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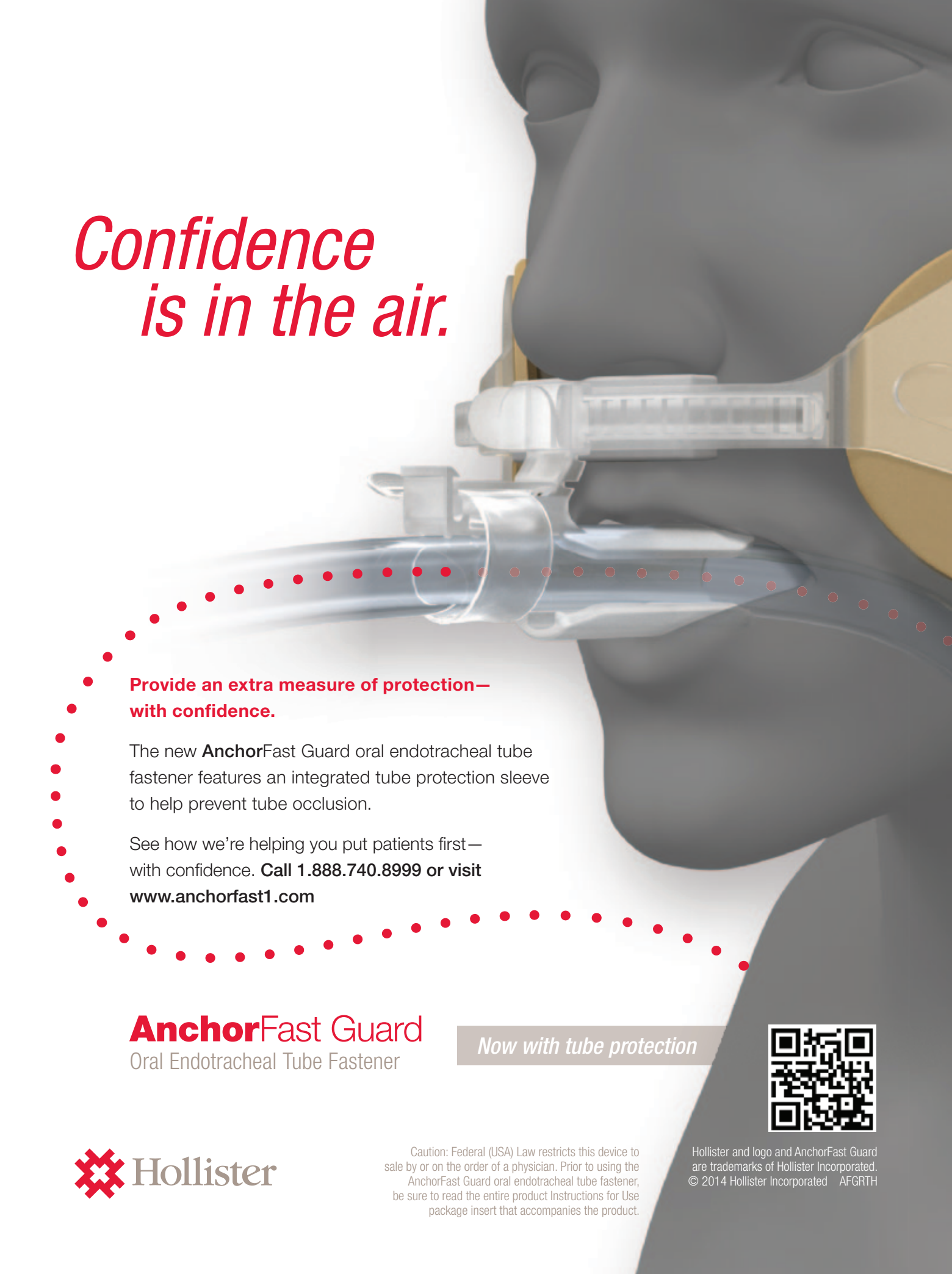
Respiratory Therapy™

The Journal of Pulmonary Technique



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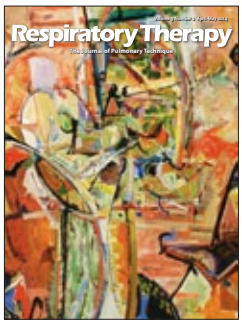

Respiratory Therapy™
The Journal of Pulmonary Technique

Vol. 9 No. 2
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Editorial

Cell-based Therapies: Beginning of a New Era?

Recent advances in medicine have resulted in improved survival for our tiniest and most vulnerable preterm infants born at the edge of viability. Unfortunately, this increasing survival is at the expense of an increase in morbidities such as chronic lung disease (aka bronchopulmonary dysplasia, BPD), neurological impairment, and behavioral issues. BPD was first described by Northway almost four decades back as a respiratory disease of now near-term infants who require oxygen and/or mechanical ventilation. Since then, the disease itself has been modified which is now referred to as new BPD and is clinically defined as oxygen requirement of > 21% for at least > 28 days as assessed at 36 weeks corrected gestational age. Despite advancements in care, the disease itself has not changed with limited understanding and available therapies. At present, approximately 1 in 3 infants born less than 30 weeks gestational age develop BPD, varying from mild to severe.

Alexander Maximow first used the term "stem cell" to describe hematopoiesis where all blood cells develop from a single precursor cell. Since then considerable interest has developed in stem cell field and their utilization for therapeutic purposes. Recent years have seen an increase in hype about stem cell-based therapies for diseases like BPD. Although animal research has shown promising results with stem cell use in various disease models, data are lacking on their effectiveness in humans. Similarly, several preclinical and clinical papers have described a potential role of stem cells in lung diseases and BPD. Stem cells can be harvested from amniotic fluid, embryo, bone, blood, and umbilical cord.

Challenge in stem cell field is that the biggest advantage of a stem cell is also its biggest disadvantage. The word stem cell is self-explanatory in the sense that a single stem cell has a potential for self-propagation and inadvertent growth leading to tumor formation. This has limited investigators in making final dossier of stem cells to be used as a therapeutic modality. Work in animal models utilizing stem cell conditioned media/secretome which is free of cells has shown promising results like stem cells themselves in prevention and/or reversal of BPD. Interest of pharmaceutical companies in this exciting field is paramount but at present outside the United States given federal regulations. In fact, the very first human trial of utilization of stem cells for BPD treatment has been conducted in Korea approved by the Korean FDA. The trial drug, Pneumostem, is comprised of human umbilical cord-derived mesenchymal stem cells manufactured by Medipost Co Ltd. and the trial was registered at clinicaltrials.gov. Although this trial has been completed in 2012, the results are still not released despite the fact that phase 2 trial has been in progress already.

Given so much uncertainty about the proper dose and mode of delivery of stem cells and/or their secretome and reports of stem cell-based therapies outside US, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health convened the Cell Therapy for Lung Disease Working Group in 2012 to review and formulate recommendations for future research directions. The group concluded that cell-based therapies are a new pillar of drug development but further bench work is required before these therapies can be pioneered to bedside approaches. Work on questions like cell origin, mode of delivery, cellular vs. cell-free dossier, mechanistic assessments, side effect profile, etc. should run parallel to the standard clinical trials to maximize efficacy and minimize side effects.

In conclusion, cell-based therapies are a new era of treatment for BPD and other lung diseases which currently lack effective treatment but an aggressive bench and bench-to-bedside approach is needed to make this a reality.

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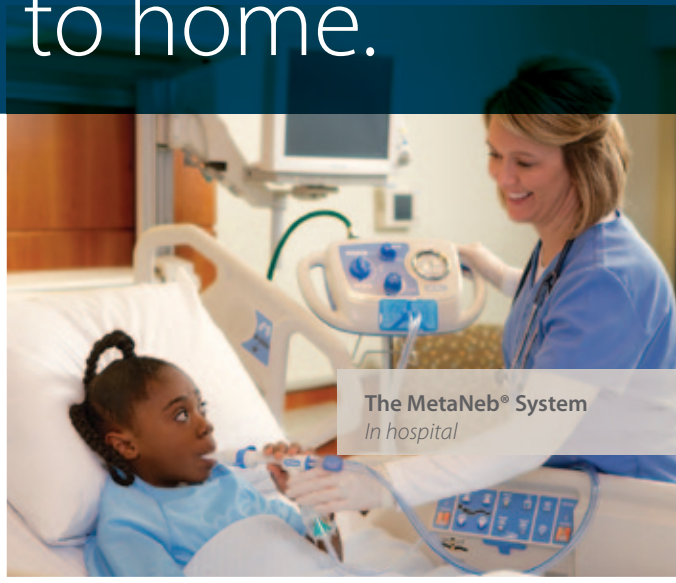

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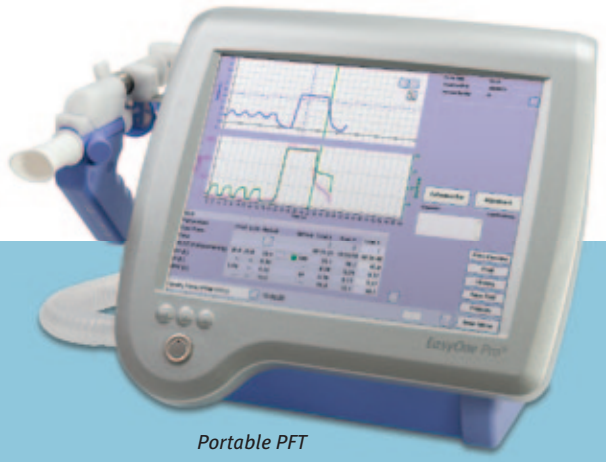

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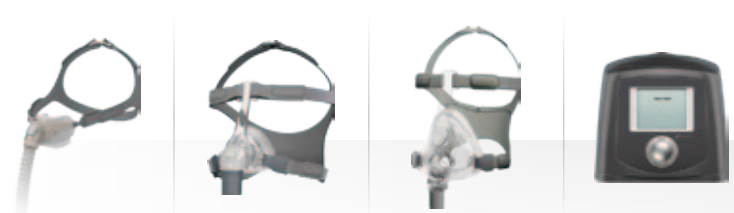

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News

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Addendum

Part II of "Airway Pressure Release Ventilation (APRV): Building a Better (Safer) Mechanical Breath" will be published in the June/July issue of Respiratory Therapy. Please refer to Part I in the February/March issue Vol. 9 No. 1.

Ventilation Cleared for MRI Setting

Ventilation specialists Hamilton Medical have announced they have received FDA 510(k) clearance for their Hamilton-MR1, a device that allows critically ill or injured patients to be ventilated even during MR imaging. The device covers a full range of clinical requirements such as: invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and non-invasive Ventilation (NIV). The Hamilton-MR1 can be used at the 500 gauss line, in the presence of either 1.5T or 3T magnets. In the MRI environment, where strong magnetic fields pose a danger for both the patient and the operator, safety is the highest priority. With the effectively shielded, MRI-compatible Hamilton-MR1 ventilator, ventilation performance and MRI quality is guaranteed throughout the procedure. The integrated TeslaSpy gaussmeter is programmed to alarm if the clinician places the device too close to the MRI magnet, which helps the clinician to properly position the Hamilton-MR1 at the 50mT (500 gauss) line or less. The Hamilton-MR1 can be used in ICU special care areas, cardiac surgery recovery rooms, step-down or sub-acute care units, and when transporting patients to the MRI-department. In these cases, the device guarantees uncompromised, continuous ventilation care from the ICU to the MRI and back with its 6-hour battery life. Alternatively, the device can be used as an MRI-proprietary ventilator, waiting in the MRI department for the patient. In the MR environment — when the clinician is unable to stay close to the patient for routine adjustments — the ASV mode will automatically adapt to the patient's lung condition. Positioning a medical device too close to the MRI can have fatal consequences and cause serious injury to the patient or clinician. In addition, significant financial losses can occur if a shutdown of the MRI is required. The Hamilton-MR1's integrated gaussmeter continuously monitors the magnetic field and gives the clinician both an audible and a visual signal if the device is getting too close to the MRI magnet. For increased MRI safety and ease of use in the MR environment, the integrated gaussmeter continues monitoring — even when the ventilator is not in use. Close proximity of the ventilator to the MRI machine is crucial. The Hamilton-MR1 includes a trolley made out of non-ferrous materials, which will not be attracted to the powerful electromagnetic forces emanating from the MRI's magnet. The trolley also has a "fail-safe" braking system.

Company Licenses Its Technology

Irish respiratory drug delivery company Aerogen announced it had capped off an "incredible" 2013 and set a new path for 2014 by signing a technology access and licence agreement with Philips, which also includes the acquisition of select assets solely related to Aerogen's home-care business. This transaction will allow Aerogen to focus on its corporate strategic goal to expand its leadership position in the respiratory drug delivery acute-care and home-care ventilation settings. The deal consists of an initial upfront payment with further royalty income based on exploitation of the licensed technology. Further details of the transaction were not disclosed, but Aerogen said the deal would allow it to focus on expanding its core business in the acute care setting. Aerogen was honoured in 2013 with the prestigious Zenith Award from the American Association of Respiratory Care (AARC) in November and went on to win the Medical Technology Company of the Year Award presented by the Irish Medical Device Association (IMDA) in December. Both Aerogen and Philips said they are committed to ensuring that the transaction will enhance the supply of products and services to their respective customers. Aerogen's acute-care and home ventilator drug delivery business is unaffected by the transaction and no employees will transfer to Philips.

Path Cleared for Airway System

The next generation of airway clearance systems has been cleared for market by the US Food and Drug Administration. Electromed, Inc., a global medical device company, announced it received notification that its SmartVest Airway Clearance System, the model SQL, has been cleared to market. According to Eletromed, in addition to being significantly smaller, quieter, and lighter than its previous versions, some of the features include enhanced ramping, an enhanced pause feature and more user-friendly graphics. The model SQL is an electrically powered precursor device designed to deliver high-frequency chest wall oscillation to promote airway clearance, improve bronchial drainage and enhance mucus transport under the order of a physician's prescription. It is prescribed to patients with a wide range of pulmonary-related health conditions, including bronchiectasis, chronic obstructive pulmonary disease, cystic fibrosis, muscular dystrophy, and cerebral palsy. HFCWO has been demonstrated to reduce lung infections and reduce health-care costs associated with recurrent pneumonias, antibiotic use, and hospital stays. In addition to the innovative SQL generator, the system boasts a lightweight soft-fabric garment with several patented features.

Line of CPAP masks cleared for launch

A line of CPAP masks from 3B/BMC has been approved by the US Food and Drug Administration to be launched on the market. The iVolve family of CPAP interfaces rounds out 3B/BMC's CPAP mask offering with a new premium, ultra lightweight and comfortable line of interfaces. The iVolve mask line has dual soft silicone lining for added comfort, and extremely quiet ventilation. The iVolve line of mask consists of the N2 Mini-Nasal, Nasal and Full Face Mask. Market launch on the iVolve series of masks is scheduled for February 2014.

Foundation Now Accepting Submissions

In response to a request from the chronic obstructive pulmonary disease (COPD) medical community, The COPD Foundation (COPDF) announced it will launch a free, digital and open access journal. Chronic Obstructive Pulmonary Diseases: Journal of the JCOPDF will publish quarterly, with the first

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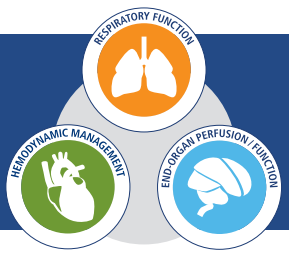

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issue launching in May 2014 to coincide with the COPDF's 10th anniversary. Members of the medical community are invited to submit articles via email to COPD@NJHealth.org. The foundation said that providing wide access to educational materials and research is a critical part of the COPDF's mission. An open access journal helps researchers and readers by removing the barrier that a subscription model creates. Traditionally, medical journals have been read by researchers, but open access has paved the way for the readership of scientific journals to expand beyond researchers to include professionals in the field, global users, journalists and students. James Crapo, MD, professor of Medicine at National Jewish Health and the University of Colorado Denver, a principal investigator of the COPDGene Study, and editor-in-chief, JCOPDF, has assembled an international editorial board featuring leaders in the COPD field. Articles submitted to the JCOPDF will undergo rigorous peer review, and once accepted will be published online.

CPAP's Other Benefits

New research suggests that treating obstructive sleep apnea with continuous positive airway pressure could also help lower blood pressure among people with both the sleep disorder and hypertension. Obstructive sleep apnea is a sleep disorder that is characterized by pauses in breathing during sleep, leading to disrupted sleep and daytime fatigue. Hypertension is considered a risk factor for sleep apnea, according to the Mayo Clinic. Spanish researchers found that for people with both conditions, receiving CPAP treatment for 12 weeks resulted in decreased blood pressure levels compared with those who didn't receive CPAP. The study, published in the Journal of the American Medical Association, is based on data from 194 people across 24 teaching hospitals with both hypertension and obstructive sleep apnea. People in the study had what is called resistant hypertension, meaning they required at least three medications to control their high blood pressure. Half of the study participants received CPAP treatment for 12 weeks, while the others did not receive CPAP and only took their typical blood pressure medication. The researchers purposely chose not to use a placebo for the control group (in the form of sham CPAP) because people who receive it can often figure out that they are receiving a placebo. The participants assigned to receive CPAP experienced a greater drop in average blood pressure and diastolic blood pressure than those who did not receive CPAP; they also experienced nocturnal blood pressure benefits. There were no significant differences in systolic blood pressure between those who were treated with CPAP and those who weren't. The findings are important, given that many people with resistant hypertension also experience obstructive sleep apnea, researchers noted.

Flying the Sleepy Skies

The Federal Air Surgeon has announced the FAA will move forward with implementing mandatory screening and testing for obstructive sleep apnea despite opposition from the pilot and aviation medical communities. The FAA recently announced that it would require aviation medical examiners to calculate body mass index (BMI) for all pilots. Those with a BMI of 40 or greater would have to be screened and, if necessary, treated for obstructive sleep apnea (OSA). The AME may issue a medical certificate at the time of the examination; however, the FAA will follow up with a request for additional evaluations, including a sleep study and evaluation by a board-certified sleep

specialist. Pilots who don't undertake the evaluation within 60 days would face receiving a letter of disqualification. Over time, the FAA would lower the BMI requirement, compelling more pilots to be screened by a sleep specialist. The FAA currently lists 5,000 pilots with a BMI of 40 or greater and more than 120,000 who qualify as obese with a BMI of 30 or higher. The group Aircraft Owners and Pilots Association and others have objected to the new testing requirements, saying they force AMEs to venture into predictive medicine, rather than focusing on their mandate of determining the likelihood that a pilot will be medically incapacitated at some point in the duration of the medical certificate. The association also has argued that such a significant change needs to go through the rulemaking process to allow public input and the opportunity to explore less intrusive and less costly methods for addressing concerns about sleep disorders. While the FAA acknowledged that there have been no fatal GA accidents attributed to sleep apnea, the FAA is pursuing this policy because sleep apnea is a serious problem in other modes of transportation and the agency believes many pilots may be flying with undiagnosed sleep disorders. Information is from an article by Elizabeth A Tennyson that appeared on Aircraft Owners and Pilots Association. Copyright AOPA.

Neurostimulator Could Unmask Patients

The standard treatment for people with moderate to severe obstructive sleep apnea is a mask worn at night that helps them breathe without interruption. The mask is considered by some to be unwieldy and uncomfortable, however; one study found that 46 to 83% of patients with obstructive sleep apnea do not wear it diligently. Now scientists may have found an alternative, at least for some patients: a pacemaker-like device implanted in the chest that stimulates a nerve in the jaw, helping to keep part of the upper airway open. The device, called a neurostimulator, helped reduce breathing interruptions and raise blood oxygen levels in about two-thirds of sleep apnea patients participating in a trial, researchers reported in The New England Journal of Medicine. The new trial was funded by the maker of the device, Inspire Medical Systems. At 22 sites internationally, in 126 patients, doctors surgically implanted a remote-controlled neurostimulator that, activated at night, sends regular electric impulses to a nerve inside the jaw. The impulses cause the tongue to move forward during inhalation, opening the airway. Patients experienced a decline in breathing pauses after using the device for a year, to 9 per hour on average, from 29.3 episodes per hour. The number of dangerous drops in blood oxygen levels also declined, to 7.4 per hour on average, from 25.4 per hour. There was no control group during this phase of the study, however, and other experts said that diet, exercise or other factors may have contributed to the reductions. At a year, only two of 126 patients stopped using their upper airway stimulator at night, and 86% reported daily use. But sleep apnea worsened in about 20 patients using the device, though it is unclear why. In the second phase of the study, 46 patients doing well with the stimulators after one year were randomly assigned to either continue with the therapy or have it withdrawn for a week. The therapy-continuation group had little change in the number of breathing pauses per hour or drops in blood oxygen levels. But in the patients from whom the stimulation therapy was withdrawn, the number of such breathing pauses increased sharply, to 25.8 per hour on average from 7.6 per hour. The episodes of blood oxygen level drops rose to 23 per hour on average, from 6 per hour.

The neurostimulator is not yet approved by the Food and Drug Administration and may only benefit a subset of sleep apnea patients, including those with a body mass index of less than 32 and people whose obstructions stem from airway collapse behind their tongues. Only patients who could not or would not use mask therapy participated. Information is from an article by Catherine Saint Louis that appeared on nytimes.com. Copyright New York Times.

GPS for Lungs

Each year, 200,000 Americans are told they have lung cancer and 160,000 die. The disease is often deadly because patients are diagnosed in the late stages when the cancer has spread. Now, there's a new way to spot tumors earlier that is like a GPS system for the lungs, according to Samir Makani, MD, FCCP, Director, Interventional Pulmonology and Bronchoscopy, Associate Clinical Professor of Medicine, University of California, San Diego and San Diego VA Healthcare System. Dr Makani performs electromagnetic navigation bronchoscopy. First, he maps the target using special software. Then, he places a bronchoscope down the patient's windpipe. A catheter navigates to the tumor in real-time that takes him to where the lesion is, Dr Makani explained. A traditional biopsy may require a needle through the chest and into the lung and could cause bleeding, or a collapsed lung. Electromagnetic navigation nearly eliminates the risks. Information is from an article by that appeared on Ivanhoe Newswire.

Portable Spirometry

The new Spirobank II is being touted as the ideal solution for prevention in primary care, occupational medicine and hospital use. Test results are immediately available on the display for data analysis, with advanced version with optional oximetry module. All tests are memorized in Spirobank II that are downloadable into WinspiroPRO, a unique full-featured PC software, which comes standard with all MIR devices. USB and Bluetooth connectivity (advanced version) and easy integration into Electronic Medical Record (EMR) or Practice Management Software through HL7 interface.

Device Updated

Inogen announced an improved Inogen One G2 portable oxygen concentrator as part of the company's greater plan to provide oxygen therapy to increase freedom and independence for oxygen therapy users. The Inogen One G2 oxygen concentrator has been a mainstay in the Inogen family of products for years, and now produces 40% more oxygen at its highest setting than the original. The product improvements allow users more versatility to accommodate higher flow requirements. The device has been expanded from 5 flow settings to 6, and offers the highest oxygen output of any portable oxygen concentrator of the same weight. This product improvement will allow oxygen users with higher flow requirements to achieve the independence and freedom that Inogen offers. In addition to increased oxygen delivery, the Inogen One G2 oxygen concentrator is now lighter at 7 pounds, while battery run time has been increased to up to 5 hours on a single battery and up to 10 hours on a double battery. These product specifications apply to all new units purchased after October 1, 2013.

Putting a Finger On It

Nonin Medical, Inc., the inventor of finger pulse oximetry and a leader in noninvasive medical monitoring, announced the launch of its NoninConnect direct-to-consumer Bluetooth Smart wireless finger pulse oximeter at the International Consumer Electronics Show in Las Vegas. The NoninConnect pulse oximeter features Bluetooth Smart (low energy) wireless technology, a unique user-facing display, and a proprietary algorithm that tells users if their finger is placed properly in the device for correct readings. NoninConnect is designed for use by athletes, pilots and Quantified-Self trackers who want to measure their arterial blood oxygen saturation and pulse rate. Users can easily store and share their readings by downloading a Nonin or future third-party pulse oximetry software application onto their Bluetooth-Smart-ready iOS, Android or Windows mobile device.

COPD Care Inconsistent in Europe

Care and prevention for chronic obstructive pulmonary disease (COPD) is inconsistent around the world, according to a non-profit network of allergy, asthma and COPD patients organizations. The European Federation of Allergy and Airways Diseases Patients' Associations (EFA), which represents 35 national associations in 22 countries and over 400,000 patients, has published a book on minimum standards of care for COPD patients in Europe. The book is based on EFA's survey in 16 countries in Europe through its member associations. The EFA found that in Poland, the healthcare system does not fund smoking cessation services, even if tobacco smoke is the primary cause of COPD, and in many other countries they are free only for people at risk. In Austria, diagnosis is often made too late, and spirometry tests to diagnose COPD are not part of the annual health check-ups. In Italy, not all patients can access rehabilitation, which is key to keep patients active. In Portugal, there are even shortages of medicines because of the economic crisis, whereas in Finland it has led to difficulties in transferring patients from specialist to GPs. According to the EFA, early diagnosis is the single most effective measure to take, followed by care that supports independence of patients. This book is designed to be a tool for policy makers, healthcare professionals, patient groups and other interested parties to "gear towards 'solving COPD' especially in this economic situation where every cent spent must create value for society." Among the EFA's recommendations are that general practitioners should be adequately educated to administer spirometry testing and interpret the results so as to assure early and accurate diagnosis. The EFA also wants better access to smoking cessation services.

Masks Unveiled

Health products designer Sleepnet is showing off its two new masks. Unveiled recently was the Aura—the world's first nasal mask featuring Sleepnet's unique Custom Fit Technology and an Active Headgear Connector. The soft shell mask has a shapeable wire allowing for optimum flexibility, fit, and comfort. The Active Headgear Connector moves when you move to help maintain a seal throughout the night. With three sizes and a Flexible Spacebar, the Aura will give you the rest you deserve. The Veraseal 2 Full Face disposable mask brings AIR gel technology to the acute care environment for a giant step forward in patient comfort. Three color-coded elbow designs make choosing the right mask for CPAP/Bi-level, single or dual limb circuit NIV systems simple. The Veraseal 2 fits quickly and easily while enhancing patient comfort.

'Enemy' Microbes Embraced

The Annals of the American Thoracic Society has released a comprehensive supplement on the 56th annual Thomas L. Petty

Aspen Lung Conference entitled "The Lung Microbiome: A New Frontier in Pulmonary Medicine." More than 170 microbiologists, basic respiratory scientists, and pulmonary clinicians traveled from nine countries to convene at the three-day conference, which took place in June 2013 in Aspen, CO. Research from 12 state-of-the-art speakers, 24 oral research presentations, and 20 posters from pioneers in the emerging field are included in the supplement, as well as an introduction from conference chairs Richard J. Martin, MD, Sonia Flores, PhD, and Monica Kraft, MD, and a conference summary from James Kiley, PhD. The lungs of healthy humans have traditionally been considered to be sterile when examined by culture-based techniques, according to James Beck, MD, chief of medicine at the VA Eastern Colorado Health Care System in Denver, adding that molecular identification techniques are now being used to explore the lung microbiome in ways that mirror study of other body sites and organ systems. This emerging and exciting field of investigation is expected to lead to new ways of thinking about the lung and lung disease. In the conference summary, Dr Kiley, the director of the Division of Lung Diseases at National Heart, Lung, and Blood Institute, notes: "Part of the new frontier is that microbes were originally considered the 'enemy,' and the approach was to eradicate a bug and cure the disease. We now recognize this paradigm has evolved from microbes being enemies to being partners, and a new challenge is to understand the delicate balance and symbiosis of those communities in defining the role of the microbiome(s) in health and disease."

EXECUTIVE PREVIEW OF THE FOCUS CONVENTION

Caire Medical

Booth #415

Description: eQuinoxT

The eQuinoxT provides continuous flow options from 0.5 LPM to 3.0 LPM and 9 pulse flow settings from 16mL to 192mL. The Multi-Language Voice Interface offers a new layer of comfort to users by providing verbal confirmation of changed flow rate settings, battery times, and any alarms. Weighing in at only 14 lbs, the newly designed, easy-to-maneuver frame makes the SeQual eQuinox the lightest-weight POC able to offer 3.0 LPM continuous flow.

Description: Companion 5T

The Companion 5T has been designed specifically to operate at a low decibel level to provide a comfortable, quiet environment for noise-sensitive patients and provides patients with an oxygen concentration of 93% at 5 LPM. Nearly maintenance-free, only two filters need to be changed, and both are accessed through easily opened doors. With its low maintenance, high reliability, and high standard of product quality, the CAIRE Companion 5 makes managing home oxygen therapy even easier.

Electromed

Booth #703

What products will you be presenting at Focus?

Electromed, Inc. will present its SmartVest Airway Clearance system including SQL, the next generation model which received FDA clearance in December 2013.

What new products or upcoming developments will you be highlighting?

We will be highlighting the SmartVest SQL, which is 25% smaller, at a minimum 5db quieter, and 25% lighter than the previous SV-2100 model.

Why should Focus participants visit your display?

To learn about the features and benefits of the SQL and find out how they can receive a dry erase educational lung poster.

Hollister

Booths #613 & 615

What products will you be presenting at Focus?

Hollister Incorporated is featuring the new AnchorFast Guard Oral Endotracheal Tube Fastener and the AnchorFast Oral Endotracheal Tube Fastener.

What new products or upcoming developments will you be highlighting?

The new AnchorFast Guard oral endotracheal tube fastener is the right choice for critical care teams who want an extra measure of protection for their patients. With the addition of integrated tube protection to our trusted securement system, the AnchorFast Guard tube fastener can help to bring a new level of confidence to the ICU.

Discuss educational/training materials you'll be offering at the convention.

Quick reference care tips as well as the AnchorFast e-Learning module will be featured at the Hollister booth.

What speakers or papers will your company be featuring?

Hollister will distribute copies of the peer-reviewed journal article: "Retrospective Review of the Reduction of Oral Pressure Ulcers in Mechanically Ventilated Patients: A Change in Practice" as reprinted from Critical Care Nursing Quarterly, Vol.35 No.3 July/September 2012. Authors: Sunniva Zaratkiewicz, BSN, RN, CWCN; Christopher Teegardin, RRT; JoAnne D. Whitney, PhD, RN, CWCN

Why should Focus participants visit your display?

Hollister is featuring the new AnchorFast Guard oral endotracheal tube fastener, now with integrated tube protection. Come by the booth to speak with one of our Hollister representatives and learn more.

Impact

Booth #1024

We will be presenting the Eagle II and the Eagle II MRI portable, critical care ventilators at FOCUS this year. Participants should visit our booth because the Eagle II ventilators offer significant enhancements over traditional portable ventilators. They are full-featured including AC, SIMV and CPAP/BiPAP with pressure and volume targeted breaths and pressure support in a compact, 9.5 lb package.

MGC Diagnostics

Booth #705

What products will you be presenting at Focus?
MGC Diagnostics will feature recent product developments and technology advancements including BreezeSuite WebReview physician review software for test interpretation; Platinum Elite body plethysmograph and Ultima Series cardiopulmonary diagnostics systems with RTD real-time diffusion MultiGas technology; together with our latest version of BreezeSuite cardiopulmonary diagnostic software incorporating the latest HIPAA and HITECH Security Safeguards protecting patient identifiable health information.

Discuss educational/training materials you'll be distributing or promoting.
Managing the MGC Diagnostics exhibit will be our Best-in-Class clinical, sales and support staff available to answer not only product questions, but provide expert consultation for clinical application and cardiorespiratory business needs.

MGC Diagnostics continues to provide educational opportunities with our annual Cardiorespiratory Diagnostics Seminar held in Orlando, Florida in October. Participants will advance their knowledge of diagnostic techniques, performance standards, quality assurance procedures, and clinical applications. The program format includes lectures, hands-on demonstrations and small group discussions—all conducted by a faculty of experts.

Why should FOCUS participants visit your display?
MGC Diagnostics delivers diagnostic solutions for detection, classification and management of cardiorespiratory patients worldwide. Our enduring experience and single-minded focus give us unmatched insight into the real needs of our customers.

NJR

Booth #404

What products will you be presenting at Focus 2014?
The No-Bite V suction catheter introducer for the oral airway. Every RT is familiar with nasopharyngeal or nasotracheal suctioning and the many problems associated with inserting a suction catheter up a patient's nose. To name a few: bleeding, pain and trauma, coiling of suction catheter, nasal blockages, MRSA colonizations in nares, and the list goes on. So basically with the No-Bite V, you can avoid all these problems by avoiding the nose altogether, especially on those difficult or contraindicated patients! It makes suctioning easy for not only the caregiver but also the patient.

Are there any new products you wish to emphasize?
The No-Bite V has been out on the market for about 3 years and we have been gaining serious traction! It is now becoming popular worldwide, we started up in Japan, South Korea, and Saudi Arabia in 2013. The Respiratory Care community has been very excited about adding the No-Bite V to their toolbox.

Discuss educational/training materials you'll be offering.
At our booth we will be offering No-Bite V in-servicing on mannequin heads, everybody is welcome to practice the techniques in a return demonstration. Also, we always offer a free online No-Bite V training with an opportunity to earn 0.5 CERP credits on our website www.NJRMedical.com. Once you finish the online course, you can print out your certificate.

What speakers or papers will you be featuring?
We will have the inventor of the No-Bite V at our booth and assisting the demos. Also we will have case studies documenting the success of the No-Bite V in both the ICU environment as well as the Hospice and Palliative Care setting.

Why should AARC participants visit your display?
The No-Bite V is needed in every hospital! It's not for every patient, but we all know there is difficulty with nasal route suctioning and sometimes even contraindications. This makes RT's lives easier and that is why every RT needs to learn this product at our booth. It's not only easier for the RT, but also the patient. It's easy to learn, we even have laypeople in the home care setting using the No-Bite V on their own loved ones.

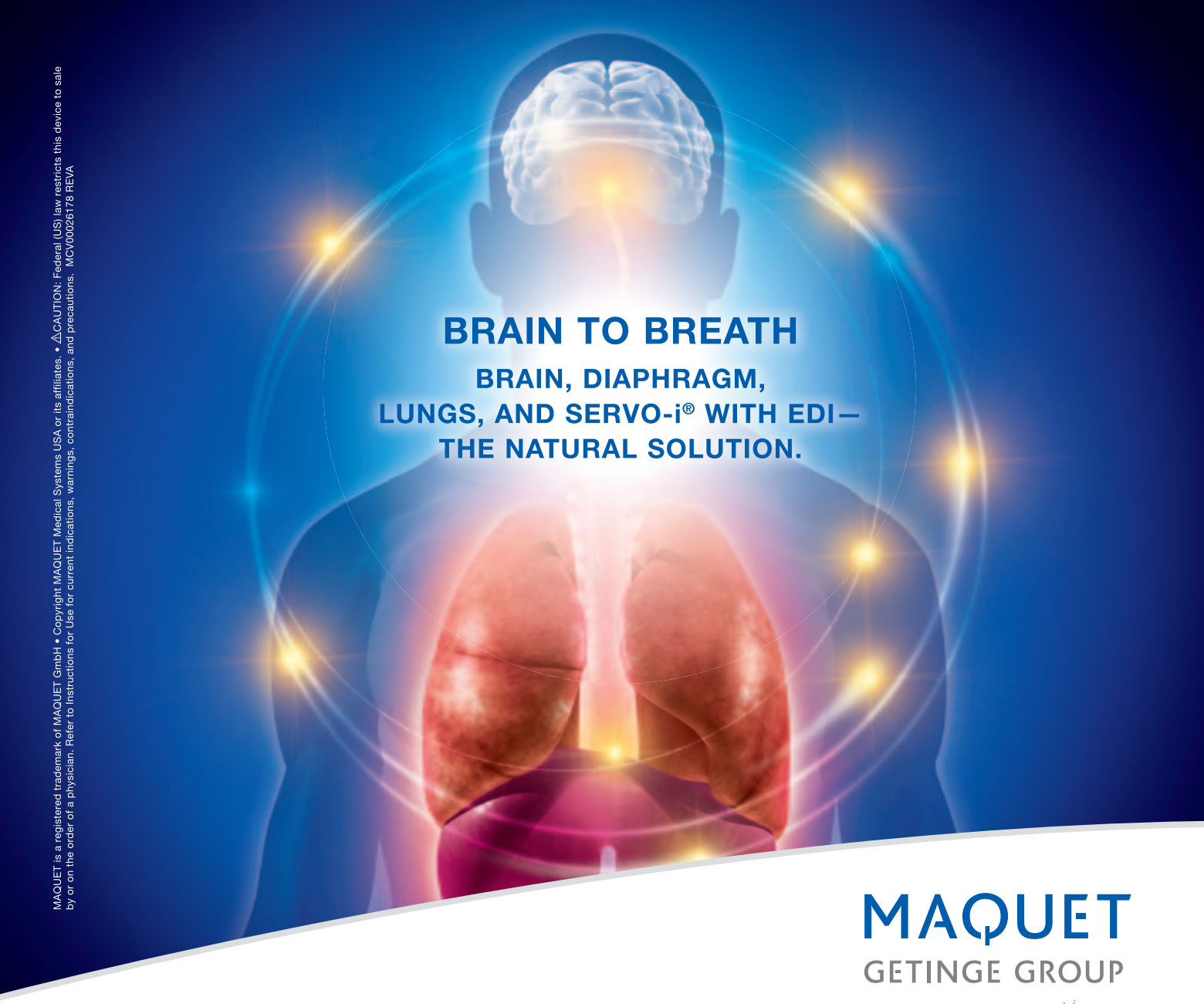
Vortran

Booth #308

What products will you be presenting at Focus?
We will be showing our current products, the VAR, PercussiveNEB, IPPB, APM and E-Surge Kit.

What new products or upcoming developments will you be highlighting?
We are currently working on new products but are not ready to show them yet.

Discuss educational/training materials you'll be offering at the convention.
We will have free training CDs available for the VAR. Visit our booth to see the PercussiveNEB, mucus clearance device.



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The electrical activity of the diaphragm (Edi) provides a dynamic view of each patient's unique natural interaction of brain, diaphragm, and lungs.

Using this respiratory vital sign, SERVO-i becomes an even more powerful tool for you to effectively assess and address critical clinical challenges that can break the patient's natural respiratory cycle such as ineffective triggering[1], patient/ventilator asynchrony[1] and ventilator-induced diaphragmatic dysfunction (VIDD)[2]. SERVO-i with Edi is the natural solution to support your goal of restoring the respiratory continuum for optimized weaning and patient comfort[3].

SERVO-i with Edi—the natural solution.

Learn More

MAQUET will donate $250 to Make-A-Wish® for any single purchase order of $50,000 or more (before tax, shipping and install) received between March 1, 2014 and February 28, 2015, with a minimum guaranteed contribution of $50,000, up to a maximum of $150,000. For more information about Make-A-Wish visit wish.org.

1. Piquilloud L, Vignaux L, Bialais E, et al. Neurally adjusted ventilatory assist improves patient-ventilator interaction. *Intensive Care Med.* 2011 Feb;37(2):263-71.
2. Sassoon CSh, Caiozzo VJ. Bench-to-bedside review: Diaphragm muscle function in disuse and acute high-dose corticosteroid treatment. *Critical Care.* 2009;13(5):221.
3. de la Oliva P, Schüffelmann C, Gómez-Zamora A, et al. Asynchrony, neural drive, ventilatory variability and comfort: NAVA versus pressure support in pediatric patients. *Intensive Care Med.* 2012 May;38(5):838-46.

www.maquetusa.com

In this new feature Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Allison Atkinson, Speech-Language Pathologist.

Passy-Muir Center of Excellence: Warm Springs Specialty Hospital-Victoria

Warm Springs Specialty Hospital of Victoria (WSSHV) is a 26-bed long-term acute care hospital, specializing in medically complex patients, weaning from mechanical ventilation, rehabilitation and wound management. WSSHV wanted to offer a different approach to critically ill patients, one that provided hope for patients recovering from traumatic accidents, injury and illness. They began to utilize the Passy-Muir Valve as part of their protocol for all tracheostomy and mechanically ventilated patients, and also formed a multidisciplinary tracheostomy team approach to their care. WSSHV is now a Passy-Muir Center of Excellence. Through the Centers of Excellence Program, Passy-Muir recognizes facilities that Passy-Muir determines have developed a multidisciplinary team approach to the treatment of tracheostomized and ventilator dependent patients and utilize the Passy-Muir Valves successfully, and by doing so, have enhanced the quality of life and decreased the recovery time for their patients.

Respiratory Therapy: Why did WSSHV want to incorporate the Passy-Muir Valve into the plan of care for patients?
Allison Atkinson: Patients were obviously frustrated when they could not communicate with their caregivers and family members after tracheostomy. This frustration led to anxiety and fear at times and this had a negative impact on their motivation to participate in therapy. In addition, patients who were on the ventilator for extended periods of time were not able to participate in making medical decisions. Family members often spoke for them. At WSSHV, we wanted to give our patients the ability to communicate their wishes to their family members and to the staff. We knew that using Passy-Muir Valves (PMV) could restore their ability to communicate verbally and also improve their potential to eat safely, even while on the ventilator. Returning patients to an oral diet also helped them feel like they were making real, tangible progress. These two milestones really helped with the momentum in their healing process.

Since there are risks associated with working with critically ill patients, we were initially met with some resistance. Fortunately, at that time, Gail Sudderth from Passy Muir, Inc. traveled to WSSHV to provide an on-site in-service with local SLPs, RTs and physicians. This helped jumpstart our program.

Following our initial in-service, we wanted to make sure that we had a process in place that ensured staff demonstrated competency for use of the PMV. The Speech Therapy Department and the Respiratory Department researched and developed the content for an Inter-disciplinary Team PMV Evaluation. We then developed a protocol and training program for the facility after it was approved by the Medical Executive Committee and the Director of Quality Control. Using the PMV became our standard of care with all tracheostomized and mechanically ventilated patients.

RT: What step did you take to achieve recognition as a Passy-Muir Centers of Excellence?
AA: We learned about the opportunity to become a Passy-Muir Center of Excellence from the Talk Muir Newsletter. We researched the process for applying and realized that we had completed many of the requirements including a comprehensive protocol and competency for Passy-Muir Valve placement which can be found at passy-muir.com/policiesandprocedures.

Passy-Muir, Inc. clinical specialists eagerly assisted us with the process. Their feedback concerning our program was invaluable. They were able to assess our strengths and weaknesses and help us organize the program into one of excellence. Gail Sudderth and Cheryl Wagoner provided hours of web-based education for our team, the nursing, respiratory and therapy staff. They then traveled to WSSHV for a second time to offer on-site and in-depth Passy-Muir Valve training for vent-supported patients. Gail also reviewed and fine-tuned the policy and procedure for Passy-Muir Valve.

We felt it was important to apply for the designation in order to be recognized for the process we fought for and worked on for so many years. The excitement of national recognition has provided motivation for all involved. The process of the consultative relationship with Passy-Muir, Inc. also facilitated the finalization of our current program to offer the benefits of the Passy-Muir Valve to all of our patients.

RT: What has the valve and the designation as a Passy-Muir Center of Excellence provided for your patients and your facility?
AA: Long Term Acute Care Hospitals (LTACH) treat many patients with respiratory failure who require ventilator support. Since incorporating the Passy-Muir Valve as our standard of care, the team at WSSHV has noticed that our patients are communicating more effectively, eating sooner, and weaning from the ventilator more quickly.

Becoming a Passy-Muir Center of Excellence allows us to increase awareness to local physicians that early intervention with the valve improves outcomes. It also assures them that we have advanced and specialized training of use of this technology to take care of their patients. This recognition sends a message to families that their loved one will receive the highest quality of care and that the clinical staff at Warm Springs Hospital will go above and beyond to improve our patients' quality of life.

In this new feature Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with John R. Bach, MD, who is a Professor of Physical Medicine and Rehabilitation at the New Jersey Medical School.

Respiratory Therapy: What is mouthpiece ventilation (MPV) and what types of patients could benefit from its use?
John R. Bach: It is a method of providing full ventilatory support, noninvasively, that is, intermittent positive pressure ventilation, via a mouthpiece.

RT: Is MPV safe/recommended for children and pediatrics?
JB: Small children either never need it or do not have the lip strength to use it, however adolescents with Duchenne muscular dystrophy and other neuromuscular conditions use it well and perfectly safely since they can also usually glossopharyngeal breathe so they don't ever need to worry about accidental disconnections or sudden ventilator failure.

RT: How long can a neuromuscular patient be effectively treated using MPV?
JB: A number of our post-polio patients have been using it in a regimen of total, around-the-clock ventilatory support for over 55 years, Duchenne patients over 25 years, high level spinal cord injury patients up to 38 years, ALS patients 8 years, etc.

RT: How long could a clinician potentially delay a tracheostomy by introducing a patient to MPV?
JB: Tracheostomy tubes are virtually never needed for any patients with neuromuscular conditions, spinal cord injury, post-polio, obesity-hypoventilation, central sleep apnea, kyphoscoliosis, spinal muscular atrophy (even type 1) or other such conditions with the exception of bulbar ALS and 42% of the latter can have tracheotomy delayed by up to 8 years by using full noninvasive ventilatory support.

RT: By incorporating these features into ventilators, does it make the implementation of MPV easier and reduce hesitancy of physicians whose only option was to turn alarm packages off?
JB: The "kiss trigger" facilitates air stacking and mouthpiece air delivery in general and the ability to turn off useless alarms is also very helpful.

RT: Do you recommend a protocol for neuromuscular patients on MPV?
JB: We have been recommending a protocol that eliminates tracheostomy tubes for virtually all neuromuscular disease patients for the last 20 years. It is simply to use noninvasive ventilation (daytime usually via mouthpiece), and mechanically assisted coughing (essentially the CoughAssist) to maintain O2 saturation 95% or greater during intercurrent respiratory tract infections to prevent pneumonia, hospitalization, and respiratory failure, and to use noninvasive intermittent positive pressure ventilation (not "BiPAP") for nocturnal ventilatory support and muscle rest as well. By doing this, most, if not all patients with neuromuscular disorders can weaken to the point of requiring continuous ventilatory support for decades without ever being hospitalized.

RT: Could MPV be used on demand by restrictive patients, to aid in reducing CO2?
JB: Obviously, indeed, with our patients who have 0 ml of vital capacity, it is not a question of "reducing CO2" it is a question of full ventilatory support.

Input on questions was provided by Judith Hale. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

In this new feature Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Our premiere interview is with Andrew Slezak, MEd, RRT-NPS, Neonatal Clinical Education — St Joseph's Women's Hospital, Tampa, FL, discussing his hospital's use of the Neo-Tee by Mercury Medical.

Respiratory Therapy: What areas/departments could the hospital benefit from using the Neo-Tee?
Andrew Slezak: The most value comes from the use of the Neo-Tee in the delivery room. With so much unpredictability in the delivery of a newborn, it is extremely valuable to have a single device that can provide both CPAP for slow transitions and consistent ventilation in emergencies. This is especially true with our premature neonates. Having a Neo-Tee at the bedside for our NICU patients gives us the ability to respond quickly to apneas, bradycardic episodes, and other respiratory emergencies. Using a Neo-Tee allows the therapist to alter the level of support needed quickly while also providing a safer mode of resuscitation for our bedside nurses. A flow-inflating resuscitation bag needs skill and experience to operate safely while the Neo-Tee allows someone with little experience to still give consistent pressures during resuscitation (other than occluding the hole for the respiratory rate and not releasing).

RT: How many L&D and NICU beds does your facility have?
AS: A 64-bed NICU and a 22-bed L&D.

RT: How does the Neo-Tee assist clinicians in providing better patient outcomes?
AS: It reduces the risk of barotrauma during positive pressure delivery by providing consistent pressures during each breath. Due to its simplicity, it allows delivery team members to concentrate on other aspects of resuscitation by taking the guess work out of the breathing equation. With a flow-inflating resuscitation bag, the clinician must concentrate on squeezing the bag appropriately each breath. That's 40-60 breaths a minute!

RT: Do you see a benefit by having a manometer at the patient interface (on the Neo-Tee)?
AS: It allows the clinician to check the peak pressure/PEEP while also observing the quality of the seal for the mask and the appearance of the baby. Having a manometer attached to the care center can be distracting and requires the clinician to remove his/her eyes from the baby.

RT: Many clinicians have stated that feeling "lung compliance" with a resuscitation bag is very important. What are your thoughts on this considering that Neo-Tee does not allow for the "feel"?
AS: I do consider this to be a drawback from this device. The Neo-Tee is very mechanical and doesn't allow the clinician to get a feel for what is going on inside the lungs. The flow-inflating resuscitation bag has a distinct advantage in this way but there are ways to counter this problem. Listening to breath sounds, observing chest rise are still reasonable measures of assessment.

RT: Has the Neo-Tee prevented intubations that may have occurred by the use of other resuscitation devices? If so, how does this help support reducing healthcare costs? (Can an actual dollar savings be applied to your facility?)
AS: The Neo-Tee has helped by way of transporting the baby from the delivery room to the NICU. The Neo-Tee doesn't need to be held on the ETT while squeezing the bag which can cause the ETT to become dislodged. The Neo-Tee makes it easy to hold the airway in place while also providing consistent breaths during ventilation.

RT: How has Neo-Tee helped your department with respect to infection control?
AS: We've reduced the number of devices required from delivery to bedside emergencies. Having one device that is disposable reduces your chance for infection versus having two or more devices opened and being used.

RT: What else can you tell us about the Neo-Tee that you hadn't mentioned but has been beneficial and would be valuable for other clinicians to know?
AS: It helps to have a device that can't be easily manipulated or damaged during a chaotic resuscitation or emergency. PEEP valves and flow restrictors can be moved or changed during hectic procedures. The Neo-Tee is always consistent.

Input on questions was provided by Scott Horowitz, Product Manager, Mercury Medical. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

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Be sure to visit the Mercury Medical Booths, #309 & #311 at the Focus Meeting, Orlando, Florida, May 15 - 17, 2014

Covidien

Tell us about your currently available oximetry products.
Our Nellcor™ line with OxiMax technology features a diverse range of pulse oximetry products — including bedside and handheld devices — with cardiac-based signal processing technology. Specific devices include:

- Bedside monitors, such as the Nellcor Bedside SpO_2 Patient Monitoring System and Nellcor™ Bedside Respiratory Patient Monitoring System. Both systems, featuring user-friendly color interfaces, continuously monitor blood oxygenation in patients across all hospital care settings and can be used on patients of all ages, including infants.

- The largest line of disposable, reusable and specialty sensors on the market to meet the needs of a wide range of patients. For example, our forehead sensors can be used in poorly perfused patients with reduced blood oxygen to quickly capture accurate pulse oximetry readings when traditional finger sensors can't detect signals.

- Alarm management features including Saturation Pattern Detection (SPD) Alert, which identifies patterns of desaturation indicative of repetitive reductions in airflow in adults, and SatSeconds, which differentiates between serious hypoxemia and minor transient events by calculating severity and duration of a desaturation.

Note: Our Nellcor pulse oximetry technology is compatible with the monitoring systems of our more than 70 Original Equipment Manufacturing (OEM) partners.

Discuss the range of your oximetry products' applications.
Covidien offers a range of Nellcor pulse oximetry solutions to meet the monitoring needs of neonate, pediatric and adult patients across all hospital care settings. Many of our pulse-oximetry products are also used in hospital-type facilities, at home and during intra-hospital transport. Covidien offers an extensive portfolio of sensors, including Nellcor specialty sensors, which address individual patient needs. For instance, Nellcor non-adhesive sensors protect delicate skin. Covidien also added Respiration Rate to the Nellcor oximetry platform to provide a continuous measurement of respiration rate, SpO_2 and pulse rate using a single sensor.

Additionally, Nellcor pulse oximetry technology has been shown to be a simple and economical tool to aid healthcare providers in CCHD (critical congenital heart defect) screening. It provides highly accurate readings in neonates (±2 digits), largely because it relies on cardiac-based signals to generate readings closely tied to the patient's physiology. The result is consistent performance during a number of challenging conditions, including patient motion, noise and low perfusion, all of which can impede the assessment of patient respiratory status.

What oximetry products do you have in development?
At Covidien, we're continually building upon our "Sensing Systems" portfolio to provide customers with solutions they need to detect subtle, but critical variations in patient status through a combination of pulse oximetry and other monitoring technologies. Our Sensing Systems provide a holistic view of patient oxygenation and ventilation status through interrelated pulse oximetry, respiration rate and capnography technologies.

What type of customer assistance and training do you offer?
We partner with customers to ensure our pulse oximetry and other portfolios best meet the needs of clinicians and patients. Specific support includes in-service programs, in-house continuing education (CE) programs, field-based technical training and web-based tools.

Professional Affairs and Clinical Education (PACE) online platform from Covidien (http://www.covidien.com/pace/pages.aspx) features clinical education content on a variety of topics, including pulse oximetry. The pulse oximetry training module is available by visiting http://www.covidien.com/pace/pages.aspx?page=ClinicalEducation/Event/260992.

Masimo

Tell us about your oximetry products currently available.
Since its inception, pulse oximetry was plagued by unreliability when it was needed most — during patient motion and low perfusion. The industry had given up and considered the problem "unsolvable." Clinicians were forced to live with the results — excessive false alarms, delayed notification due to long averaging times, inaccurate data, and an inability to obtain data on the most critical patients. Conventional pulse oximetry works under the assumption that by looking at only the pulse and normalizing the pulsating signal over the non-pulsating signal, oxygen saturation (SpO2) can be measured without calibration. Although this was a big step forward in the evolution of pulse oximetry, it has one major flaw — it assumes the only pulsating component is arterial blood. Unfortunately for conventional pulseoximetry, venous blood moves every time the patient moves or breathes.

Masimo SET (Signal Extraction Technology) overcame the technological limitations of conventional pulse oximeters, making it more accurate during the challenging conditions of patient motion and low perfusion. Masimo SET has made pulse oximetry a clinically useful tool and, for the first time since pulse oximetry was introduced in the 1970s, it has been shown in clinical studies to improve patient outcomes. To date, more than 100 independent and objective studies have shown that Masimo SET outperforms all other pulse oximetry technologies, providing clinicians with the sensitivity and specificity to make critical patient care decisions. Masimo SET Measure-through Motion and Low Perfusion technology is at the core of Masimo noninvasive monitoring instruments, such as the:

- Radical-7 — Three-in-one monitor (bedside, handheld, transport), designed to automate the process ofcare and enable clinicians to instantly adapt to changing monitoring needs in individual patients and care areas. Features the full suite of Masimo SET and rainbow measurements including oxygenation (SpO2), pleth variability index (PVI), perfusion index (PI), noninvasive and continuous hemoglobin (SpHb), and acoustic respiration rate (RRa).
- Rad-87 — Offers Masimo SET pulse oximetry and upgradable rainbow technology in a versatile, easy-to-use bedside monitor.
- Rad-57 — The world's most versatile, portable handheld oximeter features Masimo SET pulse oximetry and upgradable rainbow technology.
- Pronto-7 — Offers noninvasive and quick spot-check testing of total hemoglobin (SpHb), SpO2, pulse rate, and perfusion index.

Discuss the range of your oximetry products' applications.
Masimo SET has allowed pulse oximetry to succeed in markets where conventional pulse oximetry had failed — including home and long-term acute care facilities. Our rainbow measurements have also allowed us to increase our impact beyond the hospital, from helping emergency personnel detect carbon monoxide poisoning at the scene of a fire to enabling noninvasive hemoglobin spot-check testing in the physician's office. And as more caregivers gain access to our products, we know that more lives will be improved and saved.

We also entered the animal health market, offering a variety of differentiated solutions to domestic and large animal veterinarians, with the same appreciative feedback that we received when we introduced our solutions to the "people care" community. We also launched our first-ever monitoring device for the promising consumer health and wellness market — iSpO2. We expect both these new markets to grow in 2014 and beyond.

What oximetry products do you have in development?
Masimo's innovation engine has fueled many industry firsts, which have significantly improved patient care and reduced costs. As one example, Masimo's noninvasive and continuous total hemoglobin (SpHb) monitoring has been shown to help clinicians reduce the number of risky and costly blood transfusions in surgical patients, speed up blood transfusion for those who need it, and in multiple cases has demonstrated its lifesaving potential to help clinicians detect occult bleeding. Masimo rainbow technology has also been shown to help clinicians assess fluid responsiveness, improve fluid management, identify changes in breathing, and assess carbon monoxide levels for faster therapy for those with CO poisoning.

In 2013, Masimo re-wrote the rules for monitoring and connectivity with the launch of Root. Now available in the US, Root is a powerful new patient monitoring and connectivity platform that integrates Masimo's full suite of rainbow measurements with multiple additional parameters in an integrated, clinician-centric platform. Masimo's approach is designed to unleash innovation in patient monitoring via third-
Continued on page 31…

Nonin

Oximetry Products Currently Available

Nonin Medical invented finger pulse oximetry and is a global leader in developing noninvasive medical monitoring solutions that improve the quality of people's lives. Technology driven, we provide pulse and cerebral oximeters, capnographs, sensors, OEM, and vet solutions that meet customers' needs today and tomorrow. The company's wide range of oximetry products include:

• Finger Pulse Oximeters
The Nonin Onyx brand of finger pulse oximeters for clinicians, and the GO2 brand of finger pulse oximeters for personal home use provide proven accuracy in the widest range of patients and conditions. Hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, home healthcare services, the military and consumers rely on Nonin's finger pulse oximeters for accurate spot checking of blood oxygen saturation and pulse rate.

• Pulse Oximeters and Sensors
Nonin's table-top, wrist-worn and hand-held pulse oximeters used by clinicians, the military, veterinarians, and others for spot-checking and continuous monitoring of blood oxygen saturation and pulse rate in neonate through adult patients.

• Regional Oximeters and Sensors
Nonin's highly portable and absolutely accurate EQUANOX Regional Oximetry Systems are used by clinicians in surgery and critical care settings to continuously monitor in real time the oxygenation of blood in the brain and other tissues. EQUANOX is the only cerebral/somatic oximeter available that has patented dual emitter/dual receiver sensor technology for accurate, consistent, reliable rSO2 measurements on adult, pediatric and neonatal patients.

• OEM Pulse Oximetry
Nonin's OEM pulse oximetry products are available as wireless, internal, or external solutions.

Nonin products include the Onyx II 9560, the 3230 Bluetooth LE (BLE4.0), finger pulse oximeters and the WristOx2 3150 wrist-worn pulse oximeter. These products are used by a variety of customers especially in the sleep, home oxygen, eHealth, EMS, mHealth and telehealth industries for monitoring patients in their homes.

External pulse oximeter — Plugs into a medical device through an external port such as a mini-12 or USB connector. Nonin products include the Xpod and Ipod. These products are used in telehealth, eHealth, sleep medicine, monitoring, ventilators, EMS, home care and oxygen therapy markets.

Internal pulse oximeter module — Integrates inside a medical device, such as a sleep diagnostics system, monitor or ventilator. These products are used by a variety of companies in a wide variety of settings.

Range of Oximetry Product Applications

Nonin pulse oximetry and regional oximetry products provide reliable and accurate readings in a variety of environments.

Pulse Oximetry

Nonin Medical offers one of the most reliable, cost-effective, complete lines of pulse oximetry solutions available for a variety of markets including:
- Homecare
- Sleep Laboratories
- Respiratory Therapy
- eHealth
- Consumers
- Professional Military
- Veterinary

Regional Oximetry

Nonin's EQUANOX Regional Oximetry Systems are used in a variety of clinical settings to provide accurate, reliable and consistent measures of tissue oxygen saturation for real-time management of patients at risk for compromised oxygen saturation to the brain and other tissues. Common clinical uses include:
- Cardiovascular operating rooms
- Neonatal Intensive Care Units
- Pediatric Intensive Care Units
- Centers that perform surgeries in the beach chair position

Products in Development

The Nonin SenSmart Universal Oximetry System is the first dedicated oximeter system that provides measurements of both regional oximetry (rSO2) and pulse oximetry (SpO2). While providing industry-leading rSO2 accuracy, the SenSmart system provides comprehensive monitoring of up to six-channels of rSO2 and SpO2 monitoring. No other oximeter system provides more than four channels of monitoring. The signal processor is substantially smaller than previous versions. The system allows clinicians to quickly react to reverse tissue ischemia events before they become critical. SenSmart currently has a CE Mark and is 510(k) pending in the US.

Customer Assistance

Nonin has a library of training materials including videos available for viewing and download located at www.nonin.com/ProductTraining. We also have phone support available by calling +1-763-553-9968 or in Europe +31(0)13-79 99 040.

Assessment of Endotracheal Tube Obstruction Using a Test Lung Simulator and Sound Wave Technology

Christopher J. Russian, M.Ed., RRT-NPS, RPSGT, RST, Joshua F. Gonzales, MHA, RRT-NPS, RRT-SDS

Abstract

Background: Identification of airway obstruction is vitally important to any patient with an artificial airway. Secretion accumulation on the internal wall of the artificial airway is a common occurrence and presents challenges to mechanical ventilatory function. Mechanical ventilation data on inspiratory and expiratory parameters should alert the bedside clinician to impending complications such as mucus accumulation. However, our routinely monitored mechanical ventilator data may not provide the clearest picture of airway obstruction. In addition, newer technology may provide a better means to assess airway obstruction. The goal of this research project was to investigate methods that may provide early warning signs of an ETT obstruction including assessment of specific ventilator parameters and use of a new monitoring technology that estimates the degree of ETT obstructions in real time.

Methods: The ASL 5000 was used to generate inspiratory and expiratory flow changes in the face of a partial airway obstruction. Pre-manufactured airway obstructions were used to generate a 25%, 50% and 75% reduction in endotracheal tube diameter. The ASL 5000 and the SonarMed AirWave were used to generate data based on the airway obstruction.

Results: Bivariate correlation assessed the strength of association between airway obstruction and over 55 items generated by the ASL and the AirWave combined. A strong negative correlation was demonstrated between ETT obstruction and maximum pressure drop (-.894), inspiratory work (-.880) and inspiratory tidal volume (-.919). A strong positive correlation was demonstrated between the ETT obstruction and the AirWave readings (.995), expiratory work (.863), peak airway pressure (.855), and pressure time product (.810).

Conclusions: This bench evaluation provided insight into a number of variables that may signal a partial airway obstruction. Some current critical care ventilators do not routinely report some of the variables discovered in this study. The variables, which include a new device that provides real-time assessment of airway obstruction, can perhaps aid the bedside clinician when treating patients with artificial airways.

Background and Significance

Invasive mechanical ventilation requires the use of an artificial airway (AA), e.g. endotracheal tube or tracheostomy tube, to facilitate the delivery of fresh gas into the lungs. The internal diameter of the AA is much smaller than the human airway thus presenting several challenges to gas delivery. Additionally, there is a tendency for secretions to accumulate on the internal wall of the AA due in part to the removal of our natural mechanisms for humidification and directed coughing.[1] When AA lumen size further narrows due to intrinsic factors, e.g. secretion accumulation, the challenges of mechanical ventilation increase further due to an increased amount of airway resistance. Mechanical ventilation data on inspiratory and expiratory parameters should alert the bedside clinician to impending complications such as mucus accumulation. For example, during volume controlled ventilation an increase in peak airway pressure (Paw) could indicate an increase in airway resistance and/or decrease in lung compliance.[1] However, it is possible that a Paw change of small magnitude, e.g. 1 cmH2O every 2 hours, could go unnoticed by the bedside clinician during routine ventilator checks. There are instances where a change in Paw is not substantial enough to warrant further investigation. Previously published research supports our hypothesis that Paw and tidal volume may be insensitive to signaling impending airway obstruction.[2-5]

The goal of this research project was to investigate methods that may provide early warning signs of an ETT obstruction including assessment of specific ventilator parameters and use of a new monitoring technology that estimates the degree of ETT obstructions in real time. Early detection is key to reducing patient complications. Partial airway obstruction is a patient safety issue. In situations where complete airway occlusion is not realized, the patient is placed in a life threatening/emergency situation. Changes in peak airway pressure and tidal volume represent the most commonly monitored parameters signaling an airway obstruction. We believe additional parameters can provide indication of early partial airway obstruction.

Methodology

Equipment: The Ingmar Medical ASL 5000 Breathing Simulator, software 3.2, (Ingmar Medical, Pittsburgh, PA) provided the breaths and recorded all monitored parameters. The breathing simulator is composed of a single cylinder piston with a total volume of three liters and a default, uncompensated residual volume of 0.5 liters. The authors wrote a manual script using the flow pump option (60 LPM, 12 BPM) to generate each breath. SonarMed's Airwave monitoring system was also used in our research. The AirWave, a device that uses acoustic reflectometry

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to probe ETTs, provided an estimation of the ETT occlusion percentage. The AirWave device also provides ETT position relative to the carina and movement of the ETT; however, these features were not investigated for this project.

Endotracheal tube obstruction was simulated using resistance inserts manufactured by SonarMed, Inc (Carmel, IN). The inserts provide 25%, 50% and 75% ETT diameter occlusion and measured about one-half inch in length. We used the following adult ETT sizes: 6.5mm, 7.0mm, 7.5mm, 8.0mm. The inserts are manufactured based on the internal diameter of each ETT used.

Procedure: Following a calibration period using an unobstructed ETT, SonarMed's AirWave sensor was connected to the test ETT in place of the hub. We then inserted the ETT into large bore corrugated tubing to serve as the mock intubated trachea. The corrugated tubing was then connected to a test lung. The AirWave sensor was connected to the ASL 5000 using a 15mm adapter. Testing began with no obstruction in the ETT, followed by a 25% obstruction, 50% obstruction and finally 75% obstruction. We did not enter any obstruction information into the AirWave device. Therefore, the obstruction percentage that was displayed was the result of the Airwave technology and not the researchers. Each ETT was tested in this manner. Data for analysis were generated from two sources, the ASL 5000 and the AirWave device. We generated ASL data on 10 breaths for each ETT obstruction. We recorded 10 AirWave percentages for each of the ETT obstructions to match the 10 breaths of ASL data.

Statistical Analysis

We used bivariate correlation coefficient to analyze the data. A correlation of .60 or greater was considered strong. A $p<.05$ was considered statistically significant. Statistical Package for the Social Sciences (SPSS, IBM, Chicago, IL) was used for all data analysis.

Results

We found a strong negative correlation between the ETT obstruction and maximum pressure drop (-.894), inspiratory work (-.880) and inspiratory tidal volume (-.919). We found a strong positive correlation between the ETT obstruction and the AirWave readings (.995), expiratory work (.863), peak airway pressure (.855), and pressure time product (.810). All correlation results were statistically significant. The reason the inspiratory work presents as a negative correlation and the expiratory work presents as a positive correlation is based on how the numbers are generated within the ASL 5000, i.e. opposite movements/ phases of the piston. Figures 1-7 show the scatterplot of the SonarMed, Peak Airway Pressure, Inspiratory Tidal Volume, Inspiratory Work, Expiratory Work, Maximum Pressure Drop, and Pressure Time Product data, respectively.

Discussion

The goal of this research project was to investigate methods that may provide an early warning sign to ETT obstruction including assessment of specific ventilator parameters and use of a new monitoring technology that estimates the degree of ETT obstructions in real time. We used the ASL breathing simulator to generate a flow pump breath and to record multiple data points. We also generated data recordings from the SonarMed AirWave device.

Some of the results we report are consistent with the mechanical ventilation equation of motion. If volume is not held constant we expect tidal volume to decrease as the degree of obstruction increases. Tidal volume was not set directly or held constant in this project. In addition, we expect peak airway pressure to increase as the degree of obstruction increases if delivered pressures are not held constant by the ventilator. Inspiratory pressure was not set directly thus was allowed to vary with breath delivery. Our results demonstrated that as the percent obstruction increased the tidal volume decreased and the peak airway pressure increased.

We report the other parameters for two reasons. One, they exhibited a strong correlation with obstruction. Two, they are not routinely monitored during mechanical ventilation. Maximum pressure drop is defined in the ASL manual as deflection of pressure from baseline to a pressure minimum.[6] The value is generated during the trigger phase and will reach greater negative values as the difficulty to trigger the breath increases. As the degree of obstruction increased in our experiments the maximum pressure drop during the trigger phase became progressively more negative. There was a greater change in negative pressure from the 50% to the 75% obstruction compared to the 25% to 50% obstruction. This indicates that maximum pressure drop could go unnoticed during lesser obstructions and may not be visible until significant obstruction exists.

Inspiratory work and expiratory work both demonstrated strong correlations with the degree of airway obstruction. These parameters are an indication of work of breathing on both sides of the ventilatory phase. The numbers generated by the ASL indicated that work of breathing increased as the degree of obstruction increased. This is not an unexpected occurrence.

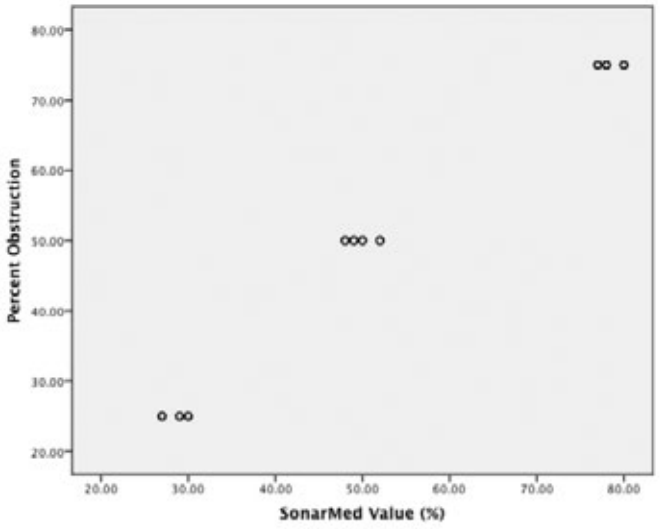

Figure 1: Scatterplot of the SonarMed AirWave data. Three obstruction percentages were used for this project (25%, 50%, 75%). The AirWave data demonstrated a very strong correlation with the obstruction percentages.

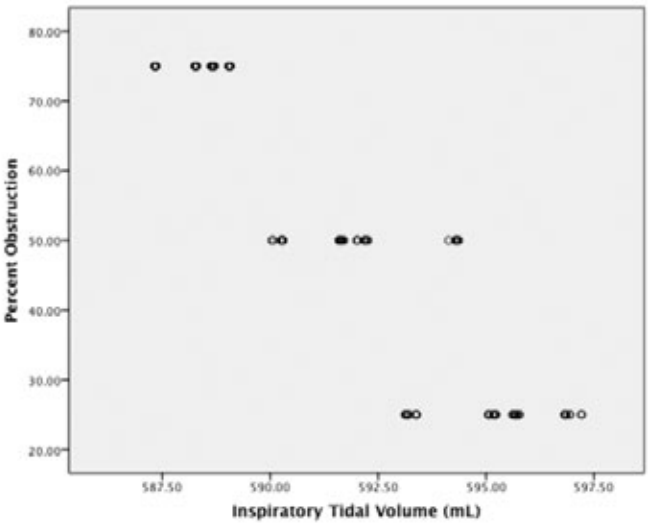

Figure 3: Scatterplot of the Inspiratory Tidal Volume data. Three obstruction percentages were used for this project (25%, 50%, 75%). Tidal volume demonstrated a negative correlation with obstruction percentage.

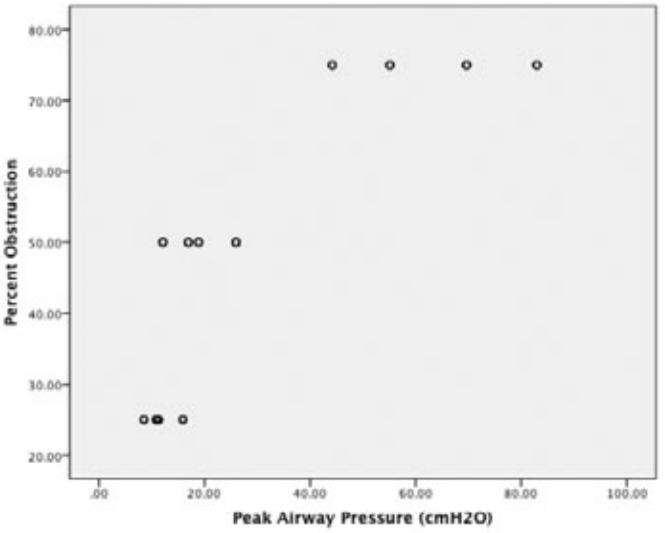

Figure 2: Scatterplot of the Peak Airway Pressure data. Three obstruction percentages were used for this project (25%, 50%, 75%). There was a smaller increase in Paw from the 25% obstruction to the 50% obstruction versus between the 50% and 75% obstruction.

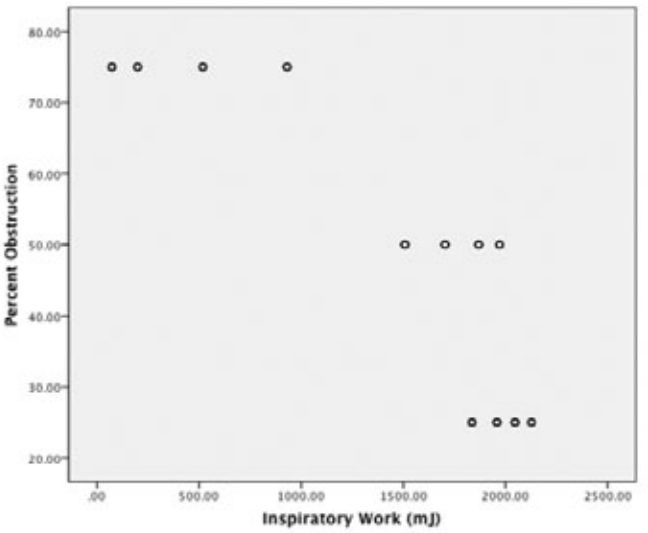

Figure 4: Scatterplot of the Inspiratory Work data. Three percent obstructions were used for this project (25%, 50%, 75%). There was a smaller increase in Inspiratory Work from the 25% obstruction to the 50% obstruction versus from the 50% and 75% obstruction.

Poiseuille's Law proves that airway resistance increases 16-fold with a one-half reduction in airway diameter. Additionally, airflow characteristics change from laminar to turbulent with increases in airway resistance and decreases in airway diameter. Lastly, increases in airway resistance increase the patient's work of breathing. The problem is the routine reporting of work of breathing during mechanical ventilation is limited. It is possible that the typical manner to obtain work of breathing data, i.e. use of an esophageal balloon, limited its inclusion on mechanical ventilator data screens. The ASL 5000 offers a noninvasive way to generate work of breathing numbers based on the data accumulated during the inspiratory and expiratory phases of ventilation. Reporting of work of breathing values could and should be the norm for all mechanical ventilators.

Pressure time product can serve as a surrogate for trigger work of breathing. As the degree of obstruction increased the pressure time product also increased indicating the work of breathing increased. Increases in breathing workload due to endotracheal tube internal diameter has received attention in the available literature.[7,8] However, there is limited reporting on the correlation of inspiratory and expiratory data and airway obstruction using non-invasive tools. These results offer another avenue for potentially identifying the development of an airway obstruction. Although the ASL 5000 results demonstrate a strong correlation with simulated airway obstruction it is still likely that an airway obstruction can be missed during routine mechanical ventilator use. The trending of data included here and the data routinely included on a ventilator screen may limit sentinel events like artificial airway obstruction. The ASL data does

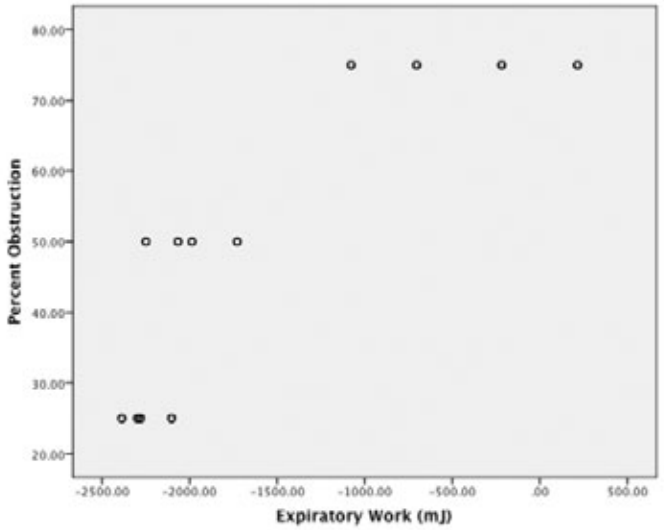

Figure 5: Scatterplot of the Expiratory Work data. Three obstruction percentages were used for this project (25%, 50%, 75%). There was a smaller increase in Expiratory Work from the 25% obstruction to the 50% obstruction versus from the 50% and 75% obstruction.

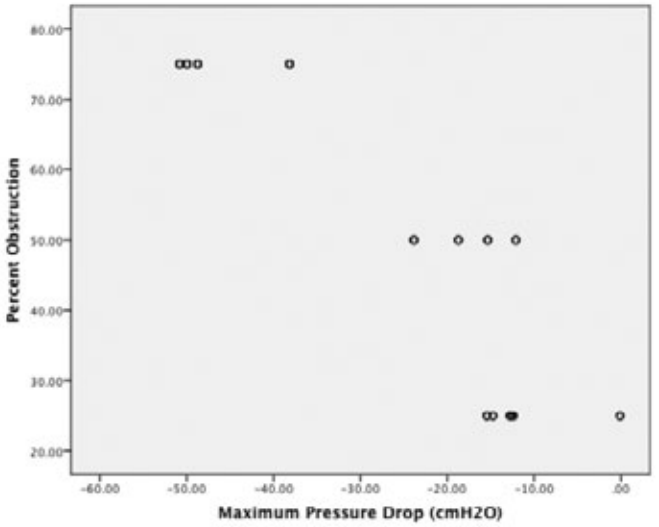

Figure 6: Scatterplot of the Maximum Pressure Drop data. Three obstruction percentages were used for this project (25%, 50%, 75%). Maximum pressure drop demonstrated a negative correlation with obstruction percentage. There was a smaller increase in Maximum Pressure Drop from the 25% obstruction to the 50% obstruction versus from the 50% and 75% obstruction.

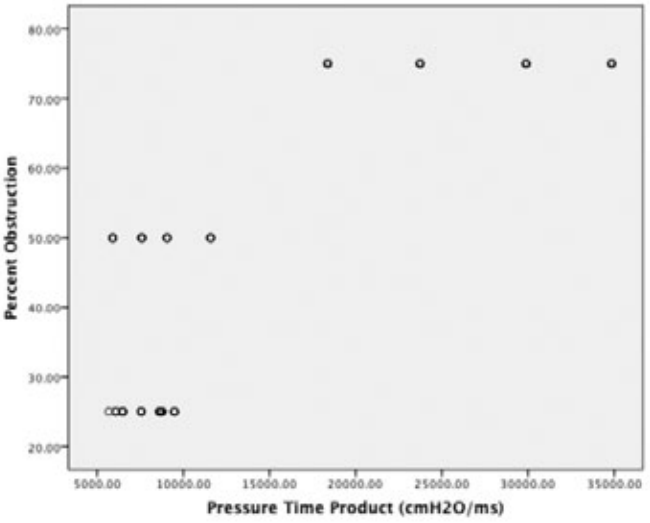

Figure 7: Scatterplot of the Pressure Time Product data. Three obstruction percentages were used for this project (25%, 50%, 75%). There was a smaller increase in pressure time product data from the 25% obstruction to the 50% obstruction versus from the 50% and 75% obstruction.

require interpretation by a clinician who is versed in the phases of ventilation, work of breathing, and the equation of motion as related to mechanical ventilation.

Although all reported parameters above returned strong correlations with simulated airway obstruction the SonarMed AirWave device provided an immediate indication of ETT obstruction. The AirWave data demonstrated a correlation of 0.995 with ETT obstruction. The AirWave uses sound wave reflection to provide direct, real-time monitoring of artificial airway obstruction. An obstruction percentage was displayed on the monitor of the AirWave as soon as the obstruction appeared. Although we can follow the trend line with the recorded ASL data parameters, in most cases small ETT obstructions, i.e. 25%, generated only minor changes in the ventilator parameters. However, the AirWave was clearly able to detect an obstruction and accurately display information about the obstruction percentage on its screen. Thus determining if an obstruction is present is much easier with the AirWave versus using inspiratory and expiratory flow characteristics and viewing pressure time product changes. The AirWave removes the subjective guesswork from the data. Implementation of this or similar technology should be considered the standard of care for intubated patients especially if the patients are experiencing excessive mucus accumulation.

Limitations

We tested the impact of airway obstruction on ventilator parameters using a flow pump model. We did not gather data on actual human patients. It is possible that patient results will vary from the values presented within our paper. We were not able to assess all possible scenarios that a clinician would experience in the hospital setting. We investigated the impact of a fixed airway obstruction, manufactured obstruction inserts placed in a single location within the ETT, on parameters of mechanical ventilation. It is possible that an airway obstruction that is located and shaped differently from that used in our project could return different results. This project was not designed to test the ability of the SonarMed AirWave device to correctly display a variety of different obstructions and obstruction locations. We tested the correlation of the SonarMed AirWave device reading and an artificial airway obstruction.

Conclusion

The results from our bench evaluation may provide useful data for ventilator manufactures and hospital clinicians. It seems possible for non-traditional values to be added to the reported data from current critical care ventilators. Also, the inclusion of an immediate, real-time assessment of ETT obstruction, e.g. SonarMed technology, should be investigated further to determine its usefulness in alerting and preventing airway obstruction.

References

1 Cairo JM. (ed). Pilbeam's Mechanical Ventilation: Physiological and Clinical Applications. 5th ed. St. Louis (MO):Elsevier, 2012.

2 Kawati R, Lattuada M, Sjöstrand U, Guttmann J, Hedenstierna G, et al. Peak airway pressure increase is a late warning sign of partial endotracheal tube obstruction whereas change in expiratory flow is an early warning sign. Anesth Analg 2005;100:889-93. doi: 10.1213/01.ANE.0000160011.19863.9B

3 Kawati R, Vimlati L, Guttmann J, Hedenstierna G, Sjöstrand U, Schumann S, et al. Change in expiratory flow detects partial endotracheal tube obstruction in pressure-controlled ventilation. Anesth Analg 2006;103:650-7. doi: 10.1213/01.ane.0000229777.80271.4a

4 Guttmann J, Eberhard L, Haberthür C, Kessler V, Lichtwarck-Aschoff M, Geiger K. Detection of endotracheal tube obstruction by analysis of the expiratory flow signal. Intensive Care Med 1998 Nov;24(11):1163-72.

5 Tung A, Morgan SE. Modeling the effect of progressive endotracheal tube occlusion on tidal volume in pressure-control mode. Anesth Analg 2002;95:192-7. doi: 10.1213/01.ANE.0000018528.85505.10

6 IngMar Medical. Active Servo Lung 5000 User's Manual, Software 3.2 (1st ed.). 2010. IngMar Medical, Ltd. Pittsburgh, PA. Available at: http://www.ingmarmed.com/download.htm

7 Boque MC, Gualis B, Sandiumenge A, Rello J. Endotracheal tube intraluminal diameter narrowing after mechanical ventilation: use of acoustic reflectometry. Intensive Care Med, 2004;30:2204-2209. doi: 10.1007/s00134-004-2465-4

8 Bolder PM, Healy TE, Bolder AR, Beatty PC, Kay B. The extra work of breathing through different sized endotracheal tubes. Anesth Analg 1986;14:1028–1031.

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party development of new measurements. With a dock for the Radical-7, an instantly interpretable display, and a networking/connectivity gateway, Root integrates multiple streams of data and simplifies patient care workflows, empowering caregivers to make quicker patient assessments, earlier interventions, and better clinical decisions throughout the continuum of care.

What type of customer assistance and training do you offer?

Masimo offers interactive e-Learning courses on our learning website, Masimo U. These courses consist of review material, demonstration videos, and assessment. Masimo also has a large Clinical Specialist team that offers follow-up to e-Learning with return demonstration verification as well as live classroomtraining as needed. Additionally, Masimo Clinical Specialists can provide Super User training to designated personnel if desired. Masimo Clinical Specialist and Project Management teams handle everything from the initial order of equipment, to device check-in documentation, to education, placement, and return of decommissioned equipment if applicable.

M.O.R.E. Program: An Acuity-based Approach to Patient Care

Doug Orens, MBA, RRT

Introduction

Healthcare providers in various patient care settings are facing an ever-changing landscape. The emphasis to provide proficient healthcare is moving from a traditional focus of addressing patients' immediate clinical needs to that of prevention and wellness. The emergence of protocols and patient care paths reflecting current evidence-based guidelines are valuable tools in providing appropriate cost-effective care in all healthcare settings. The role of non-physicians is expanding to address our aging population allowing physicians to focus on more critical patient issues. In today's healthcare environment hospitals are developing tactics to address readmissions and reduce costs. Many home health care and durable medical equipment providers are becoming more innovative in their practice to address patient care post-discharge. Perhaps no other law in recent history has had such a dramatic impact on our healthcare system than the Patient Protection and Affordable Care Act, more commonly known as the Affordable Care Act (ACA) or Obamacare.

Readmissions & Reimbursement

An important feature of the ACA as identified by the Center for Medicare and Medicaid (CMS) is the focus on the quality aspect of providing care to patients and its effect on reimbursement.[1] Hospital readmissions are seen as an indicator of quality of care. Excessive readmissions equate to poor quality of care and need to be addressed. Reducing hospital readmissions has become the focal point of health care institutions and other patient care providers. Hospital readmissions that frequently occur have been identified as costly and many potentially avoidable. Once discharged to home many patients' care has been less than effective resulting in frequent exacerbations with trips to the emergency room or readmission to the hospital. Gone are the days of patients receiving hurried hospital discharge instructions with little or no follow-up.

Currently 1 in 5 of all Medicare patients is readmitted within 30 days with an annual cost of $17 billion.[2] The Hospital Readmission Program (HRRP)[3] is a change in the way the federal government is impacting the healthcare system by tying Medicare payments to reflect the quality of care patients receive. This program began in fiscal year 2013 (October 1, 2012) by mandating that hospitals with higher than expected readmissions will receive lower Medicare payments. Reduction of total Medicare payments is capped at 1% in 2013, 2% in 2014 and 3% in 2015. The current focus is on patients with a primary admitting diagnosis of pneumonia, acute myocardial infarction and heart failure that are considered to have excessive readmissions.

Starting in 2015, excessive readmissions for patients with Chronic Obstructive Pulmonary Disease (COPD) along with angioplasty, CABG and vascular disease will result in reduce reimbursement for all Medicare payments. An emphasis on addressing hospital readmissions for COPD patients is a focus of numerous healthcare providers' particularly respiratory therapists in all healthcare settings. COPD has been identified as the third leading cause of death in the US[4] and the fourth leading cause of readmissions.[5] Medicare reports that beneficiaries with COPD have a 22.6% readmission rate within 30 days after hospital discharge.

Addressing readmission

In order to address the readmission issue various strategies have been developed. Many hospitals are creating patient care teams with members from various health care disciplines to supply input with a focus on providing comprehensive or coordinated care.[6] This care starts during the hospital admission and carries over to post discharge of the patient. There is emphasis on patient education, medication adherence, self care, nutrition and routine follow-up with physicians.

Another strategy is the development of chronic disease management programs which has a reported significant reduction in both length of stay and total hospitalization. Some hospitals may send care-givers to patient homes or partner with a home care or durable medical equipment company to ensure a continuation of optimal care in the home. For comprehensive care to be successful there must be some form of interaction between patients and healthcare professionals in the home environment. It is essential for patients living with a chronic disease that care in the home is a continuation of the appropriate care they received while in the hospital.

Healthcare providers in the home

Many home care and durable medical equipment companies employ healthcare professionals to care for patients. The home healthcare professional provides an interface between the patient and physician. They evaluate the patient's understanding of their disease state; reinforce education of equipment, medications, nutrition, evaluate clinical needs, and perform a home assessment which is crucial in terms of safety and well-

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Table 1. Patients Enrolled in the M.O.R.E. Program by Diagnosis and Acuity Level

Patients Categorized by Diagnosis	Patient Acuity Level
COPD = 519 (23%)	High = 59 (35)
OSA = 1327 (60%)	Medium = 1210 (54%)
CHF = 143 (7%)	Low = 956 (43%)
Hypoxemia = 93 (3%)	
Miscellaneous = 143 (7%)	

Table 2. Acuity Levels of COPD and OSA Patients

COPD Patients	OSA Patients
High = 27 (5%)	High = 20 (2%)
Medium = 410 (79%)	Medium = 509 (38%)
Low = 16%)	Low = 798 (60%)

Table 3. Respiratory Modalities by Acuity Level

Oxygen Therapy
High = 35 (5%)
Medium = 680 (85%)
Low = 141 (10%)
PAP Therapy
High = 23 (1%)
Medium = 503 (37%)
Low = 753 (62%)
PAP Therapy and Oxygen Therapy
High = 12 (11%)
Medium = 74 (69%)
Low = 22 (20%)

Table 4. Key Follow-Up Survey Results

Are you experiencing any shortness of breath while using your oxygen?
Yes, during exertion (respiratory therapist alert) = 5 (3%)
Yes, during rest (respiratory therapist alert) = 0
Yes, while sleeping (respiratory therapist alert) = 1 (0.6%)
No = 160 (96.4%)
Are you using your oxygen at the prescribed setting?
Yes = 165 (99.4%)
No (respiratory therapist alert) = 1 (0.6%)
Are you using your CPAP equipment more than 4 hours every night?
Yes = 59 (98.3%)
No (respiratory therapist alert) = 1 (1.7%)
Have you been to the emergency room or been readmitted to the hospital in the last 30 days?
Yes, the E.R. = 2 (0.9%)
Yes, the hospital = 11 (4.8%)
No = 214 (94.3%)
Do you have an upcoming follow-up appointment with your prescribing physician?
Yes = 226 (99.6%)
No (Encourage the patient to keep their physician involved in their therapy, health, and wellness) = 1 (0.4%)

designing the home to maximize the activities of daily living. In recent years there have been reported successful efforts to improve patients' respiratory care in the home by various hospital-based home care or durable medical equipment providers. Programs such as Discharge, Assessment & Summary @ Home (D.A.S.H.) at Klingensmith Healthcare in Pennsylvania[7] and Roberts Home Medical in Maryland are demonstrating that respiratory therapists interaction in the home improve patient outcomes while reducing emergency room visits and hospital readmissions.[8]

The M.O.R.E. Program

Acuity-based approach

The M.O.R.E. Program (Measuring Outcomes through Respiratory Evaluation) developed by the Medical Service Company, Cleveland, Ohio provides a unique approach to address patient care in the home. The goal of this program is to provide a focus for all patients receiving respiratory therapy based on their level of acuity. The program identifies risk factors while treating respiratory conditions and monitoring patient outcomes. This approach is a way to concentrate on the components of comprehensive patient care while reducing hospital readmissions and costly emergency room visits. The strategy of the program allows for more interaction and follow-up with patients and a focus of providing feedback to physicians with up to date clinical information and patient issues. This is extremely important as resources and reimbursement continues to decline not only in the hospital but also for home care and durable medical equipment companies.

The M.O.R.E. Program requires the respiratory therapist taking care of the patient to ask a series of clinical questions ranging from smoking history to patient travel requirements. These questions are designed to address patient care in the home environment. Each of these questions has a point value associated with a level of severity. The therapist utilizes a scoring system which in turn establishes an overall acuity level of the patient. There are three acuity levels, high, moderate and low. Therapist visits and follow-up calls are formulated based on the patient's level of illness. Patients with higher acuity scores require more visits and follow ups than those with lower acuity scores. By focusing on patients that have greater clinical requirements it maximizes the therapist patient interface which in turn may produce enhanced patient outcomes.

Starting in September 2012 all patients receiving any respiratory therapy modality in the home were enrolled in the M.O.R.E. Program. Patient information was collected and identified by sex, age, diagnosis, acuity level, and modality, effectiveness of current therapy, potential for additional physician evaluation, emergency room visits and hospital readmissions. Currently there are 2225 patients enrolled in the program. Of these 23% have a diagnosis of COPD, 60% obstructive sleep apnea (OSA), 7% congestive heart failure (CHF), 3% hypoxemia and 7% make up a miscellaneous category. A review of level of acuity shows that 57% of patients were classified as high or moderate and 43% were in the low category (Table 1).

COPD & OSA Patients

COPD and OSA patients with a primary or secondary diagnosis comprise 83% of the total population enrolled in the M.O.R.E. Program. The majority of respiratory therapy services in the home are devoted to these two patient groups. By applying the strategy of the M.O.R.E. Program to these two groups, more frequent care is afforded to patients that exhibit a higher level of severity. This allocation of care allows resources to be utilized in an effective manner. A review of the acuity levels of COPD and OSA patients is shown in Table 2. Another category is respiratory

modalities that patients are receiving to determine trends of acuity by modality (Table 3). It may be possible to establish more efficiency in staffing and equipment requirements by looking at the acuity mix of patients on different respiratory modalities. We found that the majority of patients receiving PAP therapy fall into the least acute group (62%). Conversely 90% of the patients receiving oxygen therapy had a high or moderate level of severity. Eighty per cent of patients receiving a combination of PAP and oxygen therapy were in the high and moderate severity categories. These trends may allow for utilization of resources and equipment in the most efficient manner.

Better assessment, lesser exacerbations

An important element of the M.O.R.E. Program is a feedback loop from patients to their physicians by respiratory therapists asking significant clinical questions and providing the information to the physician. During the initial assessment by the respiratory therapist it was found that 11.8% of patients not receiving oxygen therapy in the home said they were short of breath during mild or moderate exercise. A review of this group's acuity showed that 88.3% were in the high or moderate level ($p<0.016$). Of the patient's currently receiving oxygen therapy 4.8% were falling asleep more frequently or occasionally falling asleep during waking hours. The physician is afforded the opportunity to pursue additional evaluation if he or she considers it to be appropriate, with the understanding that these are subjective patient concerns. The initial appraisals reveal that 7.1% of current patients are active smokers. Reinforcement of smoking cessation is performed by the respiratory therapist and the physician is made aware that the patient is currently smoking. Identification of the above issues may be beneficial in preventing exacerbations resulting in emergency room visits or hospital admissions. A follow-up to this issue will be to see the number of patients receiving additional testing and if their results reveal the need for supplementary therapy.

Surveying

A key component of the M.O.R.E. Program is a follow-up survey in which patients receive a phone call following 30 days after their initial respiratory modality set-up. The purpose of the survey is to identify the effectiveness of the program. The review allows Medical Service Company personnel to follow-up with patients and identifies any clinical, technical or educational issues. A review of 227 patient follow-up surveys was done to determine the value of the program. A series of key questions in categories having to do with symptoms, understanding of equipment, activities of daily living, follow-up physician appointments, and recent emergency room visits or hospital admissions. If a patient is having any problems their respiratory therapist is notified and immediately follows-up. This has proven to be an effective strategy in addressing any potential issues that may lead to the deterioration of the patient's condition. A focal point of the survey shows that emergency room visits were at 0.9% of patients and 4.9% of patients were readmitted to the hospital ($p<0.001$). Of those patients readmitted 46% of had a primary respiratory diagnosis. Table 5 shows the results of key follow-up questions.

Results

The M.O.R.E. Program provides a distinct approach to treating patients receiving respiratory care in the home. It provides a way to treat patients more frequently that exhibit a high degree of illness. The program allows for assessment, increased patient contact and information flow to the physician. While there is more than one approach to successfully treating patients we feel this method addresses one of the more effective means of providing respiratory care in the home in a time of limited resources and reimbursement.

References

1 Dubow J. Fact Sheet 197. AARP Public Policy Institute July 2010.
2 Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee for service program. N Eng J Med 2009; 360 (14):1418 –1428.
3 Centers for Medicare & Medicaid Services website: Available at cms.gov/ section 3025 of the Affordable Care Act.
4 Hoyert DL, Xu JQ. Deaths: preliminary data for 2011. Natl Vital Stat Rep. 2012;61(6):165. Hyattsville, MD: National Center for Health Statistics.2012.
5 Brown GL, Dunne PJ. COPD in-patient care: time for a new paradigm. AARC Times Nov 2011:35(11)34.
6 Pittsburgh Regional Health Initiative (PRHI): A manual for preventing hospitalizations Jan 2011.
7 Carlin BW, Wiles K, Easley D, Rees N. Transition of care program and rehospitalization rates for patients with COPD who require home oxygen therapy following an exacerbation: an update (Abstract). Respir Care 2011; 56(10):1691.
8 Kaufman LM, Smith AP, Effect of a home care respiratory therapist education program on 30 day hospital readmissions of COPD patients (Abstract). Respir Care 2011; 56(10):1691.

Surfactant Therapy for Respiratory Distress Syndrome

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Respiratory distress syndrome (RDS) aka hyaline membrane disease (HMD) is observed in prematurely born infants (<37 weeks gestation) with risk and severity inversely proportional to the gestational age of the infant. Data on RDS dates back to 1929 when Kurt von Neergaard performed experiments suggesting the presence of pulmonary surfactant and its relevance to the newborn's respiratory status. About 30 years later, Mary Ellen Avery and Jere Mead published convincing evidence that preterm neonates dying of RDS had a deficiency of pulmonary surfactant. The first trials of nebulized synthetic (protein free) surfactant to treat RDS were published soon after the death of President John F. Kennedy's son. However, these trials were unsuccessful, and in the early 1970's Goran Enhorning and Bengt Robertson demonstrated that natural surfactants were effective in an immature rabbit model of RDS. Soon after, Forrest Adams showed that a natural surfactant was also effective in an immature lamb model. Two years later Tetsuro Fujiwara published a seminal article reporting the responses of 10 preterm infants with RDS to a bolus of modified bovine surfactant.

During the 1980's there were numerous randomized controlled trials of many different natural and synthetic surfactants, after which natural surfactants were found to be superior. Since the introduction of surfactant, the odds of death in the hospital for very-low-birth weight infants (<1500g) has been reduced by 30-40 percent. Eighty percent of the decline in the U.S infant mortality rate between 1989 and 1990 can be attributed solely to the use of surfactant. We know that insufficient surfactant leads to reduced pulmonary compliance and increased surface tension which leads to an increased risk of alveoli and terminal saccules collapse that then causes a decrease in total surface area for gaseous exchange. Some degree of RDS can be expected in up to 60 percent of infants born at 30 weeks gestation and less.

Animal-derived or natural surfactant is similar in morphology to that of human surfactant and is currently the choice compared to protein-free synthetic surfactant (colfosceril [Exosurf]). There are three commonly used and researched natural surfactants.

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Berectant (Survanta) is extracted from minced bovine lung with addition of Dipalmitoylphosphatidylcholine (DPPC), palmictic acid and tripalmitin. Calfactant (Infasurf) is another bovine product extracted by broncho-alveolar lavage that contains DPPC, surfactant protein SP-B, and SP-C. Compared to Beractant, Calfactant has higher phospholipid content (95% vs 84%) and a greater SP-B concentration, which suggests improved surfactant effect. Poractant (Curosurf) is derived from minced porcine lungs and undergoes purification procedures to remove neutral lipids and contains SP-B and SP-C. It consists of 99% polar lipids and 1% low molecular weight hydrophobic proteins. This superior concentration of phospholipid (200 mg/kg/initial dose) is constructed to potentially maximize efficacy. There are recent published guidelines surrounding the use of surfactant in the treatment of RDS in the United States and Europe.[1,2] The table compares and contrasts the three commercially available natural surfactant as well as the newly approved synthetic surfactant (discussed below).

However, due to the cost, possibility of anaphylaxis, inconsistent efficacy and risk of pathogen contamination, the search for a synthetically derived surfactant with the same effectiveness as the natural continues. In 2012, the Food and Drug Administration approved Lucinactant (Surfaxin) for the prevention of RDS in premature infants at high risk. It is a totally synthetic formulation consisting of phospholipids, a fatty acid, and sinapultide (KL4 peptide, a 21-amino acid hydrophobic synthetic peptide resembling SP-B). Both short and long term data (1 year follow-up) showed Lucinactant to be as effective (or even better) as other natural surfactants (Beractant and Poractant).[3] There currently is no agreed standard of care in terms of which surfactant neonatologists prefer, as well as use, even though in Europe, Poractant appears to be the preferred choice.[2] Most use of surfactant choice is dependent on the facility and which of the 3 natural derived surfactants they stock in house. Other recent debate of interest is the route of surfactant administration as there are few European trials demonstrating effective surfactant administration via a feeding tube into the trachea without need for intubation.[4] Additionally, more interest is devoted recently to study whether surfactant can be effectively delivered via nebulization.[5] At present, more evidence is required to determine whether one surfactant preparation is superior to the other as well as whether route of administration can alter efficacy.

Table 1: Composition and dosage of commercially available surfactants.[1]

Surfactant	Main Phospholipid	Proteins	Phospholipid Concentration	Dose/kg	Phospholipid per dose per kg
Natural					
Beractant (Survanta)	DPPC & PG	SP-B (<0.1%) & SP-C	25 mg/ml	4 ml/kg	100 mg/kg
Calfactant (Infasurf)	DPPC & PG	SP-B (0.7%) & SP-C	35 mg/ml	3 ml/kg	105 mg/kg
Poractant (Curosurf)	DPPC& PG	SP-B (0.6%) & SP-C	80 mg/ml	2.5 ml/kg (I) 1.25 ml/kg (S)	200 mg/kg 100 mg/kg
Synthetic					
Lucinactant (Surfaxin)	DPPC &POPG	KL4 peptide as SP-B	30 mg/kg	5.8 ml/kg	175 mg/kg

DPPC, dipalmitoyl phosphatidylcholine; PG, phosphatidylglycerol; POPG, palmitoyloleyl phosphatidylglycerol; SP surfactant protein; I, initial; S, subsequent; SP-C concentration is ~1% in all natural surfactants.

References

1 Polin RA, Carlo WA; Committee On Fetus And Newborn. Surfactant replacement therapy for preterm and term neonates with respiratory distress. Pediatrics. 2014 Jan;133(1):156-63. doi: 10.1542/peds.2013-3443. Epub 2013 Dec 30.

2 Sweet DG, Carnielli V, Greisen G, et al. European consensus guidelines on the management of neonatal respiratory distress syndrome in preterm infants—2013 update. Neonatology. 2013;103(4):353-68. doi: 10.1159/000349928.

3 Moya F, Sinha S, Gadzinowski J, et al. SELECT and STAR Study Investigators. One year follow-up of very preterm infants who received lucinactant for prevention of respiratory distress syndrome: results from 2 multicenter randomized, controlled trials. Pediatrics. 2007;119(6).Available at: www.pediatrics.org/cgi/content/full/119/6/e1361

4 Göpel W, Kribs A, Ziegler A, et al. Avoidance of mechanical ventilation by surfactant treatment of spontaneously breathing preterm infants (AMV): an open-label, randomised, controlled trial. Lancet. 2011 Nov 5;378(9803):1627-34. doi: 10.1016/S0140-6736(11)60986-0.

5 Pillow JJ, Minocchieri S. Innovation in surfactant therapy II: surfactant administration by aerosolization. Neonatology. 2012;101(4):337-44. doi: 10.1159/000337354.

Perioperative Implementation of Continuous Positive Airway Pressure: A Review of the Considerations

Suzanne Karan, Shira Black and Falan Mouton

Abstract

OSA patients present unique challenges in the perioperative period. They routinely require more monitoring, oxygen therapy, unplanned ICU admissions, longer hospital stays, and have more adverse events than healthy counterparts. Some data suggest that perioperative CPAP use is associated with reduced morbidity and mortality of patients with OSA, and yet its application remains inconsistent. This review aims to summarize existing literature on the perioperative use of CPAP, identify barriers to its implementation, and begin defining an algorithm for the practical application of peri-operative CPAP.

Introduction

Obstructive sleep apnea (OSA) remains an underappreciated cause of morbidity and mortality in the general population. The syndrome affects 2%-9% of women and 4%-24% of men [1] with 80% or more of the population as yet undiagnosed [2]. OSA occurs when a compromised airway collapses, disrupting the flow of air during sleep. With the ensuing hypoxia and hypercarbia, the respiratory drive is stimulated, a stronger inspiratory effort is made, and the cycle repeats itself throughout the night. The gold standard for diagnosis of OSA remains the polysommnogram (PSG). During the sleep study a patient must be observed to have at least five or more apneas or hypopneas per hour of sleep [3] which last at least 10 seconds each. Severe OSA is generally defined as 30 or more apneic and hypopneic events per hour [4].

Post-operative changes amplify the disease [5-9]. Residual anesthetics weaken the muscles of the upper airway [10, 11] and depress the respiratory drive [12, 13]. Thus, a mild pre-operative case of OSA can easily become a severe post-operative one. OSA patients require more monitoring, oxygen therapy, and unplanned ICU admissions [14]. When compared with controls, OSA patients have longer hospital stays and more adverse events than non-OSA patients [15]. Additionally, an OSA diagnosis is associated with increased post-operative complications, including, but not limited to: airway obstruction, cardiac arrhythmias, hypoxemia, encephalopathy and death [14, 16]. Adverse outcomes related to respiratory events remains the largest class of injuries reported in the American Society of Anesthesiology Closed Claims study—in cases involving general anesthesia, sedation and monitored anesthetic care (MAC) [17].

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It is clear from the medical literature that continuous positive airway pressure (CPAP) immediately reverses sleep-related apnea and hypopnea by acting as a pneumatic splint [18, 19]; though, the benefit of CPAP during the post-operative period, remains the subject of debate [20]. While some studies have suggested a role for CPAP for diagnosed and suspected OSA patients post-operatively, there is still a paucity of evidence on which to develop a protocol for its standardized utility.

Though the benefit of CPAP would seem intuitive, its application remains the subject of debate [20]. How do we identify the undiagnosed OSA patient? Is it necessary for every patient with a diagnosis of OSA to receive CPAP, or can it be tailored to the severity of the disease and the procedure. Should CPAP be applied pre-operatively, post-operatively, or both? If a patient has a diagnosis of OSA but does not use CPAP at home should it mandatorily be applied perioperatively? This review paper aims to summarize the existing literature on the perioperative use of CPAP and to start defining an algorithm for its practical application. Additionally, it aims to address gaps in our knowledge and practice in order to direct further research.

Post-op CPAP reduces complications

It has been shown in several studies that OSA patients have a greater incidence of post-operative complications [15, 21, 22]. However, the post-operative application of CPAP has not been proven to be curative of these problems in a randomized double-blinded trial. In an unblinded study by Squadrone et al., CPAP application to treat hypoxemia after major abdominal surgery significantly reduced re-intubation rates, and correlated with a reduction in ICU length of stay, post-operative pneumonia, infection, sepsis, and death. Another review of 16 cases [23] reported a reduction in post-operative complications in patients who used CPAP therapy pre-operatively, upon extubation, and nearly continuously for 24 to 48 hours after surgery. While supplemental oxygen alone may prove beneficial for many patients with hypoxemia, its use should be cautioned in the surgical OSA patient population, as it may reduce the hypoxic respiratory drive, thereby increasing the incidence and duration of apneic episodes [24].

The severity of OSA may predict the post-operative course

Though presence of signs and symptoms of OSA are generally elicited during the pre-operative interview, it is unknown whether the severity of the disease predicts a worse outcome. If a patient's home CPAP setting is 12 cm H2O, is he/she worse off

than one whose setting is only 5 cm H2O? Or, are both of these patients better off than someone who needs CPAP but does not use it?

Schwartz and colleagues identified a means to predict the potential for upper airway collapse by capitalizing on the reverse of CPAP – namely, by using negative airway pressure to measure the collapsibility of the upper airway [25]. In short, the theory is based upon the modeling of the upper airway after a Starling resistor; being a collapsible tube between two non-collapsible segments. With this reasoning, if positive airway pressure splints open the upper airway in a dose dependent fashion, then it can be theorized that negative airway pressure application potentiates the collapse of the upper airway in a dose dependent fashion. The level of negative airway pressure beyond which airway collapse occurs is called the critical pharyngeal pressure (Pcrit). The value of the Pcrit has been validated and reproduced across many research studies as a predictor of airway compromise that varies by patient factors [26], drugs [13, 27-30], and position of head and body [31]. This value has yet to be validated in the clinical setting, but Eastwood and colleagues correlated the value of the Pcrit to the severity of AHI in a small cohort [32]. Though it remains unknown whether the absolute AHI or level of CPAP used at home predicts worse outcomes perioperatively, the measure of Pcrit holds promise as a laboratory method to tease out the variables that interact in causing more vulnerability to the upper airway.

Another measure of severity of OSA that has predicted outcomes is the oxygen desaturation index (ODI). A change of 4% from baseline (ODI-4%) has been identified in the literature as differentiating patients who have worse post-operative outcomes. In a study by Hwang et al., patients with ODI4% of five or more times per hour (ODI4% 2:5), had significantly greater incidences for complications than those with ODI4%<5. Patients with ODI4%2:5 had prolonged PACU stays as well [22].

How do we determine when to apply post-operative CPAP and in whom?

Even without a firm evidence base, experts still recommend post-operative application of CPAP in select patient groups [33]. It seems obvious that those who use CPAP at home would make up the largest group of post-operative CPAP users, and then additional patient populations would be identified to benefit from this treatment. But, even in home CPAP users there remain questions regarding titration of pressure and duration of use to confer the greatest perioperative benefit. Thus, we are left with many more questions than answers when considering the determination of CPAP use post-operatively.

There are many stratifications of OSA patients

In considering the selection of patients for CPAP use post-operatively, we will break down the following sections by:

1 Home users of CPAP,
2 Non-compliant patients, and
3 Suspected OSA patients who have never been prescribed CPAP.

Contraindication to CPAP use post-operatively will also be touched upon. Finally, we considered a separate indication for CPAP use during ambulatory cases that require sedation.

1. Home CPAP Users

The 2006 ASA guidelines regarding the perioperative care of OSA patients state that patients who use CPAP at night should use CPAP post-operatively. It also states that OSA patients should receive monitoring in additional duration and frequency post-operatively. While the latter recommendation seems vague in establishing timing for the care of these patients, it would seem that the former recommendation is straightforward. As we start to devise a protocol aimed at implementing the use of CPAP appropriately in the post-operative period, it would seem that the easiest population to implement post-op CPAP use within is precisely in those who use CPAP at home.

One study [34] demonstrated that when patients were screened for home CPAP/BiPAP use, previous positive test for OSA, snoring, or daytime sleepiness, and evaluated post-operatively for respiratory compromise by a respiratory therapist in the PACU and placed on CPAP when necessary, the hospital eliminated all cases of acute respiratory compromise during the treatment interval. It may also seem obvious that those patients who use CPAP at home would naturally be expected to wear this device while in the hospital and in bed. In a study by Ramachandran et al., 83% of patients who used CPAP at home brought their machines to the hospital for use. However, another study by Liao et al., showed only 49% of OSA patients to actually receive CPAP post-operatively [14]. In order to encourage perioperative use of CPAP amongst home using patients, some hospitals have implemented a service that checks CPAP machines pre-operatively, and patients are called to bring in their own machines and masks.

It should be noted that even when CPAP machines are brought in from home for hospital use, the settings may still need to be adjusted to account for the increased collapsibility of the airways. For example, one study showed a lack of CPAP efficacy in the first 24 hours post-operatively when patients used their CPAP at the polysomnographic-prescribed pressure settings [16]. However, this finding may have been the result of an inadequate post-operative CPAP titration, as narcotics and anesthesia decrease upper airway tone, and their administration may necessitate increased levels of CPAP in the post-operative period. This consideration was taken into effect by Ramachandran et al., as they implemented the use of a respiratory therapist who was charged with titrating CPAP level to effect in their study [34].

2. Patients Who Do Not Use Their Prescribed CPAP

Most patients who have been prescribed home CPAP are somewhat non-compliant with this therapy [35]. Some studies cite 50% to 80 % of OSA patients who are prescribed to use CPAP actually using their device [36, 37]. And while Liao et al., reported that 63% of patients who presented for elective surgical procedures were compliant with their CPAP [14], the average duration of use is generally 3.4 to 4.5 hours per night [38]. Of 65 diagnosed OSA patients, Gupta reported only 33 to use CPAP pre-operatively [15]. Patient CPAP compliance is generally hindered by the obtrusive nature of the device [19].

Currently, we lack a robust evidence base to support the prescription of CPAP in the hospital for all patients who are non-compliant with its use at home. One can certainly argue that patients who have been prescribed CPAP, but do not use it, are more at risk than those who do use it. The risks involved include suboptimization of sleep and the chronic toll of nighttime hypoxemia in causing cardiac side effects such as arrhythmias and hypertension, to include a few. And while

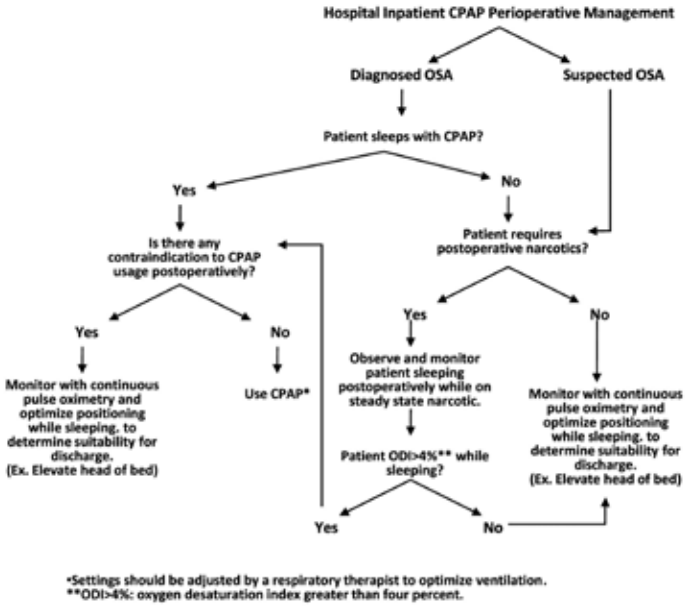

Figure 1. This algorithm is meant to guide the management for application of post-operative CPAP. Although its efficacy has not been proven in randomized controlled trials, it remains a logical approach for the surgical patient based on the review of the literature cited in the present article.

it seems reasonable to prescribe CPAP for those patients who need it in preparation for elective surgery, we still do not have an evidence base to guide the acceptable duration of treatment. On the flip side, these patients would probably also benefit from post-operative application of CPAP for select cases; though, we do not have the evidence, either, to support its standard use. Hospitals that are considering implementing protocols for CPAP application post-operatively should take into account the availability of the resources to titrate the appropriate level of CPAP and the follow up of these patients after discharge with the pulmonary medicine service. In our institution, any patient who receives an order for the "new" application of CPAP needs to also receive a consult from the critical care service in order to ensure continuity of post-operative care.

3. The Suspected OSA Patient

The fact remains, though, that OSA is notoriously under diagnosed. In the perioperative setting, Bolden identified 438 of a total of 22,067 (2%) surgical patients to have known or suspected OSA [16]. Recognizing patients with OSA is critical in determining who could potentially benefit from CPAP. In the literature, patients suspected to have OSA (identified because they report a history of snoring among other symptoms) are often lumped into the moderate-severe OSA patient category with fairly reasonable correlation as described by Young and colleagues [39]. However, the literature varies in its definition of the "suspected OSA" group and this makes the review of treatment effects difficult to interpret. Chung and colleagues have established well validated screening methods for standardizing the identification of the suspected OSA group. If these patients are properly identified pre-operatively, the need for post-operative CPAP would be more easily implemented. Unfortunately, most of these patients are still being identified during post-operative quality improvement review of a poor outcome. Once identified, this group of patients should be treated similarly to those who have been prescribed CPAP but do not use it.

The role for CPAP during sedation remains poorly defined

The majority of sedations in the United States are overseen by non-Anesthesiologists, such as Gastroenterologists and Radiologists and administered by nurses. There are many reports of the safe administration of these sedations, even with drugs not specifically approved for this indication, such as propofol [40, 41]. However, the majority of the morbidity and mortality related to sedation practice is the result of respiratory compromise. There is a substantial body of evidence that supports the notion that the respiratory vulnerability does not only lie in the central control of respiration (cortical drive), but actually moreover in the maintenance of a patent upper airway. Upper airway collapse has been reliably evidenced in the laboratory during moderate sedation even in healthy non-OSA subjects [12, 42]. Thus, OSA patients who already collapse their airways during "normal" sleep would likely be at increased risk of heightened airway collapsibility when normal sleep interacts with sedation/narcosis. In the gastrointestinal endoscopy literature, OSA has been diagnosed in patients who have been noted to snore during their sedation for outpatient colonscopy [43, 44]. Some have advocated for the application of CPAP during preoxygenation and as an adjunct to sedation during regional anesthesia [45]. During induction of anesthesia, for example, preoxygenation with 100% oxygen until the exhaled or end-tidal oxygen is at least 90% can be accomplished by using CPAP at 10 cm H_2O for 3 to 5 min with the patient in a 25° head-up position [46]. This clinical management pearl is applicable to many at-risk patients presenting for sedation (mostly performed by non-anesthesiologists) who would benefit from some degree of upper airway splinting with proper positioning and not just by the application of oxygenation. Others have even advocated the use of a jaw thrust device [47] and other airway maintenance maneuvers (including CPAP) during upper endoscopies in order to maintain airway patency [48]. Future studies to validate the effectiveness of CPAP to ensure safer sedation practices are needed.

Post-op CPAP is not without risk

While it seems like we made the argument for everyone being on CPAP who has a diagnosis or suspicion for OSA, there are reported contraindications and hesitations for its use in the immediate post-operative period. For instance, CPAP has not been universally accepted for patients following upper gastrointestinal surgery because of concerns that pressurized air will inflate the stomach and proximal intestine, resulting in anastomotic disruption and post-operative nausea and vomiting [49]. Others, however, have recommended its use specifically for these cases [50] with good evidence of it not increasing the risk of developing post-operative anastomotic leaks [51]. There has yet to be a general consensus for its benefit outweighing the hypothesized risks. Recommended practice would be to consult with the surgeon before implementing CPAP post-operatively so the hypothetical risks and benefits may be weighed by the entire health care team on a case by case basis. If CPAP is indeed contraindicated (i.e specific facial surgeries), these patients must be monitored closely in the appropriate setting and may require prolonged intubation, as well.

Taking this all into account, the following is an algorithm (Figure 1) for determining CPAP use post-operatively. Stratification of CPAP use by post-operative need for narcotic medication was considered as per the ASA guidelines concerning the perioperative care of OSA patients [52].

References

1 Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep 1997; 20: 705-6.

2 Stierer TL, Wright C, George A, Thompson RE, Wu CL, Collop N. Risk assessment of obstructive sleep apnea in a population of patients undergoing ambulatory surgery. J Cl in Sleep Med 20 10; 6: 467-72.

3 Gould GA, Whyte KF, Rhind GB, et al. The sleep hypopnea syndrome. Am Rev Respir Dis 1988; 137: 895-8.

4 The Report of an American Academy of Sleep Medicine Task Force. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep 1999; 22 : 667-89.

5 Benumof JL. Obstructive sleep apnea in the adult obese patient: implications for airway management. Anesthesiol Clin North Am 2002; 20: 789-811.

6 Marshall BE, Wyche MQ, Jr. Hypoxemia during and after anesthesia. Anesthesiology 1972; 37: 178-209.

7 Catley OM, Thornton C, Jordan C, Lehane JR, Royston O, Jones JG. Pronounced, episodic oxygen desaturation in the postoperative period: its association with ventilatory pattern and analgesic regimen. Anesthesiology 1985; 63 : 20-8.

8 Hines R, Barash PG, Watrous G, O'Connor T. Complications occurring in the postanesthesia care unit: a survey. Anesth Analg 1992; 74: 503-9.

9 Hi llman DR, Loadsman JA, Platt PR, Eastwood Pro Obstructive sleep apnoea and anaesthesia. Sleep Med Rev 2004; 8: 459-71.

10 Hillman DR, Walsh JH, Maddison KJ, et al. Evolution of changes in upper airway collapsibility during slow induction of anesthesia with propofol. Anesthesiology 2009; III: 63-71.

11 Eikermann M, Fassbender P, Zaremba S, et al. Pentobarbital dosedependently increases respiratory genioglossus muscle activity while im pairing diaphragmatic function in anesthetized rats. Anesthesiology 2009; 110: 1327-34.

12 Bailey PL, Pace NL, Ashburn MA, Moll JW, East KA, Stanley TH. Frequent hypoxemia and apnea after sedation with midazolam and fentanyl. Anesthesiology 1990; 73: 826-30.

13 Norton JR, Karan SB, Bailey PL, Voter W, Palmer LS, Ward OS. The effects and interaction of sedative doses of intravenous midazolam or propofol, and hypoxia, on upper airway obstruction. Anesthesiolgy (abstract). ASA. Ref Type: Abstract 2003.

14 Liao P, Yegneswaran B, Vairavanathan S, Zilberman P, Chung F. Postoperative complications in patients with obstructive sleep apnea: a retrospective matched cohort study. Can J Anaesth 2009; 56: 819-28.

15 Gupta RM, Parvizi J, Hanssen AD, Gay PC. Postoperative complications in patients with obstructive sleep apnea syndrome undergoing hip or knee replacement: a case-control study. Mayo Clin Proc 200 I; 76: 897-905.

16 Bolden N, Smith CE, Auckley O, Makarski J, Avula R. Perioperative complications during use of an obstructive sleep apnea protocol following surgery and anesthesia. Anesth Analg 2007; 105: 1869-70.

17 Bhananker SM, Posner KL, Cheney FW, Caplan RA, Lee LA, Domino KB. Injury and liabi lity associated with monitored anesthesia care: a closed claims analysis. Anesthesiology 2006; 104: 228-34.

18 Sullivan CE, Issa FG, Berthon-Jones M, Eves L. Reversal of obstructive sleep apnoea by continuous positive airway pressure applied through the nares. Lancet 1981; 1: 862-5.

19 Flemons WW. Clinical practice. Obstructive sleep apnea. N Engl J Med 2002; 347: 498-504.

20 Drummond GB, Stedul K, Kingshott R, et al. Automatic CPAP compared with conventional treatment for episodic hypoxemia and sleep disturbance after major abdominal surgery. Anesthesiology 2002; 96: 817-26.

21 Riley RW, Powell NB, Guilleminault C, Pelayo R, Troell RJ, Li KK. Obstructive sleep apnea surgery: risk management and complications. Otolaryngol Head Neck Surg 1997; 117: 648-52.

22 Hwang D, Shakir N, Limann B, et al. Association of sleep-disordered breathing with postoperative complications. Chest 2008; 133: 1128-34.

23 Rennotte MT, Baele P, Aubert G, Rodenstein DO. Nasal continuous positive airway pressure in the perioperative management of patients with obstructive sleep apnea submitted to surgery. Chest 1995; 107: 367-74.

24 Fletcher EC, Munafo DA. Role of nocturnal oxygen therapy in obstructive sleep apnea. When should it be used? Chest 1990; 98: 1497-504.

25 Schwartz AR, Smith PL, Wise RA, Gold AR, Permutt S. Induction of upper airway occlusion in sleeping individuals with subatmospheric nasal pressure. J Appl Physiol 1988; 64: 535-42.

26 Gleadhill IC, Schwartz AR, Schubert N, Wise RA, Permutt S, Smith PL. Upper airway collapsibility in snorers and in patients with obstructive hypopnea and apnes. Am Rev Respir Dis 1991; 143: 1300-3.

27 Litman RS, McDonough JM, Marcus CL, Schwartz AR, Ward DS. Upper airway collapsibility in anesthetized children. Anesth Analg 2006; 102: 750-4.

28 Litman RS, Hayes JL, Basco MG, Schwartz AR, Bailey PL, Ward DS. Use of dynamic negative airway pressure (DNAP) to assess sedative-induced upper airway obstruction. Anesthesiology 2002; 96: 342-5.

29 Eastwood PR, Szollosi I, Platt PR, Hillman DR. Collapsibility of the upper airway during anesthesia with isoflurane. Anesthesiology 2002; 97: 786-93.

30 Eastwood PR, Platt PR, Shepherd K, Maddison K, Hillman DR. Collapsibility of the upper airway at different concentrations of propofol anesthesia. Anesthesiology 2005; 103: 470-7.

31 Isono S, Tanaka A, Nishino T. Lateral position decreases collapsibility of the passive pharynx in patients with obstructive sleep apnea. Anesthesiology 2002; 97: 780-5.

32 Eastwood PR, Szollosi I, Platt PR, Hillman DR. Comparison of upper airway collapse during general anaesthesia and sleep. Lancet 2002; 359: 1207-9.

33 A Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 1996; 84: 459-71.

34 Ramachandran SK, Kheterpal S, Haas CF, Saran KA, Tremper KK. Automated notification of suspected obstructive sleep apnea patients to the perioperative respiratory therapist: a pilot study. Respir Care 2010; 55: 414-8.

35 Lindberg E, Berne C, Elmasry A, Hedner J, Janson C. CPAP treatment of a population-based sample--what are the benefits and the treatment compliance? Sleep Med 2006; 7: 553-60.

36 American Thoracic Society. Indications and standards for use of nasal continuous positive airway pressure (CPAP) in sleep apnea syndromes. Official statement adopted March 1944. Am J Respir Crit Care Med 1994; 150: 1738-45.

37 McArdle N, Devereux G, Heidarnejad H, Engleman HM, Mackay TW, Douglas NJ. Long-term use of CPAP therapy for

sleep apnea/hypopnea syndrome. Am J Respir Crit Care Med 1999; 159: 1108-14.
38 Weaver TE, Maislin G, Dinges DF, et al. Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. Sleep 2007; 30: 711-9.
39 Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med 1993; 328: 1230-5.
40 Bitar G, Mullis W, Jacobs W, et al. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures. Plast Reconstr Surg 2003; 111: 150-6.
41 Walker JA, McIntyre RD, Schleinitz PF, et al. Nurse-administered propofol sedation without anesthesia specialists in 9152 endoscopic cases in an ambulatory surgery center. Am J Gastroenterol 2003; 98: 1744-50.
42 Norton JR, Ward DS, Karan S, et al. Differences between midazolam and propofol sedation on upper airway collapsibility using dynamic negative airway pressure. Anesthesiology 2006; 104: 1155-64.
43 Sharma VK, Galli W, Haber A, et al. Unexpected risks during administration of conscious sedation: previously undiagnosed obstructive sleep apnea. Ann Intern Med 2003; 139: 707-8.
44 Sharara AI, El Zahabi L, Maasri K, et al. Persistent snoring under conscious sedation during colonoscopy is a predictor of obstructive sleep apnea. Gastrointest Endosc 2010; 71: 1224-30.
45 Nozaki-Taguchi N, Isono S, Nishino T, Numai T, Taguchi N. Upper airway obstruction during midazolam sedation: modification by nasal CPAP. Can J Anaesth 1995; 42: 685-90.
46 Herriger A, Frascarolo P, Spahn DR, Magnusson L. The effect of positive airway pressure during pre-oxygenation and induction of anaesthesia upon duration of non-hypoxic apnoea. Anaesthesia 2004; 59: 243-7.
47 Mandel J. Airway appliances in endoscopy. Tech Gastrointest Endosc 2009; 11: 188-91.
48 Atkins J. Ventilation strategies in gastrointestinal endoscopy. Tech Gastrointest Endosc 2009; 11: 192-6.
49 Meng L. Postoperative nausea and vomiting with application of postoperative continuous positive airway pressure after laparoscopic gastric bypass. Obes Surg 2010; 20: 876-80.
50 Oberg B, Poulsen TD. Obesity: an anaesthetic challenge. Acta Anaesth Scand 1996; 40: 191-200.
51 Verse T. Bariatric surgery for obstructive sleep apnea. Chest 2005; 128: 485-7.
52 Practice guidelines for the perioperative management of patients with obstructive sleep apnea: a report by the american society of anesthesiologists task force on perioperative management of patients with obstructive sleep apnea. Anesthesiology 2006; 104: 1081-93.

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NIOV System Gives Senior His Active Life Back

Chris Campbell

Looking back on most of the life of Dr James Phipps, one thing is clear — the man never slowed down.

As both a father of four active sons and a physician — board certified in orthopedic surgery — Dr Phipps was kept on his toes. After he received his medical training in St. Louis, he undertook new challenges, such as supporting the war effort through the "doctor draft" program, practicing in Baltimore, Staten Island and eventually San Francisco where he became an assistant clinical professor at the University of California, San Francisco. Nothing, it seemed, could slow Dr Phipps down.

Nothing, except chronic obstructive pulmonary disease (COPD).

A pack-a-day smoker for 42 years, Dr Phipps quit the habit in 1984, but the damage was done. After he retired and grew older, he found his quality of life deteriorating, especially when it came to exercise. At the age 93, Dr Phipps has a history of (CHF), COPD, two myocardial infarctions, and atrioventricular nodal ablation following pacemaker placement.

According to a case study by Nishith Patel, RRT-NPS, Dr Phipps "experienced increasing dyspnea on exertion over the past few years that accelerated in 2011. He reported he could only walk short distances before having to sit to catch his breath. He used oxygen: 2 l/min via nasal cannula at rest, 4 l/min with exercise and 2 l/min during sleep with bi-level positive airway pressure."

These conditions make living an active life virtually impossible, as Dr Phipps desperately wanted to return to community activities and even do household chores. But his health wasn't just holding him back from being active. The respiratory symptoms were so severe due to pending heart failure, that he felt his life was perhaps ending, and so he entered hospice care.

In order to obtain a pulmonary consult, Dr Phipps signed himself out of hospice care. That pulmonary consult changed everything — especially with the help of the Breathe Technologies Non-Invasive Open Ventilation (NIOV) device.

According to Patel's findings, "unlike conventional noninvasive ventilation devices which are impractical for ambulatory use,[1] Breathe Technologies Non-Invasive Open Ventilation (NIOV) is one pound and driven by the patient's compressed oxygen supply. The NIOV device is designed to be a practical therapy

that promotes increased physical activity. In two prior clinical trials, severe COPD patients using the NIOV system showed increase in mean 6-minute walk tests of 57 (± 54) meters[2] and 36 (± 34) meters,[3] respectively. A third clinical trial that was conducted in a pulmonary rehabilitation setting, where severe COPD subjects reported that using the study device would result in less dyspnea, reduced work of breathing, and greater mobility and exercise endurance compared to their current oxygen systems."[4]

After pulmonary consultations for the management of his advanced COPD disease, Dr Phipps left hospice and was prescribed physical therapy to strengthen his skeletal muscle. Skeletal muscle dysfunction is a major contributing factor to the limitations in exercise capacity.[5] COPD patients commonly suffer

Chris Campbell is the Senior Editor for Respiratory Therapy.

from exertional symptoms of dyspnea and fatigue that can lead to an impaired health status. This functional loss may lead to a sedentary lifestyle, which ultimately results in deconditioning, said Patel. Inactivity due to exercise intolerance often results in a downward health spiral, including more frequent pulmonary exacerbations, and eventually early mortality.[6]

Dr Phipps underwent physical therapy and saw small improvements. According to Patel, "he did show promising signs of improvement with physical therapy, and therefore it was decided to initiate a formal pulmonary rehabilitation program to help him gain better control of his dyspnea. After weeks of pulmonary rehabilitation, he experienced a noticeable degree of relief from his respiratory insufficiency symptoms managing to perform mild, low intensity exercise without oxygen. However, he was still experiencing dyspnea, which he felt limited his exercise endurance and his ability to perform his activities of daily living."

Dr Phipps' stated goal was to perform vigorous exercise and his pulmonologist recommended the Breathe NIOV System. NIOV therapy was initiated in January 2012, and Dr Phipps noticed an immediate relief in his dyspnea. He continued to use the NIOV device during and after his pulmonary rehabilitation sessions, which has reduced his work of breathing and increased his exercise endurance. Dr Phipps performed vigorous exercise in the form progressive resistance training on a NuStep increasing his settings from 4 to 10.

Dr Phipps told his medical team that before NIOV therapy he often was "gasping for air when attempting to exercise needing to take a break every 5 minutes to catch his breath." He reports that with the help of the NIOV, he has optimized his ability to condition his lower extremities, which has made a noticeable impact on his stamina, balance, and performance in ADLs. He now engages in intense exercise training for one hour without stopping.

Dr Phipps has also reported a significant improvement in his strength and energy levels during upper-limb muscle training with the NIOV System, which has led to a shift in the respiratory load that has had the added benefit of strengthening his diaphragm, while improving thoracoabdominal synchrony and dyspnea.

In the six months prior to using NIOV, Dr Phipps reported two hospitalizations with an average length of stay of five days. Since initiation of NIOV therapy in January of 2012, Dr Phipps reports no hospitalizations due to respiratory symptoms or COPD exacerbations.

COPD makes exercise nearly intolerable, even though it is vital that people with the condition stay as active as possible.

The NIOV System, according to Patel, is designed to improve mobility and ambulation for patients with respiratory insufficiency.

Now, at the age of 93 and with the Breathe NIOV device, Dr Phipps is able to do many of the things he loves to do, from gardening to daily walks. He also is able to attend his exercise sessions three days per week.

References

1 Boudestein L., Rutten F., Cramer M., et al. The impact of concurrent heart failure on prognosis in patients with chronic obstructive pulmonary disease. Eur J Heart Fail 2009;11:1182-8.

2 Zeng Q., Jiang S. Update in diagnosis and therapy of coexistent chronic obstructive pulmonary disease and chronic heart failure. J Thorac Dis 2012;4(3):310-315

3 Evans R. Developing the model of pulmonary rehabilitation for chronic heart failure. Chronic Respiratory Disease. 2011;8(4):259-69.

4 Casaburi R. Activity Promotion: A Paradigm Shift for Chronic Obstructive Pulmonary Disease Therapeutics. Proc Am Thorac Soc. August 1, 2011 2011;8(4):334-337

5 Dreher M, Doncheva E., Schwoerer A., et al. Preserving oxygenation during walking in severe chronic obstructive pulmonary disease: noninvasive ventilation versus oxygen therapy. Respiration. 2009; 78(2):154-160

6 Hilling L, Cayou C, Wondka T, Kops R. Improved 6MWT distance with a highly portable non-invasive ventilator [abstract]. Am J Respir Crit Care Med 2010;181:A1198.

7 Garvey C, Hilling L, Cayou C, Escobar R, Heron G, McCabe L. Open, Noninvasive ventilation using a 1 lb ventilator, oxygen, and a low profile mask improves 6MWT distances in advanced COPD [abstract}. Am J Respir Crit Care Med 2011;183:A3971.

Biphasic Cuirass Ventilation as a Tool to Expedite Weaning from Positive Pressure Ventilation

Gary Mefford

Due to the many well known and documented side effects of positive pressure ventilation (PPV) and the potential of weaning efforts becoming serially unsuccessful with prolonged repeated efforts, all means possible should be undertaken to facilitate its discontinuance as expeditiously, and as safely possible if at all possible. Many techniques have been proposed to assist this process, one of the most effective is use of a standardized approach to weaning such as a unit or facility wide protocol that specifies parameters for initiation, monitoring, and progression, and that defines tolerance and intolerance as well as what ultimate success is considered. In most cases PPV discontinuance is achieved without delay and the patient is extubated and progressed relatively quickly without any special consideration for a more prolonged approach to weaning. A subset of patients' physiologic derangements; however will pose a challenge to the process, and it is for these patients that a weaning protocol as well as other special care considerations relative to their difficulty at resuming spontaneous ventilation are needed or prolonged mechanical ventilation (PMV) becomes a potential. In cases where discontinuance from PPV is not readily achievable there are several accepted causative factors that are known to frequently come into play physiologically, individually or in combination. As a tool to facilitate expeditious weaning from and discontinuance of PPV there is no adjunctive therapy that offers the potential of supporting the process and providing a means of overcoming these factors causing weaning failure as well as Biphasic Cuirass Ventilation (BCV). BCV offers an adjunctive therapeutic tool that can shorten the duration of the process of weaning from PPV and maximize the chances for success in both the short and long term.

PMV is a very cost, labor and risk intensive treatment. Patients who require long term support of ventilation are frequently interfaced with PPV via a tracheostomy or potentially if non-invasive, a facial mask interface. A tracheostomy requires constant maintenance and infection control measures. These requirements are not always well adhered to in home or long term care venues making those patient readily prone to infection and reinfection. Even under the most ideal conditions a tracheostomy is an open pathway to the lungs and significantly increases infection risk. Mask or Noninvasive PPV (NIPPV) patients will develop facial skin ulcers and may experience severe difficulty with secretion retention along with the many other challenges that come with this type of support when used for prolonged periods. BCV offers significant advantages to both the PPV and the NIPPV patient as an alternative. In many cases if the tracheostomy is placed only to secure a reliable interface to PPV and is not needed for airway protection, with implementation of BCV, goals for decannulation can be established, and carried out as the patient is transitioned to this form of support that will not require the direct tracheal interface. For the patient that is using NIPPV, BCV offers an alternative that naturally facilitates secretion clearance and uses the patient's natural ability to humidify their inspired gas while it poses no potential of ablating capillary blood flow to facial skin.

Weaning from PPV and PMV are both improved when the patient's lungs are well recruited and their airways are kept clear of secretions. BCV unlike any other form of pulmonary support offers a dual repeatable cycle of cuirass applied High Frequency Chest Wall Oscillation (HFCWO) or vibration that is followed in cycle by an assisted cough that is delivered via cuirass providing a very effective means of both lung recruitment and secretion/airway clearance.

This paper will describe the physiologic reasons for and the process of utilizing BCV to facilitate weaning from PPV, transitioning from NIPPV or from PPV and the many advantages of long term use of BCV as an alternative when long term support of ventilation and airway clearance is needed.

Table 2—*Causes of Ventilator Dependency*

Causes	Description
Neurologic controller	Central drive; peripheral nerves
Respiratory system	Mechanical loads: respiratory system mechanics; imposed loading
	Ventilatory muscle properties: inherent strength/endurance; metabolic state/nutrients/oxygen delivery and extraction
	Gas exchange properties: vascular properties and ventilation/perfusion matching
Cardiovascular system	Cardiac tolerance of ventilatory muscle work; peripheral oxygen demands
Psychological issues	

From Evidence-Based Guidelines for Weaning and Discontinuing Ventilatory Support.

Success with PPV discontinuance is a matter of balance between load elements that contribute to weaning intolerance and physiological readiness to assume these loads that contributes to weaning tolerance.

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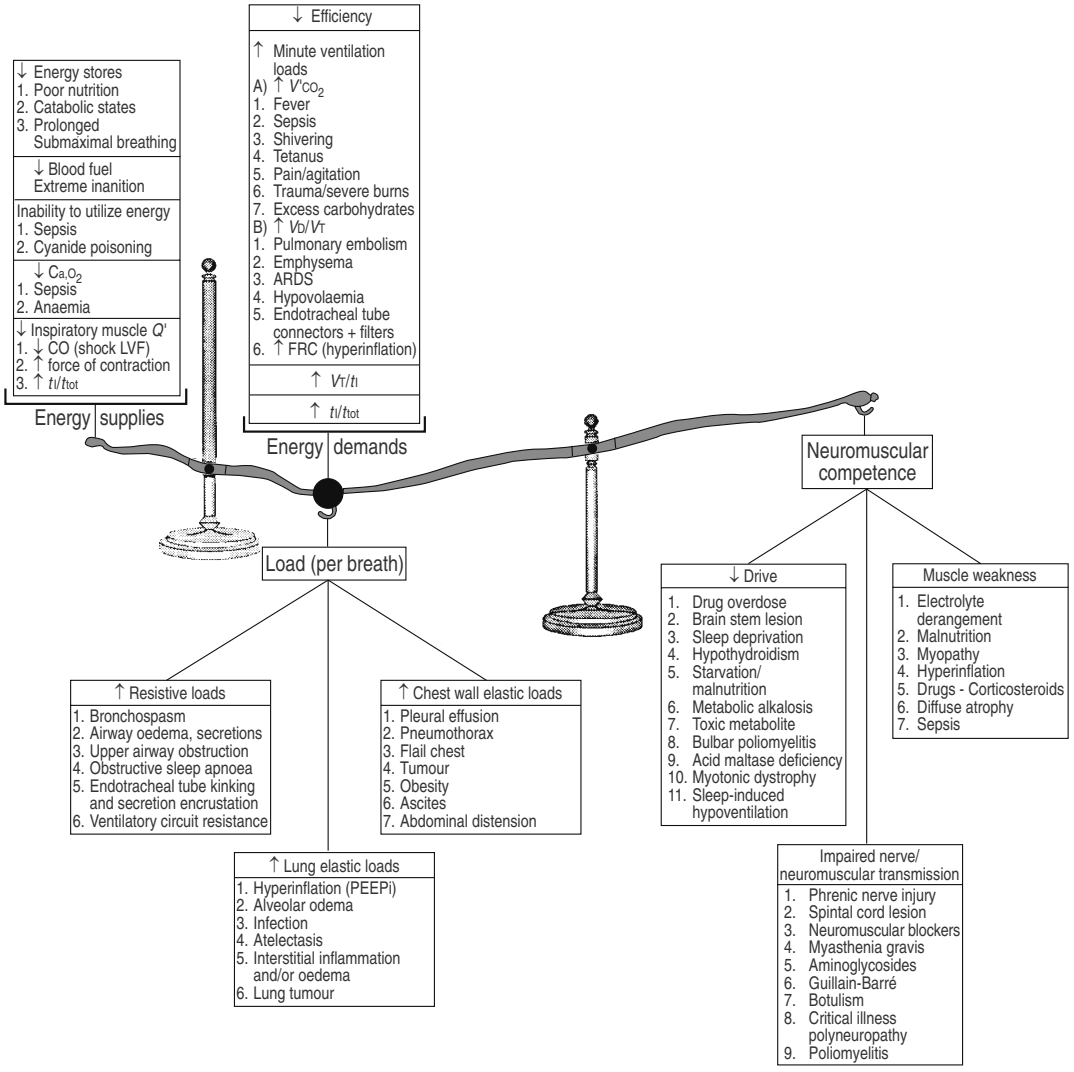

The various factors that can move the central hinge downwards by their fine interplay, leading to the inability to sustain spontaneous breathing and, thus, to weaning failure due to the imbalance between ventilatory needs and neurorespiratory capacity. Ca,O2: arterial oxygen content; Q': perfusion; CO: cardiac output; LVF: left ventricular failure; V'CO2: carbon dioxide elimination; VD/VT: physiological dead space/tidal volume ratio; ARDS: adult respiratory distress syndrome; PEEPi: intrinsic positive end-expiratory pressure.[3]

Causative factors for weaning failure are a mixed bag of a finite number of physiologic problems the majority of which can be quantified into several categories: Neurological, Respiratory System, Cardiovascular System and Psychological. Patients rarely present with weaning failure that represents purely one of these areas. BCV often offers a means to expedite weaning from PPV due to its therapeutic effects on primarily the respiratory and cardiovascular systems, but can be a positive factor for all of these areas. The use of BCV as part of the weaning process can move things forward when little else will.

Neurological based weaning failure issues are generally related to problems with central drive and peripheral nervous system. BCV has much to offer patients with these problems.

1 Central drive issues: These patients will generally need some level of assistance depending on the degree of the drive abnormality. BCV offers a means of supporting this type of patient that can be applied without the requirement for a mask or the invasive interface of a trach allowing them to be transitioned from PPV.
2 Peripheral nervous system issues: BCV will offer a means of partial or complete support that can decrease work of breathing during use. BCV also allows patient to eat, drink and speak if those capabilities are preserved while receiving full support. By virtue of the pulmonary muscle conditioning effect of BCV, if the patient has any nervous system communication with pulmonary muscle that remains intact, the muscles capabilities can be improved resulting in possibly greater ventilator free time and less hours per day of support needed. With time this effect may completely eliminating the need for support. Additionally these patients without BCV are very likely to experience gradually decreasing chest wall mobility or range of motion and secretion retention due to their neuro-muscular deficits. BCV can not only provide the support they need as described, but can provide good chest wall expansion, secretion mobilization as well as assistance of airway clearance with the built in high frequency chest wall oscillation (HFCWO) and assist cough modes when used for treatment. These beneficial factors of BCV offer the patient with peripheral nervous system compromise a means of part or full time respiratory support that is non-invasive and simpler to manage than trach and PPV or mask and NIPPV. These patients will have decreased need for acute hospital services when managed in the long term with BCV rather than PPV or NIPPV.

Respiratory System challenges to achieving discontinuance of PPV are the most frequent problems encountered when patients demonstrate intolerance of weaning. These fall into several sub categories all of which BCV can help with:

1 Imposed loads: Loads that tip the balance toward failure can come from several sources. These loads may come from within the respiratory system or may include those imposed by the artificial airway, secretions, the ventilation system or settings and/or dynamic hyperinflation. BCV provides multiple effects that facilitate the patients abilities to achieve separation from PPV. BCV can be established as a means of non-invasive support that can be implemented

while the artificial airway is present. Tidal volume can be managed by adjustment of the differential between the negative and positive pressures applied through the cuirass. With BCV work of breathing can be completely relieved providing an ability to rest the patient and replenish the pulmonary muscles that moves the process further from PPV and more towards support that eliminates imposed loads from the artificial airway and poor synchrony with PPV. Due to the natural way BCV moves air in and out of the lungs, secretion clearance is facilitated just by its use for support so clearance of retained secretions is a benefit of BCV even when the specific secretion clearance mode is not utilized and even more so when it is. Since BCV is set to produce a mean negative pressure against the thorax small airway dilation is one of the physiologic benefits. The increase in caliber of the small airways produces a decrease of dynamic hyperinflation, which can be enhanced further by the active expiratory phase. In many cases the Continuous Negative mode of BCV can produce adequate changes in factors on the tolerance side of the balance. For patients failing to separate successfully from PPV due to imposed mechanical loads beyond their ability to tolerate, BCV provides a means of altering the load to load tolerance balance to a point that allows the patient to have a better chance for success of separating from PPV.

2 Pulmonary muscle status including inherent strength and endurance at the time weaning is attempted: The muscles status as far as fuel available within the muscle, the muscle's ability to receive fuel and oxygen and its ability to utilize nutrients and clear the byproducts of muscle metabolism are the elements providing challenge in this area. BCV's unique means of moving air by working from the outside of the thorax provides an effect on the muscles of respiration of pumping them through their functional range. This is thought to produce an effect of improving nutrient and oxygen delivery and utilization within those muscles. Patients will demonstrate increased measures of pulmonary muscle strength and endurance following use of BCV. As strength and endurance are improved, the patient will demonstrate better tolerance of breathing without support and chances for weaning success is improved.

3 Functional status of the lungs ability to exchange gasses, which may be related to perfusion or ventilation deficits: Excessive shunt around alveoli collapsed from atelectasis or rendered ineffective by retained secretions or deadspace ventilation that is the result of poorly perfused regions of the pulmonary capillary bed can pose severe challenges to the patient having difficulty working to separate from PPV. BCV uses negative pressure around the thorax to produce lung inflation. During lung inflation areas of the lung collapsed with atelectasis are reinflated and restored to the ventilation portion of the ventilation: perfusion equation. BCV provides a potent means of clearing secretions from alveoli and airways. The negatively balanced pressures of BCV while being applied to the airways and alveoli is also applied to the vascular structures within the thorax. Pulmonary capillary perfusion is thereby enhanced, providing improvements to the perfusion side of the ventilation to perfusion equation.

Unlike any other form of ventilation BCV is actually therapeutic and creates improvements in the functional abilities of the lungs in both ventilation and perfusion improving exchange of gasses through use.

These benefits are a very powerful means of increasing the success of weaning efforts when the functional status of the lungs as gas exchange units have been compromised.

4 Secretions, airway inflammation, and bronchospastic airways: These can all pose difficulties for patients working to produce adequate gas exchange that may result in poor tolerance of the weaning process. Airways that are blocked by secretions, inflammation or bronchospasm will move the load tolerance to load intolerance balance into the intolerance zone very readily for patients who are having difficulty weaning from PPV successfully. BCV clears secretions as it ventilates and provides a secretion clearance mode with assistance of cough so secretions are more easily removed. The application of CNEP and/or properly balanced control or respiratory synchronized modes create an effect of increasing the caliber of the conducting and small airways which provide a decrease in the work of breathing thus the CO2 produced from that work and can shift the balance back to tolerance of spontaneous breathing that will allow success of weaning efforts.

Many times attempts at weaning patients from PPV will fail due to difficulties that are the result of cardiac based intolerance to the switch for various reasons. BCV offers these patients a means of overcoming many of these difficulties:

1 Poor cardiac response: Failure of the heart to respond adequately to the need for increased cardiac output to increasing demand of work of breathing can cause the weaning process to be delayed or stalled. BCV has been demonstrated to improve stroke volume and ejection fraction in patients with various types of cardiac compromise. As the requirement for increased cardiac output develops as the patient begins to resume their own work of breathing the support of cardiac function can assist these patients through this sometimes difficult transition period.

2 Increased myocardial O2 demand: Increased O2 demand related to the patient resuming their own work of breathing, dyspnea and anxiety that goes along with that change can cause weaning efforts to fail. Using BCV to decrease the work requirement will attenuate this effect. The patient will have a ready source of non-invasive support that can help manage dyspnea. The decrease of work of breathing associated with the resumption of spontaneous breathing while using Continuous Negative mode versus resumption of spontaneous breathing without BCV will decrease myocardial demands associated with these efforts.

Psychological elements that are resultant from efforts to move the patient from PPV to spontaneous ventilation can derail the process.

Patients that have failed multiple attempts to wean from PPV are frequently highly deconditioned and intolerant of dyspnea. There is often anxiety from having PPV decreased. As the patients pulmonary system is required to manage their gas exchange needs the increase in demand can produce dyspnea. Many patients will develop high levels of anxiety in anticipation of and during weaning trials. Increased demands on the pulmonary muscles combined with dyspnea will result several challenging factors including increased metabolic demand and a mechanically ineffective respiratory pattern. Introducing BCV into the weaning process can lessen dyspnea due to decreased muscle work required to achieve adequate gas exchange and assistance that helps maintain an effective respiratory pattern. This combined with the ability to provide noninvasive support as

needed when dyspnea presents helps reduce much of the anxiety these patients experience.

Case study 1: 79 Y.O. female s/p MVC with multiple severe fractures and contusions post ARDS. Multiple failure of weaning efforts in short term acute hospital, trached and moved to long term acute care LTAC hospital PPV dependent. Persisted with failure to tolerate weaning efforts several weeks post LTAC admission. Max tolerance of CPAP with PSV only several minutes regardless of PS level used.

BCV use day 1: BCV initiated in afternoon. After determining appropriate BCV Control rest settings patient placed on CNEP -10 with PPV standard rest settings. Secretion clearance started and applied q4h.

BCV use day 2: Following 8:00 am secretion clearance treatment patient placed in CPAP with PS using CNEP -10 cm and quickly progressed to CPAP 5 PS 10 FiO2 .4 and CNEP -10 with minimal change in VS from rest. 10:00 am patient advanced to trach collar with CNEP -10. No signs of intolerance noted with all monitored variables stable using CNEP only with .4 t-collar. At noon patient making significant efforts at communication. Patient's trach cuff deflated and speaking valve placed. Patient able to hear her own voice for first time in weeks, very thrilled and encouraged. Communication needs met, speaking valve removed. Patient continued without dyspnea or other signs of intolerance through afternoon. Family arrived for visits late afternoon. Speaking valve placed for brief period during family visits. Family very excited to communicate with patient verbally for first time in weeks. Patient continued on CNEP until bedtime. BCV switched to control mode for rest. Patient rested well. CNEP resumed next morning. Patient never returned to PPV, speaking trials progressed, BCV continued with CNEP during day, Control at night. Weaned well with gradual reduction of BCV support. Patient ultimately discharged to Rehab with no requirement for any means of support using low flow O2.

Case study 2: Patient 3 y.o. female s/p Berlin Heart placement that resulted in diaphragmatic paralysis. Heart transplant carried out. Patient discharged following transplant. Several months post discharge patient developed pneumonia. Returned to PPV following readmission. Not able to tolerate extubation following multiple attempts. Trach and long term vent advised. Family refused. BCV initiated in CNEP following determination of good BCV Control mode rest settings. Patient on CPAP 5 cm with PS 10 cm and CNEP -8 cm. Patient took nap shortly after initiation of BCV in CNEP while still on PPV. Volume reading on PPV indicated VT approximately 50% less during sleep than when awake. BCV switched to Control settings to achieve similar VT to PPV during nap. Patient awakened from nap returned to CNEP still on CPAP and PS. No signs of intolerance and was extubated less than 3 hrs following initiation of BCV. Staff very anxious due to previous extubation failures several of which resulted in severe instability. Patient remained on CNEP and took a second nap post extubation. Control mode resumed at levels used previously. Following second nap patient was removed for short period from cuirass. Patient was noted to be in very good spirits even moving arms, head and shoulders, to staff's surprise, dancing to baby bop music. BCV resumed using CNEP when awake, Control mode during sleep and secretion clearance with assist cough 3-4 times daily. Patient discharged little more than a month later utilizing BCV at home never having returned to PPV or needing trach.

BCV Weaning Guidelines from Hayek Medical's "RTX Guidelines and Information for Clinician"

Weaning from Invasive Positive Pressure Ventilation (IPPV)

Transitioning to BCV from IPPV needs to be undertaken slowly as BCV is ventilating the lung differently. It is important to realize that BCV ventilates different areas of the lung than positive pressure ventilation. Negative pressure is applied uniformly to the chest. By virtue of this fact BCV will open up and ventilate areas of collapse or consolidation not previously ventilated with positive pressure ventilation. The mechanics of BCV ventilation are very different from IPPV. Due to BCV utilizing the patient's chest wall to effect ventilation BCV involves the patient's own respiratory muscles to ventilate.

Weaning can be undertaken in a variety of different ways and it is usually a case of determining which method suits your individual patient best. Either control mode or respiratory synchronized can be used. BCV can be used in support of facility or practitioner specific weaning flow utilizing a similar approach to one of the following:

1) apply BCV with pressures about the same or slightly greater than as IPPV and then slowly wean the IPPV
2) apply BCV at lower than IPPV pressures gradually building them up and once they are near the IPPV pressures and or the patients respiratory state allows decrease the IPPV pressures
3) apply BCV to patient in continuous negative mode, enabling the patient to become familiar with the sensation of the cuirass, then place the RTX in control mode or respiratory synchronized mode and wean the IPPV

The method chosen will depend on the individual patient and their current respiratory support needs, tolerance and status.

Guidelines for stepwise use of BCV as tool to wean from IPPV utilizing facility standard IPPV weaning protocols or flow

Step 1. Verify patient meets standard criteria for spontaneous breathing trial (SBT)

Step 2. Approximately 12-24 hrs prior to SBT begin lung recruitment with BCV

2a. Secretion clearance with oscillation at 600-800 cpm for 3-4 minutes followed by assisted cough for 2 minutes repeated x 5 for total of 25-30 minutes q4h with gentle suctioning during final seconds of cough assist cycles.

2b. In conjunction with patient's normal IPPV resting settings apply BCV in CNEP at -10 to -15cm. Once CNEP established decrease PEEP on IPPV by half as tolerated. (PEEP and CNEP are both sources of augmented RV. PIPs and MAP with IPPV breaths may increase unless PEEP decreased. If PIPs or Pplat increased with PEEP halved decrease to 0. Derecruitment will not occur as long as cuirass is in use with adequate mean cuirass pressure. Resume prior PEEP level if cuirass removed for any reason, and return to half normal or 0 PEEP when cuirass replaced on patient.

Step 3. BCV can be utilized to rest patient post extubation if signs of fatigue develop or nightly rest is desired. It works very well to titrate BCV while patient is still connected to IPPV in order to verify volume exchange and BCV settings required. To do so; with patient on IPPV place in AC with standard VT 6-8 ml/kg. Set RR low so patient is triggering most breaths from IPPV. To titrate BCV for rest initiate control mode at rate equal to or slightly greater than rate patient is triggering IPPV. Initiate

pressures at -24/8 with I:E 1:1. BCV will take a few minutes to ramp to those pressures. When at about -20 Peak Inspiratory Cuirass Pressure (PICP), adjust IPPV to CPAP with CPAP of 3 and PS titrated to achieve VT equal to resting VT that was used in AC. Once BCV reaches -24/8 PS should be able to be decreased and volume maintained. Goal is to decrease PS to 5-8 cm or (Automatic tube compensation (ATC) only if available) while maintaining Δ 6-8 ml/kg. If unable to decrease PS to this level greater span or Δp is required. Increase or decrease BCV span incrementally by 2-3 cm until return volumes are in desired range (span <20 very rare, always verify MCP more negative than -4 cm at rates <60/min). Once this is reached, this will be the resting BCV setting levels. Patient should be allowing BCV to support them for the most part. This can be seen by a 1:1 capture of BCV cycles from the IPPV. If patient does not synchronize with control mode settings then titrate span similarly using BCV in respiratory synchronized mode keeping back up rate at about half of patient's spontaneous rate once pressure settings are determined. These settings will remain in memory and can be utilized prn need for rest. Monitoring of ETCO2 or an ABG may be warranted as V/Q can improve with BCV and patient may be hyperventilated after a period of use and rate may need to be decreased somewhat.

Step 4. Begin SBT when ready as per normal protocol or process for weaning technique, assessment and progressing except utilize CNEP -10 to -15 and utilize half normal or 3 cm CPAP level if using CPAP and not weaning via T-bar or T-collar.

Step 5. Progress wean as per routine protocol or standard flow with secretion clearance continuing q4h prn during active weaning and q4 between SBTs. Utilize standard weaning termination criteria. Patient may be rested on standard IPPV rest settings, BCV with low CPAP with PS as previously titrated or preferably off of IPPV on BCV in control or respiratory synchronized as previously titrated for rest if tolerable.

Step 6. Once standard extubation/IPPV d/c criteria met with BCV still in use, IPPV can be d/c'd and extubation may be carried out.

Step 7. With demonstration of continued tolerance CNEP can be adjusted by 1-2 cwp incrementally until at -5.

Step 8. If patient able to tolerate -5 without difficulty for 1 hour attempt placing BCV in standby. CNEP can be resumed prn returning to the -10 to -15 levels.

Step 9. If patient able to tolerate standby for 1 hour remove cuirass. CNEP can be utilized prn for any signs of fatigue or on routine schedule with secretion clearance and cough assist as indicated, (this is a good strategy for patients prone to atelectasis and/or secretion retention problems). Nightly rest may be and usually is desirable using BCV as previously titrated with ongoing secretion clearance needs being met as well with oscillation and cough assist at desired intervals and frequency. Contact Hayek at Home at 855 2 GET BCV (855-243-8238) to assist with discharge planning to provide BCV for long-term home use to prevent readmission.

Weaning from all modes of BCV

Control mode: Lower rate to normal rate range for patient if elevated. Decrease span until patient demonstrating spontaneous rate greater than machine rate. May advance directly to period of CNEP or move to respiratory synchronized.

Respiratory Synchronized / Respiratory Triggered

Wean the pressures as above—Then:

1) Take patient off for periods of time gradually increasing time off and decreasing time on.
2) Or place patient into CNEP then wean off by giving periods of time off of triggered mode on CNEP and gradually increasing duration of these periods then wean from CNEP as described below.

Continuous Negative

1) With demonstration of continued tolerance, CNEP can be adjusted by 1-2 cwp incrementally until at -5.
2) If patient able to tolerate -5 without difficulty for 1 hour attempt placing BCV in standby. CNEP can be resumed prn returning to the -10 to -15 levels.
3) If patient able to tolerate standby for 1 hour remove cuirass. CNEP can be utilized prn for any signs of fatigue or on routine schedule with secretion clearance and cough assist as indicated, (this is a good strategy for patients prone to atelectasis and/or secretion retention problems). Nightly rest may be and usually is desirable using BCV with ongoing secretion clearance needs being met as well with oscillation and cough assist. Contact Hayek at Home at 855 2 GET BCV (855-243-8238) to assist with discharge planning to provide BCV for long-term home use to prevent readmission.

Dealing with inadequate weaning tolerance

Weaning processes can present a two steps forward one-step back then repeat type of progress. Each step should be preceded by demonstrated tolerance of the previous step. At any point in the progression the patient's strength, endurance or cardio-pulmonary and systemic capacities may be met. Exceeding them by much can set the process back sometime significantly. In the event that patient's limits are reached in the weaning effort it is important to have a ready strategy to manage their status back to baseline, provide a recovery period and resume efforts until weaning achieved or deemed unachievable. Typically having resting settings programmed into control or respiratory synchronized mode and returning patient to this support level and allowing a good recovery is an adequate strategy, but in the event greater intervention is need the following basic strategies may be useful.

Oxygenation

Affected most by manipulation of the mean cuirass pressure (MCP).

Make MCP more negative for poor oxygenation by:

1. making your settings balance more negatively i.e. go from -20 over +10 to -25 over + 5, you still have the same pressure swing but more inflation from the negative side and a more negative MCP will result.
2. changing your I:E ratio to a longer inspiratory time will make MCP more negative.

Carbon dioxide retention

Affected most by manipulation of minute ventilation (VE)

1. increase amplitude by increasing your pressure span/ amplitude i.e. -15 +5 span of 20 to -18 +5 span of 23
2. increase frequency
3. hypercarbia can also potentially be improved by increasing duration of expiratory phase i.e. from 1:1 to 1:1.5 as long as MCP is kept more negative than -4.

There are many advantages to use of BCV as a long term means of support versus PMV or long term use of mask applied NIPPV. Mask or artificial airway is not required. Patients may

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The Benefits of Breathing Heliox for Infants with Bronchopulmonary Dysplasia

Chris Campbell

There is no such thing as a one-sized-fits-all treatment for a medical condition. Some treatments put tremendous strains on a human body. When it comes to a fragile preterm infant struggling to breathe, extra care is needed so treatments don't do more harm than good.

The team of Wolfson et al.—from the Department of Physiology, Temple University School of Medicine, and Section of Newborn Pediatrics, Pennsylvania Hospital—studied this issue when it came to the area of breathing difficulties and finding treatments that reduce the strain on these tiny patients. Originally published in the May 1984 edition of the Journal of Pediatrics, researchers reported on a study of 12 infants with Bronchopulmonary Dysplasia (BPD). The study found that during Heliox breathing there was significant decrease in pulmonary resistance, resistive work of breathing and mechanical power of breathing, whereas ventilation remained unchanged.

The studied found therapeutic value in Heliox—a lower density gas mixture—by reducing muscle fatigue in these vulnerable preterm infants and also making more calories available for growth and recovery because the babies weren't working as hard to breathe.

The Condition

It's called Bronchopulmonary Dysplasia (BPD), which has associated functional changes including tachypnea, decreased lung compliance and elevated airway resistance.[1-5]

Basically, BPD vastly increases the workload when it comes to breathing, sapping the energy level of patients and draining their calories. For a preterm infant, that last part greatly slows down their ability to grow at a crucial time.

The researchers theorized that since previous studies had found that adults benefited from a Heliox—through decreased airway resistance—then infants with BPD should also benefit because of the excessive amounts of energy they were being forced to expend.[6-12]

Methods

The 12 infants were selected from the Neonatal Intensive Care Unit of Pennsylvania Hospital and criteria included the presence of clinical signs of respiratory distress, including tachypnea and retractions. All infants were breathing spontaneously and had abnormal pulmonary functions at the time of the study, as well as having had mechanical ventilation and supplemental oxygen therapy. The existing clinical management of the infants included oxygen concentrations ranging from 0.21 to 0.33.

According to researchers, the infant was calmed and held in the cradled position for the 20-minute duration of the study. In the control condition, the infant spontaneously breathed a gas mixture of 0.21 to 0.33 balanced by nitrogen. Two pre-blended and analyzed Heliox gas mixtures (80:20, 70:30) were substituted during the experimental period.

The infants who were breathing room air received the 80:20 Heliox mixture. The five patients with inspired oxygen concentration of 0.28 to 0.33 during control gas breathing received the 70:30 Heliox mixture during the experimental phase, delivered in sequence for 5 to 10 minutes through a common valve to an anesthesia bag (1 L), which served as a reservoir. Delivered gas flow rates were constant at 5 L/min, and a blow-off valve prevented pressurization of the reservoir.

Mechanics of breathing were studied by simultaneously monitoring esophageal pressure, inspiratory and expiratory flow rates, and tidal volume.

Control gas breathing determinations were made after the infant adapted to the mask (<1 minute). The reservoir was effectively flushed, and measurements during Heliox breathing were made at least 5 minutes after the gas was introduced, to provide time for equilibration. Similarly, recovery determinations (control gas after Heliox) were made in infants at least 5 minutes after the switch back to the control gas mixture. This sequence provided a representative volume and frequency history in each infant. Mechanics and energetics of breathing were based on the average of at least 6 uniform breaths.

The Findings

After studying the infants, the researchers found that clinically they "appeared to breathe more regularly and with less effort during the Heliox phase. The amplitude of the esophageal pressure wave, or peak-to-peak pressure, decreased during Heliox breathing as compared with control."

The study also found "noteworthy" that the computed resistive work of breathing was reduced overall during Heliox breathing.

In the study's discussion area, the researchers wrote that "based on theoretical concepts and experimental conditions, these functional alterations in breathing appear to be related to the differences in the physical properties of the control and helium gas mixtures."

Researchers said that one major benefit of the Heliox is that by

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breathing more regularly and with less resistance, "this modality may reduce respiratory muscle fatigue." This would greatly reduce the stress on a preterm infant.

The second benefit was found in the area of calories. The energy expended as an infant struggles to breathe may reduce the available calories for growth and further complicate recovery, the study said.

"We estimated that Heliox breathing resulted in a caloric savings of approximately 2 kcal/kg/day. By reducing the caloric expense of breathing, Heliox breathing could potentially conserve calories for growth."

The study found that "alternative explanations for the changes in pulmonary mechanics and energetics of breathing can be excluded with reasonable certainty."

Researchers monitored the entire process to ensure minimal mask leakage, and uninterrupted transition from control gas to Heliox to prevent the possibility of dilution. All measurements were taken during steady-state conditions, represented by a typical volume and frequency recording.

"Our results suggest that breathing a lower density gas mixture such as Heliox effectively reduces the WOB in infants with BPD."

References

1 Northway WH, Rosan RC, Porter DY: Pulmonary disease following respiratory therapy of hyaline-membrane disease: bronchopulmonary dysplasia. N Engl J Med 276:357, 1967.
2 Goldman SL, Gerhardt T, Sonni R, Feller R, Hehre D, Tagia JL, Bancalari E: early prediction of chronic lung disease by pulmonary function testing. J Pedatr 102;613, 1983.
3 Shaffer TH, Fox WW: Pulmonary function abnormalities with hyaline membrane disease and bronchopulmonary dysplasia in lung development. In Farrell P, editor; biological and clinical perspectives, vol. 2. New York, 1982, Academic Press.
4 Moomjian AS, Schwartz JG, Wagaman MJ, Shutack JG, Shaffer TH, Fox WW: The effect of external expiratory resistance on lung volume and pulmonary function in the neonate. J Pediatr 96:908, 1980.
5 Stocks J, Godfrey S: The role of artificial ventilation, oxygen and CPAP in the pathogenesis of lung damage in neonates: assessment by serial measurements of lung function. Pediatrics 57:353, 1976.
6 Grape B, Channin E, Tyler JM: the effect of helium and oxygen mixtures on pulmonary resistances in emphysema. Am Rev Respir Dis 81:823, 1959.
7 Barach AL: The therapeutic use of helium. JAMA 107:1273, 1936.
8 Murphy TM, Clark WH, Buckingham EPD, Young WA: Respiratory gas exchange in exercise during helium-oxygen breathing. J Appl Phyiol 26:303. 1969.
9 Otis AB, Bembower WC: Effect of gas density on resistance to respiratory gas flow in man. J Appl Physiol 2:300. 1949.
10 Ishikawa S, Segal M: Reappraisal of helium-oxygen therapy on patients with chronic lung disease. Ann Allergy 31:356. 1973.
11 Barnett TB: Effects of helium and oxygen mixtures on pulmonary mechanics during airway constriction. J Appl Physiol 22:707. 1967.
12 Mink SN, Wood LDH: How does He-O2 increase maximum expiratory flow in human lungs? J Clin Invest 66:720. 1980.

Biphasic Cuirass Ventilation…continued from page 48
be transitioned from PPV and patient extubated without trach being needed. Patients can speak, eat and drink if abilities are neurologically preserved while on support when using BCV allowing fluid and nutritional status to be managed naturally while preserving the patient's ability to participate in their own care. Patients will aslo have much lower stress levels due to being able to be understood by care givers and loved ones. Transitioning patients from each type of support requires a strategy that prepares for the patient or alternative support measures adequately assuming the support needs that were being provided by the prior means. The strategy for determining rest settings in Step 3 above will provide a level of support that closely matches the level being provided by the PPV settings. Hayek Medical has a specific plan for adjustment of BCV to replace PPV or NIPPV devices and can provide onsite training and support. ABGs, pulse ox and ETCO2 monitoring can be used as a guide to determine adequacy of the final settings chosen for BCV.

There are many risks and side effects associated with the use of PPV. A strategy to significantly reduce those risks is to discontinue use as soon as safely possible. BCV when applied with skill towards the goal of reducing the duration of PPV offers a means of achieving that goal in the most expeditious way possible. For patients that cannot assume the loads on the cardio-pulmonary system or are neurologically incapable in the long term, BCV offers an alternative that does not require trach or facial interface while providing a means of maintaining clear lungs and maximizing pulmonary health. BCV can open new potentials for discharge for these patients and provide a means to decrease readmission potential related to pulmonary illness.

References

1 Index: Selected Publications On Biphasic Cuirass which can be accessed at https://app.box.com/s/f9pp2g9iqdjptkvijzdu
2 Evidence-Based Guidelines for Weaning and Discontinuing Ventilatory Support http://journal.publications.chestnet.org/data/Journals/CHEST/21971/375S.pdf?resultClick=1
3 Respiratory Muscles and Weaning Failure http://erj.ersjournals.com/content/9/11/2383.full.pdf

A Short Questionnaire for the Assessment of Quality of Life in Patients with Chronic Obstructive Pulmonary Disease: Psychometric Properties of VQ11

Gregory Ninot, Franck Soyez, and Christian Préfaut

Abstract

Background: There is a need for a validated short instrument that can be used in routine practice to quantify potential short-term change in Health-Related Quality of Life (HRQoL) in patients with chronic obstructive pulmonary disease (COPD). Our aim is to determine the validity and reliability of the VQ11 questionnaire dedicated to the routine assessment of HRQoL.

Methods: 181 COPD patients (40-85 yrs, I to IV GOLD stages) completed the VQ11, and several tests. One week later, 49 of these patients completed the VQ11 again.

Results: Confirmatory factor analysis supported the two-level hierarchical structure of the VQ11 with 11 items covering three components and HRQoL at a higher level. The VQ11 showed good internal consistency and good reproducibility (r = 0.88). Concurrent validity showed significant correlations between VQ11 total scores and St George's Respiratory Questionnaire-C (r = 0.70), Short Form-36 (r = -0.66 for the physical component and -0.63 for the mental component). We obtained significant correlations with MRC Dyspnea Grades (r = 0.59), the Hospital Anxiety and Depression Scale total score (r = 0.62), and the BODE index (r = 0.53).

Conclusion: The VQ11 has good measurement properties and provides a valid and reliable measure of COPD-specific HRQoL. It is ready for use in routine practice.

Background

Self-administered questionnaires are required in order to estimate global outcomes of COPD.[1] Available disease-specific Health-Related Quality of Life (HRQoL) measures, mainly the St George's Respiratory Questionnaire (SGRQ),[2] and the Chronic Respiratory Disease Questionnaire (CRDQ),[3] are reliable and valid, and widely used in clinical trials. There is increasing evidence that HRQoL questionnaires can also be useful in clinical settings;[4] however, existing instruments are lengthy and have complex scoring algorithms, making them poorly suited for routine use in clinical practice and repeated assessment.

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Most patients require short questionnaires (reducing fatigue, eliminating redundancy of items, and facilitating spontaneous responses).

A standardized, patient-centered assessment instrument covering key aspects of COPD HRQoL facilitates information gathering and improves communication between patient and clinician, particularly for general practitioners. An ideal instrument would identify specific areas of greater severity that would serve as focal points for targeted management or the evaluation of management goals, thereby improving both the process and outcome of care. The instrument must be sensitive enough to measure mild-moderate COPD,[5] but also reliable,[6,7] valid for evaluative studies, and useful for determining rehabilitation routines. Previous studies have shown significant changes in quality of life score between three and six months in patients with COPD participating in a rehabilitation program[8] or, after discharge from a rehabilitation program.[9,10]

Recently, short self-administered questionnaires, the COPD Clinical Questionnaire (CCQ),[11] the Short Form Chronic Respiratory Disease Questionnaire (SF-CRQ),[12] the Visual Simplified Respiratory Questionnaire (VSRQ),[13] the COPD Assessment Test (CAT),[14] and the COPD specific HRQoL (VQ11),[15] have been validated with similar psychometric properties (Table 1) and some limitations.

In practice, the 8-item VSRQ and the 8-item CAT include no subscales. Conversely, the 8-item SF-CRDQ does not provide a total score. The SF-CRDQ, VSRQ and CAT mix answers for frequency and intensity, which could be difficult to distinguish in patients with COPD.

Conceptually, these instruments establish confusions to estimate the impact of COPD between health status and HRQoL. The concept of health status refers to the impact of health on the individual's ability to perform daily life activities and to benefit from them.[16] HRQoL refers to the three broad dimensions of health: physical (e.g., autonomy, capacity, symptoms), psychological (e.g., pain, self-esteem, and symptoms), and social (e.g., social relationship, family relationship).[17] Thus, an instrument dedicated to the measure of HRQoL needs to provide 3 dimensions (physical, psychological and social) and an overall total score.

Qualitatively, the SF-CRDQ and the CAT include information on daily symptoms, activity limitation and other physical manifestations of COPD (Table 2). These instruments are

specific to the functional and psychological outcomes of COPD (symptoms, function and confidence in living at home), whereas the social effects produced by COPD can only be assessed by HRQoL measures.[18] The VSRQ and the CAT do not include any item on depression, which is prevalent in COPD patients and alters HRQoL.[19] The 10-item CCQ includes one social life question and relates directly to respiratory problems. The VQ11 is a short instrument that was designed to measure the functional, psychological and social aspects of COPD consequences and provide an overall score for specific HRQoL.

Psychometrically, for all the above instruments but the CAT and VQ11, the item reduction selection was made by a committee of experts and without the use of statistical analysis such as Confirmatory Factor Analysis. A previous study showed that the VQ11 has good content and internal properties.[15] This study was carried out to verify its construct's validity and reliability in comparison to other short instruments (Table 1).

Methods

Participants

Participants were recruited from three pulmonary clinics and two medical offices between January 2008 and June 2009 using advertising flyers. To be included in the study, patients had to be aged between 40 and 85 years, and have an incompletely reversible limitation in airflow (forced expiratory volume in 1 s (FEV_1) to forced vital capacity (FVC) ratio ≤ 70%) and I to IV GOLD stage (FEV_1 < 80% th). Patients with severe or uncontrolled comorbidities (unstable and/or uncontrolled cardiac disease, terminal disease, dementia, or an uncontrolled psychiatric illness) were excluded. 181 (123 males and 58 females) participated in the study after providing informed written consent. Demographic and clinical characteristics are listed in Table 3. The subjects did not participate in any other research study during this period. This study was approved by the University of Montpellier 1 Ethics Committee and the Regional Ethics Committee (authorization number: A00332-53).

Study design

Upon recruitment, the following examinations were performed for each participant: a clinical assessment, the collection of cardio-respiratory family history and number of exacerbations for respiratory (or other) reasons, a respiratory function examination (spirometry, blood gas analysis), an electrocardiogram, and a six-minute walk test (6MWT). Participants were also required to complete the experimental questionnaire, the external validity questionnaires (Medical Outcome Survey Short - SF-36, SGRQ-C, Hospitalization Anxiety Depression Scale—HADS, Physical Self-Worth—PSW) and a datasheet on their socio-cultural situation. Appointments were made with participants who were able and willing to undergo a follow-up assessment one week later. Forty-nine participants completed the VQ11 again to test its reproducibility. To ensure uniform assessments in this multicentric study (Montpellier, Paris, Osséja), the medical and scientific committee of the healthcare network developed recommendations and one teaching session for a standard protocol for instrument use and patient assessment.

Completion of questionnaires

The participants completed the battery of self-administered questionnaires, presented in a randomized order, while resting between physical tests. Participants who took part in both sessions were examined by the same researcher on both occasions.

VQ11

The VQ11 is a brief, self-administered HRQoL questionnaire that was specifically designed to allow individual monitoring of COPD patients over a short-term period. The questionnaire's preliminary versions were developed according to the standard stages of questionnaire validation,[20,21] including evaluation of content validity, item clarity and construct validity.[15] An initial version of the questionnaire was drawn up by a panel of experts consisting of 20 COPD professionals and 15 patients with

Table 1 Psychometric properties of short HRQoL questionnaires for COPD patients

	CCQ [11]	SF-CRDQ [12]	VSRQ [13]	CAT [14]	VQ11 [15]
Dimension	Symptom	Dyspnea	Total	Total	Total (HRQoL)
	Physical	Fatigue	(HRQoL)	(COPD impact)	Functional Psychological Social
	Mental	Emotion			
	Total	Mastery			
Items	10	8	8	8	11
Answer	Frequency	Frequency or intensity	Frequency or intensity	Frequency or intensity	Intensity
	Likert 6	Likert 6	Likert 11	Likert 6	Likert 5
Range	0 - 6 (Total)	1 - 14 per dimension	0 - 80	0 - 40	11 - 55
Item reduction	From 77 to 10	From 20 to 8	From 18 to 8	From 21 to 8	From 24 to 11
	Expert committee	Authors	Expert committee	Rasch	Confirmative factor analysis
Model	None	Principal component analysis	Principal component analysis	Rasch analysis	Structural equation modeling
α Chronbach	.91	.82	.84	.88	.83
Test-retest	.94	-	.77	.80	.72
r Total SGRQ	.71	-	-	.80	-
r FEV_1	-.38	-.07 to -.28	-	-	-

Table 2 Item coverage of short HRQoL questionnaires for COPD patients

Dimension	Aspect	CCQ	SF-CRDQ	VSRQ	CAT	VQ11
	Shortness of breath	2	1	1	1	1
	Fatigue		2	1	1	1
Functional	Activity limitations	3	1	1	1	1
	Phlegm	1			1	
	Cough	1			1	
	Chest tightness				1	
	Low self-confidence				1	1
Psychological	Anxiety	1	2	1		1
	Depression	1	1			1
	Sleep		1	1	1	1
	Sexual life trouble			1		1
Social	Life project limitation			1		1
	Social support lack					1
	Social life restriction	1		1		1

different degrees of COPD and different psychosocial levels. The clarity of each item was then tested on 20 patients with different degrees of COPD and different psychosocial levels. After making adjustments to the initial questionnaire, the committee produced an experimental questionnaire with 24 items, covering three theoretical components (functional, psychological and relational) and 11 sub-components. Each sub-component consisted of two or three items. This experimental questionnaire was tested on 166 COPD patients. Confirmatory factor analysis showed that the best model was a two-level hierarchical model with an initial level comprising 11 items (one per sub-component) distributed across three components (functional = 3 items; psychological = 4 items; social = 4 items) and a top level (lower score indicates better HRQoL) combining these three components. Cronbach's alphas were calculated to test the internal consistency scales. The resulting values were 0.83 for the functional component, 0.69 for the psychological component, 0.57 for the social component and 0.83 for the total scale. Table 4 shows the French version of the VQ11 and a cross-cultural translation produced by three native speakers of English.

Other questionnaires

The MOS-SF-36,[22,23] the SGRQ-C,[24] the HADS,[25] and the PSW of the French version[26] of the Physical Self-Perception Profile[27] were assessed.

MMRC scale

The degree of dyspnea was measured using the Modified Medical Research Council (MMRC) scale,[28] which correlates well with other scales and health status scores.[29]

Analyses of respiratory function

The pulmonary function tests (PFTs) included simple screening spirometry, formal lung volume measurement, diffusing capacity for carbon monoxide, and arterial blood gases. We measured the volume-time curve and the flow-volume loop, as well as FVC and FEV_1 in order to calculate FEV_1/FVC indices.[30]

Table 3 Clinical characteristics and HRQoL measures for 181 patients (123 males and 58 females)

	Mean	SD	Min	Max
Sociodemographic and overall characteristics				
Age (yrs)	61.4	9.8	37	85
BMI (kg/m^2)	25.7	5.4	13.1	39.7
BODE score	3.5	2.4	0	10
Dyspnea MMRC	1.4	1.3	0	3
Smoking history				
Pack-years (smokers)	33.5	32.3	0.1	135.0
Pack-years (ex-smokers)	45.5	28.9	0.8	157.5
Spirometry				
Pre-BD FEV_1 (ml)	1395	645	460	4090
FEV_1 (% pred)	49.0	20.5	15	112
FEV_1/FVC (%)	47.7	12.4	25	69
Exercise tolerance				
Dyspnea 6MWD end	6.0	2.1	2	10
6MWT distance (m)	470.9	122.1	90	812
6MWT distance (% pred)	70.9	17.3	14	121
HRQoL Measures				
SGRQ-C Symptoms score	54.3	18.9	6.8	97.3
SGRQ-C Activity score	55.3	22.7	7.3	100.0
SGRQ-C Impact score	34.2	18.7	4.2	89.1
SGRQ-C Total score	46.3	18.5	9.7	97.7
VQ11 Functional (3–15)	8.8	2.8	3	15
VQ11 Psychological (4–20)	10.2	3.2	4	18
VQ11 Social (4–20)	9.0	3.8	4	19
VQ11 Total score (11–55)	27.9	8.8	11	49
SF-36 Physical functioning	56.3	22.8	0	100
SF-36 Role physical	40.1	35.0	0	100
SF-36 Role emotional	55.7	40.2	0	100
SF-36 Energy/vitality	46.9	18.6	0	100
SF-36 Mental Health	64.0	15.3	20	100
SF-36 Social functioning	74.4	23.4	0	100
SF-36 Bodily pain	70.2	26.7	0	100
SF-36 General health perceptions	36.2	19.9	0	95
SF-36 Physical Component Scale	50.5	22.1	8.5	96.3
SF-36 Mental Component Scale	60.3	19.0	16.0	93.5
Other Measures				
HADS Anxiety score (0–21)	8.2	3.8	0	19
HADS Depression score (0–21)	6.0	3.4	0	17
HADS Total score (0–42)	14.2	6.3	1	33
Physical self-worth (1–6)	2.8	1.1	1.0	5.6

Exercise tolerance

The 6MWT test was performed twice with more than 30 minutes between tests in order to allow heart rate and dyspnea to return to their initial rest values.[31] A dyspnea score was measured on a

Table 4 Content and structure of the VQ11 questionnaire and its cross-cultural translation by three native speakers of English

	English	French
Information	The following sentences express feelings about the consequences of COPD. For each sentence, tick the intensity that best reflects your feeling at this moment (from "not at all" to "extremely"). There are no wrong answers. Each one is personal.	Les phrases suivantes expriment des sentiments sur les conséquences de la BPCO. Pour chacune, cochez l'intensité qui vous correspond le mieux maintenant (de « pas du tout » à « extrêmement »). Aucune réponse n'est juste. Elle est avant tout personnelle.
Dyspnea	*I suffer from breathlessness*	*Je souffre de mon essoufflement*
Anxiety	*I am worried about my respiratory condition*	*Je me fais du souci pour mon état respiratoire*
Closeness	*I feel my entourage (family, friends, etc.) misunderstands me*	*Je me sens incompris(e) par mon entourage*
Mobility	*My respiratory condition prevents me from moving about as easily as I would like*	*Mon état respiratoire m'empêche de me déplacer comme je le voudrais*
Sleep	*I feel sleepy during the day*	*Je suis somnolent(e) dans la journée*
Life project	*I feel unable to achieve my objectives*	*Je me sens incapable de réaliser mes projets*
Fatigue	*I quickly get tired when doing day-to-day activities*	*Je me fatigue rapidement dans les activités de la vie quotidienne*
Physical confidence	*Physically, I am dissatisfied with what I can do*	*Physiquement. je suis insatisfait(e) de ce que je peux faire*
Social life	*My respiratory disease disrupts my social life*	*Ma maladie respiratoire perturbe ma vie sociale*
Depression	*I feel sad*	*Je me sens triste*
Emotional life	*My respiratory condition restricts my emotional life*	*Mon état respiratoire limite ma vie affective*

10-cm visual analog scale (VAS) before and immediately after the test.

Statistical analyses

CFA was used to confirm the theoretical model found during the internal validation (Statistical Software Mplus 5.1).
Fit assessment of the CFA models was based on multiple indicators,[32-34] including the Chi-square statistic (χ^2), comparative fit index (CFI), Tucker-Lewis Index (TLI), root mean square error of approximation (RMSEA), and 90% confidence interval (CI) of the RMSEA. Values greater than 0.90 for CFI and TLI are considered to indicate adequate model fit, although values approaching 0.95 are preferable. Values smaller than 0.08 or 0.06 for the RMSEA indicate acceptable and good model fit, respectively.[33,34] For the RMSEA 90% CI, values less than 0.05 for the lower bound (left side) and less than 0.08 for the upper bound (right side) or of 0 for the lower bound and less than 0.05 for the upper bound (right side) indicate acceptable and good model fit, respectively.[35] Factor loadings, squared multiple correlations, standard errors and t values were inspected for appropriate sign and/or magnitude.

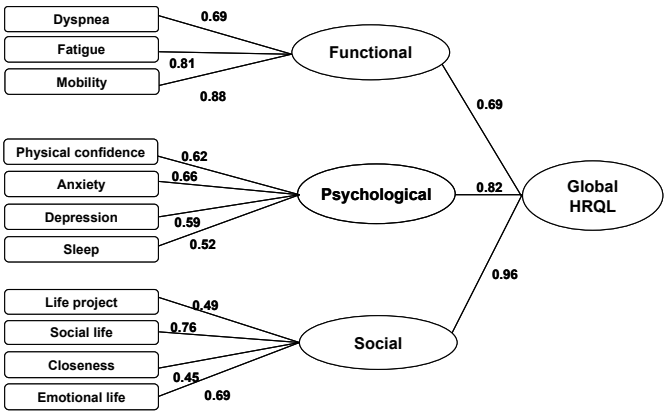

Figure 1. Hierarchical model and indices obtained for the VQ11 using confirmatory factor analysis (n = 181 COPD patients).

Concurrent validity was assessed by analyzing Pearson correlation coefficients between the dimensions of the study questionnaire and those of another questionnaire measuring similar concepts. Spearman correlation coefficients were calculated between the VQ11 (total and component scores) and other independent variables. In order to confirm good concurrent validity but no redundancy, the new questionnaire had to show moderate correlation (0.40 to 0.70) with a well-established mea surement tool.

Reliability is the degree to which an instrument is free from random error. It is evaluated by measuring internal consistency reliability and reproducibility. Internal consistency reliability refers to the homogeneity of the items of the scale and was assessed using Cronbach's alpha. Reproducibility establishes the stability of an instrument over time in a stable population and was tested using a Pearson correlation.

Results

Patient demographics

One hundred eighty-one participants completed the study baseline questionnaires and 49 participants completed the follow-up questionnaires. The mean ± SD and range of the physiological and patient-reported outcomes for the study population are summarized in Table 3.

Factor validity

A CFA supported the validity of a two-level hierarchical model with a three-component initial level and a single top level (Figure 1). The weighted least squares mean- and variance-adjusted χ^2 estimator analyzed all the items as categorical variables. Fit indices were acceptable ($\chi^2 = 133.090$; df = 24; CFI = 0.910, TLI = 0.955; RMSEA = 0.158). The fit for the one-factor model was as good as the fit for the three-factor model ($\chi^2 = 135.573$; df = 25; CFI = 0.909, TLI = 0.956; RMSEA = 0.156), but it was less acceptable with the difftest (difftest = 12.277; df: 3; p = 0.0065).

Reproducibility was assessed in terms of the correlations

Table 5 Clinical characteristics and HRQoL measures by quartiles of VQ11 score

VQ11 quartiles	Q1(≤20) (N = 45)	Q2 (20–28) (N = 51)	Q3 (28–34.5) (N = 37)	Q4 (>34.5) (N = 44)	*Scheffe***	*F* *P value*$
Clinical characteristics						
Age (yrs)	62.1 ± *9.1**	60.9 ± *10.6*	61.2 ± *11.0*	61.6 ± *8.1*		0.94
BMI (kg/m^2)	25.3 ± *5.0*	25.9 ± *4.7*	25.0 ± *5.4*	26.6 ± *6.3*		0.55
MMRC Dyspnea	0.36 ± *0.77*	1.23 ± *1.26*	1.8 ± *1.2*	2.4 ± *1.1*	Q1 < Q3; Q1 < Q2 < Q4	<0.0001
Pre-BD FEV_1 (ml)	1676 ± *727*	1413 ± *586*	1176 ± *576*	1267 ± *590*	Q1 < Q3,Q4	0.002
FEV_1 (% pred)	55.8 ± *18.7*	51.4 ± *21.6*	43.5 ± *19.2*	44.2 ± *20.5*	NS	0.013
FEV_1/FVC (%)	53.1 ± *10.3*	47.5 ± *13.2*	44.4 ± *11.7*	45.5 ± *12.6*	Q1 < Q3,Q4	0.006
Dyspnea 6MWD end	5.2 ± *1.9*	6.1 ± *1.9*	5.9 ± *2.1*	6.7 ± *2.2*	Q1 < Q4	0.026
6MWT distance (m)	521 ± *85.0*	504 ± *119*	449 ± *111*	403 ± *132*	Q1,Q2 < Q4	<0.0001
BODE	1.8 ± *1.6*	3.1 ± *1.9*	4.2 ± *2.2*	5.2 ± *2.4*	Q1,Q2 < Q4; Q1 < Q2,Q3	<0.0001
HRQoL Measures						
SGRQ-C Symptoms	43.1 ± *15.3*	52.5 ± *17.1*	59.1 ± *16.8*	64.0 ± *20.0*	Q1 < Q3,Q4; Q2 < Q4	<0.0001
SGRQ-C Activity	38.9 ± *17.2*	51.8 ± *19.4*	60.7 ± *18.9*	71.5 ± *21.9*	Q1 < Q2 < Q4; Q1 < Q3	<0.0001
SGRQ-C Impact	16.3 ± *9.2*	31.6 ± *13.7*	42.3 ± *16.8*	48.9 ± *16.5*	Q1 < Q2 < Q3,Q4	<0.0001
SGRQ-C Total	28.9 ± *10.6*	43.3 ± *13.5*	53.4 ± *14.6*	61.4 ± *17.0*	Q1 < Q2 < Q3,Q4	<0.0001

*Mean ± *SD*.
**Significant at 0.05 level.
$Analysis of covariance for variables showing both normal distributions and homogeneous variance; Kruskal-Wallis test for variables showing normal distributions and/or homogeneous variance.

between the measures produced by the 49 COPD patients who were reassessed after a one-week period (42 patients under 10% of variation; 7 patients under 20% of variation). Correlation coefficients were 0.76 for the functional component ($p < .01$), 0.65 for the psychological component ($p < .01$), 0.73 for the social component ($p < .01$), and 0.88 for total VQ11 ($p < .01$).

Reliability

Cronbach's alphas were 0.80 for the functional component, 0.68 for the psychological component, 0.77 for the social component and 0.89 for the whole scale. Alphas computed using the Spearman-Brown formula were 0.91, 0.81 and 0.87, respectively.

The low correlations between VQ11 and FEV_1 (functional component, -0.26; total, -0.19) suggest that there are no significant differences between groups classified by grade of severity and VQ11 score.

Table 5 presents the clinical characteristics and HRQoL measures of the 181 COPD participants according to quartiles of VQ11 score. Associations between increasing VQ11 quartiles and clinical characteristics were found for FEV1, pre-BD FEV1, FEV1/FVC and 6MWT distance (negative association), as well as for BODE score and dyspnea from both MMRC classification and the 6MWT-end measure (positive association). There were no significant associations between VQ11 quartiles and either age or BMI. HRQoL measures from SGRQ were all positively and significantly associated with VQ11 quartiles including SGRQ symptoms, activity, impact and total scores ($p < 0.0001$).

Construct validity

The construct validity results are shown in Tables 6 and 7. The VQ11 showed good correlation with SGRQ total scores (0.71), SF-36 component scores (-0.61 for MCS and -0.61 for PCF), HADS total scores (0.61), and physical self-worth (-0.59). SGRQ total scores correlated most strongly with the functional component of the VQ11 (0.66), whereas MCS and HADS scores correlated most strongly with the psychological and social components of the VQ11 (-0.61 and 0.63; -0.60 and 0.61 respectively). Furthermore, we found significant correlations between VQ11 total scores and 6MWT end dyspnea scores, 6MWT distances (in meters and in percentage of the predicted distance) and total BODE scores (0.26, -0.37, 0.51 respectively). These correlations were particularly satisfactory for the functional component of the VQ11 (0.28, -0.42, 0.56 respectively). Correlations with FEV_1, FEV_1 as a percentage of the predicted value, FEV_1/FVC and pack-years for smokers were low.

Discussion

This study examined the validity and reliability of the VQ11, a short, self-administered questionnaire specifically designed for repeated assessment of patients with COPD and for use in routine care. The results show that the VQ11 provides a simple and reliable measure of overall COPD-related HRQoL and physical, psychological, and social components of HRQoL as expected by experts.[17]

The hierarchical structure of a preliminary version of the VQ11 had previously been tested on a sample of 166 COPD patients.[15] Therefore, the initial aim of the present study was to use CFA to verify this factorial structure with a new sample of COPD patients. Our findings demonstrated that the higher-order factor model provided a satisfactory fit to the data and a better fit than the alternative models. These results confirm those from a previous study.[15] The model contains physical, psychological, and social components, in line with guidelines for HRQoL questionnaires.[17,22,34] Our analysis showed that these components can be examined separately.

The concurrent validity of the VQ11 was confirmed by the correlation between VQ11 scores (for the individual components and for the total score) and the SF-36 or the SGRQ-C. VQ11 total scores strongly correlated with scores for the physical and mental components of the SF-36, and with scores on the eight

Table 6 Correlation between VQ11 and other variables of interest

	Functional	Psychological	Social	Total
Age	0.10	−0.11	−0.08	−0.04
BMI	0.13	0.05	0.05	0.08
Pack-years (smokers)	0.01	0.10	0.06	0.06
Pack-years (ex-smokers)	**0.29**	0.19	**0.20**	**0.25**
Pre-BD FEV_1	**−0.28**	−0.14	**−0.16**	**−0.21**
FEV_1 % pred	**−0.26**	−0.14	−0.13	**−0.19**
FEV_1/FVC	**−0.26**	**−0.17**	**−0.16**	**−0.22**
MMRC Dyspnea Grade	**0.61**	**0.49**	**0.51**	**0.59**
Dyspnea 6MWD start	**0.17**	0.04	0.10	0.11
Dyspnea 6MWD end	**0.28**	**0.20**	**0.24**	**0.26**
Dyspnea 6MWD difference	**0.17**	**0.19**	**0.16**	**0.19**
6MWT distance (m)	**−0.42**	**−0.25**	**−0.34**	**−0.37**
6MWT distance (% pred)	**−0.41**	**−0.26**	**−0.35**	**−0.38**
BODE Index	**0.56**	**0.41**	**0.43**	**0.51**

In bold type, $p < .05$.

Table 7 Correlation between VQ11 and other questionnaire scores

	Functional	Psychological	Social	Total
SGRQ-C				
Symptoms	**0.43**	**0.41**	**0.40**	**0.46**
Activity	**0.57**	**0.48**	**0.54**	**0.59**
Impact	**0.63**	**0.60**	**0.64**	**0.69**
Total	**0.66**	**0.61**	**0.65**	**0.71**
MOS SF-36				
Physical functioning	**−0.64**	**−0.50**	**−0.53**	**−0.62**
Physical role	**−0.45**	**−0.38**	**−0.36**	**−0.43**
Emotional role	**−0.28**	**−0.42**	**−0.36**	**−0.39**
Energy/vitality	**−0.44**	**−0.56**	**−0.54**	**−0.58**
Mental health	**−0.21**	**−0.46**	**−0.41**	**−0.41**
Social functioning	**−0.40**	**−0.53**	**−0.63**	**−0.59**
Bodily pain	**−0.40**	**−0.38**	**−0.46**	**−0.46**
General health perceptions	**−0.42**	**−0.54**	**−0.51**	**−0.55**
Physical Component Scale	**−0.52**	**−0.57**	**−0.56**	**−0.61**
Mental Component Scale	**−0.42**	**−0.61**	**−0.60**	**−0.61**
HADS				
Anxiety	**0.21**	**0.49**	**0.46**	**0.44**
Depression	**0.47**	**0.59**	**0.58**	**0.62**
Total	**0.39**	**0.63**	**0.61**	**0.61**
Physical Self-Inventory				
Physical self-worth	**−0.47**	**−0.62**	**−0.50**	**−0.59**

In bold type, $p < .05$.

scales that make up these components. As expected, the highest correlation was for the physical functioning scale.[36] Also as expected, the highest correlations were between corresponding components of the VQ11 and the SF-36 (VQ11-functional scale and the SF-36 physical component and physical functioning scales; VQ11-psychological scale and SF-36 emotional role, energy/vitality, mental health, general health perceptions and mental component scales; VQ11-social scale and SF-36 social functioning scale). By contrast, the correlation between the component and total scores on the VQ11 and the SF-36 bodily pain scale was not particularly strong. However, because the SF-36 was not designed to measure sleep disturbances and respiratory complaints, this relatively weak correlation does not affect the concurrent validity of the VQ11. As expected, VQ11 total scores correlated well with SGRQ-C scores and three specific domains.

As expected also,[37] VQ11 total scores correlated well with HADS depression and total scores. The results also supported the weak correlations between airway obstruction and HRQoL.[7,38,39]

The three components of the VQ11 are disease-specific domains of HRQoL for COPD patients. VQ11 functional scores correlated with dyspnea (MMRC grade and 6MWT distance), BODE index, exercise tolerance (6MWT distance), the activity and impact scores of the SGRQ-C, and the physical functioning and physical components of the SF-36. The items of the VQ11 reflect the main symptoms perceived by patients with COPD, dyspnea,[28] physical limitation[24] and fatigue.[37,38,40]

Significant correlations were found between the psychological component of the VQ11 and the HADS anxiety and depression scales, the SGRQ-C impact scale, the emotional role and mental components of the SF36, and physical self-worth (defined as physical self-esteem). This emphasizes that disease-associated anxiety and depression are important HRQoL factors for COPD patients. The degree of anxiety felt by COPD patients has been shown to be related to their degree of pulmonary dysfunction.[41]

The social component of VQ11 correlated with the social functioning and mental components of the SF36. Social relationships are affected by chronic respiratory disease, especially in patients with severe respiratory insufficiency who often depend on close social relationships to manage daily activities.[42] Patients with COPD experience losses in several areas of their lives, and they may feel useless, experience reduced sexual activity, depend on others for their personal care and lose interest in future projects.

The total, functional, psychological, and social components of the VQ11 showed good reliability over a period of one week for patients without clinical change. The correlation coefficient for the psychological component was the lowest. This result can be explained by intra-individual variability in the perception of disease and health status. A recent study noted higher day-to-day instability in self-esteem, which is a major correlate factor of HRQoL for COPD patients compared with healthy adults.[41] Consequently, it would be advisable for clinicians to ask patients to complete the VQ11 every three to six months, in order to assess the stability of patients' perceptions of their illness, as this perception may be a sign of vulnerability and of the likelihood they will not fully adhere to their treatment.

There were limitations to the study. The sample was relatively homogenous, with all subjects having moderate to severe COPD, the majority being ex-smokers with a significant smoking history. The concept of quality of life and its implications on daily life are different for men and women.[21] We could not validate the

new questionnaire separately for men and women due to the small sample size. The VQ11 also needs to be studied in other ethnic populations and cultures for cross-cultural validity. In addition, the responsiveness of the VQ11 to interventions and comparisons with other quality of life questionnaires is also required. Last, using a new patient-reported outcomes questionnaire requires the determination of the minimal clinically important difference.[43]

In practice, there are four general benefits to using the VQ11: (1) It helps clinicians quickly detect the worsening of HRQoL in COPD patients. This deterioration can then be explained by the acknowledgment of COPD, poor disease self-management (routine or acute situation), the presence of comorbidities (depression, sleep trouble, metabolic syndrome…) and/or weak support from family and friends. Possible consequences include an increase in the exacerbation risk and aggravation of COPD, the development of health-risk behavior or of a new disease, and/or the deterioration of communication with caregivers, family or friends. (2) The three components of the VQ11 allow caregivers to assess and correct a number of situations: based on a high score on the functional component, informed decisions can be made on therapy, modification of current treatment, new assessment, physiotherapy or comprehensive rehabilitation; with a high score on the psychological component, those decisions can be made regarding new assessment, psychological support, education, or comprehensive rehabilitation; finally, with a high score on the social component, decisions can be made concerning social support, psychological support, education, membership in a health network or patients association. (3) Based on the anticipated validation of a Minimal Clinically Important Difference, the VQ11 can also help monitor the efficacy of an individual's therapeutic decision. (4) Lastly, the VQ11 provides clinicians with meaningful cues to examine a COPD life consequence more specifically when an answer to an item is more than three. Moreover, the back of the form includes an educational message with a space for drawing and commenting in which individual messages can be exchanged between patients and caregivers, family or friends.

Conclusions

This study showed the validity and reliability of the VQ11, a short, self-administered questionnaire specifically designed for repeated assessment of patients with COPD and for use in routine care. The VQ11 provides clinicians and patients with a simple and reliable measure of overall COPD-related HRQoL. The VQ11 facilitates discussions about the overall consequences of COPD arising from the illness's physical symptoms and psychological perceptions, observance behaviors, health behaviors, life projects with COPD, and social support. Additional information is needed to provide responsiveness to change at the individual patient level, an essential feature for its use in clinical practice.

References

1 Domingo-Salvany A, Lamarca R, Ferrer M, Garcia-Aymerich J, Alonso J, Felez M, Khalaf A, Marrades RM, Monso E, Serra-Batlles J, Anto JM: Health-related quality of life and mortality in male patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2002, 166:680-685.

2 Jones PW, Quirk FH, Baveystock CM: The St George's respiratory questionnaire. Respir Med 1991, 85 Suppl B:25-31. discussion 33-27

3 Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW: A measure of quality of life for clinical trials in chronic lung disease. Thorax 1987, 42:773-778.

4 Global Initiative for Chronic Obstructive Lung Disease: Global strategy for diagnosis, management, and prevention of COPD. In Book Global Initiative for Chronic Obstructive Lung Disease. Global strategy for diagnosis, management, and prevention of COPD Edited by Editor eds. 2009. http://www.goldcopd.org/

5 Jones PW: Quality of life measurement for patients with diseases of the airways. Thorax 1991, 46:676-682.

6 Jones PW, Kaplan RM: Methodological issues in evaluating measures of health as outcomes for COPD. Eur Respir J Suppl 2003, 41:13s-18s.

7 Jones PW, Quirk FH, Baveystock CM, Littlejohns P: A self-complete measure of health status for chronic airflow limitation. The St. George's respiratory questionnaire. Am Rev Respir Dis 1992, 145:1321-1327.

8 Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, Mullins J, Shiels K, Turner-Lawlor PJ, Payne N, Newcombe RG, Ionescu AA, Thomas J, Tunbridge J: Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation included: a randomized controlled trial. Lancet 2000, 355:362-368.

9 Ries AL, Kaplan RM, Myers R, Prewitt LM: Maintenance after pulmonary rehabilitation in chronic lung disease. Am J Respir Crit Care Med 2003, 167:880-888.

10 Brooks D, Krip B, Mangovski-Alzamora S, Goldstein RS: The effect of post-rehabilitation programmes among individuals with chronic obstructive pulmonary disease. Eur Respir J 2002, 20:20-29.

11 van der Molen T, Willemse BW, Schokker S, ten Hacken NH, Postma DS, Juniper EF:Development, validity and responsiveness of the Clinical COPD Questionnaire. Health Qual Life Outcomes 2003, 1:13.

12 Tsai C-L, Hodder RV, Page JH, Cydulka RK, Rowe BH, Camargo CA Jr: The short-form chronic respiratory disease questionnaire was a valid, reliable, and responsive quality-of-life instrument in acute exacerbations of chronic obstructive pulmonary disease. J Clin Epidemiol 2008, 61:489-497.

13 Perez T, Arnould B, Grosbois JM, Bosch V, Guillemin I, Bravo ML, Brun M, Tonnel AB, Group TS: Validity, reliability, and responsiveness of a new short Visual Simplified Respiratory Questionnaire (VSRQ) for health-related quality of life assessment in chronic obstructive pulmonary disease. Int J Chron Obstruct Pulmon Dis 2009, 4:9-18.

14 Jones PW, Harding G, Berry P, Wiklund I, Kline Leidy N: Development and first validation of the COPD assessment test. Eur Respir J 2009, 34:648-654.

15 Ninot G, Soyez F, Fiocco S, Nassih K, Morin AJS, Prefaut C: [The VQ11, a short health-related quality of life questionnaire for routine practice in COPD patients]. Le VQ11, un questionnaire de qualite de vie specifique a la BPCO utilisable en clinique. Rev Mal Respir 2010, 27:472-481.

16 Curtis JR, Martin DP, Martin TR: Patient-assessed health outcomes in chronic lung disease: what are they, how do they help us, and where do we go from here? Am J Respir Crit Care Med 1997, 156:1032-1039.

17 Mahler DA: How should health-related quality of life be assessed in patients with COPD?Chest 2000, 117:54S-57S.

18 Kaptein AA, Scharloo M, Fischer MJ, Snoei L, Hughes BM, Weinman J, Kaplan RM, Rabe KF:50 years of psychological research on patients with COPD—road to ruin or highway to heaven? Respir Med 2009, 103:3-11.

19 Maurer J, Rebbapragada V, Borson S, Goldstein R, Kunik ME,

Yohannes AM, Hanania NA, Anxiety AWP, Depression in C, Kunik M, et al.: Anxiety and depression in COPD: current understanding, unanswered questions, and research needs. Chest 2008, 134:43S-56S.
20 Marsh HW, Ellis LA, Parada RH, Richards G, Heubeck BG: A short version of the Self Description Questionnaire II: operationalizing criteria for short-form evaluation with new applications of confirmatory factor analyses. Psychol Assess 2005, 17:81-102.
21 Streiner DL, Norman GR: Health Measurement Scales: a practical guide to their development and use. Oxford: Oxford University Press; 2008.
22 Ware JE Jr, Sherbourne CD: The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992, 30:473-483.
23 Leplege A, Ecosse E, Verdier A, Perneger TV: The French SF-36 Health Survey: translation, cultural adaptation and preliminary psychometric evaluation. J Clin Epidemiol 1998, 51:1013-1023.
24 Meguro M, Barley EA, Spencer S, Jones PW: Development and validation of an improved, COPD-specific version of the St. George respiratory questionnaire. Chest 2007, 132:456-463.
25 Zigmond AS, Snaith RP: The hospital anxiety and depression scale. Acta Psychiatr Scand 1983, 67:361-370.
26 Ninot G, Delignières D, Fortes M: L'évaluation de l'estime de soi dans le domaine corporel:35-48. Revue STAPS 2000, 53:35-48.
27 Fox KR, Corbin CB: The physical self-perception profile: development and preliminary validation. J Sport Exerc Psychol 1989, 11:408-430.
28 Mahler DA, Wells CK: Evaluation of clinical methods for rating dyspnea. Chest 1988, 93:580-586.
29 Hajiro T, Nishimura K, Tsukino M, Ikeda A, Koyama H, Izumi T: Comparison of discriminative properties among disease-specific questionnaires for measuring health-related quality of life in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1998, 157:785-790.
30 Quanjer PH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault JC: Lung volumes and forced ventilatory flows. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. Eur Respir J Suppl 1993, 16:5-40. PubMed Abstract
31 Troosters T, Gosselink R, Decramer M: Six minute walking distance in healthy elderly subjects. Eur Respir J 1999, 14:270-274.
32 Byrne BM: Factor analytic models viewing the structure of an assessment instrument from three perspectives. J Pers Assess 2005, 85:17-32.
33 Hu LT, Bentler PM: Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. Struct Equ Modeling 1999, 6:1-55. Publisher Full Text
34 Vandenberg RJ, Lance CE: A review and synthesis of the measurement invariance literature: suggestions, practices, and recommendations for organizational research. Organ Res Meth 2000, 3:4-70. Publisher Full Text
35 MacCallum RC, Browne MW, Sugawara HM: Power analysis and determination of sample size for covariance structure modeling. Psychol Methods 1996, 1:130-149.
36 Kaplan RM, Ries AL, Reilly J, Mohsenifar Z, Grp NETTR: Measurement of health-related quality of life in the national emphysema treatment trial. Chest 2004, 126:781-789.
37 Kunik ME, Roundy K, Veazey C, Souchek J, Richardson P, Wray NP, Stanley EA:Surprisingly high prevalence of anxiety and depression in chronic breathing disorders. Chest 2005, 127:1205-1211.
38 Jones PW: Health status measurement in chronic obstructive pulmonary disease. Thorax 2001, 56:880-887.
39 Kaplan RM, Ries AL: Quality of life: concept and definition. Copd 2007, 4:263-271.
40 Breslin E, van der Schans C, Breukink S, Meek P, Mercer K, Volz W, Louie S: Perception of fatigue and quality of life in patients with COPD. Chest 1998, 114:958-964.
41 Hill K, Geist R, Goldstein RS, Lacasse Y: Anxiety and depression in end-stage COPD. Eur Respir J 2008, 31:667-677.
42 Ninot G, Delignières D, Varray A: Individual differences in stability of physical self: examining the role of chronic obstructive pulmonary disease. Eur Rev Appl Psychol 2010, 60:35-40. Publisher Full Text
43 Beaton DE, Boers M, Wells GA: Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. Curr Opin Rheumatol 2002, 14:109-114.

Chronic Cough and Obstructive Sleep Apnea in a Sleep Laboratory-based Pulmonary Practice

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Abstract

Background: Obstructive sleep apnoea (OSA) has recently been identified as a possible aetiology for chronic cough. The aim of this study was to compare the incidence of chronic cough between patients with and without OSA and the impact of continuous positive airway pressure (CPAP) treatment in resolving chronic cough.

Methods: Patients referred to the sleep laboratory from January 2012 to June 2012 were retrospectively enrolled. Clinical data, treatment course and resolution of chronic cough were analysed. Specifically, gastro-oesophageal reflux (GERD), upper airway cough syndrome, asthma, apnoea-hypopnoea index and the impact of CPAP treatment on chronic cough were assessed.

Results: A total of 131 patients were reviewed. The incidence of chronic cough in the OSA group was significantly higher than the non-OSA group (39/99 (39.4%) vs. 4/32 (12.5%), p = 0.005). Both GERD and apnoea-hypopnoea index were significantly associated with chronic cough in univariate analysis. After multivariate logistic regression, GERD was the only independent factor for chronic cough. Moreover, the resolution of chronic cough was more significant in the OSA patients with CPAP treatment compared with those not receiving CPAP treatment (12/18 (66.7%) vs. 2/21 (9.5%), p = 0.010).

Conclusion: The incidence of chronic cough was significantly higher in the OSA patients. In addition, CPAP treatment significantly improved chronic cough. Therefore, OSA may be a contributory factor to chronic cough.

Introduction

The incidence of chronic cough ranges from 9% to 33% of the adult population [1,2]. The most common aetiologies for chronic cough in non-smokers are upper airway cough syndrome (UACS), gastro-oesophageal reflux (GERD) and asthma, all of which are empirically treated [2,3]. However, the aetiologies of 12% to 42% of coughs are unexplained despite thorough evaluation [4]. Therefore, it is important to explore other possible aetiologies for chronic cough. A recent study reported four patients with unexplained chronic cough who were found to have obstructive sleep apnoea (OSA). Moreover, a prospective study also reported that of 108 patients being referred to sleep clinics for sleep disordered breathing, 33% had a co-existing cough [5], which suggests an association between chronic cough and OSA. In addition, another study reported that 44% of patients with chronic cough had OSA, 93% of whom demonstrated a significant improvement in cough with continuous positive airway pressure (CPAP) treatment [6]. The mechanism between chronic cough and OSA is still not clear, although GERD, UACS and airway inflammation have been proposed to be involved [7]. However, studies on these topics have lacked an adequate control group or included a small sample size [5-7]. Therefore, the aim of this study was to evaluate the prevalence of chronic cough and the associated factors in patients with OSA, and the effect of CPAP treatment.

Materials and methods

Study population: We retrospectively recruited patients with suspected OSA who were referred to our sleep lab by thoracic doctors from January 2012 to June 2012 in Chang Gung Memorial Hospital, a tertiary hospital in Taiwan. Patients were excluded if they were smokers, or if they had had an acute upper airway infection in the past 4 weeks, abnormal chest X-rays or any history of malignancy. The Chang Gung Medical Foundation Institutional Review Board approved this study (102-2103B) and waived the requirement for informed consent due to the retrospective nature of the study.

Study design: The medical records of each patient were reviewed to collect the clinical characteristics and laboratory results. In addition, data on comorbidities, aetiologies for the chronic cough such as GERD, UACS and asthma, medications, pulmonary function, Epworth sleepiness scale and clinical follow-up for 3 months after CPAP treatment were analysed. The improvements in cough are decided according to patients' self-report during following visits.

Definitions: A chronic cough was defined as a cough lasting for 2 months or more. Upper airway cough syndrome was defined as: (1) patients describing the sensation of "having something drip down into their throat" and/or the need to frequently clear their throat; (2) computed tomographic imaging or

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Table 1 Subjects demonstration

Characteristics	OSA	Non-OSA	*p*-value
	n = 99	n = 32	
Age	52.2±11.6	48.3±13.1	0.105
Male, n (%)	75 (75.8)	17 (53.1)	0.025
BMI	28.9±4.1	24.9±4.3	0.000
Epworth Sleepiness Scale	12.9±4.5	12.8±5.5	0.884
Total AHI, /h	53.6±24.7	10.1±4.3	0.000
Pulmonary function test			
FEV_1/FVC	83.7±8.4	82±12.5	0.394
FEV_1 (% predicted)	82.6±20.1	82.6±17.5	0.993
FVC (% predicted)	82.4±17.9	86.8±22.3	0.278
Chronic cough	39 (39.4)	4 (12.5)	0.005
Upper airway cough syndrome	79 (79.8)	23 (71.9)	0.340
Gastro-esophageal reflux disease	43 (43.4)	5 (15.6)	0.006
Asthma	18 (18.2)	5 (15.6)	1.000
Medication			
Nasal steroid	72 (72.7)	20 (62.5)	0.276
Anti-histamine	79 (79.8)	23 (71.9)	0.340
ACEI or ARB	11 (11.1)	0 (0.0)	0.065
Inhaled corticosteroid	18 (18.2)	5 (15.6)	1.000
Long-acting β_2 agonist	4 (4.0)	2 (6.2)	0.634
Proton pump inhibitor	43 (43.4)	5 (15.6)	0.006

Data are presented as mean ± SD; *BMI* body mass index, *FEV1* forced expiratory volume in one second, *FVC* forced volume capacity, *ACEI* angiotensin converting enzyme inhibitor, *ARB* angiotensin receptor blocker.

Water's view showing chronic sinusitis, or a positive finding by nasopharyngoscopy; (3) response to intranasal corticosteroids or anti-histamines [8,9]. Asthma was defined as a positive result of provocation test or PEF variability rate >20% [8]. GERD was defined as a response to anti-GERD medication [8], or if 24-h pH level exceeded the 95th percentile for percentage total time with a pH < 4 of > 4.8% [9]. Sleep stages and arousals were scored according to the AASM criteria [10]. Established criteria were used to score respiratory events such as hypopnea, obstructive apnoea, central apnoea, mixed type apnoea, and Cheyne-Stokes respiration [11]. Apnoea was defined as oronasal flow cessation for more than 10 seconds. Hypopnea was defined as a 50% reduction in oronasal flow for more than 10 seconds or a 30% reduction followed by arousal or more than 3% decrease in SaO2. Based on the polysomnography results, OSA was defined as an apnoea/hypopnea index (AHI) > 15 per hour, of which ≥ 50% were obstructive. CPAP titration to determine the optimal pressure was performed according to standard guidelines [12].

Table 2 Univariate analysis of the variables associated with chronic cough

Parameter	beta	Standard error	95% CI	P value
BMI	0.060	0.042	0.98 to 1.15	0.153
Male	−0.033	0.406	0.437 to 2.15	0.936
AHI	0.016	0.007	1.00 to 1.03	0.019
GERD	2.379	0.434	4.61 to 25.27	0.000
Upper airway cough syndrome	0.539	0.481	0.67 to 4.40	0.262
Asthma	0.778	0.468	0.87 to 5.44	0.096
FEV1 (%)	−0.005	0.010	0.98 to 1.02	0.650

BMI body mass index, *AHI* apnoea-hypopnoea index, *GERD* Gastro-oesophageal reflux disease, *FEV1* forced expiratory volume in one second.

Statistical analysis: Data were expressed as mean ± SD (standard deviation) or mean ± SEM (standard error of the mean). The Student's t test was used for comparisons of continuous variables between the two groups, while the Mann–Whitney test was used for non-normal distributions. Categorical variables were compared by chi-square or Fisher's exact tests. The Pearson product correlation coefficient was used to examine correlations between variables and chronic cough. Multivariate logistic regression analysis was used to determine the independent factors associated with chronic cough. A p value less than 0.05 was considered to be statistically significant. All analyses were performed using the SPSS software package version 13.0 (SPSS Inc., Chicago, IL, USA).

Results

Demographic and clinical characteristics of the patients

A total of 147 patients with suspected OSA were identified at our sleep lab between January 2012 and June 2012, 30 of whom were excluded due to the following reasons: 8 (5.4%) were current smokers; 5 (3.4%) had had acute upper airway infections in the past 4 weeks; 2 (1.4%) had abnormal chest X-rays, and 1 (0.7%) had a malignancy. The records of the remaining 131 patients were further reviewed, of whom 99 had OSA and 32 did not. The baseline demographic data and clinical characteristics of these patients are listed in Table 1. The mean ages of the patients with and without OSA were similar (52.2 and 48.3 years, respectively). The mean AHI in the OSA group was 53.6±24.7/h of sleep, indicating that most of the patients had severe OSA, accompanied with a higher percentage of males (75.8%) and higher BMI (28.9±4.1 vs. 24.9±4.3) compared with the Non-OSA group. Moreover, the percentage of chronic cough was significantly higher in the OSA group compared to the Non-OSA group (39.4% vs. 12.5%, p = 0.005). Interestingly, the incidence of GERD was also significantly higher in the OSA group, while the incidence of UACS and asthma was similar between the two groups. Other characteristics including Epworth sleepiness scale, pulmonary function, and medications including nasal steroids, anti-histamines, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, inhaled corticosteroids and long-acting β_2 agonists were also similar between the two groups.

Univariate and multivariate logistic regression analysis for the variables associated with chronic cough

In univariate analysis, AHI was significantly correlated with chronic cough (Table 2). GERD was also significantly correlated with chronic cough, while UACS, asthma and BMI were not significantly correlated with chronic cough. AHI, UACS, GERD and asthma were then used in the multivariate logistic regression model, which showed that GERD was the only independent factor associated with chronic cough (Table 3).

Cough response to CPAP treatment in the patients with OSA and chronic cough

A total of 39 patients with both OSA and chronic cough were identified, of whom 18 (46.2%) received CPAP treatment for 3 months (Table 4). A significant improvement in the chronic cough was noted in the patients who received CPAP treatment compared to those who did not receive CPAP treatment (12/18 (66.7%) vs. 2/21 (9.5%), p = 0.010). In addition, CPAP treatment was also beneficial for the patients with both OSA and asthma,

Table 3 Multivariate analysis with logistic regression: factors associated with chronic cough

Factors	beta	SE	P value	OR
AHI	0.009	0.008	0.245	1.009
Upper airway cough syndrome	0.291	0.556	0.601	1.337
GERD	2.339	0.453	0.000	10.373
Asthma	0.884	0.554	0.110	2.422

AHI apnoea-hypopnoea index, *GERD* Gastro-oesophageal reflux disease.

whose chronic cough was significantly improved by CPAP treatment compared to those who did not receive CPAP treatment (3/4 (75%) vs. 1/7 (14.3%), p = 0.044). Similar results were also found in UACS and GERD (2/18 (11.1%) vs. 10/14 (71.4%), p = 0.001; and 1/15 (6.7%) vs. 8/14 (57.1%), p = 0.005, respectively).

Discussion

This study demonstrated that the prevalence of chronic cough was significantly higher in the OSA group. In univariate analysis, AHI and GERD were significantly associated with chronic cough. In multivariate analysis, GERD was the only factor associated with chronic cough, which was significantly improved after CPAP treatment. To the best of our knowledge, this is the first study to report an association between chronic cough and OSA.

The most common etiologies of chronic cough are GERD, rhinosinusitis, and asthma [13]. Recently, several reports have suggested an association between chronic cough and obstructive apnoea [5-7]. Chan et al. reported that the prevalence rate of chronic cough in OSA patients is up to 33% [5], which is much higher than that in the general population [14,15]. In Chan et al's study [5], both GERD and rhinitis played important roles in chronic cough, however, there was no control group and the number of cases was relatively small. In the present study, the prevalence of chronic cough in the patients with OSA was 38.6%, which is similar to the results of Chan et al. [5]. In addition, the number of cases in the present study was larger, and most importantly, the present study enrolled a control group. Compared to the control group, the incidence of chronic cough was significantly higher in the OSA group. Interestingly, the incidence of GERD was also significantly higher in the OSA group, but not UACS or asthma.

GERD is known to be an important aetiology of chronic cough, and a higher prevalence of GERD is expected in patients with OSA due to large intrathoracic negative pressure swings during apnoea episodes aggravating the severity of GERD [16]. Several sleep lab-based studies have reported incidence rates of GERD in OSA patients ranging from 64.7% to 100% [17-19]. In a large cross-section epidemiology study, subjects with nocturnal GERD had a significantly higher incidence of OSA than those without nocturnal GERD (16% vs. 5%). Nasal CPAP has been shown to reduce GERD in patients with OSA [19,20], suggesting a strong relationship between GERD and OSA. In the present study, only AHI and GERD were associated with chronic cough in univariate analysis, and only GERD was associated with chronic cough in multivariate analysis. This implies that GERD may be the most important aetiology of chronic cough in patients with OSA. However, the present study is a retrospective study, and further large-scale prospective studies are needed to draw a more definitive conclusion.

Table 4 Comparison of the OSA patients with chronic cough who did and did not receive CPAP treatment

Characteristics	OSA with CPAP treatment	OSA without CPAP treatment	*p*-value
	n = 18	n = 21	
Age	49.8±9.5	57.1±10.8	0.055
Male, n (%)	16 (88.9)	14 (66.7)	0.139
BMI	29.2±5.4	29.1±3.4	0.602
Pulmonary function test			
FEV_1/FVC	78.9±12.5	85.3±6.0	0.193
FEV_1 (% predicted)	76.6±23.5	85.4±16.8	0.317
FVC (% predicted)	79.4±19.5	86.2±16.6	0.367
Epworth Sleepiness Scale	12.9±4.1	13.4±5.3	0.618
Upper airway cough syndrome	18 (85.7)	14 (77.8)	0.682
Gastro-esophageal reflux disease	14 (77.8)	15 (71.4)	0.726
Asthma	4 (22.2)	7 (33.3)	0.497
Sleep parameters			
Total AHI, /h	59.5±26.4	51.8±27.1	0.353
CPAP titration pressure	8.8±3.0	7.3±1.8	0.318
Improved cough, n (%)	12 (66.7)	2 (9.5)	0.010

Data are presented as mean ± SEM.
BMI body mass index, *FEV1* forced expiratory volume in one second, *FVC* forced volume capacity, *AHI* apnoea-hypopnoea index.

Nasal obstruction is also associated with OSA, and possible mechanisms such as the Starling resistor model, unstable oral breathing, nasal-ventilatory reflex and nitric oxide have been identified [21]. In the Wisconsin Sleep Study, subjects with self-reported nocturnal nasal congestion had a three-fold increase in the incidence of snoring [22]. On the other hand, a prospective study reported that allergic rhinitis is directly associated with OSA [23]. The use of nasal steroids has been reported to improve sleep quality, but not the severity in patients with severe OSA [24] or in those who receive nasal surgery [25]. Therefore, it is reasonable to assume nasal steroids or surgery does not improve chronic cough, which is related to OSA. In the present study, a high percentage of rhinosinusitis was noted in the OSA patients, and most of them were treated with nasal steroids and anti-histamines while only some with nasal surgery. Further, rhinosinusitis was not associated with chronic cough in the present study.

The incidence of asthma in patients with chronic cough has been reported to range from 16% to 41.8%, and coughing has been reported to be significantly improved by inhaled corticosteroid treatment [26]. However, a significantly higher dose of inhaled corticosteroids is needed to control asthma when sputum coexists with eosinophils and neutrophils [27]. Moreover, neutrophils are activated and delay apoptosis [28,29] during the process of ischemia/reperfusion caused by OSA. Therefore, OSA is an important factor in aggravating asthma control, which can be reversed by CPAP treatment [30]. In addition, the asthma-related chronic cough, which is aggravated by OSA, can also be improved by CPAP. In the present study, chronic cough was significantly improved in the patients with both OSA and asthma by CPAP treatment compared to those who did not receive CPAP treatment (3/4 (75%) vs. 1/7 (14.3%); p = 0.044). However, asthma was not an independent factor contributing to chronic cough in

this study, and the number of case was relatively small. Further large-scale studies are needed to clarify this issue.

The major limitations of the present study are its retrospective nature, which may have led to bias in patient selection. Second, the sample size of the study is small, and therefore the results of the study should be interpreted with caution. A prospective study with a larger sample size is warranted to further confirm the results. Finally, the population in this study was based in a sleep lab, so extrapolation of the results to the general population should be done with caution.

Conclusions

In conclusion, the incidence of chronic cough was significantly higher in the patients with OSA. Both GERD and AHI were significantly associated with chronic cough in univariate analysis, however GERD was the only independent factor associated with chronic cough in multivariate analysis. Chronic cough was significantly improved after CPAP treatment for the patients with OSA, and therefore OSA may be a contributory factor to chronic cough.

References

1 Chung KF, Pavord ID: Prevalence, pathogenesis, and causes of chronic cough. Lancet 2008, 371:1364-1374.
2 Morice A: Chronic cough: epidemiology. Chron Respir Dis 2008, 5:43-47.
3 Pratter MR, Brightling CE, Boulet LP, Irwin RS: An empiric integrative approach to the management of cough: ACCP evidence-based clinical practice guidelines. Chest 2006, 129:222S-231S.
4 McGarvey LP: Idiopathic chronic cough: a real disease or a failure of diagnosis? Cough 2005, 1:9.
5 Chan KK, Ing AJ, Laks L, Cossa G, Rogers P, Birring SS: Chronic cough in patients with sleep-disordered breathing. Eur Respir J 2010, 35:368-372.
6 Sundar KM, Daly SE, Pearce MJ, Alward WT: Chronic cough and obstructive sleep apnea in a community-based pulmonary practice. Cough 2010, 6:2.
7 Birring SS, Ing AJ, Chan K, Cossa G, Matos S, Morgan MD, Pavord ID: Obstructive sleep apnoea: a cause of chronic cough. Cough 2007, 3:7.
8 Lai K, Chen R, Lin J, Huang K, Shen H, Kong L, Zhou X, Luo Z, Yang L, Wen F, Zhong N: A prospective, multicenter survey on causes of chronic cough in China. Chest 2013, 143:613-620.
9 McGarvey LP, Heaney LG, Lawson JT, Johnston BT, Scally CM, Ennis M, Shepherd DR, MacMahon J: Evaluation and outcome of patients with chronic non-productive cough using a comprehensive diagnostic protocol. Thorax 1998, 53:738-743.
10 EEG arousals: scoring rules and examples: a preliminary report from the Sleep Disorders Atlas Task Force of the American Sleep Disorders Association. Sleep 1992, 15:173-184.
11 Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep 1999, 22:667-689.
12 Kushida CA, Chediak A, Berry RB, Brown LK, Gozal D, Iber C, Parthasarathy S, Quan SF, Rowley JA: Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med 2008, 4:157-171.
13 Birring SS: Controversies in the evaluation and management of chronic cough. Am J Respir Crit Care Med 2011, 183:708-715.
14 Di Pede C, Viegi G, Quackenboss JJ, Boyer-Pfersdorf P, Lebowitz MD: Respiratory symptoms and risk factors in an Arizona population sample of Anglo and Mexican-American whites. Chest 1991, 99:916-922.
15 Voll-Aanerud M, Eagan TM, Wentzel-Larsen T, Gulsvik A, Bakke PS: Changes in respiratory symptoms and health-related quality of life. Chest 2007, 131:1890-1897.
16 Ing AJ, Ngu MC, Breslin AB: Obstructive sleep apnea and gastroesophageal reflux. Am J Med 2000, 108(Suppl 4a):120S-125S.
17 Graf KI, Karaus M, Heinemann S, Korber S, Dorow P, Hampel KE: Gastroesophageal reflux in patients with sleep apnea syndrome. Z Gastroenterol 1995, 33:689-693.
18 Penzel T, Becker HF, Brandenburg U, Labunski T, Pankow W, Peter JH: Arousal in patients with gastro-oesophageal reflux and sleep apnoea. Eur Respir J 1999, 14:1266-1270.
19 Kerr P, Shoenut JP, Millar T, Buckle P, Kryger MH: Nasal CPAP reduces gastroesophageal reflux in obstructive sleep apnea syndrome. Chest 1992, 101:1539-1544.
20 Green BT, Broughton WA, O'Connor JB: Marked improvement in nocturnal gastroesophageal reflux in a large cohort of patients with obstructive sleep apnea treated with continuous positive airway pressure. Arch Intern Med 2003, 163:41-45.
21 Georgalas C: The role of the nose in snoring and obstructive sleep apnoea: an update. Eur Arch Otorhinolaryngol 2011, 268:1365-1373.
22 Young T, Finn L, Palta M: Chronic nasal congestion at night is a risk factor for snoring in a population-based cohort study. Arch Intern Med 2001, 161:1514-1519.
23 McNicholas WT, Tarlo S, Cole P, Zamel N, Rutherford R, Griffin D, Phillipson EA: Obstructive apneas during sleep in patients with seasonal allergic rhinitis. Am Rev Respir Dis 1982, 126:625-628.
24 Craig TJ, Hanks CD, Fisher LH: How do topical nasal corticosteroids improve sleep and daytime somnolence in allergic rhinitis? J Allergy Clin Immunol 2005, 116:1264-1266.
25 Li HY, Lee LA, Wang PC, Chen NH, Lin Y, Fang TJ: Nasal surgery for snoring in patients with obstructive sleep apnea. Laryngoscope 2008, 118:354-359.
26 Abouzgheib W, Pratter MR, Bartter T: Cough and asthma. Curr Opin Pulm Med 2007, 13:44-48.
27 Matsuoka H, Niimi A, Matsumoto H, Takemura M, Ueda T, Yamaguchi M, Jinnai M, Inoue H, Ito I, Chin K, Mishima M: Inflammatory subtypes in cough-variant asthma: association with maintenance doses of inhaled corticosteroids. Chest 2010, 138:1418-1425.
28 Schulz R, Mahmoudi S, Hattar K, Sibelius U, Olschewski H, Mayer K, Seeger W, Grimminger F: Enhanced release of superoxide from polymorphonuclear neutrophils in obstructive sleep apnea. Impact of continuous positive airway pressure therapy. Am J Respir Crit Care Med 2000, 162:566-570.
29 Dyugovskaya L, Polyakov A, Lavie P, Lavie L: Delayed neutrophil apoptosis in patients with sleep apnea. Am J Respir Crit Care Med 2008, 177:544-554.
30 Lafond C, Series F, Lemiere C: Impact of CPAP on asthmatic patients with obstructive sleep apnoea. Eur Respir J 2007, 29:307-311.

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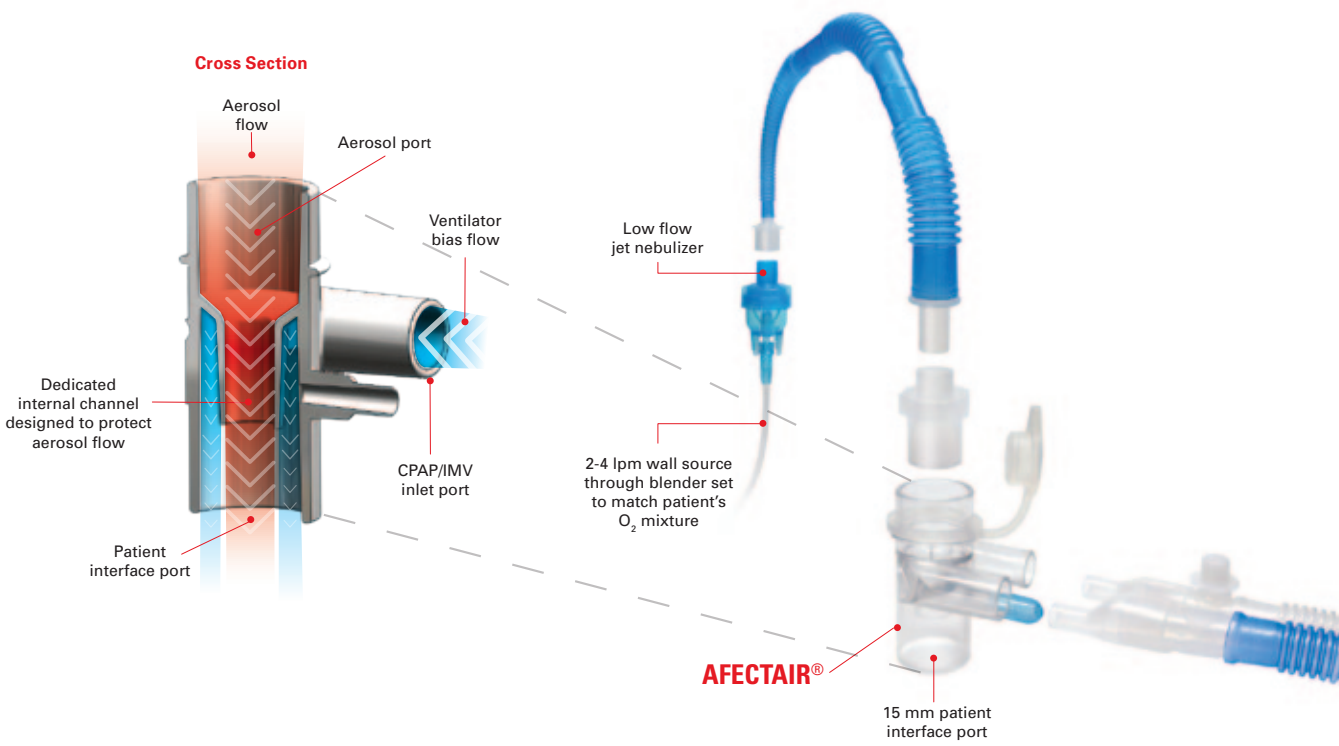

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