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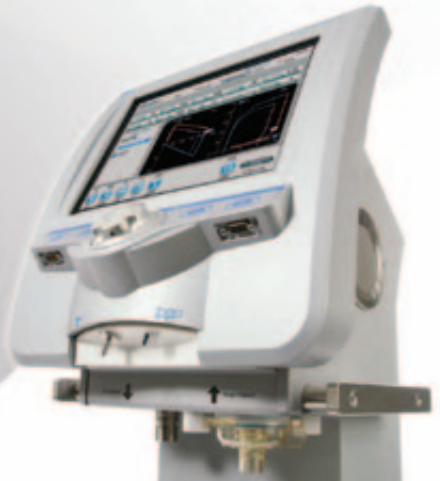

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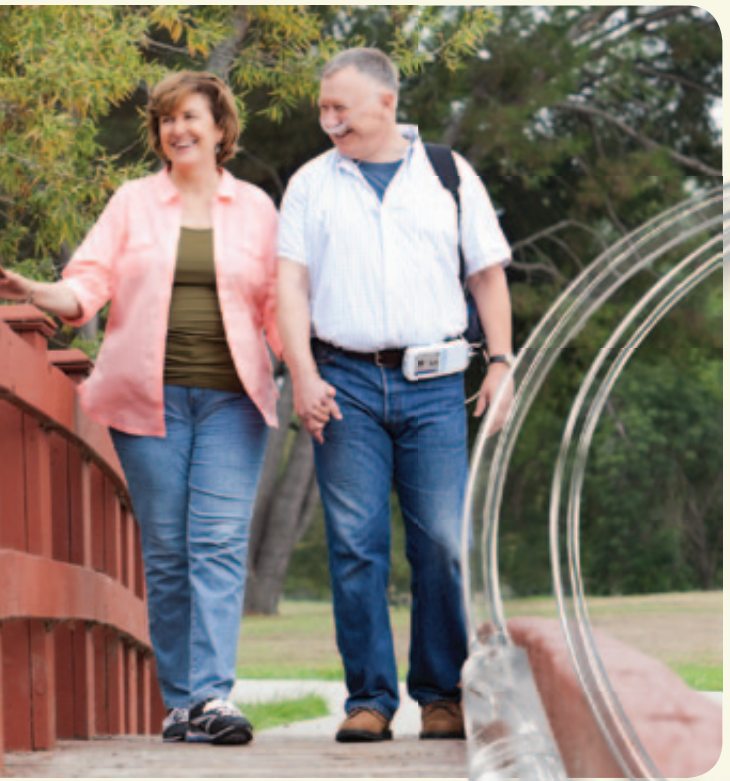

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Respiratory Therapy™
The Journal of Pulmonary Technique

Vol. 6 No. 6
December 2011-January 2012

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Editorial

Are You Next?

How likely is it that respiratory therapists may one day be called "Doctor?" Pshaw, you might say, yet there's an increasing trend for non-MD professionals to earn PhDs and to call themselves doctors when addressing their patients. For example, see the news article in this issue, "Paging 'Dr' Doctor."

Recently, the New York Times ran an extensive piece about this, noting that it will be increasingly routine for patients that someone who is not a physician is using the title. According to the Times, "Doctorates are popping up all over the health professions, and the result is a quiet battle over not only the title 'doctor,' but also the money, power and prestige that often comes with it." By way of example, according to the Times, "Last year, 153 nursing schools gave doctor of nursing practice degrees to 7,037 nurses, compared with four schools that gave the degrees to 170 nurses in 2004… In 2008, there were 375,794 nurses with master's degrees and 28,369 with doctorates."

Of course this is throwing physicians into a tizzy, since they see the trend as an erosion of their authority, and they are even pushing legislation to stop it in its tracks. But the argument cuts deeper. Everyone is aware that there's a shortage of doctors who are front-line caregivers, what with so many physicians opting to specialize. The Times notes, "As demand for healthcare services has grown, physicians have stopped serving as the sole gatekeepers for their patients' entry into the system. Teamwork is the new mantra of medicine, and [so-called] 'physician extenders' have become increasingly important care providers." With the rationing of healthcare, it's unlikely that MDs will continue to have it both ways – there is simply too much demand to increase services and lower costs.

There are many sides to this argument that will be hashed out in the coming years, having to do with the cost of education, demand for higher fees by the new PhDs, patient perceptions of caregivers, and so forth. And of course we still haven't touched on what this really portends for RTs, who typically have a BS or at most an MS in their field. So is this an imminent reality for respiratory therapists, or a pipe dream? Well, it didn't take long to find evidence on the internet, simply by googling the topic. Right at the top of the search was a website by worldwidelearn.com, titled "PhD Degree Programs in Respiratory Therapy," which noted: "Schools may begin to offer PhD programs in respiratory therapy. Though it would likely be years before such a degree becomes a professional requirement for clinical practitioners or educators in respiratory therapy, hiring managers in academia and high-level research groups may consider it evidence of the highest-possible level of commitment to the field." You can also see this little YouTube video: http://youtu.be/Ab3QhR19aQI.

It'll be interesting to see just how long it takes until you introduce yourself to your patients as "Doctor." (Your comments are welcome.)

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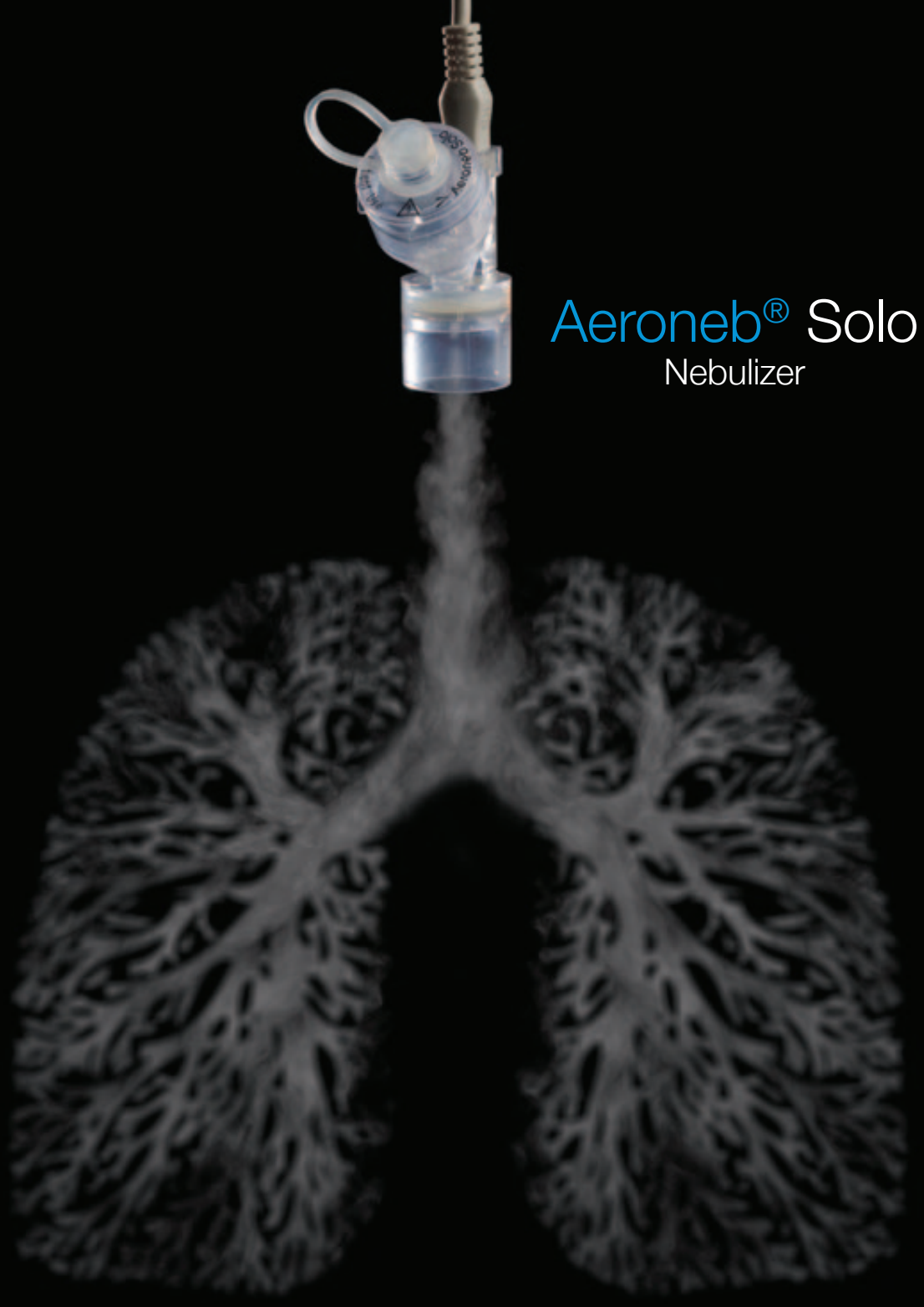

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News

☐ December 2011-January 2012

PAGING "DR" DOCTOR

Many nurses are going back to school to earn doctorate degrees, but does that give them the right to call themselves doctor? That's the question asked by a recent article in the New York Times (Oct 2). More and more nurses are getting degrees and identifying themselves as doctors, and physicians are fraught, even pushing for legislation that would codify who can call themselves "doctor." One doctor said the trend is a slippery slope that "will be followed by the loss of control over the profession itself." (But haven't insurance companies already accomplished this?) On the Times blog, readers responded: "It is easy, if you earn a medical degree (DO, MD, MBBS etc) you are a doctor. If not, you are not. Psychologists with PhDs are not called doctors, at least my hospital. Patient's are already confused enough." … "Of course it would be confusing. I find it confusing when I make an appointment with my doctor and get his nurse practitioner instead." … "Medical doctors do not have a monopoly on the title 'doctor,' they need to just get use to it. Perhaps some clever person can come up with a more inflated title for medical doctors to distance themselves from the rest of us with our apparently not so exalted 'doctorates.'" [Editor's note: I just look at the my caregiver's id badge. Not that the designation has ever made any difference in the quality of my care.]

WEIGHT AND WHEEZE

An extensive three-decade review of pregnancies by the University of San Diego revealed that women with poorly-managed asthma are at an increased risk of having a low birth weight baby, a premature baby and other pregnancy complications, such as preeclampsia. The study found that the infants of women with asthma were likely to weigh an average of 0.2 lbs less at birth compared to babies of mothers without asthma. Mothers with poorly-controlled asthma were at a 25% increased risk of preterm birth and 50% increased risk of developing preeclampsia. The study didn't clarify why this was the case, but the researchers are monitoring asthma medications used during pregnancy.

HIGH COST

The high personal cost of COPD to its sufferers was reported by researchers at the European Lung Foundation, who found that 80% of COPD patients between 45 and 65 years old were unable to maintain the same lifestyle as before. One in four said they couldn't take care of their families as they had, and one in five felt they were a burden to their families. More than half said they

went out less and that when they did, they felt their coughing was an embarrassment. More than 40% said they couldn't plan for their future, and a third said their earnings had decreased as a result of the disease.

DON'T FORGET

Primatene Mist can no longer be prescribed or sold after December 31. CNN reports that the nonprescription asthma inhaler by Armstrong Pharmaceuticals ends its run at the end of the year, because it contains chlorofluorocarbons, which are the propellant moving the medication. CFC inhalers have been replaced by those with hydrofluoroalkane, HFA, but there is no current version of such inhalers with epinephrine. Physicians have noted that the HFA inhalers taste and feel different. There are two other prescription inhalers that use CFCs that won't be phased out till 2013.

CONVEYOR BELT CARE

Douglas Farrago, MD, in Authentic Medicine Gazette, writes: "Everyone wants to get in and out of the ER as fast as they can, right? Well… some ERs are instituting 'lean management principles' used by such companies as Toyota. They are using such ideas as NOT giving some patients beds or using 'less-costly' providers other than doctors. Sounds great. Hey, here are some new ideas. How about using a conveyor belt that patients are placed upon and doctors can see them as they fly by? Or, instead of using beds we can put them on hammocks or hooks? Wait, I got it. How about everyone gets a piece of Velcro and are stuck to the wall? That will save tons of space. It's all about efficiency, you know. I understand ERs get overcrowded. Part of the reason is that there is no incentive to go into primary care and there will be less and less primary care docs around so patients have to go to the ER. Usually with this supply and demand issue you would increase the salaries of PCPs to fix the problem. Nope. Also, the other issue is no patient is ever allowed to be turned away from the ER no matter how trivial his/her issue. I can't tell you how many times I see ER records come by for sore throats or sprained knees when I had openings in my office at that same time. But go ahead, let's bring the MBAs and find new ways to see patients in the ER. Why stop at NPs or PAs? Let's go deeper and have Nurse Practitioner Assistants or Physician Assistant Assistants." Authentic Medicine Gazette, formerly Placebo Journal, is going out of business, but back issues are available at placebojournal.com.

SEE BREATH THROUGH WALLS

Wireless networks that can see through walls may be used to measure the breathing of patients, those with sleep apnea, and babies at risk of SIDS, according to engineers at the University of Utah. The technique uses wireless transceivers like those on home computer networks, so it's said to be less expensive than other monitoring methods. Still in development, the wireless system could measure breath rates without anything connected to the patient. Such wireless technology could also be used to "see" people trapped by fire, or kids partying at a house while the parents are away, or burglars. The researchers have demonstrated that 20 wireless transceivers around a hospital bed could reliably detect breathing and can estimate breathing rate to within two-fifths of a breath per minute based on 30 seconds of data. Each of the 20 transceivers can transmit and receive to the other 19, meaning there can be up to 380 measurements of radio signal strength within a short period of time. The researchers also want to test if the system can detect two people breathing at once but out of sync, which could, for example, detect the location of hostages in a building, and how many were being held together.

ANTI-ANTIOXIDANTS

Giving patients with lung problems omega-3 fatty acids and antioxidants does more harm than good, according to a report by Rob Stein in the Washington Post (Oct 5). Researchers studied 272 adults with acute lung problems and failed to find any benefits to the regimens, which were previously thought to be beneficial, based on smaller studies. In the current study, patients received the substances twice a day within 48 hours of mechanical ventilation. The study was terminated early after those getting the antioxidants ended up spending more days on a ventilator and more days in intensive care. Patients getting omega-3 fatty acids and antioxidants had 14 vs 17 days off the ventilator, and 38 patients died, compared with 21 who received a placebo.

TOO THIN

Underweight patients with COPD are at a higher risk of dying, according to a study at Uppsala University, Sweden. The study involved 552 patients, and revealed that the skinny ones faced a 1.7-times higher risk of death compared with people of normal weight. The researchers also

found that people with COPD who also had heart disease or cardiac failure had a 1.9-times higher risk of death compared to those suffering from COPD alone. Information is from Medical News Today, written by Petra Rattue, copyright Medical News Today.

PATCH IT UP

The Huffington Post reported that many types of monitoring equipment may soon be replaced by a "tiny, wireless patch, sort of like a temporary tattoo." Researchers at the University of Illinois have embedded electronic sensors in film thinner than a human hair that can stick to skin without adhesives and can remain in place for 24 hours. The patches could monitor brain waves, muscle movement, larynx movement, and other functions. A company in Massachusetts, MC10 is working on developing commercial uses. HuffPo said, "The current design has a small coil and could be powered by induction – by placing it near an electrical coil – that would permit intermittent use, and for longer-term monitoring a tiny battery or storage capacitor could be used."

DISTURBING THE PEACE

Researchers at the University of Liege in Belgium, using fMRI and EEGs, studied how the brain responds to noises during sleep, using brain imaging. The imaging revealed that brain activity confronted with noise is controlled by waves, called sleep spindles, that prevent the transmissions of sound to auditory brain regions. At the same time, brain waves called K-complexes activate larger auditory areas. As such, perception of noise during sleep varies over the sleep cycle, depending on what kinds of waves are in play.

SLEEP SLOWLY

Older men who don't get enough deep sleep, called slow wave sleep, are at a greater risk of developing hypertension, said researchers at Harvard Medical School. Slow wave sleep (SWS) is Stage 3 and 4 non-REM sleep, characterized by brain wave patterns with a frequency of less than 4 Hz and peak-to-peak amplitude of 75 microV. Researchers said older men with the lowest SWS levels had an 80% higher risk of developing hypertension compared to men of the same age without reduced SWS. Reduced SWS among men generally occurred in those who slept for shorter times and woke up more often during the night, or had severe sleep apnea. Reported in Medical News Today, written by Christian Nordqvist, copyright Medical News Today.

DON'T USE IT AND YOU LOSE IT

The benefits of CPAP for OSA are reversed in a few days after the therapy is withdrawn, according to Swiss researchers at the University Hospital of Zurich. Patients were randomized to either continue CPAP therapy or to have CPAP withdrawn for two weeks. After baseline polysomnography, patients underwent nightly at-home assessment of respiration and oxygen saturation each day of the study period. Polysomnography was repeated at the end of two-weeks. At the end of the study period there was a significant increase in apneic events, oxygen desaturations and the number of arousals during sleep. As a consequence of the recurrence of sleep-disordered breathing, subjective sleepiness increased in the CPAP withdrawal group. Endothelial function deteriorated considerably in the CPAP withdrawal group, and there was an increase in blood pressure and heart rate. The researchers found a significant increase in urinary catecholamines, which implied that withdrawal of CPAP has a measurable negative effect on the cardiovascular system.

DID YOU KNOW

A study of over 400 US critical care units revealed that 27% of admissions received mechanical ventilation and 7.5% received noninvasive ventilation, according to Hamilton Medical. That translates to 34.5% of admitted patients receiving some form of ventilation with about 1 in 5 on non-invasive ventilation. A study of 30 ARDS patients revealed that FRC was reduced to only 30% of normal, further suggesting the need for simple bedside techniques to assess which patients have recruitable lungs. It's estimated that, on average, 60% of ventilator length of stay is in the acute phase versus 40% of ventilator time in the weaning phase. The PaO_2/FIO_2 ratio is a component of the definition of ARDS. Some have suggested that the current PEEP level could "bias" this ratio criteria and that perhaps the P/F ratio should be determined at a standard PEEP setting. However, a recent study analyzing the ARDSnetwork database found no correlation between PEEP level at time of P/F ratio measurement and mortality. A recent study of 96 patients revealed that almost 50% of responsive patients on mechanical ventilation experienced dyspnea. The only ventilator parameter associated with dyspnea was the use of "assist-control" ventilation (volume control with a constant flow) for which the dyspnea scores were at least 2 times higher than patients on pressure support ventilation. Reduction of anxiety did not reduce dyspnea and adjustments to flow rate reduced dyspnea in 35% of patients. Approximately 70% of neonatal/pediatric units surveyed reported at least a 3 month orientation period is provided for respiratory therapists without prior NICU/PICU experience. Reported by Hamilton Medical in its newsletter, by Paul Garbarini, MS, RRT, Clinical Manager, Hamilton Medical, Inc.

GET ORGANIZED

INTERASMA was founded over sixty years ago and is the oldest international medical association devoted to asthma, in all its aspects. Over the decades INTERASMA's worldwide network of regional branches has enabled it to contribute to medical and professionals' lifelong education and training. This has included drafting scientific material and holding themed meetings and symposia focusing on asthma conducted jointly with the medical societies of many countries and regions. In addition, INTERASMA hosts its own regional and world congresses. INTERASMA's current Executive Committee has recently nominated several excellent asthma specialists for its international chapters. These individuals, jointly with the Executive Committee and the association's members are working to improve and develop INTERASMA's activities in asthma, promoting asthma research projects in a country or region. Contact interasma.org.

DUH

Douglas Farrago, in Authentic Medicine Gazette, reports: "Emergency departments with a lot of temporary doctors and nurses were found to have twice as many medication errors than hospitals with stable staff members. The actual cause is unknown because these hospitals could just suck in general and that is why the staff keeps leaving rather than the mistakes being made by those temps. The study by Johns Hopkins came out in the Journal of Healthcare Quality. Here is what I see happening from this. Instead of putting money into good doctors and nurses who will stay, I predict these hospitals will hire more administrators to study the issue in detail. Then they can hire other personnel to form subcommittees and focus groups. This should end up with 'action teams' who will reassess the issues at hand. Then all these people can go on a retreat (after going to

a few 'healthcare quality conferences' of course) and decide on a pilot program that would include some of the newest fads and trends in expediting patient care with less staff in general. Or they could just treat and pay the ER staff better." For back issues of similar articles, visit placebojournal.com.

CONSEQUENCES

The negative effects of moderately premature birth on the lungs can show up at a later age, according to researchers at Cardiff University, who examined the lung function of children at age 8 and 14. Spirometry revealed that babies born at 33 weeks had significantly lower lung functions at age of 8 compared to full term babies. But by the time these kids reached l4, lung function improved.

MOOOVE AWAY

Emissions from livestock farms cause asthma and COPD exacerbations in patients living nearby, according to researchers at Utrecht University. The chances of contracting Q fever from sheep and goat farms increased in proportion to the number of animals in the vicinity. Researchers measured levels of particulate matter with toxins and screened medical records from 50 doctors serving 200,000 patients in areas with high and low densities of livestock farms. In areas with many farms, people with asthma or COPD had twice the rate of pneumonia and upper respiratory tract infections. The risk of contracting Q fever increased with the proximity of goat and sheep farms.

CLIMATE CHANGE

Death rates linked to climate change will increase in several European countries over the next 60 years, according to researchers at the WHO and Umea University in Sweden. The World Health Organizations noted that climate change has already resulted in 140,000 excess deaths annually. In the current study, researchers used emission scenarios to model the health impact of climate change, and compared various baseline period. They found that since 1961, Belgium, Ireland, The Netherlands and the UK have had the most ozone-related deaths, and predicted that the largest increase in the next 50 years is likely to occur in Belgium, France, Spain and Portugal, while the Nordic and Baltic countries were predicted to have a decrease. The reason for the increases was posited as resulting from ground-level ozone formation due to increases in temperature.

HELP AND HURT

Hormone replacement therapy, which helps women through menopause, can also lead to severe exacerbations of asthma, according to researchers at the Danish Pediatric Asthma Center and the Danish Cancer Society. The researchers looked at 23,138 women who had HR therapy and noted how many required hospitalization for asthma. The women who had HRT were 1.3 times more likely to be admitted to a hospital for asthma. The longer the women used HRT, the more the risk increased, up to 1.5 times more likely at ten years.

THE END

Joseph Maraachli, the terminally ill 20-month old baby at the center of a legal and ethical battle, recently died at his Windsor, Ontario home. The baby had Leigh's disease. The parents wanted him to have a tracheotomy so he could die at home. After Canadian doctors refused to perform the procedure, calling it invasive and futile, Maraachli's parents fought to have the baby transferred to the US, arguing that while Joseph's disease was terminal, a tracheotomy would extend his life and allow him to die at home. The parents said he breathed mostly on his own but medical personnel claimed he remained on a ventilator. After several months, Maraachli was transferred to a Catholic hospital in St Louis, where the procedure was performed. The Canadian hospital had said the baby was in a persistent vegetative state, but the parents said he responded to tickling. In any event, the child died five months after the tracheotomy.

WORK EXPOSURE

Danish researchers found a correlation between a mom's work exposure to certain chemicals and asthma in their children. Researchers examined the records of 42,696 children and their asthma prevalence at age 7, and compared the results to their moms' occupations. The mothers' jobs included working with vehicle parts, furniture, shoes, paints, varnish, glues, and wood products. Out of the children whose moms who worked with such substances, 18.6% had asthma, compared to 15.8% of the entire cohort.

HEART ACHE

People who have chronic COPD or reduced lung function are at a higher risk for developing cardiovascular disease, according to researchers in Sweden. The researchers collected info on nasal symptoms and heart disease from 993 people with COPD and the same number without. Nasal symptoms were common among those who had both COPD and heart disease, at 53%, compared to about 36% with normal lung function and heart disease. More than 62% of those with restricted lung function and cardiovascular disease had nasal symptoms. The researchers suggested that physicians monitor their patients for co-morbidities. Information is from Medical News Today, from an article written by Grace Rattue, copyright Medical News Today.

BELLY AND BREATH

Central obesity, or belly fat, is linked to asthma, according to Norwegian researchers. Researchers looked at 23,245 adults with asthma and measured their BMI and waist circumference over an 11 year period. People with belly fat were 1.81 times more likely to have developed asthma. Central obesity is also associated with insulin resistance and metabolic syndrome.

THAT FIRST HIT

Smokers who light up a cigarette first thing in the morning have a higher risk of developing lung, head and neck cancers than those who wait till later, according to researchers at Penn State College of Medicine. Researchers looked at 4,775 lung cancer cases and 2,835 controls who were smokers. Compared with people who smoked an hour or more after waking up, those who smoked in the first half hour were 1.31 times as likely to develop cancer, and those who lit up right at waking were 1.79 times as likely to develop it. Researchers posited that those who had to light up right away had a higher dependence on nicotine, and thus had more of it in their systems.

DRINK UP

Drinking alcohol can reduce the risk of asthma, according to researchers in Denmark who looked at 19,349 twins between age 12 and 41 and compared alcohol intake with the risk of developing asthma. The lowest risk of asthma was for those who drank moderately. The highest risk was for those who never drank, who were 1.4 times more likely to develop asthma. Heavy drinkers were 1.2 times as likely to develop it. Beer drinkers were more likely to develop asthma than those with other beverage preferences.

ASBESTOS AND DEATH

Researchers with the World Health Organization are warning of a huge increase in future deaths from asbestos-related lung diseases, especially in Asian countries, which accounted for 64% of asbestos consumption in recent years. Asbestos has been identified as an extremely dangerous occupational carcinogen used for insulation in construction. The WHO noted that asbestos related lung diseases typically appear many years after exposure.

WOOF!

Dogs could be used to sniff out lung cancer, by detecting volatile organic compounds in people's breath, according to researchers from Schillerhoehe Hospital in Germany. Using specially-trained dogs, researchers worked with 220 patients, including those with lung cancer, COPD, and healthy volunteers. The dogs identified 71 out of 100 lung cancer samples, and 372 from 400 who didn't have lung cancer. Plus, the dogs could differentiate between lung cancer and COPD, and weren't fooled by tobacco smoke. Information is from Medical News Today, written by Petra Rattue, copyright Medical News Today.

CHANCY

One out of four people aged 35+ will develop COPD at some point, according to researchers at the Institute for Clinical Evaluative Sciences in Toronto. This means people are more likely to develop COPD than heart failure, heart attacks or cancer. For men, the risk of developing COPD is three times as high as getting prostate cancer. By 2030 COPD is predicted to be the third most common cause of death worldwide. Researchers looked at data from 13 million people and 579,466 cases of COPD. Men had a higher risk, as did the poor or those living in rural areas. Information is from an article in Medical News Today by Grace Rattue, copyright Medical News Today.

WHAT VALUE?

Placebo Journal (Authentic Medicine Gazette) reported: "Here is some interesting news. The government is going to start the pay-for-performance payment system two years *earlier* than they promised. They won't, however, pay the doctors the higher or lower rate until two years after the start. Huh? Yeah, I know. Who would think that the government would start an unproven system, rename it (now called 'value-based'), cram it down our throats and do it against all the wishes of the major medical specialties." From placebojournal.com, where back issues of the journal are available.

RACE AND READMISSIONS

Black patients over 40 had a 30% higher hospital readmission rate after treatment for COPD than Hispanics, Asians and Pacific Islanders, and a 9% higher readmission rate than whites, according to a study by the Agency for Healthcare Research and Quality. Of all patients readmitted, 7% were for COPD and the rest for other health conditions. Hospitals in the 15-state survey initially admitted 190,700 COPD patients at $7,100 per patient. The average readmission cost was $8,400. Patients from the poorest areas had a 22% higher readmission rate, and males had a 13% higher readmission rate than females. Reported by Petra Rattue, Medical News Today, copyright Medical News Today.

BUT DON'T USE DRUGS

Opioids are associated with a higher risk of pneumonia, according to researchers at the University of Washington, who studied 3,061 adults aged 65 to 94. Benzodiazepines, however, did not carry the same risk. About 2-million 65+ year old Americans take opioids, including morphine, codeine and fentanyl. The researchers measured whether people with pneumonia were more likely than controls to have taken opioids or benzodiazepines before the start of their illness. Among pneumonia cases, 13.9% were using opioids and 8.4%, benzodiazepines. In subjects without pneumonia, 8% used opioids and 4.6% benzodiazepines. Patients taking long-acting opioids were more than three times as likely to get pneumonia. During the first 14 days of opioid use, patients were three times as likely to get pneumonia.

NEWS FEATURE

Effects of Implementing Adaptive Support Ventilation in a Medical Intensive Care Unit

Jeff Borrink, BS, RRT

Jeff Borrink is Clinical Support Specialist, Hamilton Medical, Inc. This article is from Hamilton's newsletter.

A recent study published in the July 2011 issue of Respiratory Care concluded that utilizing Adaptive Support Ventilation (ASV) on patients recovering from respiratory failure, who were being mechanically ventilated for at least twenty-four hours in a medical intensive care unit, helped facilitate liberation from mechanical ventilation and may improve weaning outcomes.[1] The study by Chen, et al, compared 79 patients who were prospectively managed with ASV in a medical intensive care unit that had respiratory therapist coverage during the day but not at night, to a control group of 70 patients from the same intensive care unit who were managed with conventional ventilation and a ventilator weaning protocol during the six month period immediately preceding the ASV study period. ASV utilizes volume-targeted closed-loop regulation of some ventilator settings in response to the patient's respiratory mechanics and spontaneous breathing, which some studies have shown may be as good or better at adapting to the patient's needs than conventional modes.[2-4]

ASV allows the patient to transition to spontaneous breathing without switching modes, and will automatically wean the pressure as the patient's lung mechanics and/or respiratory drive improves, while still guaranteeing a minimum clinician set minute ventilation. Chen, et al, hypothesized that by utilizing ASV, the process of liberating the patient from the ventilator would not be interrupted, even when staff support is limited. The results of the study showed that 20% of the patients in the ASV group achieved extubation readiness within one day, compared to only 4% of the patients in the non-ASV group. The median time from enrollment to extubation readiness was only 1 day for the ASV group, and 3 days for the non-ASV group, and patients in the ASV group were more likely to be liberated from mechanical ventilation at 3 weeks. ASV was associated with shorter time to extubation readiness. Extubation readiness was not recognized in a timely manner in at least 15% of the patients recovering from respiratory failure, even with a ventilator weaning protocol in place. The authors concluded that ASV helps to identify

these patients and may improve their weaning outcomes, and that these results support the need for additional randomized controlled trials.

We would comment that since closed loop systems are not limited to weaning support just "once-daily," they can move care forward when resources limit timely interventions. [References: 1. Chen-Wen C, Chin-Pyng W, Yu-Ling D, Wann-Cherng P, Chih-Feng C, Wen-Lin S, Yuh-Chin TH. Effects of implementing adaptive support ventilation in a medical intensive care unit. Respir Care. 2011. Jul;56(7):976-83. 2. Burns KE, Lellouche F, Lessard MR. Automating the weaning process with advanced closed-loop systems. Intensive Care Med 2008;34(10):1757-1765. 3. Dojat M, Harf A, Touchard D, Lemaire F, Brochard L. Clinical evaluation of a computer-controlled pressure support mode. Am J Respir Crit Care Med 2000;161(4 Pt 1):1161-1166. 4. Dojat M, Harf A, Touchard D, Laforest M, Lemaire F, Brochard L. Evaluation of a knowledge-based system providing ventilatory management and decision for extubation. Am J Respir Crit Care Med 1996;153(3):997-1004.]

PRODUCTS

PROPELLANT-FREE

Boehringer Ingelheim Pharmaceuticals, Inc announced that the FDA has approved COMBIVENT RESPIMAT, a new, propellant-free inhaler product that uses a slow-moving mist to deliver the same active ingredients of COMBIVENT Inhalation Aerosol in a metered dose inhaler (COMBIVENT MDI). COMBIVENT RESPIMAT will be available for patients in mid-2012. COMBIVENT RESPIMAT and COMBIVENT MDI are indicated for use in patients with COPD on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator. In a 12-week, randomized, double-blind, placebo and active-controlled clinical trial, COMBIVENT RESPIMAT was shown to be clinically comparable to COMBIVENT MDI, in terms of FEV1. These are the only short-acting bronchodilator products that offer two different medicines in a single inhaler. Clinical studies in patients with COPD have shown that the combination of ipratropium bromide and albuterol sulfate provides patients significantly greater improvement in lung function than either component alone. COMBIVENT RESPIMAT uses a new type of inhaler with a propellant-free delivery mechanism to produce a slow-moving mist. It requires one inhalation per dose as compared to COMBIVENT MDI, which requires two inhalations per dose. It also offers a dose indicator to inform patients of the amount of remaining medication in the inhaler. It does not use a propellant so it doesn't release CFC or HFA. Contact boehringer-ingelheim.com.

NUTS TO YOU

Phadia announced that the uKnow Peanut Test, its peanut allergen component test, is now commercially available in the US through the Phadia Immunology Reference Laboratory (PiRL). The uKnow Peanut Test reports specific IgE results to five FDA cleared peanut allergen components in addition to carbohydrate cross-reactive determinants, a laboratory developed test. With the uKnow Peanut Test, physicians can detect the allergic sensitization to the specific allergen components within the whole peanut to help assess the risk that a patient will experience a severe anaphylactic reaction upon exposure to peanut. Current literature points to the protein Ara h 2 as one of the key culprits in producing anaphylaxis. Sensitization to some other proteins within the peanut may not be as relevant to the risk of more severe allergic reactions. In addition, symptoms due to cross-reactivity to allergens such as birch pollen can often mimic sensitization to peanuts when traditional diagnostic testing using the whole peanut extract is performed. A study published last year in the Journal of Allergy and Clinical Immunology estimated that nearly 80% of children

diagnosed with peanut allergy were not truly allergic. In the study, results from Phadia's peanut allergen component tests were 95% correlated to an allergic reaction. Contact (800) 346-4364 or uKnowPeanut.com.

MOBILITY

The CareFusion LTV 1100 ventilator is designed to significantly enhance the mobility of patients with spinal injuries or neuromuscular diseases who require continuous ventilation to breathe. The LTV 1100 offers features common to ventilators used in hospital intensive care units, but in a small, easy-to-use, durable package for patient and caregivers. The system enables all-day portability for active, ambulatory patients in vehicles, wheelchairs, walkers or scooters, or can be attached to a wall, bedside table or patient gurney. For patients with chronic ventilatory failure, the LTV 1100 ventilator enables non-invasive positive pressure ventilation, an approach reported to reduce the risk of respiratory infection, improve voice function and enhance quality of life. The ventilator also features a spontaneous breathing trial (SBT) mode, which uses a rapid shallow breathing index to evaluate a patient's readiness to be weaned off of the ventilator. Clinicians can customize the SBT setting to individual patients, ensuring optimal levels of support as patients are tested on their required level of breathing support. Contact carefusion.com.

REVEILLE

CareFusion announced the launch of the ReVel ventilator, a new high performance, portable device designed for pediatric to adult (min 5Kg) patients who require breathing support during transport. The ReVel ventilator is a complementary addition to CareFusion's Alternate Care portfolio, including emergency and military respiratory care, which is focused on helping clinicians improve patient care, optimizing ventilator therapy and reducing costs. Specifically, the ReVel has the capability to manage the most critical, intubated and non-invasively ventilated patients from the initial point of emergency, during transport and through the hospital, allowing for potentially lifesaving ventilation during transport. The ReVel weighs 9.5 pounds, compared to the typical 20+ pound systems. Its small size and ergonomic design mounts easily in ground and air emergency vehicles, including ambulances, helicopters and military aircraft. The ReVel allows clinicians to provide pediatric and adult patients with the highest level of care with a light-weight and portable system through the continuum of care. It also provides monitoring and clinical tools to assist clinicians in best managing and caring for patients in hospital or alternate care facilities. Its Spontaneous Breathing Trial (SBT) technology provides data to help clinicians decide when to safely wean patients from ventilation. The device also features an integrated pulse oximeter to monitor a patient's pulse rate and oxygen saturation level during transport situations in lieu of costly additional equipment. Contact carefusion.com/revel.

PARTNERING

Hamilton Medical and Rega are joining together, with Hamilton's recently-launched HAMILTON T1 mobile ventilator to be used on Rega's fleet of air ambulances. Rega is the first air rescue service in the world to equip their fleet of air ambulances with this advanced mobile intensive care ventilator. The HAMILTON-T1 ventilator features a compact, powerful design that increases the availability of appropriate modes of therapy for ventilated intensive care patients outside the hospital. It covers the full range of clinical requirements: invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV) – invented by Hamilton Medical, and non-invasive ventilation (NIV). This portable transportation platform is appropriate for all patients, from pediatric to adult. Hamilton manufactures all its products at its green manufacturing facility in Switzerland. Contact hamilton-medical.com.

KID MASK

ResMed Corp has released its new Pixi nasal mask, the first pediatric mask in the industry developed specifically for the treatment of obstructive sleep apnea in children aged two and older. This is not just a scaled down adult mask; every feature on the Pixi was carefully designed to address and improve comfort, acceptance and the overall therapy experience for both the child and caregiver. The headgear was designed using the specific head and facial anthropometric data of children aged two and up, and includes three points of adjustment—at the top, side and bottom straps—to cater to a wider range of children. These adjustment locations are also intended to help the caregiver easily adjust the headgear while facing the child. Made of comfortable Breathe-O-Prene material, the headgear sits away from the child's eyes and ears, minimizing the chance of irritation and obstruction. The Pixi's nasal cushion is designed to minimize pressure on children's soft and sensitive faces while still providing an effective seal. The mask also provides flexibility with two tubing positions that accommodate different sleeping positions, as well as a spring-flex lightweight tube that stretches and bends easily for kids who are active sleepers. Combining the Stellar 100 ventilation device and the Pixi nasal mask, ResMed offers the ideal pediatric therapy solution – particularly in a hospital or institutional care setting. The Stellar offers built-in battery backup and real-time on-screen information. The wide range of settings allows the Stellar to synchronize with a child's breathing. Contact resmed.com.

STAR POWER

Passy-Muir, Inc joined the production company, World Progress Report on location to make a documentary on the Passy-Muir Valve. The nine minute video highlights the story of how David Muir's invention has changed the lives of tracheostomized and ventilator dependent patients of all ages for over 25 years. The physicians and therapists from Madonna Rehabilitation Hospital in Lincoln, NE were chosen for the filming of this documentary, as they have experienced first-hand the numerous clinical benefits that the Passy-Muir Valve offers their patients. The hospital graciously opened its doors to the cameras in order to capture the clinicians and patients using the Passy-Muir Valve at the bedside and in therapy. These images, along with staff and patient interviews, give testimony to why the Passy-Muir Valve has become the standard of care for not only Madonna Rehabilitation Hospital but for facilities across the world. Contact passy-muir.com.

VITAL

The FDA announced it has granted the new Fluke Biomedical ProSim Vital Signs Simulators 510(k) clearance. These innovative new patient simulators offer advanced technology for patient monitor testing. The ProSim 8 all-in-one multifunction tester is designed to perform most preventive maintenance (PM) testing in five minutes or less. ProSim 8 simultaneously simulates ECG, respiration, temperature, IBP/cardiac catheterization, cardiac output, NIBP, and SpO_2, and is the only simulator in the world capable of testing new Masimo multi-wavelength SpO_2 Rainbow SET in physiologically synchronized pulses. For patient monitor troubleshooting on the go, the ProSim 4 quick-check

touchscreen simulator provides one-touch testing for fast and simple patient monitor performance checks and troubleshooting in the field. Designed to get test results in as quickly as sixty seconds, ProSim 4 offers 12-lead ECG simulation, respiration, IBP and NIBP testing in the palm of your hand. Featuring stay-connected ECG posts to ensure secure lead connections and smart, no-hassle navigation, this quick-check tool with patient pre-sets and autosequences is your first line of defense for on-the-go troubleshooting and testing. Contact flukebiomedical.com/prosim.

FINGER ON THE PULSE

Nonin Medical, Inc, the inventor of finger pulse oximetry, announced the launch of the Onyx Vantage 9590 professional finger pulse oximeter at the European Respiratory Society (ERS) 2011 Annual Congress in The Netherlands. The Onyx Vantage accurately captures SpO_2 and pulse rate measurements even in the presence of low perfusion. The new device features 6,000 spot checks, making it the most versatile and reliable finger pulse oximeter for clinicians. The new Onyx Vantage finger pulse oximeter is engineered with Nonin Medical's clinically proven PureSAT pulse oximetry technology – the same accurate technology used in its full line of oximeters. Peer-reviewed articles about Nonin's proven accuracy can be found online at onyxvantage.com. For more contact nonin.com.

CLINICAL STUDIES

Covidien sponsored four clinical studies presented at ANESTHESIOLOGY 2011, which looked at outcomes associated with postoperative pulmonary and cognitive complications, and EVAC tube efficacy. Covidien also sponsored an educational symposium and exhibited its portfolio of advanced respiratory and monitoring technologies. Subjects included Airway Management, Obesity and DSA; Clinical Investigations in Geriatric Anesthesia; and Anesthesia Risks. Covidien also sponsored a symposium on "Regional Oxygen Saturation Monitoring with Near-Infrared Spectroscopy in the OR," and product demonstrations. Contact covidien.com.

UP-SIDE

Uptake Medical announced it has received the CE Mark for the InterVapor System, the first endoscopic lung volume reduction system for the treatment of severe emphysema that uses the body's natural healing processes without leaving foreign materials behind. The CE Mark will allow Uptake Medical to commercialize InterVapor in key markets within the European Community. This announcement coincides with the presentation of the six-month results from the worldwide, multi-center VAPOR trial at the European Respiratory Society Annual Congress. The clinical trial data shows significant improvement in breathing capacity, shortness of breath, exercise capacity and quality of life. The InterVapor System was developed in response to the needs of patients with severe emphysema and is designed to directly target the hyperinflation in the lungs. The VAPOR study was an open label, single-arm trial of InterVapor (Bronchoscopic Thermal Vapor Ablation) in patients with upper lobe predominant emphysema. Primary endpoints measuring lung function improvement (FEV_1) and health-related quality of life (SGRQ) achieved both statistical and clinical significance at six months. Additionally, 83% of patients met a combined endpoint for clinical improvement. Efficacy was consistently demonstrated across all endpoints. Secondary endpoints demonstrated that patients treated with the InterVapor procedure have significant physiologic improvements (including decreased hyperinflation and gas trapping) as well as clinical improvements (reduced breathlessness and improved exercise capacity). All treatments were performed successfully without intra-procedural complications. Contact uptakemedical.com.

LET'S FACE IT

Kimberly-Clark Health Care (KCHC) announced that it has received 510(k) clearance from the FDA to market the Kimberly-Clark Child's Face Mask. This marks the first time that the FDA has granted any manufacturer 510(k) clearance for a pediatric face mask and establishes the product with the designation of a Class II medical device. The decision by KCHC to undertake the 510(k) regulatory submission pathway for the Child's Face Mask was in response to a call for action from the Society for Healthcare Epidemiology of America (SHEA), the Association for Professionals in Infection Control and Epidemiology (APIC) and the Association of periOperative Registered Nurses (AORN). KCHC worked with the FDA to develop standardized clinical measurements that are specific to the unique circumstances of pediatric mask use and performance in healthcare settings. The Kimberly-Clark Child's Face Mask is a single-use device that is intended to be worn by children ages 5-12 to provide protection for the respiratory tract, and has been specifically designed to fit small faces to maximize effectiveness, comfort and compliance. Featuring colorful Disney characters on its outer-facing panel to create familiarity and appeal, the mask is intended for use in healthcare settings such as waiting areas and exam rooms to protect children who may be at increased risk for infection. Contact kchealthcare.com.

POSITIVE

Boehringer Ingelheim's investigational tyrosine kinase inhibitor (TKI) BIBF 1120 demonstrated a positive trend in reducing lung function decline in patients with idiopathic pulmonary fibrosis (IPF), according to phase II clinical trial results. In the TOMORROW study (To Improve Pulmonary Fibrosis with BIBF 1120), patients treated with 150 mg of BIBF 1120 twice daily demonstrated a 68% reduction in the rate of forced vital capacity decline compared to placebo. Patients treated with 150 mg of BIBF 1120 twice daily also had a lower incidence of acute exacerbations, defined as sudden deterioration of clinical status, compared with placebo. In addition, treatment with 150 mg of BIBF 1120 twice daily resulted in a small decrease in impairment of quality of life, as measured by the SGRQ. Gastrointestinal symptoms and liver transaminase increases were more frequent in patients receiving 150 mg of BIBF 1120 twice daily than placebo and adverse events leading to discontinuation were mostly diarrhea, nausea and vomiting. BIBF 1120 received orphan-drug designation from the FDA in June 2011. Two pivotal phase III clinical trials are currently underway enrolling a total of 970 patients in 20 countries. The phase II TOMORROW trial was a 12-month, randomized, double-blind, placebo-controlled trial conducted at 92 sites in 25 countries. Contact boehringer-ingleheim.com.

WEB ENHANCED

Radiometer announced the launch of its new website, which offers convenient downloads and other user-friendly features. This enhanced online resource provides information on the issues surrounding acute care testing, while focusing on the needs of customers. Visitors to the site will enjoy several user-friendly features, including convenient downloads (under the Services menu), topics in point-of-care testing, links to accredited live and on-demand webinars, and integration with

social media such as Facebook, LinkedIn, Twitter and YouTube. Contact radiometeramerica.com.

AWARDS PROGRAM

Kimberly-Clark Health Care announced that submissions are now being accepted for the 2012 HAI WATCHDOG Awards. The program aims to recognize the efforts of dedicated healthcare professionals working to prevent healthcare-associated infections (HAIs) in their facilities. The deadline to submit a program for consideration is January 31, 2012. Kimberly-Clark Health Care will award five programs in the US and Canada with an educational grant. Programs with completed and measurable results will be judged by a panel of infection prevention healthcare professionals, while education and awareness programs with non-measurable results will be judged by online public voting by fellow healthcare professionals. To see the categories in which nominations are being accepted, go to: http://haiwatchdog.com/pg/hai_contest_pages/read/contest_about.

PRESSURE MONITOR

VORTRAN Medical Technology 1, Inc introduced the VORTRAN-APM (Airway Pressure Monitor), MSRP $425. The VORTRAN-APM, battery operated device connects to the patient through connection tubing to monitor conditions of resuscitators, like the VAR (VORTRAN Automatic Resuscitator). The APM is available for both pediatric and adult patients with differing alarm limits. The APM displays PIP, PEEP, Respiratory Rate, Inspiratory and Expiratory Time, and I:E Ratio. The APM provides non-cycling, high rate, and high PIP alarms with predetermined limits. The APM has audible alarms and a flashing red LED, with alarm conditions displayed on a LCD screen. Contact vortran.com.

KEEP IT CLEAN

Kimberly-Clark announced a new program to educate patients about HAIs and steps they can take to aid in their prevention at the ANCC National Magnet Conference. The program is based in-part on survey data that examined perceptions of more than 1,000 participants. The data revealed that 56% of respondents were not very familiar or not at all familiar with HAIs. Less than one percent were able to distinguish accurately between factors that do and those that do not contribute to HAIs, and 69% said they would not consider using a hospital with a higher HAI rate even if it was their physician's choice. Kimberly-Clark's HAI Patient Education Program provides education directly for patients and their families through a website, toolkit and support of community events. In addition, Kimberly-Clark provides resources and training to hospitals and other organizations that wish to conduct their own training. The program began in October 2011 and extends through December 2013. Contact haiwatch4you.com.

INVESTMENT

Cyberonics, Inc announced an initial investment of $4 million in ImThera Medical, Inc, which developed an implantable neurostimulation device for the treatment of obstructive sleep apnea. ImThera's Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy combines a multi-contact electrode specifically designed to control certain muscles of the tongue with an implantable pulse generator and an external programmer. Through targeted tongue-muscle stimulation, ImThera's open-loop hypoglossal nerve multi-contact device delivers muscle tone to key tongue muscles during sleep, opening the upper airway and substantially reducing or eliminating OSA events. The company is currently pursuing CE Mark regulatory approval in the European Union and expects to initiate a pivotal clinical trial in the US in the near future. Cyberonics, Inc markets the VNS Therapy System, which is FDA-approved for the treatment of refractory epilepsy and treatment-resistant depression. Contact cyberonics.com or imtheramedical.com.

TRUSTED

Hamilton Medical, Inc announced that they have signed a multi-year agreement with HealthTrust Purchasing Group, LP, under which Hamilton Medical's advanced critical care and transport ventilation systems are now available to HealthTrust's hospitals nationwide. The HealthTrust Agreement provides a diverse ventilator system and advanced ventilation technology portfolio through October 31, 2015. HealthTrust Purchasing Group, LP is a group purchasing organization that supports nearly 1,400 not-for-profit and for-profit acute care facilities, as well as 10,600 ambulatory surgery centers, physician practices, and alternate care sites. Contact Hamilton-medical.com.

HIGH IQ

Philips Respironics offers its latest technology for treating and managing OSA with its new REMstar Pro with AutoIQ. The new AutoIQ mode has the ability to track a patient's progress over several nights, establish or readjust to an ideal therapy pressure, and check back periodically to reassess and adjust treatment as needed, without requiring the provider to visit the patient's home. There are two phases of the AutoIQ mode: Auto-Trial and Auto-Check. Auto-Trial uses the auto algorithm for periods of three days or more, adding up to a total of 30 days, to deliver breath-by-breath therapy and learn the patient's treatment needs. Auto-Trial days can be saved to reassess therapy at a later date. At the end of the Auto-Trial phase, the device analyzes the data to identify and automatically deliver the ideal pressure for the patient, and can also deliver a fixed pressure that has been set by the clinician. Auto-Check checks back every 30 hours to see how the patient is progressing with therapy. This phase determines if a pressure change is needed and automatically adjusts the pressure (within the limits set by the clinician) to meet therapeutic needs. Contact healthcare.philips.com.

MUST-SEE

Covidien announced that it has signed an exclusive agreement with Aircraft Medical to market and distribute the proprietary McGRATH MAC video laryngoscope in the United States, United Kingdom, Japan, Latin America, Australia and New Zealand. The McGRATH MAC video laryngoscope combines video and direct visualization to support intubations. Its anterior camera is designed to improve viewing to support rapid, seamless tube placement and to reduce "tunnel vision" encountered with conventional direct-view-only laryngoscopes. In everyday practice, the device is designed to reduce the risk of blind, misplaced or delayed intubations, as well as aid in more difficult airway procedures. In addition, its slim-line MacIntosh-style blade provides greater maneuverability in small mouth openings, helping to reduce dental interaction during intubation. Use of the McGRATHMAC video laryngoscope has demonstrated enhanced visualization, with no requirement for additional training in conventional laryngoscopy technique. Contact covidien.com.

COMPANY OF THE YEAR

Kimberly-Clark Health Care announced that it has been named Company of the Year, Medical Device Category, in the PM360 Trailblazer Awards competition. The company was recognized for its industry leadership as demonstrated by initiatives

including the Knowledge Network, Education Bus, Facebook page and partnership with Rhode Island School of Design (RISD). Contact kchealthcare.com

PETITIONED

FDA petitioned to retract pediatric extension for Ikaria's INOmax nitric oxide product: The US Department of Health and Human Services has been sent a Citizen Petition requesting that the Food and Drug Administration rescind the Pediatric Exclusivity extension approved for Ikaria in 2010 that extends their patent protection for their nitric oxide gas for six months beyond the US patent expiration date. The Pediatric Exclusivity Statute was designed to give extended protection to pharmaceutical companies that perform new pediatric studies at the request of the FDA. FDA documents disclosed that Ikaria first approached the FDA in April of 2008 requesting that the FDA write them a letter requesting additional studies for INOmax nitric oxide gas to study the effects on premature infants to prevent BPD.[1] Ikaria submitted three studies, two of which were statistically negative trials, to fulfill the requirements of the Statute. The third study demonstrated a statistical benefit, however the FDA found that because of issues raised by their analysis (data quality, different post hoc statistical analyses, and lack of p value adjustments for interim analyses), the statistical determination was difficult to discern.[2] However, the Pediatric Exclusivity Guidance Document specifically states that, "FDA does not believe it would be consistent with the intent of the statute to accept data collected prior to the Written Request if such data are already known to provide no useful information."[3] The petitioner cited the irregularity of the Ikaria request in that all three studies were completed by March of 2008, two of which were completed in 2005. Therefore, at the time of the Ikaria letter to the FDA and the subsequent FDA letter to Ikaria, the data from the negative trials had been collected (two of the trials were published in 2006)[4,5] and therefore as negative trials, should never have been submitted or accepted by the FDA in applying for coverage by this statute. The petitioner argued that this extension granted to Ikaria prevents generic suppliers of pharmaceutical nitric oxide gas from entering the market. The petitioner expects that the FDA will review their granting of the Pediatric Exclusivity and hopefully open the market to generic competition six months earlier, potentially saving the US healthcare system tens of millions of dollars in that period. [Footnotes: 1. Curtis J. Rosebraugh, Department of Health and Human Services, Food and Drug Administration, Written Request, IND 106088, NDA 020845, Application Type: GI-1, Ino Therapeutics Inc., 04/30/2010. 2. Medical Officer Review, Division of Pulmonary, Allergy and Rheumatology Drug Products (HFD-570), Application #: 20-845, Proprietary Name: INOmax, Review Date: November 19, 2010. 3. Guidance for Industry, Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Revised, September 1999. 4. Kinsella JP, et al. Early Inhaled Nitric Oxide Therapy in Premature Newborns with Respiratory Failure. N Engl J Med 2006;355:354-64. 5. Ballard RA, et al. Inhaled Nitric Oxide in Preterm Infants Undergoing Mechanical Ventilation. N Engl J Med 2006;355:343-53.]

SPOTLIGHT ON BLOOD GAS

ANALYZER

Nova Biomedical announced the availability of a new blood gas critical care analyzer. pHOx Ultra analyzer offers the most comprehensive features of any whole blood, critical care analyzer. It features the broadest test menu in one analyzer, with 20 user selectable tests including pH, PCO_2, PO_2, sO_2%, Hct, Hb, Na+, K+, iCa, iMg, Cl-, Glucose, BUN, Creatinine, Lactate, CO-Oximetry and tBil. pHOx Ultra's large, high resolution, color touch screen offers fast and easy operation. Bright color and graphic highlighting provide exceptional readability. Onboard, automated True QC saves time and labor versus manual QC, and assures optimum analyzer performance. pHOx Ultra's complete, onboard Data Manager, networking and interface capabilities save thousands of dollars compared to the purchase of a separate data manager. The Data Manager can consolidate multiple, networked pHOx Ultras into a comprehensive database for capture, archiving, and extensive data reporting. It also provides a single HIS/LIS interface for multiple pHOx Ultras throughout a network, saving thousands of dollars in separate interface costs. Remote review and remote control of multiple, network connected analyzers can also be performed from the onboard Data Manager. Earlier generations of pHOx Ultra analyzers have proven to be accurate and reliable in more than 10,000 installations throughout the world. The 20-test, customizable menu, simple operation, extensive data management and networking, and low cost of operation make this new pHOx Ultra ideal for multiple testing locations including Lab, OR, ICU and ED. Contact novabiomedical.com.

CRITICAL

The GEM Premier 4000 critical care analyzer from Instrumentation Laboratory measures pH, blood gases, electrolytes, metabolites, Total Bilirubin and CO-Oximetry (integrated), with Basic Metabolic Panel assays in development. The analyzer features Intelligent Quality Management (iQM) for continuous, real-time quality control, delivering the lab-quality results to any point-of-care location: ICU, NICU, CVOR, and ED. Exceptionally easy to use, the GEM Premier 4000 is virtually maintenance-free and features the only single-component, multi-use cartridge on the market. GEMweb Plus Custom Connectivity allows remote control of all GEM Premier analyzers in the network for total connectivity, regardless of location, optimizing point-of-care flexibility. Contact ilus.com.

BLOOD GAS APP

Radiometer's blood gas handbook is available for iPhone and iPad. Blood gas status plays a key role in evaluating the condition of critically ill patients. Evaluation of blood gas parameters can be divided into subgroups of oxygen status, related metabolic parameters and acid-base status. Because each subgroup consists of several parameters, the amount of data to interpret may be overwhelming. Radiometer's new blood gas app is an easy-to-use guide to assist you with this task. The app offers guidance to the evaluation of arterial oxygen status based on comprehensive blood gas analysis (including oximetry) and a closely related metabolic parameter, lactate. Users can add and edit their own reference intervals as well as notes for individual parameters. In addition, Radiometer's new app provides a description of the parameters available on Radiometer's blood gas analyzers, including blood gas and acid-base parameters, metabolic parameters and electrolytes, as well as guides to evaluating them. Other features are: search, import and export of user defined notes and reference intervals via iTunes, and zoom on images. Although such a guide always has to be used with caution, as not every possible detail or condition can be covered, it can help the clinician make decisions with regard to the need for further tests and therapeutic interventions. The app supports

English and Danish language depending on the language setting of the device. It is compatible with iPhone, iPod touch, and iPad. Requires iOS 4.0 or later. You can download the Radiometer's blood gas app on the App Store.

APPROVED

ABL800 FLEX from Radiometer has been FDA-approved for pleural fluid pH. Radiometer's ABL800 FLEX Series blood gas analyzers now offer a dedicated, FDA-approved mode for measuring pH in pleural fluid. The American College of Chest Physicians (ACCP) consensus panel on the medical and surgical management of parapneumonic effusions recommends that, as the preferred pleural fluid chemistry test for pleural effusion, pleural fluid pH should be measured on a blood gas analyzer. The use of pH meters or test strips can overestimate pleural fluid pH. This may lead to a diagnostic misclassification of the effusion, a potential underestimation of the problem and under-treatment of the condition. Measurement of pH in pleural fluid on the ABL800 FLEX has been validated per FDA guidelines. This means that, unlike an off-label application (as performed on many blood gas analyzers), labs with ABL800 FLEX will require only limited validation, saving them valuable resources. Also, because pleural fluid responds differently than whole blood, the ABL800 FLEX has a unique pH-pleura mode to ensure accuracy. In addition to measuring pH in pleural fluid, the ABL800 FLEX measures blood gas, electrolytes, metabolites and CO-oximetry. Many of the analyzer's key functions, including quality control and sample analysis, mixing and identification, are automated, reducing the risk of manual errors and increasing patient safety. Contact radiometeramerica.com.

QUALITY CONTROL

RNA Medical has been providing quality control materials and Calibration Verification Control/Linearity materials to health care systems, research laboratories, and instrument manufacturers for over twenty years. RNA does not sell or distribute blood gas analyzers, thus providing unbiased results. RNA Medical quality control and calibration verification control materials offer a long shelf life and the option to reserve a single lot of control, pending availability and shelf life. Our controls for blood gas analyzers measuring pH, pCO_2, pO_2, Na+, K+, Cl-, Ca++, Mg++, glucose, lactate, and BUN (urea), have a minimum shelf life of 36 months from date of manufacture and the option of room temperature storage up to nine or twelve months, depending upon the material. Our Full Range CO-Ox Control material provides an alternative for those needing a control that parallels the human physiologic range for tHb, O_2Hb, and COHb. RNA Medical quality control materials are assayed for a wide array of blood gas instruments, therefore allowing one control to be used over many blood gas instruments. Contact rnamedical.com.

RAPID!

Siemens Healthcare Diagnostics has launched the RAPIDPoint 500 Blood Gas System, the company's latest cartridge-based point-of-care analyzer for critical care testing. With results in approximately 60 seconds, the RAPIDPoint 500 analyzer offers a comprehensive menu of critical-care tests for pH and blood gases, electrolytes, glucose and lactate* and full CO-oximetry, including neonatal total bilirubin and total hemoglobin, all from a single, whole-blood sample. Additionally, the measurement cartridges last up to 28 days and contain a full complement of tests, which reduces downtime. Equipped with fully automated calibration and quality control (QC), the RAPIDPoint 500 system is also designed to help POC professionals satisfy organizational and regulatory compliance requirements. Plus, the self-contained Automatic Quality Control (AQC) cartridge operates without manual intervention, helping reduce POC staff's administrative tasks. An integrated bar code reader – conveniently located on the front of the system – offers a wide scanning area to accommodate patient and operator identification to ensure overall data entry integrity. The RAPIDPoint 500 analyzer can be integrated with the Siemens RAPIDComm Data Management System, offering centralized management of multiple Siemens blood gas and urine and diabetes analyzers and operators. [*Under development. Not available in the US]. Contact siemens.com/bloodgas.

LEAP FORWARD

An epoc leap in Point of Care (POC) testing: The epoc Blood Analysis System provides wireless blood gases, electrolytes and metabolic panel results in about 30 seconds at the patient bedside. It's the cost effective POC testing solution, easily integrating into any critical care setting, and delivering accurate, actionable results to enable timely clinical decisions. It features: • Room Temperature Test Card Storage; • 9 Analytes on 1 Test Card: pH, pCO_2, pO_2, Na+, K+, Ca++, Glu, Hct, Lac; • Calculated Values: cHCO3-, $cTCO_2$, BE(ecf), BE(b), cSO_2, cHgb; and • Critical Result Reporting. (epoc is a registered trademark of Epocal Inc.) Contact epocal.com.

SPOTLIGHT ON SPIROMETRY

COMPUTER-BASED

Medical Graphics Corporation, St Paul, MN, offers the MEDGRAPHICS CPFS/D USB computer-based spirometer. From simple spirometry to complete bronchial provocation, the CPFS/D device offers various testing capabilities and meets or exceeds all current ATS/ERS recommendations for accuracy and performance. The proprietary MEDGRAPHICS preVent flow sensor provides accurate measurement and superior infection control. Its snap-in design allows for replacement between patients. Combined with BreezeSuite diagnostic software, the CPFS/D spirometer delivers quick testing, resulting in fast patient turn-around. Contact (800) 655-1133; medgraphics.com.

EASY DOES IT

The EasyOne Plus from ndd offers the new standard in spirometry. The EasyOne Plus offers ndd true flow technology, with ultrasound transit time measurement. The ndd true flow technology is absolute flow, and is used as OEM for major manufacturers. The device offers low operating costs, needing no calibration, no maintenance and no down time. The spirette is simple, and a comfortable fit for adults and children. It is hygienic, single-patient-use disposable, and has no sensor elements. The ndd EasyOne Plus's memory can handle up to 700 subjects, and is secured against accidental loss due to low battery. Multiple units may be used with one cradle and a single copy of EasyWare PC software. It generates reports on plain paper, has a direct USB connection, and exports to excel, and is Pictbridge compatible. The display offers five lines of clear text and presents instant results and interpretation. The EasyOne Plus Screen PC connection shows real-time FV and VT curves. It is easy to operate with simple operator prompts. ndd offers toll-free technical support, and a three-year exchange warranty. Contact nddmed.com.

CONSISTENT RESULTS

Research grade spirometry results in every practice: Office or

portable, KoKo Spirometers from nSpire Health, Inc, have been proven to provide the most consistent results, making them the industry leading spirometers in both clinical trials and hospital or physician's practices. Featuring the time tested fleisch-type pneumotach, KoKo PFT Spirometer comes with easy-to-use software with enhanced visualization of test details, built-in trending and comparison, and incentive graphics for increased test performance. Optional HDnet provides seamless networking and connectivity to EMR/EHR. Contact nspirehealth.com.

HOME CARE UPDATE

The information in this article is from Passy-Muir's newsletter, Talk Muir, Summer 2011.

Home mechanical ventilation has changed radically, according to Mike Harrell and Linda Dean, writing in Passy-Muir's newsletter. Home mechanical ventilation began in the mid 20th century. During the polio epidemic in the 1950s, a person who needed mechanical support for breathing would be placed in an iron lung. This made trips to the store impossible. Mechanical ventilation back in those days meant immobility and hardship.

Current estimates say that approximately ten thousand people in the United States receive invasive home mechanical ventilation. Modern home ventilators now use computer technology, light-weight materials, and smaller batteries with longer life to give unprecedented freedom of mobility to this growing number of patients.

Special Needs

Established in 1986, International Ventilator Users Network (IVUN) meets the information needs of polio survivors experiencing new respiratory problems and chronicles long-term ventilator use in people with other neuromuscular conditions, such as ALS, Duchenne muscular dystrophy, spinal muscular atrophy, CCHS, and spinal cord injury. IVUN uses its website, ventusers.org, to educate, advocate, network and promote research among users of home mechanical ventilation, health professionals who treat them and the manufacturers and companies who provide related equipment and service. Among other elements, the website offers: • Resource Directory for Ventilator-Assisted Living http://www.ventusers.org/net/vdirhm.html. This directory includes listings of health professionals, respiratory home care companies/DMEs, in-home care agencies, ventilator user lists, ventilator equipment and aids, manufacturers' addresses, organizations, associations and foundations, facilities with long- term ventilator units and congregate homes for long-term ventilator users. • IVUN's Home Ventilator Guide http://www.ventusers.org/edu/HomeVentGuide.pdf. This guide presents a comparison of the technical specifications of ventilators for home use currently on the market. These include bilevel units, volume and pressure support/control ventilators, and multimode ventilators. • Take Charge, Not Chances, http://www.ventusers.org/vume/index.html. This is a document developed in response to negative hospital experiences of users of home mechanical ventilation. It contains four sections that assist ventilator users and their caregivers in collecting information to better prepare for hospitalization. IVUN disseminates information bi-monthly in its newsletter, Ventilator-Assisted Living: http://www.ventusers.org/edu/valnews/index.html. The organization advocates for users of mechanical ventilation by writing letters on behalf of its members and by educating the professional and consumer communities about issues that affect ventilator users.

Case Study

In the article, Reach for the Finish Line, Julie Kobak with Passy-Muir, writes: Jessica Leahy is an 8 year old with Mobius Syndrome and central respiratory dysfunction which necessitates a tracheostomy tube and night-time ventilation. Jessica's disabilities do not stop her from living a full and active life. She loves school and ballet and for the past two years has participated in The Katie Lynch Purple Shoes Challenge.

The Purple Shoes Challenge welcomes athletes of all ages with physical and/or sensory limitations to set performance goals, train vigorously, and challenge themselves to wheel, walk or run their personal best marathon. This event is organized by the Katie Lynch Foundation, whose mission is to fund programs that promote opportunities and respect for people with disabilities, thereby welcoming all to lead active, fulfilling lives.

Jessica's mother, Julie Leahy said, "I wanted Jessica to enjoy exercise and work towards a goal." Jessica's personal goal was to walk 1.3 miles. She trained for two months prior to the event by walking to or from school. On May 15, Jessica reached her goal and walked the full 1.3 miles in a little over one hour. She was sore and tired the next day but her mother said, "Even though the event is over, she hasn't stopped walking and continues to reach further towards her next goal."

FACILITY REPORT

Wyoming Medical Center is a 207 bed not-for-profit acute care facility located in Casper, WY, and was founded in 1911. The hospital is one of only two regional referral/trauma centers in the state (the next closest ICU is 180 miles away) and includes the Heart Center of Wyoming, Wyoming Neuroscience and Spine Institute and Wyoming Life Flight, Wyoming's only emergency air transport service. The hospital has more than 190 physicians on its medical staff and more than 1,300 employees. Wyoming Medical Center prides itself in being the state's largest, most comprehensive healthcare facility. The hospital prides itself in patient care. One recent example of breakthrough results in care is with the ICU's use of both protocol and products to reduce the incidence of potentially deadly ventilator-associated pneumonia (VAP).

Wyoming Medical Center has a 14-bed intensive care unit (ICU) and provides services such as ventilator management, trauma, general surgery, and neurotrauma. The ICU also has a 24x7 intensivist service. The ICU department serves a varied population from the elderly to younger neurotrauma patients engaging in high-risk activities. In particular, the hospital's neurotrauma department treats traumatic accidents from across the state and those who attend and are seriously injured in the annual Sturgis Bike Rally. Those victims combined with last year's H1N1 outbreak victims, left Wyoming Medical Center with a spike in its VAP rates. The system was seeing rates as high as 11 VAP instances per 1,000 ventilator days.

In an effort to reduce its VAP rates, the hospital implemented the Institute for Healthcare Improvement (IHI) recommended VAP bundle and had incorporated all of the IHI recommendations. In doing so, the hospital tried to mirror the best practices of the nation's hospitals in reducing VAP. Even with all of the various

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High Flow Therapy (HFT): From Hospital to Home

Nick Macmillan, AGS, RRT, FAARC

Introduction

High Flow Therapy (HFT) was introduced over ten years ago into the acute care sector, including critical care wards, emergency departments, and other relatively high acuity settings. It is estimated that HFT is used in over a thousand hospitals nation-wide. The basic concept behind HFT is that by delivering breathing gases to the patient at ideal conditions, that is near or at body temperature and saturated with water vapor, nasal flows could be set to exceed a patient's spontaneous inspiratory flow rate. The capabilities to deliver HFT are founded on technological advancements in breathing gas conditioning as well as energy preservation of the conditioned gas as it travels to the patient interface thus preventing rainout. The peer-reviewed outcomes of this therapy warrant a serious exploration of what high flow therapy is and how it can change the way you care for pulmonary impaired patients today.

High Flow Therapy Defined

HFT is the delivery of respiratory gas conditioned to body temperature / humidity and delivered by nasal cannula in an open system at a flow rate that exceeds a patient's spontaneous inspiratory flow. In the acute care setting, HFT has been used to treat respiratory distress or failure, and in these applications has been shown to improve respiratory gas exchange[1] and mechanics.[2] The mechanisms of action for HFT in the acute care setting are summarized below, however, a more complete description of these mechanisms can be found in a review paper by Dysart, Miller and colleagues (Dysart K, Miller TL, Wolfson MR, et al. Research in high flow therapy: mechanisms of action. Respir Med 2009; 103:1400-1405).[3]

From a technical standpoint and depending on the specific product, FDA cleared HFT acute care systems deliver flows between 1 and 40 liters per minute (LPM), oxygen percentages (FIO_2) from 21-100% and at temperatures from 30-40°C. Where devices vary the most is in their ability maintain the gas at desired temperature and humidity, thus providing optimal therapy and mitigating rainout.

High Flow Therapy Mechanisms of Action

HFT in its simplest form is the provision of precise fractions of oxygen or other respiratory gases to a patient, in that the cannula flow rates exceed inspiratory demand and no room air is entrained. However, because the high gas flows purge the nasopharynx between inspiratory efforts, and therefore wash out nasopharyngeal dead space, HFT has a number of other influences that result in more favorable gas equilibrium values in the lungs and reduced respiratory effort. The key factors considered to be mechanisms of action for HFT are as follows:

1. HFT provides for washout of nasopharyngeal dead space, which contributes to establishing improved fraction of alveolar gases with respect to carbon dioxide as well as oxygen.[4,5]
2. The dispensability of the nasopharynx provides significant resistance on inspiratory efforts relative to expiratory efforts.[6] HFT provides adequate flow rates to match inspiratory flow and thus eliminates the inspiratory resistance associated with nasopharynx, and the related work of breathing.
3. The provision of adequately warmed and humidified gas to the conducting airways is associated with improved conductance and pulmonary compliance compared to dry, cooler gas.[7]
4. The provision of adequately warmed and humidified gas through the nasal pharynx reduces the metabolic work associated with gas conditioning.
5. When manipulated correctly, the flow flushing the nasopharynx can be, although not necessarily, restricted such to provide positive distending pressure for lung recruitment.[8]
6. The ideal humidification of the inspired gas has been shown to restore mucocilliary function and reduce symptoms of airway exacerbations.[9,10]

Based on these factors, HFT has been shown to be effective in adults[11,12] as well as children.[13] Certainly, the provision of high gas flows through the nasopharynx will tend to develop mild distending pressure,[14-16] which often intuitively seems to be the cause for the level of clinical efficacy observed. However, mechanistic research suggests that the most acutely impactful of these factors is the nasopharyngeal flush, which results in the purging of CO_2 from the dead space gas volume that would otherwise be re-breathed during a subsequent inhalation.[4]

Drivers of High Flow Therapy at Home

According to Health Research International, it is estimated that by 2012 over 500,000 patients will be treated with HFT per year. As this therapy has gained significant traction in the acute care environment, a natural progression to home care application has ensued. In a recent survey 32% of patients treated in the hospital on HFT were discharged on pressure therapy, which has its compliance and tolerances issues. Of even more concern though is that over one-third of those patients were kept in the hospital longer than desired due to a lack of a home care HFT solution. This outcome goes against the grain of current health care cost containment initiatives.

Home Care High Flow Therapy Systems

The challenges to development of HFT devices in the home is that while hospitals have access to high-pressure oxygen and air, home care environments do not. Despite this limitation, especially oxygen delivery limitations, use of high-performance blower technology has permitted the introduction of two HFT products for home care use. These devices deliver flows between

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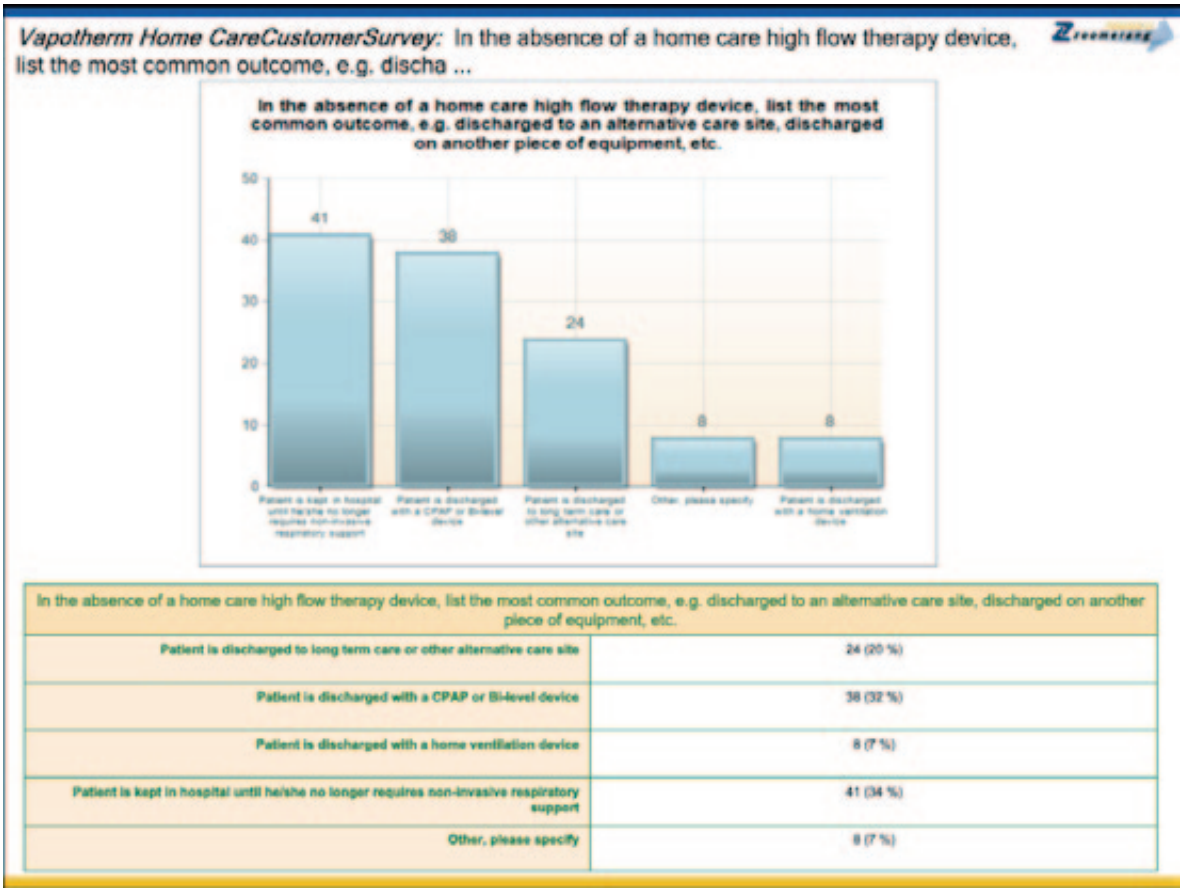

In the absence of a home care high flow therapy device, list the most common outcome, e.g. discharged to an alternative care site, discharged on another piece of equipment, etc.	
Patient is discharged to long term care or other alternative care site	24 (20 %)
Patient is discharged with a CPAP or Bi-level device	38 (32 %)
Patient is discharged with a home ventilation device	8 (7 %)
Patient is kept in hospital until he/she no longer requires non-invasive respiratory support	41 (34 %)
Other, please specify	8 (7 %)

15 and 45 LPM and FIO_2s between 21 and 46%. Temperature ranges and methodology to maintain humidity levels are compatible to the respective acute care devices. Given these specifications, it's important to match clinical flow and FIO_2 requirements to the patients' physiologic requirements. When specifying an order for home HFT, the clinician should prescribe the flow setting, FIO_2, mode of delivery, ie cannula and frequency of use. Order fulfillment is through a durable medical equipment (DME) company.

The Home Care Reimbursement Quagmire

Since HFT is a new device and does not fit into any existing Healthcare Common Procedure Coding System (HCPCS) code, manufacturers will typically submit an application to The Centers for Medicare and Medicaid (CMS) is required. The CMS HCPCS Workgroup will make a decision to either create a new code or a revise an existing code. Before an application is submitted however, the product has to have been on the market for several months and enough product utilization must have occurred in order for them to make an informed decision. In addition, CMS is more interested in clinician input, which is usually gathered through professional societies with experience with the therapy.

During this period, miscellaneous codes are used when a DME supplier is submitting a bill for an item or service and there is no existing national code that adequately describes the item or service being billed. The importance of miscellaneous codes is that they allow suppliers to begin providing the product when prescribed and to bill for the item. In addition, the absence of a specific code for a distinct category of products does not affect a supplier's ability to submit claims to private or public insurers and does not affect patient access to products.

Because of the uncertainty of reimbursement when billing with a miscellaneous code, suppliers can consider the use of an Advance Beneficiary Notice (ABN). According to CMS, ABNs are not required for care that is statutorily excluded or for services for which no Medicare benefit category exists. However, in these situations, health care providers can issue an ABN voluntarily. Additional information regarding the use of ABNs can be found at: http://www.cms.gov/BNI/02_ABN.asp.

While the process above is statutorily guided, the greatest challenge is that reimbursement is an unknown. Physicians are reluctant to prescribe because if Medicare denies reimbursement, the patient will be responsible for payment or even worse, will return the device and cease treatment. The DMEs are reluctant because their history with billing miscellaneous codes has not been positive. The down side to these scenarios is that if devices are not prescribed and CMS does not see utilization history, they have no basis or cause to make a coding and reimbursement decision.

The Future of High Flow Therapy in the Home

In one of the studies referenced above, Rea et al demonstrates that patients on HFNC at home an average of three hours per day have experienced:

- Significantly fewer exacerbation days (18.2 versus 33.5 days; p = 0.045);
- Increased time to first exacerbation (median 52 versus 27 days; p = 0.0495);
- Reduced exacerbation frequency (2.97/patient/year versus 3.63/patient/year; p = 0.067) compared with typical care.

Additionally, patients on HFNC had improvement in quality of life scores and lung function compared with typical care.

Given today's health care cost pressures driving decreased length of stays and reductions in hospital re-admissions, this relatively new and promising technology provides a new tool in our arsenal of care that has compelling scientific mechanisms, demonstrates effective outcomes and is also comfortable. It's refreshing when those stars align and as such, we can expect to see more of its use.

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best practices being employed and complied with, they were still hitting a brick wall and were not able to achieve zero VAP instances.

Frustrated with their attempts to get the VAP rates down, Senior Clinical Manager, ER, ICU, PCU Cristy Dicklich-Cobb, knew that something had to change. She took another look at the products the department was using to reduce the number of patients who were getting VAP and convinced the department to try the Kimberly-Clark KimVent Microcuff Endotracheal Tube, designed to prevent the micro-aspiration of potentially infectious secretions into the lungs, a leading cause of VAP. The Microcuff ET tube's unique cuff is made with an advanced microthin polyurethane material that allows the channels formed upon cuff inflation to "self-seal" within the trachea, increasing protection against fluid leakage into the lungs.

Cristy and her team presented the Microcuff tube to the hospital's Board of Directors, Chief Executive Officer and Chief Operating Officer. To show the superior sealing mechanism of the Kimberly-Clark KimVent Microcuff, the nurses used a glass-tube trachea model to compare Kimberly-Clark KimVent Microcuff and another tube. They filled both tubes with blue water, demonstrating that the Kimberly-Clark tube did not leak the water past its cuff. In April 2010, Cristy and her team received approval to implement the KimVent Microcuff Endotracheal Tube. Once Cristy and her team became familiar with the tube and began using them on patients, they were very pleased with the results. Cristy describes one respiratory therapist as having a "fire in her belly" regarding her excitement about implementing the tube.

Since bringing the Kimberly-Clark Endotracheal Tube to the ICU, Wyoming Medical Center has experienced a number of positive results. The implementation of the tube has allowed for nurses to have more bedside time with their patients in the ICU, and an increase in morale within the department. Cristy said, "we are nurses before we are leaders and it has been a very large uphill journey, but it's also a proud moment to go 'wow we did that.'" In addition to cost savings, Wyoming Medical Center is well positioned to battle the non-reimbursement policy for never events and HAIs by Medicare. Cristy says if there is one thing she could have changed throughout the process is that she wished she had implemented the Microcuff tube sooner. [This article was provided by Kimberly-Clark.]

Risk-Reduction and Preventive Strategies for Postoperative Pulmonary Complications: Findings from a Patient Safety Summit

Scott D. Kelley, MD

Postoperative pulmonary complications (PPCs) following surgery represent a significant clinical and economic burden, contributing to increases in patient mortality, length of hospital stay and use of resources that cost the US healthcare system approximately $12 billion annually.[1] PPCs are fairly common events in hospitals: they develop in approximately one of eight surgical patients,[1] occur almost twice as often as postoperative cardiac complications,[2] and are associated with more than two of every three in-hospital postoperative deaths.[1]

Despite the serious impact of PPCs on patients, hospitals and society, awareness of the consequences and prevention of PPCs remains relatively low. A group of 15 experts from physician, patient safety/quality and government healthcare policy organizations convened a patient safety summit to discuss ways to enhance physician awareness of PPCs and advance PPCs to a substantive public health problem demanding national attention. These experts reviewed evidence from published literature that, coupled with their experiences in the management of patients with PPCs, formed the basis for strategies to reduce the impact of PPCs and to establish an algorithm to help identify at-risk patients and track impact of interventions on the incidence of PPCs. Outcomes from the summit were published in the September 2011 issue of Critical Care Medicine.

PPCs range from minor, self-limited conditions to severe, potentially life-threatening disease states, such as acute respiratory distress syndrome and pneumonia. They are associated with a number of preoperative, intraoperative and postoperative risk factors. These include patient-related factors, such as history of smoking, underlying respiratory illness and general health status, and procedure-related factors, such as duration of anesthesia and the site of surgery, the most important factor in predicting the overall risk of PPCs.[3] Other potential contributing factors include microaspiration and postoperative mechanical ventilation, both of which can lead to healthcare-associated pneumonia. Microaspiration is the leakage of secretions and foreign material from the mouth and digestive tract into the lungs. It can occur during or after tracheal intubation, from downstream bacterial migration through or around the endotracheal tube cuff. Microaspiration is often associated with patients who have been ventilated during surgery or while in the ICU. These patients are at a higher risk for ventilator associated pneumonia (VAP), one of the most common healthcare-associated infections.

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The 2009 Patient Safety Summit was funded by Covidien. Jonathan Bloom, MD and Roger Mecca, MD are former employees of Covidien. Aryeh Shander, MD consulted for and received honoraria/speaking fees from Covidien. Luca Bigatelllo, MD and Walter Linde-Zwirble, MD consulted for Covidien.

Recommendations

The safety summit participants agreed that physicians and hospitals must have a greater understanding of patients' underlying risk factors for developing PPCs and of effective interventions to reduce the risk for development of these complications. The group identified a number of preoperative, postoperative and perioperative interventions and strategies to prevent or reduce the risk of PPCs. These include:

Preoperative interventions

- Smoking cessation
- Nutritional supplements
- Incentive spirometry

Postoperative interventions (when used together)

- Chest physiotherapy
- Bronchodilators
- Inhaled mucolytics

Perioperative interventions

- Antiseptic oral care
- Ambulation
- Careful administration of opioids

Participants recommended that measures to prevent VAP should begin in the operating room and continue into the ICU. These include general methods of infection control, such as hand-washing, appropriate use of antibiotics and proper oral hygiene and airway management. Newer endotracheal tube technologies including continuous or intermittent suctioning of subglottic secretions may also help reduce the risk of VAP. The impact of strategies to reduce VAP on duration of mechanical ventilation and mortality are unclear.

Risk marker to guide preventive interventions

The patient safety summit participants determined that prolonged (≥48 hours) mechanical ventilation is associated with increased ICU and hospital length-of-stay, increased use of resources, and a high mortality rate. (Research indicates

that more than 40 percent of patients who die after surgery are on mechanical ventilators.) Members agreed that cumulative postoperative mechanical ventilation >48 hours is the most practical, measurable marker to identify patients at highest risk for PPCs who are the most likely to benefit from risk-reduction interventions. This marker also will allow clinicians to track the effect of interventions on the incidence, morbidity, mortality and cost of PPCs.

The participants concluded that much of the additional costs incurred by PPCs are avoidable or preventable if necessary steps are taken to decrease the incidence of these events. They agreed on the need to identify key medical, quality/safety and regulatory stakeholders to implement educational programs to raise awareness about PPCs and effective strategies to mitigate the incidence and severity of these complications.

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Ambulatory Augmented Ventilation – going beyond basic long term oxygen therapy

Robert McCoy, BS RRT FAARC

The progression of chronic respiratory disease eventually produces respiratory insufficiency and limits a patient's mobility. Portable oxygen systems are essential for patients who exhibit hypoxemia with activity, and these systems have evolved to provide light-weight, long-lasting devices that can increase FiO_2.[1] Yet, these oxygen systems cannot compensate for reduced ventilatory capacity.

In order to maintain cardiovascular status, respiratory status, secretion clearance, and most importantly, a positive mental attitude, patients with chronic lung disease need to remain active and mobile for as long as possible. The lack of an effective portable oxygenation/ventilation system for patients with chronic lung disease encourages a pattern of reduced activity, decreased clearance of secretions, infection, exacerbation, and hospitalization. Unfortunately, these "frequent flyer" patients are well known to hospitals and caregivers, and attempts to prevent re-hospitalizations are often unsuccessful. Patients return to their homes and the vicious downward pattern begins again.[2]

Oxygen therapy, even when effectively prescribed and applied, does not address the need for augmented ventilation. Yet, the combination of augmented ventilation and oxygen therapy during ambulation has not been available. The recent development of a novel non-invasive open ventilation (NIOV) ventilator that provides both oxygenation and ventilation in a lightweight system, portable enough to be worn by a patient, may change the playing field.

Hospitals use a variety of products to treat patients in respiratory failure. Initial treatment often includes the use of noninvasive positive pressure ventilation (NIPPV) to help patients surmount an acute ventilatory crisis. Based on their response to NIPPV, patients may go on to require invasive mechanical ventilation, or conversely, be downgraded to a high-flow oxygen delivery system until they are stable enough for discharge. Patients are often stationary during hospitalization and spend most, if not all of their time in bed. Under these conditions, ventilators need not be portable or mobile and can be fixed at the patient's bedside.

After patients are discharged and return to their homes, activities of daily living (ADLs) require them to be mobile and active. To reduce the potential for further episodes of respiratory exacerbations occurring at home, a mobile augmented ventilation device is needed that can allow patients to continue to perform ADLs while maintaining adequate oxygenation and ventilation. NIOV provides a means for patients to accomplish these at-home ADLs objectives.

What is NIOV?

Breathe Technologies' NIOV system provides a new modality that is targeted at patients who suffer respiratory insufficiency while at rest and/or while ambulating. The NIOV ventilator weighs only one pound and is intended to be carried by patients (Figure 1) as they perform ADLs. The ventilator boosts each spontaneous breath with a clinician-selected augmentation volume. Three levels of activity/volume augmentation (low, medium, high) are available for use, and are patient-selectable, based on the individual's perceived workload. Thus, patients can choose the activity/volume level that best suits their needs during rest, moderate activity, or exertion, simply by pressing the desired button on the ventilator.

Figure 1. The Breathe Technologies Non-invasive Open Ventilation System.

The NIOV system utilizes a lightweight and comfortable nasal interface (Figure 1). The low profile nasal interface incorporates a venturi entrainment port that supplements the tidal volume set on the ventilator. The entrainment of ambient air adds volume to the breath and dilutes the FiO_2 to approximately 0.40 at a set volume of 250 mL. In addition, the ventilator provides patient/clinician selectable trigger levels, clinician selectable inspiratory settings, plus audible and visual cues and features to help clinicians and patients correctly use the product.

Based on user responses from initial clinical trials, the light-weight ventilator, with its patient-selectable augmentation levels and comfortable nasal interface, is proving to be a very desirable offering.[3] Study patients have commented on the comfort and ease-of-use of the device, which are critical attributes for gaining

This article was provided by Breathe Technologies. NIOV is a registered trademark of Breathe Technologies.

patient compliance in any homecare product. In addition, the NIOV system has demonstrated the ability to reduce perceived work of breathing, dyspnea, and to improve the six-minute walk distance in a majority of patients tested.[3]

Understanding NIOV: Bench Testing

The best way to understand a product's capability is to control variables and evaluate the product's performance under several test conditions. To help understand the effects the NIOV ventilator can have on a patient's breathing pattern, the system was tested at a respiratory product testing facility using a lung simulator. The following graphs were taken from analyses of these lung simulation data using the NIOV system. The lung simulator was set to 20 breaths/minute, with a tidal volume of 600 mL, using normal lung conditions (resistance = 5 $cmH_2O/L/sec$, compliance = 100 mL/cmH_2O, using a modified sine wave).

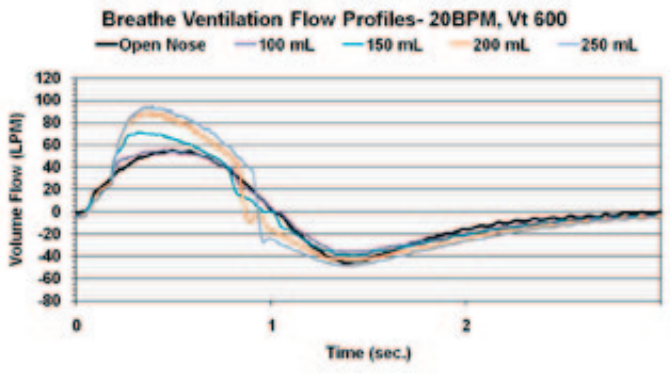


Figure 2. Note that as the volume setting increases on the ventilator, peak flow to the lung increases. In this lung simulation, baseline ("Open Nose") peak flow during inhalation was approximately 55 LPM, while at the highest volume setting (250 mL), the ventilator increased the observed peak flow to approximately 90 LPM.

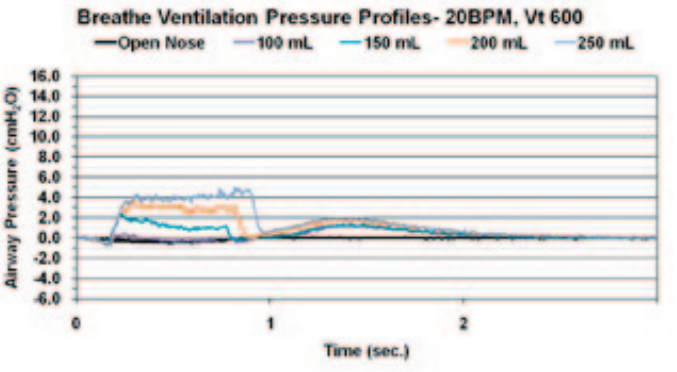


Figure 3. With NIOV, the combination of volume delivered by the ventilator plus the volume of entrained air from the venturi, generates a moderate positive pressure in the airway during inhalation. In this simulation, with the ventilator set to highest volume setting (250 mL), approximately 4 cmH_2O pressure is generated in the airway during inhalation.

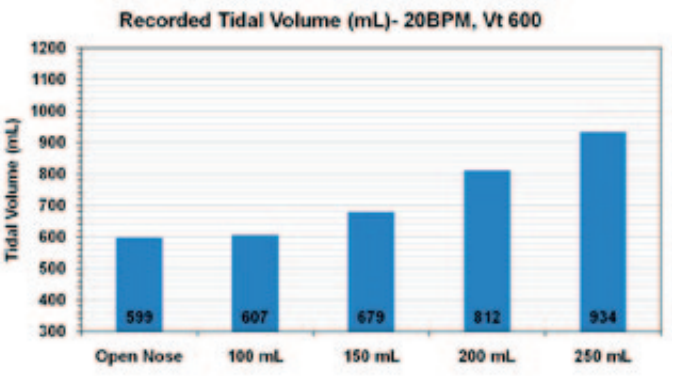


Figure 4. Augmented tidal volumes generated using the NIOV system. In this simulation, the volume setting of 100 mL began to add to the patient's spontaneous tidal volume, and at the 250 mL setting, lung volume increased to 934 mL. At volume settings lower than 100 mL, lung volumes were not notably augmented, although the simulator lung still received oxygen volumes and measured FiO_2s were higher than what many intermittent flow oxygen delivery systems provide.

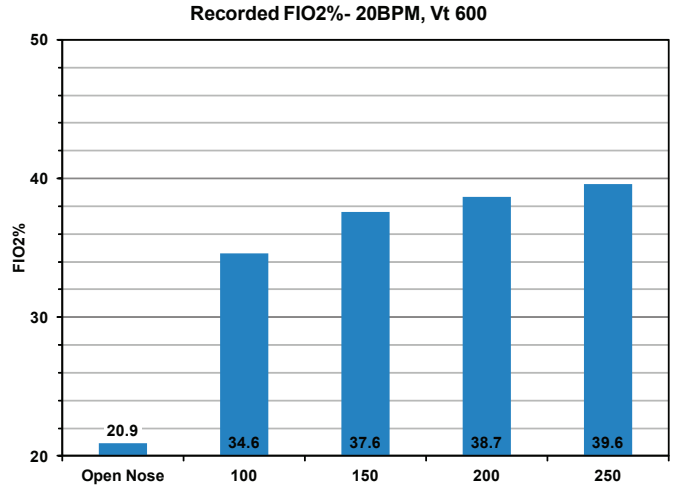


Figure 5. FiO_2 delivery at various set volumes exhibited slight variability, however were consistently higher than typical homecare oxygen delivery systems. Continuous flow oxygen systems provide variable FiO_2s, based on factors such as respiratory rate, inspiratory time, and tidal volume. The NIOV system delivered consistently higher oxygen concentrations than most home oxygen delivery systems, at all volume settings and with variable respiratory rates.

Chronic lung disease is progressive and reduces a patient's ability to oxygenate and ventilate effectively over time. Respiratory therapy options in the home have included medications that reduce bronchoconstriction and infection, secretion mobilization, oxygen therapy, and exercise. Pulmonary rehabilitation is the first step in preparing the patient for living with chronic lung disease in the home and has gained widespread acceptance. Education creates the foundation for patients to understand their disease, learn how to live with it, and how to minimize complications arising from the disease. Nonetheless, drugs, devices, and special techniques may provide only a modicum of relief once a patient loses significant ventilatory capacity.

Hospital ventilation for chronic lung disease has evolved from invasive critical care ventilation to include non-invasive Bi-Level intervention in less severe circumstances. Patients requiring invasive ventilation can be difficult to wean, and may spend *Continued on page 39…*

Case Study: Via Christi Health

Introduction

Via Christi Health is a Catholic-sponsored health ministry affiliated with the Marian Health System and Ascension Health. The largest provider of healthcare services in Kansas, Via Christi Health serves the region through hospitals, senior villages, physician services and health services. Via Christi Health employs more than 9,000 in Kansas and northeast Oklahoma. Via Christi's three acute-care hospitals in Wichita have 1,604 licensed beds and more than 4,400 employees.

According to an annual study by HealthGrades, one of the nation's leading independent healthcare ratings organizations, the clinical performance of Via Christi Health's Wichita hospitals is among the top 5 percent in the nation. As a result, in 2011 Via Christi was recognized with a HealthGrades Distinguished Hospital for Clinical Excellence award, one of only 92 hospitals nationwide to receive the award for five consecutive years.

In addition, Via Christi received HealthGrades' Pulmonary Care Excellence Award for a fourth consecutive year, Stroke Care Excellence Award for a sixth year in a row and Critical Care Excellence Award for a third year in a row and continues to rank No. 1 in Kansas for pulmonary care, stroke treatment, critical care and gastrointestinal medical treatment.

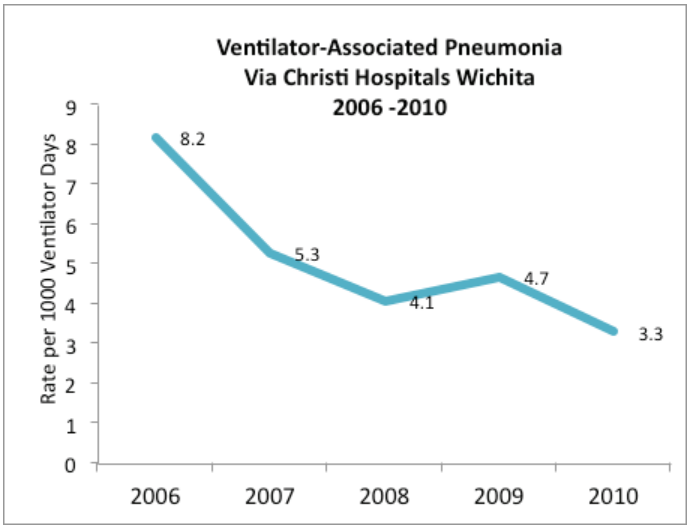
Case Example — Implementation of Kimberly-Clark KimVent Microcuff Endotracheal Tube

Via Christi's respiratory care department is made up of 125 therapists who provide care driven by clinical protocols in critical care and medical/surgical units. Ventilation includes conventional, percussive ventilation, and oscillatory ventilation, as well as jet ventilation in the NICU when indicated.

Since implementing new ventilator-associated pneumonia (VAP) prevention protocols, the hospital reduced the incidence rate of VAP by approximately five infections per 1,000 ventilator days from an average rate of 8.2 in 2006 to 3.3 in 2010.

The Challenge

Via Christi's Wichita hospitals provide a comprehensive range of services and tertiary care, including a Level I Trauma Center, Transplant Institute, Cancer Institute, Level III Neonatal Intensive Care Unit and Regional Burn Center as well as pediatric, cardiac, cardio thoracic, neuro critical, general and medical ICUs. As a result of its intensive care patient population, the hospital at any one time has a high volume of patients on ventilators. In 2006, the ICUs were seeing a higher than desired VAP rate of 8.2 infections per 1,000 ventilator days.



VAP is a healthcare associated infection (HAI), which is recognized as a serious problem nationwide in hospital intensive care units. Experts say that VAP can affect as many as 28 percent of patients who receive mechanical ventilation for at least 48 hours. VAP also imposes a significant financial burden, with some studies estimating the per-case cost of VAP at $12,000 to $40,000.[2] VAP increases ICU stays by up to 22 days and hospital stays by up to 25 days,[3] contributing to the high cost and toll it can take on patients, hospitals and the healthcare system. The mortality rate attributed to VAP is estimated to be as high as 27.1 percent.[4]

To reduce its VAP rates, Via Christi adopted a prevention protocol, including the use of a closed suction catheter system that keeps the ventilator circuit closed as much as possible, good hand washing, elevating the head of patients' beds, incorporating an oral care strategy, maintaining cuff pressure and selective use of heated humidification. In early 2007, the hospitals launched a formal multi-disciplinary team of individuals from infection control, hospital intensivists, ICU nursing leadership, administration and data specialists. Director of Respiratory Care Don Carden and Clinical Specialist Jeff Suderman, both registered respiratory therapists, provided leadership to the team and its efforts to reduce the VAP rate at Via Christi's Wichita hospitals.

This article was provided to us by Kimberly-Clark. Via Christi Health can be reached at www.viachristi.org.

As part of that effort, the team took a closer look at the devices and products the department was using in its VAP prevention efforts and became one of the first adopters of the Kimberly-Clark KimVent Microcuff Endotracheal Tube. The Microcuff ET Tube is designed to prevent the micro-aspiration of potentially infectious secretions into the lungs, a leading cause of VAP. The Microcuff ET Tube's unique cuff is made of an advanced microthin polyurethane material that allows the channels formed upon cuff inflation to "self-seal" within the trachea, increasing protection against fluid leakage into the lungs.

The Solution

In 2007, the Via Christi team selected the Kimberly-Clark KimVent Microcuff Endotracheal Tube and began using it on a regular basis. According to Carden and Suderman, the Microcuff ET Tube provided a solid cost-benefit advantage in that the department was able to seamlessly transition to the Microcuff ET Tube, with minimal education on how the tube works and minimal staff involvement in the training of its use. In addition, they found that when compared to competitive tubes with the same inner diameter, the Microcuff ET Tube had a smaller outer diameter. This was seen as an advantage to both RTs and patients during intubation. Also, when deflating the Microcuff ET Tube, the cuff more tightly hugs the shaft of the endotracheal tube which may allow for easier intubation. Finally, the availability of a pediatric Microcuff ET Tube option through Kimberly-Clark also made the selection more compelling for instances of treating pediatric patients.

The Results

Since implementing a strong multidisciplinary team effort, the department lowered its VAP rate to 3.3 infections per 1,000 ventilator days. Four out of 10 units have achieved a rate of zero infections per 1,000 ventilator days. "We have excellent respiratory therapists, critical care nurses, unit intensivists, advanced practice pharmacists, infection control, and microbiology," said Carden. "Assuring compliance with all elements of the VAP reduction bundle is critical." Suderman agreed, adding, "Everybody knows how important this is. It's not just the nurses' responsibility, not just the RT's responsibility, but it's everyone on the team. You have to keep VAP on the front burner."

Carden agrees, noting that every hospital needs someone to be the VAP champion to keep the issue alive. "Keeping the issue alive is an ongoing challenge, but this needs to be done in order to see successful and continued reductions in VAP," he said.

Via Christi is well-positioned to provide great care and to battle the non-reimbursement policy for never events and HAIs by Medicare, which now—more than ever—provides a further incentive to get patients off ventilators as soon as possible to cut down on the incidence of VAP to keep patients healthy and reduce hospital costs.

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Comparison of Physical and Mechanical Features of Commercially Available Inspiratory Pressure Threshold Load Trainers

Toni Chiara, PT, PhD

Abstract

Purpose: To examine and compare physical and mechanical features of three commercially available pressure threshold load (PTL) respiratory muscle trainers (RMT)s. To determine in healthy, college adults, if there was a difference in training effect between the various RMTs.

Method: During Phase One the physical and mechanical features of three brands of PTL RMTs were examined. During Phase Two 37 (17 females) healthy, college adults completed inspiratory muscle strength training with one of four trainers. Initial and post evaluations included respiratory muscle strength and lung function assessment, while weekly evaluations involved respiratory muscle strength assessment.

Results: During Phase One predicted opening pressures based on compression spring stiffness and actual opening pressure achieved through the use of a 3 liter volume syringe were found to be substantially different. During Phase Two respiratory muscle strength improvement was achieved but no difference in strengthening capacity was found between four RMTs designed for general population and/or athletes.

Conclusions: Physical and mechanical features of the various commercially available PTL RMTs influence the effect of respiratory muscle strength training. Use of PTL RMTs improves maximal respiratory muscle strength without changing lung function.

Introduction

Just over a century ago the first respiratory muscle trainer, known as the "diaphragm meter and exerciser" was patented.[1] Since the mid-1970s, numerous investigations have occurred on respiratory muscle endurance and/or strength training in athletes, healthy individuals, and patient populations.[2-6] Respiratory muscle training (RMT) has been accomplished with many different types of devices since its inception such as isocapnic hyperpnea, resistive (flow or pressure), pressure threshold load, or computer-controlled trainers.[3,7,8] Though there have been investigations comparing various research trainers[9-14] no study exists that has studied the currently available commercially offered hand-held pressure threshold load trainers. In this study several of the commercially available trainers, the Respironic Threshold Inspiratory Muscle Training (IMT), PowerBreathe, and the PowerLung, were examined and used for inspiratory muscle strength training (IMST). The purpose of this study was to examine mechanical aspects, ie spring stiffness and valve opening pressure (Phase 1) and determine if there is a difference in ability of the trainers to improve inspiratory strength, as measured by manometry, and lung function, as measured by spirometry, in healthy college age adults (Phase 2).

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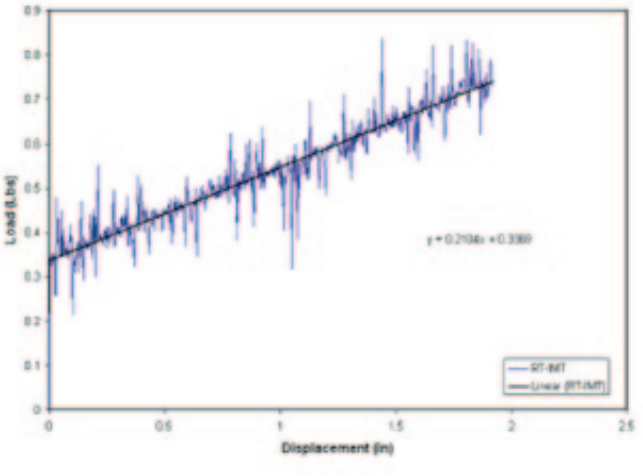
Methods

Phase 1. Examination of Physical and Mechanical Characteristics of the Trainers: Valve opening pressure is dependent on spring stiffness and the amount of compression or shortening of the spring against the valve. Two springs from each of the following trainers were removed: the PowerBreathe (Wellness, Fitness and Sports Performance, Classic models) and PowerLung (BreatheAire, Trainer and Sport, Active Series models). One spring was removed from the Respironics IMT trainer, yielding a total of 13 spring samples. An Instron Universal Testing Instrument (Model 1125 E, Grove City, PA) was used to provide a compressive load on each spring. The spring stiffness was measured by a load transducer (500 kilogram load cell) mounted between the spring and the crosshead of the testing instrument and displayed in Newton per meter (N/m). Each spring was compressed from its full length to its shortest possible compressed length at a rate of 0.2 in/min. The load to achieve the displacement (compression of the spring) was recorded simultaneously on chart paper moving at a speed of 0.2 in/min. Figure 1 illustrates the load, ie, the force needed to compress the spring, compared to the displacement, ie, full length to fully compressed for the Respironic (IMT) Inspiratory Muscle Trainer. Similar figures were generated for each spring.



Calculated Opening Pressure versus Measured Opening Pressure

Calculated Opening Pressure: The stiffness of the spring is an important feature of the pressure-threshold load. Spring stiffness is defined as the ratio of force over displacement, which can be written as k=F/d where spring stiffness is notated as k, F is the static force and d is the displacement.[15,16] Spring stiffness is expressed in terms of how much force is needed to compress a spring one inch. If a spring is rated at 4 lbs, this means that it takes 4 lbs of pressure to deflect the spring by one inch.[17]

The pressure required to open a trainer's valve against which the spring is compressed can be determined by using the spring stiffness measurement. Determination of calculated opening pressure for each of the seven models of the trainers included measuring the length of the springs without any compression. For example, with the PowerLung, the resting length was 76.4 mm. Next, the length of the spring was measured when the spring was placed at the lowest setting of the trainer. For the PowerLung this measurement was 74.9 mm. Then, the length of the spring was measured following a single complete 360 degree turn of the trainer's dial throughout the range of the device. This step resulted in obtaining the change in the length of the spring throughout the range of the device, and in this case it equaled .50 mm for each turn. The next step was to calculate the required force to open the pressure threshold valve on the devices and covert this force to a measure of pressure in centimeters of water (cmH_2O). Force was defined as F = k (Newton/meter [N/m]) total change in spring length for each turn in the device dial. Spring stiffness (k) was determined by use of the Instron Universal Testing instrument. Force (F) was converted to pressure using a standard conversion table.

Measured Opening Pressure: Pressure necessary to open the valve of each trainer was determined through the range of the trainers' resistance levels. The circumference of each trainer was marked off in 1 cm increments along the outside of the PowerLung trainer body at the inspiratory port and along the outside of the PowerBreathe spring housing (the handle of this trainer). Each trainer was connected in series to a mechanical ventilator oxygen tap which in turn was connected to a Hytrel Tube (Vacuumed, Ventura CA) 30.48 cm in length with an internal diameter (ID) of 22 mm connected to the calibration pump. A polypropylene tube 45.8 cm in length with an ID of 5mm was used to connect the mechanical ventilator oxygen tap and the P1 inlet of a Smart Manometer (model 350 Series, Merriam Instruments, Cleveland, OH). Pressure to open the valve was determined by generating a negative air flow produced manually by pulling the handle of the calibration pump (3 Liter ± 0.4% calibration pump; Jaeger, Germany) over a 10 sec period. At each centimeter around the circumference of the trainer 10 measurements were made.

Phase 2. Testing Inspiratory Muscle Training in Healthy Young Adults: The two highest levels of the PowerBreathe, the Fitness and Sports Performance, and of the PowerLung, the Trainer and Sport, were tested for capability of increasing maximal inspiratory pressure (MIP) in healthy college age adults. Participants include 25 females, age range 21-35 years and 11 males, age range 20-31 years. They were all of average height and weight.

Assessment included two baseline sessions which were 24 to 48 hours apart, and one post-training session. Measurements included MIP and maximal expiratory pressure (MEP) by the use of a manometer (MicroMedical RPM, Micro Direct, Inc, Lewiston, ME) and pulmonary function (forced vital capacity (FVC), forced expiratory volume in the first sec (FEV1), peak expiratory flow (PEF) and peak inspiratory flow (PIF)) by the use of a spirometer (Discovery Spirometer, FutureMed America Inc, Granada Hills, CA). Each participant completed an average of 5 to 7 maximal manometry maneuvers and 3 American Thoracic Society acceptable spirometry maneuvers. The top three manometry maneuvers within 5% of each other for MIP and for MEP were used for analysis. The highest measurements of the spirometry were used for analysis. Following the baseline assessments, participants were randomized to use one of the four trainers (PowerBreathe: Fitness or Sports Performance or PowerLung: Trainer or Sport). The trainer setting was always set at 75% of each participant's current MIP. During the four weeks of training, participants completed 5 sets of 5 maximal inhalations once per day, 5 days per week. Participants completed a training log, recording each training breath with a checkmark, noting the date and time of training, and their rating of perceived exertion. Participants returned to the lab weekly for re-assessment of MIP, again using the mean of the highest three maneuvers that were within 5% of each other. Adjustment of the trainer pressure threshold load occurred and the participant completed his/her training for the day, being observed by the investigator to assess correctness of use.

Data Analysis

A paired sample t-test was used to analyze the difference in measured and calculated valve opening pressure of the trainers. An ANOVA was used to analyze (SPSS, 14.0 for Windows, SPSS Inc, Chicago, IL) the change in MIP, MEP, FEV1, FVC, PEF, and PIF from baseline to post-training with trainer type as the between subject factor and assessment as the within subject factor. Secondary data analysis examined if there as a difference in MIP between the genders (M n=12 and F n=32) and nationalities (Caucasian n=26, Asian Indian n=13, African-American n=1, and Oriental n=4). Probability level was set at $p = 0.05$.

Results

Phase 1. Examination of Physical and Mechanical Characteristics of the Trainers – Physical Description of the Trainers: Table 1 presents the number of models per trainer style, plus the physical features, eg, the length and circumference of the body of the trainers, and the size and type of mouthpiece. Of the three brands of trainers only the Respironics Threshold IMT shows its range of pressure threshold on the unit (7 cm H_2O to 41 cm H_2O). The PowerBreathe had three raised edges which since have been replaced by numbered lines. The PowerBreathe pressure threshold load ranges from 17 cmH_2O to 274 cmH_2O dependent on which model is being used and may vary between units of the same model as the pressure threshold load was noted to be influenced by different breathing rates.[18] The load corresponding to the line on the trainer is provided in the owner's manual. The PowerLung has six lines on the inspiratory port with a minimum and maximum noted. However, no data could be found as to the corresponding pressure threshold load for each line.

Spring Stiffness: Spring stiffness ranged from 36.84 to 1062.97 Newton per meter (this being 0.2 to 6.07 pounds per inch). Extreme spring stiffness was found at the highest level of PowerLung, the Sport, which at the tightest spring compression

Table1. Physical Description of the Pressure-Threshold Load Trainers										
Trainer	Number of Models	Disassembles (Yes/No=√)		Body of Trainer (mm)		Mouthpiece Opening (mm) Oval-shaped		Mouthpiece	Pressure Markings on the trainer cmH_20	
		Yes	No	Length	Cir.	Length	ID	Material Style & length	Yes	No
Threshold IMT	1		√	120	110	28	7	hard plastic triangular 5 cm	X 7-41 cmH20	
PowerBreathe	3	√		80	105# 93*	32	9	soft plastic scuba 3.5 cm		X
PowerLung	3	√		1550	125	32	9	soft plastic scuba 3.5 cm		X

required generating a pressure-threshold load 5.7 and 7.5 times greater than the average MIP for young healthy adult males (120 cmH_2O) and females (90 cmH_2O), respectively. The spring stiffness of the PowerBreathe Sport Performance would require an individual to generate is approximately 1.95 and 2.6 times normal MIP for young healthy adult males and females.

Valve Opening Pressure: Significant differences were found between the calculated and measured valve opening pressures for the Respironic Threshold IMT, for the PowerBreathe Wellness and for the PowerLung Sport, but not for the PowerBreathe, Fitness and Sports Performance models or for the PowerLung Trainer and BreatheAir. Additionally, the PowerLung BreatheAir and Trainer produced comparable calculated (93.07 and 94.70 cm H_2O, respectively) and measured (77 and 72 cm H_2O, respectively) opening pressures. See Table 2 for the outcome of the statistical comparisons data and Table 3 for a listing of the measured and calculated valve opening pressures for each trainer.

Table 2. Mechanical versus Calculated Opening Pressure Differences	
Respironic Threshold® IMT	t= -5.770, df=8, ***p*=0.000**
PowerBreathe® Wellness	t = -2.411, df =8, ***p* = 0.042**
PowerLung® Sport	t = -14.929, df =12, ***p* = 0.000**
PowerBreathe® Fitness	t = 0.969, df =9, *p* = 0.534
PowerBreathe® Sports Performance	t = -1.935, df = 9, *p* = 0.085
PowerLung BreatheAir	t = -.428, df = 12, *p* = 0.639
PowerLung® Trainer	t = -2.411, df =12, *p* = 0.261

Table 3. Measured (M) and Calculated (C) Trainer Valve Opening Pressures															
Turns	Trainers														
	Respironics Threshold IMT		PowerBreathe						PowerLung						
			Wellness		Fitness*		Sports Performance *		BreatheAir		Trainer*		Sport*		
	M	C	M	C	M	C	M	C	M	C	M	C	M	C	
1	6	6.12	5	8.52	7	5.62	25	7.57	13	4.23	14	4.30	6	78.27	
2	9	12.24	8	19.88	12	22.46	41	37.86	19	8.46	25	17.22	23.5	130.44	
3	13	18.37	13	25.56	13	39.31	58	53	25	16.92	26	21.52	54.5	156.53	
4	16	22.96	32	34.08	17.5	56.16	69.5	83.29	29	21.15	36	30.13	72	208.71	
5	19	27.55	42	48.29	24	73.01	94	106.01	30	25.38	27.5	34.43	75	260.89	
6	22	32.14	59	53.97	38	89.86	103	136.30	31	33.84	43.5	38.74	165	286.98	
7	27	36.73	65	65.33	68	106.71	138	159.01	33	38.08	47	47.35	192	313.07	
8	31	41.33	71	76.69	174	129.17	118	189.30	34	46.54	54	55.96	205	365.24	
9	31	42.86	77	79.53	197	151.64	207	212.02	42	50.79	48.5	60.26	260	417.42	
10				82.37	211	168.49	215	234.74	47	59.23	64	68.87	288	469.60	
11									47	63.46	58.5	73.17	340	495.69	
12									69	67.69	64	81.78	370	521.78	
13									77	76.15	72	86.09	400+	573.95	
14										93.07		94.70		678.31	

Descriptive Results of Mechanical Features: The Respironics Threshold IMT calculated opening pressure corresponded to the manufacturer's listed measurements; however the measured opening pressure was inconsistent. We did find the device light-weight and its resistance easy to adjust. Resistance of the PowerBreathe and PowerLung trainers was easy to adjust, but the resistance level is not known to the user as it is not displayed on the trainers like it is with the Respironics Threshold IMT. The PowerBreathe Sports Performance and Fitness trainers calculated opening pressures increased by approximately 26 cmH_2O and 17 cmH_2O, respectively, for each full turn. An inconsistent gain in measured opening pressure for each of the PowerBreathe trainers may be due to the fact that the manufacturer acknowledges that the pressure threshold load may be variable and is affected by one's breathing pattern.[18,19] Calculated opening pressure of the PowerLung Sport increased by approximately 52 cm H_2O per turn, while the Trainer and Breathaire increased by approximately 5 cm H_2O per turn. Similar to the PowerBreathe measured opening pressure, the PowerLung trainers also had no consistent increase in opening pressure. Having an inspiratory and expiratory trainer in one unit, such as the design of the PowerLung, eliminates the need for using two separate trainers. However, the measured opening pressure for inspiration (6 levels) was found to be dependent on the setting for expiration (3 levels). The difference in measured opening pressure ranged from 2 to 15 cm H_2O and was dependent on the setting of the expiratory port. The measured opening pressure for inspiration was greater if the expiratory valve was set at level 3 versus level 2 versus level 1. The calculated opening pressure for the PowerLung Sport at or above the 4th turn was substantially greater than physiological norms for maximal inspiration.[20-23]

Phase 2. Inspiratory Muscle Training in Healthy Young Adults: Though a significant gain (t = -6.193, df =39, p = 0.000) in MIP occurred between baseline and post-training (M±SD, 90.23 ± 33.23 cm H_2O and 120.81 ± 32.94 cm H_2O, respectively) for all participants, no difference was found between the four respiratory trainers' ability to improve MIP (F= 1.056, df = 33, p = 0.54). The mean ± standard deviation post-training MIP values were 108.8 cm H_2O ± 33.6 and 98.9 cm H_2O ± 29.8 for the PowerLung Sport and Trainer, respectively, and 126.5 cm H_2O ± 36.3 and 113.5 cm H_2O ± 48.8 for the PowerBreathe Sports Performance and Fitness, respectively.

Though the training was directed at inspiration, a statistically significant change (t = -2.536, df = 36, p = 0.016) was found in MEP from baseline and post-training (116.70 ± 42.84 cm H_2O and 128.22 ± 44.27 cm H_2O respectively). No statistically significant changes were found in pulmonary function (FVC p = 0.868, FEV1 p = 0.377, PEF p = 0.392, and PIF p = 0.227). No statistically significant changes were found in the secondary analyses (gender p=0.296; nationality p=0.231)

Discussion

Mechanical differences exist between the commercially available pressure threshold load trainers examined in this study, particularly the compression spring stiffness. Evaluations undertaken in Phase One showed differences in mechanical (calibrated) and calculated opening pressure exists in each trainer. In Phase Two use of the trainers, promoted for the general population (PowerBreathe Fitness and PowerLung Trainer) and for athletes (PowerBreathe Sport Performance and PowerLung Sports), by college age healthy adults for 4 weeks of inspiratory muscle training resulted in significant gain MIP but

no change in pulmonary function. However, no difference was found between the four models' ability to improve respiratory muscle strength or pulmonary function. This finding provides more assurance that the devices are equivalent in producing similar training outcomes with regard to increasing inspiratory muscle strength.

Respiratory muscle endurance and/or strength assessment and training has been studied with a wide variety of devices, such as units with weighted plunger,[13,24] and solenoid valves,[9] and isocapnic hyperpnic,[25] resistive load, 26 and pressure threshold load devices,[13,27] in athletes,[13] healthy,[28] and patient populations, with pulmonary,[12,14] cardiac,[13] or neuromuscular[29] diseases. Studies comparing features of different weighted-plunger[10-14] or solenoid threshold load[9] devices are not comparable to this study as the mechanism of the trainers are not similar to the current commercially available pressure threshold units using spring-loaded poppet valve. Hand-held portable threshold load trainers were introduced by Larson et al.[30] Several modifications of that original concept are now available. Currently, pressure-threshold load trainers are the recommended device to use for respiratory muscle training, be it for endurance or strengthening.[4,7]

To date no other study has compared the mechanical features of the commercially available pressure threshold trainers nor has any study compared the ability of these trainers to improve MIP. However, previous studies have compared different types of respiratory muscle trainers. Johnson et al[13] compared a weighted-plunger and the Respironics Threshold Inspiratory Muscle Trainer (Threshold IMT). These investigators reported the Threshold IMT valve opens at pressures several cm H_2O below the intended opening, at low flow rates the pressure remains below the set pressure, and at high pressures the measured opening pressure across the trainer valve exceeds the set value by up to 5 cm H_2O. In agreement with Johnson et al[31,13] we found that the measured opening pressure was less than the calculated opening pressure (see Table 3), increasing as the set value was increased. Differences in our findings maybe that Johnson et al[13] compared ten different Threshold IMT trainers, whereas we examined the compression spring and the measured opening pressure of only one Threshold IMT.

Limitations of this Study: The number of springs tested for each trainer was limited. Test on spring compression was completed on a single sample of the springs used in the Respironics IMT and 2 springs from each of the three models of the PowerBreathe and the PowerLung. Each spring was compressed once.

The number of trainers examined for opening pressure by the use of a 3 L syringe was one of each model. Each incremental measurement was repeated ten times at both a fast and a slow speed, a 3 second and 10 second count, respectively.

Method of opening the spring-loaded valve: Use of a mechanical syringe may have provided a more consistent negative pressure and airflow. Wells et al[32] used a vacuum to produce sufficient negative pressure to create a flow through the PowerLung trainer's inspiratory port.

Number of individuals who trained with the individual trainers: It was intended that there be ten individuals per each trainer. This sample size is comparable to some studies that have investigated the effect of respiratory muscle trainers on various populations; however the sample size may have been too small to measure a difference between trainers.

Pressure threshold load by definition should be free of air flow. In the current study we did not examine the relationship between pressure and airflow. Previous studies have reported that for each of the devices examined in this study the pressure is influenced by air flow.[7,30,32,33]

Conclusion

In healthy college age adults inspiratory muscle strength training improves MIP and MEP, but has no influence on pulmonary function, eg FEV1, FVC, PEF, or PIF. Respiratory muscle strength gains achieved in this study are not generalizable to other study populations. As more pressure-threshold load trainers become commercially available, additional study will be needed to determine if the trainers' physical and mechanical features provide similar improvement in respiratory muscle strength as the current models.

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Ambulatory Augmented Ventilation …continued from page 32
much of their lives on some form of mechanical ventilation. This greatly complicates care, as ventilated patients require intensive resources that are associated with high costs and highly skilled personnel.[4] Non-invasive positive pressure ventilation has evolved and matured to the point that hospital staff are familiar with the technique and are able to manage patients very effectively. Weaning procedures are established that allow most patients to quickly come off NIPPV and to rapidly move towards discharge. While NIPPV is available in the home, it is only available as a stationary modality. Conversely, NIOV provides augmented ventilation and oxygenation in a package that is practical and comfortable for patients to use in both stationary and ambulatory situations.

The future of NIOV will be determined by understanding how the product can be used to prevent complications and exacerbations associated with respiratory insufficiency. The Breathe NIOV system addresses an unmet need for many patients with chronic respiratory insufficiency. As with LTOT, further research and education will create a solid foundation and scientific basis for using NIOV to improve the outcomes of patients requiring continued treatment of their chronic respiratory disease in the home setting.

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Clinical Utility Study on LTOT Patients

Beth Ann Davic, RRT

Introduction

Long term oxygen therapy (LTOT) is an accepted medical intervention for individuals suffering from chronic hypoxemic respiratory insufficiency. Various oxygen delivery systems to provide LTOT have been developed to accommodate unique environments, lifestyle activities, and physical limitations. Efficacy of this therapy is in part based on the patient receiving the prescribed liter flow rate, delivered in an uninterrupted fashion. However, an inherent drawback of all oxygen delivery systems is the unexpected reduction of gas flow due to system leaks, or total cessation of flow caused by catastrophic failure of the supply source. These limiting factors may compromise the effectiveness of LTOT. Failure to correct the "set liter flow-to-patient delivery" gap in a timely manner could degrade cardiopulmonary and systemic function to negatively impact morbidity. To optimize LTOT and ensure safety, both the user and caregiver need to periodically monitor the oxygen liter flow rate setting on the delivery system and make certain it corresponds with the flow rate emitted to the patient.

Ingen-Technologies, Inc has designed an inline flow gauge positioned proximal to a nasal cannula that monitors the oxygen flow rate delivered to the patient (Figure 1). The Oxyview, a reusable flow meter and the Smart Nasal Cannula, a disposable flow meter attached to a cannula and seven-foot tubing, indicates the oxygen liter flow rate entering the nasal cannula. A spring-loaded flow gauge, gravity independent, operates in any position. Ingen-Technologies manufacture gauges to monitor flow rates from 0-3 lpm (graduated indictors in ½ lpm markings) and 0-6 lpm (graduated indictors in 1 lpm markings). The cylindrical flow gauge is approximately 1.4 inches in length, 0.4 inches in diameter and weighs 3.98 grams. Cannulas are sized for adult, pediatric and infant populations.

Study Objectives

A study was conducted to assess the patient and caregiver's perception of the utility of the Smart Nasal Cannula.

The author is a volunteer with Healthy Lungs Pennsylvania, Pittsburgh. This study was of the Oxyview and the Smart Nasal Cannula, provided by Ingen-Technologies for the study. Participation in this study was strictly on a voluntary basis. No compensation, whether monetary, incentives or otherwise was received by the participants or the author of this study. Prior to participant enrollment, an Informed Consent was signed, reviewing the objectives, data collection, and permitting publication of the study's results.

Method

Patients receiving LTOT were evaluated with the Smart Nasal Cannula (model 206NCA) for eight days and provided feedback on their experience. Participants were instructed to observe the flow gauge and compare the reading with the flow rate set on their oxygen delivery system. If a discrepancy was found, the participants were encouraged to perform troubleshooting maneuvers, looking for gas leaks, tubing disconnections and power supply issues. After eight days, each patient completed a questionnaire, commenting on ease of use, comfort of fit, and any benefits received from use.

Enrollment

Participant demographics

- Number of patients: 10
- Age: Mean 77 (66 – 83)
- Gender: 5 male, 5 female
- All patients had COPD with noteworthy secondary diagnoses including: pulmonary artery hypertension, coronary artery disease, post lung reduction surgery, congestive heart failure and diabetes.
- No participant or caregiver had significant eyesight impairment.

Oxygen Delivery Systems (Some participants used a combination of oxygen delivery systems that was appropriate for their activity and location, i.e., portable liquid oxygen when ambulating and a stationary oxygen concentrator during sleep.)

- Stationary oxygen concentrator, continuous flow: 8 participants evaluated with a median flow rate of 3 lpm (range 2 to 6 lpm). Bubble-type humidifiers were used by 6 participants.
- Portable liquid device, continuous flow: 4 participants evaluated with a median flow rate 3 lpm (range 2 to 12 lpm).
- Portable liquid device, pulse flow: 6 participants evaluated with a median flow rate 3 lpm (range 2 to 6 lpm).

Results

All questions were responded to by 10 participant teams (patient and/or caregiver).

• **Question:** Evaluate the ease to read and understand the Smart Nasal Cannula gauge? (Using a scale of 1-5, 1 being very easy and 5 being extremely difficult). **Response:** Mean 1.2 (range 1-2)

• **Question:** Evaluate your feeling of assurance that the Smart Nasal Cannula could readily determine the oxygen flow rate

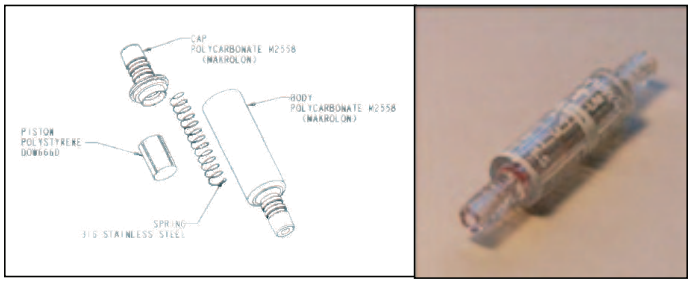

Figure 1. Oxyview Flow Meter

being received? (Using a scale of 1-5, 1 being very reassuring and 5 having no assurance). **Response:** Mean 1.4 (range 1-4)

• **Question:** Would you recommend the Oxyview and/or the Smart Nasal Cannula to others needing long term oxygen therapy? **Response:** YES - 10, NO - 0

• **Question:** Did you have any positive or negative experiences or opinions regarding your use of the Smart Nasal Cannula? If so, please describe. **Response:** a) Did not work effectively on Spirit 300. The oxygen system auto-triggered and reduced available oxygen use time. (1 participant); b) Cost prohibitive. (1 participant); c) Non-tapered cannula uncomfortable. (1 participant); d) Reassuring to know that the oxygen concentrator was delivering the flow rate that was set. (1 participant); e) Satisfied with performance on the EverGo portable oxygen concentrator, pulse system. (1 participant).

Discussion

The Smart Nasal Cannula had varied performance when applied to pulse dose oxygen delivery systems. In this regard, participants observed 6+ lpm flow rates that synchronized with their pulse dose. This did not correspond to the set liter flow but it did indicate the timing of the delivered gas. Those using the Spirit 300 liquid portable system (Caire, a division of Chart Industries, Cleveland, OH) in the pulse dose mode noted significant reduction of available oxygen use time. Post study, an evaluation of this unanticipated event identified auto-cycling that correlated with the movement of the spring loaded flow gauge. This phenomenon could rapidly deplete oxygen system reserves without the patient's knowledge. Satisfactory performance was achieved with the EverGo portable oxygen concentrator (Respironics, a division of Philips Healthcare, Andover, MA) in the pulse dose mode. In addition, the Smart Nasal Cannula was unable to be used with liquid portable devices requiring a dual-lumen cannula connection.

One study participant commented that the profile of the cannula prongs was less comfortable than experienced with other manufacturers' oxygen cannulas. Although this criticism may seem trivial, the effectiveness of LTOT is in part due to the patient's compliance in wearing the oxygen delivery apparatus. If use of the Smart Nasal Cannula is determined to be unsatisfactory due to fit, an acceptable modification would be to attach the Oxyview gauge to a more contoured cannula.

Conclusion

Study participants unanimously agreed that the Smart Nasal Cannula provided a visual indicator that their prescribed liter flow rate was being effectively delivered. When a disruption in flow occurred, the problem was easily identified and the flow gauge verified the results of the troubleshooting maneuvers. In addition, the flow gauge was easy to read and instructions for operation were minimal.

As technology advances, more LTOT delivery systems incorporate gas flow modes that synchronize with the patients breathing pattern. Testing should be conducted to study the performance of the Oxyview and Smart Nasal Cannula with these oxygen delivery systems that actuate due to sensing the patient's inspiratory effort. Undetected depletion of oxygen supply caused by auto-triggering generated by the flow gauge may markedly increase the risk of a hypoxemic induced injury if not detected.

Supplying the Oxyview or Smart Nasal Cannula to all patients requiring LTOT may be financially prohibitive and therefore more research is required to evaluate the cost effectiveness of these devices for routine use. However, serious consideration of Oxyview or Smart Nasal Cannula use is warranted for selected patients who have experienced repeated hypoxemic episodes because of gas leaks or interruption in operation of their oxygen delivery system.

Short Term Noninvasive Ventilation Post-surgery Improves Arterial Blood Gases in Obese Subjects Compared to Supplemental Oxygen Delivery

Martin Zoremba, Gerald Kalmus, Domenique Begemann, Leopold Eberhart, Norbert Zoremba, Hinnerk Wulf, Frank Dette

Abstract

Background: In the immediate postoperative period, obese patients are more likely to exhibit hypoxemia due to atelectasis and impaired respiratory mechanics, changes which can be attenuated by non-invasive ventilation (NIV). The aim of the study was to evaluate the duration of any effects of early initiation of short term pressure support NIV vs. traditional oxygen delivery via venturi mask in obese patients during their stay in the PACU.

Methods: After ethics committee approval and informed consent, we prospectively studied 60 obese patients (BMI 30-45) undergoing minor peripheral surgery. Half were randomly assigned to receive short term NIV during their PACU stay, while the others received routine treatment (supplemental oxygen via venturi mask). Premedication, general anesthesia and respiratory settings were standardized. We measured arterial oxygen saturation by pulse oximetry and blood gas analysis on air breathing. Inspiratory and expiratory lung function was measured preoperatively (baseline) and at 10 min, 1 h, 2 h, 6 h and 24 h after extubation, with the patient supine, in a 30 degrees head-up position. The two groups were compared using repeated-measure analysis of variance (ANOVA) and t-test analysis. Statistical significance was considered to be $P < 0.05$.

Results: There were no differences at the first assessment. During the PACU stay, pulmonary function in the NIV group was significantly better than in the controls ($p < 0.0001$). Blood gases and the alveolar to arterial oxygen partial pressure difference were also better ($p < 0.03$), but with the addition that overall improvements are of questionable clinical relevance. These effects persisted for at least 24 hours after surgery ($p < 0.05$).

Conclusion: Early initiation of short term NIV during in the PACU promotes more rapid recovery of postoperative lung function and oxygenation in the obese. The effect lasted 24 hours after discontinuation of NIV. Patient selection is necessary in order to establish clinically relevant improvements.

All the authors except N. Zoremba are with the Department of Anesthesia and Intensive Care Medicine, University of Marburg. N.Z. is with the department of the same name at the University of Aachen, Germany. The authors thank Dr Hans-Jörg Aust for the initial help in designing this study. For statistic support they thank Prof Helge Müller. Reprinted from BioMed Central, BMC Anesthesiology,

Background

Acute respiratory failure is a major complication within the early post-operative period.[1] In patients with hypercapnic[2] or non-hypercapnic[3] acute respiratory failure, non-invasive ventilation (NIV) can reduce intubation rate, morbidity, mortality and the overall and intensive care unit (ICU) lengths of stay. NIV is thus well established in clinical practice. It is mostly applied in an intensive care setting; only a few studies have evaluated its use within the first 24 postoperative hours,[4,5] although the optimum duration of treatment and ventilator settings are not defined.[6,7] Nevertheless it seems feasible that early initiation of a NIV therapy immediately after surgery may be beneficial, when residual drug effects are still present. Obesity presents a particular problem; increased BMI correlates with loss of perioperative functional residual capacity (FRC), expiratory reserve volume (ERV) and total lung capacity (TLC), up to 50% of preoperative values.[8] These changes promote atelectasis and an increased Va/Q mismatch[9] resulting in increased work of breathing. Additionally obese patients are more likely to exhibit upper airway collapse.[10] Most of the events leading up to respiratory complications occur in the post-anesthesia care unit (PACU).[11]

Obese patients are often scheduled for day case surgery, thus it is important to promote pulmonary recovery within a short time.[12,13] We designed this study to evaluate the 24 hour-effects of early initiation of short term pressure support NIV during the PACU stay in obese day case surgery patients.

Methods

Study population: The study was approved by the Ethics Committee of the University of Marburg (AZ 70/08), and informed written consent was obtained. Between 2009/2010 we prospectively included 72 obese adult patients (BMI 30-45, ASA II-III) scheduled for minor peripheral surgery (Table 1). We excluded patients having abdominal surgery or surgery requiring head down tilt. The minimum duration of surgery was set at 45 minutes, maximum of 120 minutes. We also excluded patients with a history of gastroesophageal reflux disease, hiatus hernia or requiring emergency operation with rapid sequence induction. Additionally we excluded patients with suspected presence of difficult airway or pre-existing lung impairment (pregnancy, asthma, severe renal dysfunction) as well as cardiac disease resulting in marked limitation of physical activity, corresponding to NYHA class >II, severe psychiatric disorders or difficulties in cooperating during measurements. All were informed about the NIV technique at the pre-anesthetic visit. They were allocated randomly

Table 1 Basic data for 60 patients undergoing elective minor peripheral surgery

	NIV (n = 30)	*Control (n = 30)*
Age(yr)	52 ± 11	53 ± 13
BMI	35 ± 3.3	35 ± 2.5
Surgery time (min.)	78 ± 26	79 ± 24
Remifentanil consumption (µg)	1315 ± 210	1279 ± 199
Propofol consumption (mg)	665 ± 122	679.0 ± 143
BIS-Value during surgery	49 ± 5.9	46 ± 5.2
BIS-Value at discontinuation of anesthesia	62 ± 5.1	63 ± 6.7
Time to extubation (min.)	8.3 ± 4.9	9.2 ± 5.3
fast track score >10 (min.)	11.2 ± 3.5	10.5 ± 3.9
Postoperative pritramide(mg) consumption (within 24 h)	7.5 ± 4.3	8.1 ± 5.8
Knee Arthroscopy	n = 12	n = 10
Minor breast surgery	n = 10	n = 14
TUR-Prostate	n = 5	n = 2
Hand surgery	n = 3	n = 4

(adaptive randomization by a study nurse not involved in this study) to a non-invasive ventilation group (NIV-group) (n = 30), or to a control group (n = 30). Patients who did not achieve fast track criteria within 20 minutes after surgery or exhibit adverse events during course were withdrawn from the study.

General anesthesia: Twelve hours before surgery patients were premedicated with oral chlorazepat 20 mg. All were pre-oxygenated for 3 minutes at an adjusted fraction of inspired oxygen (FiO_2) of 1.0. Thereafter anesthesia was induced with fentanyl 2-3 µg kg^{-1} and propofol 2 mg kg^{-1} and maintained with remifentanil (0.1-0.2 µg kg^{-1} ideal body weight) and propofol 3-6 mg kg-1 h-1.[14] Orotracheal intubation was performed after a single dose of rocuronium (0.5 mg kg^{-1} ideal body weight); no additional neuromuscular blocking agent was given. A continuous cuff pressure device (Rüsch GmbH, Kernen, Germany) was used to maintain a 30 cmH_2O cuff pressure by the respective anesthetist. Standard monitoring was performed throughout (pulse oximetry, non-invasive blood pressure and electrocardiography), plus monitoring of anesthetic depth levels (BIS EEG, BIS Quatro; Aspect Medical Systems, Freising Germany). Recovery from neuromuscular blockade was monitored with a peripheral nerve stimulator (TOF-Watch, Organon Teknika Germany) by Train-Of-Four (TOF) ratio (relationship between first and last/fourth neural muscle innervation) assessment to ensure a ratio >0.9 before extubation.[15] During pressure controlled mechanical ventilation, the rate was adjusted to maintain an end-tidal CO_2 pressure of 4-4.7 kPa at an inspiration to expiration ratio of 1:1.5 and a positive end expiratory pressure of 10 cmH_2O. A maximum peak

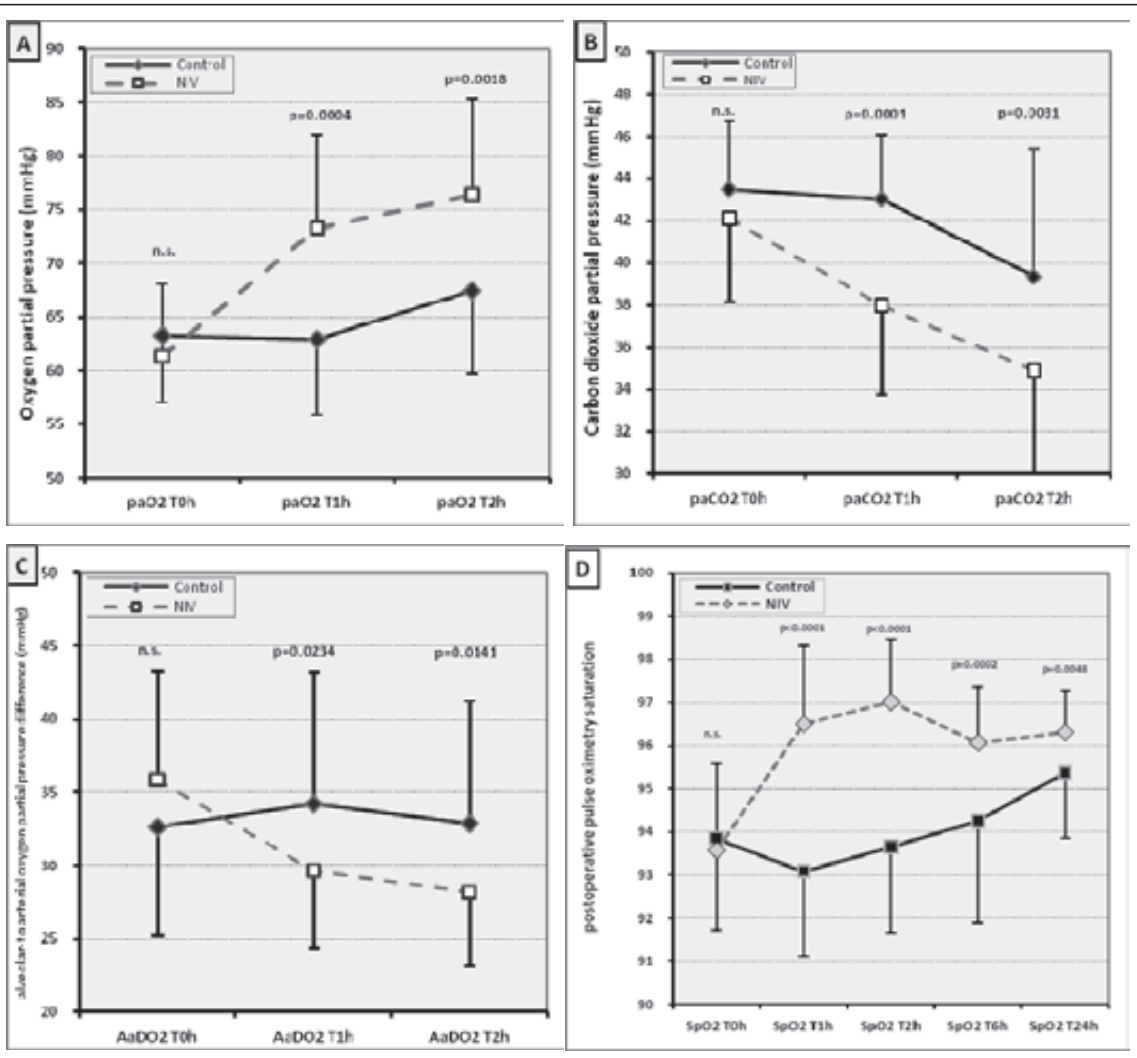

Figure 1 Postoperative blood gas analyses and pulse oximetry values. Postoperative pulse oximetry - Difference from preoperative baseline. P-value: t-Test. Interaction between the study groups (ANOVA; $p < 0.0001$). Bars indicate SD. (n.s.= no significance). All measurements were performed after 5 minutes of breathing room air

Table 2 Preoperative lung function and pulse oximetry saturation baseline values breathing room air (n.s. = no significance)

	SpO2(%) before premed.	*SpO2(%) after premed.*	*FVC (l)*	*FEV1 (l)*	*PEF* (l/s)	*MEF 25-75 (* l/s)
NIV	96.9 ± 1.0	95.8 ± 1.5	3.81 ± 1.1	3.05 ± 0.9	6.9 ± 1.9	3.15 ± 1.2
Control	97.0 ± 1.4	95.9 ± 1.9	3.69 ± 1.0	2.98 ± 0.7	6.8 ± 2.3	3.09 ± 1.1
t-test p < 0.05	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

pressure of 30 cmH_2O was allowed. FiO_2 during anesthesia was 0.5. Fifteen minutes before extubation, each patient received dolasetron (25 mg iv) and dexamethason (4 mg iv) as PONV prophylaxis. The oral cavity was suctioned before extubation. When the patient was fully awake and spontaneously breathing, the trachea was extubated without suction in a head up position with a positive pressure of 10 cmH_2O at an adjusted FiO_2 of 1.0. Thereafter patients were transported to the post-anesthesia care unit (PACU), where they were nursed in the 30° head up position.

General postoperative care: Before randomization, blood gas analysis and any signs of postoperative residual curarization (PORC) or opioid overdosage were evaluated by the anesthetist. A sufficient level of vigilance according to the respective fast-track criteria as well as head up lift for 5 seconds and normal tongue spatula test was achieved in every patient included. The control group received supplemental oxygen via venturi mask at an adjusted oxygen flow of 6 l/min. No additional respiratory treatment or mobilization was performed in either study group during the PACU stay. Blood gas analysis was performed in every patient at each measurement point in the PACU after breathing air for 5 minutes.

Postoperative pain management: Both groups received basic non-opioid analgesia with intravenous (iv) paracetamol 1 g and metamizol 1 g iv. Pain was assessed using a visual analogue scale (VAS) at fixed intervals (15 minutes). Analgesia was supplemented with piritramide i.v. whenever the visual analogue scale (VAS) was >4. Overall piritramide consumption was recorded within the first twenty-four hours.

Noninvasive ventilation: Immediately after the first assessment (T0h) pressure support NIV was commenced within the NIV-Group, initially set at 5 cmH_2O inspiratory pressure, 10 cmH_2O positive end-expiratory pressure (PEEP) at an adjusted FiO_2 of 0,5 with each patient in a 30° head-up position using a Dräger "Carina" with the respective NIV full face masks (Dräger AG, Lübeck, Germany). Settings were subsequently titrated according to patient tolerance to achieve an expiratory tidal volume of 6-8 ml^{-kg} ideal body weight. PEEP was tolerated located within a range of 8-10 cmH_2O; pressure support ranged between 0-10 cmH_2O. The target duration of the pressure support NIV was 120 minutes.

Spirometry and pulse oximetry: Spirometry and pulse oximetry were standardized, with each patient in a 30° head-up position[16] after breathing air for 5 minutes. At the pre-anaesthetic visit, a baseline spirometry measurement and pulse oximetry were taken (Tbase) after thorough demonstration of the correct method. Vital capacity (VC), forced vital capacity (FVC), forced expiratory volume in 1 s (FEV1) mid-expiratory flow (MEF25-75), peak expiratory flow (PEF), peak inspiratory flow (PIF) and forced inspiratory vital capacity (FIVC) were measured. At each assessment time, spirometry was performed at least three times to be able to meet the criteria of the European Respiratory Society (ERS) and the best measurement was recorded.[17]
In the recovery room (about 5-10 min after extubation), we repeated spirometry (T0) as soon as the patient was alert and fully cooperative (fast track score >10);[18] pain and dyspnea were assessed during coughing using the fast track score (>10) before and, if necessary, after analgesic therapy (all patients included in this study met this criterion within 20 min of extubation). Spirometry and pulse oximetry were repeated in the PACU at 1 h (T1) and 2 h (T2). To evaluate the progression of postoperative lung function after PACU discharge, we performed further measurements at 6 h (T3) and 24 h (T4) after extubation. Piritramide requirements were documented prior to each assessment, as soon as the patients were free from pain on coughing. Factors that interfered with breathing (e.g. pain, shivering) were eliminated or at least minimized to produce reliable measurements.

Statistical analysis and randomization: A prospective power analysis performed with the PASS2002 software (Number Cruncher Statistical Systems, Kaysville, UT) revealed that 17 patients per group provided a more than 80% chance to detect an absolute improvement of 10 mmHg arterial oxygen partial pressure breathing room air (eg 50 mmHg to 60 mmHg) with an expected standard deviation of 10 in both groups using Student's t-test with a type-I error of 5%. To compare postoperative respiratory data and pulse oximetry between the two groups, we tested the null hypothesis (H_0) that postoperative pulse oximetry values are comparable. In order to demonstrate normal data distribution, a Kolmogorov-Smirnov-Test was performed before each analysis. If normally distributed, a t-test analysis was performed, otherwise the Wilcoxon-Mann-Whitney test was applied. For further characterization we performed repeated-measure analysis of variance (two factor mixed measures analysis of variance) and displayed the interaction between and within the study groups. H_0 was rejected at an adjusted p of < 0.005 due to multiple testing (Bonferroni). To avoid pre and intraoperative observer bias, randomization was performed after postoperative inclusion criteria were achieved and the first measurements in the PACU were performed. All values of the respective BIS-Index, remifentanil and propofol consumption were collected through an online documentary system (Medlinq Easy Software, Hamburg, Germany). Statistic analysis was by JMP 8 for Windows (SAS Institute Inc, Cary, NC).

Results

Overall 72 patients were recruited; two declined to continue and measurements were unsatisfactory in a further eight as a result of missed fast track criteria (<10) within 20 min after surgery. Two patients in the control group had laryngo-bronchospasm and were excluded. As a result, we present data for 60 patients (m/w) with 30 individuals per group (Table 1).

The mean duration of surgery was 79 (SD 26) minutes, range 45 -120 minutes. Basic data exhibit no significant differences (Table

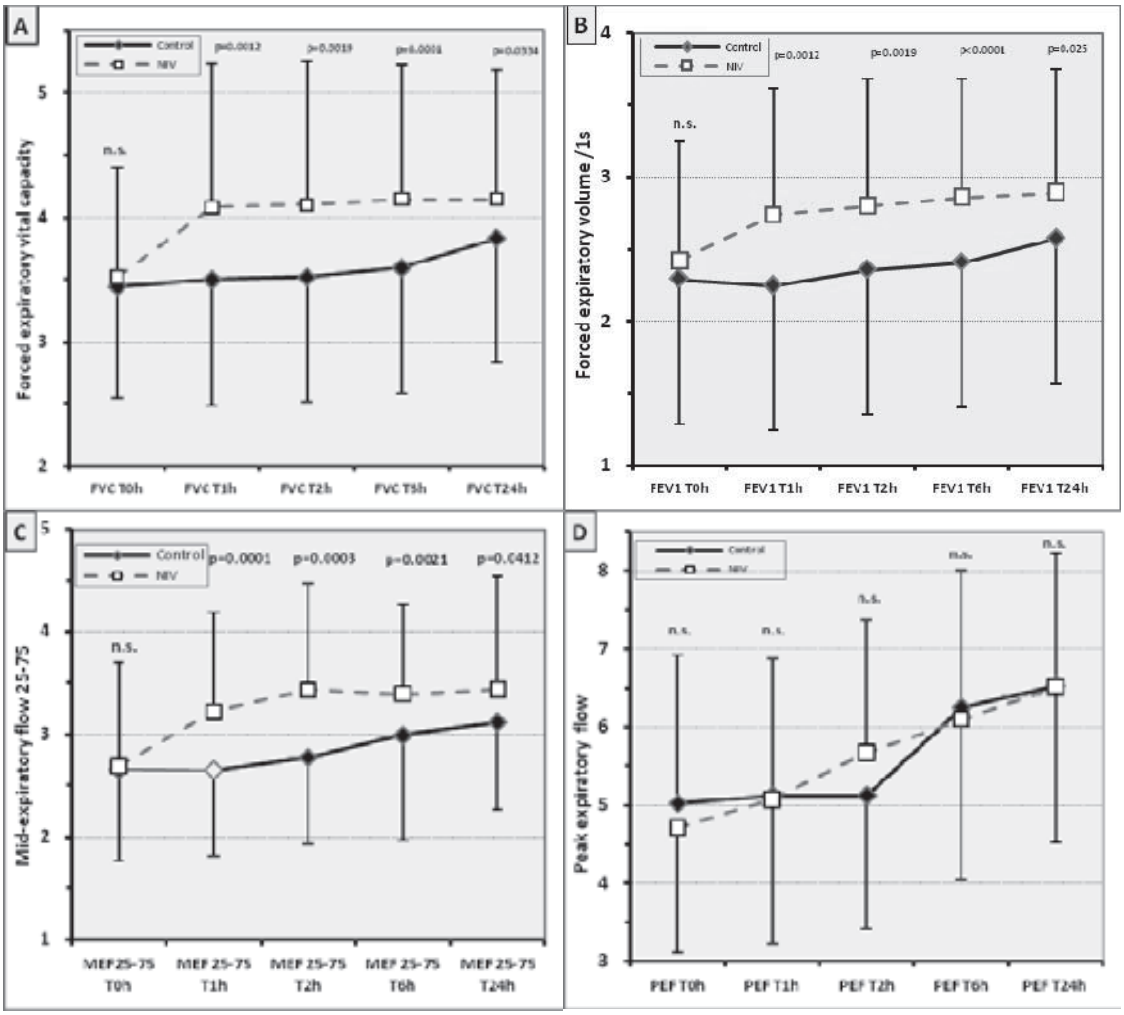

Figure 2 Postoperative lung function measurements (FVC/FEV1/MEF25-75/PEF) - Bars indicate SD. n.s.=no significance. For abbreviations, see text.

1). All patients had been ventilated according to the respective target values and there were no unexpected intubation problems. Antagonism of muscle relaxation was not necessary in any patient. Severe desaturation (SpO_2 <85%) did not occur in any patient.

Blood gas analyses: In order to control postoperative ventilation and oxygenation we obtained blood gas analysis within fixed intervals in the PACU by radial arterial puncture. At first assessment in the PACU the groups exhibited a similar reduction in oxygen partial pressure. There was no hypercapnia. Overall the NIV-group had significantly better oxygen and carbon dioxide pressures in the PACU (Figure 1 a/b $p < 0.004$), and the alveolar to arterial oxygen partial pressure difference ($AaDO_2$) was less (Figure 1c, $p < 0.03$). This improvement was located at T1h for paO_2 11 ± 8 mmHg (95% CI 6 to 14 mmHg), $paCO_2$ 5 ± 3 mmHg (96% CI 3-6 mmHg), $AaDO_2$ 5 ± 9 mmHg (95% CI 2-9 mmHg), at T2h for paO_2 9 ± 7 mmHg (95% CI 6-12 mmHg), $paCO_2$ 4 ± 3 (95% CI 3-6), $AaDO_2$ 5 ± 8 mmHg (95% CI 2-9 mmHg).

Pulse Oximetry: Baseline (preoperative) pulse oximetry values were within the normal range of 95-99%; there were no differences between groups before or after premedication (Table 2). In both, the lowest values were found directly after extubation, in the PACU, after achieving a fast track criteria value >10. At the first measurement point in the PACU before initiation of pressure support NIV, there was no difference between groups. Overall pulse oximetry saturation ranged between 99 and 85% (mean 94%) at first assessment in the PACU. During the first hour in PACU (T0h-T1h; $p < 0.0001$, Figure 1d) the NIV group had better pulse oximetry values than the controls (ANOVA $p < 0.0001$), and also thereafter at 6 h and 24 hours after surgery (Figure 1d; $p < 0.005$). Overall mean pulse oximetry values differed by three percentage points.

Spirometry: Preoperative in- and expiratory spirometry values (baseline) were within the normal range between the upper limit of normal and the lower limit of normal (LLN) as previously described (Table 2).[19] Postoperative spirometry values, except of peak inspiratory, showed a similar pattern to pulse oximetry (Figure 2). The NIV group recovered lung function faster during the PACU stay, almost reaching preoperative baseline values (Figure 2; $p < 0.001$-between interaction) while the control group recovered in- and expiratory lung volumes only moderately. This time effect (T0h-T1h; $p < 0.0001$) within the study groups ceased during course. Even after the first postoperative mobilisation and on the first day after surgery, lung function values in the controls were up to 20% below baseline (Figure 2 $p < 0.05$). Although the overall difference in lung function between groups had decreased 24 hours after surgery, significant differences still remained.

Postoperative management: No patient experienced severe

postoperative pain; the maximum VAS scale pain score before analgesia was six in both groups. Opioid consumption for the first 24 hours was comparable in the two groups (Table 1). At each measurement, every patient had an acceptable level of vigilance, and no pain. Shivering or nausea, which might have interfered with spirometry, was not present in any patient.

Discussion

Atelectasis and respiratory impairment are common after general anesthesia.[20,21] Perioperative atelectasis occurs within minutes, mostly due to compression and oxygen reabsorption caused by a high fraction of inspired oxygen (FiO_2).[22] A high FiO_2 is commonly used at the discontinuation of general anesthesia, although its detrimental effects on lung function are well known.[23,24] Hypoventilation as well as lack of vigilance may also contribute to early postoperative lung impairment.

Several studies have documented the favorable effects of NIV in acute respiratory failure, mostly in an intensive care setting. This suggests that many trials of NIV are required, at times uninterrupted for several hours, to achieve positive results.[25-29] Our data show that even short term NIV in the PACU when commenced immediately after extubation is sufficient to enhance pulmonary function for the following 24 hours at least.

Overall differences were small and pulse oximetry measurement as well as lung function measurement has a certain bias.[30,31] Such bias would affect both study groups, but cannot be completely ignored. The measured effect may be altered due a lack of preselecting in terms of risk factors eg obstructive sleep apnea (OSA). This may reinforce the overall magnitude of the effect of a short term NIV.

There is no question that NIV and CPAP improve gas exchange, minimize atelectasis, and increase functional residual capacity.[4,32,33] Previous findings indicated that early, pre-emptive, initiation of either mode reduces overall pulmonary complications, although study objectives and overall treatment times varied greatly.[25,26,34] In contrast, short term approaches or late initiation are of no benefit.[35,36] An alternative approach using chest physiotherapy proved beneficial in terms of pulmonary function, although not clearly superior to NIV,[37] and staff costs may have been larger than using technical devices.

What else may be responsible for our findings? Postoperative vigilance may be important, and the painful stimulus of blood gas collection may have altered postoperative wakefulness; fast track scores are too crude for a detailed evaluation of postoperative consciousness. Lingering drug effects may promote increased upper airway collapse in the obese.[38] Postoperative residual curarization (PORC),[39,40] which cannot be excluded even when neuromuscular monitoring is used, may have a greater impact in the obese. This hypothesis is supported by our expiratory peak flow measurements which exhibit no significant differences between groups while displaying similar (temporary) limitation of inspiratory flow within the first postoperative hour. Drug effects are more marked after short procedures and are aggravated with increasing age.[40,41] Especially upper airway muscle tone can be negatively affected by propofol.[42]

We found short term NIV beneficial, possibly because it was commenced earlier than in studies performed following different types of surgery and in a population of normal weight. NIV may have been more beneficial in our obese patients as the associated respiratory changes are predominantly based on loss of functual residual capacity. NIV ventilation with PEEP attenuates these effects if initiated early after extubation, increases alveolar ventilation and improves gas exchange. The effect was not due to supplemental oxygen, as measurements were performed five minutes after discontinuation of NIV/supplemental oxygen.

Even mobilization does not completely abolish post-operative respiratory changes.[43] Thus it seems feasible that short term NIV is beneficial and has a lasting effect, most probably due to increasing functual residual capacity, improved alveolar ventilation and avoidance of atelectasis. Anyhow overall improvements are small and clinical significance has to be established. In this regard patient selection has to be improved. It is not clear whether therapeutic benefit would be obtained after major surgery or in patients with OSA.[44] Nevertheless, short term NIV seems to be a reasonable therapeutic option in the obese after general surgery. As day case surgery becomes more frequent even for the morbidly obese, it may become more necessary.

Conclusion

Early initiation of short term NIV during in the PACU promotes more rapid recovery of postoperative lung function and oxygenation in the obese. The effect lasted 24 hours after discontinuation of NIV. Patient selection is necessary in order to establish clinically relevant improvements.

Limitations: As indicated within the methods section, overall pulmonary function testing was not blinded and thus a bias may be possible. As preoperative blood gas analysis was not allowed by the ethics committee, preoperative differences between the study populations cannot be excluded. Another major limitation factor is the pre-selection of our obese patients scheduled for minor peripheral surgery. Only 11 of these (6 NIV-group, 5 Control-group) were morbidly obese. Moreover, no operations with abdominal insufflations (laparoscopy) or head down tilt were included, nor any patients with gastro-oesophageal reflux disease or hiatus hernia, which may limit the applicability of our results for major surgery. Nevertheless major surgery, especially abdominal, affects respiratory mechanics to a greater degree and there is more post-operative pain. The primary aim of our study was to examine the impact of NIV on lung volumes in the obese in the immediate postoperative period, when the impacts of surgical trauma and anesthesia are most likely to trigger pulmonary morbidity. Therefore using this study design we minimized possible factors interfering with our measurements.

NIV requires trained nurses and initial equipment expenses, and criteria for its prophylactic use in the immediate postoperative period have not yet been defined. Additionally, we do not know whether NIV is superior to CPAP alone. Furthermore we cannot draw any conclusion about clinical outcome or other gold standards such as the incidence of pneumonia. Large scaled studies, especially on day cases, and focussing on patients at risk for postoperative pulmonary complications (eg OSA) are required.

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Care Alternatives for Pediatric Chronic Mechanical Ventilation

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Abstract

Objectives: To determine the impact of transferring a pediatric population to mechanical ventilator dependency units (MVDUs) or to home mechanical ventilation (HMV) on bed availability in the pediatric intensive care unit (ICU).

Methods: This is a longitudinal, retrospective study of hospitalized children who required prolonged mechanical ventilation at the MVDU located at the Hospital Auxiliar de Suzano, a secondary public hospital in São Paulo, Brazil. We calculated the number of days patients spent at MVDU and on HMV, and analyzed their survival rates with Kaplan-Meier estimator.

Results: Forty-one patients were admitted to the MVDU in 7.3 years. Median length of stay in this unit was 239 days (interquartile range = 102-479). Of these patients, 22 came from the ICU, where their transfer made available 8,643 bed-days (a mean of 14 new patients per month). HMV of eight patients made 4,022 bed-days available in the hospital in 4 years (a mean of 12 new patients per month in the ICU). Survival rates of patients at home were not significantly different from those observed in hospitalized patients.

Conclusions: A hospital unit for mechanical ventilator-dependent patients and HMV can improve bed availability in ICUs. Survival rates of patients who receive HMV are not significantly different from those of patients who remain hospitalized.

Introduction

Mechanical ventilator-dependent children are a group of pediatric patients with complex care needs, due to continuous use of apparatuses for providing ventilation assistance and to prolonged hospitalizations. This population has been growing in recent years, as a result of technological advances for treating severe chronic patients, as well as increased public access to medical resources.

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Even when patients are clinically stable, many remain hospitalized in intensive care units (ICU) for periods that vary from few months to years. This situation exposes patients and their families to problems associated with prolonged hospital stays, such as nosocomial infections, and also psychological and relationship disturbances in the family. For the hospital, prolonged bed occupation in the ICU by stable patients impairs the capacity to receive new patients with severe conditions, besides the fact that it increases expenditure.

As an alternative to lengthy ICU stays, many patients have been transferred to services of lower complexity, such as mechanical ventilator dependency units (MVDUs). Patients who have favorable clinical and socioeconomic conditions may be indicated for home mechanical ventilation (HMV).

There are no data available about bed occupation and length of stay associated with patients who require MVDU or HMV in developing countries. In Brazil, few services offer prolonged mechanical ventilation for pediatric patients.

In our study, we aimed to evaluate the impact that transferring this population to an MVDU and to HMV had on bed availability in a pediatric ICU.

Materials and Methods

This is a longitudinal, retrospective study that included hospitalized children who required prolonged mechanical ventilation at the MVDU provided by the Hospital Auxiliar de Suzano in São Paulo, Brazil. This hospital receives pediatric mechanical ventilator-dependent patients from Instituto da Criança proceeding from three sectors: ICU, nursery and step-down unit. Both institutions are state public hospitals and linked to Hospital das Clínicas of the Medical School of Universidade de São Paulo (USP). Beginning in 2001, care for pediatric patients who are clinically stable but still require prolonged ventilation has been provided by the MVDU. This unit has 14 beds, with an average monthly occupation rate of 100%. Three physicians are on duty during weekdays (each one for a period of 4 hours during the day), while one physician is in charge during night shifts and weekends. The criterion for a child to be considered as dependent of mechanical ventilation, and consequently being suitable for transfer from the ICU to MVDU, is the one adopted by the United Kingdom Working Party on Paediatric Long Term Ventilation: "any child who, when medically stable, continues to require a mechanical aid for breathing, after an acknowledged failure to wean, or a slow wean, 3 months after the institution of ventilation."

In May of 2005, the Hospital Auxiliar de Suzano started a program that aimed to discharge patients who were hospitalized in the MVDU but were in a suitable condition to receive care at home. The criteria for patient eligibility were: 1) clinical stability; 2) suitable family conditions (education, habitation, socioeconomic situation); and 3) existing supportive local health care service (professional assistance, medical materials, transportation). The discharge procedures take place only if the patient (when intellectually able) and his/her family express the wish to go home and after receiving all necessary relevant information about HMV. In these cases, the hospital lends patients an apparatus with bi-level ventilator (BiPAP), energy manager, and a set of batteries. The apparatus is provided by a private company, which also offered maintenance and technical support both periodically and in emergency situations. The hospital expenses with this apparatus are posteriorly reimbursed by Brazilian public health care system - Sistema Único de Saúde (SUS). This reimbursement is due to specific legislation. Before the patient is discharged, his/her family receives specific training for taking care of the patient, both in routine tasks and basic emergency procedures. The SUS, through the patient's local government health agency, provides staff to supervise the care. In case of an emergency, the public health care system is responsible for providing assistance as well.

Patients were included in this study according to the following criteria: 1) to be hospitalized in the pediatric unit of the Hospital Auxiliar de Suzano during the period between 5 February 2001 and 10 June 2008; and 2) to match the definition of prolonged ventilation by the United Kingdom Working Party on Paediatric Long Term Ventilation, as cited above.

Data on hospitalization and the main diagnosis of each patient were obtained from patient charts provided by the hospital. Patients were classified according to preceding division (ICU, nursery, and step down unit) and then by disease group (neuromuscular, metabolic, hypoxic-ischemic encephalopathy, neurologic malformations, genetic syndromes, central nervous system tumors, and others). We calculated the length of stay for each patient in the MVDU. Next, we calculated the number of bed-days for groups of patients according to preceding division and disease group. Re-hospitalization was defined as any episode in which the patient needed a short hospitalization during the period when he/she was receiving care at home. Patients who needed to be re-hospitalized and were unable to return home shortly afterwards were no longer considered to be patients who were receiving care at home.

We proceeded to the survival analysis of the groups of patients who remained in the MVDU (group 1) and of those who were discharged with HMV (group 2). The Stata 11 software was employed to calculate the Kaplan-Meier estimator and other statistical data. We considered two situations: in the first one, we compared survival rate of group 1 to the survival rate of group 2. In order to control the groups of diseases as a possible confounding factor, in a second situation we modified group 1: we maintained in it only those patients who belonged to the same groups of diseases as the patients of group 2, and excluded those who did not fill this criterion. This group of patients was called group 1A. We assumed that there are groups of diseases whose patients tend to be more clinically stable than patients of other groups, a situation that would increase their chance of survival, as well as their chance of being discharged with HMV.

Results

The total study period of patients in the MVDU was 2,682 days, which corresponds to 7.3 years. For patients in the HMV, the study period was 1,476 days, which corresponds to 4.0 years.

We identified 41 patients who matched our inclusion criteria. All 41 were included in the study. Twenty patients were males and 21 females. The mean age was 5.4±5.0 years. Among the patients included in this study, we identified 24 diseases of different etiologies. Eight patients were discharged and received care at home. Of the 33 patients who remained hospitalized, 10 died before the HMV program was established, 14 had no clinical stability to be discharged to receive care at home safely (12 of them died), one patient was transferred to a hospital closer to her house (and was still alive at the end of data collection), six had inadequate family conditions (one died), and in two cases the local government health agency of the city of the patient was unable to be responsible for the home care of the patient.

The median of length of stay in the MVDU was 239 days (interquartile range = 102-479).

As for the patients on HMV, eight children represented 4,022 bed-days. The median of length of stay of patients on HMV was 330 days (interquartile range = 160-760).

The estimated total time of re-hospitalization was 88 bed-days, which corresponds to 2.2% of the total bed-day time that patients remained at home. One of the patients was re-hospitalized and did not go back home due to clinical instability.

For the first part of survival analysis, we included 33 patients who remained in the MVDU in group 1, and eight patients who received HMV in group 2. Survival rate in group 1 after 6 years was 0.106±0.076, while in group 2 was 0.552±0.195 ($p = 0.040$). In the second part of analysis, we included 14 patients in group 1A, and group 2 was the same, with eight patients (Figure 1B). The groups of diseases found both in group 1A and in group 2 were: neuromuscular diseases (five patients in group 1A and 5 in group 2), metabolic diseases (five patients in group 1A and 2 in group 2), and malformations (four patients in group 1A and 1 in group 2). Survival rate in group 1A after 6 years was 0.264±0.146, and group 2 kept the same survival rate of 0.552±0.195 ($p = 0.224$). Other groups of diseases had no patients on HMV due to one of the following reasons: insufficient clinical stability, lack of adequate family conditions, or lack of adequate support from local health services.

Discussion

The ICU was the division that referred patients to the MVDU the most. The transfer of 22 patients from the ICU to the MVDU made 8,643 bed-days available for new hospitalizations in the pediatric ICU. This corresponds to 98 bed-days per month. If we consider the mean length of stay in ICU as 6.66±8.86 days,21 these 8,643 bed-days may represent the hospitalization of 1,298 patients in the ICU in 7.3 years, or 14 new patients per month. Likewise, patients transferred to the HMV made available 4,022 bed-days in the MVDU over 4 years. As the median of the length of stay of patients in this division is 239 days, this transfer of patients enabled hospitalization of 17 new patients in the MVDU. Indirectly, this could represent 604 hospitalizations in the ICU in 4 years, or 12 new patients per month.

The survival rate of the patients in HMV (group 2) was

significantly higher compared to that of all those who remained in the hospital (group 1). The result was expected, as the patients who were able to receive care at home were more stable than those who remained hospitalized. When we considered in group 1A only those patients who belonged to the same groups of diseases as those of group 2, the difference between the survival rates was not significant. The groups 1A and 2 have some differences in the proportion of disease groups in their composition, a factor that may impair the comparison. Nevertheless, the absence of significant difference in survival rates may be due to clinical similarities between these patients.

It is noteworthy that the Kaplan-Meier estimator demonstrated that HMV did not impair the survival rate of patients receiving care at home. We believe that this can be explained not only by patient's clinical stability, but also by the skill of caregivers. We observed that the family caregivers acquire great knowledge about the patient's clinical condition and can successfully perform all the required tasks to their care with no major difficulties.

According to disease group, patients with neuromuscular diseases constituted the group that occupied most beds per day at the MVDU, with 7,258 bed-days (41.2%), followed by hypoxic-ischemic encephalopathy (25.8%) and malformations (12.5%).

Bed availability in pediatric ICUs is an important issue in Brazil's public health. Two of Brazil's greatest cities (São Paulo and Rio de Janeiro) have shortage of pediatric ICU beds in public hospitals, with an uneven distribution.22,23 Around 80% of Brazilian population relies on public health services,24 so this scarce and expensive resource must be used judiciously. Although the number of mechanical ventilator-dependent patients in our study is small, their lengthy stays represent a burden for ICUs, reducing bed availability. The implantation of MVDU and HMV services for mechanical ventilator-dependent patients may be a useful measure for optimizing pediatric public ICU bed occupation, without damage to patients' survival.

It is important to mention that the transference of a patient to a MVDU, and subsequently to HMV, has other important aspects for the hospital and for the patients' family as well. For the hospital, this transference may represent a great reduction in economic costs, once many expensive resources available in the ICU are not needed in the MVDU. For the family, the caring activities bring not only an increased amount of workload to the caregivers, but also health, social, and economic burdens. However, there are also important positive aspects: the patient is relieved from the hospital stressful environment and from affective isolation, and regains his/her social links. The parent who accompanies him/her (frequently the mother) can return home as well, restoring the family group. These aspects must be considered and discussed with the family before the discharge.

This study reports the experience of a single university hospital and was done considering a small number of patients. Here we showed that the transfer of stable patients who are under mechanical ventilation to a MVDU or to HMV leads to a greater number of beds available in the ICUs. This greater availability of beds enables the hospital to provide a better service to the community.

Ventilation Post-surgery…continued from page 47

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Pneumothorax and Subcutaneous Emphysema Secondary to Blunt Chest Injury

Jahan Porhomayon, Ralph Doerr

Abstract

This is the case of a patient with a history of blunt chest trauma associated with subcutaneous emphysema and pneumothorax. The patient complained of inspiratory stridor on presentation. Anatomical relationships can explain the pathophysiological process.

Case Report

A 49-year-old male presented to the trauma service 10 h after blunt chest injury. Initial presentation included respiratory failure with a respiratory rate of 26 beats per minute, a pulse rate of 110 beats per minute, and blood pressure of 150/80 mmHg. He complained of dysphonia and facial swelling.

Physical examination revealed inspiratory dyspnea and crepitations suggestive of subcutaneous emphysema of the face, neck, and upper portion of his chest. Pharyngeal examination revealed swollen mucosa with crepitations on palpation (Figure 1a). Chest X-ray indicated extensive subcutaneous emphysema apparent in part as a group of muscles in the upper chest wall, but with no obvious pneumothorax (Figure 1c). Computed tomography of the chest confirmed subcutaneous and submucosal emphysema involving the pharynx. It also revealed obvious pneumomediastinum associated with left pneumothorax from rib fractures (Figure 1b and 1d). Physical examination and bronchoscopy ruled out laryngotracheal mucosal rupture. The patient remained dyspneic after placement of a chest tube. Twenty-four hours later, inspiratory dyspnea, dysphonia, and submucosal emphysema had resolved. Subcutaneous emphysema resolved in 4 days. The patient's recovery was uneventful.

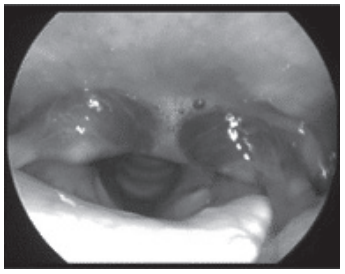

Figure 1. A

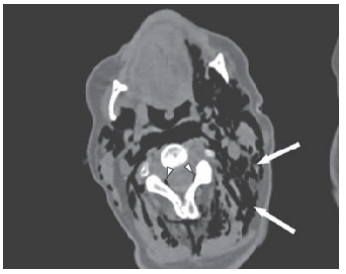

Figure 1. B

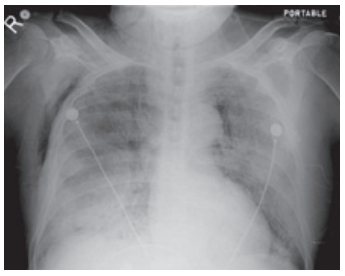

Figure 1. C

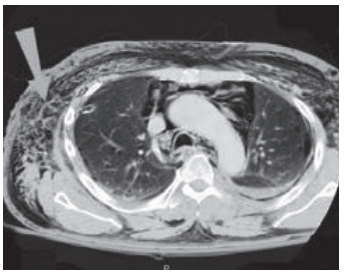

Figure 1. D

Discussion

Subcutaneous emphysema can occur in critically ill patients after blunt trauma to the chest and result in a pressure gradient between the intra-alveolar and perivascular interstitial space.[1,2]

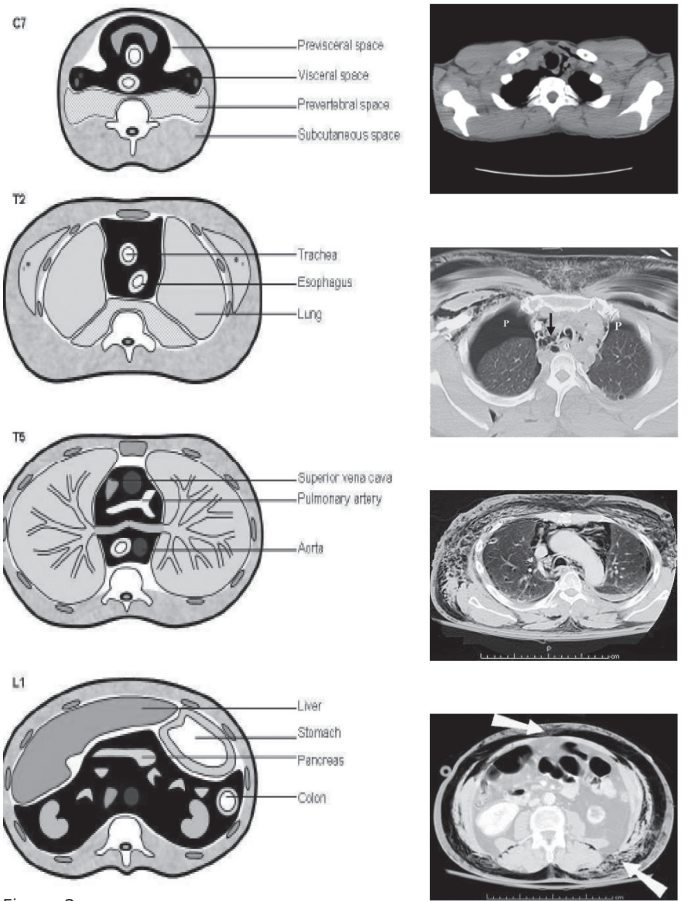

Figure 2.

Continued on page 58…

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Acute Bronchodilator Responsiveness and Health Outcomes in COPD Patients in the UPLIFT Trial

Nicola A. Hananiaa, Amir Sharafkhaneha, Bartolome Cellic, Marc Decramer, Ted Lystig, Steven Kesten, Donald Tashkin

Abstract

Background: Debate continues as to whether acute bronchodilator responsiveness (BDR) predicts long-term outcomes in COPD. Furthermore, there is no consensus on a threshold for BDR.

Methods: At baseline and during the 4-year Understanding Potential Long-term Improvements in Function with Tiotropium (UPLIFT) trial, patients had spirometry performed before and after administration of ipratropium bromide 80 mcg and albuterol 400 mcg. Patients were split according to three BDR thresholds: ≥12% + ≥200 mL above baseline (criterion A), ≥15% above baseline (criterion B); and ≥10% absolute increase in percent predicted FEV1 values (criterion C). Several outcomes (pre-dose spirometry, exacerbations, St. George's Respiratory Questionnaire [SGRQ] total score) were assessed according to presence or absence of BDR in the treatment groups.

Results: 5783 of 5993 randomized patients had evaluable pre- and post- bronchodilator spirometry at baseline. Mean age (SD) was 64 (8) years, with 75% men, mean postbronchodilator FEV1 1.33 ± 0.44 L (47.6 ± 12.7% predicted) and 30% current smokers. At baseline, 52%, 66%, and 39% of patients had acute BDR using criterion A, B, and C, respectively. The presence of BDR was variable at follow-up visits. Statistically significant improvements in spirometry and health outcomes occurred with tiotropium regardless of the baseline BDR or criterion used.

Conclusions: A large proportion of COPD patients demonstrate significant acute BDR. BDR in these patients is variable over time and differs according to the criterion used. BDR status at baseline does not predict long-term response to tiotropium. Assessment of acute BDR should not be used as a decision-making tool when prescribing tiotropium to patients with COPD.

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Background

Chronic obstructive pulmonary disease (COPD) is characterized by airflow limitation which is not fully reversible.[1] There has been much interest in whether acute bronchodilator responsiveness (BDR) based on a predefined threshold of a change in forced expiratory volume in the first second (FEV1) is a prognostic factor in COPD.[2,3] A 1-year trial with tiotropium showed that acute responsiveness was not predictive of whether patients improved clinically.[4] However, whether such responsiveness can predict disease progression or health outcomes beyond 1 year has not been established. Further, the reliability of currently recommended criteria for assessing responsiveness (also referred to as reversibility) differs according to various guidelines. The American Thoracic Society considers a 200 mL and 12% increase from pre-bronchodilator baseline FEV1 as a positive BDR,[5] while a 15% increase from baseline[6] or 10% increase in normalized FEV1 is considered positive BDR by other groups.[2,7,8]

The Understanding Potential Long-term Improvements in Function with Tiotropium (UPLIFT) trial was a 4-year placebo-controlled clinical trial evaluating the long-term effects of tiotropium 18 mcg daily on lung function, exacerbations, health-related quality of life and mortality in a large group of patients with COPD.[9,10] Spirometry was performed before and after administration of short-acting bronchodilators (ipratropium bromide and albuterol) at baseline and during follow-up visits every 6 months throughout the 4-year duration of the study.[11] In addition to lung function data, the study collected information on health-related quality of life, COPD exacerbations and mortality.

Therefore, the UPLIFT study provided a unique opportunity to examine several aspects of the BDR in a large cohort of patients with COPD. Data describing the acute bronchodilator response at baseline from the UPLIFT trial were previously published.[11] In this study, we further evaluate the acute bronchodilator response over the four years of the trial.

Methods

Study design: The UPLIFT study details have previously been reported and are briefly summarized in the subsequent paragraphs.[9,10] The present study was performed to examine: a) the prevalence of significant acute BDR using three predefined criteria in a large cohort of COPD; b) the predictive ability of

Table 1: Baseline characteristics of tiotropium and placebo groups according to different threshold criteria for bronchodilator responsiveness.

	Criterion A (Δ % Predicted FEV_1 ≥12% and ≥200 mL)				Criterion B (Δ % Predicted FEV_1 ≥15%)				Criterion C (Δ % Predicted FEV_1 ≥10%)			
	Nonresponder (n = 2750)		Responder (n = 3033)		Nonresponder (n = 1995)		Responder (n = 3788)		Nonresponder (n = 3553)		Responder (n = 2230)	
	Tio (n = 1357)	Placebo (n = 1393)	Tio (n = 1520)	Placebo (n = 1513)	Tio (n = 995)	Placebo (n = 1000)	Tio (n = 1882)	Placebo (n = 1906)	Tio (n = 1769)	Placebo (n = 1784)	Tio (n = 1108)	Placebo (n = 1122)
Age (years)	64.9 ± 8.4	65.3 ± 8.4	64.1 ± 8.4	63.8 ± 8.5	64.4 ± 8.3	64.5 ± 8.5	64.5 ± 8.5	64.5 ± 8.5	64.4 ± 8.3	64.6 ± 8.4	64.7 ± 8.6	64.3 ± 8.7
Male, %	69.7	69.2	80.2	78.6	77.0	75.7	74.3	73.2	76.2	75.6	73.7	71.7
Smoking history (%)												
Ex-smoker	69.6	70.7	71.6	69.3	67.8	67.5	72.1	71.2	69.3	70.7	72.727.3	68.8
Current smoker	30.4	29.3	28.4	30.7	32.2	32.5	27.9	28.8	30.7	29.3		31.2
Mean COPD duration (years)	10.1 ± 7.7	9.8 ± 7.7	9.7 ± 7.5	9.6 ± 7.0	9.9 ± 7.6	9.7 ± 7.5	9.9 ± 7.5	9.7 ± 7.3	10.1 ± 7.7	9.7 ± 7.5	9.6 ± 7.4	9.6 ± 7.1
Baseline medication* use (%)												
LABA	60.0	61.5	59.7	59.1	56.9	59.1	61.4	60.8	59.8	61.7	59.9	57.8
ICS	62.1	62.5	60.8	60.7	58.9	59.9	62.8	62.4	61.6	61.7	61.2	61.4
Combination ICS+LABA	49.2	50.0	48.4	47.3	45.2	47.6	50.6	49.1	48.5	49.7	49.1	46.7
Anticholinergic	46.9	47.6	44.9	42.7	44.0	43.9	46.8	45.6	47.1	45.8	43.9	43.9
Theophyllines	31.6	33.0	26.3	24.3	29.0	31.4	28.7	27.0	30.7	31.7	25.8	23.4
SGRQ total score (units)	47.2 ± 17.2	48.0 ± 17.5	44.5 ± 16.7	43.9 ± 16.7	45.4 ± 17.5	46.6 ± 17.8	46.0 ± 16.7	45.5 ± 16.9	46.9 ± 17.2	47.1 ± 17.2	44.0 ± 16.6	43.9 ± 17.0

Data expressed as either proportions or mean ± SD.
Tio = tiotropium; LABA = long-acting β-acting agonist; ICS = inhaled corticosteroid; SGRQ = St. George's Respiratory Questionnaire; GOLD = Global Initiative for Chronic Obstructive Lung Disease.
*baseline maintenance inhaled respiratory medication.

baseline BDR on lung function and health outcomes over four years, and c) the variability of acute BDR over four years.

Patients: Patients were recruited from 490 investigational sites in 37 countries. They were eligible for inclusion if they had a diagnosis of COPD, were aged ≥40 years with a smoking history of at least 10 pack-years, had post-bronchodilator FEV1 ≤70% of predicted, and FEV1 to forced vital capacity (FVC) ratio of <0.70. Patients were excluded from participating if they had history of asthma, COPD exacerbation, or respiratory infection within 4 weeks of screening, prior pulmonary resection, were using supplemental oxygen for >12 hours per day, or had significant disease other than COPD that might influence the study results or ability to participate. Patients were permitted to use all respiratory medications (excluding other inhaled anticholinergics) throughout the trial.

Assessments: Pre- and post-bronchodilator spirometry was performed prior to and after four inhalations of ipratropium (total = 80 mcg) followed 60 minutes later by four inhalations of albuterol (total = 400 mcg). Post-bronchodilator spirometry was performed 30 minutes after inhalation of albuterol.
At clinic visits following randomization, study drug was administered immediately prior to administration of short-acting bronchodilators. Medication washout requirements included withholding short- and long-acting β-agonists (for ≥8 and ≥12 hours, respectively), short- and long-acting theophylline preparations (for ≥24 and ≥48 hours, respectively) and antileukotrienes (for ≥48 hours), prior to spirometry. Patients were discouraged from smoking during the study visit and were not permitted to smoke within 30 minutes of spirometry. Patients' self-report was relied upon regarding their adherence to these restrictions, as is routinely the case in clinical trials.

Spirometry and the St George's Respiratory Questionnaire (SGRQ)[12] were performed every 6 months throughout the

Table 2: Mean baseline spirometry according to bronchodilator responsiveness status.

	Criterion A (Δ % Predicted FEV_1 ≥12% and ≥200 mL)				Criterion B (Δ % Predicted FEV_1 ≥15%)				Criterion C (Δ % Predicted FEV_1 ≥10%)			
	Nonresponder (n = 2750)		Responder (n = 3033)		Nonresponder (n = 1995)		Responder (n = 3788)		Nonresponder (n = 3553)		Responder (n = 2230)	
	Tio (n = 1357)	Placebo (n = 1393)	Tio (n = 1520)	Placebo (n = 1513)	Tio (n = 995)	Placebo (n = 1000)	Tio (n = 1882)	Placebo (n = 1906)	Tio (n = 1769)	Placebo (n = 1784)	Tio (n = 1108)	Placebo (n = 1122)
Prebronchodilator												
FEV_1 (L)	1.09 ± 0.45	1.07 ± 0.43	1.11 ± 0.36	1.11 ± 0.37	1.29 ± 0.44	1.25 ± 0.42	1.00 ± 0.34	1.01 ± 0.36	1.12 ± 0.43	1.10 ± 0.43	1.08 ± 0.3538.9 ±	1.07 ± 0.36
FEV_1 % predicted	40.7 ± 13.4	40.0 ± 13.2	38.5 ± 10.6	38.6 ± 10.5	45.6 ± 12.2	44.8 ± 12.3	36.3 ± 10.6	36.3 ± 10.6	39.9 ± 13.1 2.65	39.6 ± 13.0	10.1 2.59 ±	38.8 ± 10.0
FVC (L)	2.57 ± 0.86	2.54 ± 0.85	2.69 ± 0.76	2.71 ± 0.80	2.84 ± 0.85	2.81 ± 0.84	2.52 ± 0.76	2.53 ± 0.81	± 0.83	2.63 ± 0.84	0.76	2.61 ± 0.81
Postbronchodilator												
FEV_1 (L)	1.19 ± 0.44	1.16 ± 0.43	1.46 ± 0.39	1.46 ± 0.40	1.36 ± 0.47	1.33 ± 0.45	1.31 ± 0.42	1.32 ± 0.44	1.25 ± 0.44	1.23 ± 0.44	1.46 ± 0.40	1.46 ± 0.41
FEV_1 % predicted	44.4 ± 13.3	43.7 ± 13.1	50.8 ± 11.3	50.9 ± 11.1	48.3 ± 13.0	47.5 ± 13.1	47.5 ± 12.6	47.4 ± 12.4	44.6 ± 12.9 13.8	44.2 ± 12.9	52.9 ± 10.5 38.7	52.6 ± 10.3
% Δ FEV_1	10.9 ± 10.2	11.1 ± 10.4	34.6 ± 16.0	34.7 ± 15.9	6.14 ± 6.65	6.16 ± 6.82	32.6 ± 15.2	32.4 ± 15.2	± 11.22.97 ± 0.85	13.8 ± 11.5	± 16.1 3.30 ±	38.6 ± 15.7
FVC (L)	2.81 ± 0.84	2.79 ± 0.85	3.36 ± 0.80	3.38 ± 0.86	3.02 ± 0.87	3.00 ± 0.88	3.14 ± 0.86	3.15 ± 0.91		2.95 ± 0.87	0.85	3.33 ± 0.90
GOLD Stage (%)												
II	37.4	34.2	55.9	56.9	49.8	46.6	45.7	45.7	37.0	35.8	63.4	62.2
III	48.0	50.5	41.2	39.7	41.1	43.3	46.1	45.6	50.1	50.2	35.2	36.4
IV	14.7	15.4	2.8	3.4	9.0	10.1	8.0	8.6	12.9	14.0	1.2	1.3

Tio = tiotropium; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; GOLD = Global Initiative for Chronic Obstructive Lung Disease.

Table 3: Proportion of patients with baseline bronchodilator responsiveness according to GOLD severity stage.

GOLD Stage	n	Criterion A	Criterion B	Criterion C
II	2694	1714 (64%)	1735 (64%)	1404 (52%)
III	2580	1226 (48%)	1738 (64%)	798 (31%)
IV	506	93 (18%)	315 (62%)	28 (6%)
All	5783	3033 (52%)	3788 (66%)	2230 (39%)

GOLD = Global Initiative for Chronic Obstructive Lung Disease

trial. Additionally, spirometry was performed 30 days after randomization and requested 30 days after the last dose of study medication. Information on exacerbations, exacerbations leading to hospitalization, and adverse events was collected at all clinic visits. Mortality was analyzed based on fatal events occurring during treatment until 1470 days from randomization.

Statistical methods: Data from all randomized patients with acceptable pre- and post-bronchodilator measurements at baseline were included in this analysis. Patients were split according to initial FEV1 response to short-acting inhaled bronchodilators as previously described, based on three standard criteria: ≥12% and ≥200 mL improvement over baseline (referred to as criterion A); ≥15% increase over baseline (referred to as criterion B); and ≥10 unit (%) absolute increase in the percent predicted value (referred to as criterion C). Changes in FEV1, FVC, and SGRQ total score were analyzed using a mixed models repeated measurements (MMRM) analysis of variance approach, which included adjustment for baseline measurement values. Numbers of exacerbations were estimated using Poisson regression, with adjustment for overdispersion and treatment exposure. For decline in lung function, data sets were restricted to patients with at least three post-randomization spirometry test sets. Cox regression was used to calculate hazard ratios for analyses of time to first exacerbation and for mortality.

Results

Study population: Baseline demographic data for the full UPLIFT cohort have been previously reported.[10] A total of 5992 patients were randomized and received study medication in the UPLIFT study. Of these patients, 5783 patients had bronchodilator responsiveness data at baseline, allowing them to be included in the present analysis. The mean age (SD) was 64 (8) years with 75% being male and 30% being current smokers. Mean (SD) prebronchodilator FEV1 was 1.10 (0.40) L (39.4 [12.0]% predicted). Mean post-bronchodilator FEV1 (SD) was 1.33 (0.44) L (47.6 [12.7]% predicted). Patients' demographics and baseline characteristics were similar when classified according to BDR criteria A, B, and C except for baseline SGRQ total score, which indicated worse health related quality of life for nonresponders for patients meeting criteria A and C (Table 1). Prebronchodilator FEV1 was highest in criterion B nonresponders and lowest in the corresponding responders (Table 2).

Bronchodilator responsiveness: A total of 52%, 66%, and 39% of patients exceeded the thresholds for responsiveness defined by criteria A, B, and C at baseline, respectively (Table 3). The percent of patients labeled as responsive diminished with increasing Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage of severity only when criterion A or C was used (Table 3). Figure 1 demonstrates the frequency distribution of BDR with repeated testing using the three criteria in patients randomized to the placebo arm and in whom spirometry was performed at every visit. Analysis of frequency of BDR was restricted to the 1411 patients with full data in the placebo group as bronchodilation due to tiotropium exceeds 24 hours and a full washout prior to clinic visits was not appropriate for the study. A minority of these patients failed to show BDR at any clinic visit (9% for criterion A, 4% for criterion B, and 19% for criterion

Table 4: Spirometry outcomes in tiotropium and placebo groups according to different threshold criteria for bronchodilator responsiveness.†

A	Criterion A (Δ % Predicted FEV_1 ≥12% and ≥200 mL)		Criterion B (Δ % Predicted FEV_1 ≥15%)		Criterion C (Δ % Predicted FEV_1 ≥10%)	
	Nonresponder	Responder	Nonresponder	Responder	Nonresponder	Responder
Prebronchodilator						
Difference in FEV_1 at 4 years (mL)*	76 (54, 98)	98 (77, 119)	97 (69, 124)	83 (65, 101)	78 (58, 97)	105 (81, 130)
Difference in FVC at 4 years (mL)*	134 (89, 178)	195 (153, 236)	143 (92, 194)	179 (140, 217)	139 (99, 179)	213 (165, 260)

B	Criterion A (Δ % Predicted FEV_1 ≥12% and ≥200 mL)				Criterion B (Δ % Predicted FEV_1 ≥15%)				Criterion C (Δ % Predicted FEV_1 ≥10%)			
	Nonresponder		Responder		Nonresponder		Responder		Nonresponder		Responder	
	Tio	Placebo	Tio	Placebo	Tio	Placebo	Tio	Placebo	Tio	Placebo	Tio	Placebo
Rate of change in FEV_1 (mL/year)†												
Prebronchodilator	-32 ± 2	-31 ± 2	-29 ± 2	-29 ± 2	-35 ± 2	-38 ± 2	-28 ± 2	-26 ± 2	-32 ± 2	-32 ± 2	-28 ± 2	-28 ± 2
Postbronchodilator	-37 ± 2	-37 ± 2	-43 ± 2	-47 ± 2	-38 ± 2	-42 ± 2	-42 ± 2	-43 ± 2	-39 ± 2	-39 ± 2	-43 ± 2	-47 ± 2

(A) mean differences (95%CI) at 4 years (tiotropium – placebo), (B) mean (SE) rate of change by treatment group.

†In patients with at least three measurements after Day 30. Change in FEV_1 and FVC data are based on repeated-measures ANOVA model, adjusted for baseline.

Rates of decline in FEV_1 data are based on random-effects model.

*$p \leq 0.001$ versus placebo. Tio = tiotropium; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity.

Table 5: Exacerbations outcomes in tiotropium and placebo groups according to different threshold criteria for bronchodilator responsiveness.

	Tiotropium	Placebo	Hazard (or Rate) Ratio (95%CI) (tiotropium/placebo)	p-value
Patients with ≥1 exacerbation, n (%)				
Responsiveness Criterion A				
Nonresponder	913 (67.3)	946 (67.9)	0.86 (0.79, 0.94)	0.0014
Responder	1021 (67.2)	1036 (68.5)	0.86 (0.79, 0.94)	0.0008
Responsiveness Criterion B				
Nonresponder	634 (63.7)	676 (67.6)	0.85 (0.76, 0.95)	0.0029
Responder	1300 (69.1)	1306 (68.5)	0.87 (0.80, 0.94)	0.0003
Responsiveness Criterion C				
Nonresponder	1198 (67.7)	1204 (67.5)	0.89 (0.82, 0.96)	0.0036
Responder	736 (66.4)	778 (69.3)	0.82 (0.74, 0.91)	0.0002
Number of exacerbations/patient year, mean				
Responsiveness Criterion A				
Nonresponder	0.76	0.87	0.87 (0.79, 0.95)	0.0019
Responder	0.69	0.82	0.85 (0.78, 0.92)	0.0002
Responsiveness Criterion B				
Nonresponder	0.65	0.77	0.84 (0.75, 0.94)	0.0026
Responder	0.76	0.88	0.86 (0.80, 0.93)	0.0001
Responsiveness Criterion C				
Nonresponder	0.74	0.86	0.86 (0.79, 0.93)	0.0001
Responder	0.70	0.81	0.86 (0.77, 0.95)	0.0025

p-value and hazard ratio based on Cox-regression for analysis of time to first exacerbation. p-value and rate ratio based on Poissonregression with adjustment for overdispersion for analysis of number of exacerbations per patient year.

C). In contrast, some of these patients demonstrated BDR at every clinic visit (12% for criterion A, 19% for criterion B, and 6% for criterion C). Approximately 60%, 73%, and 40% of patients who completed all visits in the placebo group were considered to have BDR on ≥50% of visits according to criteria A, B, and C, respectively.

Lung function: The mean annualized rate of decline in FEV1 was similar among the different threshold criteria and was not influenced by treatment assignment (Table 4). Pre- and postbronchodilator lung function (FEV1, FVC) improved significantly with tiotropium ($p < 0.001$ versus placebo for all comparisons), irrespective of whether there was a positive baseline BDR using any of the criteria (Table 4). Furthermore, the degree of improvement in FEV1 and FVC was similar or greater in responsive compared to poorly responsive patients.

Health-related quality of life: Baseline SGRQ were similar between the responsive and poorly responsive patients regardless of the criteria of BDR used (Table 1). Differences in SGRQ total score indicated statistically significant improvements with tiotropium versus placebo in both responsive and poorly responsive groups, regardless of criterion used (Fig 2, $p < 0.001$for all comparisons).

COPD exacerbations: Risk of an exacerbation over the entire trial was reduced with tiotropium in both the responsive and poorly responsive groups at baseline regardless of the BDR criteria. Furthermore, in poorly responsive patients at baseline, tiotropium was associated with significantly fewer exacerbations compared with placebo ($p < 0.005$, Table 5). The criterion used did not appear to influence the risk or mean number of exacerbations during the trial.

All-cause mortality: The hazard ratio for a fatal event (tiotropium relative to the placebo group) was similar in responsive and poorly responsive patients regardless of criteria used. However, poorly responsive patients showed a tendency to higher all-cause mortality regardless of the responsiveness definition used (Table 6).

Discussion

Data from the UPLIFT trial demonstrated that the presence or absence of achieving a predefined threshold for increases in FEV1 after single occasion administration of maximal doses of short-acting bronchodilators in COPD patients (BDR) does not influence whether or not patients will attain long-term improvements in lung function and health related quality of life along with a reduced risk for exacerbations with tiotropium treatment. Furthermore, the absence of acute BDR at one occasion does not preclude demonstration of BDR on another occasion. Only a small minority (<20%) of the placebo patients who were tested at every visit throughout the trial remained nonresponsive (i.e. did not increase beyond a pre-defined threshold for responsiveness). Finally, the proportion of patients who have BDR was somewhat dependent on the threshold used to define responsiveness.

Bronchodilator responsiveness testing is routinely performed in clinical practice and research studies in patients with COPD. Response to tiotropium compared to placebo was not affected by responsiveness to short-acting bronchodilators at baseline regardless of the definition used and supports findings from an earlier publication of a 1- year trial.[4] The observations have important implications in pharmacotherapy of stable COPD and suggest that assessment of acute BDR using a predefined threshold should not be used as a decision-making tool when prescribing tiotropium for patients with COPD. The data and conclusions also confirm previous reports with other COPD treatments.[13,14]

Table 6: All-cause mortality in tiotropium and placebo groups according to different threshold criteria for bronchodilator responsiveness.

	Tiotropium	Placebo	Hazard Ratio (95% CI) (tiotropium/placebo)	p-value
Responsiveness Criterion A				
Nonresponder (%)	208/1357 (15.3)	225/1393 (16.2)	0.84 (0.70, 1.02)	0.07
Responder (%)	152/1520 (10.0)	164/1513 (10.8)	0.86 (0.69, 1.07)	0.17
Responsiveness Criterion B				
Nonresponder	141/995 (14.2)	151/1000 (15.1)	0.87 (0.69, 1.10)	0.24
Responder	219/1882 (11.6)	238/1906 (12.5)	0.84 (0.70, 1.01)	0.06
Responsiveness Criterion C				
Nonresponder (%)	265/1769 (15.0)	283/1784 (15.9)	0.85 (0.72, 1.00)	0.05
Responder (%)	95/1108 (8.6)	106/1122 (9.4)	0.84 (0.64, 1.11)	0.22

COPD is defined as a disease characterized by partially reversible airflow limitation. Responsiveness (or reversibility) criteria vary among various professional societies. Advantages and disadvantages of using any of the proposed criteria have been extensively discussed in the literature. To summarize, published reports suggest that a 12 to 15% increase in FEV1 compared to baseline exceeds normal within-subject variability and response to placebo inhalation.[15,16] However, a low baseline FEV1 may produce a high percent improvement from baseline with only a small absolute improvement. Thus using an absolute volume increase has been considered relevant. A threshold of 200 mL has traditionally been used, although this stems from the asthma literature since a change of 100 to 150 mL in FEV1 in COPD is usually considered clinically significant as it exceeds the minimal clinical significant difference.[17] Additional data from Herpel et al support the use of minimal absolute volume change as a criterion.[18] An additional consideration is the use of lung volumes such as inspiratory capacity and FVC in response to bronchodilators in COPD as volume changes may be more pronounced and may correlate more with clinical outcomes than a change in FEV1.[19,21]

A unique characteristic of the UPLIFT data is the repeated spirometry with acute bronchodilator testing over 10 sessions in 4 years. Upon examining the data from patients in the placebo group who had spirometry at every visit, it is apparent that there is a wide variability in the occurrence of BDR with serial spirometry, which is consistent with data previously described in other studies.[22] Among the three criteria used, criterion B classified the highest percentage of patients as always responsive, while criterion C identified highest percentages of patients as always nonresponsive. Further, as severity of COPD increased, the percent of responsive patients decreased when criterion A or C was used, while it did not change appreciably with criterion B. The differences among the thresholds again highlight the influence of inclusion of absolute volume changes. However, the more important finding is the confirmation that measurement of BDR varies with time and a one-time measurement has limited importance in the management of COPD patients.

The predictive value of achieving BDR based on predefined thresholds as a marker distinguishing patients who will have long-term positive outcomes with pharmacotherapy in COPD has been a matter of debate. Bronchodilator responsiveness grouping according to various definitions may be associated with somewhat different magnitudes of responses but the results presented here from the 4-year UPLIFT trial confirm and extend findings from previous studies that the absence of BDR does not preclude a long-term clinical response.[4,13,14] This suggests that the predictive ability of BDR testing using a pre-determined threshold is limited.

The present study demonstrated that all-cause mortality tends to be lower in responsive patients than those who did not have any BDR at baseline. This difference was most pronounced when criterion A or C was used (Table 5). This is in contrast to data from Hansen and colleagues who studied a large cohort

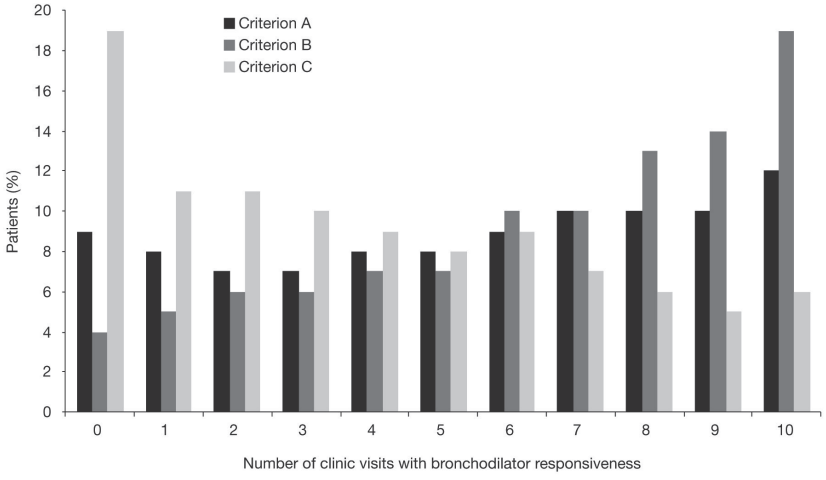

Figure 1: Proportion of patients who demonstrated bronchodilator responsiveness by number of clinic visits according to criteria A, B, and C. The histograms on the most left (0) reflect percent of patients who never met the criteria for responsiveness while the ones on the most right (10) reflect the subjects who on all the 10 occasions of testing met the reversibility criteria. Population restricted to the patients randomized to placebo group and who had spirometry performed at all 10 spirometry clinic visits.

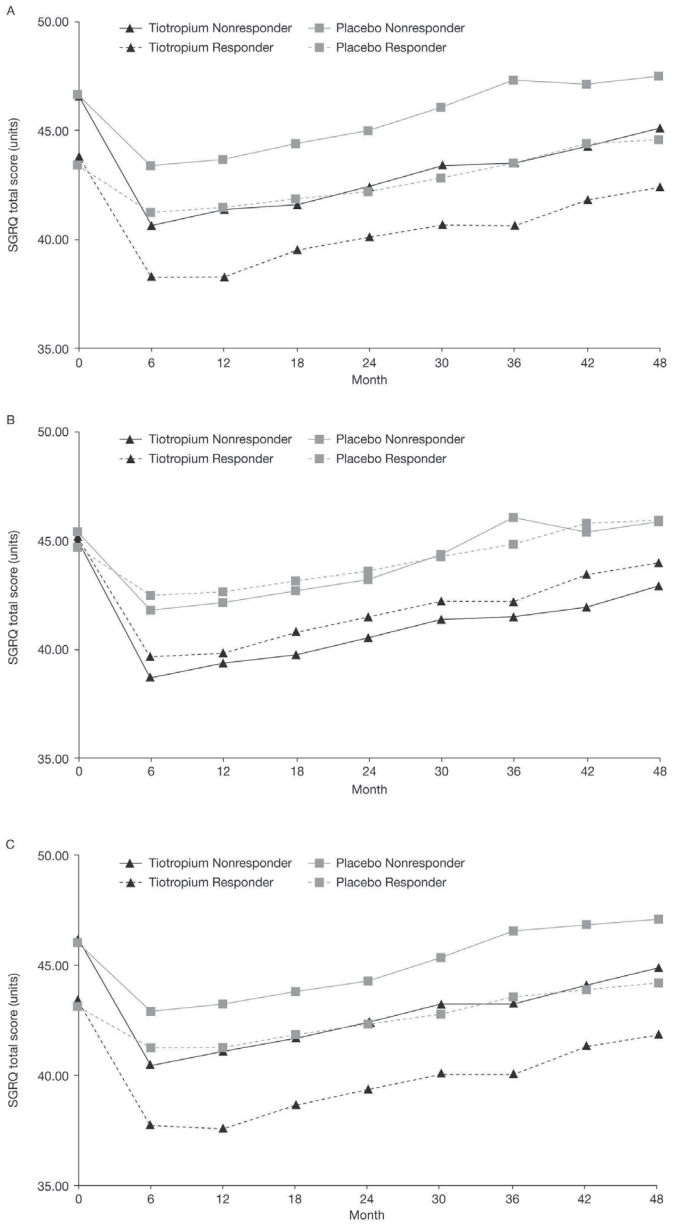

Figure 2: Mean SGRQ total scores in the tiotropium and the placebo groups according to bronchodilator responsiveness at baseline using criteria A, B, and C.

of patients with COPD followed for an average of 11.2 years and showed that bronchodilator responsiveness did not predict mortality when the best post-bronchodilator baseline FEV1 was used in the model.[23]

In addition to the criterion of BDR used, other factors may influence the presence or absence of BDR when spirometry is performed. One such factor includes the dose and type of short-acting bronchodilator used to test BDR. Traditionally, two to four inhalations of albuterol are used with post-bronchodilator testing performed 10 to 20 minutes post-treatment. However, some patients with COPD may not respond to albuterol while they may show response to short-acting anticholinergic agents such as ipratropium bromide.[24] It is important to note that our protocol in this study was more aggressive that the one used in the usual clinical settings as we measured responsiveness to two bronchodilators with different mechanisms of action; albuterol and ipratropium bromide. We also sought to maximize the potential bronchodilator response in this study using both agents in higher than standard dosing. Pre- and post-bronchodilator spirometry was performed prior to and after inhalation of ipratropium 80 mcg followed 60 minutes later by albuterol 400 mcg. Post-bronchodilator spirometry was performed 30 minutes after inhalation of albuterol (90 minutes after ipratropium); this tended to optimize the timing to coincide with the expected peak action of each of these short-acting bronchodilators. This technique has not been utilized by any of the previously published studies evaluating BDR in COPD.

One limitation to our study is that we could only accurately measure serial acute bronchodilator responses in the placebo group due to the prolonged half-life of tiotropium, which would require a washout over several weeks. Such a washout was not feasible within the context of the UPLIFT study. Nevertheless, the placebo group still provided a large subcohort of patients in whom serial bronchodilator responses could be measured. Another limitation of long-term intervention studies in COPD is the number of prematurely discontinued patients who do not have spirometry, exacerbation, or SGRQ measurements after discontinuation from the study. However, one of the strengths of the UPLIFT study is the size and duration of the study that still provides substantial data. Additionally, while not fully compensating, statistical techniques used in the analysis do consider the issue of premature discontinuation. Finally, spirometry was not measured after albuterol alone, which limits the comparison to previous studies; however, a more important issue is the possible impact of responsiveness on changes in lung function after pharmacologic intervention. Therefore, the study is unique and provides a more comprehensive understanding of the achievable lung function improvements and the implications for therapy.

Conclusion

In summary, the 4-year data from the UPLIFT trial demonstrate that the majority of patients with COPD had a variable occurrence of exceeding pre-defined thresholds of acute responses to short-acting bronchodilators when tested repeatedly over 4 years and only a small minority (<20%) failed to show a significant response on at least one occasion according to any threshold criterion. Furthermore, treatment with tiotropium improved lung function, improved health-related quality of life, and reduced exacerbations in COPD patients irrespective of their baseline acute bronchodilator response (BDR) and irrespective of the threshold criterion used for defining responsiveness. These findings indicate that acute bronchodilator responsiveness testing as measured in this study should not be used in predicting long term health outcomes and response to tiotropium in patients with COPD.

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Emphysema…continued from page 51

The chest radiograph cannot exclude pneumothorax or pneumomediastinum. A CT scan is often needed for assessment of these conditions. Oropharyngeal subcutaneous emphysema has been described with dental surgery or spontaneous rupture of oropharyngeal or bronchial mucosa.[3,4] The association of submucosal emphysema with pneumothorax is rare. However, anatomical correlation among fascial planes of the cervical area, mediastinum, and retroperitoneum can explain this relationship (Figure 2a and 2b).[1]

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