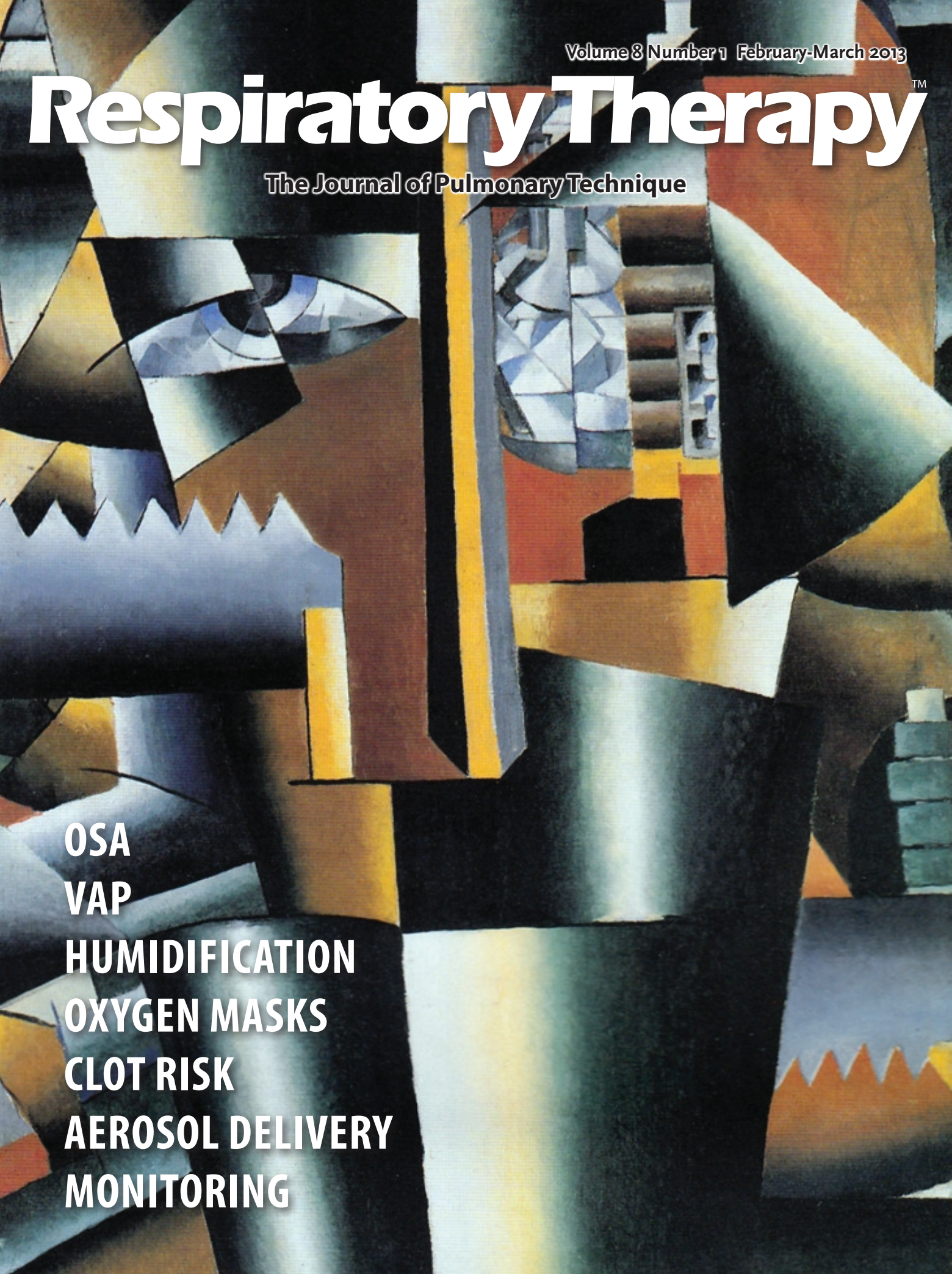
Volume 8 Number 1 February-March 2013

Respiratory Therapy™

The Journal of Pulmonary Technique



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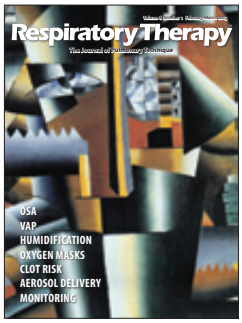

Respiratory Therapy™
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Vol. 8 No. 1
February-March 2013

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ARTICLES

Editorial

Paliative Ventilation

Here's some highlights from an interesting paper about continuous non-invasive ventilation for ALS patients with end-stage respiratory muscle failure:* "We report a case series of home-based amyotrophic lateral sclerosis-motor neuron disease patients who refused tracheostomy and advanced non-invasive ventilation to full-setting, while maintaining normal alveolar ventilation and oxygenation in the course of the disease… We present here the cases of three Caucasian patients (a 51-year-old Caucasian man, a 45-year-old Caucasian woman and a 57-year-old Caucasian woman) with amyotrophic lateral sclerosis who developed continuous non-invasive ventilation dependence for 15 to 27 months without major complications and were able to maintain normal CO2 and pulse oxyhemoglobin saturation despite a non-measurable vital capacity. All patients were wheelchair-dependent and receiving riluzole 50 mg twice a day. Patient one developed mild-to-moderate bulbar-innervated muscle weakness. He refused tracheostomy but accepted percutaneous gastrostomy. Patient two had two lung infections, acute bronchitis and pneumonia, which were treated with antibiotics and cough assistance at home. Patient three had three chest infections (bronchitis and pneumonias) and asthmatic episodes treated with antibiotics, bronchodilators and cough assistance at home. All patients had normal speech while receiving positive pressure; they died suddenly and with normal oxygen saturation… Although warned that prognosis was poor as vital capacity diminished, our patients [had] survived without invasive airway tubes and despite non-measurable vital capacity. No patient opted for tracheostomy… The main indication for NIV was the patients' self-reported symptoms (all three of them) and hypercapnia (the first two patients). All three died suddenly during the daytime, while talking to their loved ones. Perhaps they suffered a heart attack. The key points for the home management of these three patients were clinical vigilance, serial measurements of VC and coughing ability, cough assist with ambu bag, oxygen saturation overnight monitoring and advance planning. As with tracheostomy ventilation (TV), full-time NIV may affect the patient's safety and comfort but NIV is invariably preferred by patients who have used both, and besides, noninvasive management results in fewer infections and hospitalizations… All three patients had been told that NIV would palliate symptoms and 'buy time' but that with a decreasing VC prognosis, this would result in their death. Unlike using the low BiPAP spans reported in the literature that would buy little time, our patients were placed on high spans for up to full ventilatory support and/or respiratory muscle rest… All patients' dyspnea and hypoventilation were completely relieved despite loss of all breathing ability (VC non-measurable) and they could only talk because of the pressure delivered by the BiPAP. Although patients and physicians often consider NIV more desirable than invasive ventilatory support, with loss of all VC most clinicians continue to think that tracheostomy is necessary. The cases reported in this paper support the supposition that this is not so… With mild to moderate bulbar involvement, it was possible to maintain NIV with no major support or difficulties and using occasional cough assist… Unlike TV, NIV does not seem to be significantly detrimental to caregivers or patients who receive it… Using NIV when possible is more cost-effective than TV due to lower costs for both equipment and caregivers… Our patients… demonstrate the feasibility of non-invasive management to prolong survival, optimize wellness and management at home, and optimize the chances to die peacefully."

Les Plesko

* The Use of Full-Setting Non-invasive Ventilation in the Home Care of People with Amyotrophic Lateral Sclerosis-Motor Neuron Disease with End-stage Respiratory Muscle Failure. De Vito, et al, BioMed Central, the Journal of Medical Case Reports,

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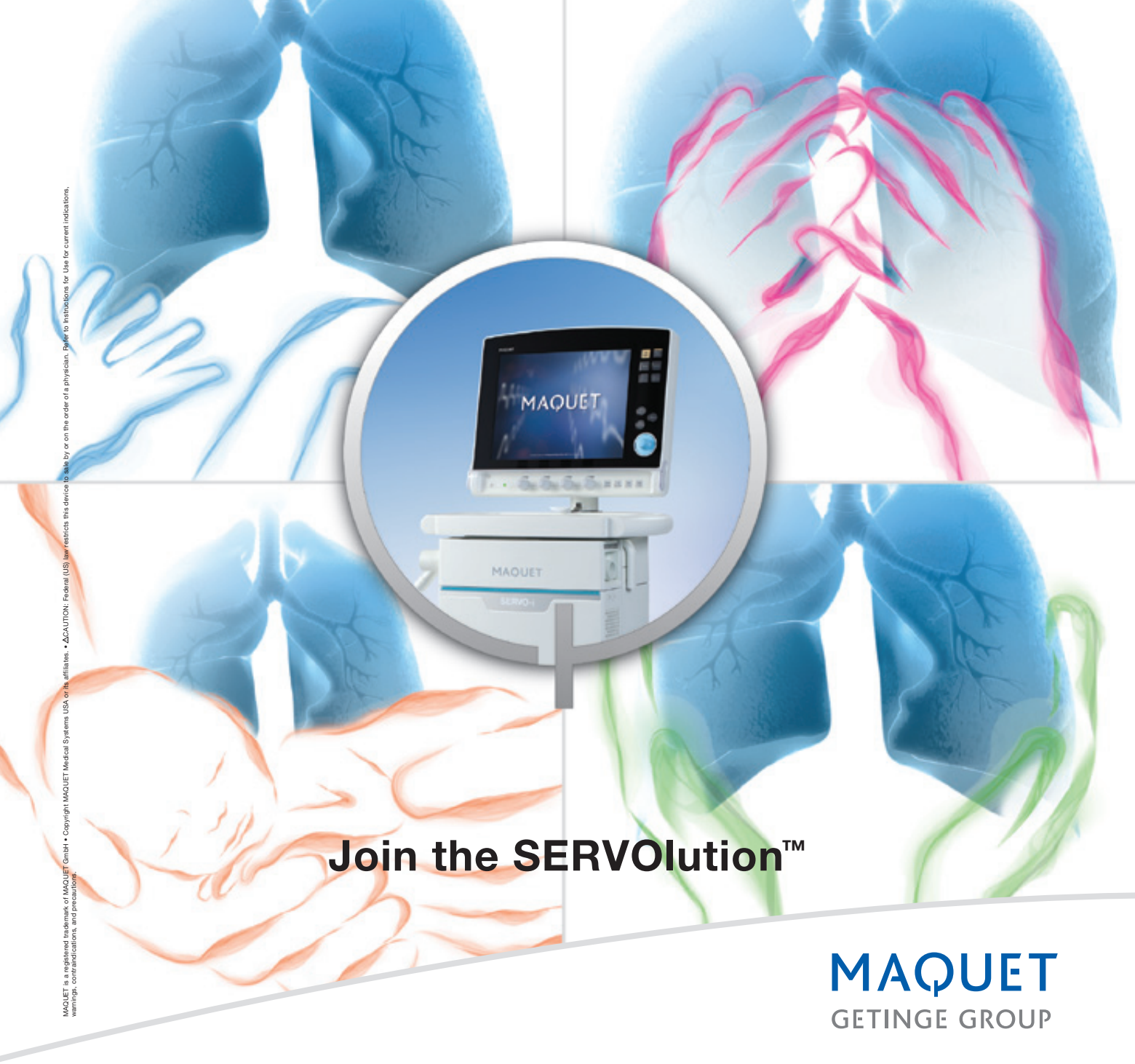

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News

■ February-March 2013

FIGHTING IPD

A new conjugate vaccine, PCV10, is 93 to 100% effective at preventing invasive pneumococcal disease (IPD; meningitis, sepsis, bacteremic pneumonia, and other blood-borne infections) in infants younger than 2 years, according to researchers at the National Institute for Health in Finland. The researchers suggest that a series of three or four shots of the new PCV10 vaccine including three additional pneumococcal strains is going to work at least as well as its predecessor, PCV7, in preventing IPD, with the potential to prevent over 70% of severe pneumococcal disease cases in children worldwide. The Finnish Invasive Pneumococcal Disease Vaccine Trial (FinIP) covered over three-quarters of the country. Nearly 46,000 children younger than 19 months were randomized to receive two to four doses, and were tracked for two years. The vaccine prevented 93% of cases of IPD in healthy infants who received at least one dose.

THAT TIME OF MONTH

Respiratory symptoms vary significantly during different stages of the menstrual cycle, with higher frequencies during the mid-luteal to mid-follicular stages, according to a new study at Haukeland University Hospital in Norway. In a cohort of nearly 4,000 women, the researchers found large and consistent changes in respiratory symptoms according to menstrual cycle phase, and, in addition, these patterns varied according to body mass index, asthma, and smoking status. A total of 3,926 women with regular cycles who were not taking exogenous sex hormones were enrolled in the study. Menstrual cycles, respiratory symptoms, BMI, asthma, and smoking status were determined by postal questionnaire. Significant variations over the menstrual cycle were found for each symptom assessed in all subjects and subgroups. Reported wheezing was higher on cycle days 10-22, with a mid-cycle dip near the putative time of ovulation (~ days 14-16) in most subgroups. Shortness of breath was highest on days 7-21, with a dip just prior to mid-cycle in a number of subgroups. The incidence of cough was higher just after putative ovulation for asthmatics, subjects with BMI ≥ 23kg/m2, and smokers, or just prior to ovulation and the onset of menses in subgroups with a low incidence of symptoms.

NO MORE ANIMALS?

A study at Harvard University that used a "lung-on-a-chip" to mimic a chemotherapy drug side effect is hastening the day when drug developers use "organ-on-a-chip" methods to replace animal testing and cell cultures. The researchers noted that their study provides proof of principle for using a biomimetic microdevice that works sufficiently like a lung to mimic pulmonary edema. The microdevice is a clear, flexible polymer the size of a memory stick, containing hollow channels. The researchers lined the channels with layers of living human cells to create a microfluidic device that replicates the alveolar-capillary interface in human lungs. The cells experience air flow and fluid flow, and a cyclic mechanical strain, created by a vacuum, that mimics normal breathing motions. When researchers injected IL-2 into the blood channel, fluid leaked across the membrane that separated it from the air channel, reducing its air supply and thereby reducing the amount of oxygen that moves into the blood cells, which duplicates what happens in the lungs of patients receiving equivalent doses of IL-2. Blood plasma proteins also crossed over into the air channel, causing blood clots to form in the air space, as it does with IL-2 treatment. The researchers also found that the physical act of breathing seemed to boost the effect of IL-2 in pulmonary edema. What this means is that doctors giving IL-2 to patients on respirators should consider lowering the tidal volume. The researchers added that this chip model of pulmonary edema could be used for in vitro identification of potential therapeutic agents. Reported by Catharine Paddock, PhD in Medical News Today, copyright Medical News Today.

MUSHROOM CURE

Scientists at The University of Nottingham have been investigating how a caterpillar fungi from the mountains of Tibet could work by studying one of the drugs found in these mushrooms. They have already discovered that the fungi cordycepin has potential as a cancer drug. Their new work indicates that it could also have anti-inflammatory characteristics with the potential to help sufferers of asthma, rheumatoid arthritis, renal failure and stroke damage. Researchers showed that cordycepin reduces inflammatory gene products in the airway smooth muscle cells that contract during an asthma attack. Cordycepin reduces the expression of inflammatory genes in airway smooth muscle cells by acting on the final step in the synthesis of their mRNAs, which carry the chemical blueprint for the synthesis of proteins. Cordycepin acts by a completely different mechanism than currently used anti-inflammatory drugs, making it a potential drug for patients in which these drugs don't work well.

IMMUNIZE

Pregnant women and moms should make sure kids have been properly immunized for whooping cough, according to The Public Health Agency, because there were an increased number of cases in 2012. A previous study revealed that the US was heading for the largest number of cases in 53 years. The current study said pregnant women should receive the vaccination if they're 28 weeks pregnant or more. Babies should be vaccinated at 2, 3 and 4 months of age. Reported by Sarah Glynn in Medical News Today, copyright Medical News Today.

DANGEROUS SYMPTOMS

Difficulty breathing, chest pain, and cough, typically symptoms of a heart attack, may also be symptoms for a pulmonary embolism, according to researchers at Saint Vincent's Medical Center in Connecticut, where researchers found 334 patients with confirmed PE who matched the foregoing symptoms. Dyspnea, chest pain, and cough were present in 72%, 38%, and 19% of the patients, respectively, and dyspnea was the only presenting symptom in 29%. Cancer was the most common risk factor present in 27%, followed by prior history of deep vein

thrombosis or PE, immobilization, and surgery in 19%, 15%, and 15% of patients, respectively.

ELBOWED

Researchers at the University of Saskatchewan have found that if you've been elbowed by your bed partner because you were snoring, you may have OSA. They asked 124 patients: Does your bed-partner ever poke or elbow you because you are snoring; and, Does your bed-partner ever poke or elbow you because you have stopped breathing? Answering "yes" to being awakened for snoring or apneic spells increased the likelihood of an apnea-hypopnea index >5/h, indicating at least mild OSA. The researchers found that as the severity of OSA increased, patients were elbowed or poked more.

COMPLIANCE

Researchers at Kaiser Permanente found that patients who met with a respiratory therapist for a total of 2.5 hours within 30 days of initiating CPAP had significant compliance after 1 month of therapy. The Kaiser team reviewed the charts of 39 patients with OSA who were treated with CPAP and on a portable compliance-monitoring device. Patient/therapist contact time included a total of three sessions, each with one-on-one contact time, totaling 150 min. On day 30, a 30-min CPAP compliance evaluation review was conducted, and data was downloaded from patients' CPAP equipment. Results showed a 75% CPAP compliance rate after 30 days.

COMPLICATIONS

Medications used to immobilize patients during surgery can increase the risk of postoperative respiratory complications, according to researchers at Massachusetts General Hospital. They also found that the agent most commonly used to reverse the action of the immobilizing drug does not prevent and may possibly increase the risk that patients will need to receive postoperative respiratory support. The researchers compared data on more than 20,000 surgeries in which intermediate-acting neuromuscular blocking agents were used with an equal number of procedures that did not use the drugs, looking at recordings of patients' blood oxygen levels after the removal of breathing tubes and whether it became necessary to replace a breathing tube within 72 hours of surgery, a procedure requiring intensive care unit admission. They also analyzed the strategies used to monitor neuromuscular function during surgery and whether a drug was administered that reverses the action of the immobilization agent. Results showed that patients who received intermediate-acting neuromuscular blocking agents had a 40% greater risk of requiring reintubation because of low blood oxygen levels. Functional monitoring of neuromuscular strength by means of visual or tactile assessment of muscular response to an electric stimulus had no significant effect on risk, but the use of the reversal agent neostigmine made the risk of reintubation even greater. The researchers noted that the use of monitoring equipment that can quantitatively measure neuromuscular function, instead of the current qualitative estimates, should more accurately reflect drug action, giving the kind of precise data required to standardize procedures.

SPIT IT OUT

Researchers at Washington University School of Medicine in St Louis have described the molecular pathway responsible for excess mucus in airway cells and have used that information to design a series of new drugs that inhibit that pathway. They discovered that a critical signaling molecule, CLCA1, has a special role in the mucus pathway and showed that CLCA1 allows the protein IL-13 to turn on the major mucus gene in airway cells. The researchers also showed that CLCA1 needs help from the enzyme MAPK13. The researchers noted that they could take advantage of the MAPK14 inhibitors that are already know, and built drugs with slimmer structures that could better fit into the protein pocket of MAPK13. Their results showed that some of the newly designed MAPK13 inhibitors reduced mucus production in cultures of human airway cells by 100-fold. The researchers noted that their drugs could work not only on COPD but other conditions with excess mucus production.

DENT IT OUT

Surgeons at Children's Hospital of The King's Daughters have fitted a patient with a device that might eliminate the need for surgery in some patients with pectus excavatum, ie sunken chest syndrome. The so-called vacuum bell "pops out the dent" much like a vacuum in an auto body shop. The vacuum bell would obviate the need for the Nuss Procedure. The device looks like a large, silicone doughnut, with a bulb attached to remove air pressure. It must be fitted snugly to the patient's chest and must be used an hour a day to slowly pull up the depressed cartilage. The depression is typically corrected in three to six months, but the patient has to use the bell for two years to make the correction permanent.

YANK IT OUT

Adenotonsillectomy may offer relief from sleep disorders in kids with Prader-Willi syndrome, according to researchers at the Prader Willi Center. The risk for sleep disorders comes from growth hormones used to treats the syndrome that also cause adenoids and tonsils to enlarge. Researchers selected 13 patients and found that 89% of those with mild-to-moderate OSA or obstructive hypoventilation normalized after receiving adenotonsillectomy. Of the four children with severe obstructive sleep apnea, two normalized after surgery and two continued to have severe apneas.

GEOGRAPHY IS DESTINY

Knowing a child's home address and some socioeconomic data can serve as a vital sign in helping hospitals predict which children admitted for asthma treatment are at greater risk for re-hospitalization or additional emergency room visits, according to researchers at Cincinnati Children's Hospital. The use of a "geographic social risk index," based on census measures of poverty, home values and number of adults with high school degrees, can also help hospitals identify families likely to report financial or psychological hardship, both of which are linked

to adverse asthma outcomes. The researchers geocoded home addresses and constructed the social risk index from assigned census tract regions. This data included extreme poverty rates, median home values and high school graduation rates. Based on this information, 601 children hospitalized for asthma were evaluated and placed in one of three categories, or risk strata: low, medium or high risk. The researchers found that 39% of all patients were rehospitalized or returned to the emergency room within 12 months. Compared to children at low geographic risk, children in the high risk category were 80% more likely to be rehospitalized or revisit the emergency room. In addition, high-risk children had caregivers who were five times more likely to report two or more financial hardships in their households and three times more likely to report psychological distress. Children in the medium-risk category were 30% more likely to be readmitted or return to the emergency room.

NO LINK TO SMARTS

Asthma is not linked to poor scores in school exams, according to researchers at the University of London, who studied data on 12,000 children from the UK's third poorest borough. Researchers analyzed the children's educational results alongside clinical, housing and benefits data to measure the effect of asthma, social adversity and ethnicity. Social adversity was linked to significantly poorer results as were mental health problems and special educational needs.

DRYING OUT

Drying clothes indoors on frames or by draping them on radiators could pose a health risk for those with asthma by creating more molds and dust mites, according to Scottish researchers. It may not save money, either, because while indoor-drying cuts energy used by tumble dryers, people who do it tend to turn up the heat in their homes. The researchers examined the laundry habits of a wide demographic mix and noted that in ill-ventilated rooms, putting wet clothes on radiators can account for a third of the moisture in the room. The researchers added that drying clothes washed with fabric conditioner could also increase the amount of cancer-causing chemicals in the air. Information is from an article by Catharine Paddock, PhD in Medical News Today, copyright Medical News Today.

FAT SURVIVORS

Researchers at the University of Alberta have found that obese patients admitted to hospitals with pneumonia were more likely to survive than those of normal weight. The researchers examined the records of 907 patients with pneumonia who were admitted to six Edmonton hospitals and also had their body mass index recorded. Two-thirds of the patients had severe pneumonia and 79 died in hospital. Of those who died, 12 were underweight, 36 were normal weight, 21 were overweight and 10 were obese. Compared to those who were normal weight, obese patients had lower in-hospital mortality rates. Mortality was 10% for those who were normal weight and 4% for those who were obese, which is a 54% reduction in mortality associated with being obese. The researchers posited that obese patients may have had better survival rates because they had more nutritional reserves.

PROTECTION

Exosomes could potentially protect the fragile lungs of premature babies from serious lung diseases and chronic lung injury caused by inflammation, according to researchers at Boston Children's Hospital. Previously, researchers had found that mesenchymal stem cells could help reduce lung injury and inflammation associated with pulmonary hypertension, but didn't know what was released by the MSCs that generated the anti-inflammatory and protective effects. They came upon exosomes, which many cell types, including MSCs, produce and release as a kind of communication vehicle. The team found that injecting just purified exosomes from MSCs reduced lung inflammation and prevented the occurrence of PH in their animal model. In contrast, neither MSC-conditioned media depleted of exosomes nor exosomes purified from other cell types had any effect on inflammation or PH in the model, indicating that something unique to the MSC-produced exosomes is required for their protective effect.

DESTROYERS

Researchers at Stanford and the University of Bern have learned how a man-made molecule, DARPin E2-79, destroys complexes that induce allergic responses, a discovery that could lead to the development of highly potent, rapidly acting interventions for a host of acute allergic reactions. The new inhibitor disarms IgE antibodies by detaching the antibody from a molecule called FcR. The researchers noted that it would be an incredible intervention if you could rapidly disconnect IgE antibodies in the midst of an acute allergic response. Currently available treatment using omalizumab can block new interactions between IgE and FcR, but it is not designed to pry the molecules apart once they've formed a bond on the surface of a mast cell. The research team discovered that an engineered protein inhibitor called DARPin E2-79 stripped IgE from the mast cell receptor. Using this inhibitor, an interaction that normally lasts for hours or days in terms of its stability was stripped off in a matter of seconds.

The researchers found that E2-79 hastens the separation of the two molecules by taking advantage of a moment of weakness in the relationship between them. Normally this brief looseness isn't enough to separate the couple, but E2-79 can swoop into the small space between them, effectively driving the couple apart.

NOT THEIR FAULT

Muscle cells on the outside of blood vessels have been wrongly accused of instigating lung disease, according to a study published in the European Respiratory Journal. While these muscle cells are responsible for constricting or dilating the blood vessels, they are not responsible for sensing the amount of oxygen that gets to the lungs, a message that instead comes from the endothelial cells that line the blood vessels.

THE NOSE KNOWS

An electronic nose, used to detect the presence of molecules in the breath of a patient, could be used to diagnose obstructive sleep apnea. Electronic nose devices have been shown to distinguish between a number of diseases by analyzing the pattern of volatile organic compounds in breath samples. Researchers analyzed the breath of 40 sleep apnea patients and 20 healthy controls. The study also aimed to assess whether the electronic nose could detect the effects CPAP. The researchers provided questionnaires and sleep examinations and collected throat washings from patients to measure any improvement in their condition following treatment with CPAP, then used a statistical analysis model to calculate the accuracy of the electronic nose. The results found that the electronic nose could effectively diagnose sleep apnea, which was detected with a sensitivity of 93%.

INDOOR AIR CONTAMINATION

In the spring issue of 2012 Pulmonary Fibrosis Foundation "Breathe Bulletin" a doctor states: "Not understanding why this disease occurs is the most frustrating aspect because every single visit someone asks why did this happen to me? In the lab we ask the same question." Thomas Quinlan of Littleton, CO has been researching the effects of low level indoor air contaminants since 1996. His emphasis has been on long term exposure of contaminated low level carbon monoxide (CO) effects on the respiratory system. Quinlan has personally been in over 50,000 homes with thousands of hours of research and testing for over 20 years.

Function of the Lungs – The primary function of a lung is to facilitate the transfer of molecular oxygen from the atmosphere to the systematic circulation. The respiratory system brings the ambient air that we breathe into close proximity with the systematic circulation. This allows the lungs to accomplish their primary function to exchange carbon dioxide for oxygen, central for the maintenance of the aerobic metabolism. The average adult human breathes in 9000-15000 liters of air daily. This exposes the lungs to a variety of potential injurious environmental agents, which can cause oxidative stress.

What Makes Carbon Monoxide Dangerous – Unsafe contaminated low levels of CO can put a person in harm's way due to the fact that CO is 300 times more attracted to our blood cells than oxygen. CO can travel in the blood plasma and cause cell damage without ever binding to the hemoglobin. Numerous studies have shown that CO in its purest form probably has no damaging effect to our respiratory system. However the CO present in the home is not pure. This contaminated form can cause myriad diseases such as Idiopathic Pulmonary Fibrosis (IPF), Sarcoidosis, and countless others.

Probable Effects – The presence of low level CO subjects the lungs to be slowly compromised over the years, causing small areas of inflammation. Most lung cancer starts in the cells lining the lung airways, which could be a result of acid being introduced into the lining through contaminated CO. The research and testing Quinlan has conducted have shown that CO has five trace elements that contaminate the indoor air environment of the home.

Trace Contaminants of Carbon Monoxide Acids in our Homes – • HCl = a highly corrosive, strong mineral acid. Potential to damage respiratory organs, eyes, and intestines. • H2SO4 = a strong acid that may cause etching and erosion of teeth, asthmatic children appear to be the critically sensitive human population for exposure to H2SO4. • HNO3 = very hazardous in case of skin contact (corrosive, irritant, penetrator), of eye contact (irritant, corrosive), of ingestion. Slightly hazardous in case of inhalation. • NaNO2 = nitrites used for killing rodents follow strict use protocols that limit exposure to fumes. Commercial products in the home may be a concern for adolescents. • HF = because of its ability to penetrate tissue, poisoning can occur readily through expose to skin or eyes, or when inhaled or swallowed. Symptoms of exposure may not be immediately evident due to interference with nerve function. [Sources: Purven Inc, Antioxidants & Redox Signaling, American Lung Association, Engineering Toolbox, American Thoracic Society, Health Protection Agency, Canadian Centre for Occupational Health and Safety, Fisher Scientific, Chem One Ltd. This article was provided by Purven, Inc.]

PRODUCTS

PULSE

Covidien announced that OhioHealth, which owns or is affiliated with 17 hospitals, has converted to Nellcor pulse oximetry and the OxiNet remote respiratory monitoring system. The nationally recognized healthcare organization is further converting to multi-parameter modules with imbedded Nellcor OxiMax digital oximetry technology. The OxiNet remote monitoring system enables continuous monitoring of patients' oxygen saturation levels at a central station. Earlier alerts to adverse events enable clinicians to act faster, greatly enhancing patient safety. OhioHealth joins 400 other hospitals in the United States that have implemented the OxiNet remote monitoring system. There are currently more than 26,000 monitored beds on OxiNet systems in the country. Contact covidien.com.

NEW TESTS

Epocal, Inc announced that the FDA has cleared the company's creatinine and chloride tests, which are performed on the epoc Blood Analysis System, for the US market. Creatinine and chloride will be added to the epoc BGEM Test Card. The test card currently includes in vitro diagnostics for pH, partial pressure of oxygen, partial pressure of carbon dioxide, sodium, potassium, ionized calcium, hematocrit, glucose, and lactate. With the epoc Blood Analysis System, creatinine can be measured at the patient's bedside to screen for and detect early kidney damage as well as monitor kidney status. In conjunction with other parameters, it can also help to inform treatment decisions related to renal function, such as the use

of renal replacement therapy or the identification of potentially nephrotoxic agents. Additionally, many critically-ill patients suffer from acid-base imbalances, especially those receiving intravenous treatment. Chloride measurements can help clinicians assess acid-base imbalances and make adjustments where necessary. The epoc Blood Analysis System delivers a full menu of results, including creatinine and chloride, in less than a minute on a PDA. Results can be easily integrated into any Laboratory Information System (LIS), and the system's broad menu will benefit clinical service lines that routinely perform blood analysis, including the emergency department, radiology, cardiac catheterization labs, out-patient centers, and critical care units. The epoc System is marketed Alere. Contact epocal.com or alere.com.

SALES MANAGER

AG Industries announced the addition of Jo Anna Dvorak to its team as the National Sales Manager and Clinical Director Homecare Division. Formerly of Tiara Medical Systems/ CareFusion and an expert in the homecare market, Jo Anna brings over 20 years of homecare and clinical experience to AG and her new role. As director of clinical development, account management and sales Jo Anna will be working closely with providers to develop new products and programs at AG. Additionally Tim Austin will assume the expanded role of Executive Vice President of Business Development; as such he will continue his focus on National Homecare Accounts and AG's expanding OEM business. AG Industries is a vertically integrated manufacturer of filters, filtration systems and medical devices for the medical industry. Contact agindustries.com.

NEW DATA

Bayer HealthCare announced that data on its investigational pulmonary hypertension compound riociguat (BAY 63-2521) was presented in a scientific forum at the American College of Chest Physicians (ACCP) annual meeting. Data from two pivotal, Phase III trials researching riociguat in patients with for pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH) were presented as late-breaking abstracts in oral presentation sessions. The studies were: Riociguat for the treatment of inoperable chronic thromboembolic pulmonary hypertension: a randomized, double-blind, placebo-controlled study (CHEST-1), and Riociguat for the treatment of pulmonary arterial hypertension: a randomized, double-blind, placebo-controlled study (PATENT-1). Riociguat (BAY 63-2521), discovered and developed at the Bayer research laboratories, is an investigational oral soluble guanylate cyclase (sGC) stimulator. It is currently being developed for its potential to treat patients with various types of PH. Riociguat is an investigational agent and is not approved by the FDA, EMA or other health authorities. Contact bayer.com.

BETTER BREATHING

Boehringer Ingelheim Pharmaceuticals, Inc and Pfizer Inc, in partnership with author and life coach, Gail Blanke, announced the launch of Better Breathing is Possible, an educational campaign designed to teach people with COPD steps to help manage their COPD and why this is beneficial. The campaign launch coincided with the World COPD Day observance, which raised awareness among the COPD community that "It's Not Too Late," the year's theme. Similarly, Better Breathing is Possible aims to encourage people living with COPD that a combination of lifestyle changes and medication can help people breathe better. Better Breathing is Possible features a new four-part video series, which can be found on YouTube.com/COPDConversations, that shows people with COPD steps they can take to help manage their COPD. The videos also provide examples of lifestyle changes and information about a prescription treatment option that may be helpful under a physician's supervision. Among the steps the campaign promulgates is taking a maintenance medication, like SPIRIVA HandiHaler, that can help manage COPD. SPIRIVA HandiHaler (tiotropium bromide inhalation powder) is a once-daily bronchodilator indicated for both the maintenance treatment of bronchospasm (narrowing of the airways) associated with COPD and to reduce exacerbations. SPIRIVA HandiHaler was the first FDA-approved long-acting inhaled muscarinic antagonist (LAMA) and can be prescribed to patients with COPD. SPIRIVA HandiHaler provides significant improvement in lung function and increased airflow for 24-hours, day and night, with convenient once-daily dosing. SPIRIVA does not replace a rescue inhaler and patients may need both long-acting and rescue medicines to help manage their COPD. Contact spiriva.com.

STRATEGIES AND SOLUTIONS

CareFusion subject matter experts and select hospital executives and clinical experts discussed respiratory care strategies and solutions at the AARC Conference. CareFusion and select clinical experts from various hospitals presented targeted respiratory solutions to help health care professionals enhance patient care, clinical workflow and operational efficiencies for patients with compromised systems. Key speaking sessions included: Ventilator-Associated Conditions/Complications (VAC), presented by Dr Carlos Nunez, Chief Medical Officer, CareFusion; Delivering oxygen therapy in today's changing healthcare environment, presented by Mike Hewitt, RRT-NPS, FAARC, FCCM; Current perspectives on respiratory devices related skin breakdown: causes and consequences, presented by Marty Visscher, PhD, Cincinnati Children's Hospital; and an overview of customer interoperability experience using the CareFusion Knowledge Portal and Respiratory Documentation Application, presented by Michael Muth MBA, RRT, RCP, Good Samaritan Hospital. CareFusion develops Alaris infusion pumps, Pyxis automated dispensing and patient identification systems, Rowa automation solutions, AVEA, AirLife and LTV series ventilation and respiratory products, ChloraPrep skin prep products, V. Mueller surgical instruments, and an extensive line of products that support interventional medicine. Contact carefusion.com.

PATIENT SAFETY

Patients on the general care floor are 5 times more likely to experience avoidable in-hospital cardiopulmonary arrest (IHCA) than those in ICU settings, accounting for almost 2/3 of hospital deaths. This was one of the patient safety issues Covidien brought to the forefront at the AARC Congress. Covidien also discussed new abstract findings pertaining to patient safety during non-invasive and invasive ventilation and its PB840 vent. The abstracts focused specifically on patient-ventilator synchrony in the presence of system leaks. Covidien also debuted its expanded patient monitoring portfolio, which now features capnography. Covidien also featured seminars and abstract presentations on PAV vs PSV, VAP to VAE, ventilator synchrony in the presence of system leaks, and a comparison of leak compensation in acute care ventilators during invasive and noninvasive ventilation. At its booth, the company featured its Oridion Capnostream 20 Patient Monitor, Oridion Microcap Plus Patient Monitor, and Nellcor Respiration Rate Software. Contact covidien.com.

FREEDOM

The G5 FREEDOM System from General Physiotherapy combines Directional-Stroking Action with the most recent technological advances for an effective, convenient, comfortable, user-friendly, and hands-free airway clearance treatment. High Frequency Chest Wall Percussion (HFCWP), oscillation in the 15-30 cycle per second range, is produced over specific lung segments to mechanically dislodge and mobilize mucus toward larger airways for clearance. The G5 FREEDOM System eliminates the need for manually administered CPT and all treatments are of the same, consistent high quality. The G5 FREEDOM System consists of a durable synthetic vest with eight Directional-stroking Percussion Pods positioned over major lung segments both topical and apical. The Percussion Pods generate High Frequency Chest Wall Percussion (HFCWP) on specific lung segments to be treated. Straps with adjustable cinches are attached to the device and positioned over the Percussion Pods so that the patient can tighten the vest for optimal HFCWP. The straps are high strength woven material to comfortably conform to various body shapes while applying optimal pressure. A user-friendly electronic control module is connected to the G5 FREEDOM System that enables the user to set the treatment time, choose a treatment program, vary the cycle per second range for each Percussion Pod, and start, pause, and stop the treatment. Featuring Lung-Select technology, patients or therapists can select any combination of the 1-8 Percussion Pods to activate, specifying the oscillation or cycle per second range for each individual Pod. User-Defined treatment settings can be saved for easy, 1 button selection for future treatment sessions. The variable oscillation or cycle per second range capabilities of the individual Pods is important because the lower cycle per second range dislodges thick, tenacious secretions from the lung walls while the higher frequency liquefies and mobilizes (directs) the secretions toward the trachea for removal. This tri-fold process (dislodging, liquefying, and mobilizing) moves mucus toward the larger airways where it can be cleared by coughing or suctioning. A custom designed power pack (step-down transformer) enables the product to be powered by a 110-240 volt outlet and steps the power down to 12 volts; hence, it can be used anywhere in the world. The G5 FREEDOM System does not require special skills or techniques to administer quality airway clearance. Most patients are able to perform this therapy on their own. Contact g5.com.

GO SHOPPING

Dräger's e-commerce website offers instant online access to an extensive range of clinical accessories and consumables. This secure, interactive Web facility enables customers to purchase products 24 hours a day, 7 days a week from an online catalog of more than 600 products that support a variety of Dräger medical products, including anesthesia, neonatal and respiratory care devices. DrägerShop helps reduce the limitations that normal office hours impose on purchasing departments in clinical environments that operate 24/7. The shop gives customers the flexibility to tailor solutions to their facilities' individual processes. Product catalogs are quick and easy to use. Customers can browse the entire catalog or use the extended search capabilities that assist with product selection. For those who require assistance or want more information, the site contains convenient product-specific inquiry forms and direct email links, as well as telephone, fax and instant message chat assistance. DrägerShop provides transparency into pricing and ordering. Once registered on the website, customers can see individual prices, as well as any specific GPO discounts that may apply. Delivery dates and tracking systems are an integral part of the purchasing process. Electronic invoicing is also available on request. The system has been optimized for use on small screens for electronic notepads and smart phones. The site also offers a product rating feature where customers can provide comments and feedback on individual products. Contact draeger.com.

INSTALLATION

Covidien announced the company's largest capnography installation connected to a centralized remote monitoring system at the Medical Center of Central Georgia (MCCG). MCCG's new 7,583 square foot Logistics Hub now provides connectivity to Nellcor N-85 pulse oximeters with capnography. This allows MCCG's clinicians to continuously monitor patients' ventilation and oxygen saturation levels, through EtCO2 and SpO2, even when the clinician is not at the bedside. The OxiNet III remote monitoring system and Nellcor N-85 monitors with Oridion Microstream capnography address the recommendations put forth by the American Society of Anesthesiologists, Anesthesia Patient Safety Foundation, the Institute for Safe Medication Practices and The Joint Commission calling for continuous monitoring of ventilation of hospitalized patients receiving opioids postoperatively. The OxiNet III remote respiratory monitoring solution provides customizable systems that effectively monitor any floor in a facility. Relaying data from the bedside to a central station like MCCG's Logistics Hub creates a remote respiratory monitoring system. If a patient's EtCO2 or SpO2 levels dips below the accepted level, clinicians are alerted via visible and audible alarms at the central station. Contact covidien.com.

TAKE A BREATH

Dräger announced the launch of an innovative new interactive community for respiratory care professionals. Called "A Breath Ahead," the portal provides continuing respiratory care education, along with the ability to interact with peers, academics, researchers and clinicians. Respiratory care professionals can participate in forums, polls, and discussion groups, exchanging information and ideas with peers and experts in the field. Participants can earn complimentary Continuing Respiratory Care Education (CRCE) credits online through the educational component of the portal. Developed in collaboration with leading clinicians and educators, the "A Breath Ahead" website enables respiratory care professionals to tap into the expertise of clinical experts and opinion leaders to discuss topics such as protective lung strategies, evidence-based best practices, neonatal/pediatric issues, and other relevant topics. Clinicians can earn complimentary CRCE credits online, without the expense and time required to attend classroom educational meetings. Providing a forward-looking approach to clinical education, this unique portal is interactive and provides valuable information and education at the convenience of the clinician's schedule. "A Breath Ahead" includes educational webinars, interviews with key opinion leaders, case studies, and FAQs. The interactive portal also provides a forum for respiratory professionals to interact with peers and opinion leaders. Participants can also take part in polls and surveys on topics of interest and concern for the respiratory care profession. Contact draeger.com/abreathahead.

CLEARED

Hamilton Medical has announced that it has received 510(k) clearance from the FDA for HAMILTON C3 Ventilation System. The HAMILTON C3 has been designed to ventilate adult and

pediatric patients in the critical care environments. The C3 incorporates a 12.1 inch high resolution wide touch-screen with single knob operation that vividly displays Hamilton's unique ventilation cockpit. The Dynamic Lung and Vent Status widow assist the clinician to immediately identify the patient's lung condition and assess the weaning process. The HAMILTON C3 offers a high-performance, ultra quiet turbine and hot swappable batteries and gives you maximum independence and flexibility to accompany your patient everywhere. The C3 supports your patients in all conventional and pressure-controlled modes, and provides a single source of invasive and non-invasive ventilation. Additional options include an integrated nebulizer, nCPAP-PS, and optional volumetric mainstream or side-stream capnography. Contact hamilton-medical.com.

GRANTED

Ikaria, Inc announced that the Center for Devices and Radiological Health (CDRH) branch of the FDA has granted 510(k) clearance for a software upgrade to enable connectivity of the INOMAX DSIR drug delivery system with hospital health information systems. This connectivity allows data regarding INOMAX usage to be transmitted directly to electronic medical records where it can easily be viewed at computer stations to reduce charting time, avoid transcription errors, and improve billing efficiency. This feature, which is aligned with the effort by major health systems to automate and capture patient data, also facilitates reimbursement for INOMAX usage. Additionally, the FDA has cleared three new, non-invasive respiratory care devices for use with the INOMAX DS and DSIR drug-delivery systems, the Fisher & Paykel Healthcare Infant Circuit Nasal Cannula and Optiflow Breathing Circuit and the A-Plus Medical Babi Plus Bubble CPAP. Sixty ventilators, anesthesia systems and other respiratory care devices have now been validated for use with Ikaria's INOMAX DS and DSIR drug-delivery systems. The INOMAX DS and INOMAX DSIR are proprietary drug-delivery systems that deliver INOMAX (nitric oxide) for inhalation, the only drug approved by the FDA to treat hypoxic respiratory failure (HRF) associated with pulmonary hypertension in term and near-term infants greater than 34 weeks gestational age. Contact inomax.com.

INTELLIGENT

Hamilton Medical's INTELLiVENT-ASV is the world's first complete closed-loop ventilation solution that offers automated adjustment of oxygenation and ventilation. With Intellivent's Quick Wean feature clinicians will have the ability to monitor and trend the complete weaning process… The new HAMILTON-MR1 is a fully featured ICU ventilator providing respiratory support to adult and pediatric critical care patients, even in the direct vicinity of an MRI scanner. With its compact design and its built-in turbine, the HAMILTON-MR1 provides maximum flexibility so that you can accompany your patient from the ICU to the MR environment. The integrated magnetometer—TeslaSpy—helps you navigate through the magnetic field and allows you to position the ventilator safely. The HAMILTON-MR1 is perfectly shielded to withstand a magnetic field of 50mT, corresponding to a distance of less than 1m from a 3T MRI scanner. Contact hamilton-medical.com.

GET SMART

Hamilton Medical has launched its E-Learning Module. To improve the quality, efficiency and coverage of the end-customer training, Hamilton Medical introduces an e-learning program called "Hamilton Medical College." It is a special website with learning modules on Hamilton Medical ventilators, advanced features and/or basic knowledge. After completion of the registration, you have no charge access to the website. Simply visit http://college.hamilton-medical.com/ and follow the steps. After successfully passing each learning module, you will receive your competency through the Hamilton College site. Hamilton Medical College enables everyone to learn anywhere, anytime.

AWARDED

The Industrial Designers Society of America (IDSA) is the world's oldest and largest, member-driven society for product design, industrial design, interaction design, human factors, ergonomics, design research, design management, universal design and related design fields. IDSA organizes the renowned International Design Excellence Award (IDEA) competition annually, where, this year, Hamilton Medical participated with the Hamilton T1 and was awarded Bronze. The design of the Hamilton T1 is based on in-depth market research regarding the needs and requirements of the customers. What emerged was the caregivers' emphasis on intuitive, fairly simple equipment that is rugged, reliable and offers great flexibility in use. The T1 fulfills the basic needs to elevate the user experience, simplify training, and ensure life-saving performance in fast-paced, stressful situations. On-site customer analysis also revealed the need for a minimalist footprint to get the ventilator where it was needed quickly and easily. Throughout development, Hamilton has also been mindful of cost considerations and the economic realities of its customers. Contact hamilton-medical.com.

GOOD TO GO

Impact Instrumentation, Inc has received FDA 510(k) clearance to market its new MRI conditional ventilator, the Eagle II MR. The Eagle II MR is a full- featured portable ventilator for patients ≥5 kg that can be used in MRI suites using 3 Tesla magnets or less. The Eagle II MR uses Impact's low dead space MRI patient circuits and the ventilator can be placed approximately 6.6 ft (~2m) from the magnet's bore opening. An MRI conditional roll stand with 5 locking wheels is available. The Eagle II MR weighs less than 10 lbs. Features include: AC, SIMV and CPAP/Bi-Level, volume and pressure targeted breaths, and both invasive and noninvasive ventilation modes. Additional features include: integral compressor and air/oxygen mixer, automatic leak compensation to help mitigate mask leaks and improve patient comfort, pressure support to minimize the patient's work of breathing and Smart-Help to assist with alarm resolution. The energy-efficient Eagle II MR operates for 10 hours between battery recharges and recharges in two hours. The Eagle II MR is manufactured in New Jersey by Impact Instrumentation, Inc, a medical device developer and manufacturer of respiratory products and measuring instrumentation. Contact impactii.com.

BEST

ImThera Medical, Inc announced that it has been named winner of the Gold Electrode Award in the Best New Product category for its aura6000 THN Sleep Therapy System, a system for the treatment of obstructive sleep apnea (OSA). The Gold Electrode Award is presented at the annual Neurotech Leaders Forum to recognize products which experts believe to have the greatest potential to impact on the neuroscience industry. The aura6000 was selected by editors from Neurotech Reports for its proprietary targeted hypoglossal neurostimulation (THN) sleep therapy. The system represents a novel treatment alternative to conventional continuous positive airway pressure (CPAP) for patients suffering from OSA. Unlike CPAP which requires

patients to use cumbersome masks and tubes while they sleep, the aura6000 is surgically implanted completely under the skin, so patients can sleep untethered. The aura6000 is not for sale in the US. Contact imtheramedical.com.

GROUNDBREAKING

Roche Diagnostics broke ground on the company's new Learning and Development Center. The center is the first element of a $300 million site transformation investment. The city of Indianapolis and the Indiana Economic Development Corporation offered Roche tax abatements, tax credits and training grants to support Roche's investment. The capital investments will support the company's growing diagnostics and diabetes care businesses. The new Learning and Development Center will host the training of more than 1,500 customers from across the nation each year. The center will employ a distinct architectural style consistent with the company's European heritage. Contact roche.com.

SNORE NO MORE

Ventus Medical made its newly introduced Theravent Snore Therapy available in a free 14-night trial for the 45 million people in the US who snore. Theravent is for snorers who do not have obstructive sleep apnea, but whose snoring reduces their sleep quality and that of their bed partner. Theravent is a disposable nightly snoring device that is FDA-cleared to reduce or eliminate snoring. It has been proven to reduce snoring in the separate clinical studies and is available without a prescription. On average, successful Theravent users reduced snoring by 76%, as measured using a decibel meter worn on the forehead. Theravent uses the same patented MicroValve Technology that was previously only available with a prescription. During inhalation, the MicroValves open, allowing nearly unobstructed airflow. During exhalation, the MicroValves partially close, which increases expiratory pressure and keeps the airway open, preventing snoring. Theravent received FDA clearance in June of 2012. Theravent is not intended to treat obstructive sleep apnea. Contact theravent.com.

INTEGRATION

Covidien announced the launch of its Nellcor Multi-Functional Respiratory Printed Circuit Board Assembly (MFR PCBA) for integration with leading patient monitor platforms. Covidien OEM partners, for the first time, can incorporate the complete Nellcor suite of pulse oximetry-based blood oxygenation (SpO2), pulse rate and respiration rate technologies into their existing patient monitoring systems, enhancing patient care in a growing number of hospitals. More specifically, through these integrations, hospitals can upgrade from their existing monitors to MFR PCBA- supported monitors that measure through a single sensor SpO2, pulse rate and respiration rate – three vital signs that can provide early warning of dangerous respiratory complications, enabling clinicians to detect and address serious health threats sooner. Clinicians also have expanded access to SatSeconds SpO2 alarm management and the Saturation Pattern Detection feature that alerts clinicians to possible significant repetitive reductions in airflow. The Nellcor MFR PCBA is now available for monitor integrations via Covidien's global network of OEM account directors. Contact coviden.com.

PRACTICAL

Illuminations Webinar Series recently presented: A Practical Road Map for EP23-A Implementation at the Point-of-Care, with Sharon Ehrmeyer, PhD, MT (ASCP) Professor, Pathology and Laboratory Medicine, and Director, Medical Technology University of Wisconsin School of Medicine and Public Health, Madison, WI. While several recent conferences and articles have focused on articulating the objectives and scope of the EP23-A guidelines, Dr Ehrmeyer, an expert in quality management, provided practical implementation recommendations that go beyond published workbooks on EP23-A. She offered strategies that leverage current practices and technologies as a basis for initiating a POC risk-based quality management program. Additionally, Dr Ehrmeyer provided an overview of the objectives and the role of risk management in quality control planning, including a review of existing principles such as EQC. Finally, Dr Ehrmeyer illustrated how evaluating and implementing a quality control plan, based on risk management, improves efficiency and ensures optimal patient care. For information about Instrumentation Laboratory webinars, contact ilus.com/illuminations.

CAN'T METH WITH IT

Acura Pharmaceuticals, Inc announced the launch of Nexafed [pseudoephedrine hydrochloride (HCl)], a 30 mg immediate-release next generation pseudoephedrine product, combining effective nasal-congestion relief with a unique technology that disrupts the conversion of pseudoephedrine into methamphetamine. Nexafed delivers the same efficacy as leading pseudoephedrine products. In a clinical study Nexafed was shown to meet FDA guidelines for bioequivalence when compared to the leading national brand product. Unlike other cold and allergy pseudoephedrine products, Nexafed is the only medicine that utilizes Acura's Impede technology that disrupts the extraction and conversion of pseudoephedrine to methamphetamine. If abusers try to extract the pseudoephedrine out of Nexafed to make methamphetamine, the inactive ingredients in the polymer matrix will form a thick gel to block that extraction and disrupt conversion of pseudoephedrine to methamphetamine. Contact acupharm.com.

HEATED

Fisher & Paykel Healthcare Inc, announced the US release of next generation Infant Evaqua 2 heated breathing circuits and the Optiflow Junior System. The new Infant Evaqua 2 heated breathing circuit uses MicroCell Technology to further minimize expiratory tube mobile condensate, while also withstanding the rigors of the critical care environment. The new Optiflow Junior System combines revolutionary cannula designed for the delicate anatomical features of neonatal to pediatric patients, with new breathing circuit technology that significantly reduces mobile condensate while meeting flow requirements up to 25 L/min. Contact fphcare.com.

SPOTLIGHT ON AEROSOL DELIVERY

CONCURRENT DELIVERY

Have you ever been faced with a difficult situation where you need to remove an oxygen mask to facilitate a nebulizer or MDI treatment? During an acute asthma attack, a patient may be given oxygen or heliox in combination with a nebulizer treatment. The challenge of this treatment strategy is the lack of a device that allows for the simultaneous delivery of medical gases and aerosolized medication. The Neb-U-Mask from Teleflex has been designed to alleviate such challenges. It is a device that allows for the concurrent delivery of aerosolized medications and high concentrations of oxygen or heliox. The system is composed of a wye design featuring a nebulizer

connection and MDI adaptor, a high concentration mask, and a 750ml gas reservoir bag. Neb-U-Mask is available in both adult and pediatric versions, and is packaged with a Micro Mist nebulizer and colored gas supply tubing to facilitate ease of use. The device nebulizes at angles up to 90° and features a swivel connector, allowing the system to be used in a manner that is most comfortable for the patient. The Neb-U-Mask advances patient care and optimizes caregiver efficiency by allowing for an effective treatment strategy in emergency situations. Contact teleflex.com.

PERCUSSIVE

The new improved next generation PercussiveNEB device is VORTRAN's high frequency intrapulmonary percussive nebulizer. It offers unique single patient, multiple use, high frequency, intrapulmonary percussive treatments. The PercussiveNEB is a safe and effective method of airway clearance. It is easy to use and preferred by cystic fibrosis patients. In a study for the treatment of atelectasis in post-operative cardiac surgery patients, the PercussiveNEB is suggested to be a more effective and efficient use of departmental resources than traditional bronchial hygiene procedures. Improvements in ease of use, durability, dependability and performance attributes have resulted in a device that is user friendly, reliable, and adjustable to patient needs. The pressure dial on the PercussiveNEB allows users to adjust pressure range and is easy to operate within the source flow range. The PercussiveNEB is designed to oscillate at higher frequencies of 11 to 30 Hz (about 660 to 1800 cycles per minute) to mobilize mucus from the lungs in patients with retained secretions. Contact vortran.com.

GOOD CHOICE

Inova Labs has introduced its LifeChoice Activox Portable Oxygen Concentrator. Weighing 4.83 lbs and offering up to 12 hours of internal battery life at 1 LPMeq, the LifeChoice Activox POC empowers patients with true freedom and mobility. The device provides a constant source of oxygen for patients requiring up to 3 LPMeq and features Auto Mode Technology which automatically adjusts patient therapy based on oxygen demand, maintaining saturation day and night. With the power of PULSE-WAVE Technology, oxygen is delivered continuously during inspiration and side effects are minimized. The LifeChoice Activox POC is travel ready — FAA-approved and certified for up to 10,000 feet for in-flight use. As a non-delivery, service-free oxygen therapy, reimbursed by Medicare and most private insurance plans, it is the ideal oxygen therapy for the active patient. Contact inovalabs.com.

SUPERIOR CARE

An easy to use nebulizer, which delivers superior patient care, the acclaimed Aeroneb Solo nebulizer delivers silent drug delivery for infants through adults. Using the patented vibrating mesh nebulization technology the Aeroneb Solo creates a fine particle, low velocity aerosol optimized for deep lung deposition. Aerosolizing solutions, suspensions, proteins and peptides the Aeroneb Solo maintains drug integrity as it does not heat, degrade or shear medications. The Aerogen nebulizer platform delivers a winning combination to pharmacists, respiratory therapists and patients alike. Pharmacists benefit from reduced costs as a result of more efficient medication delivery, RTs benefit through treatment efficacy and helping to reduce secondary infections. Patients ultimately benefit through a better hospital stay experience with silent operation and a system designed for superior care. Convenience is a key factor of this nebulizer, operating for both intermittent and continuous nebulisation. The Aeroneb Solo does not affect ventilator parameters and can be refilled without interrupting ventilation, making its ease of use second to none. The Aeroneb Solo nebulizer creates a new standard of care for nebulization. Contact Aerogen at (866) 423-7643, aerogen.com.

VENTILATION ROUNDTABLE

CareFusion

What ventilation products do you offer?

CareFusion offers a full range of ventilation products and services for a variety of applications in the hospital, transport and military environment, and in the home. We continue to be an industry leader in mechanical ventilation with the AVEA, VELA, EnVe, ReVel, 3100 series HFOV, LTV Series, and Infant Flow nasal CPAP products. In addition to mechanical ventilation products, CareFusion offers a full range of ventilation consumables.

Discuss the latest in your company's R&D efforts.

CareFusion has recently introduced the CareFusion Ventilation System – a suite of software applications comprised of the Respiratory Knowledge Portal and the Respiratory Documentation Application. These applications integrate with the CareFusion AVEA, VELA and EnVe ventilator platforms. This new system approach to ventilator therapy is designed to move respiratory care to a higher level by providing clinical analytics to help enhance patient care and by increasing the efficiency and accuracy of ventilator documentation. Building on the CareFusion Coordination Engine (CCE) used with our infusion devices – Alaris and medication delivery system Pyxis, we offer connectivity and services between ventilation, the CCE and HIT systems: • Respiratory Knowledge Portal: The Respiratory Knowledge Portal is a hosted application that provides clinicians and administrators retrospective analytics on clinical and process variability that is typically unavailable. This information is then used in combination with hospital protocols such as weaning and lung protective strategies which may help hospitals improve patient outcomes and lower the cost of care. • Respiratory Documentation Application: The Respiratory Documentation Application is designed to provide more efficient and accurate documentation of ventilator therapy. It uses a handheld device to implement positive patient identification and collect ventilator data at the point of care. Once collected, this information is then signed off by the clinician and wirelessly transmitted to the hospital EMR. Automating this process significantly improves accuracy and efficiency when compared to a manual entry process.

Discuss your product's applications; ie, hospital, home-care, etc.

From neonate to adults, invasive and noninvasive, transport, military, and from hospital to home, CareFusion has developed a solution of ventilators to cover the broad range of therapeutic modalities across the continuum of care. • Neonatal Care: AVEA, 3100A HFOV, Infant Flow SiPAP; • Pediatric-Adult Care: AVEA, VELA, 3100B HFOV, EnVe, Revel, LTV Series ventilators; • Alternate Care: VELA, EnVe, ReVel, LTV Series ventilators; • Home Care: LTV Series ventilators; • Transport: EnVe, ReVel, LTV Series ventilators; • Ventilation System: Knowledge Portal, Respiratory Documentation Application with AVEA, VELA and EnVe ventilators.

What training and support services do your offer for users of your products?
CareFusion supports the education and training of users in a variety of ways for both existing products and our latest advances. We employ clinical support teams to provide training on the use of CareFusion products as well as support materials both in written and digital format. Educational materials include on-line web training courses, iPad application training tools and clinical applications webinars. CareFusion also offers biomedical training course to CareFusion customers to empower users to support their devices in the long term.

Hamilton Medical

What ventilation products do you offer?
Hamilton Medical manufactures the G5, C3, C2, C1, and T1 ventilator systems. Hamilton was the first company to offer closed-loop mechanical ventilation and operates under the brand Intelligent Ventilation. The Hamilton Medical Intelligent Ventilation Solution includes Adaptive Support Ventilation (ASV), IntelliCuff, and integrated Aerogen nebulizer with the ability to adjust nebulization (insp only, exp only or both) and PV Tool. All Hamilton Medical ventilators have the same graphical user interface to reduce the need for additional training and each Hamilton ventilator is capable of providing invasive and noninvasive ventilation for a broad range of patients. The Hamilton G5, C3 and C2 are full-featured, high-acuity ventilators designed for neonatal, pediatric, and adult applications. The economically priced C1 provides advanced modes of ventilation and offers invasive and noninvasive ventilation for pediatric and adult patients. The Hamilton T1 is a full-featured transport ventilator offering advanced modes of ventilation, invasive or noninvasive ventilation for pediatric and adult applications.

Discuss the latest in your company's R&D efforts.
For 30 years, Hamilton Medical has been focusing exclusively on the field of ventilation and has become specialized in advanced ventilation solutions. In the past year, Hamilton Medical has provided ventilation solutions for intensive care, sub-acute care and emergency transport situations. Currently pending 510(k) clearance is the HAMILTON-MR1, a full featured ICU ventilator providing respiratory support to the adult and pediatric patient in the direct vicinity of an MRI.

Discuss your product's applications; ie, hospital, home-care, etc.
The Hamilton G5, C3 and C2 provide advanced modes of ventilation therapy in neonatal, pediatric and adult patient populations for acute care facilities. The Hamilton C1 is an ultra compact, turbine-powered system offering maximum flexibility in ICU special care areas, cardiac surgery recover rooms, step-down or sub acute care units and long-term care centers, offering invasive and non-invasive options. The Hamilton T1 is designed to ventilate the adult or pediatric ICU patient at any place around the world. It is specifically designed to cover the needs of rescue personnel, health care teams and their patients. The T1 can run from any power source, independent from compressed gas and is approved for the flight environment.

What training and support services do your offer for users of your products?
Hamilton Medical has a dedicated Clinical Support Team to provide training and education to Hamilton customers worldwide. In addition to on-site training, our Clinical Staff is available via our toll-free hotline, (800) 426-6331, 24/7/365 to address clinical questions at any time. Hamilton Medical has also introduced our e-learning program, "Hamilton Medical College." Hamilton College features a special website with learning modules on Hamilton Medical ventilators, advanced features and/or basic knowledge. After completion of the registration, customers have no charge access to the website. Simply visit http://college.hamilton-medical.com/ and follow the steps.

Future developments:
Since 2009, Hamilton Medical has supported the 2009 Vienna Declaration of the ESICM executive committee stressing the importance of quality and safety for patient care. The declaration pledge is to do whatever is necessary to provide a safe ICU environment and to design safer and more efficient devices. Hamilton Medical will continue to provide advanced ventilation solutions such as Adaptive Support Ventilation (ASV), IntelliCuff, IntelliSync, PV Tool Pro and an integrated nebulizer to enhance the safety and performance of all future generations of Hamilton Medical ventilators.

Maximizing Humidification while Minimizing Challenges: A guide to delivering optimal humidification without sacrificing clinician efficiency

Jeri E. Eiserman, MBA, RRT, FAARC

Abstract

Providing proper humidification levels to invasively ventilated patients is of key importance. When the upper airway is bypassed during invasive mechanical ventilation, humidification is necessary to prevent hypothermia, disruption of the airway epithelium, bronchospasm, atelectasis, and airway obstruction.[1] Many patients, particularly those for whom a heat and moisture exchanger (HME) is contraindicated or who require long-term ventilatory support, require the use of a heated humidification system to assure that their requirements are met. With heated humidification, however, comes the challenge of managing the condensation of water that occurs in the ventilator tubing between the humidifier and the patient.

Whether using a conventional ventilator circuit, or one with heated wires, condensation will occur when using heated humidification, and the clinician must address the removal of condensate and any consequences that may result. This paper discusses recommendations related to the use of heated humidification with invasively ventilated patients, the challenges posed by condensation removal from the circuit, and a new product option for addressing these challenges.

Humidification During Mechanical Ventilation

It is generally agreed that providing heat and humidification during invasive ventilation is mandatory and a prevailing standard of care worldwide.[1,2] Two options are available for warming and humidifying the gases delivered to the mechanically ventilated patient: active humidification via a heated humidifier, and passive humidification via a heat and moisture exchanger (HME). HMEs cannot be used in all situations, and are specifically contraindicated in some patients and under some circumstances.[1] Active humidification via a heated humidifier is then recommended to assure that adequate humidification is provided.[1,2]

Heated humidifiers actively increase the heat and water vapor content of inspired gas.[1] These systems heat both a water reservoir and the ventilator gas coming into contact with the water as it moves from the ventilator to the patient. A maximum delivered gas temperature of 37°C and 100% RH (44mg/ H2O/L) at the circuit Y-piece is recommended.[1] If the temperature of the gas cools as it travels through the ventilator circuit, condensation can occur and liquid water will collect in the ventilator tubing. If using conventional, non-heated wire ventilator circuits, the amount of condensation can be significant due to a pronounced temperature drop between the humidifier and the patient. Therefore, heated-wire circuits have increased in popularity, as they maintain the gas temperature throughout the circuit, reducing the amount of condensation build up.

If heated-wire circuits are used, however, condensation will still occur. This can be a result of changing environmental conditions, selected gas temperature and/or heated-wire settings. Therefore, condensation management and an understanding of the clinical consequences of the available options are important considerations when caring for patients receiving active humidification during invasive ventilation.

The Role of the Ventilator Circuit: challenges and consequences

Breathing circuits without heated wires (conventional circuits) have been used with heated-humidifiers for decades, and are still available and used today. When conventional circuits are used, the temperature at the humidifier must often be several degrees higher than the desired patient temperature at the Y-piece to compensate for the gas cooling between the humidifier outlet and patient. As a result, two phenomena occur: the absolute humidity (AH) of the gas leaving the humidifier is higher; and the gas cools significantly between the humidifier and the patient. Both are exacerbated by cold environmental temperatures and lead to large amounts of condensation in the circuit that must be dealt with on an ongoing basis.

Heated wires are frequently used as a means of controlling the amount of condensation in the ventilator circuit. When heated-wire circuits are used, two things occur: 1) the heated humidifier is able to operate at a lower temperature because it does not have to compensate for significant heat loss between the humidifier and the patient; and 2) the amount of cooling that is allowed to occur once the gas leaves the humidifier and traverses to the patient is reduced. However, when using heated-wire circuits it is important to remember that insufficient heat and humidification can occur, resulting in complications if the heated wires are not used properly. As stated in the AARC Clinical Practice Guideline, Humidification During Invasive and Non-Invasive Mechanical Ventilation: 2012, "When using a heated-wire circuit, consideration should be given to the fact that heating the gas between the outlet of the humidifier and the Y-Piece in an effort to control condensation, will decrease the RH of the delivered gas. The magnitude of the decrease

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will be dependent upon the temperature gradient between the humidifier outlet and the patient, and environmental conditions in the immediate patient care area. Decreased RH may result in drying of secretions inside the endotracheal tube, with potential risk of its occlusion."[1]

Therefore, as clinicians strive to ensure adequate absolute and relative humidity levels to patients being invasively ventilated in a variety of environmental settings, some condensation will naturally occur even with heated-wire circuits and must be drained and discarded.

Categorization and Handling of Circuit Condensation

Condensation that collects in the ventilator circuit is considered to be contaminated, and care should be taken to avoid cross-contamination of other patients.[1,3] In addition, because circuit condensation is considered to be infectious waste, it is recommended that strict universal precautions be used when handling it, that it is never drained back into the humidifier reservoir, and that care is taken to avoid accidental drainage of condensate into the patient's airway.[1,2,3,5] For infection control purposes for those patients being transported,[4] the Centers for Disease Control and Prevention recommendations for preventing exposure to tuberculosis and droplet nuclei are to be implemented when the patient is known, or suspected, to be immunosuppressed or have tuberculosis.

The same concerns apply for the caregiver as well, in light of the above. The collection and disposal of circuit condensation is a matter for concern and an issue that clinicians must address daily in the care of invasively ventilated patients that require heated humidification.

Condensation Control Options and Related Concerns

When condensation collects in the ventilator circuit the clinician has two primary options: opening (breaking) the circuit and/or water trap to drain the condensate; or using a "closed-system" approach that does not require breaking the circuit to remove the accumulated condensation.

If the first option is chosen, the following consequences must be dealt with due to opening/breaking the circuit:[1,3]

a. Potential for contamination of the interior of the circuit
b. Potential for caregiver exposure to condensate during ventilator/water trap disconnection or disposal
c. Potential for cross-contamination of other patients
d. Loss of PEEP and/or de-recruitment of the lung

Because of these potential consequences, it is recommended that opening the circuit to drain condensate is to be avoided if possible. The SHEA/IDSA Practice Recommendation Strategies to Prevent Ventilator Associated Pneumonia in Acute Care Hospitals indicates that one strategy to minimize contamination of equipment used to care for patients receiving mechanical ventilation is to remove condensate from ventilator circuits, and to keep the ventilator circuit closed while doing so.[5] The AARC Clinical Practice Guideline, Care of the Ventilator Circuit and Its Relation to Ventilator-Associated Pneumonia states that it makes sense that care should be taken to avoid breaking the ventilator circuit, which could contaminate the interior of the circuit.[3]

It is also recognized that opening the circuit to drain accumulated condensate increases the potential for caregivers to be contaminated during ventilator disconnection. As the AARC Clinical Practice Guideline, Humidification During Invasive and Noninvasive Ventilation: 2012 states, "When disconnected from the patient, some ventilators generate a high flow through the patient circuit that may aerosolize contaminated condensate, putting both the patient and the clinician at risk for nosocomial infection."[1] This can occur if the ventilator cycles while the circuit is open, essentially blowing aerosolized condensate out of the tubing and/or open water trap into the atmosphere or onto surfaces, caregivers or others in the immediate care area.

While caregiver exposure to aerosolized condensation when opening the circuit to drain and dispose of condensate is of concern; care must also be taken to avoid cross contamination of other patients.[3]

A final concern when breaking the circuit to drain condensate is the loss of PEEP to the patient, which can result in hypoxemia, shock and/or de-recruitment of the lung.[4,6,7] The benefits of using PEEP in the treatment of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) and in the prevention of ventilator induced lung injury (VILI) has been reported in the literature.[6,7] It has long been known that an injured lung is at a greater risk for superimposed infection; and the presence of underlying lung injury, especially acute lung injury, imposes a several-fold increase in the incidence of VAP.[7] Ventilator Induced Lung Injury (VILI) is a form of acute lung injury that can occur from repeated opening and closing of atelectatic alveoli in an injured lung, causing a shearing injury.[7] The use of expiratory pressure to prevent alveolar derecruitment can help ameliorate this injury.[7] During positive pressure ventilation cyclical atelectasis may occur due to the repeated application of inspiratory pressure that initially opens (recruits) lung unit, followed by collapse during expiration (derecruitment). An approach to reducing cyclical atelectasis is to maintain alveolar recruitment with PEEP.[7] Ideally, the lung should be recruited with pressure high enough to open recruitable lung and sustained with adequate PEEP after lung recruitment so as to avoid derecruitment.[6] If the benefit is sustained, no additional recruitment maneuvers are needed. However, if PEEP is not maintained after recruitment, as would occur if the ventilator circuit is disconnected to drain condensate, the recruited lung is almost immediately derecruited.[6]

Clearly there are the recognized risks associated with opening the ventilator circuit to drain condensation. However, not draining the circuit frequently in order to reduce these potential risks also has significant consequences. Excessive accumulation of condensate in the circuit can lead to accidental drainage of condensate into the patient's airway and unintentional tracheal lavage. This can happen when the patient is turned or repositioned in the bed. Accumulated condensation, which is considered to be infectious waste, may also accidentally drain back into the humidifier.[1,2]

The Challenge and a Solution

Since the provision of heat and humidity during mechanical ventilation is the recognized standard of care for patients with artificial airways; and since many patients require the humidity levels provided by an active heated humidification system; condensation management will continue to be a critical factor in the care of these patients. Breaking the circuit to drain circuit condensate is accompanied by a host of potential risks to the patient and the caregiver as discussed above. Not draining the circuit when needed to avoid those risks is also fraught with

consequences. Finding a solution that will aid the clinician in efficient condensation management without breaking the circuit will help improve the quality of care and help increase patient and caregiver safety.

The Hudson RCI ISO-Gard Closed Circuit Condensation Management System, when used with the ConchaTherm Neptune Heated Humidifier, allows the clinician to meet the unique humidification needs of every patient, while helping to avoid the risks associated with breaking the circuit to drain condensate.

The ConchaTherm Neptune adjustable Patient Airway Temperature and Gradient Control allow the clinician the ability to adjust absolute and relative humidity based on unique patient, ventilation and environmental conditions. This is in keeping with the AARC Clinical Practice Guideline, Humidification During Invasive and Noninvasive Mechanical Ventilation: 2012, which states that in order to avoid insufficient heat and humidification resulting in complications, the temperature selection should be based on clinical assessment of the patient, rather than pre-set and nonadjustable.[1]

The ISO-Gard Closed Circuit Condensation Management System allows for the collection of condensate in its reservoir, and is offered in an 80 cc capacity for adult applications and a 40 cc capacity for pediatric and infant applications. Measurement markers on the transparent reservoir allow for the monitoring of condensate volumes and humidification trends. The color-coded suction port on the reservoir and suction wand allow for the timely and efficient removal of condensate in the inspiratory and expiratory limb of the circuit without breaking the circuit or disrupting ventilation due to its closed circuit design. The ISO-Gard Closed Circuit Condensation Management System, when used in conjunction with the ConchaTherm Neptune Heated Humidifier, enables the clinician to customize therapy based on ventilator type, humidification needs and environment factors.

Conclusion

Providing heated humidification to patients requiring invasive ventilator support is the acknowledged standard of care. When doing so with an active heated humidification system, condensation is an expected consequence of providing optimal humidity to the patient, regardless of the type of ventilator circuit being used. Condensation collection and disposal, therefore, is required and should be done in a manner that avoids the acknowledged risks associated with breaking the ventilator circuit. The Hudson RCI ISO-Gard Closed Circuit Condensation Management System and ConchaTherm Neptune Heated Humidifier provide just such a solution.

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Oxygen Masks: Past, Present and Future

Edward Reesor, RRT

I recently attended the AARC conference in New Orleans; the world's largest gathering of respiratory therapists and exhibition of the most innovative equipment available. Despite the constant growth of modern technology, most if not all respiratory therapists continue to rely on conventional oxygen masks for a significant part of their role in healthcare. The following article discusses the evolution of conventional oxygen masks and how they have changed in form and function over the years.

Identified by Joseph Priestly in 1774, the use of oxygen as a therapeutic agent was first described in 1857 when it was observed to decrease shortness of breath in tuberculosis patients. An increasing number of scientific studies using larger patient populations followed, however the application was in smaller, time-separated doses instead of continuous administration. It would be an additional 60 years before oxygen via continuous administration would become common practice.

In 1922, J.S. Haldane first described the concept of administering oxygen using a reservoir bag attached to an anesthesia mask. He challenged the existing practice of simply adding oxygen to a patient's room by administering oxygen therapy as close to the patient's mouth and nose as possible. This system resulted in immediate and noticeable improvement in patient conditions. In 1938, Mayo Clinic physicians Doctors Boothby, Lovelace and Bulbulian developed the first reliable interface for oxygen delivery to an individual (Figure 1). Although the BLB Mask was designed for high altitude flight crews, its application to healthcare was readily apparent. The initial design of the BLB Mask was that of a true rebreather where the patient would exhale into the reservoir, capturing the first 150 mL of the exhaled breath from the anatomic deadspace; gas that had not undergone gas exchange. This gas would then be inhaled, allowing gas delivery optimization in environments where resources were extremely limited.

Today, oxygen delivery is performed using a variety of devices in the form of cannulae, catheters and masks. The traditional delivery method for low level oxygen concentrations is the nasal cannula using 2-6 Lpm oxygen flow. It is generally believed that gas delivery to the patient is between 24-44% as it relies on the use of the oropharynx as a natural reservoir. For patients requiring higher levels of oxygen, masks are used although high flow cannulae have emerged on the market in recent years.

Figure 1. BLB Oxygen Mask

The most common oxygen masks used in North American healthcare today are the venturi mask, the simple/or medium concentration mask, the aerosol mask for medications and the non-rebreather mask. Partial rebreather masks are often confused with non-rebreather masks but with the common misperception that the term "rebreather" refers to the ability to intentionally entrain ambient air through the exhalation ports. While many assume that the partial rebreather mask offers lower oxygen concentrations, its design is closer to the original BLB Mask such that it delivers maximum oxygen concentrations by capturing exhaled breaths for subsequent inhalation.

Accuracy of Delivered FiO2

The variations of the original BLB Mask are perceived to offer patients much higher oxygen concentrations than nasal cannula. The sole purpose of the conventional non-rebreather mask is to maximize oxygen delivery to spontaneously breathing patients. In the original design of non-rebreather masks, the exhalation

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Figure 2. Conventional Non-rebreather Oxygen Mask (Note unvalved port on left for antisuffocation protection and one way valve covering port on right.)

Figure 3. Side port of Non-rebreather mask. Each hole is 2 mm in diameter with an area of 3.14 mm2. Eight holes create an opening greater than 25 mm2.

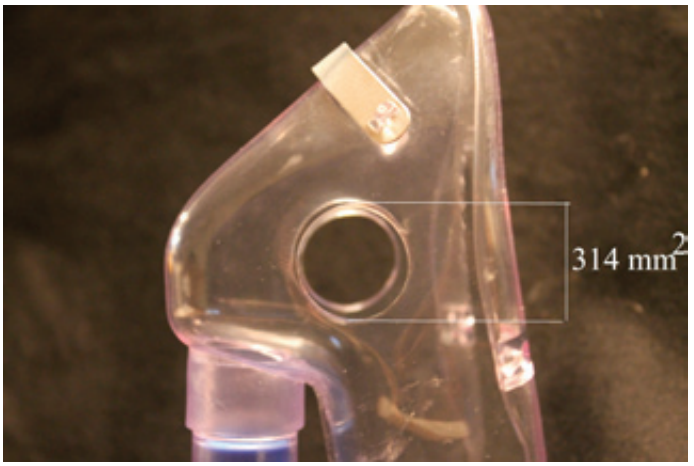

Figure 4. Area of side port. There are two holes, each with an open area of 314 mm2.

ports are completely valved to provide one-way gas flow out of the mask. Antisuffocation protection often requires that one of the two valves be removed in the event that source gas failure occurs (Figure 2).

The extent that ambient air can be inhaled through these open side ports is grossly underestimated and patients receiving oxygen therapy can receive dramatically lower oxygen concentrations than intended.

The associated hazards of unrecognized sub-therapeutic gas delivery include the assumption of a worse cardiopulmonary shunt than actually exists. This can lead to further deterioration of the patient's condition, moving to more advanced therapies such as non-invasive positive pressure ventilation, endotracheal intubation or premature death. These approaches carry significant risk to the patient while incurring additional and unnecessary costs and increased length of hospital stay.

Most conventional non-rebreather masks with one valve removed results in several small holes through which room air is entrained. The size of the unvalved opening can range from 19-42 mm^2 depending on the size and number of holes (Figure 3). Many textbooks report oxygen delivery for the non-rebreather mask at 80-95%, however these values are non-referenced assumptions based on the original two valved design. Published studies have revealed that conventional oxygen masks under-perform to the extent that patients inhale as much room air as oxygen.

Many organizations carry standards for their oxygen delivery equipment, often requiring that non-rebreather must deliver a minimum of 80-90% oxygen @10-15 Lpm.[1] Several studies have demonstrated that conventional non-rebreather masks operating at normal oxygen flows resulted in 57-71% oxygen being delivered to the patient.[2,3,4,5]

Non-rebreather masks are often used to administer helium/oxygen mixtures; however successful outcomes may be hindered from unrecognized room air dilution. While many studies have demonstrated the efficacy of helium administration, research examining the use of non-rebreather masks for helium/oxygen delivery concluded that non-rebreather masks were not suitable for specialty gas delivery.[1] The resurgence of helium/oxygen administration has increased demand for accurate, disposable and economical administration devices.

The conventional non-rebreather mask therefore delivers significantly lower gas levels despite having the sole function of offering maximum oxygen concentrations to patients during acute and critical episodes of distress. While not all patients require maximum oxygen delivery, critical care healthcare providers require the ability to provide it.

Unfortunately, the same theory applies to other oxygen masks but to a greater degree. Venturi and aerosol masks have two significantly larger holes with a combined area of 628 mm^2, substantially increasing the ability to entrain room air with each breath (Figure 4).

Without a designated reservoir, one has to consider the dilution of oxygen when using any mask that has unvalved side ports.[7]

Role in Filtering Exhalation

Currently, conventional oxygen masks have no filtration capability and have been associated with contributing to the spread of respiratory borne particles. Patients identified with carrying a potentially infectious respiratory illness are normally placed in isolation. During transport outside the isolation areas, caregivers don masks and gowns to reduce exposure; however the presence of an oxygen mask prevents the ability to place a mask on the source of the infection, the patient.

Somogyi[8] demonstrated the potential leakage of respiratory borne particles through the exhalation ports of common oxygen delivery masks, aided by the positive pressure flow. Hui[9,10] also performed several studies on the role of oxygen masks and their potentiating the spread of potentially infectious particles, resulting in descriptions of how oxygen masks contribute. The presence of a filter in an oxygen mask provides an increased barrier between any exhaled particles from an undiagnosed patient and the surrounding environment.

Multifunction Masks

Regardless of the concentration of oxygen delivered, oxygen

masks used in international healthcare are primarily single function devices. For example, the average healthcare provider must rely on a series of different devices to achieve the goals and plans for patient care, whether they use non-rebreather masks, partial rebreather masks, simple masks, venturi masks or aerosol masks for medication delivery.

Several masks are available that allow variable FiO2 levels to be delivered, such as a variable venturi aerosol mask or the Oxy Mask. Despite allowing a range of oxygen concentrations, these devices are limited to oxygen delivery and are not used for medications or filtration of exhaled particles. The original HiOx^{80} Mask was designed with a 22mm exhalation port that accepted standard filters to capture exhaled particles. Because it was released for sale during the 2003 SARS crisis, it quickly became the mask of choice for containing potentially hazardous respiratory borne diseases.

The FLO2MAX High Concentration Oxygen Mask uses a closed mask design and a valve assembly similar to those found in manual resuscitators to deliver variable oxygen concentrations between 30 and 100% oxygen. Like a resuscitator, input oxygen flow can be reduced to allow intentional room air admixture. For patients requiring maximal gas delivery during medication administration, a special "Y" connector can be used to allow nebulizer use with the reservoir at the same time. The FLO2MAX valve assembly incorporates an integral 3M filtrate at the exhalation port to capture exhaled particles and medications. This was added to the mask to contain the spread of potentially harmful particles. When used in a mini-nebulizer configuration, exhaled particles and medications are contained within the mask. Recent modifications have provided an MDI port in the reservoir, where the reservoir acts as a spacing device. This innovation allows the FLO2MAX to become a 5-in-1 multifunction mask. Equally efficient in high concentration gas delivery, the O-Mask High Concentration Oxygen Mask does not have a dedicated exhalation filter but was designed for those with specific filter requirements.

Oxygen has been provided to patients for over 150 years yet the delivery interfaces have been largely unchanged for half of that time. The presence of unvalved exhalation ports allow significant amounts of room air to dilute gas delivery on each inhalation, effectively reducing the intended therapy by half. Under-estimating the amount of oxygen the patient receives can create the impression of a worse cardiopulmonary shunt than actually exists, potentiating the need for more invasive and expensive therapies. The emergence of multi-function delivery and filtrations devices will assist healthcare providers by offering more precise therapy while relying on less products.

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Eliminating Clot Risk with the New cobas b 123 POC System

"Clotted samples, formerly the bane of a blood gas machine operator's life..." Price 2nd edition, (2004). p35/36.

With the ever-increasing demand for Point-of-Care (POC) testing, the laboratory has moved closer to the patient, allowing the almost immediate availability of test results.[1-3] Results can subsequently be acted on faster and more efficiently, and can then be used to guide drug therapy, surgical strategy and medical management, a particular benefit in emergency medicine and the operating environment.[2,4] It is now accepted that POC testing has medical, financial and operational benefits,[5,6] and the potential to improve patient outcome from earlier treatment.[6]

However, pre-analytic, analytic and post-analytic factors can influence the quality of POC testing leading to data errors and misinterpretation,[3] for example, due to sample clotting.[7-9]

In a study of over 65,000 samples assessed over a 2-year period in inpatients for routine and stat samples,[10] overall 14.2% were found to have clotted pre-analytically, with 63.6% of these samples being in pediatric departments. Another analysis in an outpatient clinic showed that 13.4% of samples had clotted.[14]

While being able to run a sample immediately through a POC instrument gives the sample less time to coagulate and can help to ensure its integrity,[12] blood clots can still form and can be awkward to remove from a blood gas analyzer.[13] For cartridge-based instruments, a clot has the potential to result in the failure of the entire cartridge long before its normal expiration time, with all the accompanying costs of this.[1]

The inefficiencies caused by clotting in POC testing systems

Clotting of samples is always a concern, particularly in neonates in whom blood gases are the most common test performed.[12] Clotting can result in:

- Delayed blood gas results in critical care patients leading to subsequent delays in appropriate management
- Highly inconvenient downtime for the critical care POC analyzer user
- Increased stress and unplanned increased workload for already over-stretched hospital staff/POC analyzer users
- Unplanned significant costs for a service engineer, replacement of consumables, laboratory time, etc.
- Possible subsequent increase in time a patient remains on the critical care ward (and the associated costs)

The new POC analyzer from Roche — cobas b 123 POC system — is specifically designed to eliminate these clot blockage risks and associated costs.

"There are [now] systems … to prevent clotted samples … from entering key areas of the [POC] instrument." — Point-of-care Testing, Christopher P. P., Andrew St.J., Jocelyn M.H. (2004), 2nd edition.

As an added new feature, the cobas b 123 POC system includes several methods of ensuring that blood clots do not stop it functioning, thereby allowing POC test users to get on with their every day work, with no interruption to patient care and no costs associated with clot blockages.

Mechanisms of clot prevention with Roche's new cobas b 123 POC system

Three key clot prevention features have been integrated into the new cobas b 123 POC system in response to customer needs. Although they are simple to understand, the research and development at Roche that allowed their inclusion was extensive and complex.

1. High quality sample collection

While focus has traditionally been on the analytical phase of testing, the pre-analytical phase remains an important consideration for testing accuracy and offers room for improvement in test results and sample quality.[7] One review of over 40,000 samples confirmed that pre- analytical errors occurred in 68.2% of samples taken in a stat laboratory.[15] Another recent analysis of over 67,000 samples in a clinical laboratory over one-year found that pre-analytical errors occurred in 77.1% of cases.[16]

Roche has a wide range of anticoagulated syringes and capillaries. The use of suitable balanced dry-spray heparinized syringes and capillaries not only ensures high quality results with no dilution or ion bias effects, properly handled, eliminates the risk of clotting at the point of care. For total clot-free confidence combined with Roche plastic clot catchers, clots can be prevented before a sample is presented to the analyzer.

2. Clot catcher defense; pre-analytical feature

The pre-analytical New Clot Clearance feature integrated into the cobas b 123 POC system stops any clot that may be present in the patient's blood sample moving from the syringe or capillary into the analyzer.

First, a sample port needle acts as a bottleneck for the whole pathway of the sample; this prevents clots entering the analyzer.

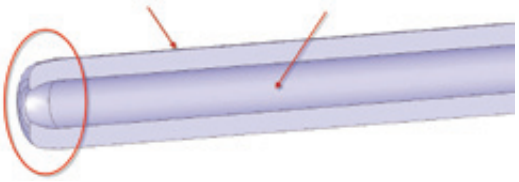

Figure 1: Bottleneck at front end of sample port needle

Second, there is an additional bottleneck in cobas b 123 models with co-oximetry measuring chambers. This means that clots are collected, and can be removed by the automated default washing routine that rinses away the sample.

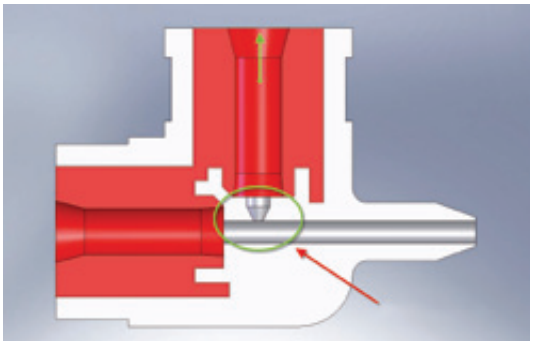

Figure 2: Bottleneck at HEOX bypass

This dual-action pre-analytical barrier prevents any clot-contaminated samples from instantly blocking the system.

3. Clot expulsion; preventative feature

Clot detection within the analysis chamber is one of the features of critical care analyzers that minimizes the risk of errors and contributes to ease of use.[1] In situations where blockage of the sample path does occur, the cobas b 123 POC system using its in-built optical sensors, detects whether the lack of fluid path flow is due to a clot. If it is, the analyzer then performs a series of automated expulsion steps to remove the clot and permit it to continue its analysis uninterrupted.

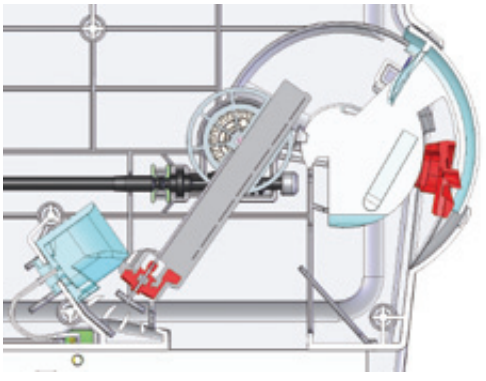

Figure 3: Needle in expulsion position

If a clot is detected:

a) The pump within the cobas b 123 POC system automatically reverses and expels the clot into a spill area positioned in the fluid pack where it is absorbed.
b) To perform this, the needle automatically turns to the expulsion position.
c) The analyzer then automatically turns back to its ready state, with no user action necessary.

The evidence for clot prevention with Roche's new cobas b 123 POC system

Several externally performed tests with cobas b 123 POC system prototypes in the clinical environment of the University Hospital in Graz, Austria, confirm the robustness of this new analyzer to prevent clot formation.

- In 2,000 samples of cord blood (umbilical whole blood), no samples showed clots or blockages. In addition, no clot expulsion was required.
- In 142 samples from non-heparinized syringes (the stress test designed to deliberately introduce clots), there were no observed clotting issues.
- In 816 whole blood and 816 plasma samples from two different laboratories with four pilot instruments, there were no observed problems regarding clotting/ blockage of the sample path.
- In over 700 samples across six sites in Europe (100-120 samples/site), assessment of six instruments (one per site) also confirmed no reports of clotting/ blockage of the sample path.

Overall, in both internal and external ongoing evaluations, clotting has not occurred in any samples. In fact, to date, over 3,500 whole blood samples have been assessed using the cobas b 123 POC system with no clot formation reported.

Summary of clot preventative measures in new cobas b 123 POC system

- Clot formation reduces POC analyzer efficiency and increases critical care workload and costs.
- The new cobas b 123 POC system is a multi-parameter, flexible analyzer for use in critical care settings at the point of care. It rapidly and accurately analyzes all major blood gases needed at the bedside, with easy-to-use on-screen step-through instructions and a built-in automated quality control system.
- Three key clot prevention features have been intgrated into the new cobas b 123 POC system in response to customer needs.
- Over 3,500 whole blood samples have been assessed using the cobas b 123 POC system with no clot formation reported.
- The cobas b 123 POC system offers an attractive, clot-free solution for POC testing, designed for maxi- mum system up-time and simplified workload, at no cost risk to the hospital.

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Safety Assessment of a Novel Neonatal Ventilator Circuit Patient Interface Connector for the Delivery of Aerosolized Medication to Mechanically Ventilated Infants

Christopher Henderson; Timothy J. Gregory, PhD; Jan Mazela, MD, PhD; Russell G. Clayton, DO.

Abstract

Background: Aerosolized medications are frequently used as part of the treatment regimen for patients requiring positive pressure ventilatory support. Recently, a novel ventilator circuit (VC)/patient interface connector has been developed to simplify the introduction of aerosolized medications into neonatal positive pressure circuits. This connector includes an internal channel that is intended to direct the aerosol flow towards the infant while shielding the aerosol from the bias flow in the positive pressure circuit. As part of a safety assessment of the connector, studies were conducted to determine the dead space volume and the resistance to gas flow through the VC connector relative to a standard wye connector. In addition, the interaction between the ventilator circuit gas and the aerosol carrier gas was studied using both configurations.

Methods: Mechanical dead space was measured volumetrically. The resistive pressures of a standard wye connector and the VC connector were assessed using a testing system at various ventilator settings within a range appropriate for neonatal positive pressure ventilator support. A second test system was assembled to assess the dilution effect of aerosol carrier gas using both connectors. One end of the inspiratory limb of the circuit was connected to a source of 21% oxygen. 100% oxygen was delivered to the aerosol port of the VC connector or a tee connector in the inspiratory limb. Oxygen was measured at the tip of an endotracheal tube.

Results: Dead space volume of the VC connector was within the range of typical standard neonatal wye connectors. Resistive pressures were similar between comparably-sized connectors at all ventilator settings tested. Ventilator circuit gas was minimally affected by the aerosol carrier gas when delivered at the tee connector, but dilution of the ventilator circuit gas by the aerosol carrier gas was profoundly changed when the aerosol carrier gas was delivered through the VC connector.

Conclusions: When used correctly, the novel VC connector is comparably safe relative to standard wye connectors and aerosol delivery configurations. Further studies are needed to determine the impact of use of the VC connector relating to delivery of aerosolized medications to mechanically ventilated infants.

The authors are with Discovery Laboratories, Inc. Mazela is also with the Department of Neonatology, Poznan University of Medical Sciences, Poznan, Poland. This article was provided by Discovery Laboratories, Inc. Christopher Henderson, Timothy Gregory, and Russell Clayton are employees of Discovery Laboratories, Inc. Jan Mazela is a consultant to Discovery Laboratories, Inc. Christopher Henderson and Jan Mazela are inventors of the VC connector. Discovery Laboratories, Inc holds the patent on the VC connector.

Background

Aerosolized medications are frequently used as part of the treatment regimen for patients requiring positive pressure ventilator support.[1] Recently, a novel ventilator circuit/patient interface connector (Afectair, Discovery Laboratories, Inc, Warrington, PA) has been developed to simplify the introduction of aerosolized medications into the ventilator circuit. This novel connector includes an internal channel that is intended to direct the aerosol flow towards the patient while shielding the aerosol from the bias flow in the positive pressure circuit. As part of a safety assessment, this study assessed the dead space volume of the novel neonatal connector and the resistance to gas flow through the connector relative to a standard wye connector, as well as the interaction between the positive pressure circuit flow and the aerosol carrier gas introduced through the connector compared with a standard of care (SoC) configuration for introducing aerosolized medication into a positive pressure ventilator circuit.

Methods

Equipment

The novel connector is a disposable, single-patient use ventilator circuit connector. It has five dedicated-use ports for connection with the inspiratory and expiratory positive pressure circuit limbs, the aerosol source, a proximal pressure port, and a patient interface such as a mask or endotracheal tube. The novel connector also has an internal aerosol channel that extends just beyond the inlet of the inspiratory limb port (Figure 1). The neonatal connector is intended for use with 10 mm neonatal positive pressure circuits. The novel connector replaces the standard patient wye connector and has a capped port for aerosol introduction. This allows for simplified introduction of aerosol into the ventilator circuit and reduces the need to disconnect parts of the circuit to initiate aerosol therapy.

Mechanical dead space was calculated for four standard wye connectors typically used with neonatal ventilator circuits: Intersurgical (Intersurgical Ltd, Workingham, Berkshire, UK), Neo2-Safe (B&B Medical Technologies, Carlsbad, CA), Fisher & Paykel RT-131 (Fisher & Paykel, Irvine, CA), and Hudson 780-12 (Hudson RCI, Research Triangle Park, NC). The Hudson wye connector was for all standard of care (SoC) testing.

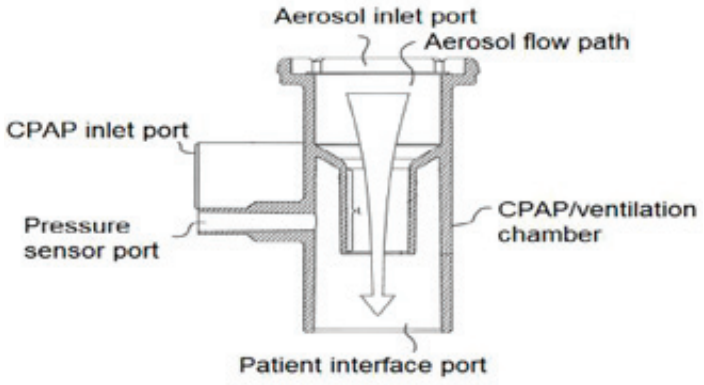

Figure 1. Schematic of the novel connector.

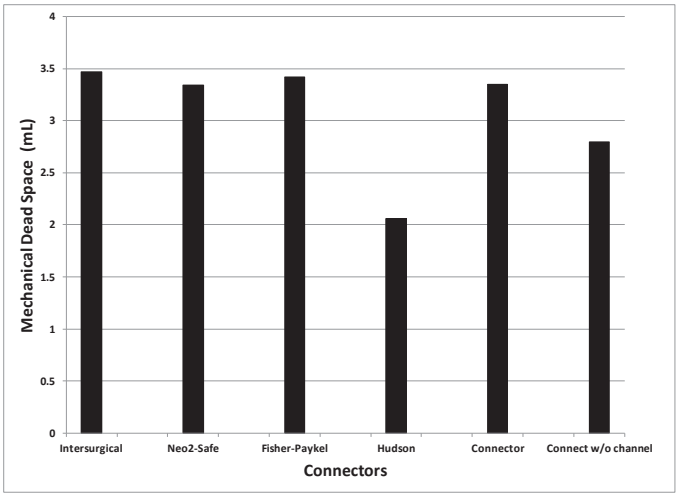

Figure 2. Mechanical dead space of four typical standard wye connectors: Intersurgical (Intersurgical Ltd, Workingham, Berkshire, UK), Neo2-Safe (B&B Medical Technologies, Carlsbad, CA), Fisher-Paykel RT-131 (Cardinal Health, Dublin, OH), and Hudson 780-12 (Hudson RCI, Research Triangle Park, NC). Mechanical dead space of the novel neonatal connector with (Connector) and without (Connector w/o channel) compensation for the volume of the internal channel is also shown.

The SoC aerosol delivery circuit consisted of a 10 mm neonatal positive pressure breathing circuit (Hudson RCI, Research Triangle Park, NC and Fisher & Paykel, Irvine, CA) and a standard wye connector (Hudson RCI, Research Triangle Park, NC). The aerosol delivery SoC was simulated by placing a tee connector (Hudson RCI, Research Triangle Park) into the inspiratory limb of the circuit approximately 18 cm from the standard wye connector.[2]

Resistance was determined using utilizing a Sechrist Millennium ventilator (Anaheim, CA) and a Biopac MP150 with AcqKnowledge v 4.1 (BioPac Systems, Inc, Goleta, CA). A pressure port was inserted into the circuit proximal to the connector for measurement of pressure. A pneumotachometer (Hans Rudolph, Kansas City, MO) was placed between the patient interface port of each connector and a NVM-1 Neonatal Volume Monitor test lung (BC Biomedical, St Charles, MO) for measurement of flow.

Gas dilution was determined by measuring oxygen concentration using an OxyCheq Expedition O_2 analyzer (OxyCheq, Marianna, FL) connected to the tip of a 3.5 mm ID endotracheal tube (Vygon Corporation, Montgomeryville, PA). When 21% oxygen/balance nitrogen positive pressure gas flow through the circuit was required, an air compressor (Maquet, Inc, Wayne, NJ) was used to introduce the gas into the ventilator circuit. When 100% oxygen was introduced into the ventilator circuit, the gas flow was provided from a gas tank containing 100% oxygen. Flows were regulated with rotometers (Precision Medical, Northhampton, PA) and measured using a mass flow meter (Sierrra Instruments, Inc, Monterey, CA).

Connector Dead Space
The mechanical dead space of the novel neonatal connector and four typical standard wye connectors was determined by calculating the internal volume from the patient interface port to the insertion of the inspiratory/expiratory ports. In the case of the novel neonatal connector, the volume of the internal channel was subtracted because this volume was not considered to be re-breathable volume. During aerosolization aerosol flows from the internal channel, eliminating the potential of it contributing to re-breathable volume. When aerosol is not being delivered, the aerosol port is capped, creating a column of air that is not expected to mix with exhaled air. Therefore, it should not contribute to re-breathable volume.

Resistance Testing
Resistance testing was conducted on the novel neonatal connector and the SoC circuits using the settings noted in Table 1. All test conditions were conducted in triplicate (n=3). Resistance was calculated as $R = \Delta P/\Delta F$, where R is resistance, ΔP is the change in pressure, and ΔF is the change in flow.

Dilution Testing
Dilution testing was conducted on both the novel neonatal connector and the SoC circuits. Positive pressure gas flow through the ventilator circuit was first set at 6 L/min for the neonatal connector and the corresponding SoC circuit. Aerosol carrier gas flows through the novel connector and the tee connector in the SoC circuit were tested at 0, 1, 2, 3, 4, 5, and 6 L; single readings were captured 5 times (n=5), separated by at least 15 seconds. The first reading was not made until at least 60 seconds from initiation of each run to allow for stabilization. The positive pressure gas flow through the ventilator circuit was then set at 12 L/min for the novel neonatal connector and the corresponding SoC circuit, and the testing was repeated. All tests were conducted with ventilator circuit gas of 21% oxygen/balance nitrogen and aerosol carrier gas of 100% oxygen, and then conversely with ventilator circuit gas of 100% oxygen and aerosol carrier gas of 21% oxygen/balance nitrogen.

Results
Mechanical Dead Space Determinations
The total volume of the novel neonatal connector was 3.35 mL. After subtracting the volume of the internal channel that is not expected to contribute to re-breathable dead space, the mechanical dead space volume was 2.80 mL (Figure 2). For the four standard wye connectors used the mean (SD) dead space was 3.07 (0.68) mL with a range of 2.06 to 3.47 mL.

Resistance Determinations
Resistance to gas flow at all settings tested was similar between the novel neonatal connector and the standard wye connector (Figure 3). The average resistance ranged from 2.01 (0.29) cmH_2O/L/min to 3.57 (0.03) cmH_2O/L/min for the novel neonatal connector, and from 1.87 (0.24) cmH_2O/L/min to 3.57 (0.14) cmH_2O/L/min for the standard wye connector.

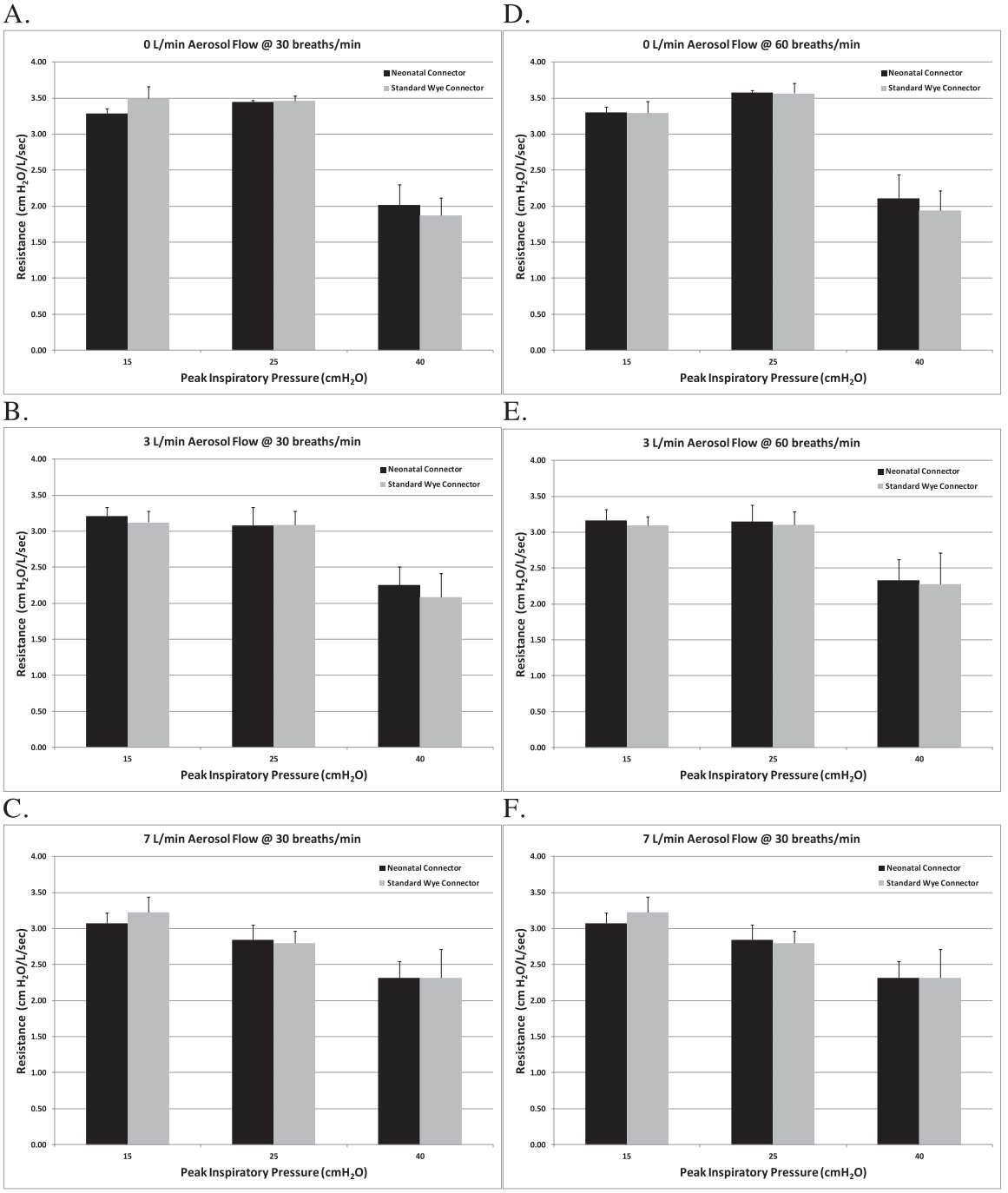

Figure 3. Neonatal resistance testing: Dynamic resistance was measured at peak inspiratory pressures (PIP) of 15, 25, and 40 cmH2O and a respiratory rates (RR) of 30 (Fig 2A-C) and 60 (Fig 2D-F) bpm for the novel neonatal connector and standard wye connector. Aerosol carrier gas was introduced into the aerosol port of the novel neonatal connector at flow rates of 0, 3, and 7 L/min. For the standard wye connector, aerosol carrier gas was introduced at a flow rates of 0, 3, and 7 L/min using a tee connector placed in inspiratory limb of the circuit approximately 18 cm proximal to the connector.

Dilution Studies

At all aerosol carrier gas flows greater than 1 L/min, the aerosol carrier gas delivered through the novel neonatal connector completely diluted the 6 L/min positive pressure circuit gas (Figure 4). When 100% oxygen was used as the aerosol gas, the concentration of oxygen that was measured at the tip of the endotracheal tube was 97.4% at an aerosol carrier gas flow of 1 L/min and a ventilator circuit gas flow of 6 L/min. When the aerosol carrier gas flow was at least 2 L/min, the measured oxygen concentration was 100%. When the ventilator circuit gas flow was increased to 12 L/min, the oxygen concentration was 67.7, 85.3, 98.0, and 100% at aerosol carrier gas flows of 1, 2, 3, and 4-6 L/min, respectively. In contrast, the aerosol carrier gas delivered through the tee connector in the corresponding SoC circuits only partially diluted the positive pressure circuit gas, even at aerosol carrier gas flows up to 6 L/min (Figure 4).

Discussion

A novel connector has been developed to simplify the introduction of aerosolized medications into the ventilator circuit. These studies were conducted to evaluate the safety of use of the novel neonatal connector, specifically the dead

	Neonatal Connectors		
RR (bpm)	30		60
PIP (cmH_2O)	15	25	40
Aerosol Flow (L/min)	0	3	7

Table 1. Ventilator parameters for resistance studies

space volume, the resistance to gas flow through the connector and the potential for aerosol carrier gas introduced through the connector to dilute the ventilation gas.

The mechanical dead space volume is the volume within the connector between the ventilator gas flow channels and the patient interface where potential re-breathing occurs.[3] The mechanical dead space volume becomes particularly important when ventilating a patient with small tidal volumes. The mechanical dead space volume of the novel neonatal connector was 2.80 mL and was within the range of the dead space volumes of typically used standard wye connectors. The 1.41 mL difference between the smallest and largest dead space measurements is trivial relative to the continuous bias flow in the ventilatory circuit and therefore is not likely to be clinically relevant. Therefore, during clinical use of the novel neonatal connector, dead space should not be a safety consideration unless very low bias flows are utilized during ventilation.

All parts of the ventilator circuit add resistance to the patient's respiratory efforts during mechanical ventilation, with the endotracheal tube contributing the most to resistance.[4] Increased resistance in the ventilator circuit can add to work of breathing and affect the ability to decrease ventilator support or provide synchronized ventilation to the patient. Therefore, it is important to determine whether the internal aerosol channel adds to the resistance of the ventilator circuit. Resistance to gas flow at all settings tested was similar and within error measurements between the novel neonatal connector and the standard wye connector. Therefore, when compared with a standard wye connector, the novel neonatal connector does not add additional resistance to the ventilator circuit.

The delivery of aerosolized medications can alter the concentration of oxygen in the gas delivered to the patient if a matched blended gas source is not used to drive the aerosol device. This potential problem is recognized by the American Association of Respiratory Care and listed as a caution in the policy of delivering aerosolized medication to patients on mechanical ventilation.[5] Nevertheless, in the hospital setting, wall source air and oxygen provide a convenient source for aerosol carrier gas, and practitioners may elect to use either 21% or 100% oxygen to deliver the aerosol rather than match the blend of gas in the positive pressure circuit. This study demonstrates that, regardless of the method used to introduce the aerosol into the positive pressure circuit, the aerosol carrier gas can alter the gas mixture delivered to the patient when the aerosol carrier gas mixture is not matched to the gas mixture in the ventilator circuit. However, when delivered through the novel connector, the aerosol carrier gas can dramatically change the ventilator circuit gas mixture, even when introduced at relatively low flows. Thus, when delivering aerosol through the novel neonatal connector, the aerosol carrier gas mixture should be equivalent to the gas mixture in the ventilator circuit in order to maintain the prescribed gas mixture.

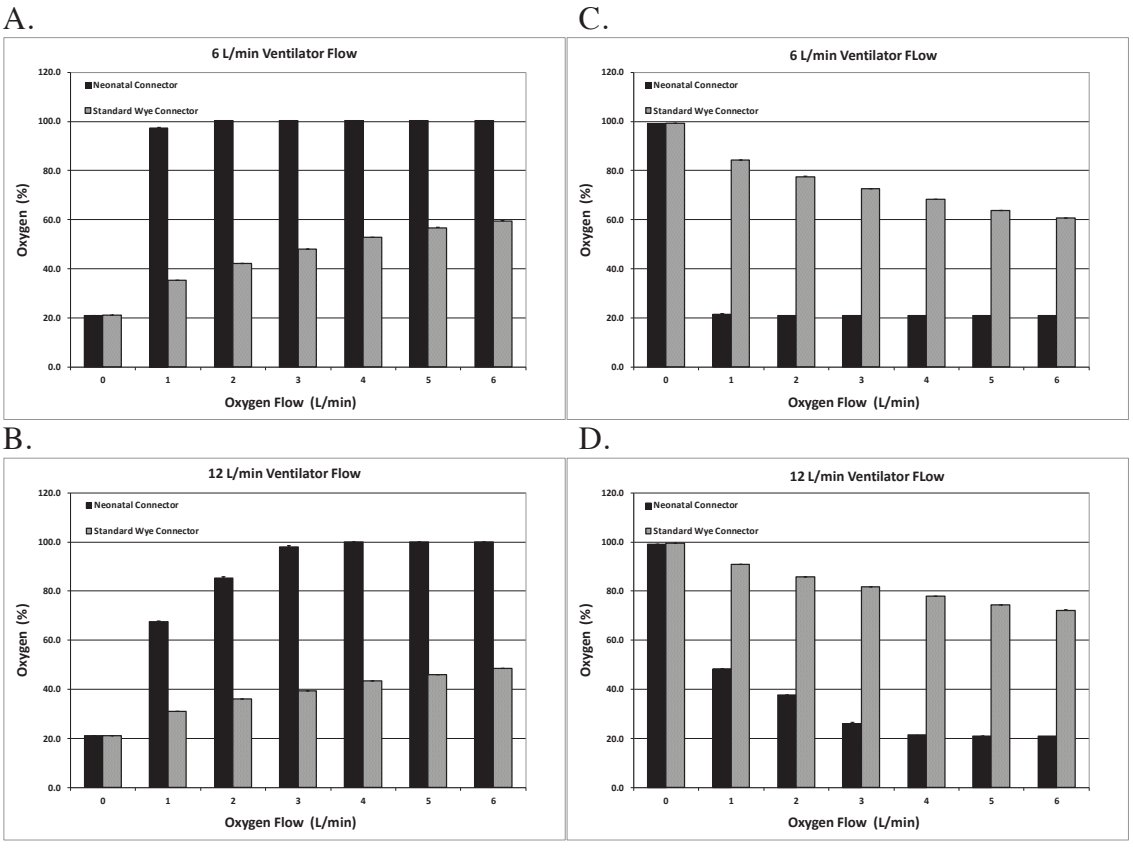

Figure 4. Neonatal dilution testing: The oxygen concentration was measured at the tip of the endotracheal tube for the novel neonatal connector and standard wye connector at aerosol flows ranging from 0 to 6 L/min of 100% oxygen and ventilator circuit gas flows of 6 and 12 L/min of 21% oxygen (Fig 3A-B). Oxygen concentration was also measured at aerosol flows ranging from 0 to 6 L/min of 21% oxygen and ventilator circuit gas flows of 6 and 12 L/min of 100% oxygen (Fig 3C-D).

The lack of dilution effect when the aerosol carrier gas is introduced through the novel neonatal connector suggests that the delivery of an aerosolized medication to a patient may increase when administered through the novel neonatal connector, relative to the current SoC. Clinicians who employ non-standard dosing regimens when delivering aerosolized medications to patients receiving mechanical ventilation should be aware that more medication may be delivered to the patient if the novel neonatal connector is used. Further study is necessary to verify this observation and quantify the relative difference in the delivery of aerosolized medication between the novel neonatal connector and the SoC.

Conclusion

The novel connector is comparably safe when compared to the typically-employed standard wye connectors. The use of the novel neonatal connector appears to allow for an increased delivery of the aerosol carrier gas relative to the current SoC. Therefore, when using the novel neonatal connector, the aerosol carrier gas mixture must be equivalent to the gas mixture of the ventilator circuit to maintain the gas mixture delivered to the patient. Further studies are needed to determine whether the use of the novel neonatal connector results in an increased delivery of aerosolized medications and therapeutic medical gases.

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Health Experts Discuss Four Flawed Monitoring Practices

Sean Power

Recently four health experts participated in a webinar on The Joint Commission's Sentinel Event Alert on the safe use of opioids.[1] On the panel were patient safety experts including Dr Frank Overdyk, Professor of Anesthesiology at Hofstra North Shore-LIJ School of Medicine; Ray Maddox, Director of Clinical Pharmacy, Research and Pulmonary Medicine at St. Joseph Candler; Tammy Haslar, Oncology Clinical Nurse Specialist at the Franciscan Alliance at St Francis Health, and Debbie Fox, Director of Respiratory Care at Wesley Medical Center.

Below we've outlined four flawed monitoring practices discussed in the webinar that can be fixed to improve outcomes for patients using patient-controlled analgesia (PCA) pumps.[2]

1. Trusting that intermittent spot checks of vital signs are sufficient for assessing respiratory rate and CO2 levels.
Vital sign monitoring occurs at two- to four-hour time intervals. When a patient receives a particular dose of opioids in between spot checks, it is impossible to predict how the patient will respond to the dose in terms of respiratory depression. As Dr Overdyk observes, some of the "tell-tale signs" of opioid induced respiratory depression[3] are best appreciated by trends in vital signs of nursing assessments such as respiratory rate, level of CO2, and level of consciousness. "Spot checks completely miss these trends," says Dr Overdyk.

Instead of intermittent spot checks, Dr Overdyk recommends continuous monitoring of ventilation and oxygenation with capnography and pulse oximetry.

2. Continuously monitoring only "high risk" patients.
"The Joint Commission recommends risk stratifications[4] as to who we monitor continuously," says Dr Overdyk. The list of risk factors include a number of criteria including patients who are on higher opioid doses, morbid obese, at extremes of age, experience sleep apnea/snoring, are opioid naïve, smoke, use synergistic RD drugs such as sleeping pills, and a have history of tolerance or abuse. Meeting one of these conditions makes a patient "high risk" according to The Joint Commission. "To be honest," continues Dr Overdyk, "I look at this list, I can't remember a patient in recent history who did not have one or more of these conditions."

Part of the challenge to categorizing patients as "high risk" is that some of these criteria go undiagnosed. For instance, 12.5 million Americans take pain relievers for non-medical uses and there exist 8 million chronic opioid users in the United States. Obstructive sleep apnea[5] is undiagnosed in 85-95% of patients. These conditions may not appear in a patient's history.

Sharing his own experience implementing a continuous monitoring program[6] at St Joseph Candler, Mr. Maddox says the hospital learned that "undiagnosed sleep apnea is more prevalent than expected." The difficulty in assessing risk level makes risk stratification ineffective in some cases.

The solution is to continuously monitor all patients using PCA pumps after surgery. "That would serve a zero tolerance policy," explains Dr. Overdyk, helping hospitals to meet the 2006 recommendation by the Anesthesia Patient Safety Foundation that no patient shall be harmed by opioid induced respiratory depression[7] in the postoperative period.

3. Relying on pulse oximetry alone to detect respiratory depression.
As Ms Fox presents, "The respiratory cycle has two separate processes: ventilation and oxygenation."

Dr Overdyk explains, "Pulse oximetry and capnography basically measure two different processes that are vital to our existence; namely, the intake of oxygen on one side and the elimination of carbon dioxide on the other."

Until recently, pulse oximetry, which measures oxygenation, was the only way to assess respiratory function. When respiratory depression occurs, oxygenation levels will gradually fall to a point where the pulse oximeter detects the respiratory depression event.

According to Ms Fox, this delay between the moment when pulse oximetry detects an RD event and the moment when the event actually occurs is increased by supplemental oxygen. "The patient may be breathing," says Ms Fox, "but the oximeter will not reveal quantitatively how well the patient is actually ventilating and moving air."

Monitoring end tidal CO2[8] measures breath-to-breath ventilation and detects hypoventilation. Oximetry measures oxygenation and detects hypoxia. "If you want to effectively monitor the

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Croup and the Precision Flow Heliox: A Product Case Study Based on Clinical Experience

Thomas L. Miller, PhD; Jenna Flores, MS, RRT

The concept of reducing work of breathing by ventilating with helium-oxygen gas mixtures (heliox) has been in practice for more than 80 years. Because helium has a much lower density than nitrogen, breathing heliox results in an immediate and dramatic reduction in airway resistance, and therefore work of breathing, compared to conventional air-oxygen blends.[1] However, a limitation of heliox use has been accessibility, whereby configuring blenders, tanks and patient interface components limit the speed at which the therapy can be applied. In this regard, other therapeutic options for the treatment of acute incidences of airway obstruction have been implemented ahead of heliox, despite the potential for heliox to limit the need for more invasive ventilation strategies and ultimately lower treatment costs while improving patient experience. Recently, the availability of products designed and approved for use with heliox can simplify administration, improve reaction times and reduce length of stay and associated healthcare costs.

This article presents a patient case scenario we experienced first-hand in 2012. This scenario is associated with the release of the Precision Flow Heliox, a high flow nasal cannula system designed for the delivery of heliox therapy. Now, imagine an infant aged 3 months presented in the ED with suspected croup. The physician orders heliox…

Lets imagine a typical scenario. You have a cylinder, but can't find a regulator or wrench, or a humidifier to connect to a blender with an adapter for heliox. Timely patient care hangs in the balance as you scramble to cobble everything together. As we understand, reduced work of breathing is associated with increased respiratory muscle stamina, which can help avoid potential respiratory failure. The success of a therapy, including heliox, can be dramatically impacted by the methods and devices used. The all too common practice of modifying commercially available devices to function outside of the range of their intended design creates risks for the patient, clinicians and the institution. In the interest of patient safety, one of the best ways to minimize these risks is to use devices that are cleared by the Food and Drug Administration (FDA) and designed specifically for use with heliox.[2]

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Let's consider some important aspects of heliox delivery

Heliox typically comes in pre-mixed cylinders; common mixtures are 80% helium / 20% oxygen or 70% helium / 30% oxygen. In the past, it was common to deliver the gas straight from the cylinder, through a regulator and flow meter to a non-rebreather mask. There are several problems delivering heliox in this manner. First, if not using heliox calibrated equipment, the set flow and the flow actually delivered will differ. This can cause confusion among the care team. Second, non-rebreather masks can lead to dilution with room air. In fact, a study done in 2008 by Standley and associates showed an average of only 37.2% tracheal helium in patients breathing 80/20 heliox through a non-rebreather mask.[3] In addition, patient compliance with a mask interface can be a significant challenge. Finally, lack of proper gas conditioning can be an issue with respect to both patient comfort and failure to mitigate potentially worsening disease processes. In this regard, some asthmatics will react to cold gas with bronchospasm.

The Precision Flow Heliox is the first FDA approved high flow nasal cannula system specifically designed for heliox delivery. Coupling this unit with a practical and convenient tank management system and integrated regulators designed for use with heliox makes for a complete therapy platform that can be set up rapidly for immediate use at the bedside. The device is pre-calibrated for heliox delivery, so no calculations are necessary to determine delivery flow rates; setup does not require wrenches or special tools to make connections; the device has an internal blender to allow delivery of any helium-oxygen mixture necessary (FiO2 ranges from 21-100%). And lastly, the Precision Flow Heliox has the capabilities to properly condition heliox with heat and humidity, making the gas more comfortable for patients to breath and soothing to a reactive airway.

Now, let's revisit our patient with croup in the ED

Croup (laryngotracheal bronchitis), as we know, causes obstruction in patient's airways due to swelling around the vocal cords. It can lead to increased work of breathing and features a "barking" cough. The most common cause of croup is a viral infection; however, it can also be caused by bacterial infections, allergies or acid reflux. Croup typically occurs in children 5 months to 6 years of age.[1,4]

With viral croup, treatment is typically palliative in nature. Anti-inflammatory agents are often prescribed in an effort to reduce the swelling, and pain medication is given to alleviate fevers and

pain. There is no cure. Occasionally, if the inflammation persists, work of breathing gradually increases, and additional support is necessary. Support can range from less invasive options, such as heliox therapy if respiratory muscle fatigue occurs, to more invasive measures such as intubation if respiratory failure occurs. (Respiratory failure can occur in as high as 6% of patients admitted for croup if muscle fatigue persists).[1,4,5,6]

In fact, our 3 month old patient was suffering from severe croup, and was successfully treated with the Precision Flow Heliox in the ED/ICU. He arrived with signs of increased work of breathing and a "barking cough." His WOB continued to increase and croup scores averaged 5-7. The decision was made to start heliox therapy and the Precision Flow Heliox was initiated. He started on a 5 LPM flowrate, but subsequently required an increase to 8 LPM. With that increase in flow, the oxygen concentration was able to be decreased from the initial 35% to 25%, (proportionally raising the helium concentration). His croup scores improved after therapy was initiated and averaged 3-5. All other clinical indicators improved over the next 15 hours, when the physician discontinued therapy. During heliox therapy the patient did receive five in-line racemic epinephrine aerosol treatments. Altogether, the patient was discharged home within 24 hours of being admitted and was able to stay on a non-invasive support method throughout his stay.

With the ease of use and precise control of the Precision Flow Heliox, more patients may be able to be maintained on a non-invasive support method. With an average length of stay for patients admitted with croup being two days, early discharge and the avoidance of invasive therapies saves time and money for staff and hospitals and more importantly, helps patients.[7]

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Flawed Monitoring Practices…continued from page 34

respiratory status then both capnography and pulse oximetry should be used," says Ms Fox.

4. Implementing a monitoring program without creating an education plan.

Introducing and implementing a monitoring program requires buy in and participation from key stakeholders including nurses, respiratory therapists, physicians, hospital leadership, and risk management teams. Sustaining change, notes Ms Haslar, requires patient buy in and participation, as well. By communicating the purpose and benefits of the monitoring program, hospitals can set "patient expectations for compliance with monitoring," notes Ms Haslar.

Ms. Haslar offers some ideas on communicating with community stakeholders and patients. "Consider an awareness campaign for going live," she says. Promoting the hospital's key stakeholders who were included in the decision-making process can establish peace of mind and build unity behind the program. Discuss the monitoring program "during pre-op appointments" and "while going over surgery instructions," suggests Ms Haslar. Provide a patient brochure on essential monitoring strategies. Utilize nurses, respiratory therapists, and physicians to help improve patient compliance.[9]

As Ms Fox notes, "Patient education is the key to patient compliance. It would be ideal to educate patients prior to surgery." These tactics should be part of a broader individualized patient plan that reflects monitoring strategies that minimize adverse outcomes from opioid therapies.

In addition to educating patients, hospitals need to remember to implement a training program for new hires. "It's definitely important to add education for your new hires as well," says Ms Haslar. "Sometimes that can be overlooked."

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Use of a Portable Noninvasive Ventilation System during Pulmonary Rehabilitation and Activities of Daily Living in Patients with Severe COPD

Lana Hilling, RCP, MAACVPR; Cindy Cayou, RCP; Lynn McCabe, RRT; George Heron, MS; Iva Segalman, MPD

Background

COPD remains a major public health issue and has become the third leading cause of death in the United States.[1] According to the National Heart, Lung, and Blood Institute (NHLBI), the number of Americans diagnosed with COPD is approximately 15 million, with an estimated 12 million persons currently undiagnosed.[2] Statistics on COPD's financial burden are also alarming, with direct costs estimated to be more than $30 billion in the US.[3] In addition to direct costs, which include hospital stays, emergency room visits, and physician office visits, indirect costs related to lost productivity are estimated to top $10 billion annually.[3] On average, employed patients with COPD miss 9 work days per year.[4]

The social burden of COPD is an equally important aspect of the disease. As COPD progresses from early to more severe stages, patients notice changes in their quality of life. Performance of routine activities of daily living (ADLs) often become too difficult and patients become dependent on others to do their daily chores. This lack of activity and exercise intolerance may lead to a reduced health-related quality of life (HRQoL)[5] and may also have psychological consequences such as depression.[6,7] Increasing activity, such as with pulmonary rehabilitation, can enhance daily functions and restore a higher level of independence.[5]

Oxygen therapy and noninvasive ventilation (NIV) are two of the treatments recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD). Delivering supplemental oxygen while receiving augmented ventilation has the potential to improve patient mobility,[8] enhance the rehabilitation process,[9] and increase activities of daily living (ADLs),[10] with the end result being more independence and a better quality of life. Unfortunately, the use of NIV systems designed for bedside use can reduce or negate any beneficial effects and providing a portable system suitable for use during exercise and ambulation has been a major obstacle.[11] Recently, however, a portable noninvasive open ventilation (NIOV) system has been introduced by Breathe Technologies, Inc. The NIOV system consists of a wearable 1 lb ventilator capable of delivering oxygen-enriched augmentation volumes from 50-250 mL, a non-sealing "open" nasal pillow interface, and a high-pressure oxygen source (Figure 1). In addition, the nasal pillow interface incorporates dual Venturi ports to entrain ambient air so that total augmentation volumes may exceed 450 mL with FiO2s in the range of 0.35-0.45.[12]

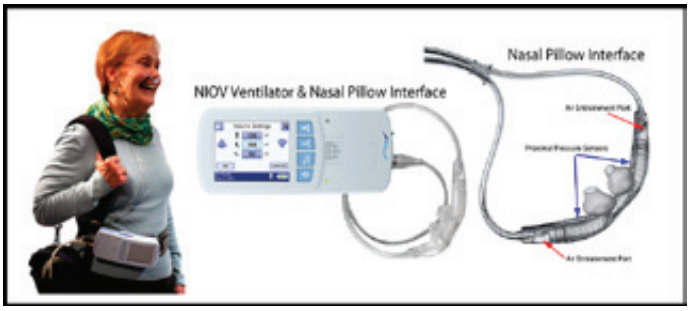

Figure 1. The NIOV system

In two prior clinical trials, the NIOV system has demonstrated improvements in 6-minute walk tests (6MWT) in subjects with severe COPD and other forms of respiratory insufficiency. In the first study, conducted at two pulmonary rehabilitation centers, NIOV increased 6MWT distance in 25 of 30 subjects compared to standard oxygen therapy via nasal cannula.[13] Mean improvement in 6MWT using NIOV was 57 ± 54 meters. In the second clinical trial, completed at four pulmonary rehabilitation centers, there was a mean improvement of 36 ± 34.1 meters while using NIOV.[14] In a subset of subjects with baseline 6MWT distances of less than 300 meters, the mean improvement was 73 meters. In both clinical trials, the NIOV system was well-tolerated and subjects reported that it was comfortable to wear.

Methods

In this study, we evaluated the NIOV system in subjects with severe but stable, oxygen-dependent COPD, in an open-label study at three pulmonary rehabilitation centers. Inclusion criteria included supplemental oxygen use during rest and exercise, notable dyspnea upon exertion, and current or recent participation in a pulmonary rehab program. The primary objective was to evaluate the NIOV system with regard to acceptability, comfort, and usability. Subjects completed five consecutive, 6-hour clinic days in which the NIOV system was worn continuously while at rest, while exercising, and during simulated ADLs, including vacuuming, folding laundry, carrying a bag of groceries, and gardening (Figure 2).

Throughout the study, subjects were able to self-select from three volume augmentation levels (low, medium, high),

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Figure 2. Study subjects performed a variety of activities and exercises while using the NIOV system.

depending on their activity level and perceived needs. Each day, subjects were asked to record their responses to questions related to a self assessment of performance paired with comfort, comparing each answer with the previous day's experience. Subjects were also asked to rate whether the NIOV system was comfortable and would be acceptable for prolonged use. Further, subjects were asked to indicate whether they preferred the NIOV system over their standard oxygen therapy. Upon acclimation to the NIOV, baseline assessments were taken. After each activity, subjects were asked to rate their shortness of breath using the modified Borg Dyspnea Scale,[15] and to record their emotions. At the end of the day, subjects were asked to self-assess their overall experience. Subjects were asked whether or not their performance improved through the days of the trial. The first day of using the NIOV system was compared to each subject's perception of his/her normal performance ability and each subsequent day was compared to the day before.

Results

Nineteen subjects were screened and enrolled and 18 subjects (9 male, 9 female), aged 60-85 years, completed the study. Mean FVC % pred was 54% ± 16 and mean FEV1 % pred was 33% ± 11. Mean NIOV augmentation volumes were 100, 130, and 180 mL for low, medium, and high activity levels, respectively.

Regarding their perception of normal performance ability, 17 of the 18 subjects indicated improvement and ended the trial at a greater level of perceived performance ability than at baseline (Figure 3). When comparing their performance ability to the day before, 5 of 18 reported continuous improvement each day from the first day of use to the last. Only one subject reported a "flat" performance ability equal to standard oxygen therapy over the study's course.

Regarding their feelings while using NIOV, the subject's emotional state followed a similar trend to that of performance ability (Figure 4). Sixteen of 18 subjects indicated an improvement in mood during the 5 study days, ending the study at a better emotional state than at baseline. Five subjects indicated a steady improvement, indicating that their feelings improved each subsequent day of the trial. Only 2 subjects indicated no change in emotional state over the study's course. None of the study subjects reported feeling worse at the end of the study compared to baseline.

When asked to describe their experience using the NIOV system, subjects reported that using NIOV was a positive experience and that the reduction in work of breathing was noticeable. One subject described NIOV's volume augmentation by stating, "When I'm on the ventilator, I feel like my lungs are expanding. I feel like I can breathe better, and I feel like I have much more energy." Another subject noted that, "the main thing we [subjects] seemed to share was that we all felt so much better. We would exercise, and the first day we had to rest in between. The second day we did a little more. Third day we did a little more. Pretty soon we weren't resting. We were just exercising and having a great time." Finally, subjects indicated a strong preference (median Likert scores of 5/5) for using the NIOV

Figure 3. Self-assessment of performance while using NIOV

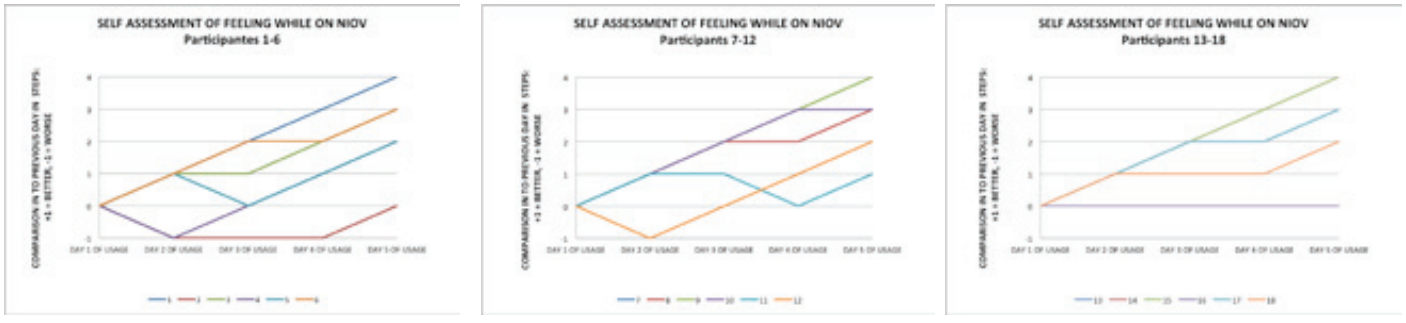

Figure 4. Self-assessment of feeling while using NIOV

When walking or exercising with the NIOV device compared to oxygen therapy my feeling of being out of breath is:	When walking or exercising with the NIOV device compared to oxygen therapy my energy level is:	When walking or exercising with the NIOV device compared to oxygen therapy my feeling of dryness in my nose and throat is:	I would prefer to use this device (NIOV) instead of oxygen therapy when exercising	I would prefer to use this device (NIOV) instead of oxygen therapy for errands, socializing	I would prefer to use this device (NIOV) instead of oxygen therapy for performing household tasks	The (NIOV) nasal pillows were comfortable in my nose
5	**4**	**4**	**5**	**5**	**5**	**5**
5 = much less out of breath	4 = somewhat more energetic	4 = somewhat less dryness	5 = completely agree	5 = completely agree	5 = completely agree	5 = completely agree

Table 1. NIOV Study exit questionnaire responses, (5-point Likert scale, median, n=18)

system over their standard oxygen systems with regard to performing errands, household tasks, and exercise (Table 1).

Discussion

Subjects' comments during this study support that a perceived improvement in physical ability may be intrinsically linked to an improved emotional state.[16,17] Study subjects who perceived a lower improvement in physical ability also experienced comparably smaller gains in their perceived emotional state. With each subsequent day of use, all but one subject reported physical ability improvement. In interviews, the perception of most subjects was that the NIOV system provided "much better breathing efficiency," and that this improvement in breathing allowed them to regain stamina lost because of low activity levels. This improvement in perceived physical ability directly correlated to an enhanced outlook by the subjects.

During the study, it was apparent that the NIOV engendered a strong response from the subjects, although it is difficult to assess how much actual benefit would differ from perceived benefit. The nature of this trial allowed subjects to be social and active for an extended period of time each day for several consecutive days. In this way, the trial may have affected other aspects of COPD that were not directly evaluated, such as the social and psychological burden of COPD, ie, the social isolation and resultant depression of this isolation.[18] The difference between the everyday behavior and routine of the subjects compared to the study's social group environment at the pulmonary rehabilitation centers and physical demands is unknown. It is certainly possible that some of the positive emotional response could be attributed to the social aspects of the study, including interaction with fellow COPD subjects in the study and the clinical staff, while the sense of physical

improvement could be partly due to the nature of the study: continuous, prolonged activity conducted over consecutive days.

Conclusions

Patients with COPD face many challenges and it is widely accepted that dyspnea plays a major role in limiting a patient's ability to perform physical activity.[19] Physical inactivity due to exercise intolerance often results in a downward health spiral, as progressive inactivity leads to increased disability, more frequent pulmonary exacerbations, and eventually early mortality.[20]

In this study, the NIOV system was used for 6-hours per day over 5 consecutive days. Subjects with severe COPD showed an improvement in self-assessed physical ability as well as emotional state. In most subjects, the preference for the NIOV system increased as the study progressed. Based on these data and previous clinical studies, the NIOV system appears capable of improving mobility and activity levels in patients with severe COPD or respiratory insufficiency. The NIOV system is very portable, was well-tolerated when worn over long periods, and was perceived as a positive experience when used during rest, ADLs, and exercise. The NIOV system appears to offer a practical method for promoting increased physical activities, improved independence, and the ability to perform everyday activities in patients with chronic respiratory insufficiency.

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Treatment of Obstructive Sleep Apnea with Nasal Expiratory Positive Airway Pressure (EPAP)

59 year old man with Obstructive Sleep Apnea successfully treated with EPAP after years of struggles with conventional therapies

Jessica Anderson, CMA; Nancy H. Appelblatt, MD, FACS, FAASM

A 59 y/o man presented to Sacramento ENT Sleep Disorders clinic in 2012 with a history of known Obstructive Sleep Apnea (OSA). He and his wife were frustrated and had a history of complaining to providers about treatment challenges and continuing symptoms for at least ten years. They both specifically noted that he had difficulty with memory and concentration and excessive daytime sleepiness. The patient scored 16 on the Epworth Sleepiness Scale (ESS).

A full PSG completed in 2007 was reviewed, showing
- 6.5 hours of sleep with 94% efficiency
- Sleep latency less than 5 minutes
- No slow-wave sleep; Stage 1-74%, REM-24%
- AHI 8.3
- REM AHI 18
- Multiple PVCs noted, LSO+88%, and less than 1% of his TST was less than 90% O2

A CPAP titration was ordered, and later completed. A pressure of 5 ameliorated the OSA. The sleep study had been ordered by his primary care physician, read by a remote sleep doctor, and he was referred directly to a DME for CPAP therapy. The cost of the study was $4000. After trying a few different masks, having continued problems, no improvement, and little continuity of care, he gave up in disgust. The CPAP went into the closet. The cost of the CPAP was approximately $2000 per year. He next sought out a dentist with an interest in sleep. He obtained a mandibular advancement device (MAD), which he wore for a while before discontinuing due to ear pain and pressure. Although improved, he still had symptoms. The cost of the MAD was roughly $2000.

Evaluation in our clinic included fiberoptic laryngoscopy and a CT of his sinus/tongue base. He was 71 inches tall, weighed 194 lbs and had a BMI of 27.1 kg/m2. A slightly deviated septum was noted despite prior surgery. He had significant nasal valve collapse and plus 1 turbinate hypertrophy. Further evaluation denoted a narrow pharynx with small tonsils, a Malampatti 2 soft palate and an elongated uvula. Fiberoptic laryngoscopy showed he had enlarged lingual tonsils, a narrow tongue base and interarytenoid irritation, most consistent with reflux. He also had significant signs of allergies. The CT confirmed a narrow tongue base with minor ethmoid sinus disease. Given his continued symptoms on the oral appliance, a home sleep study was done and showed the AHI was 7, with an RDI of 9, a baseline oxygen saturation of 96% with a minimum of 84%.

The patient was offered a trial of Nasal EPAP, (Provent*) at the cost of $26 dollars. The patient reported remarkable improvement and a home sleep study was performed while on Provent, which showed an AHI of 0.0, RDI of 0.0, with a baseline oxygen saturation of 96% and a minimum of 88%. His ESS on Provent is 3. Monthly Provent cost is less than $100 dollars. He has been using Provent for 11 months and states that he feels less fatigued, is sleeping more regularly, his concentration and memory have improved and he is sleeping through the night with no arousals.

Summary

This case history is interesting for the following reasons:
- The significant symptomatically that was disproportionate to the AHI but was real and remitted
- The efficacy of home studies in the assessment and the cost difference vs in-lab studies
- The utility of Provent versus other OSA treatment options.

*Nasal expiratory positive airway pressure (EPAP) marketed as Provent Therapy (Ventus Medical Inc, San Jose, CA) is a disposable, nightly use prescription device that consists of a small valve attached externally to each nostril with hypoallergenic adhesive. The device acts as a one-way resistor allowing nearly unobstructed inspiration. During expiration, the airflow is partially restricted, increasing resistance and creating EPAP. The equipment used was ApneaLink Plus.

The authors are with the Sacramento Ear, Nose, and Throat Surgical and Medical Group, Inc. This article was provided by Ventus Medical.

A Program for Sustained Improvement in Preventing Ventilator Associated Pneumonia in an Intensive Care Setting

Alexandre R. Marra, Marcelino S. Durao, Claudia V. Silva, Oscar F. Pavao dos Santos, Henrique S.S. de Neves, Michael B. Edmond, Karina T. Timenetsky

Abstract

Background: Ventilator-associated pneumonia (VAP) is a common infection in the intensive care unit (ICU) and associated with a high mortality.

Methods: A quasi-experimental study was conducted in a medical-surgical ICU. Multiple interventions to optimize VAP prevention were performed from October 2008 to December 2010. All of these processes, including the Institute for Healthcare Improvement's (IHI) ventilator bundle plus oral decontamination with chlorhexidine and continuous aspiration of subglottic secretions (CASS), were adopted for patients undergoing mechanical ventilation.

Results: We evaluated a total of 21,984 patient-days, and a total of 6,052 ventilator-days (ventilator utilization rate of 0.27). We found VAP rates of 1.3 and 2.0 per 1,000 ventilator days respectively in 2009 and 2010, achieving zero incidence of VAP several times during 12 months, whenever VAP bundle compliance was over 90%.

Conclusion: These results suggest that it is possible to reduce VAP rates to near zero and sustain these rates, but it requires a complex process involving multiple performance measures and interventions that must be permanently monitored.

Background

Ventilator-associated pneumonia (VAP) is a common infection in the ICU.[1] Recent studies describe a rate of 1 to 4 cases per 1,000 ventilator-days, although this can reach up to 10 cases per 1,000 cases ventilator-days in neonates and surgical patients.[2,3] The improvement in outcomes associated with recent initiatives suggest that many cases of VAP can be prevented by adhering to bundles of infection prevention measures.[4,5]

The attributable mortality of VAP is around 4% to 9% varying with definitions, case-mix, causative microorganisms, and treatment adequacy.[6,7] VAP is also associated with considerable morbidity, due to increased length of hospital and ICU stay, prolonged mechanical ventilation and increased hospital expenses,[8-10] as well as excessive utilization of antimicrobials with correspondingly higher costs.[8,9]

As part of the 5 Million Lives campaign, endorsed by leading US agencies and professional societies, The Institute for Healthcare Improvement (IHI) recommends that all ICUs implement a ventilator bundle to reduce the incidence of VAP to zero.[11] Since 2007, we have implemented the VAP bundle in our ICU, including oral hygiene with 0.12% chlorhexidine and continuous aspiration of subglottic secretions (CASS).[4] With these measures we were able to achieve zero incidence of VAP during a few months when a higher than 95% compliance rate with the VAP bundle was obtained.[4] However, to date there are no reports of sustained low incidence of VAP[4] (near zero).

The purpose of this quasi-experimental study was to evaluate whether the sustained implementation of the VAP bundle in our ICU could effectively reduce the incidence of ventilator-associated pneumonia (VAP).

Methods

Setting and study design: An interrupted time series study was conducted in a 38-bed medical-surgical intensive care unit (ICU) of a tertiary care, private hospital in São Paulo, Brazil. This is an open staffing model ICU where approximately 2,200 patients are admitted annually. This study was a quality improvement study that was approved by the Institutional Review Board of Hospital Israelita Albert Einstein (IRB). The requirement for informed consent was waived by our IRB in accordance with the Code of Federal Regulations and the Privacy Rule. This project was carried out after our previously published study from April 2007 to September 2008.[4] Herein we report our observations for the period from October 2008 to December 2010 to evaluate whether the sustained implementation of the VAP bundle in our ICU could effectively reduce the incidence of VAP. All these hospital epidemiology data was analyzed anonymously.

The VAP bundle included elevation of the head of the bed (HOB) (30-45 degrees); daily "sedation vacations" and assessment of readiness to extubate; peptic ulcer disease prophylaxis; and deep venous thrombosis/pulmonary thromboembolism (DVT/PE) prophylaxis for all ICU patients requiring mechanical ventilation. This ventilator bundle was monitored each

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weekday by an ICU nurse. She intervened in this process while performance monitoring was taking place at the bedside if non-compliance with an element of the bundle was detected (eg, sedation was not stopped). We also intervened in other CDC evidence- based practices for prevention of ventilator associated pneumonia[3] including: 1) no routine changing of humidified ventilator circuits, 2) periodically draining and discarding condensate collecting in the ventilator tubing and, 3) changing the heat-and-moisture exchangers (HMEs) when they showed mechanical malfunction or became visibly soiled. These CDC process measures were audited twice yearly in a small sample of mechanically ventilated patients at random intervals.

Other interventions to control VAP in the ICU were implemented in October 2007 when oral decontamination with chlorhexidine 0.12% was introduced for all mechanically ventilated ICU patients.[4] In February 2008, the continuous aspiration of subglottic secretions (CASS) endotracheal tube was implemented for patients requiring mechanical ventilation and expected to require ventilation for longer than 24 hours.[4]

Previously[4] we had compared the VAP bundle alone (phase 1), with the VAP bundle + oral decontamination with chlorhexidine 0.12% (phase 2), and the VAP bundle + oral decontamination with chlorhexidine 0.12% + continuous aspiration of subglottic secretions (CASS) endotracheal tube (phase 3). We then decided to analyze our performance after almost two years of all these interventions (including the VAP bundle) to determine whether this was a sustainable program for controlling ventilator associated pneumonia. We decided to extend data collection in phase 3 (VAP bundle + oral decontamination with chlorhexidine 0.12% + continuous aspiration of subglottic secretions (CASS) endotracheal tube) to evaluate this assumption (Figure 1). In summary, phases 1, 2 and 3 (from April 2007 to September 2008) are a consequence of our previous publication.[4] We extended data collection in this present manuscript (from October 2008 to December 2010) in phase 3. We provided monthly feedback on compliance with the bundle components to the ICU team (doctors, nurses and respiratory therapists). We also displayed posters in the ICU with bar charts showing compliance with the recommended procedures. These posters also showed the VAP rate as determined in surveys conducted by the Department of Infection Control and Hospital Epidemiology.

Definitions: VAP surveillance was performed by trained infection control specialists using the US Center for Disease Control and Prevention/National Healthcare Safety Network (CDC/NHSN) definition[12] in an independence way from the treating ICU team, the incidence of VAP was expressed as cases of VAP per 1,000 ventilator-days and the incidence of ventilator associated tracheobronchitis (VAT) was expressed as cases of VAT per 1,000 ventilator-days.

VAP was defined as the sum of the clinical criteria as described the presence of fever (temperature >38°C), new or increased sputum production, in combination with radiologic evidence of a new or progressive pulmonary infiltrate, leukocytosis, a suggestive Gram's stain, and grow of bacteria (not necessarily) in cultures of sputum, tracheal aspirate, pleural fluid, bronchoalveolar lavage (BAL), or blood.[12] Per the CDC/NHSN definition, microbiological data are not necessary for the diagnosis.

VAT was defined as the presence of fever (temperature >38°C), new or increased sputum production, a microbiologically positive respiratory sample, and the absence of pulmonary infiltrates on chest radiography.

Microbiological methods: All isolates were identified by manual or automated methods and confirmed using the Vitek 2 system (bioMerieux Vitek, Inc, Hazelwood, MO).

Statistical analysis: The variables of interest were those that indicated compliance with the VAP prevention measures. We used segmented regression analysis of interrupted time series[13] to assess the changes in VAP before and after implementation of the ventilator bundle, oral decontamination with chlorhexidine 0.12%, and CASS endotracheal tube for patients requiring mechanical ventilation, according to the interventional phases (Figure 1).

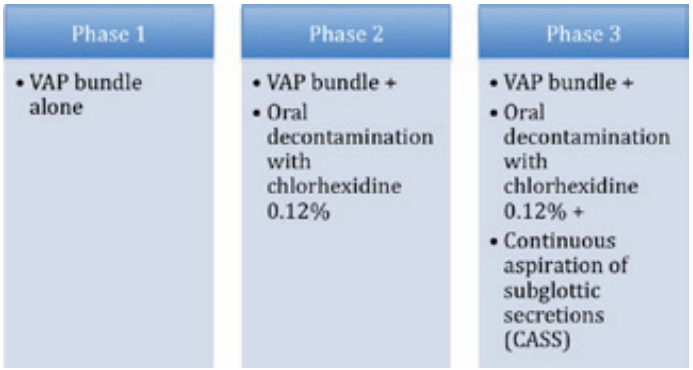

Figure 1 Study design. *Phases 1, 2 and 3 (from April 2007 to September 2008) are a consequence of our previous publication.4 We extended data collection in this present manuscript (from October 2008 to December 2010) in phase 3.

We adjusted a segmented regression model that allowed us to analyze a reduction (or an increase) in VAP rate at each study phase separately: (1) ventilator bundle only, April 2007 to October 2007; (2) ventilator bundle + chlorhexidine, November 2007 to February 2008; (3) ventilator bundle + chlorhexidine + CASS endotracheal tube, March 2008 to December 2010 (Figure 1).

The intercept and slope are the two parameters which define each segment of a time series. The intercept is the value of the series at the beginning of a given time interval, the slope is the change of the measure (VAP rate) over a certain period (eg, a month). A change in slope (β) is defined by an increase or decrease in the slope of the time step after the intervention, compared with the time step preceding the intervention. It is important to mention that this is not the same as constructing three models of simple linear regression, because the third partition parameters depend on the previous partitions' parameters. All tests of statistical significance were 2-sided with a significance level set at 0.05. All the data analyses were performed using SPSS 16.0 and SAS 9.1; SAS Institute Inc, Cary, NC, USA.

Results

Compliance with process measures in each phase: In 2009, the process measures subject to analysis included 2,396 HOB elevation observations (98.6% compliance), 611 ventilator circuits without changes (99.8% compliance) and 611 observations of HMEs changes (95% compliance). Also included in the analysis were 2,396 daily sedation vacations, gastric

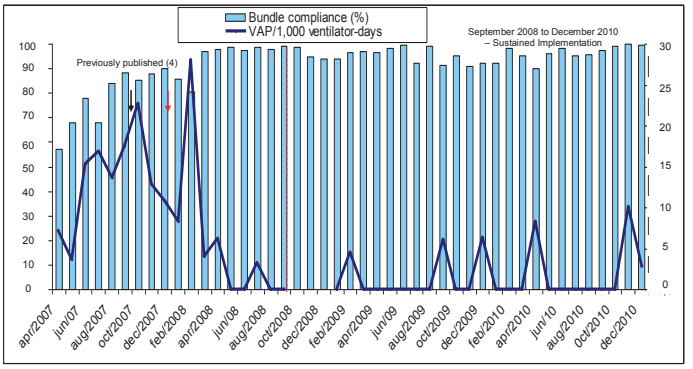

Figure 2. Bundle compliance and VAP (ventilator associated pneumonia) rate from April 2007 to December 2010. This chart shows extended data from the study published in AJIC 2009 (reference number 4). Oral decontamination with chlorhexidine 0.12% (since October/2007). Continuous aspiration of subglottic secretions (CASS) endotracheal tube (since February/2008)

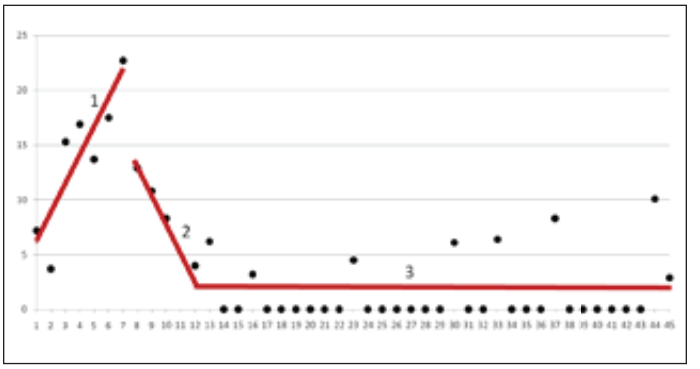

Figure 3. Segmented regression of ventilator associated pneumonia (VAP) rate per 1,000 ventilator days from April 2007 to December 2010. Segmented 1: β10 = +6.08 p = 0.004; CI 95%: [(2.06 - 10.12)]. Segmented 1 (the slope): β11 = +2.59 p <0.001; CI 95%: [(1.47 - 3.71)]. Segmented 2: β20 = –11.24 p = 0.004; CI 95%: [(–18.60) - (–3.89)]. Segmented 2 (the slope): β21 = –2.30 p = 0.272; CI 95%: [(–6.48) - 1.88)]. Segmented 3: β30 = –2.67 p = 0.682; CI 95%: [(–15.83) - 10.47)]. Segmented 3 (the slope): β31 = +0.03 p = 0.610; CI 95%: [(–0.08) - 0.13)]

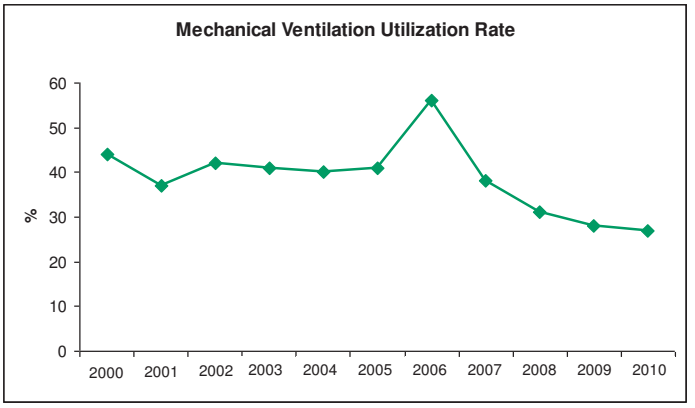

Figure 4. Secular trends of mechanical ventilation utilization rate in ICU.

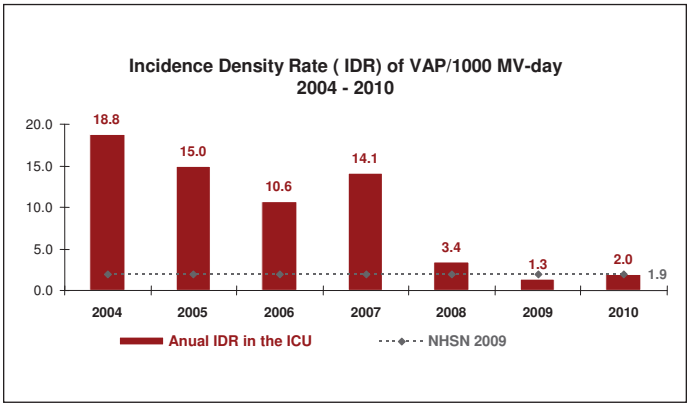

Figure 5. Incidence density rate (IDR) of VAP/1000 ventilator-days from 2004 to 2010 in ICU.

prophylaxis opportunities and DVT/PE prevention opportunities with 98%, 99% and 98% compliance, respectively. There were also 611 observations of ventilator-circuit-tubing condensate with 92% compliance. CASS was performed in 342 patients since October 2008, and all patients requiring mechanical ventilation received oral decontamination with chlorhexidine 0.12% (Table 1).

In 2010, the analysis included 2,260 HOB elevation observations (91% compliance), 390 ventilator circuits without changes (99% compliance) and 390 observations of HMEs changes (94% compliance). Daily sedation vacations, gastric prophylaxis opportunities and DVT/PE prevention opportunities had 2,486 observations with 91% of compliance in all measurements (Table 1).

Incidence density of VAP and in-hospital mortality of VAP patients: The incidence density of VAP per 1,000 ventilator days in the ICU was 1.3 in 2009 (10,889 patient-days) and in 2010 the incidence was 2 (11,095 patients-days). The incidence density of VAT per 1,000 ventilator days in the ICU was 1.0 (10,889 patient-days) in 2009 and in 2010 the incidence was 2 (11,095 patient-days).

Mechanical ventilation days, ICU length of stay, ventilator utilization ratio, number of VAPs, number of VATs, ventilator-days, ventilator-free days, in-hospital mortality of VAP patients and in-hospital mortality ICU patients are shown in Table 1.

Getting to zero VAP for one or more months has occurred since 2009 when there was greater than 95% compliance with the ventilator bundle, oral decontamination with chlorhexidine 0.12% and continuous aspiration of subglottic secretions (CASS) (Figure 2). In addition to this we continued to evaluate ventilator circuits without changes, HMEs changes and ventilator-circuit-tubing condensate.

Segmented regression analysis (Figure 3) showed a statistically significant increase in VAP rate (β11 = +2.59; $p < 0.001$) in the first segment (ventilator bundle). The transition from the first segment (ventilator bundle) to the second segment (ventilator bundle + chlorhexidine) showed a significant decrease in VAP rate (β20 = –11.24; $p < 0.001$). The slope (β21) in the second segment was negative, indicating a reduction in VAP rate upon implementation of oral decontamination with chlorhexidine (β21 = –2.30 with p = 0.272). The transition from the second segment (ventilator bundle + chlorhexidine) to the third segment (ventilator bundle + chlorhexidine + CASS endotracheal tube) was not significant in VAP rate (β30 = –2.67 with p = 0.682). In the third segment the slope (β31) was practically zero, indicating that there was no reduction in VAP rate, which was maintained along the segment (β31 = 0.03 with p = 0.610).

Microbiological features: As seen in Table 2, we had 10 cases of VAP, 4 in 2009 and 6 in 2010. Most patients were male (70%),

Table 1 Characteristics of the sustained period of "getting to zero" VAP prevention program in the ICU

	2009	2010
Patient-days (total)	10,889	11,095
Number of patients	2,705	2,717
Age, mean ± SD (in years)	67±19	66±18
Male, n (%)	1,571 (58.1%)	1,587 (58.4%)
APACHE, mean ± SD	18±6	18±7
Ventilator-days (total)	3,009	3,043
Ventilator utilization ratio	0.28	0.27
MV days – median (IQR)	4 (1–22)	3.7 (1–23)
Ventilator-free days	7,880	8,052
ICU LOS days – mean ± SD	3.9±0.4	4.0±0.3
Compliance with process measures, n (%)		
HOB observations	2362/2396 (98.6%)	2260/2486 (90.9%)
Daily "sedation interruptions"	2358/2396 (98.4%)	2273/2486 (91.4%)
Gastric prophylaxis	2393/2396 (99.9%)	2276/2486 (91.5%)
DVT/PE prevention	2363/2396 (98.6%)	2266/2486 (91.1%)
Ventilator circuits without changes	610/611 (99.8%)	387/390 (99.2%)
HMEs changed	584/611 (95.5%)	368/390 (94.3%)
Ventilator-circuit-tubing condensate	564/611 (92.3%)	360/390 (92.3%)
CASS endotracheal tube - n	342	311
Number of VAPs	4	6
Number of VATs	3	6
VAP rate per 1,000 ventilator-days	1.3	2.0
VAT rate per 1,000 ventilator-days	1.0	2.0
In-hospital mortality in VAP patients, n (%)	4/4 (100)	5/6 (83)
In-hospital mortality in ICU patients, n	196	220
In-hospital mortality in ICU patients per 10,000 patient days	180	198

CASS Continuous Aspiration of Subglottic Secretions.
DVT/PE Deep Venous Thrombosis/Pulmonary Embolism.
ICU LOS Intensive Care – Length of Stay.
HMEs Heat-and-Moisture Exchanges.
HOB Head of the Bed.
MV Mechanical Ventilation.
SD Standard Deviation.
VAP Ventilator Associated Pneumonia.
VAT Ventilator Associated Tracheobronchitis.

with a median age of 58 years old (range 20 to 85 years), the median mechanical ventilation time was 9 days (range 5 to 33 days). Eighty percent of all the microorganisms identified were gram-negative, followed by viruses (10%), and 10% unidentified microorganisms.

Pseudomonas aeruginosa accounted for over 40% of the gram-negative pathogens. The most prevalent pathogens overall were Pseudomonas aeruginosa and Acinetobacter baumannii. The majority of the pathogens were identified by tracheal aspiration. Only 25% of VAP patients (1/4) were investigate by BAL (Table 2). The mortality rate was 100% for the patients with VAP in 2009 and 83.3% in 2010.

Mechanical ventilation: The total time of mechanical ventilation was 6,052 days, with a utilization rate of 28% in 2009 and 27% in 2010 (Table 1). As seen in Figure 4, our mechanical ventilation utilization rates have been reduced since 2000, with a 17% drop from 2000 to 2010.

Discussion

Since 2007, we have set as a priority in our hospital the eradication of nosocomial infections. To this end, we have developed a set of best practices for prevention of ventilator associated pneumonia (VAP). In order to achieve a reduction in VAP rates, we have applied the Institute for Healthcare Improvement bundle model and also implemented other preventive measures (oral chlorhexidine 0.12% and CASS endotracheal tube). Our VAP rates are discussed on a monthly basis at a multidisciplinary meeting with our hospital's chief executive officer (CEO) and other senior management representatives responsible for ensuring that healthcare practices support a program for infection prevention and control that effectively prevents VAP.

Many hospitals have achieved the goal of getting VAP to zero,[14,15] while others have managed to substantially reduce VAP rates, but believe that eliminating VAP in the intensive care unit may be an unrealistic goal.[16] In a previous publication,[4] we

Table 2 Characteristics of infections causing VAP during the sustained period of "getting to zero" VAP prevention program

N	Year	Age	Gender	Diagnostic	MV time (days)	Respiratory specimen	Pathogen	Clinical outcome
1	2009	85	Male	DLOC/Hyponatremia	16	Tracheal aspirate	*P.aeruginosa*	Death
2	2009	65	Female	Hypereosinophilia/ Myelopathy	5	BAL + Tracheal aspirate	*Acinetobacter baumannii*	Death
3	2009	20	Male	Correction of GERD	19	Tracheal aspirate	*P.aeruginosa*	Death
4	2009	23	Female	Liver failure/ liver transplant	5	Tracheal aspirate	*Acinetobacter lwoffii*	Death
5	2010	56	Male	Respiratory failure/ BCP	16	Tracheal aspirate	*P.aeruginosa*	Death
6	2010	62	Male	Carotid stenosis/ Endarterectomy	8	Tracheal aspirate	*S.marcescens*	Hospital discharge
7	2010	59	Male	Chagas cardiomyopathy	10	Tracheal aspirate	*E.cloacae*	Death
8	2010	55	Female	Hepatic encephalopathy	8	Nasopharyngeal swab	RSV	Death
9	2010	61	Male	Acute respiratory failure/ BCP	33	Tracheal aspirate	*K.pneumoniae* + *P.aeruginosa*	Death
10	2010	58	Male	Cranial trauma	7	Tracheal aspirate	*E.aerogenes* + *A.baumannii*	Death

MV Mechanical Ventilation.
DLOC Decreased Level Of Consciousness.
GERD Gastroenteral Reflux Disease.
RSV Respiratory Syncytial Virus.
BCP Bronchopneumonia.
BAL Bronchoalveolar lavage.

have shown that this was only possible when the compliance with the VAP prevention bundle exceeded 95%, the CASS endotracheal tube was incorporated in daily practices and[17,18] oral hygiene with chlorhexidine was implemented.[19] In a recent systematic review and meta-analysis of patients at risk for ventilator-associated pneumonia, the use of endotracheal tubes with subglottic secretion drainage was shown to effectively prevent ventilator-associated pneumonia and to be possibly associated with reduced duration of mechanical ventilation and length of ICU stay.[18] We believe this might be the reason for our reduced time and utilization rate of mechanical ventilation, together with the daily sedation vacation included in the VAP bundle. We also believe that obtaining the commitment of all members of the ICU team was ultimately a factor in our success in the implementation of these procedures over the years.

Klompas et al[20] have called attention to the problems that may arise when we use VAP as a quality indicator, including difficulties with the subjectivity implied by the current VAP definition. Moreover, Edmond has pointed out that the "getting to zero" approach may be associated with adverse unintended consequences.[21] Moreover, the CDC/NHSN definition has been shown to have lower sensitivity than the American College of Chest Physicians definition.[22] Even though we consider it important to report VAP rates, we believe we should continuously report our compliance to the prevention measures (VAP bundle) and the adverse events associated with mechanical ventilation in ICU patients.[23] However, we were able to show that the procedures implemented since 2007 have contributed to a significant reduction in our infection rates (Figure 5) and to a decrease in the use of mechanical ventilation in recent years (Figure 4). It is important to note that our VAP surveillance was performed by trained infection control practitioners using the US Centers for Disease Control and Prevention/National Healthcare Safety Network (CDC/NHSN) definition[12] throughout the study period. Even though we have failed to demonstrate a statistically significant result using the segmented regression analysis of VAP prevention, we have achieved a zero infection rate by applying all the VAP prevention measures recommended in the literature.[8,9]

There are several limitations to this study. This is not a randomized trial but a quasi-experimental, interrupted time series study. Quasi-experimental study designs are frequently used when it is not logistically feasible to conduct a controlled trial. Thus, other unmeasured factors might have coincided with the interventions effective since April 2007 (implementation of the ventilator bundle), resulting in a decrease in VAP rates in our ICU. However, this seems unlikely because there had been no decrease in VAP rates over the previous several years (Figure 5). Data from our ICU in 2011 and in the first quarter of 2012 have shown that the VAP rate continues low (1.5 and 1.9, respectively). Finally, as this intervention was performed at a single medical center, it might be inappropriate to extrapolate our results (i.e. VAP mortality) to other hospitals. Even considering some aspects as the attributable mortality of VAP, other studies applying more sophisticated analysis such as multistate model that appropriately handle VAP as a time-dependent event or competing risk survival analysis have shown rates of attributable mortality as low as 10%.[6,24] Despite these limitations, our study further support the assumption that controlling VAP rates can be a sustained with the monitoring of multiple performance measures and quality improvement efforts.

Conclusions

The process and the outcome measures for VAP presented here are derived from published guidelines and other relevant literature. While we recognize that the VAP definition may be subject to criticism due to its many subjective aspects, we managed to keep the whole team's commitment to preventive measures for over two years, which demonstrates this is a sustainable program for preventing ventilator-associated pneumonia in the intensive care unit.

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Effect of Tracheal Suctioning on Aspiration Past the Tracheal Tube Cuff in Mechanically Ventilated Patients

Pascal Beuret, Bénédicte Philippon, Xavier Fabre, Mahmoud Kaaki

Abstract

Background: This clinical study evaluated the effect of a suctioning maneuver on aspiration past the cuff during mechanical ventilation.

Methods: Patients intubated for less than 48 hours with a PVC-cuffed tracheal tube, under mechanical ventilation with a PEEP ≥5 cm H2O and under continuous sedation, were included in the study. At baseline the cuff pressure was set at 30 cm H2O. Then 0.5ml of blue dye diluted with 3 ml of saline was instilled into the subglottic space just above the cuff. Tracheal suctioning was performed using a 16-French suction catheter with a suction pressure of – 400 mbar. A fiber optic bronchoscopy was performed before and after the suctioning maneuver, looking for the presence of blue dye in the folds within the cuff wall or in the trachea under the cuff. The sealing of the cuff was defined by the absence of leakage of blue dye either in the cuff wall or in the trachea under the cuff.

Results: Twenty-five patients were included. The size of the tracheal tube was 7-mm ID for 5 patients, 7.5-mm ID for 16 patients, and 8-mm ID for four patients. Blue dye was never seen in the trachea under the cuff before suctioning and only in one patient (4%) after the suctioning maneuver. Blue dye was observed in the folds within the cuff wall in 6 of 25 patients before suctioning and 11 of 25 after (p = 0.063). Overall, the incidence of sealing of the cuff was 76% before suctioning and 56% after (p = 0.073).

Conclusions: In patients intubated with a PVC-cuffed tracheal tube and under mechanical ventilation with PEEP ≥5 cm H2O and a cuff pressure set at 30 cm H2O, a single tracheal suctioning maneuver did not increase the risk of aspiration in the trachea under the cuff.

Background

The leakage of oropharyngeal secretions past high-volume low-pressure tracheal tube cuffs is usually considered a major risk factor for bacterial tracheal colonization and subsequent development of ventilator-associated pneumonia.[1,2] It has been demonstrated in a benchtop model that the rate of leakage around the cuff is related to the pressure differential across the cuff, namely the difference between the pressure of the subglottic fluid above the cuff and the tracheal pressure under the cuff.[3] Positive end-expiratory pressure (PEEP) improves the sealing around the cuff toward fluid leakage.[4-6] However, this preventive effect of PEEP may be compromised during prolonged mechanical ventilation by tracheal suctioning maneuver, which decreases tracheal pressure and enhances fluid leakage in vitro.[3,7,8] This clinical pilot study evaluated the effect of a suctioning maneuver on aspiration past the cuff during conventional mechanical ventilation.

Methods

Patients: The study was approved by the Committee for protection of humans in biomedical research Sud Est I. During the time of the study, the patients who needed invasive ventilation in the ICU were orally intubated with the same type of endotracheal tube (HI-LO Evac, Covidien, Elancourt, France), which is equipped with an additional lumen for access to the subglottic space above the polyvinyl chloride (PVC) cuff. The tracheal tube size was chosen by the physician in charge of the patient, usually 7-mm ID for women and 7.5- or 8-mm ID for men. Patients older than age 18 years were eligible for the study if they were intubated for less than 48 hours, under mechanical ventilation with a PEEP ≥5 cm H2O and under continuous sedation. Exclusion criteria were a known allergy to dye and hemodynamic failure. As approved by the Committee for protection of humans in biomedical research SudEst I, patients were included according to an emergency procedure. A deferred informed consent was asked from the patient's surrogate as soon as possible. As he/she recovered consciousness, a deferred informed consent was asked from the patient. If the patient or his/her next of kin refused to consent, patient's data were not entered into analysis.

The patients were studied in the semirecumbent position. At baseline, the cuff pressure was set at 30 cm H2O with a cuff inflator (Mallinckrodt Laboratories, Athlone, Ireland). Then, 0.5 ml of blue dye diluted with 3 ml of saline was instilled into the subglottic space just above the cuff. Tracheal suctioning was performed without disconnection of the ventilator, using a semi-closed system via a swivel adapter (Mallinckrodt DAR, Mirandola, Italy). The suctioning procedure was applied consistently throughout the study and was performed by the same investigator. The size of the suction catheter was 16-French, and its length was 47 cm (Vygon, Ecouen, France). The extent of negative pressure was 400 mbar, and the suctioning

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Table 1. Characteristics of the patient population.

Variable	Total
	n = 25
Age (yr)	66 (55–76)
Sex (M/F)	13/12
Height (cm)	168 (160–172)
Internal diameter of tracheal tube (mm)	7.5 (7.5-7.5)
Ratio of suction catheter outer diameter to tracheal tube internal diameter	0.7 (0.7-0.7)
Previous duration of intubation (hr)	18 (11–31)
Ramsay score	6 (5–6)
Neuromuscular blockers use	9 (36)
Tidal volume (ml)	460 (380–530)
Respiratory rate (/min)	18 (17–22)
PEEP level (cm H_2O)	5 (5–5)
Inspiratory flow (l/min)	26 (22–30)
Peak inspiratory pressure (cm H2O)	26 (23–30)

Data are number (%) or median (25th-75th percentile) values

maneuver was standardized: the suction catheter was introduced in the tracheal tube with his total length, the suction negative pressure was then applied, the suction catheter maintained in distal position during 2 seconds and then withdrawn, and the suction negative pressure was applied for a whole duration of 10 seconds. A fiber optic bronchoscopy (Pentax FI-16BS external diameter 5.2 mm) was performed before and immediately after the suctioning maneuver. The bronchoscope was advanced beyond the tracheal tube through the swivel adapter, looking for the presence of blue dye in the folds within the cuff wall or in the trachea caudal to the tube's tip.

Data collection: The following characteristics of each patient were recorded before the suctioning maneuver: age, sex, height, tracheal tube size, time from intubation, value of Ramsay score,[9] mode of mechanical ventilation, the level of set tidal volume, respiratory rate and PEEP, and peak inspiratory pressure. The main evaluation criterion was the sealing of the cuff, defined by the absence of leakage of blue dye either in the cuff wall or in the trachea under the cuff.

Statistical analysis: There was no clinical data reporting the effect of tracheal suctioning maneuver on aspiration. It was therefore a pilot study, and we decided arbitrarily to enroll 25 patients. Incidence rates were compared before and after tracheal suctioning maneuver using McNemar test. Numeric data were expressed as median (25th – 75th percentile). $P<0.05$ was considered statistically significant.

Results

Twenty-five patients were included in the study; 22 of them were admitted in the ICU for a medical reason and 3 after an emergency surgery. Table 1 displays the characteristics of the patient population at baseline. They were intubated for a median duration of 18 hours (range, 11-31). The tracheal tube size was 7-mm ID for 5 patients, 7.5-mm ID for 16 patients, and 8- mm ID for 4 patients. The median ratio of suction catheter outer diameter to tracheal tube internal diameter was 0.7 (range, 0.7-0.7). All of the patients were under continuous sedation with midazolam and analgesia with fentanyl. Nine patients were paralyzed with continuous infusion of cisatracurium. The median Ramsay score of the patients who were not paralyzed was 5 (range, 5-6). All of the patients were ventilated in volume-controlled mode. The median level of PEEP was 5 cm H2O (5-5), peak inspiratory pressure 26 cm H2O (23-30), and inspiratory flow 26 l/min (22-30).

Before suctioning, the bronchoscopy depicted blue dye around the tube just above the cuff in all patients. Blue dye was observed in the folds within the cuff wall in 6 of 25 patients and never in the trachea under the cuff. After the suctioning maneuver, blue dye was observed in the folds within the cuff wall in 11 of 25 patients ($p = 0.063$) and only in one patient in the trachea under the cuff. Overall, the incidence of sealing of the cuff was 76% before suctioning and 56% after ($p = 0.073$).

Discussion

In this study, the sealing of the tracheal tube cuff was not significantly altered by tracheal suctioning maneuver. High-volume low-pressure PVC cuffs have a diameter 1.5-2 times the diameter of the average adult trachea when fully inflated. Therefore, when these cuffs are inflated in a trachea to achieve a clinical seal, the excess material folds over itself and longitudinal channels appear in the cuff wall where subglottic secretions might leak to the lower airways. Numerous studies have shown frequent leakage of subglottic secretions past high-volume low-pressure tracheal tube cuffs, either in patients undergoing general anaesthesia[10-12] or in critically ill patients under mechanical ventilation,[11,13,14] but the level of PEEP was never controlled in these studies. It has been recently demonstrated that PEEP is a critical factor for the prevention of leakage.[4-6] In the two clinical studies where PEEP was strictly set at ≥5 cm H2O, the incidence of leakage in the trachea under the cuff was low: 10% after 5 hours,[6] and 0% after four hours in another study where the cuff pressure was checked every hour and reset at 30 cm H2O if needed.[15] However, in these two last studies, tracheal suctioning was not performed during the study period. In vitro tracheal suctioning maneuver, by decreasing tracheal pressure, induced a constant fluid leakage past the cuff, when performed either at a suction pressure of -200 cm H2O with a closed suction system,[8] or at -400 mbar with a 16-French catheter suction with a semi-closed circuit.[7] For the purpose of this clinical study, we choose this latter size of suction catheter and extent of negative pressure, because it was our clinical practice.

Yet, in this clinical study the sealing of the cuff was not significantly altered by the suctioning maneuver. The incidence of leakage of blue dye in the folds within the cuff wall was doubled after suctioning, questioning the power of this study to detect a significant difference in leakage rate. However, the crucial issue, regarding the risk of bronchial colonization and development of ventilator-associated pneumonia, is the leakage of subglottic secretions in the lower airways under the cuff,[16] which was only observed in one patient. To detect aspiration, we used blue dye as marker of subglottic secretions and bronchoscopic evaluation of leakage; this method is recognized as a reference diagnostic test and it is the sole direct method linking subglottic secretions and trachea under the cuff.[16] Several factors may explain why fluid leakage in the trachea under the cuff was constant after a suctioning maneuver in vitro but occurred rarely in this clinical study. First, in vitro fluid leakage was simulated by saline colored with blue dye. In clinical practice, subglottic secretions that pool above the cuff consist of saliva, whose viscosity may alter the pattern of leakage. Second, the plastic trachea used in vitro was connected to a test lung with a low compliance; the pressure change applied down the endotracheal tube during suctioning was then immediately transmitted around the cuff. In clinical practice,

the fall of tracheal pressure results first in lung volume loss before transmitting to the cuff. Third, the inspiratory flow from the ventilator in the clinical study (median value 26 l/min) was higher than the one of in vitro study (12 l/min). Now the degree of negative airway pressure generated by suctioning depends on the balance between the inspiratory flow from the ventilator and the suction flow.[17,18] At a constant suction flow, the lower the inspiratory flow, the lower the negative pressure in the trachea.

Our study has some limitations. First, we did not control for factors that have been shown to influence leakage, such as the level of PEEP[4,5] and the tracheal tube size.[4] Second, the cuff pressure was set at 30 cm H2O just before the suctioning maneuver to study the effect of suctioning per se. This does not reflect the clinical practice, where the cuff pressure is usually checked every 8 hours; one study showed that patients intubated with PVC-cuffed tracheal tubes spent 26% of recording time at a cuff pressure below 20 cm H2O.[19] Moreover, we are unaware of the pattern of leakage in the hours following the suctioning maneuver and we did not evaluate the effect of repeated periodic suctioning maneuvers. Finally, the suction procedure we used was the worst condition favoring leakage and does not comply with recent guidelines, which recommend a negative pressure <150 mmHg and a ratio of suction catheter outer diameter to tracheal tube internal diameter <0.5, with the objective to limit the fall of intratracheal pressure.[20] The higher the suction pressure, the greater the rate of leakage will be;[7] also using a suction catheter with a large outer diameter increases endotracheal tube resistance and aspirated gas is not rapidly replaced by the inspiratory flow from the ventilator, thus increasing the fall of intratracheal pressure.

Conclusions

In patients intubated with a PVC-cuffed tracheal tube cuff, in the conditions of the study (PEEP ≥5 cm H2O, cuff pressure set at 30 cm H2O), a single tracheal suctioning maneuver did not increase the risk of aspiration in the trachea under the cuff.

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Long-term Quality of Life in Patients with ARDS requiring ECMO for Refractory Hypoxemia

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Abstract

Introduction: The purpose of the study was to assess the long term outcome and quality of life of patients with acute respiratory distress syndrome (ARDS) receiving extracorporeal membrane oxygenation (ECMO) for refractory hypoxemia.

Methods: A retrospective observational study with prospective health related quality of life (HRQoL) assessment was conducted in ARDS patients who had ECMO as a rescue therapy for reversible refractory hypoxemia from January 2009 until April 2011 in a tertiary Australian center. Survival and long-term quality of life assessment, using the Short-Form 36 (SF-36) and the EuroQol health related quality of life questionnaire (EQ5D) were assessed and compared to international data from other research groups.

Results: Twenty-one patients (mean age 36.3 years) with ARDS receiving ECMO for refractory hypoxemia were studied. Eighteen (86%) patients were retrieved from external intensive care units (ICUs) by a dedicated ECMO retrieval team. Eleven (55%) had H1N1 influenza A-associated pneumonitis. Eighteen (86%) patients survived to hospital discharge. Of the 18 survivors, ten (56%) were discharged to other hospitals and 8 (44%) were discharged directly home. Sequelae and health related quality of life were evaluated for 15 of the 18 (71%) long-term survivors (assessment at median 8 months). Mean SF-36 scores were significantly lower across all domains compared to age and sex matched Australian norms. Mean SF-36 scores were lower (minimum important difference at least 5 points) than previously described ARDS survivors in the domains of general health, mental health, vitality and social function. One patient had long-term disability as a result of ICU acquired weakness. Only 26% of survivors had returned to previous work levels at the time of follow-up.

Conclusions: This ARDS cohort had a high survival rate (86%) after use of ECMO support for reversible refractory hypoxemia. Long term survivors had similar physical health but decreased mental health, general health, vitality and social function compared to other ARDS survivors and an unexpectedly poor return to work.

The authors are affiliated with various venues in Australia. For specific affiliations, please visit BioMed Central and type the title of the article or go to ccforum.com/content/16/5/R202. The authors wish to thank The Alfred Foundation for supporting this study with a small project grant, and would like to thank the staff of The Alfred Intensive Care Unit for their assistance, particularly Jayne Sheldrake, and the staff of The Alfred Physiotherapy Department. They also thank the patients and their families for their time and effort in follow up and wish them good health in the future. Reprinted from BioMed Central, Critical Care,

Introduction

Acute respiratory distress syndrome (ARDS) is an inflammatory condition of the lung parenchyma which can result in reduced health related quality of life up to 5 years after intensive care unit discharge.[1-5] The Australian incidence of ARDS, in the late 1990's, was reported to be 28 cases per 100,000 per annum, with a 32% (95% CI 25-40%) mortality rate.[6] In about 10% of cases, despite optimal management, patients developed sustained hypoxemia which was refractory to standard interventions and have a higher risk of mortality.[7,8] These patients frequently receive hypoxemic rescue therapies, such as recruitment maneuvers, inhaled nitric oxide, prone positioning, high frequency oscillatory ventilation or extra-corporeal membrane oxygenation (ECMO).[9-11]

Several studies have reported that ECMO may improve survival in severe ARDS, but it is potentially associated with serious complications[12-14] and there have been few studies that review the long-term survival and quality of life of ARDS patients following ECMO support.[15-18] It is unclear from the current literature if patients with ARDS have increased risk of physical, mental and cognitive disability as a result of the use of ECMO for refractory hypoxaemia.[18] Given the worldwide expansion in use of ECMO since the H1N1 influenza A pandemic in 2009, there is an urgent need to determine the long-term outcomes in survivors.[19] Decreased long term quality of life after ECMO could potentially be due to the severity of the disease, the ECMO complications or both. In a recent study of ARDS survivors from France, survivors who received ECMO as a rescue therapy had lower HRQoL (health related quality of life) compared to French age and sex matched general population at one year but not lower than age and sex matched survivors of severe ARDS who were not treated with ECMO.[18]

Australian intensive care units (ICUs) have previously demonstrated a favorable mortality profile associated with the early utilization of ECMO for refractory hypoxemia in ARDS associated with influenza.[19] However the quality of survival in this Australian patient group is unknown and therefore the aims of our study were:

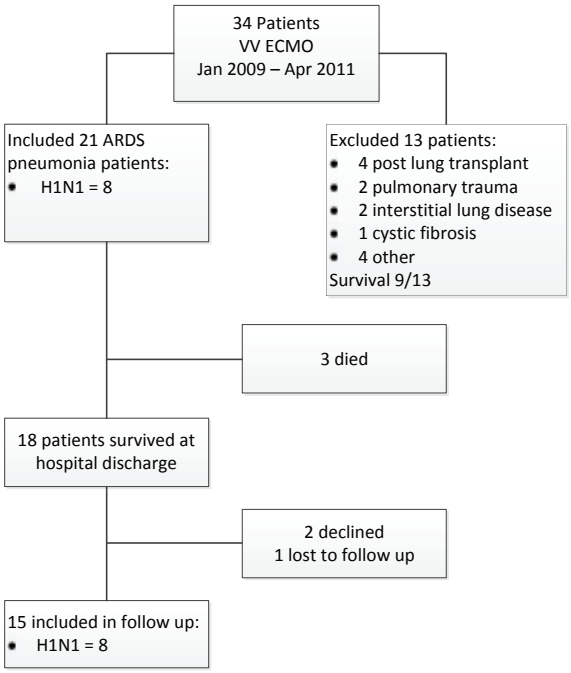

Figure 1 Flowchart of patients included in the study. ARDS, acute respiratory distress syndrome; ECMO, extracorporeal membrane oxygenation; H1N1, H1N1 influenza; VV, veno-venous cannulation.

In Australian patients previously well and receiving VV ECMO for severe hypoxemia

1. to measure the complication rates and ICU outcomes associated with ECMO
2. to pilot end points that could potentially be measured in ECMO survivors by telephone if they were retrieved from remote and rural areas
3. to measure the long term quality of survival
4. to compare our health related quality of life of Australian ECMO survivors with published international data from other research groups both with and without the use of ECMO,[17, 20] including one cohort followed up from the H1N1 pandemic[18]

Our hypothesis was that health related quality of life would be reduced in survivors of ECMO as a result of the complications of ECMO and not as a result of the severity of illness. We aimed to address this by comparing with similar international cohorts of severe ARDS. This is important as treatment of patients with severe ARDS using ECMO in Australia may demonstrate a favorable mortality profile but is an invasive and expensive rescue therapy that has yet to be proven in a randomized clinical trial.[21] If ECMO survivors did have reduced HRQoL compared to non-ECMO survivors, identification of the cause may enable clinicians to reduce the complication rate and improve HRQoL.

Materials and methods

This study was approved by the Human Research Ethics Committee at The Alfred Hospital, Melbourne, Australia, which waived the need for informed consent for the retrospective collection of demographic, physiological and hospital outcome data. However, informed consent was sought from survivors for the prospective long-term assessment of health related quality of life (HRQoL).

We studied patients with ARDS between January 2009 and April 2011 because this period was a time of high ECMO utilization due to the H1N1 pandemic. Patients were retrospectively identified from the institution's prospective ECMO database. We included all adult patients with a confirmed diagnosis of ARDS considered potentially reversible by the treating clinician.[22] Patients who were under 18 years of age or who lung disease considered irreversible (eg. cystic fibrosis) were excluded from the study. Patient's medical records were then reviewed for information regarding demographics, diagnosis, mechanical ventilation settings, pre-ECMO gas exchange parameters, ECMO technique, lung compliance and chest radiographs. Use of other rescue therapies, renal replacement therapy (RRT), vasopressors and tracheostomy was recorded.

The standard ECMO configuration for support of hypoxemic respiratory failure was veno-venous (VV-ECMO) and configured to deliver 3-7 L/min of cavo-atrial blood flow[23] driven by a centrifugal pump (Maquet-Rotaflow). A low resistance polymethylpentene oxygenator (Maquet-Quadrox-D) was used for gas exchange. Two circuit connectors were available between the pump head and the oxygenator to provide renal replacement therapy via the ECMO circuit, if required. Heparin was infused unless there was a contra-indication. All cannulae were inserted percutaneously by serial dilation without skin incision and sited using cardiac and vascular ultra-sound guidance. When the need for ECMO arose at another hospital, patients were cannulated and stabilized on ECMO by the ICU based retrieval team at their hospital of origin before being retrieved.

Patients remain in ICU for the duration of ECMO cannulation and, if successfully weaned from ECMO, until they are considered stable for transfer to the ward (no vasopressors, mechanical ventilation or hemofiltration). The ICU consultants continue to monitor patients on the ward who are discharged from ICU, but once patients are discharged from hospital there is no further follow-up and there is no specific ECMO follow-up clinic available in our state. Discharge from the ECMO hospital may occur as a ward bed becomes available at the patients original center (if the patient was retrieved), or to home or a rehabilitation center as considered appropriate by the medical team.

To assess HRQoL, patients were contacted by introductory letter explaining the nature of the study, asking for their consent to participate and informing them that they would be contacted by telephone. A trained assessor, with experience in HRQoL assessment using standardized tools then completed the Short Form 36 Quality of Life Questionnaire (SF-36v2, QualityMertric Health Outcomes, QualityMetric Incorporated, Lincoln, RI) and the EuroQol EQ-5D[24] (EuroQoL EQ5D, Rotterdam, The Netherlands) by telephone interview, and collected subjective information from the patients regarding leg weakness and/or numbness, use of ankle foot orthoses and information about return to work status.

The primary outcome variable was health related quality of life (HRQoL) measured with SF-36).[2] Other outcomes included ECMO associated complications, survival, discharge destination, HRQoL measured with the EQ5D and return to work status.

HRQoL was measured using the SF-36[2] and the EQ-5D.[17, 24] The SF-36 derives a total score from scores in eight domains: physical function, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Each item contributes to a separate domain and items are weighted to calculate transformed domain scores which range from 0–100 where 100 represent the best possible health score.[25] Two norm

Table 1 Demographics

Parameter	Result (n = 21)
Age, years, mean ±SD	36.3 ± 12.1
Male sex, n (%)	10 (48)
BMI, mean ± SD	32.1 ± 10.5
ARDS pneumonia, n (%)	21 (100)
Lung injury score, median (IQR)	4 (3.5, 4.0)
APACHE II, mean ± SD	19.9 ± 5.8
APACHE II ROD, mean ± SD	33.2 ± 18.1
APACHE III co-morbidity, n (%)*	2 (9)
Pregnancy, n (%)	3 (14)
ECMO retrieval, n (%)	18 (86)
H1N1 positive, n (%)	11 (52)

ECMO, extracorporeal membrane oxygenation; n, number; BMI, body mass index; APACHE, Acute Physiology and Chronic Health Evaluation; IQR, interquartile range; ROD, risk of death; *presence or not, of at least one co-morbidity.

Table 2 ICU patient management

Characteristics Severity of ARDS one hour prior to initiation of ECMO	N = 21
Ventilation parameters:	
Pressure control mode of ventilation, n (%)	21 (100)
Lowest PaO_2/FiO_2 ratio, median (IQR)	69 (50, 105)
Highest FiO_2, median (IQR)	1.0 (1.0, 1.0)
Highest PEEP (cmH_2O), median (IQR)	17 (15, 20)
Highest peak pressure (cmH_2O), median (IQR)	30 (27, 33)
Lowest pH, median (IQR)	7.2 (7.1, 7.3)
Dynamic lung compliance (ml/ cmH_2O), median (IQR)	16.6 (9.3, 23.1)
Quadrants of X-ray infiltrate (n), median (IQR)	4 (4-4)
Rescue therapies, n (%)	
Recruitment maneuver	16 (76)
Nitric oxide	3 (14)
HFOV	1 (5)
After initiation of ECMO	
Vasopressor, n (%)	16 (76)
Renal replacement therapy, n (%)	2 (10)
ECMO parameters	
Converted dual flow, n (%)	14 (67)
High blood flow (L/min), mean ± SD	5.2 ± 1.0
High FGF, mean ± SD	5.3 ± 1.9
Highest platelets, mean ± SD	219 ± 114
Highest Hb, mean ± SD	90.2 ± 12.7

ARDS, acute respiratory distress syndrome; ECMO, extra corporeal membrane oxygenation; FGF, free flow gas; Hb, hemoglobin; HFOV, high frequency oscillatory ventilation; IQR, interquartile range; n, number; PEEP, positive end expiratory pressure.

based component summary scores were also calculated.[26] Normative individual age and sex matched Australian population data were used for comparison with transformed domain and component summary scores.[27] The minimum important difference (MID) for SF-36 transformed domain scores has been reported to be at least five points.[28] Consistent with previous HRQoL studies in the intensive care,[2,29] a five point difference was considered clinically significant.

After a systematic search of the literature and individual correspondence with researchers reporting long term outcomes in ARDS, several international reports of HRQoL (SF-36) were chosen for comparison. These comparators were chosen if they reported HRQoL using the SF-36 at 6 or 12 months after ICU discharge. They were a general ARDS population from Canada,[2,20]

Table 3 Outcome Measures

Outcome measure	N = 21
ICU outcomes	
ICU length of stay, days, median (IQR)	20.7 (14.9, 28.6)
Duration of mechanical ventilation, days, median (IQR)	15.3 (12.0, -23.2)
Duration of ECMO support, days, median (IQR)	10.6 (3.6, 15.8)
Survival at ICU discharge, n (%)	18 (86)
Reintubation, n (%)	1 (5)
Tracheostomy, n (%)	12 (57)
Pressure areas, n (%)	17 (81)
Hospital outcomes	
Hospital length of stay, days, median (IQR)	28.4 (18.5, 37.7)
Survival at hospital discharge, n (%)	18 (86)
Cause of death, n (% of deaths)	3 (14)
Intrapulmonary hemorrhage	1 (5)
Sepsis	1 (5)
Multiple organ failure	1 (5)
Outcome of survivors	**N = 18**
Days to follow-up, median (IQR)	261 (225, 571)
Ambulant at hospital discharge, n (%)	12 (67)
Discharge destination, n (%)	
Home	8 (44)
Other hospital	9 (50)
Rehabilitation facility	1 (6)
Returned to work (n = 15)	8 (53%)
Returned to original work (n = 15)	4 (26%)

ECMO, extra corporeal membrane oxygenation; IQR, interquartile range; N, number.

a population that were retrieved for ECMO consideration in the UK[17] and an ECMO cohort described during the H1N1 epidemic by the French REVA Study Group.[18]

Summary data were collected and expressed as numbers (percentages), normally distributed data reported as means ± standard deviation (SD) and non-normal data reported as medians and interquartile ranges (IQR). For comparisons of SF-36 scores to the US and Canadian,[2,20] UK,[17] and French populations[18] Students t-test was used. Categorical variables were compared using chi-square tests for equal proportion. Analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC). To reduce the chance of a type I error due to multiple comparisons, a two sided p-value of 0.01 was considered to be statistically significant.

Results

During the 28-month period, 21 adults received ECMO support for refractory hypoxemia due to ARDS (Figure 1). The mean (SD) age was 36.3 ± 12.1 years and 52% of patients were female. Mean (SD) body mass index (BMI) was 32.1 ± 10.5 kg/m^2 with 7 (33%) patients classified obese (BMI ≥ 30 kg/m^2). Demographic data are detailed in Table 1.

The mean (SD) APACHE II score on first admission to ICU was 20 ± 6. Eighteen (86%) patients were retrieved from other ICUs by a dedicated ECMO retrieval team; two patients were retrieved from interstate centers, eight from regional centers and eight were from metropolitan hospitals. Eleven patients (52%) had H1N1 influenza A-associated pneumonitis. Three female subjects were pregnant at the time of initiation of ECMO.

Conventional ventilation and rescue therapies were used prior to ECMO (Table 2). Median (SD) lung compliance on admission

Table 4 Comparison of ARDS populations reported as mean ± SD or median (IQR)

	Current study	ECMO Group UK study [17]	REVA [28]	Non-ECMO ARDS Canada [20]
Follow-up, months	8	6	12	6
Number	21	90	12	117
Age, years	36 ± 12	40 ± 13	36 (30, 39)	45 (36, 58)
APACHE II	20 ± 6	20 ± 6	n/a	23 (17, 27)
Pneumonia (%)	100	62	100	53
ICU LOS, days	21 (15, 29)	24 (13, 41)	38 (19, 67)	25 (15, 45)
Hospital LOS, median days	28 (15, 29)	35 (16, 74)		48 (27, 77)
ECMO, %	100	76	100	n/a
Death at 6 months, n/study population (%)	3/21 (14)	33/90 (37)	24/67 (36)	78/196 (40)
Lowest PaO_2/FiO_2 ratio (day 1)	80 ± 40	76 ± 30	< 50*	< 200*
PEEP	15 ± 4.7	13.7 ± 9.6	≥ 5*	n/a

Results are presented as mean ± SD or median (interquartile range, IQR) unless stated otherwise. ARDS, acute respiratory distress syndrome; ECMO, extracorporeal membrane oxygenation; LOS, length of stay; N, numbers of patients included in the study; n/a, not available; PaO_2/FiO_2, ratio of partial pressure of oxygen to fraction of inspired oxygen; PEEP, positive end expiratory pressure; *study inclusion criteria.

to the ICU providing ECMO was 16.6 ml/cmH2O (IQR 9.3 - 23.1). All our patients were mechanically ventilated for less than 7 days prior to the initiation of ECMO. The decision to institute ECMO for severe respiratory failure is often complex. In our center, clinical triggers for VV ECMO initiation in patients include a ratio of PaO2 mmHg to FiO2 < 75 (SaO2 < 90), hypercapnea with pH < 7.15 with safe mechanical ventilation settings (plateau pressure ≤ 35mmHg and tidal volume ≤ 6 ml/Kg predicted body weight) and extensive (3-4 quadrant) lung infiltrate consistent with acute lung injury despite optimizing circulatory support (cardiac assessment with echocardiography) and inotropes or volume state therapy as appropriate, a trial of high PEEP (18-22) and recruitment maneuver (if not contraindicated) and a 2-12 hour trial of inhaled nitric oxide or alternative pulmonary vasodilator.

Eighteen patients (86%, Table 3) survived to hospital discharge and at least 17 of these people were still alive at the time of follow-up, with one lost to follow up. All three pregnant women and one fetus survived. Three patients (all with H1N1 pneumonitis) died in ICU (14%) due to the underlying severe disease process, including one patient each with severe sepsis, multiple organ failure and severe intrapulmonary hemorrhage. ECMO was provided for a median of 10.6 (3.6-15.8) days and mechanical ventilation for a median of 15.3 (IQR 12.0-23.2) days

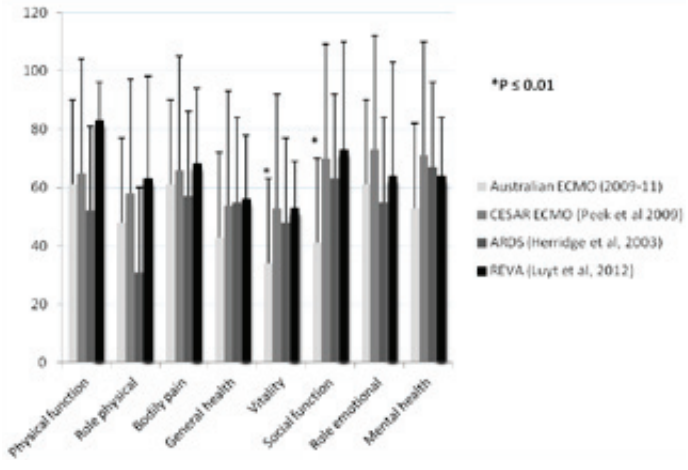

Figure 2 Comparison of adult acute respiratory distress syndrome (ARDS) survivors from different populations for Short-Form (SF)-36 quality of life (QoL). ECMO, extracorporeal membrane oxygenation; Australian ECMO, current ECMO cohort; REVA, Research in Mechanical Ventilation *(Réseau européen de recherche en Ventilation Artificielle).*

from admission to the ECMO center (Table 3). Length of stay (LOS) at the ECMO center was highly variable with ICU LOS being 20.7 (IQR 14.9 – 28.6) and ECMO center hospital LOS 28.4 (IQR 18.5 – 37.7) days (Table 3). Of the 18 survivors, 8 (44%) were discharged directly home. Nine (50%) were discharged to another acute hospital, including 3 (17%) of these to another ICU, and one (6%) to an inpatient rehabilitation facility. Only 12 (67%) survivors were ambulant at discharge. No patients described ongoing problems as a result of ECMO cannulation.

Comparison with 2 other large VV-ECMO series[15,17] (Table 4) show non-statistically significant differences in baseline variables and a shorter length of stay and lower mortality rate in our cohort. Mortality was similar to other recent Australian ECMO data[30] and has improved at our center over the past 3 years (hospital survival at our center for ARDS from 2003 – 2008 was 62% of 13 patients compared to the period from 2009 -2011 which was 86%).

Fifteen survivors (83% of 18 hospital survivors) consented via telephone to long-term follow up and were evaluated for long term outcomes and quality of life. Two refused consent to follow up and one was lost to follow up. Of these 15 patients, eight were PCR (polymerase chain reaction) positive on nasopharangeal swab for H1N1 and seven had ARDS due to other causes of pneumonia. All described bilateral limb weakness (intensive care unit acquired weakness) that continued beyond discharge and one patient had severe myopathy and polyneuropathy with ongoing disability that required a splint for the management of foot drop. Seventeen patients (81%) developed pressure injuries during their stay. No patients required ongoing use of oxygen after primary hospital discharge. Although 8 survivors (52%) had returned to work, 4 (26%) of this population had returned to previous work levels at the time of follow-up.

Sequelae and health related quality of life were evaluated for the 15 long-term survivors. Median follow up was 8.4 (IQR 6-16) months (Table 4). One patient was unable to be contacted for a prolonged period (16 months) due to a long visit overseas. There were no significant differences between patients in the study with ARDS as a result of H1N1 influenza compared to ARDS due to non-viral pneumonia for any single domain of the SF36 or for the physical component summary, although the numbers for this comparison were very small. The mental component summary score was lower for the H1N1 patients compared to non- viral pneumonia (mean 28.8 ± 13.3 versus 44.1± 13.4, P=0.04).

Table 5 Results of EQ-5D quality of life for The Alfred ARDS survivors who received VV-ECMO: comparing to other ECMO survivors

EQ5D (English v.2 © 2010 EuroQol Group. EQ-5D™ version for Australia)	Current study cohort, n = 15 (EQ5D v2, five-point scale)
Problems with mobility:	
None	7 (47%)
Slight	6 (40%)
Moderate	1 (7%)
Severe	1 (7%)
Unable	0
Problems with personal care (washing/dressing):	
None	12 (80%)
Slight	2 (13%)
Moderate	1 (7%)
Severe	0
Unable	0
Problems with usual activities:	
None	6 (40%)
Slight	2 (13%)
Moderate	2 (13%)
Severe	0
Unable	5 (42%)
Pain/discomfort:	
None	3 (25%)
Slight	5 (42%)
Moderate	5 (42%)
Severe	2 (13%)
Extreme	0
Anxiety/depression	
None	5 (42%)
Slight	2 (13%)
Moderate	3 (25%)
Severe	3 (25%)
Extreme	2 (13%)
Overall health status (VAS, 0 to 100) mean ± SD	65.9 ± 18.6

Results are presented as number (%) unless otherwise stated. ARDS, acute respiratory distress syndrome; ECMO, extracorporeal membrane oxygenation; N, number; VAS, visual analogue scale; v1, version 1; v2, version 2; VV, veno-venous.

Mean SF-36 scores were significantly lower ($P<0.05$) in patients who had received ECMO than matched healthy controls for all domains of the SF-36 except bodily pain and role emotional. This current study cohort of long-term ARDS survivors receiving ECMO support had similar scores in the domains of physical function, physical role, bodily pain, general health, role emotional and mental health compared to both comparator ARDS populations (Figure 2) but they had significantly lower scores in the domains of social function and vitality (Figure 2).

Quality of life was also reported using EQ5D (Table 5). This cohort had 5 survivors (42%) unable to perform usual activities and who described severe or extreme anxiety and depression. Interestingly, 57% of patients were ambulant at hospital discharge but 53% of survivors reported from slight to severe problems with mobility at follow-up, using the EQ5D. The majority of survivors had no problems with personal care (80%). There was no significant difference in overall health status (EQ5D - visual analogue scale 0-100) comparing our cohort with the UK CESAR study.

Discussion

Key findings: This was a small, single center long-term follow-up study of young patients with ARDS, mainly from H1N1 influenza A pneumonitis, who received rescue VV-ECMO. The survival rate was similar to other Australian published data;[30] but higher than international ECMO cohorts. Whilst these patients had a high incidence of pressure injuries and long stays in ICU and hospital, the length of stay was shorter than comparable ARDS cohorts[20] and many were discharged directly home. The HRQoL in survivors was significantly less than normal age and sex-matched Australian people, with physical and mental limitations at the time of follow up. The SF-36 domains of social function and vitality were also reduced compared to other survivors of ARDS previously reported[20] and other ECMO series.[17,18] Only a quarter of patients had returned to previous work at the time of follow up which is similar to previously described ARDS cohorts.[20]

Relationship to previous studies: On long-term follow-up, our cohort had substantial physical limitations compared with Australian age and sex matched samples. Their SF-36 physical component score was 20% lower than normal, with severe limitations in the domains of physical function, role physical, social function and mental health, general health and vitality. They also displayed reduced mental well being with their SF-36 mental component score being 27% less than normal. This was more pronounced in the patients with ARDS resulting from H1N1 compared to patients with ARDS pneumonia and may be caused by the systemic effects of H1N1 virus, rather than differences in ICU management such as the use of sedatives. This indicates frequent psychological distress and social and role disability due to emotional problems. ARDS survivors have been previously described as having considerable challenges, including reduced exercise capacity, cognitive dysfunction and depression or post-traumatic stress disorder.[31-33]

Compared to other groups of ARDS survivors in the literature, health related quality of life (HRQoL) was statistically reduced in this cohort of patients in the domains of vitality and social function (Table V).[17,20] However, consistent with previous HRQoL studies in the intensive care,[2,29] a five point difference in SF-36 transformed scores was considered clinically significant. When this definition of clinical significance was applied, this cohort had clinically reduced domains of general health, vitality, social function, and mental health.

Vitality is a lack of fatigue or feelings of energy and social function is the degree to which relationships are maintained with friends and family. It is unclear why our cohort would have reduced energy or inability to maintain social relationships compared to other survivors of ARDS. Importantly, only half of this young cohort had returned to work and a quarter of them had returned to previous work levels. Previous studies have reported an important functional association with survivors of ARDS that have moderate-severe depression symptoms and are less likely to have returned to work compared to those with less severe symptoms.[34] Depression has been reported in up to 50% of ICU survivors 12 months after discharge.[35] Psychiatric screening is also very important to assess depression and PTSD which is prevalent in ICU survivors.[2,29] However, compared with the French H1N1 cohort who received ECMO,[18] our patients who received ECMO had reduced HRQoL in both domains of vitality and social function at a median of 8 months follow-up. The study by Luyt et al (2012) found no difference between survivors of severe H1N1 that received ECMO and those that did not when assessed at 12 months after ICU. This important question needs to be further addressed in an Australian population comparing survivors of ARDS that receive ECMO compared to those that did not at the same time point.

Compared to other published series[15,17,18] of patients with ARDS receiving ECMO for refractory hypoxemia, our small cohort appeared to have good survival rates. When compared with the UK ECMO study[17] this difference was not accounted for by illness severity (Apache II, lowest PaO2/FiO2 ratio on day 1) nor patient age which were similar in both series (Table 4). It may have been accounted for by the much higher incidence of influenza A pneumonia in our cohort but when the 56 patients with H1N1 pneumonia from the UK ECMO study were separately analyzed, the mortality was still significantly higher than in our cohort (27.5 versus 14%).[36] Several factors that may have accounted for better outcomes included: the increased management of viral pneumonitis due to the H1N1 epidemic, an improved ambulance retrieval service, the ECMO technology, including ultrasound guided percutaneous ECMO cannulation, intensivist driven care from retrieval to decannulation and extensive ECMO experience (10 years) at the center.

Patients were retrieved with severe life threatening refractory hypoxemia if they did not respond to conventional rescue therapies. These included inhaled nitric oxide and recruitment maneuvers, which are consistent with previously published data[19] from Australia where the most common rescue therapies used during the H1N1 epidemic were recruitment maneuvers (67%) and inhaled nitric oxide (32%).[19] In the majority of patients in both this study (86%) and the UK ECMO study (69%), the need for ECMO arose in an external hospital and the patients were retrieved to the study center hospital. In the UK ECMO study[17] all such retrievals were performed on conventional ventilation and ECMO was initiated on arrival at the study center hospital after transfer. The UK study described three deaths before the retrieval team reached the initial hospital and two deaths in transit.

ECMO was maintained in this cohort for a long period of time in comparison to other studies of patients receiving ECMO for severe ARDS.[15,17] Despite the long duration of ECMO, our cohort had a shorter ICU and hospital length of stay at the ECMO center (Table 4) compared to the group of patients with ARDS receiving ECMO[17] or ARDS without ECMO.[20] This may be partly explained because a large portion of our cohort (50%) was discharged to other acute care facilities, mostly the destination from which they were retrieved. It may also be a result of the fact that a large proportion of our cohort had confirmed H1N1. Recent data from the H1N1 registry of the Extracorporeal Life Support Organization (ELSO)[37] showed 61% survival from 76 international centers of H1N1 requiring ECMO, including adult and pediatric data.

A large number of patients in the current study suffered from pressure injuries probably due to prolonged immobility with no long term effects as a result. This has led to a change in practice in the ICU that includes decreased time between turning patients receiving ECMO, air mattresses and mechanically rotating beds. One patient died after developing a pneumothorax prior to ECMO, then suffered a severe pulmonary hemorrhage on insertion of an intercostal catheter once ECMO and anticoagulation therapy had been commenced. One survivor suffered severe ICU acquired weakness, was discharged to a rehabilitation facility and was required to wear a splint long term for foot drop. No patients required ongoing domiciliary oxygen.

Improved survival with decreased health related quality of life places significant burden on caregivers, patients and infrastructure. Survivors have profound muscle weakness and wasting[20] which impairs exercise capacity and may be improved with early rehabilitation during the intensive care period[38,39] and a prolonged hospital stay which includes inpatient rehabilitation. More than half of our survivors reported some degree of problems with mobility at follow up (Table 5). Further research is required to establish the physical outcomes, exercise capacity and rehabilitation requirements of survivors and to identify risk factors that predict a poorer HRQoL.[31,32]

Implications of study findings: In this cohort, many patients suffered from lack of vitality and social function and reported feelings of isolation on discharge from hospital. In particular, most of this cohort did not return to previous work which may contribute to their poor social function and is different to other reports of ECMO survivors.[18] ICU outpatient review of these patients may be required to address functional limitations in survivors. While ECMO survivors had reduced HRQoL, it remains unclear whether the complications of ECMO played a role in this outcome. Future prospective studies are required to confirm these findings and are planned as part of a multi-center trial investigating outcomes of survival of ARDS patients receiving ECMO.

Limitations: This pilot study has a number of limitations. First, our major limitation is the small number of included patients, despite collection during a viral pandemic, that limits the external validity of the results. Second, owing to the nature of the pandemic, there were no injury matched controls (young, previously well patients without co-morbidities all received

ECMO if they were severely hypoxemic as a rescue therapy). Third, the data set was examined retrospectively and therefore the follow up period for health related quality if life was variable, which limits the comparison to other studies. Fourth, there is limited information on the issues contributing to a decrease in HRQoL as a result of the telephone interview process, with no in-person follow-up, although previous work examining telephone interviews has shown that the response rate is improved but patients may report more favorable health ratings.[40] Finally, we aimed to compare our results to international data that have inherent differences in the structure and provision of the ECMO service, or the management of ARDS, which may confound the results. Future work in this area, where possible, should include larger numbers with a comparator group without ECMO from the same population.

Conclusions

The high survival rate of patients receiving ECMO for severe ARDS in Australia was associated with reduced health related quality of life compared to the normal population, and also compared with other ARDS survivors, particularly in the SF-36 domains of vitality and social function. Few of the survivors returned to previous work levels. The results highlight the importance of long-term follow up and support of patients on discharge from the ICU and emphasize that traditional short term end-points in clinical studies do not always reflect long term outcomes.[41]

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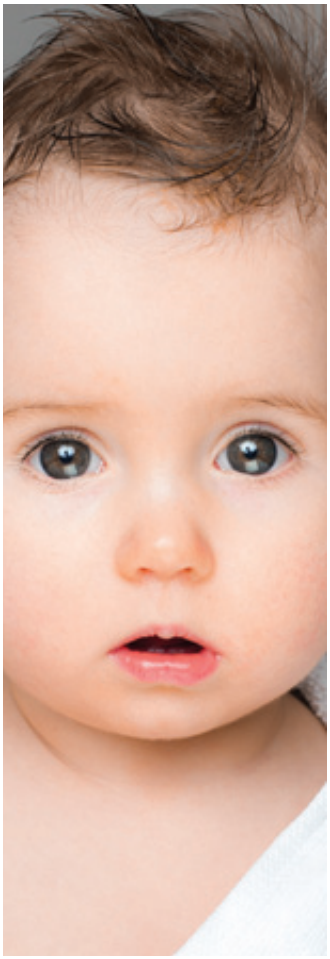

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