by People for People

www.tracoe.com



modular

Visit us at the
AARC 2015 in Tampa,
FL – Booth Nr. 1039



mini

Vincent A. Forlenza, BD's Chairman, Chief Executive Officer and President, said, "We are very excited to announce the consummation of the CareFusion acquisition, as it represents a major milestone in BD's 118-year history. This acquisition significantly accelerates BD's strategy and builds scale and depth in medication management and patient safety solutions. We look forward to the future with confidence as we become one of the largest global leaders in medical technology, and are better positioned to partner with healthcare providers around the world to provide safer, more economical and improved care." Excluding transaction-related expenses relating to the closing, BD expects the acquisition to have an immaterial impact on the company's results of operations in the second fiscal quarter, which ends on March 31, 2015. The company will provide an update to its fiscal year 2015 outlook on its second fiscal quarter earnings conference call in May. Beginning in the second half of fiscal year 2015, BD will report a new Medical segment structure, which will include CareFusion. BD is a leading medical technology company focused on improving medication management and patient safety; supporting infection prevention practices; equipping surgical and interventional procedures; improving drug delivery; aiding anesthesiology and respiratory care; advancing cellular research and applications; enhancing the diagnosis of infectious diseases and cancers; and supporting the management of diabetes.

Product Named to FDA List

The FDA has listed Kitabis Pak as a therapeutic equivalent of TOBI (tobramycin inhalation solution, USP) in their Orange Book. Kitabis Pak is listed with the AN designation meaning there are no known or suspected bioequivalence problems between Kitabis Pak and TOBI. "It makes sense that the FDA listed Kitabis Pak as therapeutically equivalent in the Orange Book, because TOBI was developed as tobramycin inhalation solution delivered with the PARI LC PLUS nebulizer," said Jan Zimmermann, portfolio manager for Kitabis Pak at PARI. "One prescription for Kitabis Pak ensures access to both tobramycin inhalation solution and the PARI LC PLUS nebulizer handset, co-packaged and dispensed together. In addition, PARI initiated a compressor access program called PARI PROVIDE that is administered through a network of specialty pharmacies." The FDA approved the New Drug Application for Kitabis Pak on December 2, 2014. Kitabis Pak is a new standard for nebulized drugs where drug and nebulizer handset are co-packaged similar to asthma inhalers where the drug and device are prescribed and dispensed together. The price of Kitabis Pak is comparable to the price of generic tobramycin drug alone. "Our definitive goal is to ensure that patients with cystic fibrosis who are prescribed tobramycin inhalation solution also get the nebulizer handset that was used in clinical trials and approved for use with TOBI. Kitabis Pak accomplishes this goal and makes it easy for patients since they come together in an easy to understand kit," stated Lisa Cambridge, director of PARI's Medical Science & Pharmaceutical Alliances.

Ventilator Donated to University

A university received a valuable education gift recently when a Hamilton GALILEO ventilator was donated to Gwynedd Mercy University where the ventilator will be used exclusively for education purposes. "It will become a valuable component of our laboratory instruction for the sophomore and junior level of our program and as such will be inviting clinical faculty to the university to provide detailed in-service education program during the didactic and laboratory phase of our curriculum.



THE RIGHT RESULT AT THE RIGHT TIME

Blood Gas & Electrolytes in about 30 seconds

The **epoc**[®] Blood Analysis System improves patient safety, workflow and operational efficiencies by eliminating steps.

- Wireless communication of results
- Room temperature storage of Test Cards
- 11 Analytes on 1 Test Card:
 - pH, pCO₂, pO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, Glu, Lac, Crea and Hct

Knowing now matters.[™]

Contact your Alere Representative about availability, 1.877.441.7440 or visit alere.com



It will allow us to enhance the mechanical ventilation module and will help us in educating aspiring respiratory therapist,” according to William (Bill) F. Galvin, Program Director at Gwynedd Valley University.

Pathway Cleared for Luna Devices

The FDA has given 3B Medical good news by giving 510(k) clearance for its new Luna Positive Airway Pressure (PAP) Device Platform. The Luna family of PAP devices is designed to offer patients the latest enhancements in sleep therapy while innovative compliance management technology allows for better patient management. The Luna sleep products offer more, free remote compliance reporting options than any other PAP device on the market. In a series of new innovations from 3B, the Luna brings both Wi-Fi wireless communication and QR Coding to sleep therapy. “Wi-Fi technology offers the ability to capture more data with greater efficiency, said Joe Toth, Vice President of Sales and Marketing. “Wi-Fi is typically faster, more reliable and, most importantly, absolutely free. With the continued developments in Wi-Fi technology and the ever growing need for more detailed and comprehensive data, we feel Wi-Fi is not only the better choice today, but tomorrow as well”, said Toth. Luna also incorporates QR Coding. The ability to capture and immediately transfer compliance data through any smart device brings yet another unique innovation to the market. Luna integrates into 3B Medical’s cloud based patient management system, iCodeConnect, which features Patient TouchPoint, a completely configurable, early intervention patient compliance coaching system. TouchPoint allows for clinicians to define individual protocols to allow them to more quickly and easily recognize potential issues with a patient’s compliance. The Luna

continues 3B Medical’s efforts to increase patient compliance and restore profitability to the sleep marketplace by offering products that provide greater flexibility, functionality and efficiency at lower cost.

Noninvasive Ventilators Introduced

ResMed has announced its Lumis series of noninvasive ventilation devices that combine personalized, simplified therapy with powerful wireless connected care capabilities. The Lumis series builds upon ResMed’s legacy of innovation as a new option for patients with respiratory challenges who are not dependent on continuous ventilation. The Lumis series comprises the Lumis 100 VPAP S, Lumis 100 VPAP ST and Lumis 150 VPAP ST noninvasive ventilators that support a variety of therapy modes, built-in wireless connectivity, integrated humidification and intuitive simplicity that are the hallmarks of the series. Lumis ventilators are designed with a broad range of automatic settings making it an ideal choice for a wide variety of respiratory conditions and individual patient preferences. Lumis is the first ResMed ventilation platform with IntelligentAir, a collection of ResMed technologies that can tailor therapy to individual breathing needs, making truly personalized ventilation possible. The complete IntelligentAir suite for Lumis includes iVAPS (ResMed’s unique volume-assurance therapy mode), iBR (an intelligent Backup Rate), and AutoEPAP (which maintains upper airway patency), as well as other features to personalize and fine-tune individual patient’s synchrony and comfort (Vsync, TiControl, and trigger and cycle settings). ResMed engineers also kept comfort top of mind when designing Lumis: each device features built-in HumidAir heated humidification capabilities and the popular Climate Control Auto setting, which automatically

SmartLab
Respiratory Analysis

LUNG SIMULATORS

Breathing Simulator

DLco Simulator

Flow Volume Simulator

Silicone Mouthpiece

Mouthpiece with Saliva Trap

Reusable and Disposable Nose clips

New 7450 V2™ Mask with 2730 2-way Y-Shape Valve

Volume Calibration Syringes

Slide Valve and Controller

Balloon Valve and Controller

O₂ Conserver Test Systems

Reusable & Disposable V2™ MASKS

6700 V2 Mask BiLevel Hybrid

6500 V2 Mask Non-Invasive Ventilation (NIV)

6600 V2 Mask CPAP/BiLevel

See these and the rest of our extensive product line at www.rudolphkc.com

Hans Rudolph, inc.
Fax: 913-422-3337 Phone: 913-422-7788

VORTRAN MEDICAL

Call us at: 800-434-4034
www.vortran.com

facebook.com/vortran
twitter.com/vortran1

The VAR® (VORTRAN Automatic Resuscitator) is the World's First Fully Disposable Ventilator!

- Unique single patient use
- Constant, reliable hands-free ventilatory support
- Portable, compact, lightweight & disposable

Provides a simple solution for difficult situations!!

Now arriving:
Flight 60[®]

Bringing **ICU quality ventilation** throughout the hospital and beyond.

MAQUET
GETINGE GROUP

When you're looking for more flexibility in ventilation, Flight 60 is a convenient and cost-effective solution. This versatile ventilator combines ICU-quality ventilation with the ability to meet the challenging clinical demands of treating and transporting patients throughout the hospital and beyond.

Intuitive and easy to use, Flight 60 provides continuity of care with high-acuity ventilators in one small package—delivering superior performance for both pediatric and adult patients outside of the ICU. It offers invasive and non-invasive capabilities along with comprehensive monitoring tools and advanced modes, including B-Lev (APRV) and Volume Guarantee. With 12-hours of battery operation and a wall-gas independent design, Flight 60 takes ICU-quality ventilation wherever you need it.



Flight 60 ventilator now distributed in the US by Maquet.

Maquet is a registered trademark of Maquet GmbH • Copyright Maquet Medical Systems USA or its affiliates. • **⚠CAUTION:** Federal (US) law restricts this device to sale by or on the order of a physician. Refer to Instructions for Use for current indications, warnings, contraindications, and precautions. MCV000303059 REV/B

Flight 60: Ready to go when you are.

www.maquetusa.com

determines optimal humidification by adjusting to ambient room conditions.

ResMed Provides Update on Study

ResMed has announced that SERVE-HF, a multinational, multicenter, randomized controlled Phase III trial did not meet its primary endpoint. SERVE-HF was designed to assess whether the treatment of moderate to severe predominant central sleep apnea with Adaptive Servo-Ventilation (ASV) therapy could reduce mortality and morbidity in patients with symptomatic chronic heart failure in addition to optimized medical care. The study did not show a statistically significant difference between patients randomized to ASV therapy and those in the control group in the primary endpoint of time to all-cause mortality or unplanned hospitalization for worsening heart failure (based on a hazard ratio [HR] = 1.136, 95 percent confidence interval [95% CI] = (0.974, 1.325), p-value = 0.104). The results from SERVE-HF are preliminary and will be submitted for future publication after further analysis. A preliminary analysis of the data identified a statistically significant 2.5 percent absolute increased risk of cardiovascular mortality for those patients in the trial who received ASV therapy per year compared to those in the control group. In the study, the cardiovascular mortality rate in the ASV group was 10 percent per year compared to 7.5 percent per year in the control group. There were no issues associated with the performance of the ASV therapy device in the trial. "Patient safety is our first and foremost priority. We have alerted and are working with appropriate global regulatory authorities about the safety signal observed in this study," said Glenn Richards, M.D., ResMed Chief Medical Officer. "The safety signal in SERVE-HF was observed only with the use of ASV therapy in people who have predominant central sleep apnea and symptomatic chronic heart failure with reduced ejection fraction. We are further analyzing the data to understand why this unexpected result was observed in this trial." ResMed is working with global regulatory authorities to proactively revise the labels and instructions for use for ResMed ASV devices to include a contraindication for people with symptomatic chronic heart failure (with left ventricular ejection fraction, LVEF, less than or equal to 45 percent). The company is also proactively informing healthcare providers, physicians, and patients of the cardiovascular safety signal observed in SERVE-HF. The safety signal observed in SERVE-HF was observed only with ASV therapy in patients with moderate to severe predominant central sleep apnea and symptomatic chronic heart failure with reduced ejection fraction. The study did not include people with central sleep apnea in the absence of heart failure. It is also important to note that SERVE-HF did not include any patients with predominant

obstructive sleep apnea, and did not include any other treatment modality such as continuous positive airway pressure (CPAP) or auto-adjusting positive airway pressure (APAP). "SERVE-HF did not meet its primary endpoint, however this study provides valuable, practice-changing guidance on how to best care for people with chronic heart failure," said Prof. Martin Cowie, M.D., the co-principal investigator of the study and Professor of Cardiology at Imperial College, London. "SERVE-HF was a well-designed and executed study and because of it we now know that ASV therapy should not be used to treat central sleep apnea in people with symptomatic chronic heart failure with reduced ejection fraction." Healthcare providers and patients who have questions or would like more information are encouraged to call 1-800-478-9010 and visit www.SERVE-HFFAQs.com

Director Gets Promoted

3B Medical is pleased to announce the promotion of Joe Toth to Vice President of Sales and Marketing. As National Sales Director, Joe helped bring significant product innovations to the market and was instrumental in the growth of the 3B brand. In his new role, Toth will continue to focus on the ever changing needs of our customers and how 3B Medical can continue to bring solutions to its clients. Joe will have a key role in the development and deployment of new products in 2015 and looks forward to further expansion of the sales and support team. "We have always been about offering innovative solutions and restoring profitability to the sleep business. 2015 is going to be an exciting year for 3B Medical. There are many challenges facing our industry and 3B is poised to help customers meet those challenges. We will continue to introduce unique, innovative solutions that will enable our customers to take better care of their patients while recognizing even greater profitability." 3B Medical/BMC, a global leader polysomnography, sleep diagnostics and sleep therapy takes great pride in bringing innovative solutions to the market.

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.

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

EMERGENCY OXYGEN
AED COMPANIONS

"An oxygen unit may be deployed 50xs more often than an AED."



www.LIFECorporation.com
800-700-0202

Do you see it? Look again.



It might be bronchiectasis.

Bronchiectasis is a condition where the lungs' airways are abnormally stretched and scarred resulting in mucus retention. Sometimes when you see COPD, chronic bronchitis, pneumonia, asthma or cystic fibrosis, you might also be seeing bronchiectasis.

Scan and look again. A high-resolution CT scan can help determine a diagnosis of bronchiectasis. Early diagnosis and intervention is the key to slowing the disease progression and helping your patients Breathe a Little Easier.™ The Vest® Airway Clearance System is one therapy option for patients with bronchiectasis.



Learn more by calling 800-426-4224 option 3
or visiting www.thevest.com

The Vest® and Breathe a Little Easier™ are trademarks or registered trademarks of Hill-Rom Services PTE Ltd. Enhancing Outcomes for Patients and Their Caregivers is a registered trademark of Hill-Rom Services, Inc. The Vest System is offered in the home by Advanced Respiratory, Inc., a Hill-Rom company.

Hill-Rom reserves the right to make changes without notice in design, specifications and models. The only warranty Hill-Rom makes is the express written warranty extended on sale or rental of its products.

© 2014 Hill-Rom Services PTE Ltd. ALL RIGHTS RESERVED.

ORDER NUMBER 186921 rev 2 07-JUL-2014 ENG - US

Enhancing outcomes for
patients and their caregivers:

Hill-Rom

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 airways. 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.

Wearable NIOV Device a Success

Breathe Technologies has announced new data demonstrating that use of its one-pound, wearable Non-Invasive Open Ventilation (NIOV) System in pulmonary rehabilitation was associated with significant improvement in exercise endurance. The study results were presented on June 5 during the biennial COPD9USA meeting taking place in Chicago. Increased physical activity and exercise capacity are important factors in improving long-term health outcomes among patients with chronic respiratory disease. Exercise has been shown to increase energy to allow continuation of normal day-to-day activities, maintain a healthy body weight to make breathing easier and reduce the frequency of disease-related respiratory exacerbations.

Study Cites Fool's GOLD

Current chronic obstructive pulmonary disease (COPD) management programs and guidelines overdiagnose elderly patients and underdiagnose young ones. Martin R. Miller, MD, from the University of Birmingham in the United Kingdom, and Mark L. Levy, MBChB, from the Harrow Clinical Commissioning Group in London, United Kingdom, wrote their article as part of a series in the journal on overdiagnosis. The Global Initiative for Obstructive Lung Disease (GOLD) strategy documents were introduced in 2001 and were intended to create a new and simple threshold for airway obstruction. A diagnosis of COPD is thus based entirely on an assessment of airway obstruction as measured by the ratio of forced expiratory volume in 1 second (FEV1) divided by the forced vital capacity (FVC). Although the GOLD guidelines are based on consensus expert opinion, they do not effectively diagnose COPD, Dr Miller and Dr Levy contend. Yet, the GOLD criteria have been adopted by the UK National Institute for Health and Care Excellence and are used extensively throughout the United States, Europe, and Australasia. In their analysis, Dr Miller and Dr Levy propose that the GOLD criteria be refined by the addition of LLN criteria. At a minimum, they suggest, the LLN should be incorporated into future studies of COPD. The authors explain that when the GOLD definition is applied to England and Wales, 22% of individuals older than 40 years meet the criteria for COPD. In contrast, the LLN criteria would diagnose 13% of individuals older than 40 years as having COPD, suggesting the current system results in a great deal of overdiagnosis. They also calculate that as many as 13% of patients diagnosed with COPD

under the GOLD criteria may be misdiagnosed (underdiagnosis as well as overdiagnosis). This misdiagnosis could lead to poor outcomes that result from inappropriate treatment. For example, use of the inhaler treatment for COPD increases the risk of the patient developing severe pneumonia, which is an unfortunate outcome for a patient who may not even need the inhaler.

CF Award Announced

A \$2.8 million agreement between Novoteris, LLC and Cystic Fibrosis Foundation Therapeutics Inc. (CFFT), the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation, has been announced to develop an inhaled nitric oxide antimicrobial therapy for people with cystic fibrosis (CF) who have airway bacterial colonization. The Novoteris investigators' pilot trial in Europe of this therapy reported encouraging microbiological and lung function changes following two weeks of treatment in patients with CF. Gaseous nitric oxide's potent antimicrobial properties, lack of bacterial resistance, and its small molecule penetration capabilities could provide a promising alternative non-antibiotic approach to treating infections in people living with the disease. Novoteris expects to begin a Phase 2b study by Q3 of 2015 to be supported in part by this award from CFFT. CF is a rare life-threatening hereditary disease characterized by the production of thick, hard to clear mucus within the lung, leading to recurrent lung infections and loss of lung function. Antibiotic therapy, routinely used to treat lung infections in people with CF, becomes ineffective as bacterial resistance develops. The thick mucus within the lungs also makes it difficult for antibiotics to penetrate bacterial colonies so there is a great need to develop alternative agents that can treat bacterial infection in people with CF. Alex Stenzler, President of Novoteris, said: "Based on the success of our pilot trial, and the broad spectrum of bacteria and fungi that our product has demonstrated effectiveness against, we anticipate a high level of patient eligibility and interest for our Phase II efficacy trial. We are expecting that our program will provide a novel and the first inhalable gaseous antimicrobial agent for the treatment of patients with this devastating disease."

Inhaled Steroids Can Make Pollutants Worse

A clinical study is warning that inhaled corticosteroids cannot adequately protect children with asthma from high levels of air pollution. In fact, they may actually exacerbate the effects of pollutants. The authors found that both long-term and short-term exposures to pollution were associated with decreased lung function and increased airway hyperresponsiveness among 1,003 children with asthma who were enrolled in a trial comparing budesonide (Pulmicort, AstraZeneca) with nedocromil (which has since been withdrawn from the US market) or placebo. Kids receiving either budesonide or nedocromil had a more pronounced worsening of airway responsiveness with exposure to carbon monoxide (CO) than the children who were assigned to placebo, according to a study from the University of Groningen, the Netherlands. The public health implications of the finding are that asthma controller medications cannot be assumed to provide adequate protection for children with asthma during days when there is heavy ambient air pollution, the authors said. The investigators looked at short- and long-term exposures to ozone, CO, nitrogen dioxide, and sulfur dioxide among children enrolled in the Childhood Asthma Management Program (CAMP) trial. They also examined the question of whether use of either budesonide or nedocromil could protect against the effects of pollution.

WHEN IT COMES TO
PREVENTING
VAP

think

of the ramifications

THERE'S NO ROOM FOR COMPROMISE.

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

DALE® ENDOTRACHEAL TUBE HOLDER ►

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



◀ DALE® TRACHEOSTOMY TUBE HOLDERS

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



MINIMIZE COMPLICATIONS.
MAXIMIZE QUALITY CARE. THINK DALE.

ThinkRamifications.com
800-343-3980

Dale® is a registered trademarks of Dale Medical Products, Inc. in the USA.
©2015 Dale Medical Products, Inc.
AD-037 Rev A

RT Schools Given Ventilators

Draeger Medical, Inc. has made a large donation to help with the training of Respiratory Therapists. Draeger is a proud corporate partner of the AARC and offers leading innovations in respiratory care, including advanced ventilation modes, lung recruitment strategies and unique knowledge-based weaning programs, which will help to maintain cost-effectiveness and improve patient outcomes. Hospitals face enormous challenges attracting qualified Respiratory Therapists to meet the increasing demands placed on our health care system today. Institutions of higher learning that offer Respiratory Care education are on the front lines of training the next generation of dedicated Respiratory Care professionals. Broad training on modern-day mechanical ventilator products is essential to ensuring a new RT graduate is prepared to enter the workforce. During the AARC Summer Forum, Dräger was pleased to offer ten ventilators to Respiratory Therapy schools. These state-of-the-art devices were raffled off during the education section meeting, which addressed trends related to contemporary RT education. "Providing the latest technology in mechanical ventilation fosters a greater learning experience in the lab setting for RT students, and better prepares graduates for the workforce," said Ed Coombs, MA, RRT-NPS, ACCS, FAARC, director of marketing for Intensive Care & Neonatal Care, Draeger Medical, Inc.

EXECUTIVE PREVIEW AARC

Covidien

Booth 725

What products will you be presenting at AARC?

Microstream Capnography, Nellcor Pulse Oximetry, Puritan Bennett Ventilators, and McGrath MAC.

Are there any new products?

Nellcor Respiration Rate V2.0 and Microstream Cap35.

What are the education and training offerings?

Medtronic Professional Education and Continuing Education (<http://www.covidien.com/pace/pages.aspx>), Covidien Implementation Connection (<http://www.covidien.com/rms/sales-support/covidien-implementation-connection>), and ICU Sedation (<http://www.covidien.com/icusedation/pages.aspx>).

What will the speakers and presentation offer?

The Link between Asynchrony & Sedation Management, and Respiratory Compromise Symposium.

Why should AARC participants visit your booth?

Respiratory Compromise is Common, Costly and Deadly:

Common: Nearly 30% of post-operative patients¹ and up to 7% of all Medicare patients² will suffer from respiratory compromise. Cases of respiratory compromise are expected to increase by 31% by 2019.²

Costly: Patients with hospital contracted respiratory compromise will on average cost the hospital an additional \$18,208+ than patients without respiratory compromise.³

Deadly: Patient with respiratory compromise that originated on the general care floor are 29 times more likely to die, compared to the rest of the patient population.³

The new Puritan Bennett 980 ventilator helps enable patients to

breathe more naturally† through some of the most innovative breath delivery technology available. Our simple, safe and smart design provides more natural ventilation that may help improve patient comfort.¹

Simple: Our innovative user interface features a highly customizable display with intuitive screen navigation.

Safe: The newly designed Puritan Bennett 980 ventilator provides a unique ventilator assurance feature and an integrated expiratory filtration system.

Smart: Advanced synchrony tools help clinicians set the ventilator to adapt to their patients' unique needs and help provide the appropriate level of support throughout the breath.

References

- 1 Linde-Zwirble WL, Bloom JD, Mecca RS, Hansell DM. Postoperative pulmonary complications in adult elective surgery patients in the US: severity, outcome and resources use. *Crit Care Med.* 2010;14: P210.
- 2 Agarwal SJ, Ersilon MG, Bloom JD. Projected incidence and cost of respiratory failure, insufficiency and arrest in Medicare population, 2019. Abstract presented at Academy Health Congress, June 2011.
- 3 Kelley SD, Agarwal S, Parikh N, Ersilon M, Morris P. Respiratory insufficiency, arrest and failure among medical patients on the general care floor. *Crit Care Med.* 2012;40(12):764

Dale Medical Products

Booth 705

What products will you be presenting at AARC?

Dale Tracheostomy & Endotracheal Tube Holders. Dale Tracheostomy Tube Holders are safe and effective products that often exceed your performance requirements. By choosing Dale you can limit the possibility of inferior quality and poor patient satisfaction from other manufacturers. Dale Endotracheal Tube Holders help prevent accidental extubation. The Stabilock provides easy access to the patient's mouth allowing the clinician to perform oral care which studies show can reduce the risk of VAP.

Why should AARC participants visit your booth?

Stop by for free evaluation samples and to speak with our representatives on the services and support Dale will provide.

Electromed

Booth 811

What products will you be presenting at AARC?

Electromed will present the SmartVest Airway Clearance System at AARC congress 2015. The SmartVest System uses high frequency chest wall oscillation (HFCWO), a proven clinical therapy prescribed for people with airway clearance needs. Clinical research shows HFCWO to be highly effective at clearing airways of excess mucus and helping reduce infections and hospitalizations that can result when impaired airway clearance is inadequately treated.

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

Astral™

Enrich life



Confident care for COPD patients

Astral offers a broad range of therapy modes and features to optimize the treatment of your complex COPD patients:

- Synchrony features to minimize inspiratory time, which is helpful in minimizing intrinsic PEEP
- High resolution waveforms to enable visual detection of intrinsic PEEP
- Integrated FiO₂ and optional SpO₂ monitoring so you can fine-tune oxygen delivery
- Pressure support with safety tidal volume in case of potentially decreasing tidal volumes

These tools and technologies for treating COPD are just another way Astral is helping you deliver confident care. **Visit us at AARC Congress 2015 in Tampa, FL to learn more!**

ResMed.com

© 2015 ResMed



squeeze simulates a “mini cough,” which acts to loosen, thin and propel mucus toward major airways, where it can be more readily coughed up or suctioned away.

Are there any new products you wish to emphasize?

Electromed recently introduced the next generation SmartVest System, model SQL. The SmartVest SQL was designed to stand apart from the competition with features that our patients and clinicians requested to improve therapy adherence. The SmartVest SQL was designed 25% smaller, 5dB quieter and 25% lighter than previous versions. In addition to being significantly smaller, quieter, and lighter, some of the features include a single-hose design for greater freedom of motion, patented Soft Start technology to better acclimate the patient to therapy and a programmable ramp option.

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 innovative SmartVest SQL System.

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. We look forward to seeing you in Tampa!

Hamilton Medical

Booth 923

What products will you be presenting at AARC?

Hamilton Medical has over 30 years of experience in advanced mechanical ventilation and has the most current ventilator technology on the market today. We have ventilator models that meets the requirements of all market segments. Hamilton Medical will be showing our full ventilator line, designed to meet the ventilation needs of all patient populations, anywhere; in a hospital, during transport in an ambulance or helicopter, and also the MRI suite. Attendees will be able to see the HAMILTON-G5, HAMILTON-C3, HAMILTON-C2, HAMILTON-C1, HAMILTON-T1, the HAMILTON-MR1, and the H900 Humidifier. We are looking forward to showcase both neonatal and NCPAP application on both the HAMILTON-T1 and the HAMILTON-C1 (currently pending FDA approval, we are expecting it to be released at the end of the year) ventilator system, to provide care for the full range of patient populations. **Neonatal option on the HAMILTON-T1 vent (pending FDA approval, potential end of summer for clearance)

Discuss educational/training materials you’ll be offering.

Aaron White, RRT-NPS, Hamilton Medical Clinical Account Manager/G5 Product Manager, will be doing live demonstrations on how to accurately set PEEP with transpulmonary pressure on the G5. There will be the opportunity to speak with the heads of technical support, clinical support, R&D, and marketing to answer any and all questions about Hamilton Medical and our products.

Hamilton Medical will also feature a demonstration of Hamilton Medical College, our on-line e-learning tool, offering courses on mechanical ventilation and the Hamilton Medical ventilators. Learn how you can train your staff effectively, meet your training requirements, and have your staff earn CRCEs without ever leaving the hospital and, all at no charge.

Attendees will have the opportunity to learn about Hamilton Medical and all the exclusive features our vents offer. They can enter for a chance to win an educational grant to attend our Clinical Experts Workshop.

Why should AARC participants visit your display?

Our 20 x 30 Island booth will house each of our products and product experts, so if you practice adult care, neonatal care, long-term care or are involved in transport care, either on the ground or in the air, Hamilton Medical is available to provide you a solution to address the needs of your daily practice.

MGC Diagnostics

Booth 301

What products will you be presenting at AARC?

MGC Diagnostics will feature recent product developments and technology advancements, including systems for pulmonary function testing: Platinum Elite Plethysmograph and Ultima Series with Real Time Diffusion (RTD) MultiGas Technology which deliver clinically significant graphic data and immediate results; gas exchange systems: Ultima Series CPX and CardioO2 with integrated ECG and the CCM Express Indirect Calorimeter. Our latest version of BreezeSuite 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 full function spirometer and ResMonPro FOT (Forced Oscillation Technique) which help to determine the degree of obstruction, expiratory flow limitation, heterogeneity, and bronchial reversibility with no forced maneuvers.

Are there any new products you wish to emphasize?

MGC Diagnostics will be highlighting our redesigned Ultima Series Cardiorespiratory Diagnostic Systems for both pulmonary function and exercise testing. We will be displaying our latest technology and invite you to stop by our booth for a personal presentation on our newest innovative products which include the Sleep Virtual product line of sleep diagnostics acquisition devices.

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 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.

ARE ALL YOUR POCT DEVICES CONNECTED?

THREE REASONS WHY YOU SHOULD CONNECT ALL OF YOUR DEVICES.

1

ACCESS YOUR POC DATA ANYWHERE, ANYTIME

Regardless of hospital location or additional facilities, TELCOR™ QML® can be accessed through Citrix® or Internet Explorer® for multiple, simultaneous access to your POC data giving you the flexibility to effectively manage your POC program—anywhere, anytime.

2

MAKE INFORMED DECISIONS WITH TIMELY RESULTS

Connecting all of your POCT devices—regardless of manufacturer—to one middleware solution, TELCOR QML, provides real-time data transmission to minimize errors and omissions, giving you accurate and consistent data to help make informed decisions.

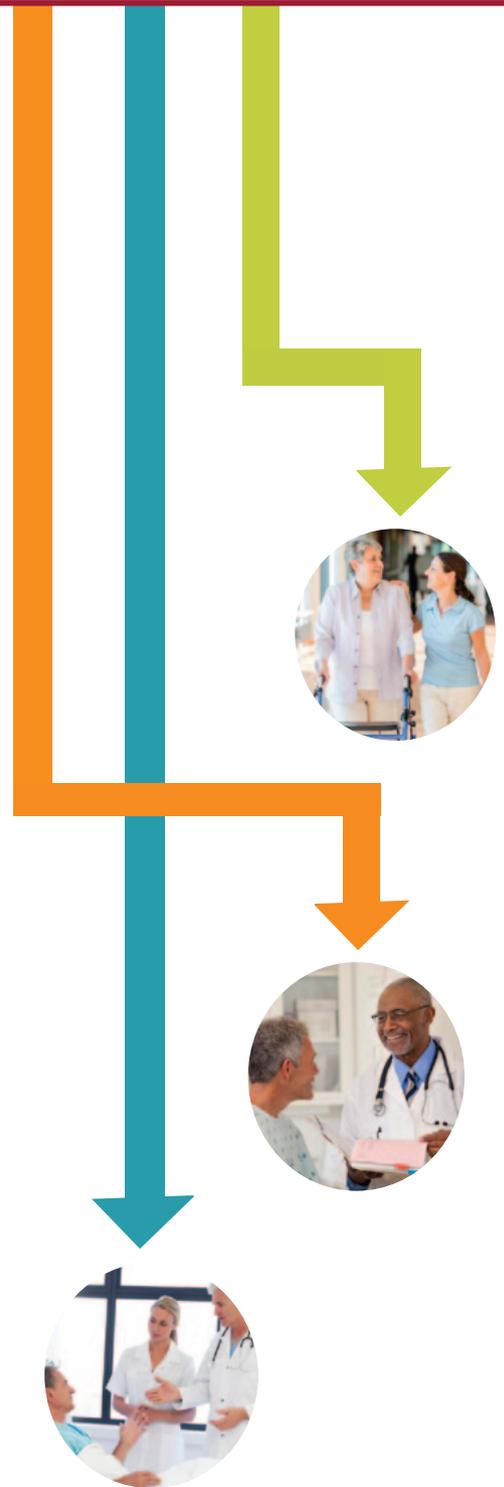
3

EASILY MANAGE COMPLIANCE

Whether it's monitoring operator training and competency assessments, or reviewing QC results, overseeing compliance can be challenging. TELCOR QML is configured to simplify and automate this process providing confidence in remaining compliant.

Regardless of device manufacturer, TELCOR QML connects “everything, everywhere point of care™.” QML interfaces with more than 40 LIS/EMRs, is used in more than 1,900 facilities and connects to 100+ devices—more than anyone in the industry.

Download a TELCOR device list at telcor.com/devicelist.



(866) 489-1207

telcor@telcor.com

telcor.com

 [@telcorinc](https://twitter.com/telcorinc)

 [TELCOR Inc](https://www.linkedin.com/company/telcor-inc)

 [TELCORInc](https://www.youtube.com/channel/UC...)

In addition to point of care software, TELCOR Revenue Cycle Management software is designed for clinical, pathology, molecular, toxicology and public health laboratories to help them improve collections, reduce operating costs and gain visibility of their laboratory business.

ResMed

Booth 101

What products will you be presenting at AARC?

ResMed will be presenting both its life support ventilation systems, Astral 100/150 ventilators, as well as its Air Solutions Sleep Disordered Breathing series of devices. Our homecare and hospital mask systems will also be on display.

Are there any new products you wish to emphasize?

Astral Ventilator, AirSense AutoSet, AirCurve bilevels and the AirView Patient Management System.

Discuss educational/training materials you'll be offering.

Product information, demonstrations and the appropriate clinical application of each.

What speakers or papers will you be featuring?

ResMed will have three case studies available that speak to the benefits of the Astral ventilators.

Why should AARC participants visit your display?

ResMed changes lives by developing treatments for sleep-disordered breathing and respiratory disorders that improve the health of those who suffer from these conditions. That is evidenced in the Astral case studies we will have available upon request from attendees. With our new Air Solutions sleep platform, we give clinicians unprecedented access to a patient's therapy data, so clinicians can stay connected with their patients and referral sources, while being more efficient.

ZOLL Medical Corporation

Booth 1528

What products will you be presenting at the AARC?

ZOLL Medical Corporation continues to expand its portfolio of resuscitation and acute critical care devices to help respiratory therapists improve patient care. New to ZOLL's product portfolio are the Eagle II and Eagle II MRI hospital portable ventilators, which ZOLL acquired from Impact Instrumentation last year. These critical care ventilators are the ideal solution for ICUs, emergency departments, and intra-hospital transport. For intra-hospital transport of infants (≥ 5 kg), pediatric patients, and adults, the Eagle II portable ventilator weighs less than 10 lbs. and has a battery run time of 10 hours. In addition to AC mode, the Eagle II offers SIMV and CPAP (NPPV/PPV) modes with pressure support. The Eagle II is available in an MRI-friendly model to support ventilation in the MRI suite. The ResQPOD Impedance Threshold Device (ITD) is a simple, non-invasive device used during CPR to increase blood flow. Attached to a facemask or advanced airway, the ResQPOD ITD enhances negative pressure within the chest to increase preload, lower ICP, and improve blood flow to the brain and vital organs. Pre-Clinical studies have shown that the ResQPOD ITD can increase survival by 25% or more when used with high-quality CPR.¹ The ResQPOD ITD helps to improve perfusion during CPR, and the latest data from the ROC PRIMED study shows that it improves survival when used with high-quality CPR.² The AutoPulse Resuscitation System provides consistent, high-quality CPR to victims of sudden cardiac arrest. Easy to use and battery operated, its load-distributing LifeBand squeezes the patient's entire chest to improve blood flow to the heart and brain. The

only device of its kind, the AutoPulse automatically sizes to the patient, and has shown improved survival in numerous clinical trials.^{3,4}

Are there any new products that you wish to emphasize?

The Eagle II and Eagle II MRI are new to ZOLL's resuscitation portfolio, although they have been on the market since 2009. Also new, as noted above, is the ResQPOD ITD, which enhances perfusion when added to the ventilation circuit.

Discuss the education/training materials you will be offering?

ZOLL will be providing critical care demonstrations by clinicians who have used them all over the world. ZOLL will also be supporting the CDC lecture at the pre-conference events on national stockpile ventilators. New DVDs and training videos on intrathoracic pressure regulation (IPR) therapy and the ResQPOD ITD will be available in ZOLL booth #1528.

Why should AARC participants visit your display?

Respiratory therapists respond to every code in a hospital, manage ventilation and airways, as well as perform CPR. ZOLL offers a comprehensive portfolio of advanced technology products that help respiratory therapists improve outcomes and increase operational efficiencies. From our family of portable ventilators that provide a range of therapies to ventilate and support infants through adults onto our ResQPOD ITD to enhance perfusion during CPR, and the AutoPulse, our automated CPR system, we offer solutions that assist respiratory therapists in their mission to help save lives.

References

- 1 Idris AH, et al. The interaction of chest compression rates with the impedance threshold device and association with survival following out-of-hospital cardiac arrest. *Circulation*. 2012; 126:LBBS-22813-AHA.
- 2 Yannopoulos D, et al. The effect of CPR quality: a potential confounder of CPR clinical trials. *Circulation* 2015; in press.
- 3 Wesfall M, et al. Mechanical Vs. Manual Chest Compressions in Out-of-Hospital Cardiac Arrest: A Meta-Analysis. *Crit Care Med*. 2013 Jul;41(7):1782-9.
- 4 Wik L, et al. The impact of CPR duration on survival to discharge between integrated AutoPulse-CPR and manual-CPR during out-of-hospital cardiac arrest of presumed cardiac origin. *Resuscitation*. 2012;83:e17.



Introducing the World's First Integrated Respiratory Information System



With Iris™ all the data you need to optimize the diagnosis, staging and management of respiratory disease is right at your fingertips.

© Copyright nSpire Health 2015. Iris a trademark of nSpire Health.

To learn more contact 800.574.7374 • sales@nspirehealth.com
www.nspirehealth.com

Vitalograph Pneumotrac

for the highest quality spirometry
with Spirotrac V software

Mention
this ad for
a free box
of filters



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

No question!



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



Vitalograph®

Your cardio-respiratory partner

1-800-255-6626 • www.vitalograph.com

email: vitcs@vitalograph.com

Be a Hero.

Make a Difference



Rebecca Wills, BA, LRCP, CRT-NPS
Madonna Rehabilitation Hospital, Lincoln, Nebraska
Passy-Muir Center of Excellence



PMV® 007
(Aqua Color™)

Restore your patient's voice and ability to participate in their care, recovery, and life.

To find out how the Passy-Muir® Valve can help restore your patient's voice, enhance swallowing, reduce aspiration, expedite weaning and decannulation, and significantly reduce the costs associated with tracheostomy, visit www.passy-muir.com/hero

Be a Hero. Give your patient a voice.

Passy Muir®
Millions of Voices, ONE VALVE™



Download the NEW TRACHTOOLS™ communication app, FREE for a limited time at the app store or www.passy-muir.com/app

Aerogen®

Pioneering Aerosol Drug Delivery

More than **twice**
the medication
in half the time¹



The **new Aerogen Ultra*** brings high performance aerosol drug delivery to spontaneous breathing patients throughout the hospital.

*Currently known as Aeroneb Solo Adapter

Call our Customer Support Unit
at **(866) 423-7643**

References: 1. Hickin S, Mac Loughlin R, Sweeney L, Tatham A, Gidwani S. Comparison of mesh nebuliser versus jet nebuliser in simulated adults with chronic obstructive pulmonary disease. Poster at the College of Emergency Medicine Clinical Excellence Conference. 2014

Benefits of Automated Intermittent Subglottic Secretion Drainage

Jesse Cozean, MBA

Nosocomial infections due to Ventilator-Associated Pneumonia (VAP) are common, costly, and dangerous to patients in ICU settings. The cause of VAP is clear, resulting from the presence of bacteria in the typically clean areas of the lower respiratory tract. The mechanical ventilator causes subglottic secretions to accumulate above the ballooned cuff of the inflated tracheal tube, which then leak or are aspirated into the lungs.

VAP is an extremely common and serious type of hospital-acquired infection (HAI), with an incidence rate ranging from 1-3 VAP/1,000 ventilator-days in the United States, and significantly higher (12-18 VAP/1,000 patient-days) in Europe, in large part due to differences in VAP definition (Damas et al, 2015). These nosocomial infections are highly dangerous, with a mortality rate associated with VAP of 13%, and infections prolong ICU stay by 6-9 days for the patient.

Multiple studies have shown the benefit of draining subglottic secretions before they can enter the lungs and cause infection. In a randomized, controlled clinical trial, Subglottic Secretion Drainage (SSD) reduced the rate of VAP from 17.6% to 8.8%, cutting nosocomial infections in half (Damas et al, 2015). The authors concluded, "Subglottic secretion suctioning resulted in a significant reduction of ventilator-associated pneumonia prevalence." Another clinical trial confirmed these results, demonstrating a 42% reduction in VAP in the patients who had their subglottic secretions drained regularly (Lacherade et al, 2010). In a meta-analysis of clinical trials conducted on ventilated patients, it was shown that SSD minimizes both the length of ventilation and stay in the ICU (Dezfulian et al, 2005). Regular secretion drainage has been shown to be a

vital component in reducing nosocomial infection, duration of ventilation, and stay in the ICU.

Despite the clinical benefits, there are significant challenges associated with proper and regular secretion drainage. Respiratory therapists are instructed to drain the secretions for each patient on ventilation every hour, which is often difficult to accomplish with the volume of patients and high patient to staff ratio. Draining the secretions by hand is time-consuming and difficult to ensure that each patient receives SSD every hour. Furthermore, it causes patient discomfort, where an invasive procedure is repeated hourly for days. Commonly the SSD causes an inflammatory response, actually increasing the amount of subglottic secretions. If the subglottic secretions are not drained properly they can then enter the lungs and necessitate a painful bronchial or endotracheal drainage procedure. According to a poster presented by the University of Texas, "Endotracheal suctioning has been associated with adverse events that include tachycardia, hypertension, hypoxemia, and atelectasis." (Acevedo et al, 2013).

There is also disturbing evidence that the manual draining of these secretions is not within the recommendations of the American Association for Respiratory Care (AARC) Clinical Practice Guidelines. The AARC specifies a pressure of 150 mmHg, but studies have found that 97.7% of observed manual suctionings exceeded these force levels, putting greater strain on the patient's trachea. The average force from wall-mounted suction was found to be 123% higher than recommended. Using a syringe is even more forceful, with average pressure of 578-722 mmHg (depending on syringe size). Current methods for subglottic drainage put between 2 and 5 times more force on the airway than is recommended.

A potential solution to the problems with current SSD techniques may be automated intermittent secretion drainage. With these devices, the suction device is permanently connected with the suction port of the tracheal or endotracheal tube, and activated automatically to drain secretions. Rather than hoping for drainage each hour, a smaller amount of fluid can be drained every 5-15 minutes, depending on the amount and viscosity of subglottic fluid accumulating.

In automating the process, the respiratory therapist gains significantly more control over the procedure. The therapist can customize the timing of the automated suctioning for the patient. The pressure of the system can be substantially lower,

Jesse Cozean is a clinical researcher who has overseen the design and operation of six different clinical trials totaling more than 15,000 patients, has received FDA approval for Stage III clinical trials on both OTC and prescription drugs, and is the author of many peer-reviewed articles. A research team that he led was just awarded the winner of the Fighting Ebola Grand Challenge from USAID, the White House Science and Technology Office, the CDC, and the Department of Defense. Jesse received his Bachelor of Science in Physics from Westmont College, and his MBA from Western Governor's University. He has served as the Vice President of Research and Development for several companies, including Abela Pharmaceuticals and Innovative BioDefense, heading research teams into pharmaceutical and OTC drug products. Jesse holds multiple patents on medical device and drug products. The author consults with Flosure Technologies.

within the AARC Guidelines, and tailored to the needs of the patient and without putting unnecessary force on the airway. By collecting the secretions at smaller intervals, even with lower pressure levels, a larger volume of the subglottic secretions can be removed, lowering the risk of VAP.

An automated intermittent subglottic aspiration system has the advantage of being specifically designed for the removal of subglottic secretions, rather than wall suction or general-purpose suction pumps that are not intended for that purpose and put substantially higher force on the patient. Wall suction have on/off cycles that are too short to be ideal for removal of subglottic secretions, pressure levels are difficult to control, and they are very noisy. Using manual suction with a syringe places even more force on the airway of the patient, requires the staff to glove up hourly and use a new syringe for suction, and handling the contagious material which can increase the risk of cross-contamination.

Automated intermittent systems have been extensively tested and widely used in Europe, and the first such product to gain FDA clearance is now available in the United States. One doctor and researcher, Dr Markus Wolf, has used automated intermittent subglottic suctioning for more than three years in the Department of Pneumology and Intensive Care (Asklepios Klinik Barmbek, Hamburg, Germany). The 18-bed ICU ward, with all patients ventilated on admission, has treated approximately 300 patients with automated devices.

“We have seen many advantages of the automated intermittent subglottic drainage,” says Dr Wolf. “In our experience, the amount of material drained increases by 10 times over what we were seeing with manual suctioning by our staff. It has saved time for our staff and reduced our contact with infectious material. And it has been beneficial to our patients, with less force put on the tracheal wall and no trauma from repeated endotracheal suctioning.”

Dr Wolf divides the patients he treats into two major groups for automated subglottic drainage. The first set of patients have a massive aspiration of saliva-type fluid, more than 500 ml per day. For this group, the settings of the automated intermittent device are for low pressure, which is sufficient to extract the fluid, on short intervals to remove as much of the secretions as possible. The second group experiences a smaller amount of thick mucopurulent material, typically less than 200 ml per day. For this group, a higher pressure setting (still within AARC Guidelines) is utilized, with longer intervals between suctioning.

One of the first clinicians to adopt an FDA-cleared automated intermittent device in the United States, Jerry Gentile, BSHA, BSRC, MBA, EdD(c), RT, RRT, has been impressed by the new equipment. “As one of the first respiratory clinicians to adopt the automated intermittent subglottic drainage devices in the United States, I have been impressed by the new equipment. We have been trialing the device on 5 patients and the results have been clinically significant. Further clinical trials are needed to assess efficacy and overall cost effectiveness” says the Director of Respiratory Care Services, Eastchester Rehabilitation and Healthcare Center (Bronx, NY).

Subglottic drainage is a vital tool in the fight to prevent VAP and nosocomial infection, and automating the process with specialized equipment may have significant advantages for

both the healthcare facility and the patient. The automated process requires less time from the staff and minimizes contact with infectious material. For patients, more secretions can be drained with less trauma and force on the airway, and the process can be customized for the individual needs of the patient while minimizing noise in the patient room. With the first FDA clearance for these devices already granted, automated intermittent subglottic secretion drainage seems to be the wave of the future.

References

- Acevedo D, Restrepo R, Gonzalez L et al, Are We Suctioning the Life Out of Our Ventilator Patients, American Association for Respiratory Care Congress, 2013.
- Damas P, Frippiat F, Ancion A et al, Prevention of Ventilator-Associated Pneumonia and Ventilator-Associated Conditions: A Randomized Controlled Trial with Subglottic Secretion Suctioning, *Critical Care Medicine Journal*, 2015; 43(1).
- Dezfulian C, Shojania K, Collard H et al, Subglottic Secretion Drainage for Preventing Ventilator-Associated Pneumonia: a Meta-Analysis, *The American Journal of Medicine*, 2005; 118: 11-18.
- Lacherade JC, Jonghe B, Guezennec P et al, Intermittent Subglottic Secretion Drainage and Ventilator-Associated Pneumonia, *American Journal of Respiratory Critical Care Medicine*, 2010; 182: 910-917.

Improving Oxygen Supply Safety for Acute Care Transports

Thomas L Miller, PhD; Charles W Dunlap, BSRT, RRT-NPS and Chris Campbell

Oxygen is essential to sustaining human life, and many patients with pulmonary compromise are dependent on supplemental oxygen for survival.¹ However, the logistics of providing an uninterrupted supply of supplemental oxygen can present a serious challenge to the care team, especially during transport situations where the oxygen source is limited.²

In hospitals today, with the increase in acuity and the ever-increasing demands on available staff, patients requiring oxygen during transport are still at risk of an interruption in their supply—whether intra or inter hospital. Interruptions can happen with little warning, requiring staff to attentively monitor the gauge.

Although there have been advances in portable oxygen cylinders for patient transports, the on-board supply remains finite. The conventional method to ascertain contents is via a rough interpretation of a pressure gauge, which requires some degree of clinical expertise. Although modern “all-in-one” oxygen cylinders no longer require caregivers to fasten a separate withdrawal device (ie, regulator), there has still been little warning to caregivers before the cylinder contents are depleted beyond carefully watching the pressure gauge.

To address the need to alert caregivers to a dwindling supply, recent advancements in technology can now help hospitals prevent the serious risks associated with a disruption in the patient’s oxygen supply during transport. This technology offers security for both the patient and the medical facility, and can reduce the burden on staff resources.

Clinical Use of Portable Oxygen Systems and the Inherent Risks

Oxygen has a long history of benefiting patients in a variety of medical environments, from ambulance to hospital teams. In 2009, the National Patient Safety Agency (NPSA) a division of the United Kingdom’s National Health Service, released a review and guidance document related specifically to oxygen safety in hospitals.³ According to this report: “Oxygen has been used in clinical practice for more than 200 years and benefits the patient by increasing the supply of oxygen to the lungs and thereby increasing the availability of oxygen to the body tissues. These days, oxygen is one of the most commonly used medicines in

hospital environments, and is used across a range of healthcare specialties. Ambulance teams and emergency department teams are likely to give oxygen to a large number of patients with conditions such as ischaemic heart disease, sepsis or trauma.”³

The report goes on to conclude that oxygen use is generally safe, but there are serious risks of harm if it is not handled and administered appropriately. Moreover, the major risks are underuse and overuse of oxygen, where pertaining to runouts, underuse of oxygen is extremely dangerous because “it exposes critically ill patients to the risk of hypoxic organ damage.”

It should be noted that although the NPSA data is UK based, it represents statistics collected on a national scale. Such data are not available publicly for the US nationally, despite a clear need.

Incidence of Run Outs

Despite the abundance of technology now utilized in clinical environments to assist with patient safety, incidents related to administration and management of oxygen delivery, including run-outs, remain a serious conceivable risk. The 2009 NPSA report reviewed several sources of data for reported patient incidences related to oxygen use, and found consistent themes including the run out of oxygen or use of empty cylinders.

One source cited by the NPSA report was the incidence data from their healthcare Reporting and Learning System. These data show 281 serious incidents reported between December 2004 and June 2009 related to the mismanagement of oxygen, and that these included 32 serious incidents involving infants and children. The report does not detail the specifics of each case, but these incidences were broken into categories and some examples of the case write-up free text were provided. The largest of these categories, encompassing 109 of the 281 cases (39%) pertained to empty cylinders, lack of equipment and related user errors. A free text example from a case description was as follows:

“Patient had arrived in X-ray Dept for an abdominal X-ray without a nurse escort. His X-ray was done and during this time he was unresponsive but was breathing. He was then moved to the waiting area to be collected by the portering staff and returned to ward. The Senior Sister in X-ray was called to see patient and he was found to be not breathing with no pulse. Although an oxygen mask was attached the oxygen cylinder was empty.”

Thomas and Charles are with Vapotherm, Inc, Exeter, NH. Thomas is also with Sydney Kimmel Medical College, Philadelphia, PA. Chris Campbell is the Senior Editor of Respiratory Therapy.

A separate category consisting of 40 of the 281 cases (14%) included unsafe practices related to transport, where oxygen cylinders are typically used as opposed to wall mounted gas manifolds. Overall, 9 of the 281 incidents were determined to have caused a patient death and another 35 incidents were determined to have contributed to a patient death. The majority of relevant incidents were reported from acute hospitals (n = 267 of 281; 95%).”

The NPSA report also cited data from the Medicines and Healthcare products Regulatory Agency (MHRA). The report states that the MHRA typically receives 30 to 40 reports a year related to oxygen mismanagement. The report attributes the majority of these incidences to user errors, which lists “Empty Cylinders” as a first example. The definition for this category of errors specifies that it is related to “lack of pre-use checking and not because of cylinder valve failures.”

Recommendations to Minimize the Occurrence of Runouts

Oxygen run-outs and interruptions during transports are preventable. Such as with other preventable adverse occurrences in the healthcare arena, it seems clear a multifaceted approach embodying staff training, incorporation of the latest technology and better reporting can go a long way to eliminating the risk of oxygen run outs.

The NPSA report included a list of actions that could be implemented to improve oxygen safety. One action was “Where the use of oxygen cylinders is unavoidable (ie transfer and emergency situations or for mental health trusts), robust systems are in place to ensure reliable and adequate supplies, including checking and stocktaking of cylinders.” The rationale was listed as, “Reported incident indicating that cylinders were found empty when required in the event of an emergency or ran empty unnoticed in transfer situations.” To ensure compliance, the report recommended the following: “Record of review of cylinder storage. Evidence that procedures for checking and replacing cylinders are included in local policy and training.” Better training being the key point.

Three main areas exist to combat preventable adverse events such as “run outs”—better training, better technology and better reporting.

Training

To help reduce the incidence of run-outs, better training is consistently recommended. One example is from the 2000-2001 annual safety report by the New York Patient Occurrence Reporting and Tracking System (NYPORTS),⁴ an adverse event reporting system implemented pursuant to New York State Public Health Law Section 2805-1, Incident Reporting. In a summary of pulmonary-related cases, under the category of “Oxygen ran out during transport; developed respiratory distress leading to death,” the risk reduction strategy was listed as “Train transport staff in oxygen tank management and the emergency procedures if tank runs out, involve respiratory in all transports with oxygen,” and the expert comments included: “Patient transport from critical care units to testing areas is always a difficult issue. Transporters are not particularly skilled in patient care and the availability of nursing staff/respiratory staff to accompany patients is something that should be examined closely.”

Technology

In the acute care setting, when the oxygen contents of a cylinder

can unexpectedly run out, there can be little warning. By convention, attentively monitoring the pressure gauge was the only means to avoid a run-out. Oxygen consumption rates can vary depending on what delivery systems are connected to the cylinder (eg, a mechanical ventilator and/or oxygen blender), which can make estimating remaining tank capacity even more difficult than if the patient is receiving a fixed flow rate. In the event that the care team loses track, run outs are only detected after the tank is empty and the patient monitors alert the team that blood-oxygen levels are beginning to reach dangerous levels.

Today, technology exists to warn that the cylinder contents are beginning to reach low levels, which gives advanced notice to care givers to change to a fresh tank or make informed assessments of time limits. Warnings include larger visual contents indicators, audible and visual alarm signals, and electronic countdown calculators to interpret the time remaining in hours and minutes to alert care-givers who have become distracted or have forgotten to check the pressure gauge.

Better Reporting

The United States Department of Health and Human Services Office of the Inspector General Report from December 2008, Adverse Events in Hospitals: State Reporting Systems, found inconsistent reporting of adverse events between US states. This report states, “As of January 2008, 26 States had hospital adverse event reporting systems and another State had taken action to develop one.” “The remaining 25 States did not have adverse event reporting systems.” For the states that did have reporting systems, these systems varied in requirements for information to be included about the event and corrective actions.⁵

Summary

The uninterrupted supply of oxygen to patients, especially during transports, continues to challenge caregivers in acute care. New technologies are now available which can help avoid run-outs, coupled with better training and improvements in reporting.

References

- 1 Mithoefer, JC, Karetzky, MS, Mead, GD (1967). Oxygen Therapy in Respiratory Failure. In *N Engl J Med* 277:947-949.
- 2 Davis MM (2008). Maintaining Supplemental Oxygen During Transport. *AJN, American Journal of Nursing*, Vol 108, No 1, Pg 35.
- 3 Rapid Response Report (2009). Oxygen safety in hospitals.
- 4 NYPORTS (2003) The New York Patient Occurrence Reporting and Tracking System Annual Report 2000/2001.
- 5 DHHS OIG Report (2008). Adverse Events in Hospitals: State Reporting Systems.

Pediatric Patient with Severe Asthma Treated with a Vibrating Mesh with Valved Adapter

Tammy Newsome, RRT, Tina Thayer, RRT, Stephen Lieberman, MD

Introduction

The patient described in this case study was well known to us with several previous intubations and lengthy hospital admissions associated with severe asthma exacerbations. He was not responding to aerosol delivery with a vibrating mesh (Aerogen Solo) adapted to an open aerosol facemask. Vibrating mesh nebulizers are more efficient than jet nebulizers. However bench studies have shown that the use of an open aerosol facemask demonstrates similar efficiency to a jet nebulizer with an open aerosol facemask voiding the benefits associated with the vibrating mesh.¹

Respiratory therapists have always believed that mouthpiece delivery is more effective than an open aerosol facemask. Alcoforado, et al. demonstrated a $22.8\% \pm 9.83$ lung dose from vibrating mesh nebulizer with valved adapter (Aerogen Ultra) via mouthpiece as compared to $4.5\% \pm 1.35$ from a jet nebulizer via mouthpiece in healthy volunteers inhaling radio-tagged aerosol.² During this episode, we had exhausted all of our standard aerosol bronchodilator delivery strategies and it appeared that our only recourse for this patient would be intubation. We theorized that the use of the vibrating mesh with valved adapter via mouthpiece could potentially produce a positive outcome and prevent the escalation of care.

Case Summary

A 12 year old male with a history severe persistent asthma requiring frequent hospitalizations and several intubations presented in the emergency room in severe respiratory distress. The patient refused less invasive treatment i.e. high flow nasal cannula (HFNC) and bipap applications. He was placed on 80/20 heliox at 8 lpm with an open aerosol facemask with no improvement (note: the patient refused to wear a valved mask or HFNC). It was determined that since the heliox could not be properly administered due to the patient's lack of cooperation that it should be discontinued.

He was scored utilizing a modified woods clinical asthma score 0-2 (mild), 3-4 (moderate) and >5 (severe). His asthma score at that time was a 5 severe, with diminished breath sounds, tight inspiratory and expiratory wheezing, a prolonged expiratory phase, substernal retractions and nasal flaring. He received 7.5 mg albuterol via vibrating mesh (Aerogen Solo) with an open aerosol facemask with no change in asthma score post treatment. One hour later

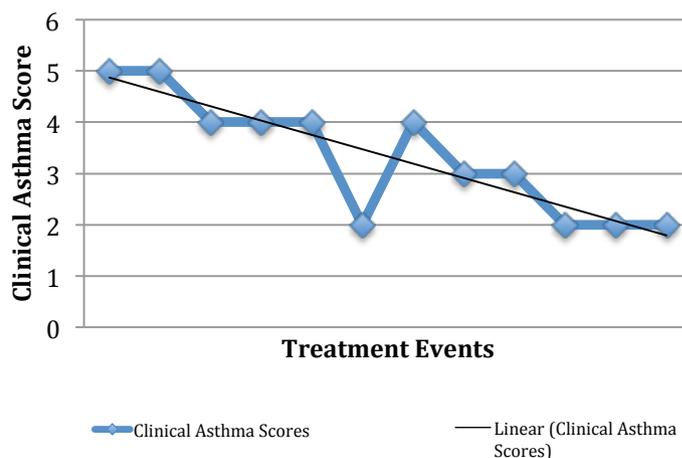


Image 1. Clinical Asthma Scores after each treatment showing drop in CAS to 2 after switch to vibrating mesh with the valved adapter and CAS for the duration of patient admission.

he received another 7.5 mg of albuterol with marginal to no improvement.

Despite intensive treatment he was still in moderate to severe asthma exacerbation, which required transfer to the PICU. Upon arrival the therapist changed him to a vibrating mesh nebulizer with a valved adapter (Aerogen Ultra) via mouthpiece, and 15 mg of Albuterol was administered. Post treatment re-evaluation revealed improved aeration, decreased accessory muscle use, subsided nasal flaring, reduction in asthma score severity to mild (2) and improved patient comfort. The patient stated that he felt better.

After another dose of 15 mg of albuterol his asthma score remained mild (2) and for the next 8 hours he received Q2 hour albuterol with dose cut in half (7.5 mg). In the morning he was weaned to Q4 hours and was discharged later that day. See Image 1 (above) documenting the patient clinical asthma scores after each treatment.

Discussion

With this frequent flyer, we believe that intervention with the combination of mesh nebulizer with adapter via mouthpiece and the greater inhaled dose made a substantial improvement resulting in clinical improvements leading to discharge.

The authors are with Baystate Medical Center.

Continued on page 36...

An Evidence-Based Study of Adolescents with Cystic Fibrosis Demonstrated that AffloVest by International Biophysics Contributed to Improved Lung Function Scores

Michael Cooper, RT

Cystic fibrosis (CF) is a life-threatening genetic disease that primarily affects the lungs and digestive system. An estimated 30,000 children and adults in the United States (70,000 worldwide) have CF. Approximately 1,000 new cases are being diagnosed each year.¹ Individuals with CF have difficulty clearing pathogens from the lung and experience chronic pulmonary infections and inflammation. Death is usually a result of respiratory failure. The median expected survival age has reached 36 years.²

For patients with cystic fibrosis, maintaining proper airway function is essential, especially for children and young adults. The primary treatment that has been widely used is Chest Physical Therapy (CPT). CPT includes Postural Drainage and Percussion (PD & P), a way to help people with cystic fibrosis (CF) breathe with less difficulty and stay healthy. PD & P uses gravity and percussion to loosen the thick, sticky mucus in the lungs so it can be removed by coughing. Unclogging the airways is key to keeping lungs healthy by helping to reduce the severity of lung infections and improve overall lung function. In children and young adults with CF, CPT can be done by physical therapists (PT), respiratory therapists (RT), nurses, and even parents.³ The Cystic Fibrosis Foundation recommends CPT and PD & P to target different portions of the lungs, as prescribed by a physician. Although effective, parental involvement in CPT becomes more difficult as the child grows and becomes more independent.

To help streamline this process, another treatment option was introduced to the CF community in the 1980s. The high frequency chest wall oscillation device (HFCWO) provided an alternative and effective treatment for patient's to use at home. The device is an air-bladder vest that is connected to hoses and an electrical air generator, thus eliminating the need for a PT, RT, nurse or parent to administer. Additional advantages included semi-portability, freedom to comply with treatment frequency in the privacy of the home and access to necessary treatment on a patients' schedule. From a technical perspective, a one-year multi-chart retrospective study conducted by Jan Tecklin, et al, concluded that Brasfield chest X-ray scores were statistically significantly better with HFCWO than CPTX.⁴ The technology typically relies on air to create a single waveform through an air bladder that delivers air in large volumes, at high amplitude to rapidly inflate and deflate the bladder. To do so, the device must tightly squeeze the patient's torso with rapid, repeated

compression, at times causing discomfort for patient users. The air-bladder type device is loud during operation, both for patients and family members, and must remain plugged into the wall for the duration of treatment, limiting patients' mobility. This technology was originally developed and introduced in the 1980's, and these air-bladder type vests have provided great benefits to thousands of patients over the years.

A new type of HFCWO vest technology is now available that offers several advantages over air-bladder type vests. The AffloVest is a portable HFCWO device that is battery operated, thus eliminating the need to be connected to an electrical outlet during use. The AffloVest technology is self-contained. It mechanically generates waveforms from 8 individual oscillating motors sewn into the vest, thus eliminating the need for an air-bladder, hoses and air generator. These 8 oscillating motors create 8 individual percussive waveforms, effectively creating disruption and mobilizing secretions in the lungs without squeezing the patient's chest. These individual motors target different areas of the lungs that can be missed by certain types of air bladder HFCWO's. The AffloVest technology does not require squeezing the patient's chest and is customizable to individual patient needs offering 3 oscillation programs (percussion, vibration and drainage) as well as 3 treatment levels (soft/5Hz, medium/13Hz and intense/20Hz). Prescribing physicians can customize treatment plans for individual patient needs. The AffloVest is very quiet and can be used while walking or during other patient activities. These advantages offer freedom to comply with treatment whenever and wherever it is convenient for the patient. This may lead to increased compliance as reported by the patients in this study.

In a study conducted by Oermann et al, published in Pediatric Pulmonology, a randomized, multicenter crossover pilot study evaluated the efficacy and patient satisfaction with high frequency chest wall oscillation (HFCWO) and oscillating positive expiratory pressure (OPEP) compared to percussion and postural drainage (PD & P) in the home use setting. The study concluded that, given a choice of therapy, 50% of subjects chose HFCWO, 37% OPEP, and 13% PD & P.⁵

In the following case study, five adolescent patients used the AffloVest by International Biophysics for 3-5 months each and saw increased Pulmonary Function Test (PFT) scores. The PFT routinely measures airflow, lung volumes, gas exchange, response to bronchodilators, and respiratory muscle function. This study was performed at a major U.S. hospital actively

Michael Cooper, RT, Chicago, Illinois.



The only oscillation vest you need for *daily treatments.*



The first truly portable High Frequency Chest Wall Oscillation (HFCWO) device, AffloVest® is noninvasive, approved by insurance and medicare, and available to your patients now.



SEE THE DATA

Read an evidence-based study of adolescents with cystic fibrosis which demonstrated that AffloVest contributed to improved lung function scores.

afflovest.com/studyinfo

The modern approach that fits.

AffloVest® is available in six sizes, offering everyday treatment...for everyone.

888-711-1145

[ibcafflovest](https://www.facebook.com/ibcafflovest) [afflovest](https://twitter.com/afflovest)



18" Chest Circumference 55+"

treating cystic fibrosis patients. The five patients involved in the study ranged in age between 14 and 18 years of age. All were using an air bladder HFCWO vest for their prescribed treatment plan, before switching to the AffloVest. The objective of the study was to measure lung function scores before and after use to determine efficacy. These data show FVC, FEV1, and FEF scores before and after using AffloVest.

Patient 1

Age: 14 years

Sex: male

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 12.5%, FEV1 increased 18.8%, and FEF increased 63.7%. The patient's mother states that her son is much more motivated to use his vest due to ease of use and freedom of movement during treatment.

	FVC (L)	FEV1 (L)	FEF 25-75% (L/sec)
Predicted Value	3.33	3.06	3.44
Air Bladder Vest	2.80	2.61	3.72
Afflovest	3.15	3.10	6.09

Trend Report

Gender: Male Age: 14
Height(in): 63 16(cm)
Weight(lb): 108 49.1(kg)
Diagnosis: Cystic Fibrosis
Date: 01/21/15
Medication Set 1:

Previous Study:

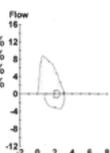
09/26/14
FVC 2.80 Liters
FEV1 2.61 Liters
FEF25-75% 3.72 L/sec
PEF 6.19 L/sec

Current Study:

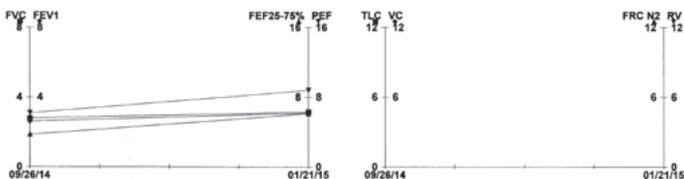
01/21/15
FVC 3.15 Liters (91) % improved by 13%
FEV1 3.10 Liters (97) % improved by 18%
FEF25-75% 6.09 L/sec (170) % improved by 64%
PEF 8.79 L/sec (129) % improved by 42%

TLC Liters
RV Liters
DLCO mL/mmHg/min

TLC Liters () % improved by
RV Liters () % improved by
DLCO mL/mmHg/min () % improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
01/21/15	3.15 Liters	3.10 Liters	6.09 L/sec	8.79 L/sec	6.19		
09/26/14	2.80	2.61	3.72	6.19			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Interpretation:

Patient 2

Age: 14 years

Sex: male

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 14.9%, FEV1 increased 17.3%, and FEF increased 23.8%. In addition, his mother states that her son enjoys wearing the AffloVest and it has helped him increase his basketball performance.

	FVC (L)	FEV1 (L)	FEF 25-75% (L/sec)
Predicted Value	3.33	3.06	3.44
Air Bladder Vest	2.62	2.08	1.93
Afflovest	3.01	2.44	2.39

Trend Report

Gender: Male Age: 14
Height(in): 62 158(cm)
Weight(lb): 107 48.8(kg)
Diagnosis: Cystic Fibrosis
Date: 11/26/14
Medication Set 1:

Previous Study:

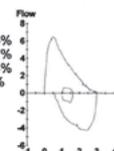
06/17/14
FVC 2.62 Liters
FEV1 2.08 Liters
FEF25-75% 1.93 L/sec
PEF 6.11 L/sec

Current Study:

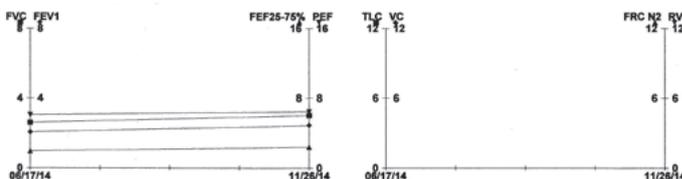
11/26/14
FVC 3.01 Liters (90) % improved by 15%
FEV1 2.44 Liters (80) % improved by 17%
FEF25-75% 2.39 L/sec (70) % improved by 24%
PEF 6.46 L/sec (98) % improved by 6%

TLC Liters
RV Liters
DLCO mL/mmHg/min

TLC Liters () % improved by
RV Liters () % improved by
DLCO mL/mmHg/min () % improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
11/26/14	3.01 Liters	2.44 Liters	2.39 L/sec	6.46 L/sec	6.11		
06/17/14	2.62	2.08	1.93	6.11			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Patient 3

Age: 15 years

Sex: female

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 5.5%, FEV1 increased 3.0% and FEF increased 3.5%. Her mother states that the vest has helped her complete her dance exercises.

	FVC (L)	FEV1 (L)	FEF 25-75% (L/sec)
Predicted Value	3.07	2.92	3.31
Air Bladder Vest	2.19	1.98	3.70
Afflovest	2.31	2.04	3.83

Trend Report

Gender: Female Age: 15
Height(in): 61 155(cm)
Weight(lb): 101 45.9(kg)
Diagnosis: Cystic Fibrosis
Date: 12/19/14
Medication Set 1:

Previous Study:

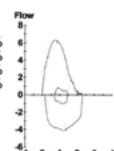
09/16/14
FVC 2.19 Liters
FEV1 1.98 Liters
FEF25-75% 3.70 L/sec
PEF 6.27 L/sec

Current Study:

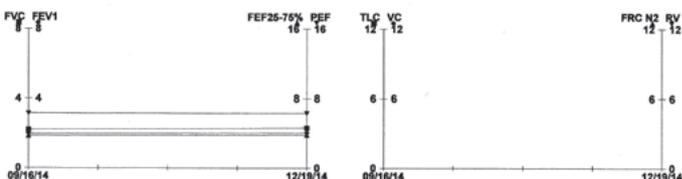
12/19/14
FVC 2.31 Liters (75) % improved by 6%
FEV1 2.04 Liters (70) % improved by 3%
FEF25-75% 3.83 L/sec (116) % improved by 3%
PEF 6.31 L/sec (105) % improved by 1%

TLC Liters
RV Liters
DLCO mL/mmHg/min

TLC Liters () % improved by
RV Liters () % improved by
DLCO mL/mmHg/min () % improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
12/19/14	2.31 Liters	2.04 Liters	3.83 L/sec	6.31 L/sec	6.27		
09/16/14	2.19	1.98	3.70	6.27			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Patient 4

Age: 18 years

Sex: female

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 9.5%, FEV1 increased 7.7% and FEF increased 2.2%. Patient indicates that she is taking the AffloVest with her to college and she has been using it more frequently to comply with treatment plan.

	FVC (L)	FEV1 (L)	FEF 25-75% (L/sec)
Predicted Value	3.13	2.98	3.36
Air Bladder Vest	2.53	2.33	4.07
Afflovest	2.77	2.51	4.16

Trend Report

Gender: Female Age: 18
Height(in): 62 156(cm)
Weight(lb): 104 47.3(kg)
Diagnosis: Cystic Fibrosis
Date: 11/26/14
Medication Set 1:

Previous Study:

06/17/14

FVC 2.53 Liters
FEV1 2.33 Liters
FEF25-75% 4.07 L/sec
PEF 7.79 L/sec

TLC Liters
RV Liters
DLCO mL/mmHg/min

Date
11/26/14
06/17/14

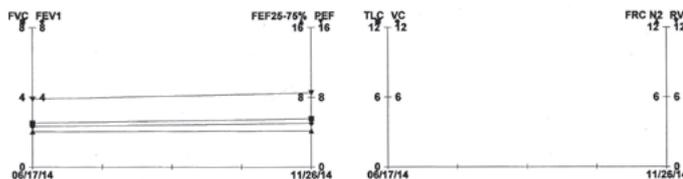
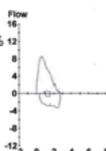
Current Study:

11/26/14

FVC 2.77 Liters (89) % improved by 10%
FEV1 2.51 Liters (84) % improved by 8%
FEF25-75% 4.16 L/sec (124) % improved by 2%
PEF 8.49 L/sec (129) % improved by 9%

TLC Liters 0 % improved by
RV Liters 0 % improved by
DLCO mL/mmHg/min 0 % improved by

FVC 2.77 Liters
FEV1 2.51 Liters
FEF25-75% 4.16 L/sec
PEF 8.49 L/sec
TLC 8.49 L/sec Liters
RV Liters
DLCO mL/mmHg/min



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Interpretation:

Patient 5

Age: 18 years

Sex: male

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 7.3%, FEV1 increased 10.2% and FEF increased 16.6%. Patient indicates that he has used it more frequently and it has helped him with his sports.

	FVC (L)	FEV1 (L)	FEF 25-75% (L/sec)
Predicted Value	4.08	3.76	4.14
Air Bladder Vest	5.99	4.61	4.03
Afflovest	6.43	5.08	4.70

Trend Report

Gender: Male Age: 18
Height(in): 66 173(cm)
Weight(lb): 182 82.7(kg)
Diagnosis:
Date: 11/19/14
Medication Set 1:

Previous Study:

08/05/14

FVC 5.99 Liters
FEV1 4.61 Liters
FEF25-75% 4.03 L/sec
PEF 10.00 L/sec

TLC Liters
RV Liters
DLCO mL/mmHg/min

Date
11/19/14
08/05/14

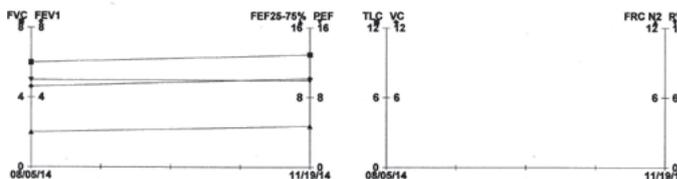
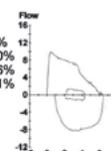
Current Study:

11/19/14

FVC 6.43 Liters (159) % improved by 7%
FEV1 5.08 Liters (137) % improved by 10%
FEF25-75% 4.70 L/sec (115) % improved by 16%
PEF 9.91 L/sec (118) % decreased by 1%

TLC Liters 0 % improved by
RV Liters 0 % improved by
DLCO mL/mmHg/min 0 % improved by

FVC 6.43 Liters
FEV1 5.08 Liters
FEF25-75% 4.70 L/sec
PEF 9.91 L/sec
TLC 9.91 L/sec Liters
RV Liters
DLCO mL/mmHg/min



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Summary

In conclusion, the data demonstrates the AffloVest improved breathing scores in the five patients followed in this study as compared to using an air bladder vest previously.

Average FVC: 0.308L, 09.5% Increase
Average Fev1: 0.312L, 11.5% Increase
Average FEF 25-75%: 0.744L, 21.3% Increase

The overall usage between tests was 3-5 months. The clinician performing this study concluded that the AffloVest showed improvement in each patient's condition. The average patient used the AffloVest 2-3 times a day, and the average settings were 8 minutes at medium (13Hz) and 16 minutes at intense (20Hz) for total treatment time of 24 minutes.

In addition to lung function improvements, patients stated that they enjoyed wearing the AffloVest and used it more often as compared to their air-bladder vest, thus increasing treatment compliance. While many variables can contribute to improved lung function, all five patients participating in this small study demonstrated improved lung function after using the AffloVest.

For more information visit www.afflovest.com or call 1-888-711-1145.

References

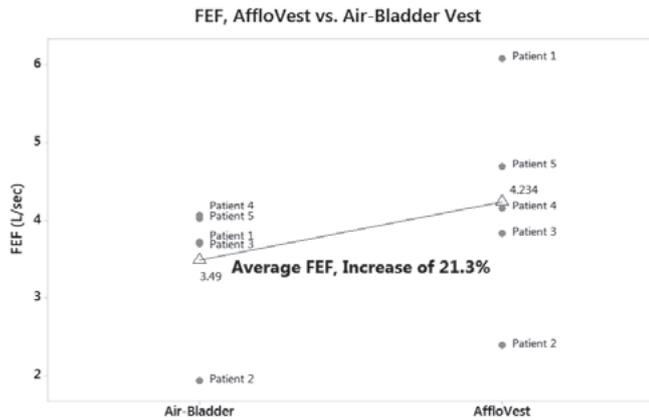
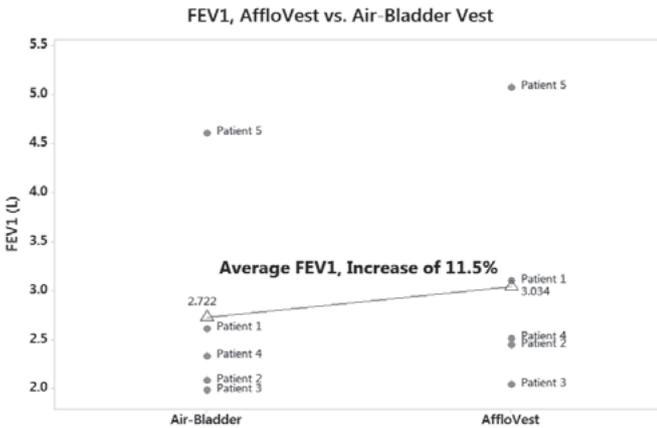
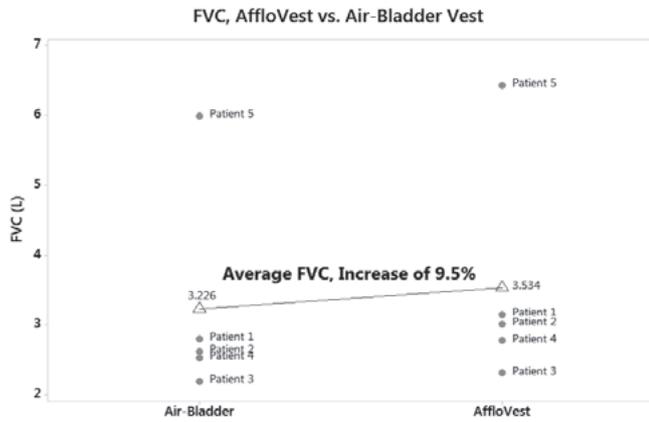
1. www.cff.org
2. Flume, O'Sullivan, Robinson, et al. Cystic Fibrosis Pulmonary Guidelines. American Journal of Respiratory and Critical Care Medicine 2007; 176:957-969.
3. Cystic Fibrosis Foundation Fact Sheet, 2012
4. Tecklin, Clayton, and Scanlin. High frequency chest wall oscillation vs. traditional chest physical therapy in CF-a large, one-year, controlled study. Pediatr Pulmonol 2000; (suppl 20):459.
5. Oermann, Retsch-Bogart, Quittner, et al. An 18-month study of the safety and efficacy of repeated courses of inhaled aztreonam lysine in cystic fibrosis. Pediatr Pulmonol 2010; 45:1121-1134.

Conclusion

We concluded that using a mouthpiece for aerosol delivery should be the preferred method versus a facemask when tolerated. The addition of a valved adapter to the vibrating mesh improves lung dose, reduces aerosol loss to the environment, improves patient clinical response to aerosolized medications and improves patient satisfaction. Further clinical studies are warranted in order to support this hypothesis.

References

- 1 Ari A, Dornelas A, Sheard M, AlHamad B, Fink JB. Performance comparisons of jet and mesh nebulizers using different interfaces in simulated spontaneous breathing adults and children. *J Aerosol Med pulm Drug Deliv.* 2014;28(0).
- 2 Alcoforado L, de Melo Barcelar J, Galindo VC, Brandao SCS, Fink JB, Dornelas de Andrade A. Analysis of deposition radioaerosol nebulizers membrane in healthy subjects. ISAM poster. Munich 2015.



Optimizing Gas Exchange through Monitoring Functional Residual Capacity for a Ventilated Trauma Patient

Wade Veneman, RRT and Wil Caliwag, BS, RRT, CPFT

While most hospitals have emergency departments that are always open, Community Regional Medical Center's (CRMC) Table Mountain Rancheria Trauma Center is the only ACS verified Level 1 trauma center in the 15,000 square-mile service area between Sacramento and Los Angeles. What sets CRMC's Level 1 trauma center apart from regular emergency departments is that they have the specialists and equipment required to treat serious life-threatening injuries 24 hours a day, seven days a week. Having the trauma team always ready, instead of "on their way," can be the difference between life and death for critically injured patients. When CRMC selected the GE Ventilator for use in their Trauma, Burn, Neuro and Medicine ICU units, it was critical to include the respiratory gas module on all 75 ventilators purchased. The decision was driven by CRMC's desire to better monitor gas exchange for its most critical patients. The following case study demonstrates the value of monitoring functional residual capacity (FRC), even in patients that have no underlying pulmonary disease.

Case Study

Subject: The patient is a 27-year-old male with a head injury. His mental status was altered and combative at the scene and was taken to Community Regional Medical Center for further evaluation. The patient arrived in the ED with a Glasgow Coma Scale (GCS) of 7 and was intubated (Figure 1).

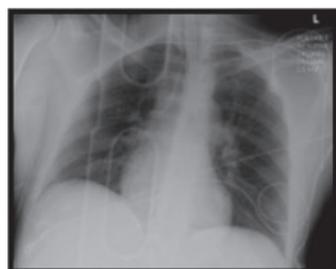


Figure 1. Initial chest film in ED. The endotracheal tube and NG tube are in good position. The size of the cardiac silhouette is within normal limits. The pulmonary vasculature is not congested. The lungs are clear.

Computerized Tomography (CT) images revealed a traumatic brain injury with multiple intracranial hemorrhages (see Figure 2). The patient was taken to the operating room emergently for a right craniotomy for evacuation of epidural hematoma and left craniotomy and craniectomy for acute subdural hematoma with malignant brain swelling. After surgery, an intracranial pressure (ICP) monitor (bolt) was placed and transported to the Surgery Intensive Care Unit (SICU). The patient was placed on the following ventilator settings: Pressure Control Ventilation-

The authors are with the Community Regional Medical Center, Fresno, CA.

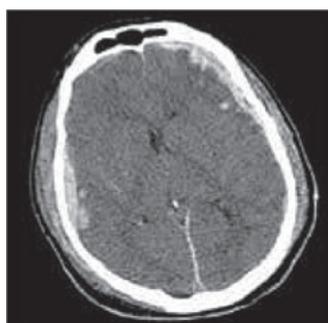


Figure 2. CT image showing extensive bilateral hemorrhage noted which is compatible with subdural and epidural hemorrhages.

Volume Guarantee (PCV-VG), tidal volume (VT) 500 mL, rate 14/min, positive end-expiratory pressure (PEEP) 5 cmH₂O, fraction of inspired oxygen (FiO₂) 1.0. Chest films were ordered each day and routine ventilator measurements were recorded every four hours. FRC was measured approximately every eight hours. We indexed FRC to the relative predicted FRC formula. Men: [0.0472 X height (cm)] + (0.0090 X age) - 5.290]. We calculated this patient's FRC at 2.7 Liters (L). Initial baseline FRC was 1.7 L (63% of predicted). Tidal volume was increased to 550 mL due to PaCO₂ of 44 mmHg above prescribed range (35-40 mmHg). FRC increased to 1.8 L. FRC around 0300 decreased to 1.6 L reducing to 59% of predicted (Table 1).

Table 1 - Ventilator settings and measurements.

Day/Time	VT	PEEP	Lung Comp.	P _{AW}	P:F	FRC Meas.	FRC%/Pred.
2/0700	500	5	50	8	307	1.7	0.63
2/1500	550	5	62	8	433	1.8	0.67
2/1900	550	5	50	8	N/A	1.8	0.67
3/0300	550	5	44	9	517	1.6	0.59

The patient remained stable with good oxygenation, respiratory system compliance and clear chest films (figure 4). However, on day 3, FRC had declined to 1.2 L (44%) from 1.6 L on the same ventilator settings. Later that day, around 1400 hrs, the Respiratory Care Practitioner (RCP) was called to the bedside for a decline in patient's SpO₂ (87%) on 0.3 FiO₂. The RCP increased the PEEP from 5 to 8 cmH₂O and FiO₂ from 0.3 to 0.4. SpO₂ increased to 95%. Two hours later, FRC was measured and increased from 1.2 L to 1.4 L after the PEEP change. During the same shift, the RCP was called again (0100 hrs) to the bedside for desaturation (86%) and FiO₂ was increased to 0.5. An arterial blood gas (ABG) was drawn with the following results: pH 7.36, PaCO₂ 41, PaO₂ 64, BE -1, SaO₂ 89%, PaO₂/FiO₂ = 128 mmHg.



Figure 3. Day 2. The lungs are clear.

PEEP was raised to 10 cmH₂O. FRC at 0300 measured at 0.93L (Table 2).

Table 2 – Ventilator settings and measurements (Day 3).

Day/Time	VT	PEEP	Lung Comp.	P _{AW}	P:F	FRC Meas.	FRC%/Pred.
3/0700	550	5	46	8	N/A	1.2	0.44
3/1600	550	8	58	10	433	1.4	0.52
4/0300	550	10	52	12	128	0.93	0.34

The desaturation events were discussed with the surgery team and were likely caused by ventilation to perfusion mismatch in the right lung base (see Figure 5). Interestingly, the FRC showed declination approximately 24 hours before the first desaturation event. Due to the low PaO₂/FiO₂, the surgery attending ordered Airway Pressure Release Ventilation (APRV). Initial APRV settings were as follows: Mode: Bilevel, P-High 26, P-Low 0, T-High 6.0, T-Low 0.6 (65% of Peak Expiratory Flow Rate [PEFR]) and FiO₂ 0.6. Two hours later, FRC was measured at 2.8 L (1.04% of predicted) and nine hours later, FRC increased to 2.9 L (see Table 3).

Table 3 – FRC measurements after airway pressure release ventilation.

Day/Time	P-High	Lung Comp.	P:F	FRC Meas.	FRC%/Pred.
4/1000	26	45	N/A	2.8	1.04
4/1900	28	29	202	2.9	1.07
5/0800	28	33	353	3.01	1.11

FRC increased to over 100% of predicted as expected, however, this may not be optimal due to the indexed FRC for the upright position (see Figure 6). Most ventilated patients are in the supine or semi-recumbent position which reduces FRC.



Figure 4. Day 3. The lungs remain clear.

As FRC continued to exceed the predicted value and gas exchange showed improvement, P-High and T-High were weaned by the “drop and stretch method”¹ and PaO₂/FiO₂ ratio increased to 353 mmHg from 202 mmHg. A chest film was taken approximately 7 hours later on APRV (see Figure 7). Over the next 6 days, APRV continued to be weaned gradually until P-High



Figure 5. Day 4. There is atelectasis in the right lung base. The left lung is clear.



Figure 6. Day 5. Bilateral mid and lower lung parenchymal opacities. The upper lung zones remain clear. No new focal infiltrates identified.



Figure 7. Day 5. Seven hours later on APRV, no evidence of acute cardiopulmonary disease. The lungs are clear.



Figure 8. Day 12, prior to extubation. Lungs are clear.

reached 14 cm H₂O and T-High 10 seconds. Lungs remained clear (Figure 8) and a spontaneous awakening trial (SAT) and spontaneous breathing trial (SBT) were conducted. However, with an unstable GCS, the team anticipated the patient would not tolerate extubation at this time.

Outcome

On day 13, GCS had improved to 10T. A SBT was performed with success and the patient was extubated to nasal cannula. The patient’s mental status continued to improve and was weaned to room air the next day. A follow-up chest film was taken and the lungs remained clear (Figure 9). The patient was transferred to a rehabilitation unit two days later.

Discussion

FRC is the resting lung volume at end-expiration, however, when a patient is lying in the supine or semi-recumbent position, FRC is decreased up to 25%.² Positive end-expiratory pressure (PEEP) is generally used to stabilize alveolar volume, minimize dead space-to-tidal volume ratio (VD/VT) and, theoretically, increase FRC. Depending on the method chosen to set optimal PEEP, the challenge is to consistently monitor the PEEP level because

Experience GE's new
CARESCAPE R860
AARC Booth #909

Introducing a touch of brilliance

GE's new CARESCAPE™ R860 represents a leap forward in touchscreen life support technology. The menu-free user interface design supports navigating past, present and future states of your ventilated patients. Swipe left to right to navigate from historical trends to present status to Clinical Decision Support tools. Intuitively organized and easily accessible, relevant content and therapy tools are not buried in menus, they are at your fingertips.



MENU-FREE ACCESS TO PAST, PRESENT AND FUTURE VIEWS

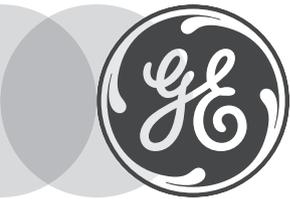
- Past (Historical Trends)
- Present (Patient Status)
- Future (Clinical Decision Support)

Imagination at work

www.gehealthcare.com/locations. Product may not be available in all countries and regions. Contact a GE Healthcare Representative for more information.

© 2015 General Electric Company.

GE, GE Monogram and CARESCAPE are trademarks of General Electric Company



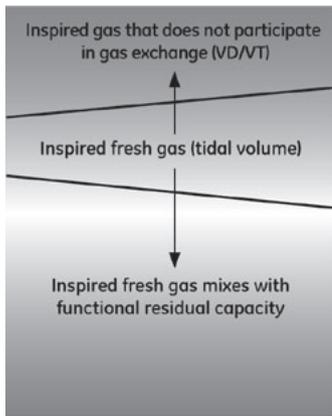


Figure 10. Gas exchange is a continuous process, breathing just tops up the alveoli with a bit of fresh air from time to time. At the end of expiration the lungs still contain over 2 liters of air (this represents the functional residual capacity, or FRC), and inspiration during normal breathing at rest only adds 500 mL to the volume of air in the lungs. Approximately 150 mL of each breath is wasted in the conducting airways as dead space (VD), leaving 350 mL to contribute to the volume ventilating the alveoli (VA).

patient illness severities are higher today and dynamically changing minute-to-minute. Preserving normal FRC is crucial for optimizing gas exchange during positive pressure ventilation due to its role as the body's physiologic reserve. By optimizing FRC, alveolar ventilation continues through diffusion without disruptions, and dead space-to-tidal volume ratio (VD/VT) is minimized. However, during an acute change in pulmonary status, such as atelectasis, gas exchange is affected and VD/VT increases (Figure 10).

Computerized tomography (CT) is considered the gold standard to measure FRC in ventilated patients,^{3,4} but this practice is not available or impractical for routine application after every ventilator change. At CRMC, monitoring disease progression is made simpler with the GE Ventilator and respiratory gas module.

Conclusion

Measuring functional residual capacity (FRC) can be an essential tool to assess the pulmonary status in patients with acute respiratory failure requiring mechanical ventilation.⁵ FRC can assist in assessing if alveolar ventilation and pulmonary perfusion are optimally matched. Unfortunately, there is no current data establishing a 'gold standard' for indexing normal FRC values for ventilated patients. This case study highlights the usefulness of how measuring FRC can identify lung derecruitment as an early indicator and guide ventilator management to optimize gas exchange while indexing to FRC predicted values. Further randomized, controlled trials are needed to determine the optimal FRC with ventilated patients.

How GE measures FRC

Accurate measurement of FRC previously required that the patient be conscious and spontaneously breathing. This changed with the GE Ventilator and the Respiratory Gas Module. Now the FRC measurement is made based on monitoring the change of N₂ (nitrogen) concentration measured at the airway (Modified Nitrogen Dilution method). The concentration of inspired nitrogen is changed by the delivered FiO₂ concentration. A comparison study was conducted that demonstrated "excellent concordance between FRC-WI/WO and FRC-CT" using the GE Ventilator and Respiratory Gas Module.⁶

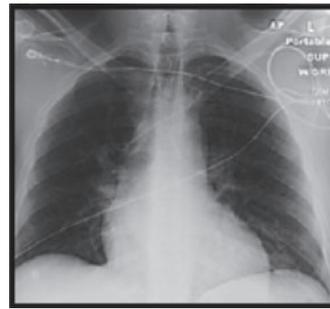


Figure 9. Day 13, following extubation. Lungs are clear.

References

- 1 Habashi N: Other approaches to open-lung ventilation: Airway pressure release ventilation. *Crit Care Med* 2005 Vol. 33, No. 3 (Suppl.).
- 2 Ibanez J, Raurich JM: Normal values of functional residual capacity in the sitting and supine positions. *Intensive Care Med* 1982, 8:173-177.
- 3 Drummond GB: Computed tomography and pulmonary measurements. *Br J Anaesth* 1998, 80:665-671.
- 4 Gattinoni L, Caironi P, Pelosi P, Goodman LR: What has computed tomography taught us about the acute respiratory distress syndrome? *Am J Respir Crit Care Med* 2001, 164:1701-1711.
- 5 Hedenstierna G: The recording of FRC — is it of importance and can it be made simple? *Intensive Care Med* 1993, 19: 365-366.
- 6 Graf J: Agreement Between Functional Residual Capacity Estimated via Automated Gas Dilution Versus via Computed Tomography in a Pleural Effusion Model. *Respir Care* 2010;55(11):1464-1468.

Putting the Modified Enterprise Point-of-Care Blood Gas and Electrolyte Analyzer to the Test in a Pediatric Hospital Setting

Chris Campbell

It's no secret that time is of the essence when it comes to medical care—especially in an Emergency Room environment. Add in a sick infant and getting critical test results back in a short turnaround time (TAT) has meant the pursuit of devices that will speed up those results. But getting things done faster doesn't mean much if it isn't done right. Time-saving measures are only worth it if the medical results are accurate. That's what researchers at the Baylor College of Medicine and Texas Children's Hospital wanted to find out when it came to arterial blood gas and electrolyte testing.¹ Their 2011-2013 study using an Enterprise point-of-care (EPOC) blood gas and electrolyte analysis system was designed to see how the portable devices performed against the more cumbersome and time-consuming benchtop devices.²

According to the study's authors, "the most significant aspect of any POC device is the accuracy and precision of laboratory values when compared with conventional or criterion standard methods. This is true because concerns about analytical performance and reliability of results of POC instruments still exist."³ The push for improved TATs in various hospital settings has produced several different POC devices for such lab tests as electrolytes, blood gases, and other metabolites. What the study's authors wanted to achieve was solid research comparing the old system and the new.

"Historically, the POC blood gas and electrolyte testing market has been dominated by the i-STAT instruments in the United States.^{4,6} In 2006, the US Food and Drug Administration approved the Enterprise point-of-care (EPOC) blood gas and electrolyte analysis system (Alere, Waltham, Mass) as a portable blood gas and electrolyte analyzer.⁷ Although both hand-held clinical analyzers measure many of the same laboratory values, the newer modified EPOC system has certain advantages over both the i-STAT POC analyzer and the conventional ABL radiometer. We performed an evaluation of the analytical performance of the EPOC hand-held blood gas analyzer in our pediatric hospital from 2011 to 2013 and performed a concordance analysis with the POC, i-STAT blood gas analyzer and conventional ABL radiometer."

Study Methods

The study was conducted using test results from patients at Texas Children's Hospital, including blood gases, electrolytes, glucose, lactate, creatinine, and hematocrit assays from

December 2011 to February 2013. Clinical Laboratory Standards Institute guidelines were followed. The whole blood samples were first run on ABL 835 Radiometer and then on EPOC and i-STAT analyzers simultaneously.

The researchers also included reader-to-reader comparison studies on randomly selected instruments (n = 8), and correlation studies were performed on 40 samples.

The Devices

"The EPOC blood gas and electrolyte analyzer is a hand-held portable device, weighing approximately 500 g with the provision of single-use test cards, which are stored at room temperature. The analyzer is based on the principles of potentiometry, amperometry, and conductometry. Each test card provides results of 11 analytes and certain calculated parameters: pH, PCO₂, and PO₂, Na⁺, K⁺, Cl⁻, Ca₂₊, Glu, Creat, Hct, and lactate."

"The ABL 835 Radiometer is a benchtop blood gas analyzer that is conventionally used as the criterion standard method for the measurement of blood gases. The ABL 835 Radiometer can measure analytes including pH, PCO₂, PO₂, Na⁺, K⁺, Cl⁻, Ca₂₊, Hct and hemoglobin (Hb)."

"The i-STAT blood gas analyzer is a portable hand-held point-of-care blood gas analyzer used for the measurement of whole blood gases (pH, PCO₂, and PO₂) and electrolytes (Na⁺, K⁺, and ionized calcium (iCa₂₊)). The system uses a disposable cartridge containing an impregnated biosensor for each analyte."

Conclusions

One of the big successes of the study is simply by expanding the amount of data comparing these devices—especially in a pediatric setting. The study authors cite the only other analysis of the EPOC system reported was by Stotler and Kratz⁷ at their tertiary academic center.

"Our evaluation reflects results exclusive to a pediatric center and carries a special emphasis on the cost-benefit analysis of the EPOC system when compared with the i-STAT system, which was not discussed with respect to their tertiary academic center." One difference the study's authors noticed was the time-saving aspect of the EPOC system.

For example, the i-STAT uses additional test cartridges, which means additional sampling is required to evaluate respiratory
Continued on page 50...

Chris Campbell is the Senior Editor of Respiratory Therapy.

Capnography Use in the NICU

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Prof. Amir Kugelman, a Clinical Associate Professor of Pediatrics in the R&B Rappaport Faculty of Medicine, Technion, Haifa, Israel.

Respiratory Therapy: Dr Kugelman, how are you currently using capnography?

Dr Amir Kugelman: In our neonatal intensive care unit (NICU) we use capnography routinely to trend the CO₂ levels in the blood for intubated infants. We don't use it instead of blood gases, but complementary to blood gases to get continuous non-invasive measurement of CO₂ levels. The idea is to prevent hypocarbia and hypercarbia because both can result in sequelae to the infant, especially for premature infants. A baby who is exposed to hypocarbia, because of hyperventilation, is at greater risk of lung and brain injury (decreases brain perfusion and increases ischemia). Hypercarbia secondary to hypoventilation may cause respiratory acidosis or brain injury, because if you have high levels of CO₂ and an increased circulation to the brain, you increase the risk of intraventricular hemorrhage.

RT: With which infants are you using capnography?

AK: We use it as a routine in intubated babies. It would be great if you could use it in non-invasive ventilation, but currently it's problematic because you may get dilution of the CO₂ reading. So currently we use it primarily in intubated babies. It's also possible to use it in infants who are not ventilated, like infants with bronchopulmonary dysplasia (BPD). We are not using it for non-intubated infants routinely.

RT: How long have you been using and publishing on capnography?

AK: We published on capnography starting back in 2002. In a 2008 publication in Pediatrics,¹ we used a novel method for sampling end-tidal CO₂. In the study published in Pediatrics we used the Microstream technologyⁱⁱ and we used it with a special double lumen endotracheal tube so we could sample etCO₂ at the distal end of the ET tube. We also published in 2010 using capnography with high-frequency ventilationⁱⁱⁱ and have ongoing studies.

The idea of using distal end-tidal CO₂ is to improve sidestream capnography because mainstream capnography is typically preferred and considered a more accurate mode for monitoring intubated patients. If we could improve the sidestream by using Microstream capnography monitoring and distal sampling, it

will allow us to get as good as or even better measurements compared to the mainstream technique. The distal sidestream capnography is easier to use in intubated infants because if you use mainstream in small infants you get more dead space and you might get kinking and increased risk of tube displacement in the small ET tubes due to the weight and bulk of the mainstream sensor which is in-line with flow sensors. Using this method, we get very nice measurements using Microstream capnography monitoring with very good agreement with PaCO₂ levels.

RT: Is it your routine now to use dual lumen ETT with Microstream technology for capnography sampling?

AK: 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 percent of the infants we use Microstream capnography monitoring via the double lumen tube. For others, we may use mainstream capnography or transcutaneous CO₂ monitoring. Yet, this routine has some limitations. While this tube allows us to get distal measurements, it's a bit softer than other tubes and sometimes you might have to use a stylet when placing the tube. It shouldn't be a problem, but you have to get used to it. And the outer diameter is 0.1 - 0.2 millimeters wider than the single lumen tube. So if there is any difficulty in introducing the tube then we put a single lumen tube in and we can't use the double lumen tube to get measurement of distal capnography. With the double lumen ET tube we can measure distal capnography and we are giving also surfactant by the extra port of the double lumen tube.

RT: You mentioned using capnography in conjunction with arterial blood gases (ABG). What are the benefits of using capnography in this manner?

AK: When we are taking blood gases it's not continuous measurement of CO₂. You can take it according to the acuity of the baby. You can take it every 4, 8, or 12 hours according to the routine of the department and the acuity of the clinical situation. But in between you don't know what happens with the CO₂ and if the baby has secretions and the tube is occluded or if the baby is moving and the ET tube becomes lodged on the side of the trachea, the CO₂ can go up or down and you won't know that's happening. So the baby can be outside of the safe range of CO₂ in between ABGs.

For monitoring oxygenation we have continuous measurement of pulse oximetry, but for CO₂ at the current time we don't

This interview was conducted by Greg Spratt BS RRT CPFT, the Director of Clinical Marketing in Patient Monitoring Market Development at Medtronic-Covidien. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstien at s.gold4@verizon.net.



MICROSTREAM™ CAPNOGRAPHY MATTERS.

FROM NEONATE TO ADULT, YOUR PATIENTS COUNT ON YOU.

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

- Intubated and non-intubated CO₂ continuous monitoring
- 50ml/min sample size for measurement of CO₂ partial pressure
- CO₂-specific algorithm for enhanced accuracy
- Ability to accurately detect up to 150bpm for CO₂ qualified respiration rate
- Smart alarm management technology



Visit our website to learn more about respiratory compromise:

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

have continuous measurement unless you use end-tidal CO₂ or transcutaneous CO₂. So the benefit is that you have continuous measurement and if the CO₂ is trending up you can make a change in the vent settings, suction, or change the position of the baby and make sure that the CO₂ returns to the safe range. If you don't monitor CO₂ continuously, there may be long periods when CO₂ was out of the safe range and you don't know it.

RT: Some point out that the difference between etCO₂ and PaCO₂ (gradient) makes capnography difficult to use in patients with significant lung disease. What are your thoughts?

AK: 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 (V/Q) 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.

It really depends on the baby. If the baby is stable and does not have significant lung disease, then gradient will be relatively small and consistent, but sometimes if there is a big ETT leak or significant lung disease with V/Q mismatch, then the gradient is not as consistent so you have to periodically recheck to make sure that the etCO₂ measurement correlates with the blood gas.

When the end-tidal to arterial CO₂ gradient is increased, it also gives you a clue on the severity of the lung disease and whether measures you are taking are working to improve the baby's condition. If you have a large gradient, then you know whether an intervention is effective when the gradient decreases.

But the idea is that in a baby who is very sick, in the first day or two if the baby had respiratory distress syndrome (RDS) we always use blood gases. And we use the end-tidal CO₂ for trending. After a few days when the baby is becoming better and the RDS is improving, typically the gradient is going to be smaller and then we don't take a lot of blood gases because the baby's doing better. At this stage, some babies do not have arterial lines anymore. But we are able to continuously assess and trend CO₂ levels by having the end-tidal CO₂. It's in that way that the blood gases and the end-tidal CO₂ are complementary.

RT: Have you measured or looked at how much you were able to reduce the number of blood gases that you draw now compared to before you had these continuous measurements?

AK: We did not, but there is a study that was published by Rowan^{iv} for the Pediatric Intensive Care Unit in the US and they compared the time period before and after using end-tidal CO₂ and they showed a reduction in the number of blood gases.

RT: Could you estimate what percentage of babies that the gradient is acceptable to use the end-tidal CO₂ to do your ventilator management?

AK: It's difficult to say but most of the time you get good correlation and agreement based on the first study that was published in Pediatrics.ⁱ Even in babies who had severe lung disease the gradient was still adequate. So in most of the babies you could trust the measurements.

If the gradient is higher, you can still use etCO₂ for trending because if you know that you have, for example, PaCO₂ of 60

mm Hg the end-tidal CO₂ of 50 mm Hg, the gradient is around ten. But if you see that end-tidal CO₂ is going up and is now at 70 or 80, you know that the PaCO₂ is also going up, and might now be 80 or 90. So in this situation you would intervene with suctioning, changing position, or changing the vent settings or you might take a blood gas to confirm the elevation and then make a change.

So even when you have an increased gradient, the etCO₂ trending can help you. And I believe the main goal of the continuous CO₂ monitoring is not to get the exact measurement of CO₂ level, but to be able to monitor the trending.

RT: In your hospital, which clinicians are responsible for using capnography monitoring?

AK: The doctors write the orders, but the nurses are involved all the time. We don't have a Respiratory Therapist in our unit so it's the senior physicians, residents, and nurses. If the nurse is watching the capnography and sees that the CO₂ is going up, he or she suction the baby, changes the position of the baby, or calls the doctor to listen to the baby to see if the ET tube is blocked. All the medical team responds to the end-tidal CO₂ measurements.

RT: You mentioned that you look for changes in CO₂ trends that may indicate you have secretions in the airway. Do you also use capnography to confirm ETT placement and monitor for tube migration or dislodgement?

AK: Yes. It's very useful in that way because when you use end-tidal CO₂ you use it partially to observe for technical problems and in part for physiologic problems. If you are looking for technical problems, it's to make sure that the tube is in place and to make sure that the tube is not occluded with secretions. And we look for physiologic changes that may indicate respiratory, hemodynamic, or metabolic conditions. So to your question it's very important to make sure that the tube is in place all the time and the end-tidal CO₂ is very helpful because if you lose your etCO₂ reading, you have to make sure that the tube is in place.

RT: Do you find that the capnography waveforms are helpful in neonates?

AK: Theoretically it should help. The problem is when you are doing end-tidal CO₂ in small premature infants you don't always have adequate end-tidal plateau, like in older children or in adults when you have very nice end-tidal breathing. Small infants breathe fast so you don't always get a very nice plateau. For the time being we have not explored to see if the capnography waveform can help us in managing the baby. It is helpful in ensuring that the end-tidal CO₂ is in place and if you don't have adequate waveform or adequate repetition of the waveforms then you have to ensure that the sampling line and ETT is properly placed or that there are no secretions in the tubing. It's the same as when you are doing pulse oximetry; you look at the waveform to make sure that readings are adequate. The same is true with the end-tidal CO₂; if you don't see a nice waveform, it could indicate that the etCO₂ measurement won't be accurate or there's a problem.

RT: You've talked primarily about use with intubated neonates in the NICU. Do you use capnography in any other applications at your facility?

AK: We always use capnography in the operating room and if we're transporting a ventilated baby from the emergency room to

intensive care unit or another hospital. Again, to make sure that the tube is in place on the way.

RT: Do you use capnography with non-intubated infants?

AK: You can use the end-tidal CO₂ measurement for non-intubated infants even when the baby is getting oxygen. You can follow the level of CO₂ in the same way that you follow the pulse oximetry in a baby. So that's an option, especially if the baby is an older baby. For example, if they have BPD, they don't have any arterial lines anymore if you want non-invasive monitoring you can use pulse oximetry for oxygenation and end-tidal CO₂ for ventilation. Theoretically you can use it all the time, but it's not routine in our unit.

RT: Are there any other studies you've completed where the use of capnography was helpful to you and your patients?

AK: We did a study using it to see how the position of the baby affects the level of CO₂ and apneas as infants mature. As you know, when babies are discharged from the hospital, parents are instructed to lay them on their back. For babies who are in the NICU and more premature, it's better for them to lie on the abdomen. And when using capnography, you can change the position and see the changes in CO₂ in different positions. That study was published in 2002.^v

RT: Do you believe that the benefits of using capnography justify the cost and have you looked at any data in that regard?

AK: It's a good question and I'll just say that we are in the process of submitting a study that looked if it's beneficial to do capnography in the NICU and we have shown that monitoring etCO₂ trends allows us to maintain the baby in a safer zone of arterial CO₂. I think this is very important. We didn't check the economic cost of doing it because it wasn't the aim of this study.

RT: What do you think the future holds for capnography in the NICU?

AK: With new ideas of how to use capnography more effectively and with improved capnography technology, I think that in the future it might become a routine to measure CO₂ continuously and non-invasively, the same way that you measure pulse oximetry now. It may improve safety of care in regard to respiratory and central nervous system, it may allow to take less blood gases, decrease infections, and increase the comfort of the infants in the NICU.

Prof. Amir Kugelman is a Clinical Associate Professor of Pediatrics in The R&B Rappaport Faculty of Medicine, Technion, Haifa, Israel. He specializes in Pediatric Pulmonology and Neonatology in Children's Hospital, Los Angeles, CA, and is currently the Director of the Pediatric Pulmonary Unit and a Senior Neonatologist in Bnai Zion Medical Center, Haifa, Israel and the Chairman of the Israeli Society of Pediatric Pulmonology. His main research is in Neonatal Pulmonology, focusing on non-invasive ventilation, non-invasive respiratory monitoring in the NICU and the Pediatric Department (capnography and transcutaneous CO₂ monitoring), and in the prevention and treatment of Chronic Lung Disease of premature infants and iatrogenesis.

References

i Kugelman A, Zeiger-Aginsky D, Bader D, Shoris I, Riskin A. A Novel Method of Distal End-Tidal CO₂ Capnography in Intubated Infants: Comparison With Arterial CO₂ and With Proximal Mainstream End-Tidal CO₂. *Pediatrics* 2008;

122:1219-1224.

ii <http://www.covidien.com/rms/brands/microstream>

iii Kugelman A, Riskin A, Shoris I, Ronen M, Shalev Stein I, Bader D. Continuous integrated distal capnography in infants ventilated with high frequency ventilation. *Pediatr Pulmonol.* 2012; 47(9): 876-83.

iv Rowan CM, Speicher RH, Hedlund T, Ahmeda SS, Swigonski NL. Implementation of Continuous Capnography Is Associated With a Decreased Utilization of Blood Gases. *J Clin Med Res.* 2015;7(2):71-75.

v Kugelman A, Bilker A, Bader D, Cohen A, Tirosh E. Sidestream end-tidal capnometry as related to infant's position and maturation. *Acta Paediatrica* 2002; 91:869-873.

Learning By Simulation (LBS)

Ghaleb Okla, RRT, RCP, FHCA, PhD, Douglas Eden EdD(c), and RRT

The authors will discuss the general history of all simulation, simulation-based medical education (SBME),¹ what simulation is, why simulation should be used, and clinical simulation lab evaluation. With simulation labs emerging internationally and across multiple disciplines we will attempt to shed some light on their value and to justify their expense. We will also discuss the central question, “Is the use of simulation a passing trend”?

Simulation was used in aviation as early as 1910 for the training of pilots during World War I.² Simulation for pilot training developed simultaneously with the initial training of pilots. Aviation continues to remain on the cutting edge of simulation use and development in the 21st century. It would be difficult to overestimate the value of simulation to pilot training over the last hundred years.

A lesser known form of simulation came about during the time of World War II to assist troopers with learning to ride horses.² Mechanical horses aided in teaching members of the military to ride who previously had no experience. As with aviation simulation, sophisticated mechanical horses continue to be used in training today.³ The military continues to be one of the leading users of simulation for much of its training. Although simulation in the military involves a long history of gaming⁴ to predict outcomes and prepare for battle; contemporary military simulation includes medical training along with combat training.⁵

Automobile simulation training may be more familiar to the average person from their personal experience. Simulation began to be used in the middle of the 20th century to properly train large numbers of new and young automobile drivers.⁶ Decades later that same version of automobile simulation has developed into a virtual reality cockpit that aids new drivers in developing proper driving techniques.⁷

Other disciplines utilizing simulation training include: aerospace (a natural extension of the aviation industry), law enforcement, and the nuclear industry. The aerospace industry has been able to maintain a high degree of training and readiness thanks to

Dr Okla is the President /CEO of Health Care Resources LLC, and program director of the respiratory care program at Carrington College, Pleasant Hill, California. No gratuities were accepted for this article and there are no ethical conflicts of interest. Mr Eden is a faculty member in the respiratory care program a Carrington College, Pleasant Hill, California and a doctoral candidate. No gratuities were accepted for this article and there are no ethical conflicts of interest.

simulation technology. Law enforcement uses simulation to prepare officers for nearly any scenario they might face on the street. The international nuclear industry has been able to achieve the reasonably safe record they established over the second half of the twentieth century due to an intensive use of simulation training.⁸

The medical profession has been a relatively recent newcomer to the use of high-fidelity simulation.⁹ One author referred to the growth of simulation in medicine as a “prolonged gestation”.⁹ Medicine has long used low-tech manikins for CPR training. By the end of the 20th century hi-fidelity simulation manikins and dedicated laboratories were becoming the new standard for medical schools, hospitals, and nursing and allied health training programs. Medical simulation manikins are now available in 3G for advanced medical training in trauma, anesthesia, obstetrics, neonatology and numerous other specialties.¹⁰ The first use of a computerized simulator for SBME is thought to have been the University of Miami Medical School in the 1960’s-1970’s.¹¹ Medical students and residents were trained in cardiology using the simulator nicknamed “Harvey”. Harvey-trained practitioners outperformed their traditionally trained peers in one study.¹² Ziv referred to SBME as an *ethical imperative*¹³ suggesting that simulation is an essential component of the medical training curriculum.

The rationale for simulation use in medicine has long been based on improving patient outcomes. The number that continues to drive the use of simulation for medical training in the United States is the widely quoted 98,000 accidental hospital deaths annually. This alarming number has remained constant for over a decade.¹⁴ The actual number of accidental hospital deaths may much higher and north of 400,000.¹⁵ To provide some perspective; these numbers exceed the sum total of deaths in the United States from automobile accidents, breast cancer, and AIDS. Two studies looked at adverse effects in hospital patients and the percentage of adverse effects that lead to death. One study revealed that in Colorado and Utah adverse events occurred in 2.9 percent of patients and that death was the outcome in 6.6 percent of those adverse events.¹⁶ Another study in New York measured adverse events in 3.7 percent of hospitalizations with death as the outcome in 13.6 percent of those cases.¹⁶

The question that naturally follows the simulation conversation in medicine is “does simulation increase patient safety”? There appears to be no definitive statistical link at this time between simulation use and positive outcomes and further studies are

encouraged.¹⁷ Though research from around the world over the last decade indicates that simulation helps safely train users of high-end technologies associated with anesthesia and surgical procedures. SBME has been linked to clinical improvement in laparoscopic surgery outcomes and ACLS protocol adherence.¹⁷ As a stand-alone training method linked to patient safety the data remains lacking. Supporters claim that it is better to train on simulators and move to live patients than to train on live patients. McGaghie claimed that SBME with *deliberate practice* was superior in achieving clinical skills to the traditional medical education of, “see one, do one, teach one”.¹⁸ For now simulation in medicine leans on the record it has in aviation as a reference for legitimacy. More studies are needed linking medical simulation training to improved patient safety.

In 2005 JCAHO’s position on simulation use in medicine was supportive. JCAHO issued a statement that recommended the adoption of simulation technology and the establishment of evidenced-based research to prove impact on patient safety. They went on to propose that those seeking to implement simulation technology pursue proposals to offset the cost.¹⁹

One physician simulation director said that medical simulation was *state of the art* and extremely valuable in the early phases of all medical training.^{20,21} For instance, simulation training has become a routine part of training for respiratory therapists in the United States.²² Respiratory therapists are frequently involved in resuscitations, trauma, and ventilator care as a daily part of their duties. Low-tech simulation laboratories have become common in respiratory training programs and high-tech simulation laboratories are slowly becoming more common.²² In colleges that share space with registered nurse training programs the cost may be more justifiable. The cost of one high-fidelity simulator with associated equipment can reach \$200,000.00.²³ The cost of building a high-tech simulation lab, or converting space, can be in excess of 1,000,000.00 and prohibitive for some budgets.

There are a variety of strategies within the discipline of simulation such as: low-fidelity (lowest cost), role playing, computer programs, haptic devices, task trainers, standardized patients, virtual experiences, and high-fidelity (most expensive). Given the importance of simulation in academic conversations; what is the goal of providing the training at any level? The short answer is to change outcomes. Simulation seeks to create an experience for users that mimics a reality situation and provides an opportunity develop and practice essential skills and abilities in a safe environment. Additionally, as with changes in other medical disciplines; changes in respiratory care practice mandates can be readily accommodated through simulation in a respiratory care education programs.

The development of medical education, at any level, fits into a general framework of clinical assessment using a simple pyramid model from bottom-to-top: knowledge, competencies, performance, and action.²⁴ All levels of simulation facilitate critical thinking skills needed in the learning process. In terms of evidenced-based research that lends legitimacy to the claims that patient safety is improved by use of simulation the literature is slowly piling up. Berkenstadt called SBME a “mistake-forgiving” environment.²⁵ There are numerous other benefits from the use of simulation in medical education and they all fit into the universal mission of improving patient outcomes. Teamwork within disciplines and interdisciplinary teams is established through the use of simulation as well as collaborative strategies.

Bearman referred to SBME as linked to a “new professionalism” that supports a patient-centered and team-based approach to healthcare.²⁶ A range of technologies is available in simulation and their use is facilitated by users based on frequency of use. Simulation allows for the development of clinical judgment and the process of acclimation to accountability for patient outcomes.

The most valuable phase of simulation may take place during the evaluation process that is often associated with a debriefing session.²⁷ Debriefing sessions are held immediately after a simulation experience with participants and evaluators sitting around a table. These sessions are designed to be a time when participants can speak freely about the simulation, watch video of the simulation, and generally and specifically discuss what went well and what needed improvement. The Debriefing Assessment for Simulation in Healthcare (DASH) program at Harvard Medical Simulation Center is a fine example of how debriefing can be utilized to enhance medical training.²⁸ A trained debriefing guide sets a friendly tone but typically does little of the talking unless problems arise. A common technique is to write down on a board lists of how the participants critique themselves (what went well and what did not go well). Debriefing guides withhold their view of what transpired during the simulation until the conclusion and only state minimal, objective facts shared in a positive light.

The simulation experience is enhanced when participants have had a live set of clinical experiences to create a framework. Often students will say that they appreciated their simulation experience more after they went to a live clinical experience. Students are allowed to make errors in the simulation environment both minor and major without fear of a penalty and they are pre-briefed about this criteria ahead of time. The simulation experience becomes more rich and valuable when students understand the philosophy of simulation and feel free to fully immerse themselves in the role playing model. At the conclusion of the simulation and debrief there should be a positive feeling of satisfaction among students, mentors, and faculty. There is an axiom in simulation that strongly discourages anyone leaving the simulation and debriefing session with negative feelings.

Simulation always provides hands-on training that students universally desire and that builds skills and confidence. From measuring a blood pressure to placing ECG leads, interpreting cardiac rhythms to manipulating mechanical ventilators, auscultating breath sounds to physical assessment, simulation allows students to develop through role playing as respiratory therapists, doctors, nurses and even family members of the patient. Students will often receive clinical contact hours for their experience in the simulation lab. High-Fidelity simulators are available, though costly, in the form of SIM-Man, SIM-Baby, SIM-Mom, and various ala carte add-ons for trauma and respiratory diseases.¹¹

Not all simulation is expensive as seen in the use of standardized patients. A standardized patient is a real person who volunteers or is paid to play the role of a hospital patient. Cases and scripts are selected and developed ahead of time and the standardized patient stays in-character through the simulation. Some patients with actual disease processes such as pulmonary or cardiac volunteer to be members of a standardized patient pool available to some simulation programs. The added value

of having simulation training with a live person able to interact authentically with participants is one way to substitute a high-value simulation experience without having a high-fidelity simulation lab. Often the value-added phase of standardized patient use occurs during debriefing when the actor provides detailed feedback about their perception of the event. Obvious limitations with standardized patients exist such as inability to simulate trauma and resuscitation scenarios and that some receive reimbursement.

Summary

The future appears bright for the use of simulation in medical education. Medical, nursing, and allied healthcare students trained through simulation have opportunities to practice hands on techniques, teamwork, and communication through trial and error before working with live patients. The cost of high-fidelity simulation will continue to make its use prohibitive and challenging for some programs. The use of low-fidelity simulation, standardized patients, and role playing continues to have measureable qualitative value. Cost center sharing is one way for programs on a tight budget who desire high-fidelity simulation to access this valuable skills-building, outcome-improving medical education adjunct tool.

References

- 1 McGaghie, W.C., Issenburg, S.B., Petrusa, E.R., Scalesek R.J. A Critical review of simulation-based education research: 2003-2009. *Medical Education*, 2010, 44(1), 50-63.
- 2 www.simulationinformation.com, 2015.
- 3 www.theatlantic.com/technology/archive/2012/09/a-brief-history-of-mechanical-horses/262942/. 2015.
- 4 www.racewood.com/dressage.php, 2015.
- 5 www.army.mil/article/11936/History_of_Military_gaming/, 2015.
- 6 www.peostri.army.mil/PRODUCTS/MSTC/, 2015.
- 7 Nolan, R.O. (1965). A Comparative study of the teaching effectiveness of the Aetna drivotrainer and the multiple car off-street driving range. Michigan State University, College of Education. Doctoral Dissertation.
- 8 www.simulatorsystems.com. 2015.
- 9 www.pub.iaea.org/books/IAEABooks/6670/Application-of-Simulation-Techniques-for-Accident-Management-Training-in-Nuclear-Power-Plants. 2015.
- 10 Bradley, P. The History of simulation in medical education and possible future directions. *Medical Education*, March, 2006, 40 (3), 254-62.
- 11 www.laerdal.com/us/nav/207/Patient-Simulators. 2015.
- 12 www.gcrme.miami.edu/harvey_features.php. 2015.
- 13 Ziv, A., Wolpe, P.R., Small, S.D., Glick, S. Simulation-based medical education: An ethical imperative. *Academic Medicine*, 2003, 78(8), 783-88.
- 14 Aggarwal, R., Mytton, O.t., Derbrew, M., et al. Training and simulation for patient safety. *BMJ Quality & Safety*, 2010, 19(2), 34-43.
- 15 www.propublica.org/article/how-many-die-from-medical-mistakes-in-us-hospitals. 2015.
- 16 www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20report%20brief.pdf. 2015.
- 17 Okuda, Y., Bryson, E.O., DeMaria, S., et al. The Utility of simulation in medical education: What is the evidence? *The Mount Sinai Journal of Medicine*, New York. 2009, 78(4), 330-43.
- 18 McGaghie, W.C., Issenberg, S.B., Cohen, E.R., Barsuk, J.H.,

- Wayne, D.B. Does simulation-based medical education with deliberate practice yield better results than traditional clinical education? A meta-analytic comparative review of the evidence. *Academic Medicine*, June, 2011, 86(6), 706-11.
- 19 www.jointcommission.org/assets/1/18/Medical_Liability.pdf. 2015.
 - 20 www.medicalsim.org/dawson.htm. 2015.
 - 21 www.cimit.org/about.html. 2015.
 - 22 <http://www.rtmagazine.com/2012/05/educating-health-professionals-with-simulation-programs-implications-for-respiratory-therapists/>. 2015.
 - 23 www.ncbi.nlm.nih.gov/pmc/articles/PMC3195067/. 2015.
 - 24 Harris, I.B., Miller, W.J. Feedback in an objective structured clinical examination by medical students serving as patients, examiners, and teachers. *Academic Medicine: Journal of the Association of American Medical Colleges*, July 1990, 65(7), 427-96.
 - 25 Berkenstadt, H., Erez, D., Munz, Y., Simon, D., Ziv, A. Training assessment of trauma management: The Role of simulation-based medical education. *Anesthesiology Clinics*, 2007, 25(1), 65-74.
 - 26 Bearman, M., Nestel, D., Andreatta, P. Simulation-Based Medical Education. *Oxford Textbook of Medical Education*. 2013, 186-97
 - 27 www.ncbi.nlm.nih.gov/pubmed/22902606. 2015.
 - 28 www.harvardmedsim.org/debriefing-assesment-simulation-healthcare.php. 2015.

H.R. 2619 RT Initiative Act: Improving Educational Requirements and Visibility of RRT's within Health Care Reform

Kristin Prater

Many changes are incurred within the new health care arena and health reformation platform. Medicare, health insurance companies, and governmental agencies are pushing for patients to become healthier with an emphasis on self-care and self-management of chronic illnesses. The modern environment of healthcare in the US is rapidly changing, attempting to evolve its policies while providing patients with better access to health care providers, better care, and lower costs. Many believe that home health care agencies will become exponentially more comprehensible and profitable with new health initiatives currently in place (Figure 1). Reimbursement and coverage from Medicare and health insurance agencies in relation to patient training, education, and self-care protocols will likely decrease the rate of patient readmittance to acute care hospitals, making home health and urgent care clinics the gold standard in pre hospital care. In lieu of acute care hospitals, patients can be seen and evaluated by allied health professionals instead of physicians, which will incrementally decrease costs associated with inpatient services. These initiatives could potentially place registered respiratory therapists in a unique position amongst new health care reforms. The RT Medicare Initiative Act (H.R. 2619) would entitle RRT's with BSRT degree or higher to autonomously provide patients with essential disease management education, facilitate key Medicare self-management agendas, and in turn, allocate reimbursement from Medicare. Even though the price of pulmonary self-management services provided under Medicare will prove costly, passing this bill will not only result in higher educational requirements for our profession, it will also advance the scope of our practice, and place RRT's in an invaluable position in the new healthcare arena.

The RRT credential was once recognized as the highest level credential within our profession. RRT's with an Associate's degree in Applied Science, who met the requirements of passing three national board exams were thought to hold the highest value in relation to employment and educational mandates. In the past, all allied health professionals have had to push for higher standards and educational requirements to be recognized by Medicare for reimbursement and billing codes. With physicians and department heads vying for RRT's to obtain a bachelor's degree or higher to provide services inside the acute care setting, Medicare reimbursement for respiratory therapy services isn't the only reason to obtain higher education. With

higher educational standards, the respiratory field would finally prove invaluable inside and outside of the hospital setting and the importance of the profession would be recognized. Respiratory therapists are the only allied health profession with specialized training in the care of pulmonary patients specifically. The American Association of Respiratory Care believes, "it's time to recognize the level of expertise that RT's can bring to pulmonary patients" (HR 2619-Medicare, 2013).

With Medicare's push to cut down on the expenses associated with readmission rates, HR 2619 would advance RRT's role outside of the acute care setting. Non acute care career options within our profession would prove viable and valuable in the current health care platform. One of the highest and most costly readmission rates amongst Medicare beneficiaries are those patients with chronic obstructive pulmonary disease (COPD). Supporters of HR 2619 feel that the expense of enacting the bill would most likely be "offset by reducing ER visits and better adherence to medication protocols" for patients clinically diagnosed with COPD (HR 2619-Medicare, 2013). COPD patient populations are very concerned about Medicare coverage in light of health care reform. With limited coverage and access to fundamental supplies to manage their disease process, these patients prove a higher risk for frequent exacerbations, increased mortality, and decreased quality of life. RRT's role in patient education for these patients is crucial in the home health setting. Currently, Medicare does not recognize or provide coverage for our services under Medicare Part B, therefore, the HR 2619 should be passed to reduce hospital admission rates and provide

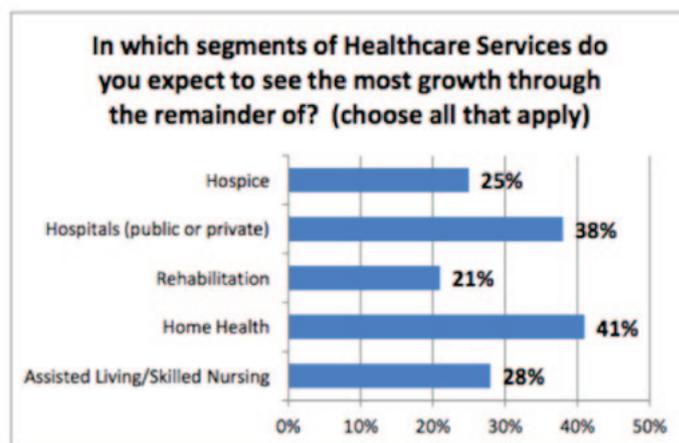


Figure 1. Segments of health care services and anticipated growth. This graph illustrates home health care is expected to provide the most growth.

Kristin is a student at Pima University and is a BSRT. She has been a Respiratory Care Instructor for the last 7 years.

health care coverage for the growing COPD population. Within the context of health care reformation, these concepts of reducing hospital remittance rates, and disease self-management put forth by Medicare could be accomplished if this bill was passed in favor of our profession.

Conversely, the House of Representatives finds that the price tag for covering respiratory services proposed by HR 2619 under Medicare would prove more costly than beneficial. The original bill (called HR 941) died in congress due to lack of support and the potential cost estimated by the Congressional Budget Office at over 250 million in ten years. It is unlikely that the CBO would consider the offset portion of that price tag; which includes saving money in the context of reducing ER admits due to proper home health education and training provided by RRT's. In addition to the cost factor, Physicians are extremely reluctant to hire RRT's to provide the services outside the acute care setting if billing codes and reimbursement for those services is not currently available. Both considerations are factored in not passing the original bill HR 914. Although the bill was updated, issues still exist in putting forth enough emphasis on the cost offset factors which would reduce expenditures by decreasing acute care remittance rates for those patients with chronic lung disease.

In conclusion, many key considerations need to be examined in relation to health care policies for managing chronic lung disease. Medicare does presently recognize reimbursement for diabetic patients, and most therapists feel that both Medicare and insurance agencies will follow suit with similar policies involving pulmonary patients. Improving educational components within our profession is more important than ever before within the new health care climate. Passing HR 2619 would not only improve access, visibility, and recognition of therapists with a BSRT degree, it would also improve patient outcomes and quality of life for those afflicted with pulmonary lung diseases.

References

1. AARC. (n.d.). aarc/advocacy. Retrieved February 22, 2014, from https://www.aarc.org/advocacy/activities/FAQs_RTInitiative_2013_Aug_2013.pdf
2. AARC. (n.d.). arc.org/advocac. Retrieved February 22, 2014, from https://www.aarc.org/advocacy/activities/FAQs_RTInitiative_2013_Aug_2013.pdf
3. Action Alert - U.S. COPD Coalition. (n.d.). Action Alert - U.S. COPD Coalition. Retrieved February 22, 2014, from <http://www.uscopdcoalition.org/p-17>
4. Government Affairs. (n.d.). Capwiz. Retrieved February 28, 2014, from <http://capwiz.com/aarc/issues/alert/?alertid=62340346>
5. Home Health Has Most Growth Potential, Say Health Care Execs. (n.d.). Home Health Care News. Retrieved February 28, 2014, from <http://homehealthcarenews.com/2013/09/home-health-has-most-growth-potential-say-health-care-execs/>

Blood Gas and Electrolyte Analyzer...continued from page 41 and metabolic acidosis and alkalosis.

When it came to accuracy for the EPOC, the study's authors said that, "although intra-assay and interassay precision studies showed a CV of less than 5% for all analytes evaluated, the accuracy and linearity studies also showed excellent accuracy and linearity of all analytes across the reportable range in compliance with the College of American Pathologists and CLIA guidelines."

Overall, compared with the i-STAT, the study's authors found 'many additional advantages' with EPOC in the area of saving time. "The EPOC system uses a single test card with all the different analytes including glucose, lactate, creatinine, and chloride, whereas the i-STAT system uses multiple test cartridges for the same results. Whereas the i-STAT system reports results in less than 2 minutes, the EPOC blood gas and electrolyte analyzer has results ready in less than 30 seconds, significantly decreasing TAT in the emergency setting. Test cards for EPOC may be stored for up to 6 months at room temperature unlike the i-STAT system. Each reagent for the EPOC has direct bar coding, ensuring easy traceability. The EPOC system has wireless connectivity (Wi-Fi and bluetooth), and transmission of data from bedside to laboratory information systems is instant and automatic. The touch screen interface of the EPOC system is easy to use. The EPOC system uses calibration before sample application to minimize the chances of error and possible redraw of patient."

The last advantage discovered in the study was in the area of cost. "The smart card technology of EPOC reduces cost and maximizes efficiency in the hospital setting. The cost of the EPOC analyzer is less than the i-STAT analyzer (\$5991 vs \$9065). Despite the additional interface cost of the EPOC analyzer, the total supply cost per annum at our pediatric hospital is less for the EPOC analyzer as compared with the i-STAT analyzer (\$5228 vs \$7274). With expansion of health care to remote facilities and need for immediate laboratory results in the critical care setting, we conclude that the operational advantages, interface capabilities, and cost-benefit ratio of the EPOC blood gas and electrolyte analyzer will propel it as a favorable bedside POC instrument particularly in the intensive care setting of both adult and pediatric hospitals."

Determining the Quality of Spirometry of Patients Presenting to the Clinician with an Acute Chronic Obstructive Pulmonary Disease (COPD) Exacerbation

G Sowman BSc¹; C Ashwell BSc¹; H Kaur-Nagra PhD¹; M Brown MSc²; P Ford MD²; D Price BA²

Introduction

Spirometry is one of the few clinical measurements that requires maximum patient effort in order to achieve acceptable and repeatable results. Obtaining valid Spirometry data from COPD patients who present to the clinic with an exacerbation can be challenging.

Having well-trained clinical staff who can coach these patients correctly can have a significant impact on the quality of Spirometry. The accuracy and quality of Spirometry is also particularly important when these patients are participating in clinical trials where Spirometry data are used as endpoints.

The ATS/ERS 2005 criteria are commonly used in clinical trials to determine the quality of spirometry results.

In two clinical trials 90% of the COPD patients that performed Spirometry were able to meet the ATS/ERS 2005 criteria for FEV and FVC repeatability.

Objective

To assess how many Spirometry Sessions meet the ATS/ERS 2005 criteria for acceptability and repeatability in COPD patients who present to clinic with an exacerbation.

Method

89 moderate to very severe COPD patients who went to hospital due to an exacerbation were entered into a clinical trial that was conducted in 11 centres in 3 European Countries. At the first clinic visit they were required to perform Spirometry for inclusion and these results were used as the baseline for measuring efficacy of the trial drug. FEV was used as the primary endpoint for the trial and FVC was a secondary endpoint.

Spirometry was performed in all centres using the Vitalograph Pneumotrac (Fleisch) run on Spirotrac software customised for the trial. The software program demanded daily calibration checks to be performed before any Spirometry testing.

Before the trial commenced all clinical staff who were responsible for conducting the Spirometry testing were trained on the correct use of the equipment and on the ATS/ERS 2005 criteria and also had to pass a competency assessment.

Once the Spirometry Session had been performed the clinical staff sent the data to Vitalograph Data Management centre.

Each Spirometry session was Over-Read by two independent Spirometry experts.

Each Spirometry session was assessed using the ATS/ERS 2005 criteria.

In accordance with the ATS/ERS 2005 criteria each patient was asked to perform up to eight manoeuvres. Of these, at least 3 manoeuvres had to be deemed acceptable with the 2 largest FEV and the 2 largest FVC values being within 150ml (0.15L) of each other. An acceptable manoeuvre required a good start of test (extrapolation volume < 150ml or 5% of FVC), no cough in 1st second of expiration, expiration time of at least 6 seconds and 1 second plateau on the volume/time curve.

In addition, if a Spirometry Session had 0 acceptable manoeuvres, these were checked to see if any manoeuvres had a usable FEV as dened by the ATS/ERS 2005 criteria.

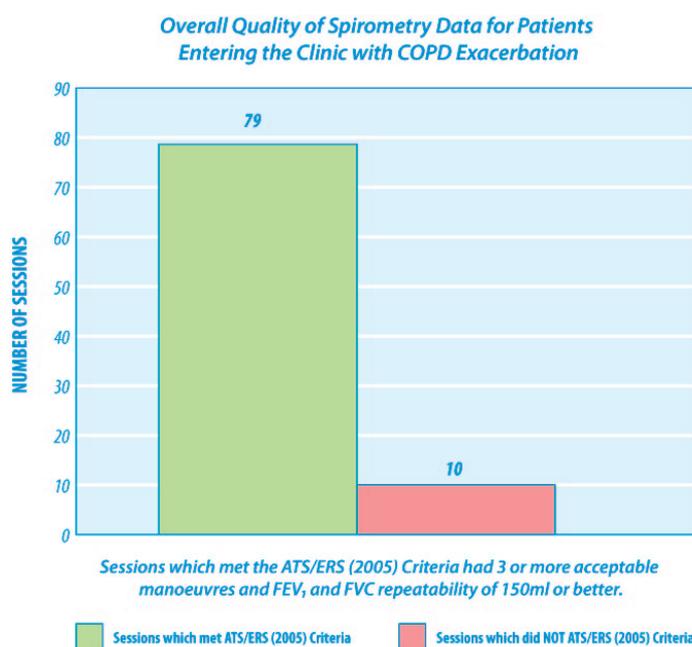


Figure 1. Number of patients who achieved the ATS/ERS criteria³

¹Vitalograph Ltd: Vitalograph Business Park, Maids Moreton, Buckingham MK18 1SW, United Kingdom. ²Novartis Horsham Research Centre, West Sussex, United Kingdom.

Quality of Spirometry Data of Patients Entering the Clinic with COPD Exacerbations arranged by Number of Acceptable Manoeuvres per Session

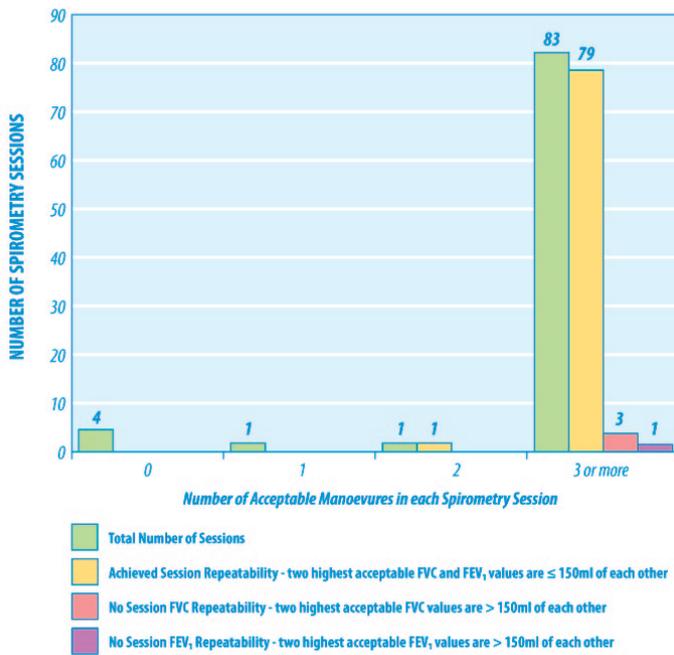


Figure 2. Number of acceptable manoeuvres within each Spirometry Session

Results

Of the 89 patients assessed, 79 (89%) were able to meet the ATS/ERS 2005 criteria within >3 manoeuvres (Figure 1). 10 patients were unable to meet the ATS/ERS 2005 criteria.

Of the 10 patients (11%) who failed to meet the ATS/ERS 2005 criteria, 1 six of these patients were able to perform 1 acceptable manoeuvre. One performed only 2 manoeuvres but these were acceptable and repeatable, three achieved 3 acceptable manoeuvres with just FEV repeatability and one had 3 acceptable manoeuvres with just FVC repeatability (see Figure 2 and Table 1).

Table 1. Breakdown of Session Quality Acceptable Manoeuvres and Repeatability).

		FVC and FEV Repeatability within 150ml	Sessions with FVC Repeatability > 150ml	Sessions with FEV Repeatability > 150ml	Total Sessions
Number of Acceptable Manoeuvres within the Session	0	NA	NA	NA	4
	1	NA	NA	NA	1
	2	1	0	0	1
	≥3	79	3	1	83

Four patients (4.5%) failed to produce any acceptable manoeuvres; however, two of these patients were still able to achieve usable FEV baseline trial data.

Conclusion

Well-trained clinical staff can successfully coach moderate to very severe COPD patients who are having an acute exacerbation to produce valid Spirometry Data as only 2 patients were unable to produce any valid FEV Data.

This is particularly important in pharmaceutical clinical trials where FEV is used as a primary endpoint to assess new drugs in treating patients with COPD exacerbations.

References

1. Miller MR et al Standardisation of Spirometry. ERJ 2005;26:319-338.
2. Herpal B et al Variability of Spirometry in Chronic Obstructive Pulmonary Disease, Results from two clinical trials. Am J Respir Crit Care Med Vol 173. pp 1106-1113, 2006

Pulmonary Ultrasound and Pulse Oximetry Versus Chest Radiography and Arterial Blood Gas Analysis for the Diagnosis of Acute Respiratory Distress Syndrome: A Pilot Study

Cameron M. Bass, Dana R. Sajed, Adeyinka A. Adedipe and T. Eoin West

Abstract

Introduction: In low-resource settings it is not always possible to acquire the information required to diagnose acute respiratory distress syndrome (ARDS). Ultrasound and pulse oximetry, however, may be available in these settings. This study was designed to test whether pulmonary ultrasound and pulse oximetry could be used in place of traditional radiographic and oxygenation evaluation for ARDS.

Methods: This study was a prospective, single-center study in the ICU of Harborview Medical Center, a referral hospital in Seattle, Washington, USA. Bedside pulmonary ultrasound was performed on ICU patients receiving invasive mechanical ventilation. Pulse oximetric oxygen saturation (SpO₂), partial pressure of oxygen (PaO₂), fraction of inspired oxygen (FiO₂), provider diagnoses, and chest radiograph closest to time of ultrasound were recorded or interpreted.

Results: One hundred and twenty three ultrasound assessments were performed on 77 consecutively enrolled patients with respiratory failure. Oxygenation and radiographic criteria for ARDS were met in 35 assessments. Where SpO₂ ≤ 97%, the Spearman rank correlation coefficient between SpO₂/FiO₂ and PaO₂/FiO₂ was 0.83, $p < 0.0001$. The sensitivity and specificity of the previously reported threshold of SpO₂/FiO₂ ≤ 315 for PaO₂/FiO₂ ≤ 300 was 83% (95% confidence interval (CI) 68-93), and 50% (95% CI 1-99), respectively. Sensitivity and specificity of SpO₂/FiO₂ ≤ 235 for PaO₂/FiO₂ ≤ 200 was 70% (95% CI 47-87), and 90% (95% CI 68-99), respectively. For pulmonary ultrasound assessments interpreted by the study physician, the sensitivity and specificity of ultrasound interstitial syndrome bilaterally and involving at least three lung fields were 80% (95% CI 63-92) and 62% (95% CI 49-74) for radiographic criteria for ARDS. Combining SpO₂/FiO₂ with ultrasound to determine oxygenation and radiographic criteria for ARDS, the sensitivity was 83% (95% CI 52-98) and specificity was 62% (95% CI 38-82). For moderate-severe ARDS criteria (PaO₂/FiO₂ ≤ 200), sensitivity was 64% (95% CI 31-89) and specificity was 86% (95% CI 65-97). Excluding repeat assessments and independent interpretation of ultrasound images did not significantly alter the sensitivity measures.

Conclusions: Pulse oximetry and pulmonary ultrasound

may be useful tools to screen for, or rule out, impaired oxygenation or lung abnormalities consistent with ARDS in under-resourced settings where arterial blood gas testing and chest radiography are not readily available.

Introduction

Acute respiratory distress syndrome (ARDS) is a common cause of mortality in the ICU.¹ The diagnosis of ARDS is established using the new Berlin criteria which consists of four elements: 1) onset within a week of a known clinical insult or new respiratory symptoms, 2) bilateral opacities on chest radiograph or computed tomography scan, 3) respiratory failure not fully explained by cardiac failure or fluid overload, and 4) impaired oxygenation defined as partial pressure of oxygen (PaO₂)/fraction of inspired oxygen (FiO₂) ≤ 300 on positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) ≥ 5 cmH₂O. Diagnosis of ARDS requires an arterial blood gas (ABG) test and chest radiography or computed tomography in the appropriate clinical scenario.

In much of the world where medical resources are limited, blood gas analysis and imaging technologies may not be available, impairing the ability to make the diagnosis of ARDS. In one study, half of all patients who clinically had ARDS in a hospital in Rwanda had a chest radiograph available for review.² However, both pulse oximetry and ultrasound are becoming increasingly accessible worldwide.^{3,4} The pulse oximetric saturation to inspired oxygen ratio (SpO₂/FiO₂) has been correlated with the PaO₂/FiO₂ ratio in ARDS.^{5,6} Pulmonary ultrasound is a rapidly developing technology in which the diagnosis of lung disease is being explored in diverse settings, and new diagnostic criteria are being developed for multiple pulmonary processes.⁷ Some of the first patterns of pulmonary ultrasound to be recognized were the distinct “A line” and “B line” artifacts.⁸ The “A-line” pattern, characterized by horizontal reflection artifacts of the pleural line deep into the lung, is seen with alveoli that are physiologically filled with air. The “B-line” pattern, characterized by the presence of three or more vertical artifacts obliterating any A-lines, correlates with the ultrasound interstitial syndrome (UIS).⁹ The presence of UIS diffusely on ultrasound is considered consistent with either cardiogenic pulmonary edema or ARDS.¹⁰⁻¹² The A line and B line patterns have proven to be easily distinguished by a bedside clinician after relatively brief teaching.^{13,14} Therefore, it is conceivable that the diagnosis of ARDS could be made using pulse oximetry and pulmonary ultrasound at the point of care.

The authors are with the Department of Medicine, University of Washington School of Medicine, Seattle, WA, USA. This is an Open Access article distributed under the terms of the Creative Commons Attribution License.

Study flowchart – daily assessment

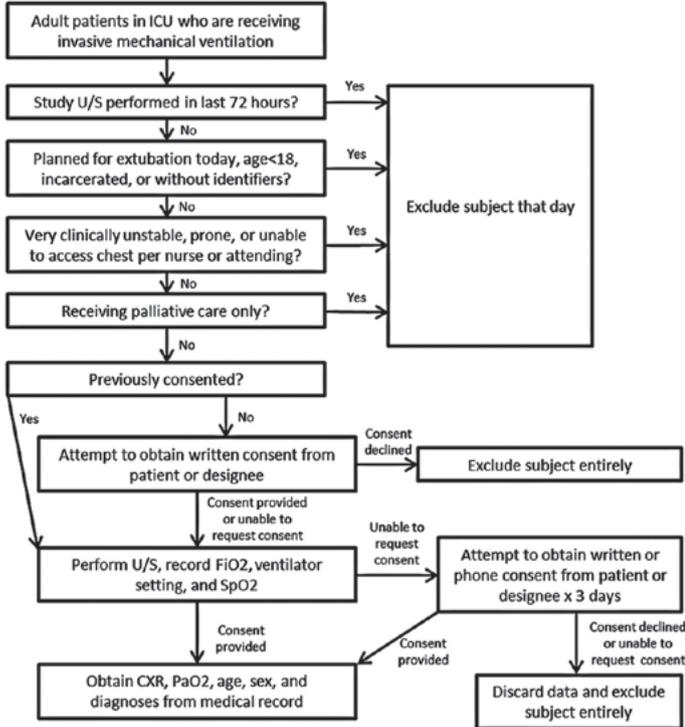


Figure 1. Study flow chart. CXR chest x-ray, FiO₂ fraction of inspired oxygen, PaO₂ partial pressure of oxygen, SpO₂ pulse oximetric oxygen saturation, U/S ultrasound.

We hypothesized that data derived from pulse oximetry and bedside pulmonary ultrasound could be used in lieu of ABG and chest radiography to meet oxygenation and radiographic criteria for ARDS. We designed a prospective study in patients with respiratory failure in the ICU to test this hypothesis.

Methods

Study procedures

The study was conducted in the ICUs at Harborview Medical Center, Seattle, Washington, USA. The study physician received 4 h of hands-on pulmonary ultrasound training from an ultrasound fellowship-trained emergency medicine attending physician. Training included ultrasound scanning and discussions at the bedside of ten patients with different lung pathologies and a brief literature review.

From 4 July to 22 August 2013, mechanically ventilated patients in the ICUs were identified by the study physician early each morning using a Quality Safety Dashboard, Monday through Friday. Patients were screened for study eligibility based on inclusion and exclusion criteria (Fig. 1). Although the study design initially included patients on high levels of supplemental oxygen via high flow nasal cannula or face mask, the revised Berlin definition of ARDS published in 2012 required administration of CPAP or PEEP, so eligibility was restricted to patients receiving mechanical ventilation. No attempts were made to determine the etiology or management of respiratory failure before enrollment. Contraindications included burns over the chest, flail chest, active hemodynamic instability or declination by the patient's nurse, receiving palliative care, age less than 18 years, incarceration, prone positioning, planned extubation the morning of study, or lack of identifying personal information.

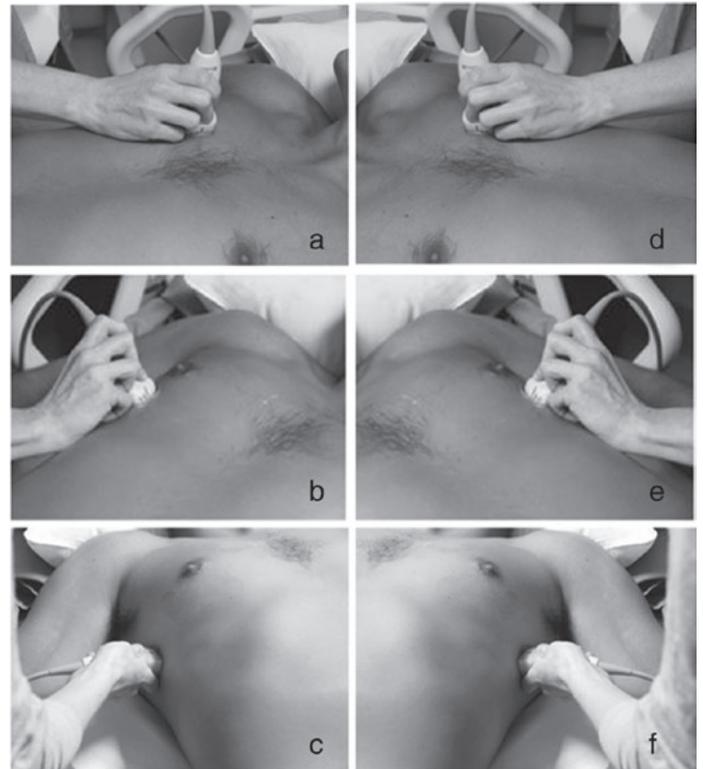


Figure 2. Placement of the ultrasound probe at six locations on the chest. a zone 1 is 2 cm below the anterior mid-clavicular line on the right side of the chest; b zone 2 is 4 cm inferior and 4 cm lateral to zone 1; c zone 3 is 2 cm inferior to zone 2 along the mid-axillary line. d-f The identical positions on the left side of the chest.

For patients who met eligibility criteria the study physician performed an ultrasound evaluation prior to reviewing the patient's chart or other imaging. A Sonosite S-ICU ultrasound machine (SonoSite, Inc., Bothell, Washington) with a p21x 5-1 Mhz phased array probe was used to capture 6-second video imaging of the lung at three sites on each side of the chest (Fig. 2), following a modification of a previously described protocol.^{10,15,16} Specifically, the six "BLUE" points were evaluated for the presence of B lines (Fig. 3). In order to mimic rapid evaluation by a single clinician in austere conditions, patients were not repositioned for the purpose of the scan and assistance

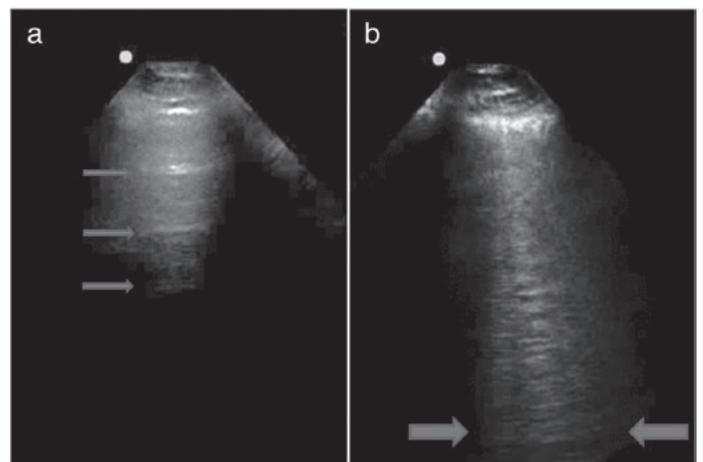


Figure 3. a "A lines": distinct horizontal reflections in a patient with normal lungs (arrows). b "B lines": three vertical lines in a single frame extending from the pleura to the bottom of the screen in a patient with ultrasound interstitial syndrome (between arrows).

Table 1 Baseline characteristics of subjects and study assessments

Characteristic	Number	Percent
Patients	77	
Male	52	68
Age, median (IQR)	56 (41–67)	
Number undergoing 2 assessments	13	17
Number undergoing 3 assessments	3	4
Number undergoing ≥ 4 assessments	8	10
Assessments	123	
Site:		
MICU	45	37
SICU	49	40
NICU	29	24
Diagnosis:		
Sepsis	36	29
Trauma	31	25
Postsurgery	24	20
CVA	21	17
Cardiogenic pulmonary edema	21	17
Pneumonia	20	16
PEA or VF arrest	13	11
PE	10	8
ARDS	10	8
Overdose	9	7
Seizure	7	6
Pancreatitis	7	6
COPD	6	5
FiO ₂ at time of ABG, median (IQR)	0.40 (0.30–0.50)	
PaO ₂ /FiO ₂ , median (IQR)	250 (180–337)	
SpO ₂ % at time of ABG, median (IQR)	99 (97–100)	
Bilateral opacities on CXR	42	34

Patients may have more than one diagnosis at the time of assessment. ABG arterial blood gas, ARDS acute respiratory distress syndrome, COPD chronic obstructive pulmonary disease, CVA Cerebrovascular Accident, CXR chest x-ray, IQR interquartile range, MICU Medical Intensive Care Unit, NICU Neurological Intensive Care Unit, PE Pulmonary Embolism, PEA Pulseless Electrical Activity, SICU Surgical Intensive Care Unit, SpO₂ pulse oximetric oxygen saturation, VF Ventricular Fibrillation

from additional staff members was not requested. No scan was permitted to take more than 5 min, including start up time for the machine and recording time for the videos. The FiO₂ and SpO₂ at the time of the ultrasound were recorded. This procedure was performed as close to 06:30 am as possible to reduce the duration between ultrasound and early morning chest radiographs and ABG measurements performed in the ICUs. Subsequently, the chest radiograph and ABG performed closest to the time of the ultrasound were abstracted from the medical record. The FiO₂ and SpO₂ recorded by transcutaneous probe at the time of the ABG were also recorded. The ICU teams clinical note for the day of the study evaluation was reviewed to capture active clinical diagnoses. If patients continued to meet eligibility criteria, repeat study assessments were performed every 3 days.

Definitions

For each study assessment, the ABG and concurrent FiO₂ data was used to calculate a PaO₂/FiO₂ value. Chest radiographs were independently reviewed by a board-

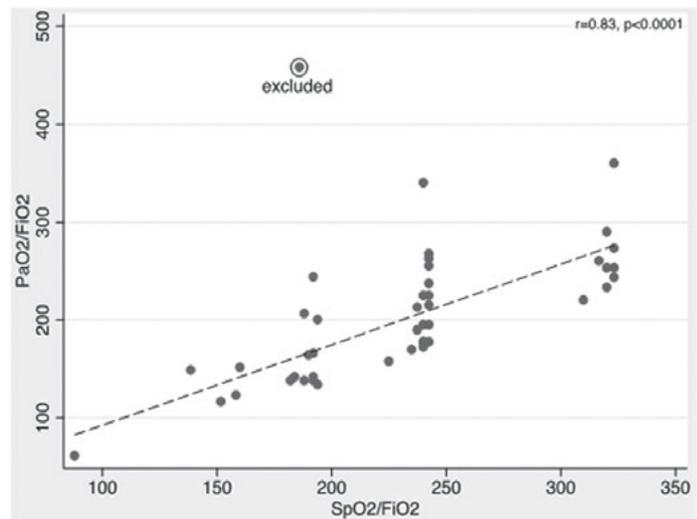


Figure 4. Correlation between SpO₂/FiO₂ and PaO₂/FiO₂ when SpO₂ \leq 97 %. FiO₂ fraction of inspired oxygen, PaO₂ partial pressure of oxygen, SpO₂ pulse oximetric oxygen saturation.

certified attending chest radiologist to determine if they met radiographic criteria for ARDS, namely bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules.¹⁷ Computerized tomography scans of the chest were not available for all patients, so this modality was not incorporated into the study design. The radiologist was blinded to all other clinical information. Study assessments with PaO₂/FiO₂ \leq 300 and a chest radiograph interpreted as consistent with ARDS were deemed to have met oxygenation and radiographic criteria for ARDS.¹⁷ PaO₂/FiO₂ \leq 200 was considered at least moderately impaired oxygenation.

For each study assessment the SpO₂/FiO₂ ratio was calculated using SpO₂ and FiO₂ recorded at the time of the ABG. Based on the relationship between SpO₂/FiO₂ and PaO₂/FiO₂ in ARDS patients derived by Rice et al,⁵ SpO₂/FiO₂ \leq 315 was considered impaired oxygenation and SpO₂/FiO₂ \leq 235 at least moderately impaired oxygenation. UIS was defined as at least three B lines in a single frozen frame in one or more lung fields. Ultrasound imaging consistent with ARDS was determined by the presence of UIS bilaterally.^{7,10,12,15} Images that were difficult to interpret due to subcutaneous emphysema, obesity, consolidations, effusions, image quality or positioning were noted, but were still designated as consistent with UIS or not. All ultrasound video clips were batch reviewed and classified by the study physician and independently reviewed and classified by an ultrasound-trained attending physician in a blinded manner after the completion of patient enrollment.

Statistics

Continuous data were displayed as mean \pm standard deviation if normally distributed or median and interquartile range (IQR) if non-normally distributed. Correlation between continuous variables was determined using Spearman's rank correlation coefficient. Diagnostic accuracy measures of sensitivity and specificity were calculated with 95% exact binomial confidence intervals (CIs). Interobserver agreement was determined using the kappa coefficient. Nonparametric receiver operating curve analysis was used to determine area under the curve (AUC). We treated each assessment as independent in our primary analysis based on frequent changes in individual patients' clinical status over 3-day intervals, but we also performed a

Table 2 Performance of SpO₂/FiO₂ as a marker of PaO₂/FiO₂ when SpO₂ ≤ 97 %

Number of observations (n = 43)			Test characteristic		95 % CI	
PaO ₂ /FiO ₂						
≤300 >300			Sensitivity	83 %	68–93	
SpO ₂ /FiO ₂	≤315	34	1	Specificity	50 %	1–99
	>315	7	1	PPV	97 %	85–100
			NPV	13 %	0–53	
PaO ₂ /FiO ₂						
≤200 >200			Sensitivity	70 %	47–87	
SpO ₂ /FiO ₂	≤235	16	2	Specificity	90 %	68–99
	>235	7	18	PPV	89 %	65–99
			NPV	72 %	51–88	

CI confidence interval, FiO₂ fraction of inspired oxygen, NPV negative predictive value, PaO₂ partial pressure of oxygen, PPV positive predictive value, SpO₂ pulse oximetric oxygen saturation

sensitivity analysis restricted to initial assessments. STATA v11.2 (College Station, TX, USA) was used for statistical analyses.

Results

Patients and study assessments

One hundred and twenty three study assessments were conducted on 77 patients, all of whom were mechanically ventilated and on PEEP of at least 5 cmH₂O. The characteristics of the study patients and assessments are given in Table 1. The median age of patients was 56 years (IQR 41–67); 52 (68%) were male, and 24 patients underwent more than one assessment. Eight (33%) were reclassified with respect to oxygenation criteria for ARDS and 9 (38%) were reclassified with respect to radiographic criteria for ARDS over serial assessments. These changes included both reclassification as meeting criteria and reclassification as no longer meeting criteria. As patients were assessed no more frequently than every 3 days and because their clinical status often changed significantly in that time period, we chose assessments as our unit of analysis, treating them as independent. The most common diagnoses at the time of assessments were sepsis (n = 36, 29%) and trauma (n = 31, 25%).

Relationship between SpO₂/FiO₂ and PaO₂/FiO₂

At the time of ultrasound the median FiO₂ was 0.40 (IQR 0.30–0.40) and the median SpO₂ was 98% (IQR 96–100). At the time of ABG, the median FiO₂ was 0.40 (IQR 0.30–0.50), median SpO₂ was 99% (IQR 97–100), and median PaO₂ was 100 (IQR 78–122). The SpO₂ at the time of ABG was used for all further analyses. The relationship between SpO₂/FiO₂ and PaO₂/FiO₂ derived by Rice et al. in a cohort of ARDS patients indicated that SpO₂/FiO₂ threshold values of 315 and 235 corresponded to PaO₂/FiO₂ of 300 and 200, respectively, when SpO₂ ≤ 97%.⁵ To validate this relationship in our cohort of mechanically ventilated patients, we restricted our analysis to the 44 observations where SpO₂ ≤ 97% at the time of ABG. In this subset, the median PaO₂/FiO₂ was 198 (IQR 155–249) and the median SpO₂/FiO₂ was 240 (IQR 191–243). The Spearman rank correlation coefficient between PaO₂/FiO₂ and SpO₂/FiO₂ was 0.74 (p < 0.0001). We identified one outlier that was characterized by marked discordance between PaO₂ and SpO₂ due to rapidly dynamic changes in oxygenation at the time of the study. Excluding this observation, the correlation between PaO₂/FiO₂ and SpO₂/FiO₂ increased to 0.83 (p < 0.0001) (Fig. 4). We performed receiver operating curve analysis to further evaluate the SpO₂/FiO₂ ratio. SpO₂/FiO₂ ratio

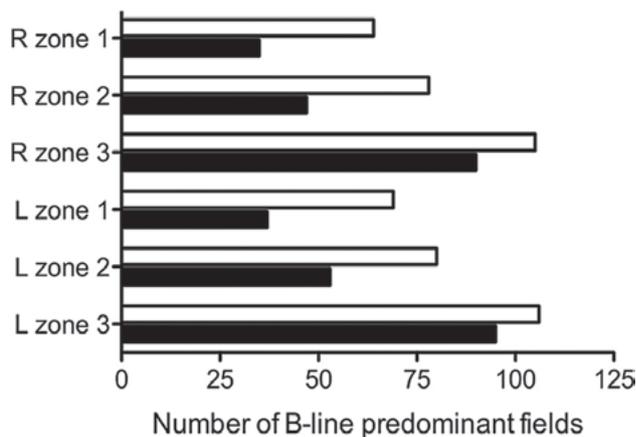


Figure 5. Distribution of B line-predominant lung fields. Black bars indicate reads by the study physician; white bars indicate reads by the independent physician. For right (R) and left (L), zones correspond to locations shown in Fig. 2.

had modest ability to discriminate PaO₂/FiO₂ ≤ 300, based on an AUC value of 0.76 (95% CI 0.34–1.00) (Additional file 1: Figure S1A). The discriminatory ability for SpO₂/FiO₂ in classifying PaO₂/FiO₂ ≤ 200, however, was considerably better, with an AUC of 0.89 (95% CI 0.80–0.99) (Additional file 1: Figure S1B). The sensitivity of SpO₂/FiO₂ ≤ 315 for PaO₂/FiO₂ ≤ 300 was 83% (95% CI 68–93), and the specificity was 50% (95% CI 1–99) (Table 2). The sensitivity of SpO₂/FiO₂ ≤ 235 for PaO₂/FiO₂ ≤ 200 was 70% (95% CI 47–87), and the specificity was 90% (95% CI 68–99).

UIS as a marker for radiographic opacities consistent with ARDS

Of the 738 lung fields evaluated by ultrasound (six fields for 123 assessments), 357 (48%) demonstrated B line predominance as interpreted by the study physician. B lines were more common in posterior lung fields but were distributed equally on the left and on the right (Fig. 5). One hundred and one ultrasound assessments were conducted within 8 h of a chest radiograph. We used this subset of assessments to evaluate optimal thresholds of UIS for determination of radiographic criteria of ARDS as various thresholds have been reported.^{7,10–12,15,18} In 35 (35%) assessments, bilateral opacities consistent with ARDS were apparent on chest radiograph. The sensitivity and specificity of UIS in at least one lung field bilaterally (UIS-2) for radiographic ARDS were 86% (95% CI 70–95) and 38% (95% CI 26–51) (Table 3). The sensitivity and specificity of UIS in at least one field bilaterally and involving a minimum of three lung fields (UIS-3) were 80% (95% CI 63–92) and 62% (95% CI 49–74). The sensitivity and specificity of UIS in at least two lung fields bilaterally (UIS-4) were 60% (95% CI 42–76) and 77% (95% CI 65–87). By receiver operating curve analysis, the ability of UIS pattern to discriminate radiographic ARDS was fair (AUC 0.73, 95% CI 0.63–0.83) (Additional file 2: Figure S2).

Interobserver reliability of UIS interpretation

To test interobserver reliability of the ultrasound interpretations, all ultrasound videos were independently reviewed by an ultrasound-trained attending physician who had not participated in training or data collection and who was blinded to the clinical scenario. The kappa coefficient between the two interpreters for designating B lines present in a lung field was 0.57 (CI 0.40–0.73), consistent with moderate agreement. In comparison to the study physician, the independent physician classified a higher proportion of lung fields as

Table 3 Performance of ultrasound diagnosis of ultrasound interstitial syndrome (UIS) as a marker of bilateral pulmonary opacities consistent with acute respiratory distress syndrome

UIS threshold	Number of observations (n = 101)			Test characteristic		95 % CI	
1 lung field bilaterally	Bilateral opacities on chest radiograph						
			Present	Absent	Sensitivity	86 %	70–95
	UIS	Present	30	41	Specificity	38 %	26–51
		Absent	5	25	PPV	42 %	31–55
					NPV	83 %	65–94
Bilateral; 3 lung fields minimum	Bilateral opacities on chest radiograph						
			Present	Absent	Sensitivity	80 %	63–92
	UIS	Present	28	25	Specificity	62 %	49–74
		Absent	7	41	PPV	53 %	39–67
					NPV	85 %	72–94
2 lung fields bilaterally	Bilateral opacities on chest radiograph						
			Present	Absent	Sensitivity	60 %	42–76
	UIS	Present	21	15	Specificity	77 %	65–87
		Absent	14	51	PPV	58 %	41–75
					NPV	79 %	67–88

CI confidence interval, NPV negative predictive value, PPV positive predictive value

B line-predominant but the relative distribution of B lines in the left lung compared to right lung, and throughout the upper, middle, and lower lung zones was comparable (Fig. 5). We evaluated the interobserver reliability for different UIS thresholds. For UIS-2, the kappa coefficient was 0.44 (CI 0.05–0.83); for UIS-3, the kappa coefficient was 0.45 (CI 0.09–0.81); and for UIS-4, the kappa coefficient was 0.47 (CI 0.07–0.87). Using the independent physician's classifications, sensitivity and specificity of UIS-2 for radiographic criteria of ARDS were 89% (95% CI 73–97) and 15% (95% CI 8–26), respectively; 89% (95% CI 73–97) and 29% (95% CI 18–41) for UIS-3; and 83% (95% CI 66–93) and 46% (95% CI 33–58) for UIS-4 (Table 3).

SpO₂/FiO₂ and UIS as marker for oxygenation and radiographic criteria for ARDS

We next evaluated the combination of pulse oximetry measurements and pulmonary ultrasound assessments as markers for the coexistence of oxygenation and radiographic criteria for ARDS in our cohort. We combined SpO₂/FiO₂ ≤ 315 and ultrasound demonstrating UIS-3 in the subset of 33 observations with SpO₂ ≤ 97%, a chest radiograph within 8 h of ultrasound, and ABG within 24 h of ultrasound (Table 4). The sensitivity of the combination of pulse oximetry and ultrasound determinations of oxygenation and radiographic ARDS criteria was 83% (95% CI 52–98) and specificity was 62% (95% CI 38–82). The positive predictive value was 56% (95% CI 31–79) and the negative predictive value was 87% (95% CI 60–98). We repeated this analysis using a threshold SpO₂/FiO₂ ≤ 235, restricting to cases of at least moderate ARDS (PaO₂/FiO₂ ≤ 200) and found that the sensitivity was 64% (95% CI 31–89) and specificity was 86% (95% CI 65–97). The positive predictive value was 70% (95% CI 35–93) and the negative predictive value was 83% (95% CI 61–95).

We considered the ultrasound interpretations of the independent physician and repeated these analyses. The sensitivity of the combination of pulse oximetry (SpO₂/FiO₂ ≤ 315) and ultrasound (UIS-3) for oxygenation and radiographic ARDS criteria was 91% (95% CI 62–100) and specificity was 48% (95%

CI 26–70) (Table 4). The sensitivity of the combination of pulse oximetry (SpO₂/FiO₂ ≤ 235) and ultrasound (UIS-3) for oxygenation and radiographic criteria of severe ARDS was 73% (95% CI 39–94) and specificity was 77% (95% CI 55–92).

Sensitivity to repeat assessments

To determine whether our treatment of each assessment as independent altered our findings, we performed sensitivity analyses restricted to the first assessment for each of the 77 patients. We did not find any significant differences in the relationships between SpO₂/FiO₂ and PaO₂/FiO₂. Diagnostic accuracy of UIS as a marker for radiographic opacities consistent with ARDS was also similar: the sensitivity and specificity of UIS-3 were 80% (95% CI 56–94) and 72% (95% CI 57–84). The sensitivity of the combination of pulse oximetry and ultrasound determinations of oxygenation and radiographic ARDS criteria (SpO₂/FiO₂ ≤ 315 and UIS-3) was 88% (95% CI 47–100) and specificity was 69% (95% CI 39–91).

Discussion

The purpose of this pilot study was to assess the performance of rapid assessment with bedside pulmonary ultrasound and use of pulse oximetry as alternatives to chest radiograph and ABG in the diagnosis of ARDS. The results of this study showed that, in mechanically ventilated ICU patients, SpO₂/FiO₂ and PaO₂/FiO₂ are highly correlated, that SpO₂/FiO₂ ≤ 315 is quite sensitive for PaO₂/FiO₂ ≤ 300, and that SpO₂/FiO₂ ≤ 235 is highly specific for PaO₂/FiO₂ ≤ 200. Our study confirms reasonable sensitivity of simplified six-point lung ultrasound in identifying patients with bilateral pulmonary opacities consistent with ARDS on chest radiograph using a threshold of bilateral UIS involving at least three lung fields in total, although specificity was lower. Finally, our data on a relatively small number of patients indicate that the combination of SpO₂/FiO₂ ≤ 315 and bilateral/3 field UIS on ultrasound is sensitive for the classification of traditional oxygenation and radiographic criteria for ARDS in mechanically ventilated patients; in contrast, the combination of SpO₂/FiO₂ ≤ 235 and bilateral/3 field UIS on ultrasound is specific for moderate-severe ARDS.

Table 4 Performance of SpO₂/FiO₂ and ultrasound interstitial syndrome (UIS) as a marker for with acute respiratory distress syndrome (ARDS) criteria when SpO₂ ≤ 97 %

		Number of observations (n = 33)		Test characteristic		95 % CI
Study physician		Oxygenation and radiographic criteria for ARDS				
		Present	Absent	Sensitivity	83 %	52–98
SpO ₂ /FiO ₂ ≤ 315 and UIS	Present	10	8	Specificity	62 %	38–82
	Absent	2	13	PPV	56 %	31–79
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	64 %	31–89
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	7	3	Specificity	86 %	65–97
	Absent	4	19	PPV	70 %	35–93
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for ARDS				
		Present	Absent	Sensitivity	91 %	62–100
SpO ₂ /FiO ₂ ≤ 315 and UIS	Present	11	11	Specificity	48 %	26–70
	Absent	1	10	PPV	50 %	28–72
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86
		Oxygenation and radiographic criteria for moderate–severe ARDS				
		Present	Absent	Sensitivity	73 %	39–94
SpO ₂ /FiO ₂ ≤ 235 and UIS	Present	8	5	Specificity	77 %	55–92
	Absent	3	17	PPV	62 %	32–86

UIS defined as 3 or more B lines bilaterally and involving a minimum of three lung fields. CI confidence interval, FiO₂ fraction of inspired oxygen, NPV negative predictive value, PaO₂ partial pressure of oxygen, PPV positive predictive value, SpO₂ pulse oximetric oxygen saturation

Overall, we found that the SpO₂/FiO₂ cutoffs established by Rice et al. were less predictive of the PaO₂/FiO₂ than originally described.⁵ Rice et al. found higher sensitivity in their study, with SpO₂/FiO₂ ≤ 235 resulting in 85% sensitivity with 85% specificity for PaO₂/FiO₂ ≤ 200, and 91% sensitivity with 56% specificity of SpO₂/FiO₂ ≤ 315 to predict PaO₂/FiO₂ ≤ 300. Several explanations may account for this. First, the use of the SpO₂/FiO₂ ratio is limited by flattening of the oxyhemoglobin dissociation curve at high SpO₂; this effect is exacerbated when FiO₂ is not maximally reduced. Many patients in our study were administered a “minimum” FiO₂ of 0.4. Rice et al. report that their studies targeted SpO₂ values between 92 and 94%, whereas very few of our subjects had SpO₂ < 97%. Second, Rice et al. analyzed 1,076 patients enrolled in ARDS studies; this contrasts markedly with our smaller, relatively unfiltered cohort of 77 mechanically ventilated patients. Third, our study is a single-center observational study, in contrast to the multicenter interventional ARDSNet studies. Future studies refining test characteristics of new ARDS criteria should determine SpO₂/FiO₂ at the lowest possible FiO₂, which would require cooperation with respiratory therapists and nursing staff.

The sensitivity and specificity of ultrasound assessments of UIS for radiographic criteria of ARDS in our study were also less than was predicted based on prior studies. There are several possible reasons for this. The original diagnostic algorithm for the BLUE protocol includes an assessment of the lung sliding by ultrasound.¹⁰ This specific criterion was removed from our study, as in trauma patients with chest injuries one might expect a loss of lung sliding without ruling out ARDS or cardiogenic pulmonary edema. An additional challenge in the trauma patient is the evaluation in the setting of significant subcutaneous

emphysema. In this setting ultrasound images are difficult to interpret, and may provide false reassurance to novice sonographers simply counting B lines or looking for hepatization. A phased-array probe was used in this study instead of the micro convex probe used in many other studies. This was chosen based on an assessment that the two probes most likely to be found in a resource limited setting were a linear probe (for superficial assessments and procedures) and a phased-array probe (for cardiac, intra-abdominal, and obstetric assessment). In addition, unlike other studies,^{10,11,18} our study used only chest radiographs and not chest computed tomography imaging to determine radiographic criteria for ARDS.

About a third of ultrasound assessments we performed had at least one lung field for which the imaging clip was considered difficult to interpret. Specifically, trauma patients with subcutaneous emphysema and supine obese patients with significant distance to the lung tissue represent a technical challenge. The division of the chest into six zones as performed in the BLUE protocol and the ICU-SOUND protocol allows rapid assessment of anterior and posterior-lateral fields.^{15,18} Other studies have utilized more lung fields, with the international consensus statement specifying an eight-zone protocol published by Volpicelli et al.⁷ Our study was designed as a rapid diagnostic tool leading to a binary outcome, but the diagnosis of ARDS in other ultrasound studies was one of several potential outcomes at the end of a diagnostic algorithm. By distilling the process to simply an “A-line” or “B-line” determination for each lung field, much of the information we acquired in the process of ultrasound was disregarded, including the presence or absence of lung sliding and images that showed clear signs of consolidation,

hepatization or effusions. In the BLUE protocol these findings would have potentially changed the final ultrasound-based diagnosis, and likely contributed to the moderate interobserver agreement we observed. Six points of examination may also not be sufficient for clear identification of alternative processes, as the study that most accurately identified ARDS using pulmonary ultrasound did so by scanning each intercostal space.¹¹

Alternative methods for ascertainment of imaging and oxygenation criteria for ARDS may be useful in a variety of settings where critically ill patients are managed. Ultrasound evaluation may be faster and offer additional benefits compared to chest radiography.^{12,19} In low-resource settings without portable chest radiography and ABG testing capacity, pulse oximeters and ultrasound machines are increasingly available.^{3,4} Ultrasound is a useful imaging modality in these settings due to its versatility and portability. Moreover, dependence on traditional tools for diagnosing ARDS in low-resource settings may substantially underestimate the incidence of disease.² The diagnosis of ARDS is important even when resources are limited because two of the management strategies demonstrated to improve mortality in ARDS—lung protective ventilation and proning^{20,21}—are cheap and potentially feasible to implement in a range of settings. While some evidence supports more liberal use of lung protective ventilation in respiratory failure,²² understanding the prevalence of ARDS is one element in a necessary effort to improve detection and treatment of respiratory diseases and critical illness in low-resource settings globally.²³⁻²⁷

Our study offers several strengths. First, our study was conducted by a novice sonographer quickly and without moving the patient. While several other studies have examined the ability of ultrasound to identify findings consistent among patients with ARDS,^{10-12,18} conditions were optimized: patients were positioned carefully and expert sonographers obtained multiple ultrasound findings in combination. Thus our study was pragmatic and modeled “real-world” conditions for busy ICU practitioners. Second, we methodically evaluated a sequentially enrolled cohort of critically ill medical and surgical patients at risk for ARDS in a large referral center, suggesting external validity of our study to other busy critical care centers. Third, we enrolled patients with a range of diseases and PaO₂/FiO₂ ratios; thus our tests of diagnostic accuracy measures should apply to similar spectra of disease. Fourth, we carefully considered the timing of various diagnostic tests in relation to each study observation in order to minimize effects of temporal changes in clinical condition on the analysis. Fifth, although we treated each assessment as independent, we confirmed that intraindividual correlation did not alter our findings. Finally, we tested interobserver effects by performing a secondary analysis of ultrasound characteristics using an independent ultrasound-trained physician to classify images.

Our study also has several limitations. Most notably, this was a small, single-center study with ultrasound data obtained by only one sonographer. Furthermore, few patients had SpO₂ < 97%, limiting the number of observations that could be analyzed according to the methodology of Rice et al.⁵ As this was an observational study, additional patients were excluded from analysis if the duration of time between their radiograph or ABG and the study observation was too long. These restrictions resulted in a small population for final analyses. In addition, if less ill patients had less frequent diagnostic tests,

our analyses may have been biased towards sicker patients. While the study physician was blinded to the clinical picture for initial assessments, repeat assessments were performed after medical record review, potentially leading to bias. Evaluating only intubated patients limits the generalizability of our results, particularly to lower resourced settings. As noted above, a six-point protocol may be insufficient and a binary “B-line predominant” determination may result in disregarding potentially important clinical information. Avoiding patient repositioning meant that there was limited visualization of the posterior lung fields, which is particularly relevant as ARDS is a posterior predominant condition. Potentially, diagnostic yield would have been higher had assistance been sought. Furthermore, chest radiography is a suboptimal gold standard when compared to chest computed tomography imaging.¹²

Conclusions

The combination of pulse oximetry and six-point rapid bedside pulmonary ultrasound assessment provides a reasonably sensitive method for identifying intubated patients who meet standard ARDS oxygenation and imaging criteria. Future, larger studies in high- and low-resource settings are needed to validate and refine the utility of these modalities in diagnosing lung disease in critically ill patients in under-resourced settings.

References

- 1 Bernard GR, Artigas A, Brigham KL, Carlet J, Falke K, Hudson L, et al. The American-European Consensus Conference on ARDS. Definitions, mechanisms, relevant outcomes, and clinical trial coordination. *Am J Respir Crit Care Med.* 1994;149:818-24. doi: 10.1164/ajrccm.149.3.7509706.
- 2 Riviello E, Talmor D, Novack V, Kiviri W, Twagirumugabe T, Banner-Goodspeed V, et al. Incidence and outcomes of ARDS in Rwanda using modified Berlin criteria for resource-poor settings. *Crit Care Med.* 2014;42:A1447-8. doi: 10.1097/01.ccm.0000457860.12587.ff.
- 3 Sippel S, Muruganandan K, Levine A, Shah S. Review article: use of ultrasound in the developing world. *Int J Emerg Med.* 2011;4:72. doi: 10.1186/1865-1380-4-72.
- 4 Funk LM, Weiser TG, Berry WR, Lipsitz SR, Merry AF, Enright AC, et al. Global operating theatre distribution and pulse oximetry supply: an estimation from reported data. *Lancet.* 2010;376:1055-61. doi: 10.1016/S0140-6736(10)60392-3.
- 5 Rice TW, Wheeler AP, Bernard GR, Hayden DL, Schoenfeld DA, Ware LB. Comparison of the SpO₂/FiO₂ ratio and the PaO₂/FiO₂ ratio in patients with acute lung injury or ARDS. *Chest.* 2007;132:410-7. doi: 10.1378/chest.07-0617.
- 6 Khemani RG, Patel NR, Bart RD, 3rd, Newth CJ. Comparison of the pulse oximetric saturation/fraction of inspired oxygen ratio and the PaO₂/fraction of inspired oxygen ratio in children. *Chest.* 2009;135:662-8. doi: 10.1378/chest.08-2239.
- 7 Volpicelli G, Elbarbary M, Blaivas M, Lichtenstein DA, Mathis G, Kirkpatrick AW, et al. International evidence-based recommendations for point-of-care lung ultrasound. *Intensive Care Med.* 2012;38:577-91. doi: 10.1007/s00134-012-2513-4.
- 8 Lichtenstein D, Meziere G, Biderman P, Gepner A. The comet-tail artifact. An ultrasound sign of alveolar-interstitial syndrome. *Am J Respir Crit Care Med.* 1997;156:1640-6. doi: 10.1164/ajrccm.156.5.96-07096.
- 9 Volpicelli G, Mussa A, Garofalo G, Cardinale L, Casoli G, Perotto F, et al. Bedside lung ultrasound in the assessment of alveolar-interstitial syndrome. *Am J Emerg Med.* 2006;24:689-96. doi: 10.1016/j.ajem.2006.02.013.
- 10 Lichtenstein DA, Meziere GA. Relevance of lung ultrasound in

- the diagnosis of acute respiratory failure: the BLUE protocol. *Chest*. 2008;134:117-25. doi: 10.1378/chest.07-2800.
- 11 Copetti R, Soldati G, Copetti P. Chest sonography: a useful tool to differentiate acute cardiogenic pulmonary edema from acute respiratory distress syndrome. *Cardiovasc Ultrasound*. 2008;6:16. doi: 10.1186/1476-7120-6-16.
 - 12 Lichtenstein D, Goldstein I, Mourgeon E, Cluzel P, Grenier P, Rouby JJ. Comparative diagnostic performances of auscultation, chest radiography, and lung ultrasonography in acute respiratory distress syndrome. *Anesthesiology*. 2004;100:9-15. doi: 10.1097/00000542-200401000-00006.
 - 13 Bedetti G, Gargani L, Corbisiero A, Frassi F, Poggianti E, Mottola G. Evaluation of ultrasound lung comets by hand-held echocardiography. *Cardiovasc Ultrasound*. 2006;4:34. doi: 10.1186/1476-7120-4-34.
 - 14 Baker K, Mitchell G, Stieler G. Limited lung ultrasound protocol in elderly patients with breathlessness; agreement between bedside interpretation and stored images as acquired by experienced and inexperienced sonologists. *Australasian J Ultrasound Med*. 2013;16:86-92.
 - 15 Lichtenstein DA, Mezière GA. The BLUE-points: three standardized points used in the BLUE-protocol for ultrasound assessment of the lung in acute respiratory failure. *Critical Ultrasound Journal*. 2011;3:109-10. doi: 10.1007/s13089-011-0066-3.
 - 16 Lichtenstein DA. Lung ultrasound in the critically ill. *Ann Intensive Care*. 2014;4:1. doi: 10.1186/2110-5820-4-1.
 - 17 Ranieri VM, Rubenfeld GD, Thompson BT, Ferguson ND, Caldwell E, Fan E, et al. Acute respiratory distress syndrome: the Berlin Definition. *JAMA*. 2012;307:2526-33.
 - 18 Manno E, Navarra M, Faccio L, Motevallian M, Bertolaccini L, Mfochive A, et al. Deep impact of ultrasound in the intensive care unit: the "ICU-sound" protocol. *Anesthesiology*. 2012;117:801-9. doi: 10.1097/ALN.0b013e318264c621.
 - 19 Ashton-Cleary DT. Is thoracic ultrasound a viable alternative to conventional imaging in the critical care setting? *Br J Anaesth*. 2013;111:152-60. doi: 10.1093/bja/aet076.
 - 20 Determann RM, Royakkers A, Wolthuis EK, Vlaar AP, Choi G, Paulus F, et al. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. The Acute Respiratory Distress Syndrome Network. *N Engl J Med*. 2000;342:1301-8. doi: 10.1056/NEJM200005043421801.
 - 21 Guerin C, Reignier J, Richard JC, Beuret P, Gacouin A, Boulain T, et al. Prone positioning in severe acute respiratory distress syndrome. *N Engl J Med*. 2013;368:2159-68. doi: 10.1056/NEJMoa1214103.
 - 22 Serpa Neto A, Cardoso SO, Manetta JA, Pereira VG, Esposito DC, Pasqualucci Mde O, et al. Association between use of lung-protective ventilation with lower tidal volumes and clinical outcomes among patients without acute respiratory distress syndrome: a meta-analysis. *JAMA*. 2012;308:1651-9. doi: 10.1001/jama.2012.13730.
 - 23 Einav S, Hick JL, Hanfling D, Erstad BL, Toner ES, Branson RD, et al. Surge capacity logistics: care of the critically ill and injured during pandemics and disasters: CHEST Consensus Statement. *Chest*. 2014;146:e17S-43. doi: 10.1378/chest.14-0734.
 - 24 Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med*. 2006;13:223-9. doi: 10.1111/j.1553-2712.2006.tb01677.x.
 - 25 Adhikari NK, Fowler RA, Bhagwanjee S, Rubenfeld GD. Critical care and the global burden of critical illness in adults. *Lancet*. 2010;376:1339-46. doi: 10.1016/S0140-6736(10)60446-1.
 - 26 Dunser MW, Baelani I, Ganbold L. A review and analysis of intensive care medicine in the least developed countries. *Crit Care Med*. 2006;34:1234-42. doi: 10.1097/01.CCM.0000208360.70835.87.
 - 27 Biddison LD, et al. Ethical considerations: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest J*. 2014;146:e145S-55. doi: 10.1378/chest.14-0742.

Role of Sedation for Agitated Patients Undergoing Noninvasive Ventilation: Clinical Practice in a Tertiary Referral Hospital

Takeshi Matsumoto^{1,2*}, Keisuke Tomii¹, Ryo Tachikawa^{1,2}, Kojiro Otsuka¹, Kazuma Nagata¹, Kyoko Otsuka¹, Atsushi Nakagawa¹, Michiaki Mishima² and Kazuo Chin³

Abstract

Background: Although sedation is often required for agitated patients undergoing noninvasive ventilation (NIV), reports on its practical use have been few. This study aimed to evaluate the efficacy and safety of sedation for agitated patients undergoing NIV in clinical practice in a single hospital.

Methods: We retrospectively reviewed sedated patients who received NIV due to acute respiratory failure from May 2007 to May 2012. Sedation level was controlled according to the Richmond Agitation Sedation Scale (RASS). Clinical background, sedatives, failure rate of sedation, and complications were evaluated by 1) sedative methods (intermittent only, switched to continuous, or initially continuous) and 2) code status (do-not-intubate [DNI] or non-DNI).

Results: Of 3506 patients who received NIV, 120 (3.4%) consecutive patients were analyzed. Sedation was performed only intermittently in 72 (60%) patients, was switched to continuously in 37 (31%) and was applied only continuously in 11 (9%). Underlying diseases in 48% were acute respiratory distress syndrome/acute lung injury/severe pneumonia or acute exacerbation of interstitial pneumonia. In non-DNI patients (n=39), no patient required intubation due to agitation with continuous sedation, and in DNI patients (n=81), 96% of patients could continue NIV treatment. PaCO₂ level changes (6.7 ± 15.1 mmHg vs. -2.0 ± 7.7 mmHg, P=0.028) and mortality in DNI patients (81% vs. 57%, P=0.020) were significantly greater in the continuous use group than in the intermittent use group.

Conclusions: According to RASS scores, sedation during NIV in proficient hospitals may be favorably used to potentially avoid NIV failure in agitated patients, even in those having diseases with poor evidence of the usefulness of NIV. However, with continuous use, we must be aware of an increased hypercapnic state and the possibility of increased mortality. Larger controlled studies are needed to better clarify the role of sedation in improving NIV outcomes in intolerant patients.

Background

Noninvasive ventilation (NIV) for acute respiratory failure is widely used; however, it is sometimes difficult to continue due to mask intolerance or inadequate cooperation. Antonelli et al. reported that 9% of NIV users for acute respiratory failure had to be intubated for such reasons,¹ and Carlucci et al. reported that the discontinuation rate of NIV due to patients' refusal was up to 22%.² Although NIV usage is not strictly indicated for agitated or uncooperative patients^{3,4} a questionnaire to pulmonologists and intensivists showed that 85% of such patients had been sedated while under NIV, with 30% receiving continuous sedation, suggesting its usefulness in clinical practice.⁵ The efficacy of sedatives for agitated patients with acute respiratory failure undergoing NIV was reported.^{3,6-10} However, such patients usually had specific diseases with strong proven evidence of NIV's usefulness and were treated in the ICU. In clinical practice, patients undergoing NIV treatment did not always have such diseases or were not always treated in an ICU.

In clinical practice, NIV introduction depends not only on underlying diseases but also on social conditions such as do-not-intubate (DNI) status. Therefore, NIV may be introduced to patients having diseases with little evidence of its usefulness. We previously reported the efficacy of NIV for life-threatening acute exacerbation of interstitial pneumonia or asthma attack,^{11,12} for which the evidence level for its usefulness was not high.³

We hypothesized that we could control agitated patients with sedation without severe complications regardless of evidence of NIV's usefulness for their underlying diseases. Therefore, we retrospectively evaluated the efficacy and safety of sedation that was used intermittently or continuously for agitated patients during NIV treatment in clinical practice.

Methods Patients

Our hospital is a 700-bed tertiary care center that plays a central role in treating emergency patients in the surrounding area. Among consecutive patients over 16 years old who underwent continuous NIV due to acute respiratory failure from May 2007 to May 2012, we retrospectively evaluated patients who received sedatives for agitation during NIV.

We assigned patients to 3 groups; one group received sedatives only intermittently (intermittent only), a second group was switched to continuous sedation after intermittent sedation (switched to continuous) and the third group was initially

1 Department of Respiratory Medicine, Kobe City Medical Center General Hospital, 2-1-1 Minatojima-minamimachi, Chuo-ku, Kobe 650-0047, Japan;

2 Department of Respiratory Medicine, Graduate School of Medicine, Kyoto University, 54 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto 606-8507, Japan; 3 Department of Respiratory Care and Sleep Control Medicine, Graduate School of Medicine, Kyoto University, 54 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto 606-8507, Japan. This is an Open Access article distributed under the terms of the Creative Commons Attribution License.

Table 1 Initial dose and increasing and decreasing dose of each sedative drug

Drug	Initial dose	Increasing and decreasing dose
Risperidone	0.5 mg perorally	
Haloperidol	2.5–5 mg by intravenous infusion	
Dexmedetomidine	0.2 µg/kg/h by continuous intravenous infusion	0.1 µg/kg/h
Midazolam	0.03 mg/kg/h by continuous intravenous infusion	0.01 mg/kg/h
Propofol	0.3 mg/kg/h by continuous intravenous infusion	0.1 mg/kg/h
Morphine	0.02 mg/kg/h by continuous subcutaneous infusion	0.01 mg/kg/h
Fentanyl	0.05–0.1 µg/kg/h by continuous subcutaneous infusion	0.05 µg/kg/h

sedated continuously (initially continuous). According to code status, we also classified patients into non-DNI and DNI groups. Patients in the non-DNI group were intubated and mechanically ventilated if control was not achieved by NIV, while patients in the DNI group were continuously controlled by NIV and were not intubated even if consciousness deteriorated following sedation or their conditions became critical. Code status of neurologically incompetent patients was determined by discussion with relatives. When patients or their families did not want ventilation to be provided (including NIV) or their baseline status was difficult to maintain with NIV, we suggested that ventilation not be applied from the viewpoint of ethics.

This study was approved by our institutional review board (Institutional Review Board of Kobe City Medical Center General Hospital; 1304-1), and informed consent was waived.

Noninvasive ventilation

NIV was started when 1) SpO₂ was <90% despite inhalation of oxygen >10 l/min via reservoir mask; 2) PaCO₂ levels were >45 mmHg with acute respiratory acidosis; or 3) patients had signs of respiratory distress, including a respiratory rate >24 and increased accessory respiratory muscle use. Patients were managed with NIV in the ICU, emergency ward, or general ward by expert respiratory staff. Patients in a general ward were put in large separated rooms for intensive care and monitored 24 h

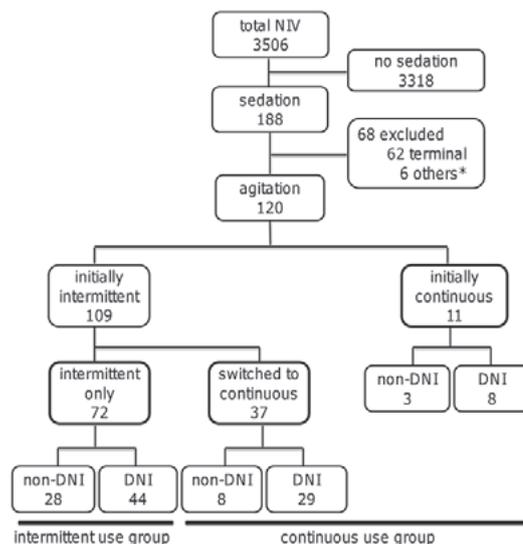


Figure 1. Number of patients at each stage of analysis and method of administration sedative drugs. Patients were categorized into the non-DNI group and DNI group. NIV, noninvasive ventilation; DNI, do-not-intubate. *: 4 patients used sedation for pain and 2 for convulsion

per day. NIV was performed with a Dräger ventilator (Carina; Dräger, Lübeck, Germany) or Philips ventilator (Respironics V60 or Respironics BiPAP Vision; Philips, Andover, MA, USA) with the pressure support ventilation (PSV) mode or continuous positive airway pressure (CPAP) mode via a full face mask. The ventilator setting and selection of either the CPAP or PSV mode were generally determined based on the criteria for initiation of NIV described above. The PSV was selected if a patient met criterion 2) and/or 3), but if a patient had only hypoxemia and met criterion 1), we selected the CPAP mode. For the PSV mode, the initial setting was a respiratory rate of 12 breaths/min, inspiratory positive airway pressure of 10 cm H₂O, and expiratory positive airway pressure of 4 cm H₂O. For the CPAP mode, the first setting was a positive end expiratory pressure of 8 cm H₂O. The FiO₂ was adjusted to keep the SpO₂ >90%. After the start of NIV treatment, NIV settings were modified by physicians proficient in NIV treatment according to each patient's condition. At first NIV treatment was performed all day. However, we discontinued NIV treatment in the cases that met

Table 2 Underlying diseases in each patient group

	Evidence level ^a	Intermittent only (n = 72)		Switched to continuous (n = 37)		Initially continuous (n = 11)		Total n = 120
		Non-DNI (n = 28)	DNI (n = 44)	Non-DNI (n = 8)	DNI (n = 29)	Non-DNI (n = 3)	DNI (n = 8)	
Acute exacerbation of COPD	1 (favorable)	0 (0 %)	4 (9 %)	0 (0 %)	0 (0 %)	0 (0 %)	0 (0 %)	4 (3 %)
Cardiogenic pulmonary edema	1 (favorable)	11 (39 %)	2 (5 %)	1 (13 %)	5 (17 %)	0 (0 %)	1 (13 %)	20 (17 %)
Acute respiratory failure in immunosuppressed state	1 (favorable)	5 (18 %)	3 (7 %)	3 (38 %)	4 (14 %)	2 (67 %)	0 (0 %)	17 (14 %)
Bronchial asthma	3 (favorable)	1 (4 %)	1 (2 %)	1 (13 %)	0 (0 %)	0 (0 %)	0 (0 %)	3 (3 %)
ARDS/ALI/severe pneumonia	2 or 3 (caution)	5 (18 %)	20 (45 %)	1 (13 %)	9 (31 %)	1 (33 %)	3 (38 %)	39 (33 %)
Acute exacerbation of interstitial pneumonia	4 (caution)	2 (7 %)	4 (9 %)	1 (13 %)	9 (31 %)	0 (0 %)	3 (38 %)	19 (16 %)
Sequela of pulmonary tuberculosis	NA	0 (0 %)	4 (9 %)	0 (0 %)	2 (7 %)	0 (0 %)	0 (0 %)	6 (5 %)
Others ^b	NA	4 (14 %)	6 (14 %)	1 (13 %)	0 (0 %)	0 (0 %)	1 (13 %)	12 (10 %)

n number of patients, DNI do-not-intubate, ARDS acute respiratory distress syndrome, ALI acute lung injury, NA not available

^aevidence level from previous report 2; Each disease is classified as favorable or caution according to evidence level of use of NIV; 1 is the highest evidence level and 4 is the lowest

^bincludes hepatogenic pleural effusion, carcinomatous lymphangitis, pulmonary embolism, reexpansion pulmonary edema, and cryptogenic organizing pneumonia

Table 3 Sedative drugs administered to each patient group

	Intermittent only (n = 72)		Switched to continuous (n = 37)		Initially continuous (n = 11)		Total n = 120
	Non-DNI (n = 28)	DNI (n = 44)	Non-DNI (n = 8)	DNI (n = 29)	Non-DNI (n = 3)	DNI (n = 8)	
Risperidone	13 (46 %)	20 (45 %)	5 (63 %)	13 (45 %)			51 (43 %)
Haloperidol	20 (71 %)	35 (80 %)	8 (100 %)	24 (83 %)			87 (73 %)
Others	0 (0 %)	10 (23 %)	1 (13 %)	0 (0 %)			11 (9 %)
Dexmedetomidine			4 (50 %)	10 (34 %)	0 (0 %)	4 (50 %)	18 (15 %)
Midazolam			3 (38 %)	5 (17 %)	0 (0 %)	3 (38 %)	11 (9 %)
Propofol			3 (38 %)	10 (34 %)	1 (33 %)	2 (25 %)	16 (13 %)
Morphine			1 (13 %)	16 (55 %)	2 (67 %)	4 (50 %)	23 (19 %)
Fentanyl			3 (38 %)	6 (21 %)	1 (33 %)	1 (13 %)	11 (9 %)

Number (%) for each sedative drug reflects use of more than 1 drug per patient
DNI do-not-intubate

all the following criteria: 1) SpO₂ was >90% with the inhalation of oxygen <10 l/min via reservoir mask; 2) PaCO₂ levels were <45 mmHg or patients did not suffer acute respiratory acidosis; and 3) patients had no signs of respiratory distress, including a respiratory rate >24 and increased accessory respiratory muscle use. When NIV treatment was not needed consecutively for 12 h, NIV treatment was considered to be finished.

Sedatives

For intermittent use, risperidone or haloperidol was usually administered every 30-60 min by either a single dose or double dose (Table 1). For continuous use, either dexmedetomidine, midazolam, or propofol was the initial choice. Physicians in this hospital preferred to use a short-acting drug or a drug with a minimal respiratory depressant effect. When despite sedation dyspnea could not be controlled, we used morphine or fentanyl to alleviate the dyspnea.

Criteria for the beginning of sedation and administration of sedatives

When NIV was started according to the criteria described above, we used the Richmond Agitation Sedation Scale (RASS)¹³ as an index of sedation for controlling agitation. Sedatives were administered when patients could not continue NIV due to agitation, and generally, +1 or more on the RASS was defined as an indication to administer sedation. Patients were most often managed between -2 and 0 on the RASS during sedation. Usually, sedation was initiated intermittently and if the target sedation level was not achieved, we began continuous administration. However, continuous sedation was introduced initially when physicians judged that intermittent sedation would not be sufficient to control agitation. At that time the attending physicians set the target range for the RASS, which was most often measured by medical staff. When the RASS deviated from the established range, the infusion rate was adjusted as shown in Table 1. When good control was not achieved with the first sedative, another was added.

Outcome measures

We examined the clinical background, kinds of sedatives used, failure rate of sedation, and complications. All clinical and laboratory data were obtained from medical records. To assess severity of the respiratory failure, the PaO₂/FiO₂ (P/F) ratio at the initiation of NIV was calculated. Decision for intubation was left to attending physicians based on lack of control of agitation or progressive respiratory deterioration. In this study, failure of sedation consisted of the need for withdrawal of NIV because of absolute intolerance by patients despite the maximized analgo-sedative strategy. That is, in the non-DNI group, failure

of sedation was declared when a patient was intubated due to agitation in spite of sedation, and failure of sedation in the DNI group was declared when NIV treatment could not be continued due to agitation. A RASS score of -4 or -5 indicated oversedation. Physiologic values were monitored and the RASS score, respiratory rate, heart rate, and blood pressure were checked before sedation and as closely as possible to 2 h, 6 h, and 24 h after the start of sedation. Arterial blood gas changes during 24 h following the initiation of sedation were also checked.

In measuring outcome, we compared differences in clinical background, 30-day mortality, and failure rate of sedation between the intermittent use group (intermittent only) and continuous use group (switched to continuous plus initially continuous groups combined) separately in the DNI and non-DNI groups.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation unless stated otherwise and were compared using the Mann-Whitney test. Categorical variables were compared using a chi-squared test or Fisher's exact test, as appropriate. A P-value <0.05 was deemed statistically significant. All statistical analyses were performed using JMP 8.0.2 software (SAS Institute Inc., Cary, NC, USA).

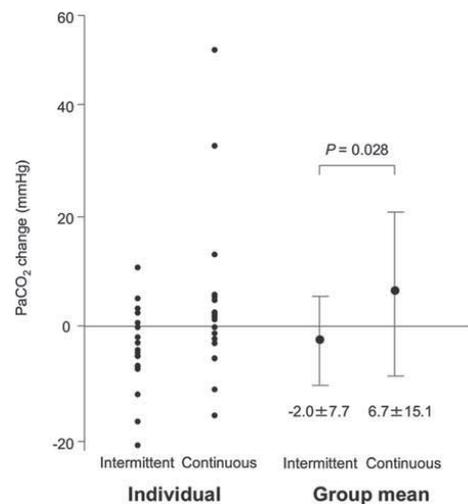


Figure 2. PaCO₂ change within 24 h after initiation of each sedative. Individual data and group means are represented. Data are shown as mean ± standard deviation.

Table 4 Baseline characteristics in non-do not intubate (DNI) and DNI groups

	Non-DNI group (n = 39)			DNI group (n = 81)		
	Intermittent (n = 28)	Continuous (n = 11)	P-value	Intermittent (n = 44)	Continuous (n = 37)	P-value
Gender (male/female)	22/6	8/3	0.70	26/18	28/9	0.11
Age (y)	71.1 ± 10.9	60.5 ± 14.3	0.035	80.5 ± 8.1	74.9 ± 9.9	0.010
Duration of NIV (d)	4.5 ± 4.5	9.7 ± 11.7	0.044	7.0 ± 4.7	8.5 ± 5.3	0.12
Duration of continuous sedation (d)	–	7.7 ± 12.0	–	–	5.1 ± 3.2	–
Managing ward						
general ward	6/28 (21 %)	2/11 (18 %)	0.82	18/44 (41 %)	9/37 (24 %)	0.11
emergency ward	17/28 (61 %)	7/11 (64 %)	0.87	23/44 (52 %)	21/37 (57 %)	0.69
ICU	5/28 (18 %)	2/11 (18 %)	0.98	3/44 (7 %)	7/37 (19 %)	0.10
Respiratory failure (without/with hypercapnia) ^a	18/5	9/1	0.42	14/28	23/11	0.003
P/F ratio (mmHg)	114 ± 49	108 ± 62	0.49	148 ± 80	111 ± 51	0.032
NIV setting (CPAP/ PSV)	15/13	7/4	0.57	13/31	11/26	0.99

P/F PaO₂/FiO₂, CPAP continuous positive airway pressure, PSV pressure support ventilation

^a6 patients in non-DNI group and 5 in the DNI group did not undergo blood gas examination

Results

Study population

From May 2007 to May 2012, 3506 consecutive patients received NIV due to acute respiratory failure. Of these, 120 (3.4%, non-DNI = 39; DNI = 81) patients were given sedatives to control agitation during NIV. Figure 1 shows the number of patients and method of administration of sedatives. Finally, sedation was performed only intermittently in 72 (60%) patients, switched to continuously in 37 (31%) and provided only continuously in 11 (9%). The reasons for poor tolerance of NIV were mostly mask discomfort, pressure discomfort, or the combination of the two. Most expressions of poor tolerance occurred immediately after the start of NIV treatment.

Underlying diseases

Table 2 shows underlying diseases of study patients. Of the 120 patients, 58 (48%) had acute respiratory distress syndrome (ARDS)/acute lung injury (ALI)/severe pneumonia or acute exacerbation of interstitial pneumonia, diseases for which evidence of the usefulness of NIV was poor.³

Sedatives

Table 3 shows the prescribed sedatives. Twenty-four (50%) patients received a single drug and the remaining patients received more than one drug for continuous use. With the exception of risperidone or haloperidol, hydroxyzine, quetiapine, diazepam or perospirone was used intermittently.

Baseline characteristics

Baseline characteristics of the non-DNI and DNI groups in the intermittent use group or continuous use group are shown in Table 4. Within the non-DNI group, patients in the continuous use group (n = 11) were significantly younger than in the intermittent use group (n = 28) and baseline severity assessed by the P/F ratio did not differ between the two groups. In the DNI group, patients in the continuous use group (n = 37) were also significantly younger than in the intermittent use group (n = 44). The proportion of patients with hypercapnia was significantly higher in the intermittent use group than in the continuous use group. P/F ratio was significantly lower in the continuous use group. Thirty-four of the 109 (31%) non-DNI or DNI patients in the initially intermittent group were managed in a general ward at first. Later 2 of these patients were transferred to the ICU for the initiation of continuous sedation with intensive monitoring.

Mortality and failure rate of sedation

Mortality rate of the study participants and failure rate of sedation are shown in Table 5. In non-DNI patients, 30-day mortality and the total intubation rate did not differ significantly between the intermittent use and continuous use groups. No patient in the continuous use group required intubation due to agitation while 2 patients (7%) in the intermittent use group required intubation due to sedation failure. After all, 2 of 36 patients with initially intermittent sedation were intubated without switching to continuous sedation due to their uncontrolled agitation. Among DNI patients, 30-day mortality was higher in the continuous use group. Two of the 44 patients (5%) in the intermittent use group and 1 of the 37 patients (3%) in the continuous use group could not continue NIV due to persistent agitation; therefore, 78 of 81 (96%) DNI patients could continue NIV with sedation. Overall, 115 of 120 (96%) patients studied continued NIV despite agitation.

Adverse events

As shown in Table 6, no patient vomited or developed aspiration pneumonitis during NIV treatment. Among the adverse events, 1 patient who had been prescribed midazolam became hypotensive requiring dopamine, 1 patient experienced delirium, and 1 patient developed ileus, which improved following the discontinuation of sedatives. Three patients who had hypercapnia before sedation exhibited drowsiness due to progressive hypercapnia, which improved following an increase in pressure support levels. Before and after the start of sedation, the RASS score, respiratory rate, heart rate, and systolic blood pressure did not differ significantly between intermittent and continuous use groups, nor did acute changes occur during the 24 h from the start of sedation. The values of arterial blood gas were rechecked within 24 h from the start of sedation in 18 patients in the intermittent use group and 18 in the continuous use group. Changes in PaCO₂ levels were significantly greater in the continuous use group than in the intermittent use group (Fig. 2). There were no significant differences in changes in pH and P/F ratio between groups.

Discussion

Of 3506 patients with acute respiratory failure administered NIV treatment in our institution, 120 (3.4%) were sedated to control agitation. Fifty-eight (48%) of the 120 patients had diseases for which there was not a high degree of evidence supporting NIV treatment such as ARDS, ALI, severe pneumonia, or acute

Table 5 Mortality rates and failure rates of sedation

	Non-DNI group (n = 39)			DNI group (n = 81)		
	Intermittent (n = 28)	Continuous (n = 11)	P-value	Intermittent (n = 44)	Continuous (n = 37)	P-value
Mortality	6/28 (21 %)	1/11 (9 %)	0.37	25/44 (57 %)	30/37 (81 %)	0.020
Total intubation	8/28 (29 %)	3/11 (27 %)	0.94			
Intubation due to agitation	2/28 (7 %) ^a	0/11 (0 %)	0.36			
Discontinuation of NIV due to agitation				2/44 (5 %) ^b	1/37 (3 %) ^c	0.66

^aincludes haloperidol in 2 patients

^bincludes risperidone in 1, haloperidol in 1 patient

^cincludes midazolam and morphine in 1 patient

exacerbation of interstitial pneumonia. However, no patient in the non-DNI group being administered continuous sedation required intubation due to agitation, and 96% of patients in the DNI group were able to continue NIV treatment. Therefore, in clinical practice, we effectively used sedation to continue NIV in both DNI and non-DNI patients with management according to RASS scores. However, as to continuous use, we must be aware of an increased hypercapnic state and the possibility of increased mortality.

In this study, we found that by using several sedatives intermittently or continuously according to RASS scores, the NIV failure rate due to agitation was quite low (4%). Previous studies have addressed the efficacy of sedation during NIV using dexmedetomidine,⁶⁻⁸ midazolam,⁸ propofol,⁹ and remifentanyl¹⁰ in patients with several diseases in which there was a high-to-intermediate level of evidence for NIV use. In addition, these patients were treated in an ICU. In this study, almost half of the patients had diseases with a low evidence level supporting NIV treatment (ARDS/ALI/severe pneumonia or acute exacerbation of interstitial pneumonia), and despite this, almost all were managed successfully with sedatives. Therefore, with the guidance of RASS scores, proficient medical teams for NIV treatment might control persistent agitation with appropriate sedatives while administering NIV, even in patients having diseases with poor evidence of the usefulness of NIV.

In this study, patients were divided into two groups; DNI and non-DNI groups. Although this resulted in a small sample size for analysis in some groups, we thought that differences in the usage of sedatives between DNI and non-DNI patients might be informative to those managing NIV treatment with sedatives. When NIV treatment is not effective in non-DNI patients, physicians usually choose intubation with mechanical ventilation. However, in DNI patients, intubation with mechanical ventilation is not performed when NIV treatment is not effective. That is, in the light of respiratory management, failure to control agitation would become fatal, and continuing NIV treatment with sedation is critical in the DNI group. On the other hand, in the non-DNI group, when we cannot continue NIV, we can perform intubation and continue mechanical ventilation. So in such cases we do not necessarily persist in continuing NIV treatment, and sedation is optional. In this study, 9 (23%) non-DNI patients were intubated for reasons other than sedation insufficiency, such as exacerbation of the respiratory status or hemodynamic instability (Table 5). Therefore, especially in patients with underlying diseases in which there is not strong evidence for the effectiveness of NIV treatment, we should avoid delaying intubation due to persistence in administering sedatives during NIV in non-DNI patients.^{14,15}

Among DNI patients, only 2 patients (5%) in the intermittent use group and 1 patient (3%) in the continuous use group

discontinued NIV treatment, indicating that a high rate of persistence could be achieved with sedation. However, we must note that 30-day mortality in the DNI patients was higher in the continuous use group than in the intermittent use group. In previous reports, mortality was reported to be 44-57% among DNI patients under NIV^{16,17} Also, among those with hypoxemic respiratory failure, the mortality rate of DNI patients was reported to be as high as 86%.¹⁸ In Japan when a patient cannot make decisions we usually provide NIV to those with a DNI status according to the family's will, even when the baseline status is too poor for rescue or there is little evidence of NIV's usefulness for the background disease. Many patients in the DNI group were severely ill and tended to become agitated and need sedation. Therefore, we often had to continue NIV with sedation as palliative care, which might on one hand contribute in some degree to the high mortality rate, and on the other hand contribute to prolonging useless agony. To avoid the latter, we discontinued NIV in DNI patients in accordance with patient's and/or family's decision in cases of persistent agitation. However, we must consider the possibility that the continuous sedation itself increased the mortality rate.

In this study, sedation during NIV treatment was introduced to 31% of the study patients in the general wards, and in most of these patients treatment could be continued in the general wards. Many members of the medical staff of our hospital are highly experienced in NIV treatment so that NIV with sedatives could be controlled in general wards. However, as we did not have data on a sufficient number of patients to make a definitive conclusion on the safety of NIV treatment with sedatives, NIV treatment with sedatives should be applied cautiously and at present should be performed in an ICU.

As to complications, the change in the PaCO₂ level within 24 h after initiation of sedation was significantly greater in the continuous use group than in the intermittent use group. This difference would be mainly due to the oversedated cases with hypercapnia, all of which had hypercapnia before sedation. However, their condition improved after increasing pressure support. Attention must be paid to the possibility of severe complications from continuous sedation such as hypotension or oversedation, especially in patients with hypercapnia prior to the start of sedation.

Our study had several limitations. First, it was retrospective and there was substantial heterogeneity in underlying diseases, sedation, therapies, and the sedatives used. However, the aim of this study was to clarify the role of sedation during NIV treatment in clinical practice, and we identified all consecutive patients using NIV to minimize selection bias. Second, the sample size was too small to detect significant differences. In addition, we could not compare the efficacy of each sedative or results according to each underlying disease due to the small

Table 6 Adverse events during sedation

	Intermittent (n = 72)	Continuous (n = 48)
Oversedation	haloperidol 1	midazolam 1, propofol 1
Hypotension		morphine 1 ^a , midazolam 1 ^b
Delirium		morphine 1
Ileus		fentanyl 1

^aimproved after discontinuation of sedatives

^bneeded dopamine

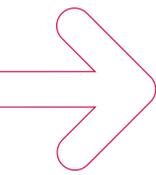
number of patients. However, we could show the practical use of sedation during NIV treatment. Third, we could not directly compare sedated patients to unsedated patients who received NIV in the same study period. This makes it difficult to examine the cause of the high mortality rate among sedated patients in the DNI group. However, comparison with previous studies could have helped to evaluate the present results. Fourth, this study was conducted in a single institution that was proficient in the use of NIV treatment; therefore, we have to consider the indication for sedation because it depends on the proficiency or system in each institution. In consideration of these limitations, larger controlled studies are needed to better clarify the role of sedation in improving NIV outcomes in intolerant patients.

Conclusions

Our results suggest that sedation during NIV can be used to enable continuation of NIV in agitated patients with either a DNI or non-DNI status with management according to RASS, even in patients with diseases for which there is little evidence of the usefulness of NIV. However, we must be aware of the possibility of an increased hypercapnic state and high mortality rate associated with continuous sedation, which may be due to the sedation itself. Also, continuing NIV under sedation is not appropriate in cases of failure to control agitation both in DNI patients in consideration of the risk of prolonging distress and agony, and in non-DNI patients considering the risk of unduly delaying intubation. In addition, it should be taken into consideration about the indication for sedation in each patient and the setting in which it is provided (general wards or ICU) because much depends on the proficiency or system in each institution.

References

- Antonelli M, Conti G, Moro ML, Esquinas A, Gonzalez-Diaz G, Confalonieri M, Pelaia P, Principi T, Gregoretti C, Beltrame F, Pennisi MA, Arcangeli A, Proietti R, Passariello M, Meduri GU. Predictors of failure of noninvasive positive pressure ventilation in patients with acute hypoxemic respiratory failure: a multi-center study. *Intensive Care Med.* 2001; 27(11):1718-1728.
- Carlucci A, Richard JC, Wysocki M, Lepage E, Brochard L. Noninvasive versus conventional mechanical ventilation. An epidemiologic survey. *Am J Respir Crit Care Med.* 2001; 163(4):874-880.
- Nava S, Hill N. Non-invasive ventilation in acute respiratory failure. *Lancet.* 2009; 374(9685):250-259.
- Liesching T, Kwok H, Hill NS. Acute applications of noninvasive positive pressure ventilation. *Chest.* 2003; 124(2):699-713.
- Devlin JW, Nava S, Fong JJ, Bahhady I, Hill NS. Survey of sedation practices during noninvasive positive-pressure ventilation to treat acute respiratory failure. *Crit Care Med.* 2007; 35(10):2298-2302.
- Akada S, Takeda S, Yoshida Y, Nakazato K, Mori M, Hongo T, Tanaka K, Sakamoto A. The efficacy of dexmedetomidine in patients with noninvasive ventilation: a preliminary study. *Anesth Analg.* 2008; 107(1):167-170.
- Takasaki Y, Kido T, Semba K. Dexmedetomidine facilitates induction of noninvasive positive pressure ventilation for acute respiratory failure in patients with severe asthma. *J Anesth.* 2009; 23(1):147-150.
- Huang Z, Chen YS, Yang ZL, Liu JY. Dexmedetomidine versus midazolam for the sedation of patients with non-invasive ventilation failure. *Intern Med.* 2012; 51(17):2299-2305.
- Clouzeau B, Bui HN, Vargas F, Grenouillet-Delacore M, Guillhon E, Gruson D, Hilbert G. Target-controlled infusion of propofol for sedation in patients with non-invasive ventilation failure due to low tolerance: a preliminary study. *Intensive Care Med.* 2010; 36(10):1675-1680.
- Rocco M, Conti G, Alessandri E, Morelli A, Spadetta G, Laderchi A, Di Santo C, Francavilla S, Pietropaoli P. Rescue treatment for noninvasive ventilation failure due to interface intolerance with remifentanyl analgesedation: a pilot study. *Intensive Care Med.* 2010; 36(12):2060-2065.
- Tomii K, Tachikawa R, Chin K, Murase K, Handa T, Mishima M, Ishihara K. Role of non-invasive ventilation in managing life-threatening acute exacerbation of interstitial pneumonia. *Intern Med.* 2010; 49(14):1341-1347.
- Murase K, Tomii K, Chin K, Tsuboi T, Sakurai A, Tachikawa R, Harada Y, Takeshima Y, Hayashi M, Ishihara K. The use of non-invasive ventilation for life-threatening asthma attacks: Changes in the need for intubation. *Respirology.* 2010; 15(4):714-720.
- Sessler CN, Gosnell MS, Grap MJ, Brophy GM, O'Neal PV, Keane KA, Tesoro EP, Elswick RK. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. *Am J Respir Crit Care Med.* 2002; 166(10):1338-1344.
- Esteban A, Frutos-Vivar F, Ferguson ND, Arabi Y, Apezteguia C, Gonzalez M, Epstein SK, Hill NS, Nava S, Soares MA, D'Empaire G, Alia I, Anzueto A. Noninvasive positive-pressure ventilation for respiratory failure after extubation. *N Engl J Med.* 2004; 350(24):2452-2460.
- Merlani PG, Pasquina P, Granier JM, Treggiari M, Rutschmann O, Ricou B. Factors associated with failure of noninvasive positive pressure ventilation in the emergency department. *Acad Emerg Med.* 2005; 12(12):1206-1215.
- Levy M, Tanios MA, Nelson D, Short K, Senechia A, Vespia J, Hill NS. Outcomes of patients with do-not-intubate orders treated with noninvasive ventilation. *Crit Care Med.* 2004; 32(10):2002-2007.
- Azoulay E, Kouatchet A, Jaber S, Lambert J, Meziani F, Schmidt M, Schnell D, Mortaza S, Conseil M, Tchenio X, Herbecq P, Andrivet P, Guerot E, Lafabrie A, Perbet S, Camous L, Janssen-Langenstein R, Collet F, Messika J, Legriel S, Fabre X, Guisset O, Touati S, Kilani S, Alves M, Mercat A, Similowski T, Papazian L, Meert AP, Chevret S et al. Noninvasive mechanical ventilation in patients having declined tracheal intubation. *Intensive Care Med.* 2013; 39(2):292-301.
- Schettino G, Altobelli N, Kacmarek RM. Noninvasive positive pressure ventilation reverses acute respiratory failure in select "do-not-intubate" patients. *Crit Care Med.* 2005; 33(9):1976-1982.



The best vest just got better.

smartvest[®] SQL[®]

SMALLER ➤ QUIETER ➤ LIGHTER

Choose the only high frequency chest wall oscillation (HFCWO) system that offers:

- **New dimensions**
Smaller, quieter and lighter — just 17 lbs.
- **Greater comfort**
Soft Start[®] with active inflate-active deflate
- **Ease of use**
Single-hose design, easy-to-read display
- **Total support**
Reimbursement assistance, in-home training and lifetime warranty



The SmartVest[®] SQL[®] is designed to help patients incorporate HFCWO therapy into their daily routines. The smaller, quieter, lighter air pulse generator — truly portable at just 17 lbs. — features Soft Start and a programmable ramp option to acclimate users to therapy more quickly and provide a more comfortable treatment experience. The SmartVest is available in eight sizes and fits like a piece of clothing, with Velcro-like closures for a customized fit.

We designed the SmartVest SQL to promote therapy adherence with features that patients and clinicians asked for. When HFCWO therapy is this convenient and easy, patients are more likely to use it.



ELECTROMED, INC.

Making life's important moments possible — one breath at a time.[®]

Big changes underway...



Fisher & Paykel Healthcare has significantly expanded its distribution and customer support networks in response to increasing demand for our world-leading respiratory technologies.

As healthcare spending moves beyond \$10,000 per person annually, delivering more care at lower cost is one of humanity's biggest challenges.

At Fisher & Paykel Healthcare we're endeavoring to create new approaches to old problems. Respiratory patient complications are old problems. These patients are among the most difficult to treat and the most significant contributors to increased hospital admissions and length of stay.

At F&P, this is a challenge we've embraced with our own form of human endeavor. Transformational technology.

Over 40 years ago, F&P helped develop the concept of humidification leading to today's world-leading respiratory technologies. But it's more than new technology; we're pioneering transformational therapies, including the rapidly emerging Nasal High Flow, designed to help improve care and outcomes and reduce the total cost of care.

As of July 19th we've moved a lot closer to you, now partnering directly with all major GPO's and distributors.

We've introduced exciting acquisition programs providing greater flexibility and access to new, market-leading MR850 technology at a significantly reduced financial commitment. And now the AIRVO™, F&P's latest endeavor, will transform the way you deliver Nasal High Flow across the hospital and home.

To provide you with the support you need to implement and develop these therapies, we've significantly expanded our team of dedicated Respiratory Sales Specialists to over 50 people nationwide. Contact one of them, or telephone our customer service team on (800) 446 3908 to arrange an appointment.

F&P Optiflow™

F&P 850™ System

F&P Evaqua 2™

F&P AIRVO™

www.fphcare.com

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

Fisher & Paykel
HEALTHCARE