Volume 1 Number 6 October-November 2006

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The Journal of Pulmonary Technique

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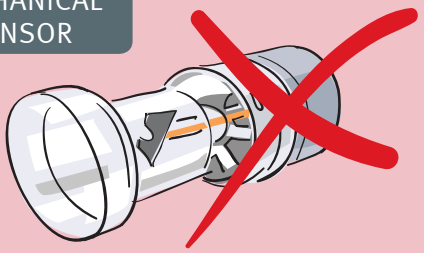

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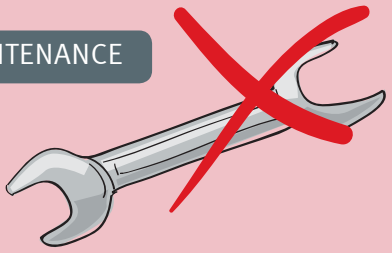

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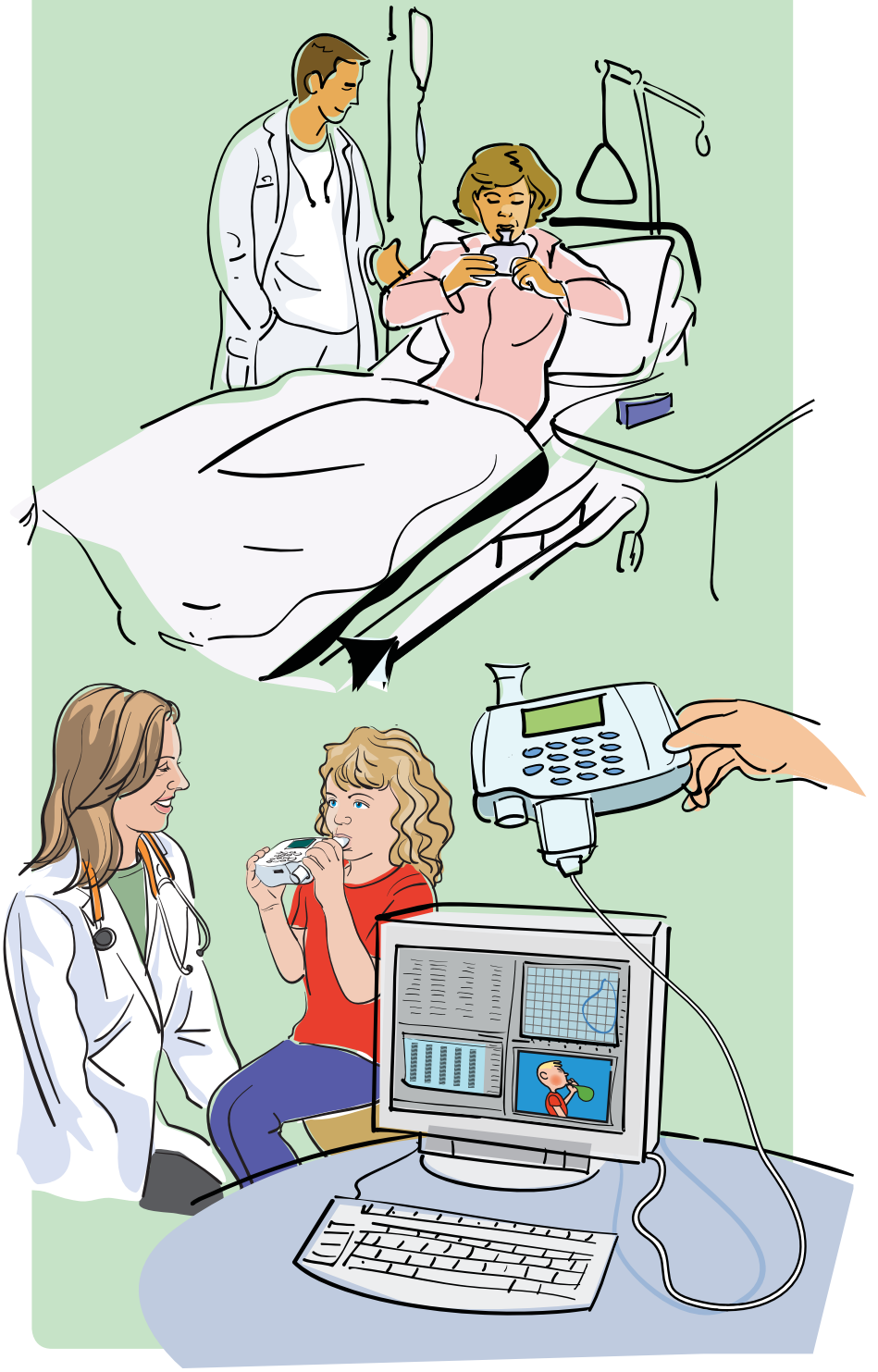

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Website: www.respiratorytherapy.ca

Publisher
Steve Goldstein

Editor
Les Plesko

Senior Editor
Carol Brass

Design and Production Management
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This is recommended by the ARDS Network's publication, funded by the National Heart and Lung Institute, which showed a 22% lower mortality with low TV ventilation strategy in patients with ALI or ARDS.[1]

Fig 1 - Rate Automatically Changes with Changing Compliance
(VAR-Plus with in-line PEEP Valve)

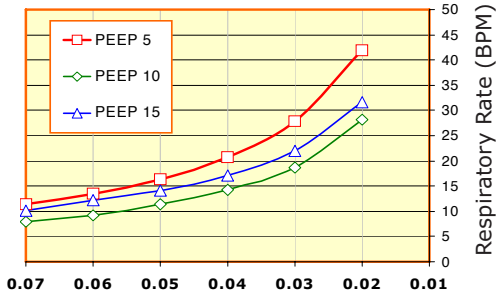
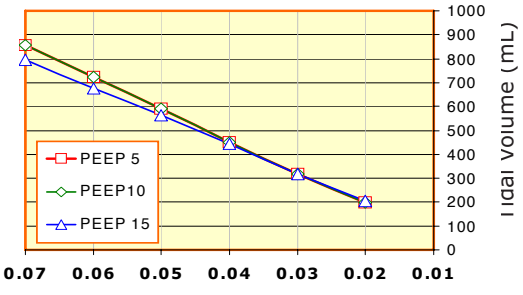


Fig 2 - TV Automatically Changes with Changing Compliance



The VAR automatically delivers a lower TV and a higher rate and is ideal for ARDS patients with decreasing compliance.

[1]Kallet, Richard H MS RRT: Implementation of a Low Tidal Volume Ventilation Protocol for Patients with Acute Lung Injury or Acute Respiratory Distress Syndrome. Respir Care 2001:46(10):1024-1037

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7/06-C

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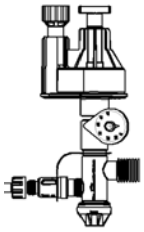
The working mechanism of the VAR consists of a moving piston or diaphragm which has mass (weight). The mass adds an additional spring force or a subtraction of spring force when the VAR is positioned with the modulator vertically up or vertically down.


Modulator vertically **UP**


Modulator vertically **DOWN**

If the VAR is moved from a horizontal to a vertical position, the addition or subtraction of spring force will affect the PIP setting by 1 to 3 cm-H_2O.

	VAR	VAR -Plus
PIP increased **UP** position	**2.4**	**1.0**
PIP decreased **DOWN**	**-2.9**	**-0.9**

The positional effect on PIP is an education and training issue. The VAR will function in any position as long as the final adjustments are made in its secured position.

Editorial

FACING A CRISIS?

In the latest issue of Hamilton Medical's newsletter, respiratory therapist Paul Garbarini asks, are RT departments facing a crisis? Says Garbarini, "RT departments are facing the same staffing shortages seen in other healthcare professions. This need is further exacerbated by the legitimate push to implement ICU process improvement strategies which include ventilator bundles, daily screening for spontaneous breathing trials, reduced errors etcetera."

To back up his assertion, Garbarini cites a recent issue of Critical Care Medicine that reports Bureau of Labor statistics which estimate a 43 percent increase in demand for respiratory therapists by 2008. Respiratory therapy is now said to be among the top 10 growth fields through the end of this decade. What does this portend for effective levels of care?

Let's look at the evidence. The Critical Care study by Paul Mathews, et al, sought to explore respiratory therapy manpower needs in critical care practice. The authors delineated the historical development of respiratory care, as well as its credentialing system, and collected data from AARC, NBRC and CoARC. The authors conducted a thorough survey about the use of mandatory overtime in RT departments, followed up by a questionnaire from a wide range of institutions where RTs worked.

Critical Care's study found a stable attrition rate of about 30 percent, and varying enrollments, and found that half the hospitals had a policy addressing mandatory overtime, while a lesser number had instituted disciplinary procedures for RTs who refused overtime. Seven of the 30 hospitals queried indicated that they used mandatory overtime frequently to keep up staffing levels. The actual ratio of beds and RCPs wasn't too far off recommended levels, but with an exponential increase of need on the way, it's only a matter of time before the need for RTs is bound to hit the critical point. According to the study abstract, "by two focused surveys, we were able to show that while mandatory overtime is a common practice in respiratory care departments, it was not overwhelming utilized. We also learned that in most hospitals, regardless of bed size, there is a perceived need for 1.3 RCPs more than the actual staff and that it appears that the critical staffing level between actual to preferred RCP to beds is between 9 and 11 beds." Another study in the same issue of Critical Care Medicine noted that "productivity, practice patterns, the aging of the workforce and patients, and other major determinants are only minimally affected by most government policy. Despite several attempts throughout the 1980s and 1990s, demand for health care has been particularly difficult to control for policymakers… There are many barriers to successful workforce policy… The task before those concerned about workforce issues is to educate policymakers about how changes in the physician workforce will affect cost, access, and quality, and to impress upon them that serious efforts to improve quality of care and reduce costs will not be effective unless qualified physicians are there to provide that care."

In his article, Garbarini notes, by way of example, that the California Code of Regulations states that the ratio of therapists to ventilators should be no greater than one to four. The average respiratory therapist is assigned to about 10 ventilator patients. Obviously, eventually, something's going to give. As recent historical events show, there's a marked tendency to deal with problems after the horses are already out of the barn. So why not start dealing with this now?

Les Plesko, Editor

For more information see the study, Respiratory Care Manpower Issues, Model and Workforce, Critical Care Medicine, Interface of Public Policy and Critical Care Medicine. 34(3) Suppl:S32-S45, March 2006. Mathews, Paul PhD, RRT, FCCM; Drumheller, Lois BS, RRT; Carlow, John J. EdD; with the assistance of the American Association for Respiratory Care; The National Board for Respiratory Care; The Council on Accreditation of Respiratory Care.

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News

☐ October-November 2006

LETTER

Last night I finished reading your journal (Vol 1, No 5) and thought that I would send a note of congratulations to you – it is excellent! I read the editorial and the entire News section which is better than most trade magazines to keep up on what's going on. I was [also] surprised by the topic coverage and number of articles. Nice job. P.S. Our ad looked good, too.

Norman H Tiffin BSc, RRT, MSA
Vice President, Marketing
Pari Respiratory Equipment

PLACEBO EFFECT

A study carried out by researchers from Manchester University, UK, found that codeine is statistically no better than a placebo for treating COPD patients for cough. The Journal of Allergy and Clinical Immunology reported that researchers tracked 24 COPD patients' coughing by placing a microphone on their lapels. Half the patients were given codeine while the other half received a placebo. Their coughing was tracked for a period of ten hours after taking their medication. At the beginning of the period both groups of patients had an average coughing total of 8.27 seconds per hour. After taking their medications, the placebo group's coughing dropped to 7.22 seconds per hour and the codeine groups coughing dropped to 6.41 seconds per hour. There was no difference between the codeine and the placebo from a statistical standpoint, even though the codeine dose their volunteers received was far higher than any OTC dose found in standard cough remedies. Very little had been known about its impact on patients with chronic lung diseases.

EXACERBATED

New data from a multinational, interview-based patient study, published in the medical journal Chest, shed light on COPD patients' comprehension, recognition, and experience of exacerbations and the burden associated with these events. Exacerbations are known to impair health-related quality of life in patients with COPD and increase the risk of mortality. The study showed that physicians often underestimate the psychological impairment experienced by patients during an exacerbation. Exacerbations cause substantial anxiety, patients reported; 12% stated they worry about dying, 10% that they worry about suffocating, 10% that they will experience a permanent worsening of their condition and 8% that they will be hospitalized. A majority of patients reported that besides influencing their activities in daily life, a significant worsening of their mood causing a variety of negative feelings, such as depression, irritability/bad temper, anxiety, isolation, anger, and guilt. Moreover 42% stated that exacerbations affected their personal relationships. According to the study, the observation that physicians fail to appreciate the considerable changes to the patient's emotional well-being demonstrates a communications gap between patients and their doctors and represents a dilemma in COPD management that may lead to

undertreatment. The study was conducted with 125 patients diagnosed with COPD from France, Germany, Spain, Sweden and the UK. The patients were age 50 or younger and had experienced a minimum of two exacerbations during the previous year. Sixty five percent were male COPD patients who, during the previous 12 months, had experienced a mean of 4.6 exacerbations with an average duration of 2 weeks and a mean recovery time of 10 days. Notably, 20% felt that they had not returned to their previous state of health after an exacerbation, demonstrating the importance of reducing these events. As a sidenote, the study reported that only 1.6% of patients understood what was meant by the widely used clinical term "exacerbations." The term used most often by patients to describe an exacerbation was "crisis," underscoring the seriousness with which patients view the worsening of their condition. Two-thirds of patients stated they were aware of the symptoms associated with their condition getting worse. Most patients (85%) experienced the same symptoms from one exacerbation to another, breathlessness being predominant. At the onset of an exacerbation, 33% of patients reported that they react by self-administering their medication while only a minority contact their physician. Reported in Medical News Today.

FLUTE OR FLUKE?

Researchers at Karolinska University Hospital, Solna, Stockholm, Sweden investigated whether bronchial responsiveness to leukotriene D4 is reduced by fluticasone propionate. The researchers conducted their research by having the study's 13 volunteers participate in an inhalation challenge with methacholine and leukotriene D4 on consecutive days before and after two weeks of treatment with inhaled fluticasone twice daily. Study results showed that although the fluticasone propionate therapy vs placebo for two weeks caused a significant reduction in methacholine sensitivity and in exhaled nitric oxide, it had no effect in blocking the bronchoconstriction that occurs when leukotrienes are inhaled, nor does it influence the production of leukotrienes, as measured in the urine. The clinical implication of the study, according to the authors, supports synergistic therapy with an inhaled corticosteroid as well as an oral antileukotriene for certain, persistent asthmatic patients.

MISDIAGNOSIS

A new study shows that more than half of patients with COPD – chronic obstructive pulmonary disease – may be misdiagnosed as having asthma. COPD is a progressive condition that leads to a worsening of respiratory symptoms, a decline in lung function and increased disability; however, it tends to be under-diagnosed and under-treated. The study results, published in the Journal of Asthma, are from the most recent prospective, patient-reported, objectively documented COPD study to examine COPD misdiagnosis.

COPD, which includes chronic bronchitis and emphysema, is characterized by a loss of lung function over time. Primarily a disease of current and former smokers, COPD affects nearly 12 million Americans. Unlike asthma, COPD is associated with a cascade of decline that leads to a diminished quality of life over time. The study, conducted in Denver and Aberdeen, Scotland, and sponsored by Boehringer Ingelheim Pharmaceuticals, Inc and Pfizer Inc, analyzed data from 597 patients age 40 and older with a history of lung disease or recent treatment with respiratory medications. Patients were then screened using spirometry, a lung function test, to confirm their diagnosis of COPD. In this study, a COPD diagnosis was defined in agreement with American Thoracic Society and European Respiratory Society guidelines as the presence of obstruction, the inability to get air out of the lungs, based on spirometry results. Of the 235 patients diagnosed with COPD by spirometry, 51.5% reported a prior diagnosis of asthma only. Only 37.9% of participants diagnosed with COPD based on the study tests reported a previous diagnosis of the disease, while 10.6% reported no prior diagnosis of COPD or asthma. Researchers said the findings were surprising given the availability of credible diagnosis and treatment guidelines specifically for COPD, and noted that patients could benefit from lifestyle modification, pulmonary rehabilitation and proper pharmacotherapy.

CHRONIC

A Europe-wide trial involving premature babies is investigating whether the risk of chronic lung disease can be halved if they are given nitric oxide gas to breathe shortly after birth. Medics from the University of Leicester, King's College London and Medway hospitals are involved in the trial. Results of a similar US based study have recently been published in the New England Journal of Medicine. Doctors involved in the study said the research is potentially very important but that there was a long way to go before an understanding could be reached about the best way to use nitric oxide and the babies that could be most helped. The intervention is very costly and this was only the second study to show a positive effect in premature babies, while half a dozen other studies have had either no effect or a negative effect. It also appeared not to have helped the sickest, most premature babies. Another similar study in the US won't be ready for two more years.

SIGH

A new study in the online edition of the American Journal of Physiology-Lung Cellular and Molecular Physiology shows that low tidal volume combined with periodic deep inflation provides the best balance between keeping the lung open and preventing VILI in mice. And, using mice, these researchers have shown for the first time that although deep inflation is necessary, it can be overdone. There is still a lot of controversy and uncertainty about how best to ventilate the lung, said the study's senior author. One controversy is whether deep inflations, the sighs that each of us takes periodically, should ever be given, and if so, how frequently. The researchers divided mice into three experimental groups. All three groups received PEEP and low tidal volume air. Each group was ventilated for two hours. The experimental groups differed according to how many deep inflations they received. They were as follows: HV received one deep inflation each breath, LV received two deep inflations each hour, and LVDI received two deep inflations each minute. In addition, there were two control groups, a surgical sham, which received no ventilation, and a group that received deep inflation every breath and no PEEP. The study found that the lungs of the mice given two big breaths every minute (LVDI) remained more open and functioned better than the LV and HV. The lungs of the mice that received only two deep breaths per hour (LV) became stiff and portions of the lungs collapsed. However, lung function returned briefly to normal when the mice received their infrequent deep inflations. This suggests that the lungs self-repair after the deep inflation, at least over the course of the first two hours. The lungs of the mice that received deep inflation every breath (HV) suffered overdistention injury to their lungs. This group was akin to a

high tidal volume group, once again demonstrating that low tidal volume is safer. The control group that received high tidal volume but no PEEP showed the highest evidence of injury, even higher than the high tidal volume group. This indicates that PEEP helps reduce the negative effects of frequent deep inflation. The researchers said they demonstrated that it's possible to give deep breaths too frequently and too seldom. The middle ground, two deep inflations per minute, provided the most benefit to the mice without injuring the lungs.

LUNG RECRUITMENT

Writing in Hamilton Medical's latest newsletter, authors Justin Tse, RRT-NPS and Jeff Borrink, BS, RRT, discuss lung recruitment in patients with ARDS: Acute respiratory distress syndrome (ARDS) was first described in 1967 by Ashbaugh, who described a syndrome of severe respiratory failure associated with pulmonary infiltrates, similar to infant hyaline membrane disease. In 1994, the American-European Consensus Committee defined ARDS as the acute onset of bilateral infiltrates on chest x-ray, a partial pressure of arterial oxygen to fraction of inspired oxygen ratio of less than 200 mm Hg and a pulmonary artery occlusion pressure of less than 18, or the absence of clinical evidence of left arterial hypertension.

The development of ARDS starts with damage to the alveolar epithelium and vascular endothelium resulting in increased permeability to plasma and inflammatory cells into the interstitium and alveolar space. Damage to the surfactant producing cells and the presence of protein-rich fluid in the alveolar space disrupts the production of pulmonary surfactant leading to microatelectasis and impaired gas exchange. Mechanical ventilation is usually initiated to restore adequate oxygen to the tissues. However, we have learned that mechanical ventilation itself can cause or enhance the effects of ARDS. Because of this, management has changed from maintaining "normal gas exchange" to decreasing the possibility of ventilator induced lung injury. Lung protection strategies generally utilize two main components: low tidal volumes to prevent stress and strain to lung parenchyma, and higher levels of PEEP to prevent derecruitment injury. Some studies utilizing low tidal volume strategies have been shown to increase survivability. Other studies have shown improved patient outcomes with higher levels of PEEP. A recent study by Gattinoni, et al looked at the relationship between the percentage of potentially recruitable lung, as indicated by computed tomography (CT), and the clinical and physiological effects of PEEP.

The study looked at 68 patients with acute lung injury (ALI) or ARDS. Nineteen patients had ALI without ARDS and 49 had ARDS. The overall mortality rate was 28 percent. Each patient underwent whole-lung CT during breath-holding sessions at airway pressures of 5, 15, and 45 cm of water. The percentage of recruitable lung was defined as the proportion of lung tissue in which aeration was restored at airway pressures between 5 and 45 cm H_2O. The percentage of potentially recruitable lung varied within the study population. The average was 13 +/- 11 percent of the lung weight, which corresponded to an absolute weight of 217+/- 232 g of recruitable lung tissue and correlated with the percentage of lung tissue which was recruited after the application of PEEP. On average, 24 percent of the lung could not be recruited. Gattinoni, et al reported that patients with a higher percentage of potentially recruitable lung had greater total lung weights, poorer oxygenation, higher levels of dead space, and higher rates of death than patients with a lower percentage of potentially recruitable lung. They concluded that in patients with ARDS, the percentage of potentially recruitable lung is extremely variable and is strongly associated with the response to PEEP. The study by Gattinoni et al generated several responses by physicians who wrote letters to the editor of the NEJM. One such response came from Drs Amato, Borges, and Carvalho, from the University of Sao Paulo. They believed that the study by Gattinoni et al suggested that the potential for lung recruitment in patients with acute lung injury is generally low and extremely variable among patients, and that this was due to a suboptimal recruitment maneuver that was used in the Gattinoni study. Dr. Amato et al referred to other studies that demonstrate a much larger potential for recruitment and greater homogeneity of response. They argued that Gattinoni et al used an inspiratory plateau pressure of 45cmH_2O, which is lower than the critical opening pressures reported in other recent studies in humans. They also argued that Gattinoni et al. allowed pressures to repeatedly fall to 5cmH_2O, which is a pressure below the closing pressures of most lung units. They go on to say that this procedure was likely to have cyclically forced the energy provided by the next pulse of inspiratory pressure to be wasted in the opening of the recollapsed units, instead of promoting the recruitment of units. They suggest that the application of the same inspiratory pressure, but a higher expiratory pressure (20 to 25cmH_2O) could have greatly enhanced the efficacy of the maneuver, thus affecting the main conclusion of the study by Gattinoni et al.

Another response by Dr Kacmarek et al expressed surprise at the level of lung recruitment by Gattinoni. Based on previous studies of recruitment maneuvers, they would have expected a higher level of recruitable lung than what was demonstrated in the Gattinoni study. They suggest that the lack of response may have been due to the length of time for which patients received mechanical ventilation (5+/-6 days) before being studied, and refer to studies that recommend lung recruitment be performed as early as is feasible in the course of ARDS.

LET IT STINK

New research shows that a chemical compound found in many air fresheners, toilet bowl cleaners, mothballs and other deodorizing products, may be harmful to the lungs. Human population studies at the National Institute of Environmental Health Sciences (NIEHS), a part of the National Institutes of Health, found that exposure to a volatile organic compound (VOC), 1,4 dichlorobenzene, may cause modest reductions in lung function. "Even a small reduction in lung function may indicate some harm to the lungs," said NIEHS researcher Stephanie London. The researchers examined the relationship between blood concentrations of 11 common volatile organic compounds and lung function measures in a representative sample of 953 adults. VOCs are a diverse set of compounds emitted as gases from thousands of commonly used products, including tobacco smoke, pesticides, paints, and cleaning products. VOCs are also released through automotive exhaust. The researchers found that of the common VOCs analyzed, which included benzene, styrene, toluene, and acetone, only the compound 1,4 DCB was associated with reduced pulmonary function and this effect was seen even after careful adjustment for smoking, The researchers found that 96 percent of the population samples had detectable 1,4 DCB blood concentration levels. African Americans had the highest exposure levels and non-Hispanic whites the lowest. The particular VOC tested, 1,4 DCB, is a white solid compound with a distinctive aroma, used primarily as a space deodorant in products such as room deodorizers, urinal and toilet bowl blocks, and as an insecticide

fumigant for moth control. The researchers used data from the third National Health and Nutrition Examination Survey (NHANES) and a special component of the study specifically designed to assess the level of common pesticides and VOCs in the US population. Data from 953 adults 20-59 years old who had both VOC blood measures and pulmonary function measures are included in the study published in the August issue of Environmental Health Perspectives. Four pulmonary function measures were used in the analyses. The researchers found modest reductions in pulmonary function with increasing blood concentrations of 1,4 DCB. There was approximately a 4% decrease in the test which measures FEV1 between the highest and lowest levels of exposure. The research suggested that 1,4-DCB may exacerbate respiratory diseases.

PRODUCTS

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Nonin announced a new Soft Sensor line to complement its comprehensive family of PureLight pulse oximetry sensors. The new line of soft sensors features a durable design that delivers consistent performance. The soft sensors perform like two sensors in one for spot-checks or continuous monitoring, with patient comfort in mind. Available in three sizes, the soft sensors are flexible for use in many medical settings including EMS, hospital and sleep. Soft sensors are easy to clean, latex-free and come with a one-year warranty. For more information contact nonin.com, (800) 356-8874.

KEEP IT IN PROPORTION

Puritan Bennett, maker of the world's best-selling critical care ventilator, the 840 ventilator, is pleased to introduce an innovative, advanced software option for mechanical ventilation to the U.S. market. The new PAV+ Proportional Assist Ventilation Plus software option delivers positive airway pressure that is directly related to a patient's inspiratory effort during spontaneous breathing. Ventilator support increases as patient demand increases, thereby optimizing the patient's contribution to the total work of breathing. The original concept of providing breathing assistance in proportion to patient inspiratory effort was invented by Dr Magdy Younes at the University of Manitoba. The basic technique amplifies the patient's inspiratory effort by increasing airway pressure during inspiration. The new PAV+ software feature, available exclusively from Puritan Bennett for its flagship 840 ventilator, augments the benefits of the basic technique by employing a sophisticated software algorithm – the "plus" – that automatically adjusts the positive airway pressure based on airway pressure measurements taken throughout the inspiratory cycle. This maintains a targeted degree of support pressure throughout each of the patient's spontaneous breaths. An appropriate support pressure is maintained based on the workload a patient needs to overcome to breathe. A clinician simply sets the target level of support desired (shown on the monitor as % Support). At a setting of 60%, for example, the ventilator performs 60% of the work of inspiration and the patient performs 40%. The PAV+ software option also graphically displays real-time assessments of patient work, airway resistance and lung compliance. This information can assist the clinician in assessing the best treatment approach for the individual patient at any given time. "The ability to turn a sophisticated clinical concept into an innovative, easy-to-use product feature is one of Puritan Bennett's core strengths," said Brent Boucher, Vice President, General Manager. "Clinicians rely on our design expertise to incorporate exceptional features into our ventilator products that can facilitate patient management. Our new PAV+ product is a very powerful tool to improve patient care." The PAV+ software option is intended for use on any patient weighing more than 25 kg who is spontaneously breathing during mechanical ventilation. Contact tycohealthcare.com, puritanbennett.com.

SMALL BUT SMART

Respironics announces the release of its new Mini*Elite* Compressor Nebulizer System for active patients who want to take their aerosol treatments wherever or whenever. The small and lightweight Mini*Elite* compressor is easy-to-use and provides efficient nebulizer treatments. This stylish, elegant compressor provides portability and can be powered by three versatile power source options, AC, car adapter and battery. The optional rechargeable lithium ion battery operates the Mini*Elite* compressor for up to 90 minutes between charges. This battery technology offers easy and fast re-charging in a lightweight design. The Mini*Elite* compressor weighs less than 1 pound and less than 1.4 pounds with the optional battery attached. "The patient-friendly design of the Mini*Elite* fits the lifestyle needs of patients," said Matt Conlon, Director of Sales and Marketing for Respironics Respiratory Drug Delivery business, "while meeting homecare providers need for cost effectiveness and product reliability." Respironics Respiratory Drug Delivery is advancing the science of respiratory care with innovative drug delivery technologies for the treatment of respiratory and non-respiratory diseases. Through ongoing research, Respironics RDD provides breakthrough solutions for pharmaceutical companies, healthcare providers and patients. Respironics is a leading developer, manufacturer and distributor of innovative

products and programs that serve the global sleep and respiratory markets. Focusing on emerging market needs, the Company is committed to providing valued solutions to help improve outcomes for patients, clinicians and health care providers. Respironics markets its products in 131 countries and employs over 4,700 associates worldwide. Further information can be found at respironics.com.

DEDICATED

Nova Biomedical announced the addition of a new model to its series of Stat Profile pHOx Analyzers providing a dedicated test menu for respiratory care. The new Stat Profile pHOx incorporates a seven-test menu, including pH, PO_2, SO_2%, hemoglobin, hematocrit, and lactate, to provide a comprehensive diagnostic picture of oxygen transport. The compact analyzer uses a liquid-only calibration system that eliminates bulky compressed tanks, gas regulators, gas tubing lines and humidifiers. To promote blood conservation, the pHOx uses just 125 uL of whole blood to measure the full seven-test menu, and only 60 uL of whole blood for a three-test micro-sample. Contact novabio.com.

BREATHE DEEPLY

Since its inception, Inogen has been dedicated to the design, development and manufacture of clinically efficacious oxygen technologies. The lack of substantial research in the area of long-term oxygen therapy and oxygen technologies has long made the provision of home LTOT a blend of art and science. Inogen recognizes that its technology is part of a paradigm shift and is leading the industry in changing the provision of LTOT in a new direction. Inogen discarded existing paradigms to design and build an oxygen concentrator that redefines how oxygen therapy is delivered. Described by industry experts as "a technological breakthrough," the Inogen One is a complete departure from current mainstream technologies, both the standard large, bulky, stationary concentrator systems and the inefficient and impractical portable devices. Working with experts in PSA and conserver technology, Inogen's engineers developed, tested and delivered a technology that eliminates the need to choose between a stationary or portable oxygen system.The Inogen One enhances the clinical efficacy of pulse-dosed oxygen delivery in a myriad of clinical applications, including sleep, and for patients with COPD. The Inogen One's technology has been thoroughly bench-tested and clinically validated through original science and work. Contact inogen.net.

LEGACY

B&B Medical Technologies carries on the legacy of Stephen Briggs III. A new team has assumed ownership and management of B&B Medical Technologies, a leading designer of specialty airway management devices and nebulizers for infants, pediatrics and adults. Continuing B&B's legacy as a respiratory therapist-owned company are David Thompson and Beth Keifer, who together bring more than 50 years in clinical, educational and technical expertise in the respiratory care field. Thompson and Keifer are supported on the core team by Robert Sprowls, a Carlsbad, CA businessman. B&B products are designed for easy, one person application, helping to minimize risk of accidental disconnects and unplanned extubations. B&B's StabilTube, LockTite, ET Tape for Adults and Infants and Bite Block provide clinicians simple solutions for comfortably securing the endotracheal tube, prevention of ventilator disconnects and a convenient answer to prevent ET tube biting. B&B's TrachGuard and TrachStay comfortably secure the ventilator circuit to the tracheostomy tube while preventing accidental disconnects. B&B's patented Hope nebulizer technology provides efficient delivery of continuous medication combined with the ability to blend gases such as Heliox without affecting medication delivery. The Hope Nebulizer is the first nebulizer specifically cleared by FDA for Heliox administration. Stephen Briggs III along with Dr. Ernie Bodai created B&B Medical Technologies in 1985 to ensure that specialty airway related products had a pathway to the clinical community. Briggs' legacy, earned through his lifetime in the respiratory therapy community will be carried on in the new ownership and management. Contact bandb-medical.com.

Fluke Biomedical

Jerry Zion

Jerry Zion is Product Manager for Fluke Biomedical.

Who is responsible within your company, by title or name or job description, for training and education of your staff and your customers?

Product managers are responsible for training the technical support and sales staff (including all worldwide channel partners) as part of the release of any new product or product enhancement. After that, the technical support associates provide help-desk and refresher training for end-users, and the sales staff (including channel partners) provide initial training for end-users when they take delivery of products purchased from Fluke Biomedical.

What types of education do you provide?

Fluke Biomedical provides initial training for end-users, and educational seminars and presentations at local biomedical society and respiratory therapy society and association meetings. The subject matter is always related to testing the performance of medical devices against their manufacturer's specifications and (in the case of medical device manufacturers) against the IEC standards and/or the national standards (whether harmonized with IEC or not).

How do you manage "off-hours" assistance for clinical questions?

Our Technical Assistance Center (TAC) is open Monday through Friday from 7 AM to 4 PM Pacific Time. Voice mail and e-mail are checked promptly after 7 AM and are responded to in a timely matter. When questions require research and cannot be answered within 24 hours, the customer is notified that we are working on the answer and given our best estimate when we will have the answer.

Do you provide technical service support, and of what nature?

Fluke Biomedical provides a Telephone Assistance Center (TAC or help desk) that can be reached via phone or e-mail. Fluke Biomedical also has two best-in-class service and calibration labs for product-support issues that require additional attention.

What formal education programs does your company provide for biomedical training and service?

Fluke Biomedical regularly presents at local biomedical and respiratory therapy meetings on topics related to testing the performance of medical devices against their manufacturer's specifications, IEC, and/or national standards.

What do you feel is important to support the customer/end-user of your product?

End-users need to understand the medical device under test, the clinical setting in which that medical device is used, the principles of the base measurement technologies used in the medical device, the testing device, and any special considerations that need to be addressed in setting up the testing to ensure accuracy of test results.

How does your company reach out to its customers regarding product performance and R&D?

Fluke Biomedical is committed to listening to its customers and providing solutions to make each customer's job easier. Sales staff, product managers, and technical support associates receive input from customers on their satisfaction with product designs and functionality. There are also regular internal efforts to gather customer feedback and data .

What mechanisms are in place to assist hospitals in their educational requirements and ongoing education?

Fluke Biomedical encourages customers to attend their local biomedical and/or respiratory therapy society/association meetings. Sales staff notify customers of any presentations which will be provided by Fluke Biomedical. Customers can request and host special seminars and are encouraged to invite their colleagues from their local area.

Where do you see the future of your product in relation to end-user requirements?

We depend heavily on the "voice of our customers" to guide our product development and enhancement. Fluke Biomedical can only deliver great products when we understand the end-user's work-model and application needs. The better educated the end-user on the product as applied to the specific testing they need to perform; the more they will use the product.

eVent Medical Ltd.

David Bennett

David Bennett is Global Service Director, eVent Medical.

Who is responsible within your company, by title or job description, for training and education of your staff and your customers?

Clinical training is provided by our clinical science department, field based clinical specialists, and our sales team. Service training is provided through our service organization, service specialists, and partners.

What types of education do you provide?

eVent provides education related to the clinical and technical application of our devices as well as assists in the education of our communities at large. Clinical, technical, and educational materials are available upon request.

How do you manage "off-hours" assistance for clinical questions?

eVent Medical provides customers with a 24 hour hotline (1-888-454-VENT).

Do you provide technical service support, and of what nature?

eVent Medical provides our customers a free 24 hour technical assistance hotline (1-888-454-VENT). Questions related

to service problems or product performance are easily answered. Additionally service courses are taught locally and at our San Diego facility on a quarterly basis.

What, if any, formal education programs does your company provide for biomedical training and service?

eVent Medical offers quarterly scheduled biomedical classes. On-site classes are also available with the purchase of our products.

What do you feel is important to support the customer/end-user of your product?

eVent Medical believes that the customer needs intelligent, immediate, and responsive support of their products. With the free hotline (1-888-454-VENT) eVent Medical can immediately direct customers to the department they need. Parts can be shipped within 24 hours of request and service is available 365 days a year. Our US standard 5-year parts warranty provides our customers with peace of mind.

What activities does your company undertake to promote the product?

eVent Medical is active in all areas of promotion. We actively support tradeshows, periodicals, web casts, and the creation of peer reviewed material (abstracts, white-papers, clinical studies). eVent is a clinician focused company and we go out of our way to help our fellow caregivers.

How does your company reach out to its customers regarding product performance and R&D?

eVent Medical continually asks customers via marketing analysis, customer satisfaction surveys, and simply by asking them to speak their mind. We regularly meet in a think tank format with leading clinicians to gain feedback on our products and ask about their future needs. Feedback is formally entered into our development process. Clinical needs, cost requirements, and ease of use implications are carefully balanced to assure our products meet our customer's needs. We are a clinician focused company that pride ourselves on supporting current clinical strategies and trends in respiratory care. We take pride in our unique ability to build our products to meet our customer's needs.

What mechanisms are in place to assist hospitals in their educational requirements and ongoing education?

eVent Medical offers "in-house" clinical and biomedical training courses to our customers. Super user training and biomedical courses are available regularly in our San Diego offices. We also offer a number of clinical and technical education tools to our customers.

Where do you see the future of your product in relation to end-user requirements?

eVent Medical Ltd was started because of the need for clinician focused respiratory products. What resulted were innovative, value-based products that offered state-of-the-art results. As the fast-paced critical needs of respiratory care change, eVent Medical will continue to lead the way in products, service, support, and in the unique way of hearing our customers – we listen.

CLINICAL TRIALS UPDATE

For information about the latest clinical trials, respiratory caregivers can now turn to clinicaltrials.gov. A recent search revealed more than a thousand active studies. A random sampling includes the following studies:

- Long-Term Results in Mechanically Ventilated Individuals With Acute Lung Injury/Acute Respiratory Distress Syndrome
  Condition: Respiratory Distress Syndrome, Adult
- C-Reactive Protein (CRP)-Guided Management Algorithm for Adults With Acute Cough
  Condition: Cough
- Computer-Based Decision Support in Managing Asthma in Primary Care
  Condition: Asthma
- Pharmaceutical Care for Asthma Control Improvement (PHARMACI)-Study
  Condition: Asthma
- Evaluate the Effect of Nebulized Budesonide and Oral Corticosteroids on Asthma Relapse in Children Following Discharge From the ER/Outpatient Care Facility
  Condition: Asthma
- Improving Asthma Care for Very Low Birth Weight Infants
  Condition: Asthma
- Evaluation and Treatment of Severe Acute Respiratory Syndrome (SARS)
  Condition: Severe Acute Respiratory Syndrome
- Sedation Management in Pediatric Patients Supported on Mechanical Ventilation
  Condition: Respiratory Failure

SAMPLE LISTING

Below is a sample of information provided on the website:

Computer-Based Decision Support in Managing Asthma in Primary Care.

This study is currently recruiting patients. Verified by McGill University September 2005.

Sponsors and Collaborators: McGill University, Canadian Institutes of Health Research (CIHR).

Information provided by: McGill University, ClinicalTrials.gov identifier: NCT00170248.

PURPOSE

Asthma is a health problem that afflicts many Canadians. Better methods are needed to provide primary care physicians with ways of implementing current guidelines into regular practice for optimal disease management. This study will test the benefits of providing computer-based decision-support for asthma to primary care physicians, with links to home monitoring for their patients. To add value and to ensure regular use for the physician for all of his/her patients, these computerized decision-support tools will be linked to an electronic prescribing and drug management system. We will evaluate the effectiveness of the computer-based decision-support system by determining whether asthma patients of physicians who receive computer-assisted management tools have better disease control after 18 months of implementation compared to asthma patients of physicians who have the electronic prescription and drug management system alone. To answer this question we will conduct a cluster randomized controlled trial in a population of 52 physicians in 24 clinics in West Montreal, and a total of 2,880 of their patients with asthma.

Condition: Asthma / Intervention: Device: computer-based decision support for asthma management

MedlinePlus related topics: Asthma

Study Type: Interventional

Study Design: Treatment, Randomized, Single Blind, Placebo Control, Parallel Assignment

Official Title: Evaluating the Impact of Computer-Based Decision Support for the Management of Asthma in Primary Care.

Further study details as provided by McGill University:

Primary Outcomes: poor asthma control

Secondary Outcomes: quality of care indicators (inhaled corticosteroid to beta2-agonist ratio, prescription of an action plan); patient outcome: self-reported symptom control.

Expected Total Enrollment: 2880.

Study start: March 2003

Background: Asthma is a chronic condition that is responsible for substantial morbidity. Direct costs for physicians, hospital care and medications in Canada are conservatively estimated at $306 million per year for persons with asthma. Existing evidence suggests that considerable reductions in morbidity could be achieved by early prevention and timely treatment. Much of the costs of asthma care are related to poor disease control due to under-use of effective prophylactic therapies, inadequate monitoring of disease severity, and insufficient patient education. A recent Canadian survey found that only 64% of patients with poor asthma control had been prescribed an inhaled corticosteroid, and of these only 52% made use of the medication on a daily basis. Further, although asthma self-management has been shown to reduce the relative risk of hospitalization for asthma by 39%, only 21% of asthma patients are provided with an action plan to institute for disease exacerbation and only 22% of primary care physicians provide action plans for their asthma patients on a regular basis. Computerized decision-support systems have provided a new set of tools for enabling integrated evidence-based care, by providing physicians with patient-specific reminders and alerts for needed preventive care and management, and timely feedback from patients. However, there has been limited use of computer-enabled decision-support in primary care, and only one reported study in chronic disease management. A key barrier to success has been the challenge of providing primary care physicians with a computerized solution that will produce value-added benefits and can be integrated easily into their routine workflow. Our prior research has shown that an integrated electronic prescribing and drug management system can provide value-added benefits for physicians because it is linked to information on dispensed medications, and alerts for prescribing problems. Early uptake and utilization of this computerized drug management system by primary care physicians provides an opportunity to develop and evaluate the effectiveness of an integrated asthma management decision-support system to enhance the use of prophylactic therapies and timely monitoring of asthma severity in primary care.

Objective: To determine if computerized decision-support and home-monitoring systems for asthma that is integrated into an electronic prescription and drug management system can: a) increase quality of disease management, b) improve treatment outcomes for patients with asthma.

Research Plan: A cluster-randomized trial with 18 months of follow-up will be conducted in a population of 52 primary care physicians in full-time private fee-for-service practice in 24 clinics in West Montreal, and an estimated 2,880 participating asthma patients within their practices. Enrolled physicians will

receive the MOXXI electronic prescription and drug management software, equipped with wireless modem to access the central databases and application server, and wireless printer. This system allows physicians to write and send prescriptions electronically, provides alerts for potential prescribing errors, a profile of current and past medications through automated links with the provincial drug insurance plan and community-based pharmacies, a medication compliance calculator based on dispensed prescriptions, and automated problem list creation based on treatment indication and verification of diagnostic codes on medical services claims files. Clinics will be randomized to receive a) computerized decision-support and home-monitoring for asthma integrated with the MOXXI system or b) the MOXXI system alone. The asthma management decision support system uses data from the patient problem and medication list to provide patient-specific management recommendations based on Canadian Consensus guidelines for asthma management. Computerized telephony technology is used to collect home-monitoring information from patients between visits and feedback to primary care physicians in accordance with options selected by the physician for each patient.

The primary outcome, measured in the last 6 months of follow-up will be poor asthma control, defined as an ER visit or hospitalization for asthma in the last 6 months of follow-up or the dispensing of > 500 doses of short-acting beta2-agonists. Secondary outcomes will include two evidence-based quality of care indicators (inhaled corticosteroid to beta2-agonist ratio, prescription of an action plan) and one secondary patient outcome (self-reported symptom control). Primary and secondary outcomes will be measured using data from the medical chart, patient questionnaire, records of prescribed and dispensed drugs, and Ministry of Health beneficiary, medical services and hospitalization databases. Effectiveness of computer-based decision support will be assessed by multivariate hierarchical modeling to take into account multiple measurements for the same patient, clustered within physician and clinic, and to adjust for baseline differences in patient characteristics.

ELIGIBILITY

Ages Eligible for Study: 5 Years - 45 Years, Genders Eligible for Study: Both

Inclusion Criteria: Physicians are eligible for inclusion if they are general practitioners or family physicians in full-time (≥ 4 days/week), fee-for-service practice in the West Island of Montreal patients where the study physician has written or dispensed prescriptions for beta2-agonists, anti-leukotrienes, or inhaled corticosteroids, and has verified the diagnosis of asthma.

Location and Contact Information: Please refer to this study by ClinicalTrials.gov identifier NCT00170248

Study chairs or principal investigators: Robyn Tamblyn, PhD, Principal Investigator, McGill University

More information: global study website

Study ID Numbers: ISRCTN58726678; 21448

Last Updated: November 21, 2005

Record first received: September 13, 2005

ClinicalTrials.gov Identifier: Health Authority: Quebec: CAI-Provincial Freedom of Information Office

Tailoring and Improving Respiratory Therapies In An Expanding University Hospital Environment

The award-winning Robert Wood Johnson University Hospital of New Brunswick, New Jersey has undergone rapid expansion in recent years to accommodate treatment of more than 200,000 patients annually. This academic medical center provides state of the art care including cardiac care and transplantation, emergency medicine, neurosurgery, and pediatric and neonatal critical care. The institution is also home to The Bristol-Myers Squibb Children's Hospital, with the region's largest pediatric intensive care unit, and a Level One Trauma Center with a pediatric commitment.

The Respiratory Care Department at Robert Wood Johnson has encountered many challenges during this rapid expansion, and has developed and standardized work processes and protocols to meet these challenges. This team effort includes members of the respiratory therapy department, together with medical directors, intensivists, and nurses in the different critical care departments.

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How has the respiratory care department expanded with the institution in recent years, and how have routines and procedures been adapted to accommodate this expansion?
Gerald Schlette, MS, RRT, RPFT, Director Respiratory Care Services: We currently have 66 staff members, and will hopefully be going up to 77. We staff seven ICUs, one stepdown unit, our NICU and our level one trauma center as well.

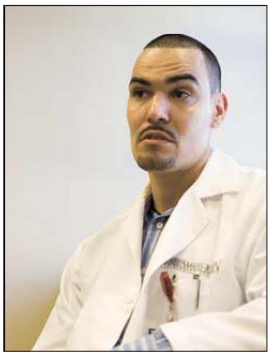
Bernadette Lewis, RRTNPS, Supervisor, Respiratory Care Services: There have been some substantial changes. The institution had undergone a reorganization and reengineering phase, which was subsequently abandoned, and we are currently going back to the way respiratory care was initially designed, in the late 80s and early 90s. We now have a structure with a Director, Supervisors and Coordinators, with the objective of improving patient care. The respiratory care department now clearly demonstrates its benefit to the institution by means of reducing lengths of stay, developing and initiating various protocols, which help improve patient care and outcomes.

How do you manage education and training with such a large department and staff?
Bernadette Lewis: In the past, we have had an educator role, but now the supervisors and coordinators all take responsibility for education and training. We schedule, develop and implement all respiratory therapy inservicing throughout the institution; not only for our own staff, but for the physicians, residents and nurses as well. In the past year, staff members have also taken an active role in inservicing their peers and colleagues on various topics.

Gerald Schlette: We have redefined our professional roles and job descriptions; for example, we have combined specialty areas such as being certified for both pediatric advanced life support as well as cardiac advanced life support. Roles from that have advanced to where we are offering different courses to the residents in both of the medical schools, teaching them not only about respiratory care but cardiopulmonary respiratory therapy, ventilation and weaning, right from the start. This makes our job

Bernadette Lewis, Supervisor, Respiratory Care Services has worked for many years and seen many changes at the institution.

Gerald Schlette is Director of Respiratory Care Services at Robert Wood Johnson University Hospital.



Louis Fuentes, RRT is one of four Critical Care Coordinators, with a pivotal role in standardizing and teaching respiratory therapy.

now, three years later, much easier, and it has worked out very well for us.

Bernadette Lewis: This past year we instituted our first SICU residents' lecture. We inserviced the residents on mechanical ventilation modes, ventilatory strategies, and the weaning process; we also conducted hands-on training. It was a series of two-hour sessions over six weeks, and we received very good reviews from the residents. It improves patient care and outcomes, if we can get to the intensive care unit and there is no question about the availability of modes and technology. Everyone working with the patient will be versed in ventilator modes, strategies and weaning protocols.

The other important aspect in these new procedures is that respiratory caregivers actually go on rounds with the physicians, so we have a lot of autonomy in the units. They start their rounds by 08.00 am, and have their plan of action for the day, for each patient.

Gerald Schlette: We want to work closely in the beginning of the day with the physicians, nurses, residents and respiratory therapists, to deliver a plan of action and course of therapy for that day for each individual patient and set goals, that can be monitored over a twenty-four hour period. The next day, everyone can check whether we are achieving the goals on schedule, or if we are ahead or have fallen back. The objective is transparency and teamwork, for the patient's benefit.

Louis Fuentes, RRT, Critical Care Coordinator: One of the things we try to institute in rounds is clinical dialogue with the physicians. We want all of our respiratory therapy staff members to have clinical input regarding their patients in the ICU. Ideally, our goal is to decrease ventilator length of stay by passing pertinent information to each other as healthcare providers, and incorporating this information into a plan for each patient that needs our intervention on a daily basis. As coordinators and supervisors, we need to be a resource for our staff and show our support. We aspire to educate our therapists by looking at x-rays, interpreting hemodynamics, and utilizing different ventilator strategies so that we maintain a dynamic mindset towards patient care. Together with the nursing staff, the therapists are the eyes and ears of the patient, when the physicians are not in the ICU. So when the physicians are present, if there is a problem, we can address it as descriptively as possible for them and give our clinical opinion for these situations in these areas.

How did you start to change the way you had been managing ventilation therapy?

Gerald Schlette: We started having a lot of problems with our older ventilators. There was no battery back up, and there were a couple of instances where there was risk of danger. I had used the Servo-i in another institution and it was something I thought was promising. I had an overnight decision to make with minimal input from the physicians here. We had an opportunity to replace our old fleet of 29 ventilators and purchase 35 new units. We currently have 41 Servo-i ventilators. That was the start of uniformity. We started to hire clinical coordinators, of which we currently have four; in the NICU, surgical ICU, medical ICU and PICU.

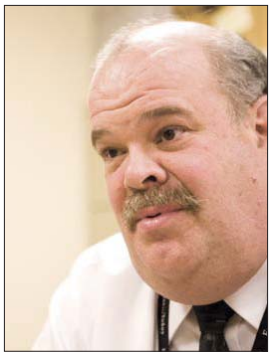
The coordinators play a pivotal role in our objectives for synchronization and efficiency. Our Critical Care Coordinator, Louis Fuentes, oversees everyone. We have instituted weaning protocols. Because each of the ICU departments is different, we have implemented protocols that are very similar, but somewhat customized to each individual department. Louis does this in collaboration with each of the Medical Directors for the individual units. Our objective is to establish an institutional database. We can now accurately track ventilator length of stay, which we were not previously able to do.

This lack of correct data became evident as an extremely important parameter that we used in a process with the UHC United Hospitals Consortium, which led us to discover that the data from the past was inaccurate. The charge initially came to us that our ventilator length of stay was a ridiculous number. Upon investigation, we discovered that their manner of estimating and accounting our ventilator days was first day on ventilator until day of discharge, which couldn't possibly be more inaccurate. So we decided to institute our own database, which Louis updates with the other coordinators every single day. Our ventilator length of stay is now marvelous for an institution this large.

What is your current ventilator length of stay?

Louis Fuentes: Presently in our trauma unit, our surgical unit and neurosurgical unit, our ventilator days average at 6 days, which is very satisfactory in these units.

In our open-heart recovery unit, the ventilator length of stay is efficient with our fast track extubation and weaning protocol. The average length of ventilator stay there is approximately 8 hours, postsurgery for fasttrack patients. We are currently



Doug Campell, Assistant Vice President of Operations described disaster coordination activities.

Dr. Jagadeeshan Sunderram is Medical Director and head of the MICU at Robert Wood Johnson University Hospital.

Kumar DeZoysa and Servillano Derikito.

discussing protocols for the medical ICU and our long-term ventilatory unit, where the patients tend to be very complicated medical patients including renal dialysis issues. Sometimes they cannot be put in a long-term facility, since these facilities are limited in New Jersey, without dialysis capabilities. Those are some of the projects we are working on now. In this department, we are considering implementation of a Volume Support/PRVC protocol, which we are discussing with our Medical Director Dr. Jagadeeshan Sunderram.

How has the ventilation technology supported the focused effort in this institution?
Gerald Schlette: Our therapists had some experiences of the Servo 300 Ventilator, some with Automode and some not. An overwhelming majority of the therapists were reluctant to ever use Automode, and I feel this was a huge disservice to our patient population.

When we implemented the Servo-i fleet with the new user interfaces and graphics, it was much easier to introduce and instruct about Automode. In our openheart recovery unit, nurses were initially very reluctant and resistant to this change. But they realized the benefit of Automode—how fast it will help the patient get off the ventilator, the interaction with the anesthesia and medication postop, and now they don't want anything else. And this has expanded from the openheart recovery unit into the SICU heart department and other areas of the hospital as well. The physicians see the sequence of events and the benefits of them.

What other types of ventilation therapies are used in addition to standard therapies?
Bernadette Lewis: We have five nitric oxide units, two in the NICU, one in the PICU and the other two units are available for the additional patient population. We also provide high frequency oscillation (HFO) when appropriate, in all patient care populations. HFO should not be used as a last resort; its use is encouraged prior to the patient's decline. We have begun to educate physicians and staff to monitor certain physiological disease states, such as ARDS that is difficult to treat, and to implement HFO before the patient reaches life-threatening circumstances.

I understand that more expansion is planned for The Bristol-Myers Squibb Children's Hospital, as well?
Gerald Schlette: Yes, Children's Specialized Hospital in Mountainside will be part of our campus in New Brunswick, joining The Bristol-Myers Squibb Children's Hospital and The Child Health Institute of New Jersey. This acute care pediatric rehab facility is scheduled to open in 2008.

Can you describe the other ICU units here?
Louis Fuentes: Our neurosurgical unit is a seven bed ICU. Our trauma unit accommodates ten critical care beds. There we see everything from uncomplicated general surgery patients to ARDS. We have an active trauma helicopter service and land transport trauma service. The cardiac ICU comprises eighteen beds, where they care for postop open-heart cases, valve replacements, aortic valve replacements, robotic surgery, and we have done transplant cases as well. Dr. Mark Anderson and Dr. Peter Scholz are the chiefs of Cardiac and Cardiothoracic Surgery. We perform rounds with the cardiac intensivists, and work closely together with them regarding patient goals. Our MICU has 16 critical care beds and incorporates a daily readiness to wean assessment on every patient requiring mechanical ventilation. Our MICU coordinator Mr. William Twaddle, RRT has worked intensely to help facilitate weaning in the MICU and CCU. Recently, we have approval on a new mechanical ET tube holder to help us prevent inadvertent extubation and potential pressure ulcers from having an artificial airway. The CCU consists of 15 critical care beds with patients suffering from a multitude of cardiac conditions.

Bernadette Lewis: The trauma unit keeps us very busy on some days. Just last week, we had seven cases come in within the period of one to two hours. It can be anything from stab wounds, to construction worker accidents, to traffic accidents with multiple victims. Numerous highways surround us, and we are a heavily populated urban area.

Gerald Schlette: In terms of acuity, the institution is pretty much at the 100% mark. We have a total of 584 beds, but we have exceeded 600 on occasion. They are looking at redesigning our holding area for the ER to accommodate these patients, as a combined solution for medical, cardiac and surgery patients.

ROBERT WOOD JOHNSON MEDICAL ICU

Critical Care News met up with Dr Jagadeeshan Sunderram between rounds at the Robert Wood Johnson Medical ICU to discuss new procedures for weaning and outcome tracking. Dr Sunderram is a pulmonologist and Medical Director and Head of the MICU at Robert Wood Johnson University Hospital.

Can you describe the impact recent development has had

on the medical intensive care unit and staff?
I have had this position since 2001 and there has been a lot of expansion since that time. The MICU has grown and is a state-of-the-art unit, with one nurse for every two patients and a pod system where the patients and monitors can be followed closely. There is a central nursing station, but this is not used as often since the pod system came into effect, which enables the nurses to be closer to the patient.

How is your cooperation with respiratory therapy?
It has been a fantastic coordination. The implementation of a Critical Care Coordinator function has enabled us to do a number of things to improve our outcomes. For example, we had very high rates of ventilator-associated pneumonia in the past, and what we have done is to institute something called multidisciplinary rounds. This includes about thirty questions that look at prevention strategies for ventilator-associated pneumonia, for gastrointestinal bleeds, and so on as recommended by the Society of Critical Care Medicine. We do that three days a week and cover the whole ICU to make sure that these recommendations are in place. We have been able to reduce our rates of 10 VAPS per 1,000 patient ventilator days, which was about the national average, down to 3 to 4 VAPS per 1,000 patient ventilator days. This is a substantial reduction. We implemented this program only five months ago, so we have seen these dramatic reductions in a very short period of time. In fact, in some months we have had no ventilator-associated pneumonias at all.

Are you implementing a series of weaning protocols?
We have a series of standard questions that the therapists ask each morning. They ask if the patient is ready for a trial of spontaneous breathing, they conduct a rapid-shallow breathing index; they look at high FiO_2 levels and high PEEP levels. They establish whether the patient is on less than 8 cm H_2O of PEEP, if the patient is at less than 60% of O_2 concentration, and whether the patient is hemodynamically stable and has no contraindications to rapid-shallow breathing index. If the answer to those three questions is yes, they conduct a rapid-shallow breathing trial. If the patient passes, the therapists inform the physician that the patient is ready to come off the ventilator. The physician may determine whether or not a trial of spontaneous breathing should be done. We have that protocol in place, and it has become very streamlined, but everything depends on patient response. It is much easier for the patient and the staff.

Will you be looking at length of stay on the ventilator?
We will definitely be looking at that data. It is not currently available, however the respiratory department will be collecting the data in a database for analysis. We have some preliminary data showing that almost 90% of the patients, who we thought were ready, did come off the ventilator. And about 50% of the patients who we did not think were ready actually came off the ventilator as well! I think it had to do with the issue of sedation. Once we examined sedation management, we changed the protocols and routines, and I think this group of patients will be reclassified in the future. That is what is so fascinating about implementing these protocols; you look at one or two aspects in detail, which may illustrate how a full change of events can occur. There are a series of links here, and at some point there is always a failure. So we are trying to identify where the failure happens, and with the data in hand we can identify that point and fix it. That is a benefit of standardizing our processes.

ROBERT WOOD JOHNSON SURGICAL ICU AND NEUROTRAUMA ICU

Critical Care News spoke with Kumar DeZoysa, BS, RRT, Critical Care Coordinator, Surgical ICU and Servillano Derikito, RRT, Staff Respiratory Therapist, to discuss how the new procedures are impacting respiratory therapy in the Surgical and Neurotrauma ICU departments.

Can you generally describe some of the cases you are treating today?
Kumar DeZoysa: We have a patient who was involved in a motor vehicle accident. The patient has a nonsignificant aortic tear, and is being stabilized for the OR. He has been at 70% O_2 concentration and 14 cm H_2O of PEEP for the last two weeks, and we have been waiting for him to be stabilized. He took a turn for the worse during transport to the CAT scan. After returning he went from SIMV/VC to AC/VC, and the patient continued to deteriorate. He was put on AC/PRVC, and the patient started to improve, which we hypothesized was due to the fact that the patient had an autoPEEP (=+20 cm H_2O) with PRVC. I am capturing the data, using the Servo-i data retrieval, and it makes for an interesting case study.

Is your neurotrauma ICU running basically at full capacity most of the time?
Servillano Derikito: Yes, basically every day of the week is busy, but we tend to get the most patients on Fridays and the weekend, when the accidents are more prevalent.

What are your experiences of implementing the weaning protocol for standardization?
Kumar DeZoysa: We were introduced to the concept of lung recruitment approximately 8 years ago, via a Siemen's instructional video on lung recruitment, and we realized that this is a way to improve patient outcomes. Dr. Burchard Lachmann's contributions have formed the cornerstone to our lung recruitment maneuver philosophy, and we have been refining our technique since then. We are trying to implement this philosophy into our ventilation management and weaning protocols to facilitate and improve the weaning process. Lung recruitment maneuvers include monitoring the PaO_2: FiO_2 ratio and appropriate PEEP titration to maintain this ratio. We believe that once the lung is optimally recruited with noted improvement in ABGs and other indicators of pulmonary status, it will be much easier to facilitate weaning. The newly implemented protocol has its basis in routine weaning maneuvers, but emphasizes the need to have an improved understanding of lung physiology and the pathophysiology of atelectasis, and incorporates monitoring of the pulmonary status.

What about your postextubation strategies for maintaining lung recruitment?
Kumar DeZoysa: We have started a research project incorporating biofeedback in conjunction with lung recruitment. Initially, we educate the patient about atelectasis and corrective actions to include incentive spirometry (IS) and deep breath and hold (DB&H) maneuvers. We provide each study patient with a pulse oximeter within the patient's visual line of sight, usually at the foot of the bed. We ask that the patient maintain a certain saturation level, such as $SpO_2 > 95\%$, by performing extra bouts of IS and DB&H exercises in addition to the requisite hourly regimen. We believe that once patients are armed with this information and a pulse oximeter, they should be able to follow

their own progress and help themselves improve by means of this biofeedback. We started this research project about two months ago and we have captured data on approximately 20 patients so far, but our objective is 500 patients. It will be interesting to see a final analysis of the data from this number of patients. Anecdotally, I can state confidently that patients with compromised pulmonary status who are compliant with the instructions improve within hours of implementation of pulse oximetric biofeedback. As the institution grows, the respiratory therapy department has more opportunities to get involved in various aspects of research. We have a very supportive anesthesia department that has volunteered to guide us through the intricacies and subtle nuances of the processes of research and publication, in addition to our primary goal of improved pulmonary and patient care.

ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL OPERATIONS

Robert Wood Johnson University Hospital is situated at the crossroads of New Jersey's chemical, biochemical and pharmaceutical industries, and is in proximity to the Northeast rail corridor, large international airports and New York City. Disaster coordination and preparedness is a significant consideration for this university hospital. Critical Care News spoke with Doug Campbell, Assistant Vice President of Operations.

You started at this institution in 1985. Have you seen considerable expansion since then?

It is amazing what has happened in the past twenty years, not only for Robert Wood Johnson but also for the city of New Brunswick. The hospital has benefited from the addition of the Children's Hospital, the Cancer Building and five new buildings are currently in the planning process. We have also benefited from our affiliation with the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, which has expanded on the New Brunswick campus as well.

What are the most significant developments in recent years?

The establishment and growth of The Bristol-Myers Squibb Children's Hospital is one of the most significant developments. When we built the Children's Hospital in early 2000, we shelled the top two floors for future use, thinking that we would not need them for some time. However, due to the growth of programs we needed the resources of additional space much quicker than we thought, so all seven floors are now completed and occupied. That development has been enormous, with the addition of the NICU and Special Care Nursery and the growth of other pediatric units, as well as the pediatric oncology service. Additionally, the construction of the Cancer Building, the expansion of the Cancer Institute of New Jersey, all have been significant developments that have affected the hospital in a positive way.

Disaster coordination and preparedness must be a significant consideration for this university hospital, with your proximity to metropolitan areas and chemical industries in New Jersey?

That's correct, and New Brunswick is at the center of the State of New Jersey. We have a major university; the Northeast corridor train line runs along the east side of our campus, there are oil refineries, the petroleum industries, the chemical industries, and pharmaceutical production, all within a close geographical area to the hospital, which is only 30 minutes from New York City. Our sister hospital, Robert Wood Johnson at Hamilton, is 30 miles to the south. This facility dealt with the Postal Service Building anthrax cases that developed in 2001. Robert Wood Johnson University Hospital really is at the crossroads for the need for statewide emergency preparedness.

We participated in Top Off 3 last year, which was a congressionally mandated series of emergency preparedness exercises, lead by the Department of Homeland Security. We participated at the top level, what we call Level Three, and the drill was conducted over three days.

We had over 380 volunteer patients over three days come through our facility, while we were operating the hospital at nearly 100% occupancy. Our courtyard was transformed into a 125 bed surge capacity area, and an Incident Command Center was set up in our boardroom. The Respiratory Therapy department did a great job; since the scenario was the dispensing of plague, they were taxed beyond what they could imagine. We established a Victim Control center, and it was one of the toughest experiences the institution has ever undertaken, but an extremely valuable experience to us. Participation in this drill was done at 100% occupancy, so we were busy treating our real patients as usual, in parallel with the simulation exercises. It taxed all of our resources but we are much better for having conducted this exercise.

It must be extremely valuable as an institution to have that experience in hand.

Yes, we know now that we can handle a certain number of extreme incidents: chemical, biochemical, and a surge of patients. These were all very important experiences in terms of reference for the future responses. The exercise went extremely well, and we continue to work towards being one of the leading facilities in the state. So much so that we received a grant of 1.5 million US dollars to construct the medical coordination center on our campus. The Medical Coordination Center will coordinate the health care emergency response in a five-county area in central New Jersey. This facility is also established to assist with the coordination of responses to emergencies anywhere in the state.

THE BRISTOL-MYERS SQUIBB CHILDREN´S HOSPITAL

Mobile intensive care unit

The BristolMyers Squibb Children's Hospital operates a fully equipped transport service. Gerald Schlette described it:

The transport service provides a fully equipped mobile intensive care unit. Patients can be intubated or have chest tubes placed during transport. The unit provides compressed oxygen, a full range of IV therapy equipment, a crash cart including an aortic balloon pump, cardioverters, and two ventilators, one for the incubator and one for older patients.

We have a broad geographical area for patient uptake: northern New Jersey, Albany New York, south New Jersey, Philadelphia and other points in Pennsylvania, Washington DC, and Virginia. These are planned emergency patient transports – the patient is usually stabilized but needs to come in for specialized care.

The critical care transport team usually consists of at least one critical care nurse from the appropriate unit, one critical care

The mobile intensive care unit of The Bristol-Myers Squibb Children´s Hospital covers a broad geographic area for patient up take.

respiratory therapist, and one or two residents, depending upon the case. It is something we are proud of at this institution.

PEDIATRIC INTENSIVE CARE UNIT

The Bristol-Myers Squibb Children's Hospital has the region's largest state-designated pediatric intensive care unit, which is operated with a family-centered focus. Critical Care News spoke with Dr Jacqueline Williams-Phillips, Director of the Pediatric Intensive Care Unit.

Can you describe your multidisciplinary team approach here in the PICU?

There are six fulltime pediatric intensivists on staff, two additional pediatric intensivists who make rounds on a parttime basis as well as three critical care nurse practitioners.

On rounds we include the bedside nurse, nurse practitioner, attending physician and respiratory therapist, as well as a pharmacist. We also have a pediatric intensive care fellow, second and third year pediatric residents, and medical, nursing and pharmacy students on rounds. The team makes rounds twice a day and the attending staff are on site essentially 24 hours a day. We have a multidisciplinary ICU which admits both surgical and medical patients. Nursing coverage for some patients may be 1:1 while others can be 1:2. We also have a stepdown intermediate care service within the facility for patients needing monitoring.

For a new facility, you seem to have grown quickly in terms of size and services.

We have a fellowship program as well as a nurse practitioner program in pediatric critical care. There are 14 beds in the ICU with provisions for up to 6 more if needed. We have an active transport service, which is run from the ICU, and we have just started a pediatric cardiac surgery program this past year.

We have almost 1,000 patient admissions per year, with almost 800 critical care transports. There were 215 mechanically ventilated patients in 2004 and 268 in 2005, representing 2,364 and 1,525 ventilator days respectively. This includes conventional, high frequency, and BiPAP/CPAP.

We used to be a children's hospital within the main hospital at Robert Wood Johnson University Hospital until 2001, when The Bristol-Myers Squibb Children's Hospital was established. A brand new state-of-the-art PICU was added, with sleeping arrangements for families, so parents never have to leave their child's bedside. We focused on family-centered care when the establishment was constructed and were honored with an award in 2005 for our PICU's family-centered care at the Society of Critical Care Medicine annual meeting.

Which types of patients and of ventilation therapies are most common here?

The ratio of medical to surgical patients is about 4:1. We take all critically ill children outside of the neonatal intensive care arena here. The types of patients requiring critical care include post-op general surgery, cardiac surgery, neurosurgery and other pediatric subspecialty surgery, as well as oncology, respiratory failure, pneumonia, ARDS, RSV and other medical critical illnesses.

We use a variety of ventilation strategies depending on the individual patient and condition. For cardiac patients postop we try to minimize volumes. For a trauma patient, the strategy will vary depending on the presence or absence of hemodynamic instability or intracranial hypertension. Most of us like to use PRVC with SIMV. Our respiratory therapists are very involved in the development and implementation of the treatment plan, and generally attend rounds, providing input and sharing strategies. We teach not only residents and fellows, but also nurse practitioners and nursing students from the local nursing schools. There are respiratory therapists in training, and we have residents from other institutions who come by on rotation, and medical students in their third and fourth years. Everyone has input and there is a lot of bedside teaching on rounds.

A number of years ago our PICU was ranked number one for lowest mortality. We belong to a national database that matches severity of illness in the PICU, and we are able to compare our unit with other children's hospitals nationally, in terms of demographics, outcome and mortality. Family-centered patient care and outcomes are our main focus, and we are proud of our staff and facility.

NAVA – A New Generation in Respiratory Therapy

An interview with Christer Sinderby, PhD

Intensive Care Units around the world have been providing their patients with mechanical ventilation for the past thirty years, ever since the first electronic ventilator technology appeared in the early seventies. And ventilation therapy, regardless of mode, has been delivered in the same manner – a clinician has regulated the pressures and volumes provided to the patient. A group of researchers in Toronto have established a new respiratory methodology, based on the neural signals provided by the patient. Research in the concept of Neurally Adjusted Ventilator Assist (NAVA) is rapidly gaining the interest of the scientific community.

Can you describe what NAVA (Neurally Adjusted Ventilatory Assist) is, and how it functions?

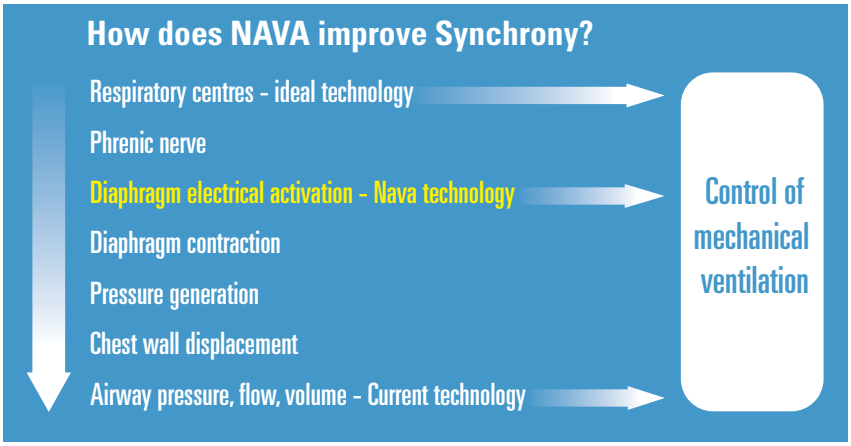
NAVA is a new mode of mechanical ventilation, where the ventilator is controlled directly by the patient's own neural control of breathing. Since the introduction of the mechanical ventilator over thirty years ago, ventilation treatment has traditionally been provided by means of adjusting airway pressure, flow and volume. With NAVA, the ventilator pressure is adjusted by the patient's own neural control system. The neural control of respiration originates in the respiratory center, and signals are transmitted through the phrenic nerve to excite the diaphragm. With NAVA, these signals are monitored by means of bipolar electrodes mounted on a nasogastric feeding tube and positioned in the esophagus at the level of the diaphragm. As respiration increases and the respiratory center requires the diaphragm for more effort, the degree of NAVA ventilatory support needed is immediately provided.

This means that the patient's respiratory center is in direct control of the mechanical support required on a breath by breath basis, and any variation in the neural respiratory demand is responded to by the appropriate corresponding change in ventilatory assistance.

Besides being a distinct mode of ventilation, NAVA also offers a complete evaluation of the neural respiratory control in the context of a respiratory monitor. For example, if no assist is provided, the drive will be very large, but if the patient is provided with assist, the drive decreases. These are rapid reflex loops that are constantly ongoing.

This provides both the neural monitoring signal and how much assist is to be delivered, at the same time. It also shows the extent of how the respiratory drive has been regulated, and the pressures used in this respect. There are no other modes that can provide these capabilities today. A pulse oximeter may tell us: "The saturation is going down to 80% and affecting PaO2, and if FiO2 is increased, the saturation increases back up to 91%." But that is only a monitor, and the clinician is in charge of making the required adjustments. With NAVA, the patient is "in charge" of adjusting the ventilation. We do not make any interventions; only observe how the patient is regulating himself. One interesting aspect is in emergency situations; we have found that it is always safest when we apply NAVA. We seem to have much better control than by any other means. In fact, we have found that the sicker the patient is, the better

Christer Sinderby, PhD is Assistant Professor at the Department of Medicine, University of Toronto, Canada, and Research Staff Scientist at St. Michael's Hospital, Department of Critical Care Medicine, Toronto. He received his MS degree from the Karolinska Institute in Stockholm, Sweden, and Doctor in Medical Science degree at the Department of Neurosurgery, Sahlgrenska Hospital, University of Gothenburg, Sweden. He has had numerous academic committee assignments, including the University of Western Australia, as a peer reviewer for American Journal of Respiratory and Critical Care Medicine and Journal of Applied Physiology, and as a member of the American Thoracic Society/European Respiratory Society task force for the ATS/ERS statement on standardization of respiratory muscle tests. He has won numerous research awards and grants including the Montreal Chest Hospital Research Institute Annual Award, the Parker B. Francis Fellowship in Pulmonary Research and Fonds de la Recherche en Santé du Québec Chercheurs Boursier Scholarship. His research has been extensively published in peer review journals and monographies. Reprinted with the permission of Critical Care News, www.criticalcarenews.com. CRITICAL CARE NEWS is published by MAQUET Critical Care.



Adapted from Sinderby et al Nature Med 1999

NAVA seems to respond. Right now in Toronto, we are studying heavily sedated patients breathing on NAVA, with very few difficulties, blood gases are normal and the patients are stable.

This is of special interest, since it is a new area of research. What led to your research in this particular area, and how did you establish this concept?
It started with signal analysis of electrical signals from the diaphragm, a field where we had been doing research for many years. We started with something called spectral analysis, which is examining the diaphragm electrical activity in the frequency domain. The frequency domain can provide a great deal of information, for example when a muscle is fatigued, the number of motor units a muscle has, and how the muscle is recruited, which is the signal used when triggering breaths. We plotted the frequency spectrum to 1024 different points, and divided the points to evaluate the signal, so we made an enormous analysis of every little sample. This in turn led to a practical solution, which a good friend of mine, Dr Paolo Navalesi, an intensive care physician, asked if we were interested in using this technology for evaluating ventilators. By this time, we were doing research on respiratory muscle fatigue during weaning.

We went ahead and evaluated the signals we had, and observed that the signals were very stable, and that there were significant delays with triggering with conventional ventilators, which made us think that we could do a much better job. So from that point on, with the signal processing research, which we had already developed, it was not very complicated to obtain algorithms for controlling the ventilator. The difficulties arise when attempting to apply these algorithms into current ventilator technology and existing platforms, where adaptations to already existing technology must be considered.

Will the biggest challenge with NAVA be that people will have to regard respiratory therapy in a fundamentally different and new way?
Traditionally, many physicians who have worked in the ICU have had a background as an anesthesiologist or an intensivist. With NAVA, this means that they may have to think in terms of neurology as well. But a neurologist typically doesn't think in terms of respiratory therapy, either. But the potential benefits may outweigh these challenges, for example when we see neonatal patients being treated with nasal ventilation, and the CT scans confirming that their lungs are completely recruited.

It is not a matter of one group being able to do something a little better than another, rather that we are opening a completely new door. It is a significant paradigm shift, which may offer opportunities to do things we never felt possible before. But this requires a totally new manner of thinking. When we have the opportunity of lecturing to ICU staff, we try to communicate that this is new, this is pioneering, and we may be able to do things that were not possible in the past. But an entire group of professionals will have to start considering this new generation of mechanical ventilation as well, which is necessary with the introduction of a new methodology.

There has been a growing interest in asynchrony in recent years; however, it is still perhaps not prioritized as it might be in daily treatment work. From your perspective, how frequently does patient ventilator asynchrony occur?
I believe that there is a level of patient ventilator asynchrony in every patient, and in every mode of pneumatically-driven ventilation. From my experience, it is rare to find patients with insufficient support. In most cases, patients are receiving too much support, and this means that the assist is prolonged beyond the neural cycle. In this situation, triggering the ventilator can become a problem for certain patient groups, for example COPD. But knowing when to terminate inspiration – there are no physiological cycling off criteria available today. We have previously observed and shown that asynchrony occurs in intubated adult patients with mixed etiology (Beck et al, 2001, Spahija et al, 2005) and in intubated infants being weaned from the ventilator (Beck et al 2004). In particular, having the ability to monitor the neural activity of the diaphragm during mechanical ventilation, opens the possibility to evaluate patient ventilator asynchrony at the bedside.

Ventilator asynchrony can be compared to other technologies:

who wants a car that has a five second delayed reaction when you accelerate, and sometimes brakes, and sometimes does not brake at all?

Or a computer mouse that reacts long after you have clicked on it, or with lightening speed so you can not catch up at all?
Exactly – this is basic supply and demand. A methodology and system should deliver a support in the amount and time that the patient needs it, which allows the level of support to decrease over time. This is the support we are striving to obtain, which is why synchrony is important.

In terms of patient risks in connection with asynchrony, what do you believe is most significant?
One of the physiological effects of patient ventilator asynchrony is that it interferes with the patient's natural breathing pattern. As we have shown in intubated infants, excessive delivery of assist (beyond the neural inspiration) prolongs expiration as compared to an unassisted breath (Beck et al 2004). In addition, if there is a delay to trigger the ventilator, this will prolong inspiratory time. With NAVA, the ventilator is cycled on when neural inspiration begins, it provides assist during inspiration proportionally, and it cycles off when the neural expiration begins. It does not interfere with the natural breathing pattern, because it follows the natural breathing pattern.

One of the greatest problems arising from excessive delivery of assist (delayed cycling off) is that extreme pressures and volumes can cause lung injury. Our most recent experience in experimental research suggests that NAVA is lung protective (Brander et al, 2006). Our clinical data also indicates the potential for lung protection as the spontaneously chosen tidal volumes are low and similar to those recommended by the ARDSNet study for reducing ventilator induced lung injury. In three preclinical studies and two human studies, we have tried to increase the NAVA assist to levels comparable to overdistention. And we have not been able to come up to these levels – there is a neurological reflex that regulates and closes pressures that are too high. Physiologically, when a volume increases to a certain level where you can no longer inspire, the body has a neurological mechanism that stops the process. This is a fundamental difference from mechanical ventilation, where a third party regulates volumes and pressures. But synchrony is two dimensional: a time scale where it might be too late to start to inspire or too early or too late to cycle off, and the other dimension is amplitude. But the protective component is not only in amplitude. For example, when we have studied neurally triggered pressure support, and deliver high pressure support levels, in these cases the patient time scale cycles off so early that it is not possible to go over a certain level. If the volume is obtained too rapidly, it stops, from a neural perspective. This is the same pattern of normal respiration, you cannot inspire above a certain level that the body does not accept. With NAVA, a ventilator would function in the same manner as the body in this case – you cannot prolong a breath. If a breath were prolonged, there would be excessive volume, resulting in lung injury. So NAVA covers both dimensions, the time scale and the amplitude. And the benefit is that you have a methodology that does not lead to a run away situation, but allows the body's physiological defense mechanism to regulate the ventilator. General asynchrony can be compared to an example: if a patient

Christer Sinderby was the recipient of a Parker B Francis Fellowship in Pulmonary Research.

tries to breathe and get insufficient support, the inspiration is insufficient. If the ventilator then should start when the patient has stopped inspiring, they receive the wrong level of assist and become agitated. If I thereafter increase the support from the ventilator to supply larger pressures, the patient might miss a few breaths, and we have initiated the downward spiral.

If patient ventilator asynchrony is so severe that the patient "fights" the ventilator, the caregiver usually resorts to sedation and or neuromuscular paralysis of the patient. However, the current trend in mechanical ventilation is to give less sedation and to help the patient breathe spontaneously. If we consider spontaneous breathing to be a true objective in ventilation therapy, we must help the patient to receive a level of support that is adapted to spontaneous breathing, and interfere as little as possible. Respiratory support should only be delivered when the patient wants it. Traditionally, it has been a matter of supplying a ventilation support that sustains a certain level of minute ventilation, but the ventilator must take care of the lung, chest wall and abdomen, and the work of breathing increases. The patient does not receive what he needs.

What considerations should be taken with NAVA in regard to intubated as well as noninvasively ventilated patients?
If you are treating an intubated patient, you have a patient who has lost some level of autonomous breathing control functions (you have blocked the upper airway defense mechanisms). Perhaps you want to protect the airways if the patient is very sedated. With neural control, it does not matter how you ventilate; we can ventilate with a mask, with a helmet, nasal prongs, a mouthpiece or an endotracheal tube. We see the same results however we deliver ventilation, the fact that we are delivering neurally controlled ventilation is not an issue. However, this difference between invasive versus noninvasive is a traditional way of thinking in regard to delivery of ventilation therapy. But for example, some patients must be sedated, if they are in pain or very ill, and NAVA can still support ventilation in these cases. NAVA delivers the support when the patient neural signals demands a breath, and NAVA delivers support that is proportional to the patient's neural request, and stops when the patient has received enough. It works if the patient is intubated or ventilation is delivered by other means.

This is a matter of disconnecting pneumatics in how we consider this: the tube, whether it is in the nose or in the throat, is only there to deliver ventilation. Today, physicians use pressure and flow as feedback for supplying support, which means a lot of information is needed from the same tube. With NAVA, we take the information from another source, directly from the brain, if you will, and that information comes directly outside any other routes.

Are any particular patient categories of special interest in terms of NAVA, at this point in time?
In regard to patient categories, I believe it is very important to gain experience in as many types of intensive care patients and disease categories as possible. Heart-lung transplant patients have many organs where the neural connection has been cut and replaced by new organs, and I do not think they would be good candidates for NAVA ventilation at this stage; it is perhaps too early yet. In regard to other different patient categories, we are in the pioneering stages.

We are entering into a new generation in mechanical ventilation. For myself as a researcher and for the team I work with, we are doing as much as we can to obtain as much good information as we can at this stage. Our total focus right now is on safety. We hope that other intensivists and research centers with a pioneering spirit will want to join us in the development of a new methodology, something fundamentally different than everyone is used to. There is an exciting journey ahead of us, with experiences that we may have not expected, but also groundbreaking therapeutic discoveries in the near future. This will require an enormous amount of communication, and forums for clinicians to share experiences with each other.

When we try something new for the first time, it may easily happen that we experience that it does not work according to our expectations, which means it is a question of diagnostics and translation, in the process of learning the patterns of treatment with a new methodology. What is important to note is that the initial physicians working with this will be true pioneers. We have a first solution how NAVA can be applied, but we will collectively need to share all of our experiences as we go forward.

A new way of thinking and a new perspective on ventilation means not only potentially new solutions, but potentially new challenges as well within the future in critical care.

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Specialists Team Up To Set Protocols For Weaning Patients From Ventilators

Special Hospital Feature – Northeast Specialty Hospital

Stephen T. Sweriduk, MD

Few in medicine would deny the immense benefits provided by mechanical ventilators. Ever since the introduction of the iron lung in the 1920s, the ability to help a patient overcome breathing difficulties while physicians took the time to cure them has saved countless lives throughout the world. And the population of ventilated patients is likely to grow in the coming years with the aging of the baby boom generation and the proliferation of life-prolonging medical advances. But mechanical ventilation also carries risks of its own, such as a higher incidence of pneumonia or lung damage. And the discomfort to patients of the endotracheal tube can be considerable.

David Neumeyer, MD; Miguel Divo, MD; and Bartolome Celli, MD.

These issues, coupled with the considerable cost of maintaining a patient on a ventilator long term (up to $1,200 per day in an ICU by some estimates) provide a compelling need for patients to be weaned off ventilators at the earliest opportunity.

To address this need, Northeast Specialty Hospital has partnered with physicians from Caritas Saint Elizabeth's Medical Center and the Lahey Clinic to provide a ventilator weaning program that has dramatically reduced weaning times and enabled numerous patients previously thought to be lifelong dependents to regain functionality and return home to lead normal lives.

The three doctors, Bartolome Celli, MD, and Miguel Divo, MD of Caritas Saint Elizabeth's and David Neumeyer, MD of the Lahey Clinic are currently drawing up a set of weaning protocols that will enable them to provide a measure of uniformity to the process and allow patients to wean even more quickly and with a higher success rate than with the more traditional physician-directed weaning.

Long-renowned for pulmonary excellence, Northeast Specialty Hospital is also an acute care hospital that specializes in providing comprehensive care for patients with complex medical, short-term rehabilitation and long-term medical and pulmonary needs. Deb Williams, Vice President of the hospital, sees the partnership as an opportunity for the Braintree-based hospital to become a true regional leader in the highly specialized field of ventilator weaning. "We are privileged to have three such high-caliber and well-respected pulmonologists working with us to support our mission in developing the region's center of excellence in pulmonary and ventilator weaning care and rehabilitation."

At the heart of the program is a multidisciplinary approach that involves not only the referring physician and the staff doctors at

the hospital, but several team members who bring numerous other areas of expertise to the process. Dr Divo, one of the hospital's Medical Directors, explains the team approach. "What we do here, which is a big difference from a typical acute care hospital, is that I sit with a case manager, a social worker, a nutritionist, a physical therapist, an occupational therapist, a respiratory therapist, a speech pathologist, the nurses and the patient," he says. "So, on multidisciplinary grounds we discuss the case. We try to coordinate, to look for goals; goals on a short, medium and long term. Everybody is trying to derive and understand what the care plan is. We address the issues as a team."

Dr Neumeyer, who is a board certified pulmonologist, intensivist and sleep specialist at the Lahey Clinic in Burlington and serves as Medical Director, along with Dr Divo, at Northeast Specialty Hospital in Waltham, concurs. "It's not just a single specialist," he says, "it's a group of people who are looking at different aspects of a patient's health and trying to determine what is actually impairing their ability to wean." Dr Neumeyer, who completed his residency in Internal Medicine and a fellowship in pulmonary medicine at New England Deaconess Hospital, as well as fellowships in critical care at Brigham and Women's Hospital and sleep disorders at the Rhode Island Hospital, has been with the Lahey Clinic Since 1997 and Northeast Specialty Hospital since the Waltham site opened in April of 2004. One of the most appealing features of the program at Northeast Specialty Hospital, was the state-of-the-art facility that has been put together at Waltham. The physicians provide coverage there 24 hours a day, seven days a week and work closely with referring physicians, as well as the patients and their families, to identify health concerns and assess each patient's strengths and limitations.

Miguel Divo, MD, has gained national recognition as a specialist in how to best wean patients from ventilators. Photo by Debra Troyanos.

One challenge all the doctors face is that the kind of care delivered in a typical acute care setting can sometimes be counterproductive to weaning a patient from a ventiator.

"In an acute care hospital," says Dr Divo, "we are very good at delivering care regarding medication, treatment, procedures, but in a secondary phase that is rehabilitation, regaining your function, reevaluating everything that makes you transition to going back home and being a functional patient, this is the place to do it."

The place he refers to is the 60-bed rehabilitation unit at Children's Hospital's suburban location on the campus of what used to be Waltham Hospital, where Northeast Specialty Hospital opened its newest location in the spring of 2004.

Northeast Specialty Hospital also has sites in Braintree, Stoughton and Natick and is in good company in Waltham, where other tenants include Newton-Wellesley Hospital and Beth Israel Deaconess Medical Center.

Dr Divo's mentor, and his Division Director at Caritas Saint Elizabeth's is Bartolome Celli, M.D., the Chief of Pulmonary Critical Care. Born in Venezuela, Dr Celli has been in Boston for 35 years. He completed his internal medicine training at Boston City Hospital, where he was Chief Medical Resident between 1975 and 1976, and his pulmonary fellowship and critical care fellowship at Boston University Medical Center. After a five-year stint back in his native country, he came back to New England to Tufts University, first as an Associate Professor and then as a Full Professor. Today he is a professor of Medicine at Tufts University School of Medicine, in addition to his role at Caritas St. Elizabeth's.

Dr Celli believes there are two important factors referring physicians must consider when assessing a patient's suitability for weaning. "We must be optimistic," he says. "Physicians who work in critical care environments, when a patient is on a ventilator and can't come off the ventilator, they're deemed impossible to be weaned or impossible to go home. However, the evidence is that about 40% of those patients will ultimately come off the ventilator and about half of them will be able to go home. Therefore, we should have an optimistic approach and say, okay, even though we have reached the end of what we can do in an acute care setting, we are only beginning what we can do in a more rehab-oriented facility.

"Number two is to not just think of the acute problems but begin to think as soon as the patient is intubated, ventilated or severely ill, of what would be the possible outcome if that patient was prevented from deteriorating too much and could go to one of these rehab units. "So optimism and foresight, those are the two recommendations I would make to the referring physicians. And getting them to us early enough that we can have maximum capacity to rehab them."

On the issue of timeliness, Dr. Divo agrees. "Time is of the essence here," he says. "I compare this, and I use this analogy with the patients, this is like fishing. So you throw your line, you have your bait, and you're waiting for the right time. And the

Dr Neumeyer is a board-certified pulmonologist at the Lahey Clinic in Burlington and serves as Medical Director, along with Dr Divo, at Northeast Specialty Hospital in Waltham.

Bartolome Celli, MD is the Chief of Pulmonary Critical Care at Caritas St Elizabeth's Medical Center, as well as Professor of Medicine at Tufts University School of Medicine.

right time is what you measure. Too much fluid in the body and you need to get rid of that. But you can't do it in one step, you do it on a weekly basis. For people recovering from big complicated surgeries, what you need is a little bit of the healing process. Some of those wounds can affect some of the breathing muscles. Surgery in the chest, when you crack the chest, you need to have that strong enough that you can use it as a way of breathing again.

"In the middle, you look for quality of life, also. So you're trying to make them talk, you're getting them to communicate. Those little things make a huge difference to the patient. My ultimate goal may be three, four or five months away."

Along the way, Dr Divo has to manage the expectations, both of his patients and their family members.

"I look for a milestone, and I share that with the patient, to go to the next one, in order to go to the final goal. And it's one of the very difficult things to get people to understand here, we need to look for little changes and little gains, not the whole ultimate goal. And we cannot think about immediate gratification and immediate results. Here everything takes a little bit more time."

A typical patient is referred from an intensive care unit of an acute care hospital and is either a healthy person who has suffered some kind of catastrophe that has caused them to become so ill that they need to be on a ventilator, or patients suffering from a multitude of chronic conditions, one of which has resulted in a pulmonary crisis that has required assistance with their breathing. Very often, previous attempts to wean them in the ICU they were referred from have failed.

"If they have failed originally, we look at why they are still failing," explains Dr Divo. "What are the little things we can improve? We look for the reversal process here. That is the daily and constant thinking from the medical perspective on the pulmonology of how can I reverse the situation: the nutrition, the rehabilitation, the re-exercising. Some of the drugs that you give in the intensive care unit, by that time, are not beneficial. By now you're trying to clean up all of that. We look for the patient to rest, recover, and get good nutrition. Basically, it's that, with a lot of science behind it."

The latest challenge is the creation of weaning protocols that will replace the physician-directed approach that most other hospitals use. "Protocols allow for a uniform approach to chronic weaning in an expeditious manner," Dr Neumeyer explains. "If you can do things on a consistent basis, then patients tend to wean faster."

For patients who need home care or other long-term care services, Northeast Specialty Hospital's parent company, Commonwealth Communities, owns and operates a number of skilled nursing and rehabilitation centers, assisted living residences and home health care services throughout Massachusetts.

Dr. Divo's parting words appropriately sum up the mission of the company. "My goal is to identify those people who can come out of the ventilator and to determine what is the shortest period of time that I can do this?"

For more information about the vent weaning program at Northeast Specialty Hospital, please call (800) 500-5715, extension 8679 or visit their website at commonwealthcommunities.com.

CPL raptor

Comprehensive Pulmonary Laboratory

Instrument performance in the longitudinal measurement of diffusing capacity (DL_{CO})

RL Jensen,[1] JG Teeter,[2] RD England,[2] HJ White,[2] EH Pickering,[2] HM Howell,[1] RO Crapo[1]
[1]LDS Hospital and University of Utah, Salt Lake City, UT, USA; [2]Pfizer Global Research and Development, Groton, CT, USA

ABSTRACT

The variability of 5 new pulmonary function test (PFT) instruments (Collins CPL, JaegerUSA Masterscreen, Medical Graphics Profiler DX™ System, Morgan Transflow Test PFT System, SensorMedics Vmax 220) was established with a DL_{CO} simulator using 3 precision gas mixtures and 3 different inspiratory volumes. Testing was performed 4 times over 12 weeks on Days 0, 30, 60, and 90. At each test session, each gas mixture and volume (9 test conditions) was injected into each instrument 6 times. The first test was discarded to ensure complete flushing of the system (180 simulations/instrument were analyzed). The same instruments were also used to measure DL_{CO} on 11 healthy subjects 6 times over a 24-week interval (Weeks 0-2, 12-14, and 24-26). Each subject performed 3 acceptable maneuvers at each session, producing 198 measurements per instrument for analysis. The overall variability of simulator and human testing is summarized in the table.

Instrument	Simulator testing		Human subject testing			
	RMS CV*	Mean†	Range†	RMS CV*	Range CV
Collins	2.02	26.8	16.7, 38.8	4.93	3.26, 6.20
Jaeger	4.04	26.4	17.4, 35.8	5.79	3.92, 8.08
Medical Graphics	6.73	27.1	19.6, 38.4	9.83	4.17, 13.9
Morgan	9.06	28.7	18.9, 38.7	9.26	3.74, 19.5
SensorMedics	3.39	28.1	20.0, 40.7	6.48	2.82, 9.18

*RMS CV = Root Mean Square Coefficient of Variation (square root of the average squared coefficient of variation for all simulations or subjects across all time points). †Measured DL_{CO} in ml/min/mmHg.

These data demonstrate that longitudinal variability in DL_{CO} assessed by DL_{CO} simulations differs significantly among commercially available PFT instruments. The variability in DL_{CO} is more pronounced in human subjects. The magnitude of the observed differences in variability has implications for designing clinical studies that utilize DL_{CO} as an endpoint.

BACKGROUND

- Longitudinal measurement of pulmonary function is an integral component of assessing the safety and efficacy of drugs delivered by inhalation. An understanding of the sources of variability associated with the longitudinal measurement of pulmonary function is essential for clinical trial design, as it is in interpreting longitudinal lung function measurements in disease states. However, methods for assessing the sources of test variability using modern Pulmonary Function Test (PFT) instruments are not readily available.
- This study was performed to assess the sources of variability in the longitudinal measurement of DL_{CO} as obtained on 5 new commercially available PFT instruments. The impact of the observed variability on sample size determinations for controlled clinical trials utilizing DL_{CO} as an endpoint is discussed.

METHODS

- One new established instrument from 5 different PFT equipment manufacturers was purchased to perform these studies. The models were:
  - Collins CPL
  - JaegerUSA Masterscreen Diffusion TP
  - Medical Graphics Profiler DX™ System
  - Morgan Transflow Test PFT System
  - SensorMedics Vmax 220.
- Each instrument was set up and maintained throughout the study according to manufacturer's specifications.
- All instruments remained powered on for the duration of the study.
- Testing was performed at LDS Hospital in Salt Lake City, UT, USA, and guided by 2 experienced technicians.
- On test days, instruments were calibrated approximately 1 hour prior to the first test.
  - Instruments would be calibration checked or recalibrated if there were long delays between subjects or when instrument problems were suspected.
- We used a DL_{CO} simulator (Hans Rudolf, Kansas City, MO, USA) to simulate a broad range of DL_{CO} values.

DL_{CO} simulator

- The DL_{CO} simulator is connected to the mouthpiece of the PFT instrument being tested and is used to simulate a single breath DL_{CO} maneuver.
- Two precision syringes are manually operated to simulate inhalation and exhalation maneuvers.
- In the present study, the first syringe was used to precisely inhale a known volume of test gas (inspired volume) from the PFT instrument.
- After a breath-hold-time of approximately 10 seconds, the second syringe containing precision gas mixtures was then used to simulate the exhalation maneuver back into the instrument.
  - Precision gas mixture concentrations were known to the nearest 0.001%.
- The observed DL_{CO} was recorded from each instrument after each simulation.
- Three different inspired volumes were used in combination with 3 "exhaled" gas mixtures for 9 total combinations to simulate a physiologically relevant range of human DL_{CO} values (~10-50 mL/min/mmHg).

Simulator testing schedule

- During DL_{CO} simulator testing, 6 repetitions of each of the 9 test gas–inspiratory volume combinations were used to test each instrument on 4 occasions over a 90-day period according to the schedule in Table 1.

Table 1. DL_{CO} simulator testing schedule

Instrument	Repetitions × gas-volume combinations/ test				Total observations analyzed per instrument
	Day 0	Day 30	Day 60	Day 90	
Collins	6×9	6×9	6×9	6×9	180
Jaeger	6×9	6×9	6×9	6×9	180
Medical Graphics	6×9	6×9	6×9	6×9	180
Morgan	6×9	6×9	6×9	6×9	180
SensorMedics	6×9	6×9	6×9	6×9	180

- To ensure complete flushing of the system, the first trial of a group of 6 repetitions was deleted from the analysis.
  - The remaining 5 observations on each occasion were analyzed for a total of 180 measurements per instrument.
- As outlined in Table 2, each of the 3 test gas mixtures were combined with each of 3 inspiratory volumes to produce the 9 simulated DL_{CO} maneuvers utilized in the protocol.

Table 2. Test gas-inspiratory volume combinations

Gas mixture	Inspiratory volume (L)
Low	2, 4, and 6
Medium	2, 4, and 6
High	2, 4, and 6

- Gas mixture compositions are outlined in Table 3.

Table 3. Test gas mixture compositions

	% Carbon dioxide	% Carbon monoxide	Tracer gas, as % of Inspired	% Oxygen	% Nitrogen
Low gas mixture	0.300	0.080	10		balance
Middle gas mixture	0.450	0.270	10	16.000	balance
High gas mixture	0.900	0.180	10	16.000	balance

- The DL_{CO} of each subject was measured twice on each of the 5 PFT instruments in Weeks 0-2, 12-14, and 24-26 according to the scheme in Table 5.

Table 5. Human subject testing schedule

Study Week	0	0	1	1	2	12	12	13	13	14	24	24	25	25	26
Week Days	1,3	3,4	1,3	3,4	1,3	1,3	3,4	1,3	3,4	1,3	1,3	3,4	1,3	3,4	1,3
Instrument 1	•														
Instrument 2		•													
Instrument 3			•												
Instrument 4				•											
Instrument 5					•										
Instrument 6						•									
Instrument 7							•								
Instrument 8								•							
Instrument 9									•						
Instrument 10										•					
Instrument 11											•				
Instrument 12												•			
Instrument 13													•		
Instrument 14														•	
Instrument 15															•

- Using a computer-generated open randomization scheme, each subject was randomized to be tested on the 5 machines in a different order.
- At each testing session, subjects were required to perform at least 3 DL_{CO} maneuvers on 2 separate days that met the acceptability standards of the American Thoracic Society (ATS).[1]
  - A total of 198 DL_{CO} measurements per instrument were analyzed.
- Serum hemoglobin was determined on all subjects at weeks 0, 12, and 24.
- All reported human subject DL_{CO} values were adjusted for hemoglobin according to the recommendations of the ATS.[1]

Analysis

- The variability associated with repetitive DL_{CO} testing on each instrument was determined from the Root Mean Square Coefficient of Variation (RMS CV = the square root of the average squared coefficient of variation for all simulations or subjects on each instrument across all time points).

RESULTS

- The overall variability of simulator and human subject testing is summarized in Table 6 and Figure 1.

Table 6. DL_{CO} simulator and human subject variability

Instrument	Simulator testing		Human subject testing		
	RMS CV*	Mean†	Range†	RMS CV*	Range CV
Collins	2.02	26.8	16.7, 38.8	4.93	3.26, 6.20
Jaeger	4.04	26.4	17.4, 35.8	5.79	3.92, 8.08
Medical Graphics	6.73	27.1	19.6, 38.4	9.83	4.17, 13.9
Morgan	9.06	28.7	18.9, 38.7	9.26	3.74, 19.5
SensorMedics	3.39	28.1	20.0, 40.7	6.48	2.82, 9.18

*RMS CV = Root Mean Square Coefficient of Variation (square root of the average squared coefficient of variation for all simulations or subjects across all time points). †Measured DL_{CO} in ml/min/mmHg.

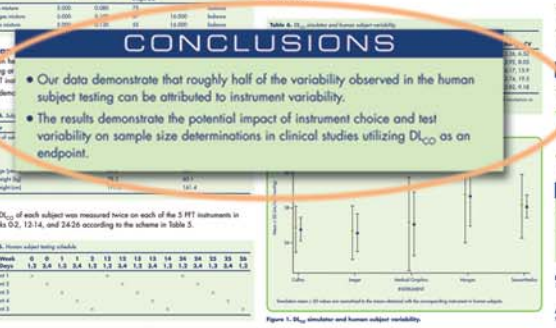

Figure 1. DL_{CO} simulator and human subject variability.

- The impact of the variability of longitudinal human subject DL_{CO} measurements on sample size determination is illustrated in Figure 2.

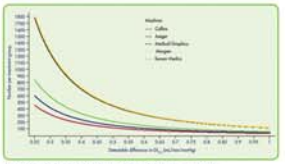

Figure 2. Sample size required to detect a difference between groups = DL_{CO}

- This figure is representative of a hypothetical controlled clinical study whose primary outcome is treatment group difference in change from baseline DL_{CO}.
- Using the human subject variability determined for each instrument tested, this figure depicts the number of subjects required (y-axis) to detect treatment group differences in change from baseline DL_{CO} (x-axis) assuming a power of 80% and α=0.05.

DISCUSSION

- This is the first study to estimate the individual components of machine and human variability associated with the longitudinal measurement of diffusing capacity.
- The variability associated with longitudinal measurement of DL_{CO} — as assessed by repetitive simulations — varied across the instruments tested in this study. The variability in DL_{CO} observed with repetitive human subject testing was larger and also varied among the instruments tested.
- These results represent analyses obtained on one instrument per manufacturer and may not be representative of all of their models.

CONCLUSIONS

- Our data demonstrate that roughly half of the variability observed in the human subject testing can be attributed to instrument variability.
- The results demonstrate the potential impact of instrument choice and test variability on sample size determinations in clinical studies utilizing DL_{CO} as an endpoint.

Reference

1 American Thoracic Society. Single-breath carbon monoxide diffusing capacity (transfer factor). Recommendations for a standard technique – 1995 update. Am J Respir Crit Care Med. 1995;152:2185-2198.

Acknowledgement

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Performance of 5 PFT Instruments in the Longitudinal Measurement of FEV_1

R.L. Jensen, J.G. Teeter, R.D. England, H.J. White, E.H. Pickering, R.O. Crapo

ABSTRACT

The variability of 5 new pulmonary function test (PFT) instruments (Collins CPL, JaegerUSA Masterscreen, Medical Graphics Profiler DX System, Morgan Transflow Test PFT System, SensorMedics Vmax 22D) was established using 24 standard waveforms with a waveform simulator. Testing was performed on Days 0, 30, 60, and 90. At each test session, each waveform was injected 5 times into each PFT instrument (480 measurements per instrument). Each instrument was also used to test 11 healthy subjects at Weeks 0, 12, and 24. At each test session, each subject performed three acceptable spirometric maneuvers. The highest FEV_1 for each subject was recorded (66 measurements per instrument). Overall variability is summarized in the table.

Instrument	Simulator testing RMS CV[a]	Human subject testing Mean[b]	Range[b]	RMS CV[a]	Range CV
Collins	0.37	3.62	2.49, 5.52	2.80	0.87, 4.91
Jaeger	1.59	3.66	2.56, 5.64	2.74	1.21, 4.31
Medical Graphics	0.74	3.49	2.19, 5.48	4.18	0.94, 9.78
Morgan	0.42	3.66	2.53, 5.58	2.56	0.89, 4.85
SensorMedics	0.85	3.46	2.38, 5.41	4.24	0.99, 11.66

[a]RMS CV = Root Mean Square Coefficient of Variation (square root of the average squared coefficient of variation for all waveforms or subjects across all time points); [b]Measured FEV_1 in liters BTPS.

These data demonstrate that the variability associated with longitudinal measurement of FEV1 assessed by repetitive waveform simulations is consistently small. Human subject variability is much larger. Differences in variability of the magnitude observed in this study have implications for the design of clinical studies that utilize FEV_1 as an endpoint.

Authors Jensen and Crapo are with LDS Hospital and University of Utah, Salt Lake City; England, White and Pickering are with Pfizer Global Research and Development, Groton, CT. This study was funded by Pfizer Inc and Aventis Pharmaceuticals Inc.

BACKGROUND

- Longitudinal measurement of pulmonary function is an integral component of assessing the safety and efficacy of drugs delivered by inhalation. An understanding of the sources of variability associated with the longitudinal measurement of pulmonary function is essential for clinical trial design, as it is in interpreting longitudinal lung function measurements in disease states. However, methods for assessing the sources of test variability using modern pulmonary function test (PFT) instruments are not readily available.
- This study was performed to assess the sources of variability in the longitudinal measurement of forced expiratory volume in 1 second (FEV1) as obtained on 5 commercially available PFT instruments. The impact of the observed variability on sample size determinations for controlled clinical trials utilizing FEV_1 as an endpoint is discussed.

METHODS

- One new instrument model from 5 different PFT equipment manufacturers was purchased to perform these studies. These models, and their basic FEV1 measurement technology, were:
  - Collins CPL (volume-based)
  - JaegerUSA Masterscreen Diffusion TP (flow-based)
  - Medical Graphics Profiler DX System (flow-based)
  - Morgan Transflow Test PFT System (volume-based)
  - SensorMedics Vmax 22D (flow-based).
- Each instrument was set up and maintained throughout the study according to manufacturer's specifications.
- Each instrument remained powered on for the duration of the study.
- Testing was done at LDS Hospital in Salt Lake City, UT, USA, and performed by 2 experienced technicians.
- On test days, instruments were calibrated approximately 1 hour prior to the first test.
  - Instruments would be calibration checked or recalibrated if there were long delays between subjects or when

instrument problems were suspected.

- A Pulmonary Waveform Generator (PWG; MH Custom Design & Mfg. L.C., Midvale, UT, USA) was used to simulate forced vital capacity (FVC) maneuvers.

- The PWG is a large mechanical syringe (approximately 9 inches in diameter with a full linear displacement of about 14 inches), which is connected to the mouthpiece of the PFT instrument being tested.
- A high precision stepper motor drives the syringe forward and backward.
- The stepper motor makes 1 revolution every 50,000-step pulses and is coupled to the syringe via a spring-loaded screwball assembly.
  - This assembly allows almost instantaneous translation of the stepper motor rotation to horizontal motion of the syringe.
- Given the cross-sectional area of the syringe and the minute forward motion resolution, the PWG can deliver volumes in increments of 0.000016 L (16 µL).
- There is also a dynamic feedback system built into the stepper motor that makes real-time resolutions on the desired programmed position of the syringe.
- During operation, a desktop computer reads 1 of the 24 digitized waveforms from the American Thoracic Society (ATS) and a set of commands for the stepper motor is buffered and readied.
- The user selects a waveform and activates it — the PWG system then delivers a precise replica of the volume-time profile for the selected ATS waveform.
- Precision of the PWG to deliver the same waveform repetitively is within 1 mL (~0.025%), and accuracy of the delivered volume is within 2 mL (0.050%).
- The PWG is calibrated yearly by using digital micrometers to verify the forward displacement of the syringe surface.

PWG TESTING

- In this study, the PWG was used to inject 5 repetitions of the 24 standard volume-time waveforms (FEV_1 target values ranged from 0.91 to 5.30 L) recommended by the ATS into each instrument on 4 separate days evenly spaced over a 90-day period, or according to the schedule in Table 1.
  - A total of 480 simulated FEV_1 measurements were analyzed for each instrument.

HUMAN SUBJECT TESTING

- Eleven healthy, nonsmoking adult subjects underwent repetitive FEV_1 testing at the LDS Hospital over a 26-week period on each of the same 5 PFT instruments used in the simulation tests.
- The demographic characteristics of these subjects are summarized in Table 2.
- The FEV_1 of each subject was measured twice on 2 consecutive days on each of the 5 PFT instruments in weeks 0-2, 12-14, and 24-26 according to the scheme in Table 3.
- Using a computer-generated open randomization scheme, each subject was randomized to be tested on the 5 machines in a different order.
- At each testing session, subjects were required to perform at least 3 FVC maneuvers on each of 2 separate days that met the acceptability standards of the ATS.[1]
- The highest single measured FEV_1 from these 3 maneuvers was reported as the subject's FEV_1 value for that day.
- A total of 66 FEV_1 measurements (2 measurements x 3 testing sessions x 11 subjects) per instrument were analyzed.

ANALYSIS

- The variability associated with repetitive FEV_1 testing on each instrument was determined from the Root Mean Square Coefficient of Variation (RMS CV = the square root of the average squared coefficient of variation for all simulations or subjects across all time points).

RESULTS

- The overall variability of simulator and human subject testing is summarized in Table 4 and Figure 1.

Table 1. *FEV_1 simulator testing schedule.*

Instrument	Repetitions × waveforms Day 0	Day 30	Day 60	Day 90	Total observations analyzed per instrument
Collins	5×24	5×24	5×24	5×24	480
Jaeger	5×24	5×24	5×24	5×24	480
Medical Graphics	5×24	5×24	5×24	5×24	480
Morgan	5×24	5×24	5×24	5×24	480
SensorMedics	5×24	5×24	5×24	5×24	480

Table 2. *Subject demographic characteristics.*

Gender	Male	Female
Number of subjects	4	7
Race:		
White	4	6
Black	0	1
Mean age (years)	45.5	35.7
Mean weight (kg)	78.3	60.1
Mean height (cm)	177.0	161.4

Table 3. *Human subject testing schedule.*

Study Week / Week Days	0 1,2	0 3,4	1 1,2	1 3,4	2 1,2	12 1,2	12 3,4	13 1,2	13 3,4	14 1,2	24 1,2	24 3,4	25 1,2	25 3,4	26 1,2
Instrument 1	×					×					×				
Instrument 2		×					×					×			
Instrument 3			×					×					×		
Instrument 4				×					×					×	
Instrument 5					×					×					×

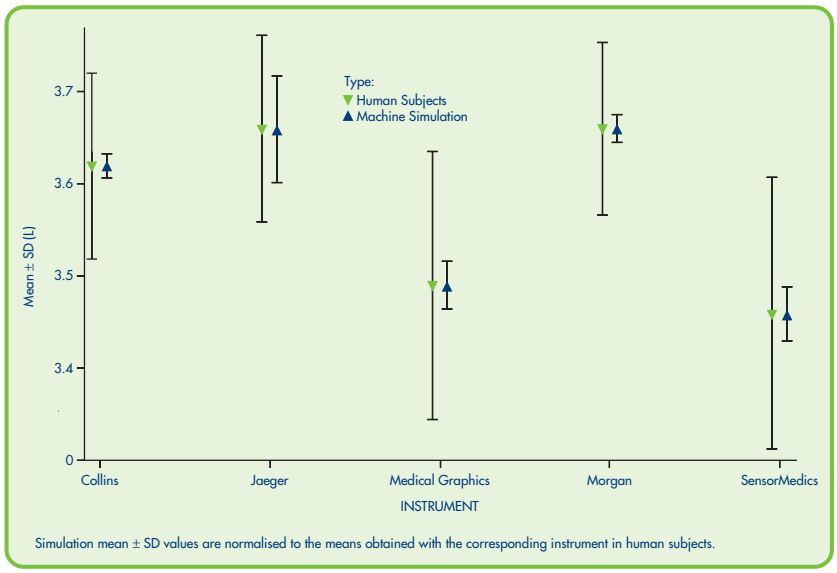

Figure 1. FEV_1 simulator and human subject variability.

Table 4. *FEV_1 simulator and human subject variability.*

Instrument	Simulator testing RMS CV[a]	Human subject testing Mean[b]	Range[b]	RMS CV[a]	Range CV
Collins	0.37	3.62	2.49, 5.52	2.80	0.87, 4.91
Jaeger	1.59	3.66	2.56, 5.64	2.74	1.21, 4.31
Medical Graphics	0.74	3.49	2.19, 5.48	4.18	0.94, 9.78
Morgan	0.42	3.66	2.53, 5.58	2.56	0.89, 4.85
SensorMedics	0.85	3.46	2.38, 5.41	4.24	0.99, 11.66

[a]RMS CV = Root Mean Square Coefficient of Variation (square root of the average squared coefficient of variation for all waveforms or subjects across all time points); [b]Measured FEV_1 in L (BTPS).

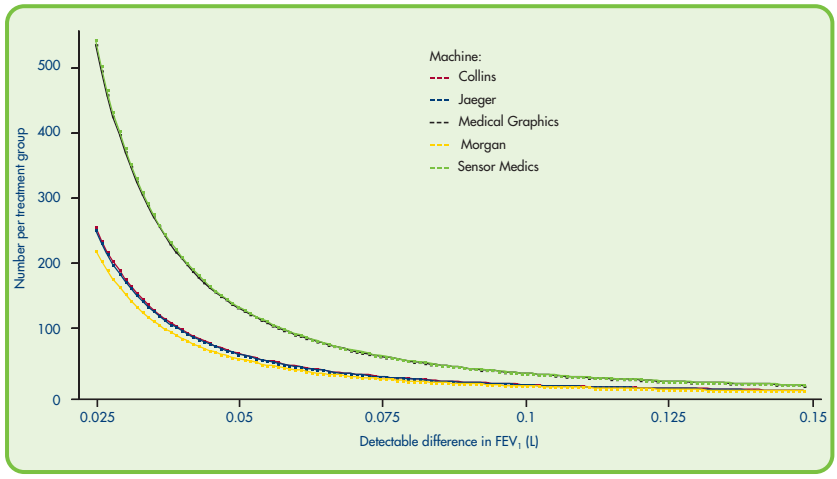

Figure 2. Sample size required to detect a difference between groups – FEV_1.

- The impact of the variability of longitudinal human subject FEV_1 measurements on sample size determination is illustrated in Figure 2.
- This figure is representative of a hypothetical controlled clinical study whose primary outcome is treatment group difference in change from baseline FEV_1.
- For each instrument tested, this figure depicts the number of subjects required (y-axis) to detect treatment group differences in change from baseline FEV_1 (x-axis) assuming a power of 80% and a=0.05.

DISCUSSION

- This is the first study to estimate the individual components of machine and human variability associated with the longitudinal measurement of FEV_1.
- The variability associated with longitudinal measurement of FEV_1 — as assessed by repetitive waveform simulations — was consistently small across all instruments tested.
- The variability in FEV_1 observed with repetitive human subject testing was much larger and varied among the instruments tested in this study.
- These results represent analyses of data obtained on one instrument per manufacturer and may not be representative of all their models.

CONCLUSIONS

Depending on the instrument tested, our data demonstrate that roughly 20-60% of the variability in longitudinal FEV_1 observed in the human subject testing can be attributed to instrument variability.

The results demonstrate the potential impact of instrument choice and test variability on sample size determinations in clinical studies utilizing FEV_1 as an endpoint.

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Ventilatory Management of Severe Tracheal Stenosis

Lodha Rakesh, Guglani Lokesh, S.C. Sharma, S.K. Kabra

ABSTRACT

We present here a 4 year old child with severe tracheal stenosis and respiratory failure. The patient was not responding to conventional ventilation settings and had significant hypercarbia. The difficulty in mechanical ventilation was handled successfully with specific ventilatory strategy: use of low respiratory rate, long inspiratory time and normal inspiratory time : expiratory time ratio. Thereafter the child was managed surgically and the stenosis was corrected. The child was discharged after a Montgomery T-tube placement.

Laryngotracheal stenosis is a congenital or acquired narrowing of the airway that may affect the glottis, subglottis or trachea. It causes severe symptoms and should be suspected in children less than 1 year of age with either multiple episodes of croup or croup which fails to respond to medical management or requires endotracheal intubation.[1] The term subglottic stenosis was previously used as the subglottic region is the most common site of airway stenosis, mostly secondary to prolonged endotracheal intubation. The onset may be acute or it may develop over a period of time and a thorough assessment, radiologic and endoscopic evaluation may be necessary to guide further therapy and management. We present a case of acquired tracheal stenosis that required prolonged ventilatory support with adaptations for the obstructive pathology and discuss the implications for ventilation of a child with upper airway obstruction.

CASE REPORT

A 4-year-old boy presented with history of intermittent high grade fever and cough without expectoration of 3 months' duration. After 5 days of onset of fever, he developed noisy breathing and progressively increasing respiratory distress. There was no history of cyanosis, wheezing episodes or any history of foreign body aspiration. There was no history of contact with tuberculosis and no past history of any significant illness. The respiratory distress and the intensity of noisy breathing increased gradually over 3 months and were now also persisting during sleep. There was no history suggestive of diphtheria and the child was immunized for age.

On presentation, the child had marked respiratory distress, was sitting up bending forward and had marked suprasternal recessions and severe biphasic stridor. He had a respiratory rate of 48/minute, and had good volume pulses with no cyanosis and SpO_2 of 99% on facemask oxygen. Chest examination showed hyperinflation of the chest wall with symmetrical movements of both sides of the chest wall, centrally placed trachea on palpation and equally resonant percussion note on both sides. Chest auscultation revealed equal air entry on both sides and conducted breath sounds. Examination of cardiovascular and other body systems was unremarkable. Initial arterial blood gas analysis showed a pCO_2 of 48.6 mm Hg and Pa_2 of 198.4 mm Hg with pH of 7.391.

At presentation the possibility of severe upper airway obstruction was kept and radiographs of soft tissue of neck (lateral view) did not show any evidence of epiglottitis or narrowing of the cervical portion of the trachea. Chest X ray showed bilateral hyperinflated lung fields with no lung parenchymal abnormalities and normal cardiothoracic ratio (48%). However, over the next few hours child showed progressive deterioration with rising pCO_2 values up to 80 mm Hg and had to be intubated for respiratory support and was therefore transferred to the Pediatric Intensive Care Unit (PICU) for further management.

On arrival to the PICU he was ventilated with Siemens Servo 300 ventilator on SIMV (volume controlled) mode with initial conventional settings but did not show adequate chest rise and had progressive CO_2 accumulation (values up to 150 mm Hg) on blood gas analysis. The initial settings were: rate 30/min, tidal volume 80 ml, Ti 0.7 seconds, I:E ratio of 1:2 and positive end expiratory pressure of 4 cm H_2O. On increasing the tidal volume alone, there was no further improvement in $PaCO_2$ levels assessed after 1 hour. The peak pressure requirement was 38 cm H_2O. On bagging with self-inflating bag, high resistance was felt and adequate chest rise could be achieved only if long inspiratory time was used. Subsequently the settings were modified in keeping with the requirements so that the ventilator now had low rates (10/min) and a prolonged inspiratory time (Ti) of 1.8 seconds, an I:E ratio of 1:2 and PEEP of 5 cm H_2O. With these settings, he maintained oxygenation and showed improvement in $PaCO_2$ levels. The peak pressure requirement also fell to 23 cm H_2O. The rationale for these settings is discussed below.

Subsequently, a fibreoptic bronchoscopy was done through the endotracheal tube in the PICU after initial stabilization and it showed severe narrowing at the distal end of the trachea just above the carina. A diagnosis of supracarinal tracheal stenosis was established and the child underwent endoscopic balloon dilatation of trachea under general anaesthesia the next morning. Intraoperatively, the stenotic area showed some granulation tissue with inflamed mucosa and loss of tracheal rings, and from this a biopsy specimen was obtained and dilatation was done

Authors Rakesh, Lokesh and Kabra are with the Department of Pediatrics; Sharma is with the Departments of Otorhinolaryngology, AIIMS, New Delhi, India. Reprinted from the Indian Journal of Pediatrics, Vol 73, Issue 5, pages 441-444,

Table 1. Case-series of Tracheal Stenosis

Series	No.	Etiology	Techniques used	Outcome
(1) Kumar P *et al*[7]	n = 17	External vascular compression=9. Post transplant strictures=4 Malignant masses=2 Postintubation =2	Airway Stenting with self-expanding metal stents in 10 cases, silicone stents in 7.	47% alive on follow up, 6/8 ventilator dependent extubated
(2) Anton-Pacheco JL *et al*[8]	n = 13	All cases Congenital: Mild – 4 Moderate – 6. Severe – 3	Costal cartilage tracheoplasty (CCT)=5. Tracheal resection – 3. Slide tracheoplasty=2. Endoscopic dilation=3 Laser Resection=1	Overall mortality 23%. 3 early deaths-all after CCT
(3) Dunham ME *et al*[9]	N= 23	Congenital complete tracheal rings producing long segment stenosis of trachea	Pericardial Patch Tracheoplasty	83% survival at mean follow up of 4.5 years
(4) Har-El G *et al*[10]	N= 19	Post-intubation or tracheotomy in 80%	Circumferential tracheal resection with end-to-end anastomosis	Anastomosis success rate of 94.7%
(5) Loeff DS *et al*[11]	N= 22	Vascular rings/slings in 50%	Localized-dilatation, tracheostomy, and resection with end-to-end anastomosis, Funnel shaped defects-tracheal reconstruction with grafts	Overall mortality rate 77%
(6) Weber TR *et al*[12]	N= 62	Acquired Tracheal Stenosis (4 weeks to 14 years age) Endotracheal intubation-44 Caustic aspiration-6 Recurrent infection-5 Bronchoscopic perf-4 Gastric aspiration-3 Site of airway stenosis Subglottic/upper – 47 Midportion-8 Distal/Carinal-7	Individualized treatment: Balloon dilatation-20, Bronchoscopic electrocoagulation resection- 44, Steroid injection-48, T tube stent-8, Resection anastomosis-12, Cricoid split-3, and Rib cartilage graft-12.	7(11%) died of unrelated causes. 44 of 55 patients (80%) are without tracheostomy.

with Fogarty's Catheter. An endotracheal tube of 4.5 Fr size was inserted under bronchoscopic guidance with tip extending beyond the stenotic segment and lying above the carina. He was subsequently continued on ventilatory support for the next 10 days with gradual weaning. A diagnosis of tubercular tracheal stenosis was considered and antitubercular therapy was started but subsequent work up did not reveal any evidence of tubercular infection. However, there was satisfactory clinical response as the fever subsided and tracheal granulations on repeat examination were absent. The biopsy from the lesion showed mild non-specific inflammatory changes with no granulomas.

A repeat fibreoptic bronchoscopy done 8 days after the dilatation procedure in the PICU showed no significant stenosis but persistence of inflamed mucosa. He was then weaned off ventilatory support but endotracheal tube was left in situ as it was bypassing the stenosed segment. He had recurrence of respiratory distress, which required resumption of ventilatory support and he then underwent repeat dilatation after 20 days of admission, which showed collapse and re-stenosis of trachea, which could be easily dilated. Tracheostomy and Montgomery T tube insertion was done for maintaining long-term patency of the airway. He was discharged from the hospital 2 months after admission and is on regular follow up.

DISCUSSION

The importance of appropriate ventilatory management of severe proximal airway obstruction is highlighted by this case and it is important to understand the rationale for the ventilatory settings described above. The trachea and the upper airway although considered to be relatively rigid conducting airways, do show some changes in caliber during the normal respiratory cycle. There is expansion of the intrathoracic airways along with the expanding lungs while the extrathoracic airway diminishes in caliber due to their intraluminal pressure being lower than atmospheric pressure. The reverse of this process occurs during expiration. If intrathoracic trachea is soft (tracheomalacia), the narrowing will accentuate during expiration due to positive intrathoracic pressure. The flow in these large airways is usually turbulent due to the high flow rates and this turbulence increases in the presence of an obstruction in the airway. This turbulence further increases the airway resistance.

The mechanics of critical tracheal stenosis is such that it would severely compromise delivery of gases beyond the obstruction and it would not allow adequate emptying out of the lungs as well. Other obstructive upper airway anomalies like subglottic stenosis could be overcome by use of tracheostomy, which would bypass the site of stenosis, but in more distal lesions of the trachea (as in this case, just above the carina) ventilatory management is more challenging.

With conventional ventilator settings in the patient with severe tracheal stenosis, there would be inadequate delivery of gases beyond the site of obstruction and there would be a build up of pressure proximal to it. In this scenario, there would be progressive CO_2 retention and inadequate lung expansion. Also because of inadequate emptying of the lungs during expiration due to limited airflow across the site of stenosis, there would be a progressive air-trapping and subsequent decrease in cardiac output. Increasing the airway pressures or frequency alone will not help overcome these effects of the obstruction. Increase in the airway pressure may increase the risk of barotraumas. In order to ensure adequate delivery of gases beyond the obstruction, it is necessary to prolong the inspiratory time (Ti) so that adequate lung expansion can be achieved. In view of the markedly increased resistance the time constant will also be increased justifying the need for high Ti. For this, the frequency of breaths would have to be kept at low values in order to allow adequate time for expiration also and at the same time avoid

progressive gas trapping (auto-PEEP). It is unlikely that use of CPAP alone would have led to adequate delivery of volumes across such severe tracheal stenosis.

There have been reports of use of percutaneous transtracheal jet ventilation for cases with tracheal stenosis and other forms of airway obstruction in the more proximal airways.[2] For patients undergoing surgical repair of the tracheal lesions, extracorporeal membrane oxygenation has also been used.[3] In animal models of tracheal stenosis, a comparison of conventional ventilation versus transtracheal jet ventilation showed that although there were no significant differences in $PaCO_2$ but mean peak airway pressure values, both at the distal portion of stenosis and at the proximal portion, decreased more significantly during jet ventilation than during conventional mechanical ventilation.[4] Overall the mean arterial pressure, mean pulmonary arterial pressure, central venous pressure, and cardiac output did not change significantly between conventional mechanical ventilation and jet ventilation with the stenosis. Pulmonary Artery Occlusion Pressure (PAOP) increased significantly more during conventional mechanical ventilation than during jet ventilation in animal models with stenosis.

During ventilation, the use of flow-volume loops would demonstrate plateaus in both inspiratory and expiratory limbs due to the limitation in both phases caused by the obstruction. Miller and Hyatt[5] showed that in patients with fixed airway obstruction, the FEV1 diminishes progressively as the resistance increases but the FVC may remain unchanged, suggesting that the flow rates will be reduced and the ratio of maximal expiratory and inspiratory flow at 50% of vital capacity (MEF_{50} /MIF_{50}) may approach unity (0.9 to 1).

Another contentious issue was the underlying cause of tracheal stenosis in this child since the duration of symptoms was 3 months and he had no respiratory symptoms prior to this illness. Initial impression of granulation tissue being visible on bronchoscopy directed towards a diagnosis of tuberculosis but the work up was negative and the biopsy from the lesion was inconclusive. However, the tracheal inflammation could be due to a tubercular lymph node in the mediastinum. Despite no objective evidence of tuberculosis, response to antitubercular therapy supports the diagnosis of tuberculosis. A possibility of acquired tracheal stenosis secondary to an initial episode of bacterial tracheitis was considered.

The most common cause of acquired laryngotracheal stenosis is prolonged endotracheal intubation, accounting for 90% of cases. Other acquired causes include postinfectious scarring, autoimmune disorders (Wegener's granulomatosis, sarcoidosis), inhalation injuries, blunt trauma to the neck, previous tracheostomy or cricothyrotomy, and gastroesophageal reflux.[6] Prior to the advent of antibiotics, scarring from infections like diphtheria and syphilis were usually a common cause of stenosis. In the trachea, the narrowing may be extrinsic or intrinsic, and diffuse or localized. Among the extrinsic lesions, disorders of the thyroid gland and great vessels are the most common while the intrinsic ones may be due to infectious, granulomatous, neoplastic, traumatic, immunologic and post-inflammatory conditions.

There are several case series of laryngotracheal stenosis in children, with majority of reports being that of surgical repair techniques. The ventilatory management of these patients has not been highlighted but it does pose problems in the perioperative and post-operative period. There have been reports where unstable children with critical stenoses requiring high airway pressures for ventilation and still having CO_2 retention, have required initiation of extracorporeal support, which was followed by diagnostic endoscopy and then finally definitive surgical repair.[3] But these facilities may not exist at all institutions and initial optimal ventilatory support in such sick children may be crucial before they can be shifted to centers where surgical repair can be done. Therefore, it is only with a understanding of the mechanics of tracheal stenosis and its optimal ventilatory management that we can ensure adequate treatment and outcome for these patients by surgical or non-surgical (eg balloon dilatation) means.

In conclusion, this case demonstrates the importance of appropriate ventilatory management of airway obstruction caused by tracheal stenosis and highlights the fact that critical stenosis of trachea may be ventilated with low rates and high inspiratory times. Management of tracheal stenosis in children is complex and requires the teamwork of specialists involved in emergency management, intensive care and otorhinolaryngology.[12]

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Trends In Expected Outcomes In Preterm Infants Treated With the 3100A HFOV: An Updated Meta-Analysis

Thomas E. Bachman, MSHA; James A. Ashurst, PhD

ABSTRACT

A consensus as to the relative benefit of high frequency ventilation in different populations and indications has not been reached. Some have recently hypothesized that improvements in conventional ventilation and improvements in other standards of neonatal care have eliminated the potential of the relative advantages of high frequency ventilation. However, results from recent mega trials of high frequency ventilation have yielded inconsistent results, rather than consistent results of no relative benefit. Rather this suggests a possibility of differences in high frequency devices, treatment strategies or treatment populations. We updated our earlier meta-analysis with data from recent trials in order to address these issues. This analysis reports on the results of seven randomized controlled trials of the 3100A HFOV in 951 preterm infants. In this group of trials with this device we found a clinically significant advantage of high frequency oscillatory ventilation with regard to reducing mortality and chronic pulmonary morbidity. We found no evidence that the relative benefit of HFOV was significantly attenuated with improvements in conventional ventilator strategy or other baseline standards of care. We also found no evidence that the relative benefits were significantly different in preterm infants of different size or severity.

INTRODUCTION

Our meta-analysis in 2002 demonstrated a clear reduction in acute and chronic pulmonary adverse effects in infants associated with the use of the 3100A HFOV (3100A).[1] Since that time two additional randomized controlled trials of that device have more than doubled the number of preterm infants studied.[2,3] In addition the results of several other large randomized controlled trials of other high frequency ventilators in preterm infants have also been published.[4-6]

In spite of the increasing number of randomized controlled trials of high frequency ventilation, more recent meta-analysis reviews of the evidence of its potential benefit in preterm infants have only highlighted a continuing lack of clarity. Henderson-Smart and colleagues found some overall advantage of oscillatory high frequency ventilation for elective use, but were troubled by the inconsistency among trials.[7] Several meta-analyses have suggested that evolution of ventilator strategies explains differences in outcomes.[8,9] Bollen and colleagues, in a cumulative meta-analysis of all types of high frequency ventilation devices and strategies, reported a trend toward no benefit as conventional ventilation strategies improved, but did report significant advantage associated with the use of the 3100A. Finally meta-analyses of the rescue indication of high frequency ventilation is compromised by the diverse population and a lack of any new prospective rescue studies in over a decade.

Most believe that the meta analysis of randomized controlled trials is the highest level of evidence.[10] It seems reasonable that the use of meta-analysis in combining the results from smaller trials might reduce the need for mega trials. This approach, however, has been found to be only somewhat predictive.[11] Bollen's cumulative meta-analysis of HFV trials[8] would suggest subsequent mega trials would show no benefit. However the four recent mega trials reported significantly conflicting results, ranging from significant benefit[3] to potential harm.[6,7] This lack of a consistent pattern of "no relative benefit" suggests the potential for inconsistencies in the patient populations, treatment strategies, or treatment devices.

We chose to update our earlier meta-analysis of the randomized controlled trials of the 3100A in preterm infants with the information from new trials. In doing so, we wanted to address two questions. First, have enhancements in conventional ventilation strategy and use of surfactant replacement and antenatal steroid therapy reduced the relative benefit of high frequency ventilation? And second, were the results of a recent mega trial of high frequency ventilation consistent with previous trials of the 3100A?

Tom Bachman is an Administrator at Mountains Community Hospital, Lake Arrowhead and Jim Ashurst is with Research Support Services, Seal Beach CA. This work was supported in part by Viasys Healthcare, Yorba Linda, CA.

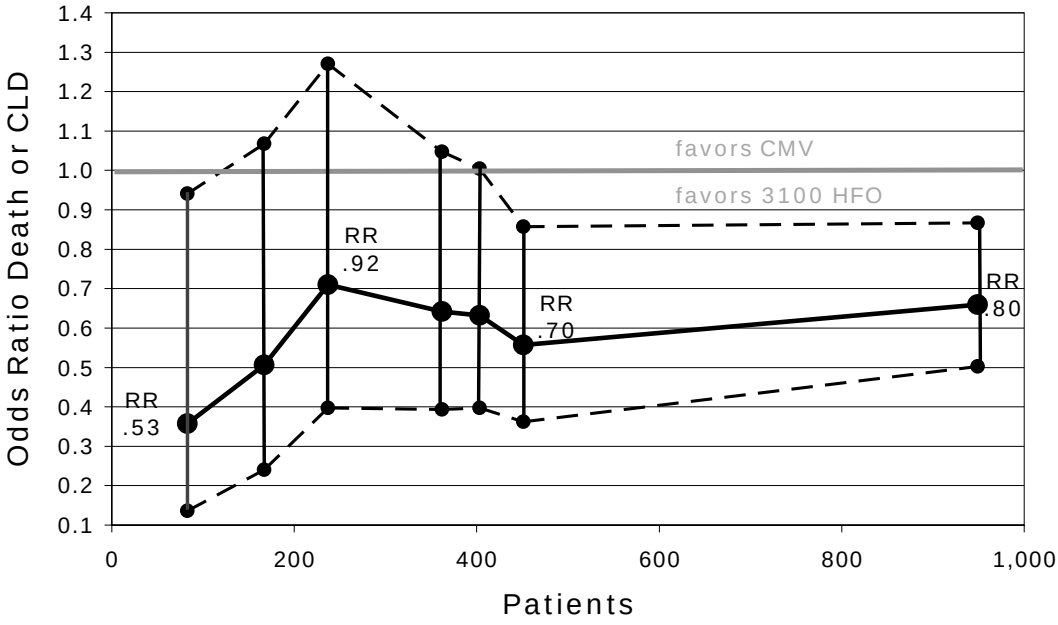

Figure 1a. Meta analysis showing the stepwise chronological inclusion of 7 RCTs. The solid line is the odds ratio of the death or chronic lung disease outcome. The dotted lines are the 95% confidence limits of the odds ratio. RR is the relative risk. Odds ratios and relative risks less than 1 favor the 3100A.

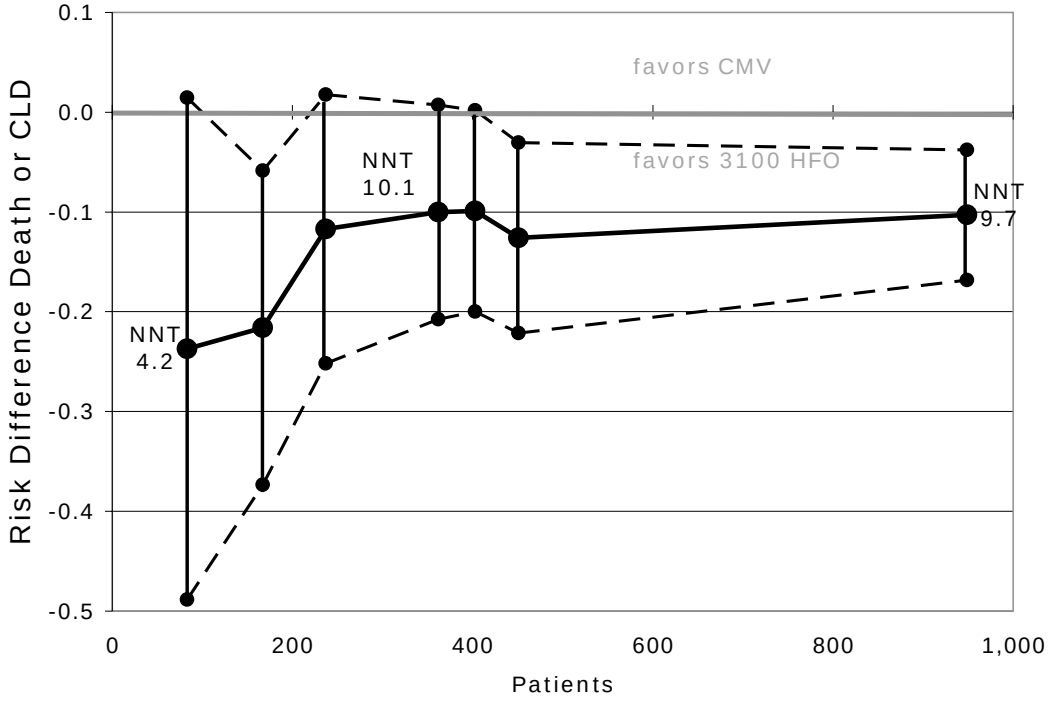

Figure 1b. Meta analysis showing the stepwise chronological inclusion of 7 RCT's. The solid line is the risk difference of the death or chronic lung disease outcome. The dotted lines are the 95% confidence limits of the risk difference. NNT is the number needed to treat to have one less infant die or survive with chronic lung disease. Risk differences less than 1 favor the 3100A.

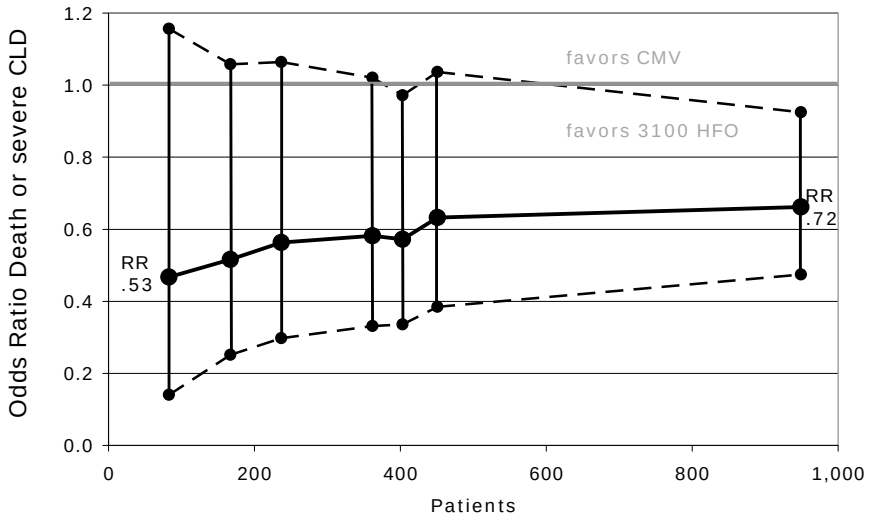

Figure 2a. Meta analysis showing the stepwise chronological inclusion of 7 RCTs. The solid line is the odds ratio of the death or severe chronic lung disease outcome. The dotted lines are the 95% confidence limits of the odds ratio. RR is the relative risk. Odds ratios and relative risks less than 1 favor the 3100A.

METHODS

We conducted a Medline and Google Scholar search to identify all randomized controlled trials of high frequency ventilation in preterm infants reported since the search for our earlier publication.[1] While our earlier analysis included 6 outcome variables, we limited this analysis to two outcomes. The first, the traditional metric, was death or chronic lung disease. Chronic lung disease was defined as the need for supplemental oxygen at 36 weeks post-menstrual age. The second was death or severe chronic lung disease, the latter being defined as the need for greater than 30% inspired oxygen or ventilation at 36 weeks post-menstrual age. The second outcome was included to address concerns that the current definition of chronic lung disease, while an important benchmark, includes many infants with minimal long-term morbidity and thus less appropriately pooled with death.

As in our earlier meta-analysis[1] we chose to include only randomized controlled trials of the 3100A. We believe that such a restriction reduces variation among trials associated with treatment strategies and device differences, and thus permits a more robust analysis. Unlike surfactant therapy and perhaps nasal CPAP where there are clear prophylactic opportunities, timing of the use of high frequency ventilation is elective. Application of high frequency ventilation can range from first intention to use at varying degrees of respiratory distress while on conventional ventilation. We therefore did not exclude any studies based on elective verses rescue indications. We did exclude studies in term infants and children, studies that did not have long term outcomes as part of their design and studies with nitric oxide treatment as part of the investigational arm.

The meta-analysis was conducted in a stepwise chronological fashion with the addition of each randomized controlled trial (ie, cumulative meta-analysis) so that trends in effect with time could be visualized. The odds ratio of the risk and risk difference were calculated along with their 95% confidence limits at each step. Relative Risk (RR) and Number Needed to Treat (NNT) were calculated to facilitate interpretation of the results.[12, 13] The homogeneity of the trial results at each step was also tested. SPSS12 for Windows was used for all the statistical calculations. A $p<0.05$ was considered statistically significant.

RESULTS

We identified six randomized controlled trials that compared the outcomes of preterm infants treated with high frequency ventilation and conventional ventilation that were published between 2001 and 2006.[2-6,14] The characteristics of these trials are summarized in table 1. Two of these trials used the 3100A exclusively,[2,3] two used a mixture of other types of high frequency devices[5,6] and two used a different high frequency device exclusively.[4,14] The results from the two new studies, which used the 3100A exclusively, were added to the preterm database from our earlier meta-analysis.[1]

We thus are reporting on the results of 7 trials and 951 preterm infants.[2,3,15-19] The summary of the characteristics of these seven trials is shown in table 2. They were reported between 1992 and 2002. These trials were conducted in patient populations of varying sizes and severity. The latter conclusion is based on the average age at intervention, which ranged between 2 and 20 hours. The standard of practice of neonatology has also evolved considerably during this decade. In the first study, completed in 1989, only 13% of the subjects received antenatal steroids and presumably none received surfactant.[14] In contrast in the last study, which began nearly a decade later, 80% of the infants received antenatal steroids and 100% received surfactant prior to enrollment.[3] The conventional ventilation strategies used in these two studies also evolved from time cycled pressure limited ventilation in 1989 to flow triggered SIMV with a focus on lung protective 5-6 ml per kilogram tidal volumes in 1999. In spite of this tremendous difference in size and severity and evolution of conventional therapies the relative benefits of the 3100A were found to be homogenous with $p=0.34$ for the death or chronic lung disease outcome and $p=0.95$ for death or severe chronic lung disease.

Figures 1a and 1b show the results of the cumulative meta-analysis for the outcome of death or chronic lung disease. The end point, that is inclusion of all the trials, shows a statistically significant ($p<0.01$) reduction in the risk of death or chronic lung disease associated with use of the 3100A. This is quantified as a Relative Risk of 0.80 and the effect size as a Number Needed to Treat of 9.7 to expect one less infant to have died or survived with chronic lung disease. As can be seen, after the

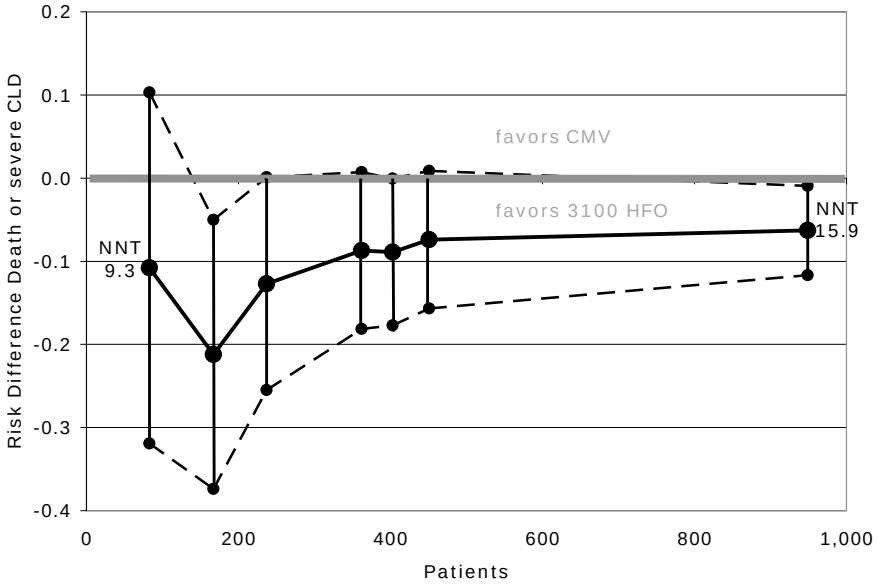

Figure 2b. Meta analysis showing the stepwise chronological inclusion of 7 RCTs. The solid line is the risk difference of the death or severe chronic lung disease outcome. The dotted lines are the 95% confidence limits of the risk difference. NNT is the number needed to treat to have one less infant die or survive with chronic lung disease. Risk differences less than 1 favor the 3100A.

second trial the size of the benefit is relatively constant ranging between a Relative Risk of 0.70 and 0.92 (figure 1a) and a NNT of 10.1 and 7.9 (figure 1b).

Figures 2a and 2b show the results of the cumulative meta analysis for the outcome of death or severe chronic lung disease. The end point, that is inclusion of all the trials, shows a statistically significant ($p<0.05$) reduction in the risk of death or severe chronic lung disease associated with use of the 3100A. This is quantified as a Relative Risk of 0.72 and Number Needed to Treat of 15.9 to expect one less infant who died or survived with severe chronic lung disease. As can be seen, after the second trial the size of the benefit is relatively constant ranging between a Relative Risk of 0.64 and 0.72 (figure 2a) and NNT of 7.9 and 15.9 (figure 2b).

Prior to the inclusion of the final large trial, Courtney et al, this meta-analysis projects a relative risk of death or chronic lung disease associated with the use of HFOV of 0.70 (i.e., a 30% reduction). The risk difference translates to a NNT of 7.9 infants to avoid one death or survivor with chronic lung disease. That final large trial of the 3100A, Courtney et al, identified a similar advantage of the 3100A (RR= .83, NNT= 10.9).[3]

DISCUSSION

We conducted a cumulative meta-analysis of all the randomized controlled trials which compared treatment of the 3100A HFOV with conventional ventilation in preterm infants. The results of this analysis show a rather consistent pattern of reduction in death and chronic pulmonary morbidity associated with high frequency oscillatory ventilation. The size of the resulting projected benefit was statistically and clinically significant (NNT= 7.9 for death or chronic lung disease and 15.9 for death or severe chronic lung disease). This analysis was conducted to explore 1) whether the benefit of high frequency ventilation has been attenuated with the evolution of neonatal respiratory care and 2) whether a meta-analysis of the first 6 trials of the 3100A would have predicted the results of subsequent large mega trials.

During the period that spans these studies surfactant replacement therapy has changed from an investigational treatment to a standard of care. The adoption of the use of antenatal steroids to enhance fetal lung maturation has also become a standard of care. Likewise the concept of barotrauma has evolved into volu/bio-trauma and conventional ventilation use has correspondingly been enhanced with widespread adoption of triggered SIMV and low tidal volume ventilation. Bollen and others suggested that the benefit of high frequency ventilation in preterm infants has been eliminated with the introduction of lung protective strategies in conventional ventilation.[8,9] That conclusion is inconsistent with the data from these trials of the 3100A. In the last trial in our series, Courtney and colleagues tested that very hypothesis and found a statistically significant advantage associated with the 3100A. In contrast, while Bollen's evaluation of 14 trials does show a continual reduction of the reported relative benefit of high frequency ventilation, our series of trials show no such trend. In fact 4 of the 7 trials of the 3100A reported a statistically significant reduction in chronic lung disease and all showed a trend toward a reduction in one of the two measures of mortality and pulmonary morbidity we selected. This consistency is not likely to be due to chance. In stark contrast none of the 14 trials included in Bollen's analysis, except those using exclusively the 3100A, showed a statistically significant reduction in death or chronic lung disease. This is also unlikely to be a result of chance.

There are several potential reasons why the trials of the 3100A might have consistently shown benefit, while those of other high frequency devices have consistently shown no benefit. First, the 3100A HFOV is a different device. There are three categories of high frequency ventilators, oscillatory (HFOV), jet (HFJV) and flow interrupter (HFFI). The 3100A is significantly different from other HFOV devices because it provides a unique asymmetrical oscillatory pattern with a longer exhalation period. It is also not sinusoidal and produces harmonics that can provide better ventilation at lower peak pressures.[20] Finally, it offers considerably more oscillatory power, offering more therapeutic flexibility/control. Second, it is likely that users of the 3100A implement a more consistent effective high/optimum lung volume strategy. This conclusion is based on the fact that they receive extensive formal training well beyond any hospital in-service. In contrast one large trial of another device designed

Table 1 Recent High frequency trials in preterm infants

Author	patients	sites	HF Device(s)
Morriette 2001	281	10	Dufour HFO
Durand 2001	50	7	3100A HFO
Johnson 2002	797	25	3100A, SLE HFO
Courtney 2002	498	26	3100A HFO
Craft 2003	46	1	Infant Star HFFI
Van Reempts 2003	300	1	3100A HFO, Infant Star HFFI

HFV = high frequency, HFO = high frequency oscillation, HFFI = high frequency flow interruptor

Table 2 Studies included in meta-analysis

Author	Patients	sites	Age (hr)	Weight (kg)
Clark 1992	83	1	8	1.1
HiFO 1993	84	4	20	1.0
Ramanathan 1995	70	1	< 2	1.0
Gerstmann 1996	125	3	2	1.5
Plavka 1999	41	1	3	.8
Durand 2001	50	7	< 4	.8
Courtney 2002	498	26	< 4	.9

*HiFO preterm strata

Table 3 Relative Benefits

Meta Analysis	NNT (95% CL) Death or CLD
3100A	7.9 (5.9 - 27.0)
Surfactant	
vs none	16.7 (9.1 - 20.0)
Prophylactic vs Elective	25.0 (14.3 - 100)
Natural vs Synthetic	33.3 (16.7 - >100)

NNT = number needed to treat, CL = confidence limits,
CLD = chronic lung disease

to use a high volume strategy discovered in a post hoc analysis that about half of those enrolled were not exposed to even the proscribed initial lung recruitment protocol.[21] The post hoc analysis did suggest benefit to the higher lung volume strategy. Finally, it is also possible that there are device/strategy interactions that are not understood. Any of these three issues might explain the outcome difference, but no data is available to appropriately speculate.

Systematic reviews of high frequency ventilation conducted by the Cochrane Collaboration have stratified analyses between early and delayed (ie, rescue) intervention, while others have excluded rescue studies to focus on the elective indication.[8,9] In our earlier meta-analysis we chose to include all studies of one device, the 3100A, to reduce the disparate potential effects of device and strategy differences. In addition we included studies ranging from rescue to first intention so that we could see differences associated with timing of intervention.[1,22] In this meta-analysis the first two studies, at least by today's standard of practice, should be characterized as rescue studies. [15,16] The timing of intervention (8 and 20 hrs) as compared to 3 hours in the Courtney trial, and initial mean airway pressures of 10 and 14 as compared to 8 cm H_2O in the Courtney trial support this contrast. Yet the projected benefit seen in the combination of these two rescue trials is slightly better, but not statistically significantly different, from the results reported in the Courtney trial. This suggests potential benefit for both rescue and first intention. Earlier analyses of the relative benefit of the 3100A and its interaction with severity at intervention did suggest a benefit of reducing the severity of severe air leak syndromes associated with earlier intervention, but no significant relative benefit of reduced chronic pulmonary morbidity.[1,22]

It has been suggested that benefits of high frequency ventilation might also be related to differing maturity of infants. Such a speculation is not consistent with our results. Three of the seven trials in our analysis series [2,3,19] enrolled the smallest infants, and each showed a trend toward reduced death and chronic lung disease associated with HFOV. The one study in our series, which enrolled significantly larger infants, also reported a statistically significant advantage of the 3100A.[18] In a randomized controlled trial of the 3100A in children, Arnold also reported a reduction in the need for supplemental oxygen at 30 days associated with 3100A, reinforcing the potential for lung protection ventilation across the spectrum of infant size.[23]

The meta-analysis of the first 6 trials of the 3100A in preterm infants accurately projected the benefits seen in the subsequent mega trial of Courtney and colleagues.[2] In contrast the other three large trials reported between 2001 and 2006 found no advantage of either high frequency ventilation or conventional ventilation. While Johnson's study suggests a comparability of high oscillatory frequency ventilation and conventional ventilation,[5] the other two trials identified trends suggesting a disadvantage. [4,6] Clearly if one combined the outcomes of these last four trials, it would appear that high frequency ventilation offered no advantage, on average. However, considering the consistency of positive results with the 3100A across 7 trials, it is also reasonable to assume that its use with standard strategies offers significant potential benefit. In contrast the use of other high frequency devices is likely to offer no benefit.

Use of high frequency ventilation to treat infants doing poorly on conventional ventilation has become widely accepted across the world. Information from the Vermont-Oxford database would suggest it is probably a standard of care, with 24% of all ventilated very low birth weigh infants in 325 hospitals receiving high frequency ventilation. In contrast only about 5% received it electively (ie, exclusively).[24] Another survey, however, suggests that the early use of high frequency ventilation is much more common in tertiary care centers.[25] Our meta-analysis suggests a significant potential benefit of adoption of the use of the 3100A HFOV across the continuum from rescue to first intention. In Table 3 this relative advantage is compared to other commonly utilized surfactant therapies.[26]

This data on the magnitude of benefit seems in conflict with the general use of these therapies, however. The common use of the outcome metric combining death with chronic lung disease came about because of the fear that some therapies might increase survival but increase lung disease among survivors. Though the data is not presented in this paper, the primary benefit seen with use of the 3100A is a reduction of chronic lung disease among survivors, while a reduction in mortality is the more pronounced effect with surfactant therapies. There is a trend towards a reduction in mortality associated with the 3100A but it is small (NNT= 64) and not statistically significant. In contrast the reduction in mortality associated with the introduction of surfactant is significant (NNT= 20). The mortality benefit associated with prophylactic versus elective surfactant use is similarly large, though its adoption has been slow. However the mortality benefit associated with the use of natural rather than synthetic surfactant (NNT=50) is comparable to that of the 3100A, and its use is essentially

universal. So neither the mortality or chronic pulmonary morbidity outcomes seem to explain the differences in the clinical adoption of these therapies. More subjective factors, other than the evidence of long term outcomes, however, seem to explain this disparity.[25]

CONCLUSIONS

The relative benefit of the use of the 3100A HFOV in preterm infants has remained relatively consistent since its introduction in the early 90's. There is no evidence that it has significantly eroded with the enhancement of neonatal care, including improvements in conventional ventilator strategy, or that there is an important difference in the relative benefits in different patient populations or for different treatment indications. In contrast it does not seem prudent at this time to anticipate similar benefits when using other high frequency devices. Studies should be conducted to better understand the limitations of other devices and their application.

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Automatic Resuscitators Can Serve As Effective "Force Multipliers" For Emergency Ventilatory Support In Mass Casualty Scenarios

Frank G. Rando

Recently, I read with fervent interest, the article "Positive Pressure Ventilation Equipment for Mass Casualty Respiratory Failure" written by Lewis Rubinson, MD, PhD, Richard Branson, MS, RRT, et al. The authors raise the issue of planning for and providing mass casualty ventilatory support during large-scale, high impact and catastrophic incidents and events, and offer guidance in application and selection of ventilatory support equipment. As a clinician, emergency planner, instructor and consultant in the health care, emergency preparedness and emergency response fields for over 30 years, I have consistently voiced my concerns regarding inadequate disaster planning and weak emergency response capabilities, and have been very proactive in enhancing emergency preparedness and response capabilities on multiple fronts, including national and international arenas.

Among my main concerns over the years, have been health care/public health readiness and the development, availability and reliability of medical and public health countermeasures and assets, including the implementation of a strategic civilian health care system designed to meet the challenges of unconventional and asymmetric threats and catastrophic events. The inducement of mass Acute Respiratory Distress Syndrome (ARDS) and subsequent Acute Respiratory Failure (ARF) from a variety of etiologies, including pandemic health threats, is plausible and worrisome.

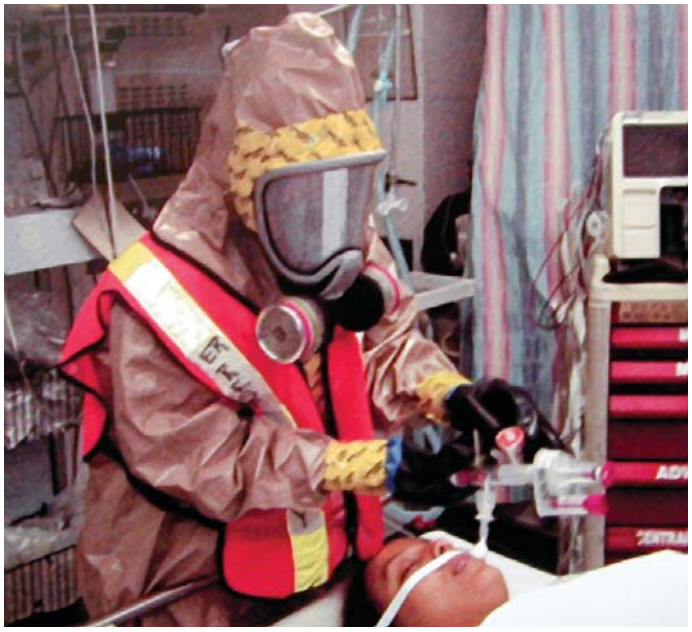
The healthcare, public health and emergency planning and response communities must utilize and adopt innovative concepts and medical devices to maximize the success of a major emergency response. While the stockpiling, deployment and application of full-feature and critical care ventilators may seem appropriate and optimal, the realities of mass casualty response and medical management dictate that the real-time activation, deployment, distribution and actual implementation of full-feature ventilators from the Strategic National Stockpile (SNS) will require substantial time, even if regional resources are tapped. Furthermore, key human assets, in the form of Disaster Medical Assistance Teams (DMATs), members of local Medical Reserve Corps and other HHS assets such as the proposed "rapid deployment force" of specially trained respiratory therapists designed to augment local medical response assets, will also require time before they are "boots on the ground."

In our business as health professionals, "time is tissue." The old and consistent emergency management adage, that initially, "all disasters are local events" must be remembered in our collective emergency planning efforts. What does the isolated, local health care system do for the first 72 hours of a critical incident or event?

While the selection and use of full-feature and critical care ventilators are the optimal choices, we must not discount the use of pneumatic driven automatic resuscitators/ventilators and other ancillary devices to provide emergent and short-term, interim ventilatory support in both pre-hospital and hospital environments, while awaiting the transition to more optimal, sophisticated ventilatory support equipment.

The authors advocate bag-valve mask ventilation (BVM) in lieu of pneumatic, automatic resuscitators/ventilators such as Vortran Automatic Resuscitator (aka SureVent) devices. As a mass casualty planner and clinician, I cannot envision providing MANUAL resuscitation and/or ventilatory support for a patient surge of 50-100 patients, simultaneously, and for an extended period during a critical incident or event, let alone where patient surges could easily exceed the thousands in large scale, high-impact events. The following two case scenarios are submitted for the readers' consideration:

Frank G. Rando, PA, RCP, CRT, CVT/CCP, EMT-P, CHMS is Consultant/SME, Senior Faculty, Project Manager/Coordinator Nuclear-Radiological, Biological, Chemical Defense-Medical/Public Health Countermeasures Specialist, HAZMAT Specialist & DHS-Certified Weapons of Mass Destruction Instructor-SME US Department of Homeland Security National Emergency Training Center Emmitsburg, Maryland. Faculty/SME US Department of Homeland Security, Noble Training Center, Ft. McClellan/Anniston, Alabama, Faculty/SME. For more information contact hazemerg@hotmail.com.



The exposure risks can be drastically minimized, if clinicians wear appropriate personal protective equipment and clothing.

Case Scenario A: A local industrial processing facility has an accidental release of a highly irritant gas in a highly concentrated area of an urbanized "mixed zoning area" during a heavy thermal inversion. The facility is located adjacent to a major elevated freeway, an inner city neighborhood, several schools and child care centers, and a major international airport. Three hospitals are located in the vicinity, and one is impinged and impacted by the plume. The release occurs on a Wednesday morning during a heavily congested and stalled freeway commute and hundreds of community residents, including school children are en route to work and school.

Case Scenario B: On a busy subway platform, several passengers suddenly become unconscious, while others are actively seizing or vomiting. An incoming train arrives and hundreds are exposed to some airborne contaminant. Within seconds to minutes, others become violently ill, collapse and lose consciousness. Not only are both scenarios plausible, they are real world case studies that have actually occurred and can occur again.

Scenario A is based on what has been described by the US Attorney's Office as "the most dangerous two miles in the US," along the Pulaski Skyway which is a major conduit from New York City to New Jersey and is dotted by gas and oil pipelines, petroleum storage facilities, chemical processing and manufacturing complexes, and major port areas. It is also based on major industrial releases, the most serious occurring in December of 1984 in Bhopal, India where a Union Carbide pesticide manufacturing plant released a large quantity of methyl isocyanate, a highly toxic irritant gas. This was a classic example of mass chemical exposure with ensuing ARDS/non-carcinogenic pulmonary edema and Acute Respiratory Failure, and has served as a frequent "lessons learned" model for emergency planners.

Scenario B is also based on the 1995 Aum Shinrikyo Sarin nerve agent attack on the Tokyo subway system. During the first hour of this terrorist act, 500 patients arrived at St. Lukes' Hospital Emergency Department. Within 24 hours, 5,500 patients were seen and treated at area hospitals.

For argument's sake let us model a scenario based on a mixed patient population of 100 actual/frank and impending cases of respiratory failure presenting at two separate emergency departments.

Is manual bag-valve mask ventilation for those requiring ventilatory assistance really a viable option given the above scenario? Many of these patients may also present with concomitant physical injuries and require other clinical interventions in addition to decontamination.

Is manual ventilation utilizing a BVM labor intensive? Is this really practical or good practice in a mass casualty event? Can we, as human operators, better overcome airway resistance utilizing a BVM, rather than an automatic resuscitator? Can we, and should we, really entrust manual ventilatory supports to non-medical augmentees, i.e. untrained individuals? If we do, we as clinicians MUST closely supervise them. Does this not detract clinicians from conducting critical functions such as triage/clinical decision-making and treatment?

Is clinical observation and patient monitoring also required during BVM use, as it is for the SureVent, for example? Are we, as clinicians really capable, and assured, of delivering a more "consistent" tidal volume using a BVM as opposed to an automatic resuscitator?

Are blood gas parameters, which indicate the efficacy/adequacy of ventilation and oxygenation, consistently better than using BVMs over automatic resuscitators? How about overall clinical outcomes?

Can we treat the causes of airway resistance by utilizing pharmacotherapeutics such as aerosolized bronchodilators and adequate, rapid atropinization coupled with suctioning for nerve agent toxicity, for example, and still utilize an automatic resuscitator device?

Does utilizing a PEEP (Positive-End Expiratory Pressure) valve with a BVM actually provide a more consistent and optimal level of PEEP than using a PEEP valve with an automatic resuscitator?

The authors claiming that medical gas supplies are a precious and highly consumable commodity in mass casualty events is true, however, this can also be mitigated if clinicians take the time to be innovative and think outside the box, which usually consists of the controlled-chaos of a sophisticated, state-of-the art critical care unit or emergency department.

The SureVent/VAR automatic resuscitators, for example come, with a mass casualty "Event-Case" capable of providing ventilatory support to seven patients via a built-in manifold system. The manifold system can be connected to a single or multiple gas supply, such as a portable H-cylinder "oxygen farm", which in many municipalities has become part of a regional or municipal mass casualty cache, or even air compressors utilizing clean air or cylinders/wall sources with medical grade air. Three (3) of these systems, placed in a triage and treatment area of a hospital, for example, would be able to

provide emergent and short-term ventilatory support to 21 patients simultaneously.

Of course, clinical observation and patient monitoring must be provided by a properly trained clinician, however, in a triage and treatment area, the deployment of personnel in those critical areas are a matter of standard protocol. This also allows clinicians to maximize their clinical performance to possibly perform other therapeutic and diagnostic procedures, especially during critical personnel shortages, as may be expected during an initial medical response.

Also, the single patient use feature of the disposable VORTRAN Automatic Resuscitator (VAR™) eliminates any cross-infectivity, cross-contamination and equipment sterilization or decontamination issues. We must also remember that when these patients are eventually interfaced with full-feature and sophisticated critical care ventilators, the patient-ventilator interface must be closely and carefully monitored by a trained clinician, usually the respiratory therapist or critical care nurse.

The patient-ventilator interface is a complex, multifactorial clinical problem, and despite the sophistication of the mechanical ventilator, the responsible and conscientious clinician can NEVER really "walk away" from the intubated, critically ill or injured, ventilator dependent patient, despite all of the "bells and whistles". Even in the modern critical care unit, it is not uncommon for a respiratory therapist or critical care professional to conduct periodic "vent checks" and assessments of physiological and ventilator parameters and settings.

While the automatic resuscitators are not designed or intended for use as full-feature critical care ventilators or for long-term mechanical ventilatory support, they have been proven to be highly useful in a variety of clinical settings and under austere conditions.

These devices do have limitations, such as pressure limits, making them an inappropriate choice for pathology associated with decreased chest wall or lung compliance. The authors also report operational failures from positional changes that can be compensated for when it occurs, and the manufacturers have been consistent in addressing this issue through training, publications and other means.

Also, automatic resuscitators, such as the VAR device are being re-engineered to provide more efficient gas consumption and a PEEP valve and intrinsic alarm system are also planned for incorporation into future models.

Clinical trials, and possibly animal models utilizing a lung injury/ARDS model, are being planned to fully evaluate the mechanics and efficacy of providing limited mechanical ventilatory support for ARDS. A pediatric model has been approved by the FDA, and has been on the market for at least two years.

The authors maintain that the close clinical observation required with the use of the automatic resuscitator will pose occupational exposure risks involving environmental or etiologic agents. This risk can be drastically minimized, if clinicians wear appropriate personal protective equipment and clothing such as a full-facial air purifying respirator or powered air purifying respirator with the appropriate cartridges, P-100 filters, or HEPA filtration system, Ty-Vek clothing, boots and inner and outer gloves. This level of protection (Level C) is sufficient to protect against a variety of chemical, biological or radiological agents, bioaerosols and airborne transmissible viruses and other microorganisms. Also, for high-risk airborne biological hazards, such as bioaerosols the use of biocontainment such as negative-pressure rooms, is highly recommended.

In a mass casualty event, compassionate, yet, realistic triage criteria and paradigms must also be in place, readily available and implemented as an integral and critical component of the health care facility's disaster plan. There should be a standardized and unwavering protocol for selective resource allocation and a diversion of critical resources, such as mechanical ventilators, from elective and clinically non-viable cases.

The deployment of mechanical ventilators for mass casualty management should utilize a tiered clinical decision-making system coupled with the strategic use of a "hybrid" system of ventilators which could be a mix of available critical care, transport and automatic resuscitator/ventilator types to augment and maximize the response and optimize clinical outcomes.

Automatic resuscitators can serve as effective "force multipliers" for emergent and short-term ventilatory support in mass casualty scenarios. Also, non-invasive ventilatory strategies should be considered in augmenting mechanical ventilator reserves that will be in high demand during large-scale, high impact, mass casualty events. Nevertheless, providing austere care in overtaxed health care delivery systems will still require efficient triage systems, so that "the most good can be done for the most people."

Accurate triage reduces the acute burden on health care facilities and organizations. On average, only 10-15% of disaster casualties present in "serious" categories to warrant overnight hospitalization. This may change significantly for pandemic health threats, for example.

Therefore, effective triage cannot be overemphasized and is crucial in providing equitable and rational casualty distribution to receiving medical facilities and reducing health care facility overloads to manageable, even "pre-disaster" levels. For the "expectant", or dead and dying category, palliative care and comfort should be provided for dying patients or care should be provided on an "as-available" basis so that they do not consume scarce resources for those who have a chance of long-term survival. These victims would include 100% total body surface area burn (TBSA), lethal, and some sub-lethal radiation injury, overwhelming sepsis, disseminated intravascular coagulation (DIC), persistent vegetative states, chronic or end-stage renal failure, end-stage cardiopulmonary disease, etc.

All of these factors and components need to interplay for an effective national health care preparedness strategy and to optimize the delivery of emergent and critical care, including mass casualty mechanical ventilatory support. We are all medical foot soldiers serving on an unfamiliar and unconventional battlefield; therefore unconventional medical threats require unconventional medical approaches and unconventional thinking.

The Vortran Automatic Resuscitator

The Vortran Automatic Resuscitator (VAR) is not a time-cycled ventilator and will respond automatically to changes in compliance, as seen in Acute Respiratory Distress Syndrome (ARDS). The VAR self-adjusts by increasing respiratory rate (RR) and decreasing tidal volume (TV) and delivers a stable minute ventilation (MV) when compliance decreases from a healthy 0.07 to a stiff 0.02 L/cm H_2O (Figure 1 & Figure 2). This is recommended by the ARDS Network's publication, funded by the National Heart and Lung Institute, which showed a 22% lower mortality with low TV ventilation strategy in patients with ALI or ARDS.[1] The VAR automatically delivers a lower TV and a higher respiratory rate (RR) and is ideal for ARDS patients with decreasing compliance.

INTRODUCTION

VAR-Plus (Model PCM) manufactured by Vortran Medical Technology[1] is the latest breakthrough in the family of disposable automatic resuscitators. It meets and exceeds ASTM guidelines for automatic resuscitators (F 920 - 93) for patients with a body mass of 10 kg and above.[2] The unique feature of the VAR family of products is its ability to respond to changing compliance at any selected pressure setting. Because the VAR cycles at a settable PIP with intrinsic PEEP, the constant (Delta-P is the difference between PIP and PEEP) produces a reduced TV at a higher RR as compliance decreases.

METHODS

The Test and Training Lung (TTL, Model 3600i, by Michigan Instruments, Inc.) with PneuView Software was used in the bench top evaluation of VAR-Plus (Model PCM-5011). An in-line PEEP valve (Model BE 142, by Instrumentation Industries, Inc.) was used to elevate the PEEP from the baseline. The VAR-Plus was initially set to deliver approximately 800 mL TV for a patient with a compliance of 0.07 L/cm-H_2O by adjusting the PIP, intrinsic PEEP and inspiratory flow to achieve a respiratory rate of 10 BPM and I/E ratio of 1:2. After establishing the initial setting, the compliance setting on the TTL was steadily decreased by 0.01 and the VAR-Plus was left untouched. Changes in TV, RR and the resulting MV were recorded, at each compliance setting, for a PEEP of 5, 10 and 15 cm-H_2O.

DISCUSSIONS

The VAR automatically delivered a reduced tidal volume (TV) at a faster respiratory rate (as shown in Figures 1 and 2) from a healthy 0.07 to a stiff 0.02 L/cm H_2O setting, maintaining the low TV ventilation protocol as recommended by the ARDS Network. Without making any adjustments on the VAR-Plus, it will deliver a stable minute ventilation (MV = TV X RR) as shown in Figure 3.

CONCLUSIONS

The ARDS Network study found a 22% lower mortality in acute lung injury and ARDS patients who were ventilated with lower tidal volumes than in those ventilated with traditional tidal volumes ventilation.[1] The VAR-Plus automatically delivers a lower TV at a higher rate and is ideal for ARDS patients with decreasing compliance.

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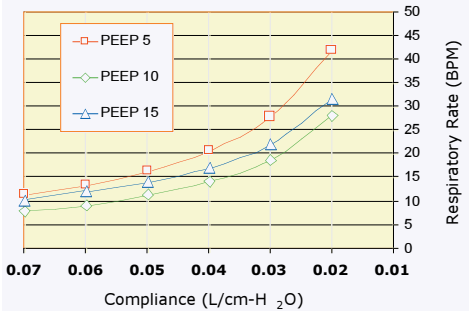

Figure 1 Rate Automatically Changes with Changing Compliance

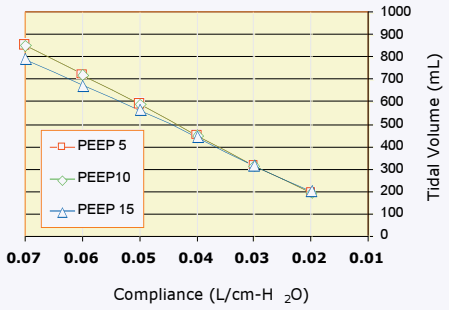

Figure 2 TV Automatically Changes with Changing Compliance

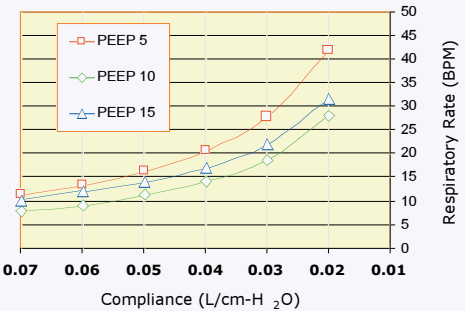

Figure 3 Delivered Minute Ventilation (MV) with Changing Compliance

Table 1 – Results of VAR-Plus with and without in-line PEEP Valve at Set PIP

COMPLIANCE (L/cm-H_2O)	PIP 17.2			PIP 21.0			PIP 26.5		
	PEEP 5.1			PEEP 9.7			PEEP 14.9		
	ΔP 12.1			ΔP 11.3			ΔP 11.6		
	BPM	TV	MV	BPM	TV	MV	BPM	TV	MV
0.07	11.5	815	9.4	8.0	855	6.8	10.2	794	8.1
0.06	13.4	671	9.0	9.1	722	6.6	12.1	675	8.2
0.05	16.4	532	8.7	11.4	590	6.7	14.1	564	8.0
0.04	20.7	402	8.4	14.2	451	6.4	17.1	445	7.6
0.03	27.9	285	7.9	18.6	316	5.9	22.0	318	7.0
0.02	41.9	178	7.5	28.1	197	5.6	31.7	204	6.4

The VAR is Positional Sensitive

The Vortran Automatic Resuscitators (VAR) will function in any position as long as the adjustments are made in a secured position (strapped or taped to the patient). Tilting movements of less than 45° have no significant effect on the PIP setting. The working mechanism of the VAR consists of a moving piston or diaphragm which has mass (weight). The mass adds an additional spring force or a subtraction of spring force when the VAR is positioned with the modulator vertically up or vertically down. If the VAR is moved from a horizontal to a vertical position, the addition or subtraction of spring force will affect the PIP setting by 1 to 3 cm-H_2O. The positional effect on PIP is an educational and training issue.[1,2] The VAR will function in any position as long as the final adjustments are made in its secured position.

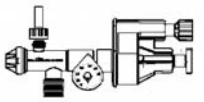

Figure 1
Modulator in the horizontal position

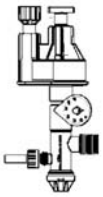

Figure 2
Set PIP with Modulator in the vertically up position

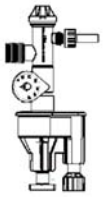

Figure 3
Rotate Modulator to vertically down position

INTRODUCTION

The Vortran Automatic Resuscitators (VAR(tm)) are pneumatically driven, flow controlled devices unlike the conventional electro-mechanical ventilators. The VAR modulator functions like a piston or a diaphragm system which cycles at PIP and PEEP. The cycling thresholds are controlled by a spring force on the piston or diaphragm. Because the piston, diaphragm and spring have mass, the position of the modulator, relative to the vertical direction, causes an increase or a decrease in the set PIP setting as the modulator is rotated. Because of this effect, final adjustments to the VAR's modulator should be made in the restrained position. However, it is of interest to know how much the set PIP pressure changes as the modulator is rotated.

METHODS

Three each of the VAR-Plus (PCM-5011) and VAR (RCM-4011) from the production lots were selected for bench top evaluation using the Test and Training Lung (TTL, Model 3600i, by Michigan Instruments, Inc.) with PneuView Software. Each device was setup initially with the modulator in the vertical up position (Fig-2) with the I/E ratio set to approximately 1:2. The PIP data was recorded. The device was then rotated to position the modulator horizontally (Fig-1), and the resulting PIP was recorded. The modulator was then turned to the down position (Fig-3), and the final PIP was recorded.

The initial PIP targets, with the modulator in the vertical up position, were 45, 40, 35, 30, 25, 20, 15 and 10 cm-H_2O for the VAR-Plus and 45, 40, 35, 30, 25 and 20 cm-H_2O, for the VAR-RCM. This yielded a matrix of PIP and PEEP values from which the pressure change from the horizontal position could be calculated.

RESULTS

Table 1 – Results of VAR-Plus Set PIP

Device	PIP with Modulator positioned horizontally	PIP increase Modulator in the vertically up position	PIP decrease Modulator in vertically down position
VAR-Plus (PCM)	44	1.1	-1.1
	39	1.0	-1.0
	34	1.2	-0.9
	29	1.1	-0.8
	24	1.1	-0.9
	19	1.1	-0.9
	14	1.0	-1.0
	9	0.8	-1.0
	AVG	1.0	0.9
VAR (RCM)	43	2.1	-3.1
	38	2.2	-3.0
	33	2.7	-2.9
	28	2.4	-2.9
	23	2.6	-2.7
	18	2.6	-3.0
	AVG	2.4	-2.9

The averaged PIP for the horizontal position are listed in Table 1. The changes in pressure when the device is rotated from vertically up to vertically down are calculated from PIP recordings, and the results illustrate the gravitational effect on the modulator components and the resultant effect. Table 1 shows that the VAR-RCM does have PIP change effects of up to 3.1 cm-H_2O when the device is rotated from horizontal up or down. The VAR-Plus exhibits significantly less positional sensitivity with a change of up to 1.1 cm-H_2O. This is a result of the improved diaphragm modulator design.

CONCLUSIONS

Although the VAR experiences PIP setting changes of 1 to 3 cm-H_2O when the device is moved, the impact should be significantly less than the inconsistencies that occur during manual resuscitation with a Bag-Valve-Mask (BVM).[3,4] The positional effect on PIP is an educational and training issue.[1,2] Users need to know that the VAR will function in any position, as long as final adjustments to the device are made after it has been positioned securely. The manufacturer of the VAR is continuing to improve the design and function of the VAR and is making every effort to reduce the changes in the PIP setting.

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Oxygen Conservation During Long Distance Transport of Ventilated Patients

Tim Lowes, MB BS, FRCA, Dip IMC.RCS (Ed); Peter Sharley, OAM, MB BS, Dip Obs RACOG, FANZCA, FJFICM

INTRODUCTION

The Royal Adelaide Hospital Mediflight Retrieval Service in Adelaide, Australia, undertakes several international retrievals/repatriations of critically ill patients each year. Currently the standard management for ventilated patients is continuous mandatory ventilation (CMV), facilitated by sedation with the addition of a nondepolarizing muscle relaxant (NDMR) as appropriate. The ventilator in current use is the Oxylog 1000 (Dräger Medical, Lübeck, Germany), which is the standard ventilator for all in-hospital transfers (eg, for radiological imaging) and also interhospital and roadside-to-hospital transportation. The amount of oxygen that has to be carried during international transfers is considerable. The size and weight of the cylinders have safety and significant cost implications.

Many of the patients transported overseas receive a form of pressure or volume assist/support ventilation, rather than CMV, before the transfer. In addition, they likely have been either lightly sedated or received no sedation at all. Increasing sedation and paralyzing patients, even for relatively short periods, may prolong the time of respiratory weaning. The use of steroid-based NDMRs in critically ill patients with regards to critical care myopathy/neuropathy may be another consideration.

OXYLOG 1000 VENTILATOR

The Oxylog 1000 is a simple, pneumatic driven, time-cycled, volume constant ventilator. Either an adjustable (0-10 cm H_2O) or fixed value positive end expiratory pressure (PEEP) value may be attached to the expiratory valve of the ventilator. The ventilator is gas driven and so does not require an electrical supply or internal battery. With no internal electrical circuit boards, less can go wrong.

For the vast majority of intrastate transfers, oxygen use is not an issue as ample supplies are carried in road ambulances, Royal Flying Doctor Service planes, and rescue helicopters. During long distance transfers, however, the use of oxygen as a driving gas in addition to that delivered to the patient becomes a negative point. When traveling by commercial aircraft, all oxygen required for the journey must be carried in cylinders within the cabin. To safely secure these cylinders requires the use of several seats, which has considerable cost implications. To address these issues we will first discuss what the oxygen requirements are and how to reduce them. Second, we will present the requirements of a suitable transport ventilator along with a review of those currently available.

OXYGEN REQUIREMENTS

Our initial assessment suggested that the ventilator problems are twofold: approximately 1 L per minute of oxygen is required as the driving gas in addition to that delivered (Dräger datasheet), and there are only 2 options for oxygen concentration: no air mix (100% O_2) and air mix (60% O_2). Oxygen is unnecessarily wasted if patients require less than 60% O_2, which would generally be the case for elective transfers. However, when looked at more closely, only the extra liter per minute to drive the ventilator needs to be considered, for the following reason.

When estimating oxygen requirements for transportation, the worst-case scenario must be taken into account. Although it would be unusual to transfer a patient who required a FiO_2 greater than 0.5, there is always the possibility with any critically ill patient that the oxygen requirement may increase during transfer. This may only be a small increase because of dependent lung atelectasis as a result of sedation and NDMR as occurs in patients during general anesthesia. The possibility of more significant deterioration, however, must be considered (eg, mucus plugging and lobar collapse, pulmonary embolus, or

Tim Lowes is with the Royal Adelaide Hospital Mediflight Retrieval Service and the Royal Army Medical Corp, UK. Peter Sharley is with the Royal Adelaide Hospital Mediflight Retrieval Service. This article was provided for use in Respiratory Therapy by Draeger Medical. Reprinted from Air Medical Journal, © 2005 by Air Medical Journal Associates. The authors thank Gp Capt George Merridew (RAAF) and ex-chief flight nurse Linda Gormly (Pacific Air Ambulance), who assisted in our research into the development and use of the Modified Circle System.

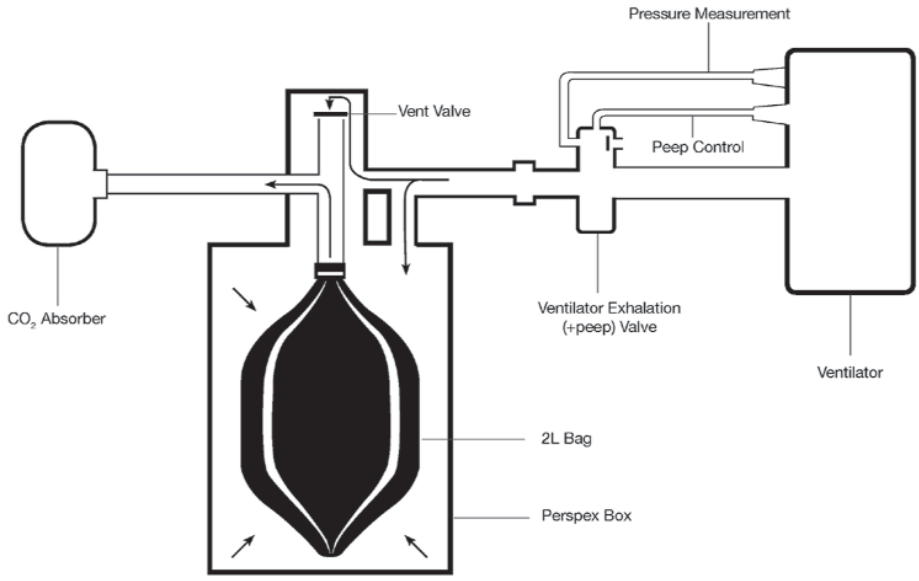

Figure 1. Adelaide Box Transfer Unit

pneumothorax). The ability to deliver up to 100% oxygen to the patient for the whole journey must be allowed for because adverse events may occur at any time during the transfer. A reserve of oxygen should be carried in addition to this to cover delays. Therefore, the minimum "safe" oxygen requirements for a 24-hour transfer with the Oxylog, ventilating with a tidal volume of 700 mL and rate of 10 bpm (i.e. MV 7.0 l/min), would be: 7.0+1.0 (incl. driving gas) = 8.0 l/min = 480 l/hr = 11,520 L (almost 8 Australian D size cylinders [standard D size cylinder volumes: Australia = 1500 L, UK = 340 L, US = 420-450 L]).

Using a ventilator powered solely by electricity saves approximately 1.0 L per minute immediately. Using the same 24-hour example, an electric ventilator would require 7.0 l/min = 10,080 L (7 D size cylinders). This saves 1 D size cylinder on a 24-hour flight. More significant oxygen conservation can be achieved by adapting the patient circuit so that oxygen is reused.

The perfect example would be a circle circuit as is found in almost all operating theaters in the developed world. These circuits all incorporate some form of a bag in bottle (BIB) system and a unit that absorbs carbon dioxide from the patient's expired gases.

The BIB systems used in modern theaters are all relatively complex, not to mention heavy and invariably directly linked to a built-in, electrically controlled ventilator unit that relies on a 4-bar gas supply (oxygen) to drive it. For transport purposes the requirement is a stand-alone BIB that can be driven by air that is delivered by an electrically powered ventilator. The FiO_2 would be monitored throughout, so the theoretical risk of a leak reducing the concentration of oxygen delivered should always be noticed before patient safety is compromised. In addition, the BIB must be simple in design and easily repairable. It must also be able to either incorporate some form of PEEP valve or be designed in such a way that it allows PEEP generated within the ventilator circuit to be transmitted to the patient circuit.

The Adelaide Box Transfer Unit (Figure 1) appears to fulfill the requirements for a transportable BIB system. Unfortunately this unit is no longer available and does not have therapeutic goods approval.

MODIFIED CIRCLE SYSTEM (FIGURE 2)

In an effort to reduce oxygen use without including a BIB, a modified circle system (MCS) has been developed by Pacific Air Ambulance in New Zealand. The MCS consists of the following component parts.

OXYGEN "DEAD SPACE" TUBING

In essence this simple addition to the circuit solves the absence of a BIB. The tubing needs to have a volume somewhat greater than the patient's tidal volume. Accepting that a tidal volume greater than 700 mL would be unusual for a ventilated patient, tubing with an internal volume of 1000 mL is adequate. Two standard lengths of anesthetic circuit tubing joined with a total static volume of 1000 mL (tested with water) were used.

SODA LIME UNIT

The components of the soda lime unit (KAB-DNIP, Disposable Circular CO_2 Absorber Medical Developments, Melbourne, Australia) include 2 unidirectional valves, a female port where the oxygen dead space tubing connects, an oxygen inlet nipple, and an adjustable pressure relief valve (designed to attach to a gas scavenging system). The pressure relief valve remains completely closed unless the circle is being flushed with high flow oxygen, in which case the valve should be partially opened to avoid an excessively large tidal volume being delivered to the patient.

The soda lime is required to absorb carbon dioxide from the expired gases. The main constituents are calcium hydroxide (94%) and sodium hydroxide (5%). The following reactions occur:

$$CO_2 + 2NaOH \rightarrow Na_2CO_3 + H_2O + \text{heat}$$
$$Na_2CO_3 + Ca(OH)_2 \rightarrow 2NaOH + CaCO_3$$

The production of heat and water can help warm and humidify

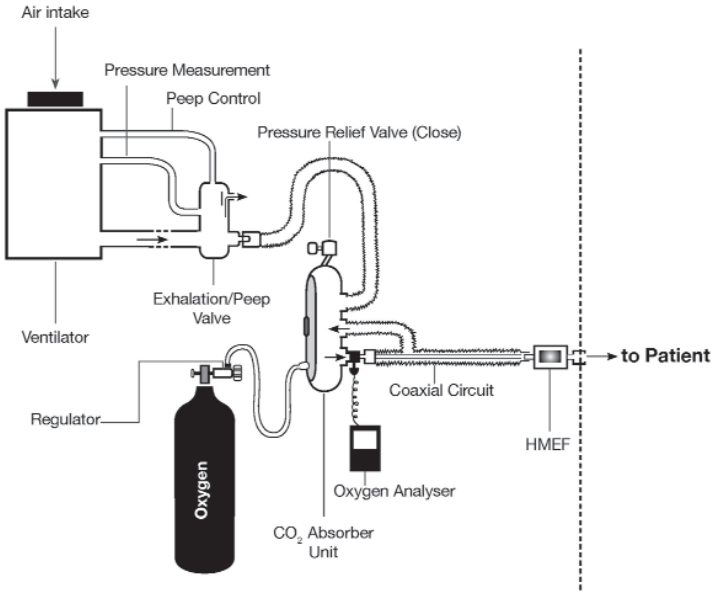

Figure 2. Modified Circle System

inspired gases. Water, however, may become a problem as a result of excessive "rain out" in the patient circuit, requiring the inclusion of a water trap.

The rate at which soda lime becomes exhausted depends on the capacity of the canister, the size and shape of soda lime beads, the fresh gas flow rate, and the rate of carbon dioxide production. As an estimate, the following calculations can be used:

- Maximum oxygen consumption of 4 mL/kg/min (ie, 300 mL/min for 75 kg patient)
- Typical R/Q quotient of 0.8 gives CO_2 production of 240 mL/min (ie approximately 15 L/hr).
- Soda lime absorbs around 15 L CO_2/100 g. A container with 400 g of soda lime should last around 4 hours.

Two reusable containers are sufficient. One is refilled while the other is in use. Some airlines may have concerns, however, about the potential spillage of soda lime during refilling. Disposable units may have to be used.

OXYGEN SUPPLY

Cylinders. In addition to the main cylinder (the size of which will depend on the length of the journey) a small (e.g., Aus C size = 440 litres), needs to be carried for both transporting the patient between ambulance and aircraft and also for emergency use if the circuit needs to be rapidly flushed with high flow oxygen (because of the 2 different regulators required).

Regulators. Regulators with fixed flow settings are required, rather than a simple gauge or ball flowmeter. Both gauge and ball flowmeters are fairly inaccurate; the latter require a stable upright position and are relatively fragile because of the exposed glass/plastic column.

As a result of the differing requirements of maintenance and emergency oxygen glows, 2 regulators may be needed:

a. The maintenance cylinder requires a regulator with flows down to 200 mL/min to maintain optimal efficiency. Higher flows can be used; however, in the patient with a low resting VO_2, a leak must be created by partially opening the CO_2 unit scavenging valve, or the patient's FiO_2 will steadily increase over time.

b. The emergency cylinder needs to be able to deliver high flows so that the FiO_2 can be increased rapidly. Higher flows are also required so that a self-inflating bag (Ambu-bag) can be used to transfer a patient between ambulance and aircraft while the circle circuit is set up on board.

Two possible regulators are low flow (0.03-3 L/min) regulator (Sabre Medical, Aldershot, England) and high flow (1-15 L/min) regulator (British Oxygen Company).

Oxygen concentrators. Oxygen concentrators can provide up to 5 L/min of oxygen, which is more than adequate for the MCS. The major concern would be failure of the power supply to the concentrator or failure of the concentrator itself. There would be no oxygen safety net unless the airline gave agreement to use the onboard emergency supply in this rare event. In addition, the accurate low flows achievable with a regulator are not possible with a concentrator. A leak may need to be introduced into the system to compensate for higher than necessary flows (by opening the CO_2 unit pressure relief value). Given the oxygen savings achieved with the MCS, the benefits of using an oxygen concentrator are probably outweighed by the possible problems.

PATIENT CIRCUIT

A coaxial circuit (Universal F, King Systems, Medical Developments, Melbourne, Australia) was used to save space and reduce tube entanglement. Alternatively, a standard 2-limb ventilator circuit with a Y-piece can be used.

OXYGEN ANALYZER

Any small portable in-line oxygen analyzer can be used. The Datex Ohmeda 5120 (Louisville, KY) is the current analyzer used

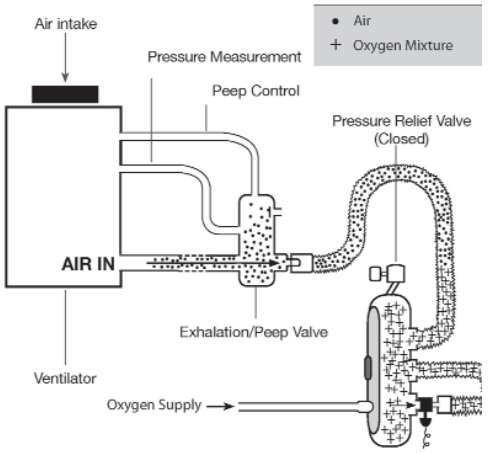

Figure 3. Inhalation

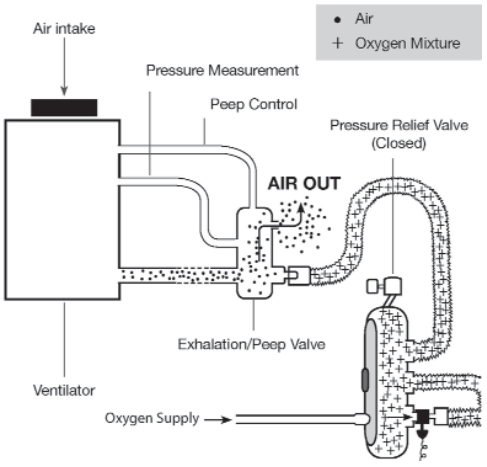

Figure 4. Exhalation

at the Royal Adelaide Hospital. Batteries (C size/LR14) are easily replaceable and last more than 24 hours.

CO_2 MONITOR

This is standard monitoring equipment. CO_2 measurement is necessary to guide minute ventilation settings because the delivered tidal volume of some ventilators is affected by altitude and a percentage of each volume is lost from expansion in the circuit tubing. In addition, the patient's CO_2 production may vary during the transfer. CO_2 readings should also be used in combination with the color change of the soda lime granules as a guide to when the CO_2 unit needs changing.

ADJUSTABLE PRESSURE RELIEF VALVE

The requirement for an adjustable pressure relief valve in the circuit is debatable. Because oxygen is entering the circuit at high pressure (albeit at low flow), there is a theoretical risk of barotrauma to the patient. This can occur only if the oxygen dead space tubing is completely occluded somewhere along its length or the patient expiratory limb is occluded. The pressure within the lungs will then steadily increase as oxygen continues to flow (0.5-1.0 L/min) into the circuit with no valve through which to escape, leading to alveolar rupture. If occlusion of the oxygen dead space tubing occurs, all ventilators should alarm for high pressure. This should alert medical staff and give them enough time to discover the problem and correct it before the patient comes to harm. The failsafe solution is to place a pressure relief valve at the patient end of the coaxial circuit. A single pressure (e.g., 40 cm H_2O) manufactured valve is simplest; a variable valve may be used but must be calibrated and the setting fixed to avoid accidental adjustment.

WATER TRAP

A self-sealing water trap (Siemens-elema, Solna, Sweden) is required to collect excess water within the patient tubing generated by the CO_2 unit. To reduce the chance of collected water accidentally reaching the patient during transport, the trap is best positioned in the expiratory limb of the circuit below patient level.

OXYGEN DEAD SPACE PRINCIPLES

In the perfect setup, the whole system—from the patient, around the circle, and back to the end of the oxygen dead space tubing (where it connects to the ventilator circuit and expiratory valve)—will contain an air/oxygen mix with a constant fixed FiO_2. The ventilator generates a column of air equal to the required tidal volume. This pushes an equal volume from the dead space tubing into the circle system, and an equal volume from the circle enters the patient's lungs (Figure 3). During expiration the gas is pushed back out of the circle into the dead space tubing, pushing the initial column of air back toward the ventilator. During this time, the ventilator opens the expiratory valve to allow this column of air to be released back into the room, rather than return through the ventilator. At the end of expiration, the original gas within the dead space tubing just reaches the ventilator expiratory valve before the next breath commences (Figure 4).

Although this ideal situation does not occur in reality, the principle holds true. The main reason that oxygen requirements (L/min) are greater than the patient's VO_2 is almost certainly a result of mixing of the air from the ventilator with the air/oxygen mix in the dead space tubing. The gases have fluid properties, and with the force and turbulence generated by the ventilator, mixing will occur. Mixing increases with larger tidal volumes and, to a lesser extent, with increased respiratory rates.

POSITION OF OXYGEN INLET

Oxygen is added to the circuit through the oxygen nipple on the back of the CO_2 unit. The option of adding the oxygen through a T-piece in the inspiratory limb was tried and discounted for the following reasons:

- It makes no difference to the FiO_2 at any given flow rate.
- It takes longer to increase the FiO_2.
- Two additional pieces of equipment are required (T-piece and cap for O_2 inlet).

CONTROLLING THE FiO_2

The downside of the circuit is that there is no easy way to dial up a specific FiO_2. The circuit should be set up with a compliant reservoir bag/test lung attached before connecting to the patient. With the ventilator running, the oxygen flow from the cylinder can be adjusted to achieve the required FiO_2. Further fine-tuning may be required as the FiO_2 may drift up or down over time. This fluctuation depends on a combination of the

Table 1

Comparison of Suitable Electrically Powered Ventilator

	Breas PV 403	Pulmonetic LTV 1000	Newport HT50	Uni-Vent 754	Puritan Bennett LP 10
Weight (kg)	5.5	5.7	6.8	5.8	16
Dimensions W x H x D (cm)	35x17.5x26	30x25x8	27x26x20	22x29x11.5	25x37x34
Cost (approx.)	A$12500	A$25000	A$18500	US$8500	A$18000
Company	Breas, Gothenburg, Sweden	Pulmonetic, Colton, Minn	Newport Medical, Newport Beach, Calif	Impact, West Caldwell, NJ	Puritan Bennett, Pleasanton, Calif
Pressure Support	Yes	Yes	Yes	Yes	No
PEEP Internal or External	Max 10 cm H_20 Int or Ext	Max 20 cm H_20 Ext	Max 30 cm H_20 Int	Max 20 cm H_20 Int	Max 10 cm H_20 Ext
Display	LCD	LED	LED and pressure meter	LCD	Pressure meter and dials only
Locked Controls	Yes	Yes	Yes and protective cover	Protective cover	Protective cover only
Operating Temperature (°C)	5 to 35	5 to 40	–18 to 50	–60 to 60	5 to 40
TV Stable at Altitude	No	Yes	Yes	Yes	No
Int. Battery Life -700x10, Norm Lung	14 hrs 20 min	2 hrs	17 hrs	Not tested (av. 3 hrs)	50 min
AC Supply 110-240	Yes	Yes	Yes	Yes	Yes
DC 12V Compatible	Yes	Yes	Yes	Yes	Yes
Hrs From 36 AmpHr Battery	12	12	70	12	10
Pros	• Simple display/ controls • Quietest ventilator •Long battery life	• Designed for transport of critically ill • Used by British Armed Forces and other Australian helicopter retrieval services • Solid yet compact and light • Detects circuit leaks as measures Exp MV • LED screens easily visible in bright and dark light (no protective cover but shock resistant, and if one LED is damaged, remaining screens continue to function) • Basic ventilator settings obvious (although complicated menus can be entered and may be difficult to return from if not familiar)	• Designed in conjunction with Israeli Defense Forces for military/ air medical use • Long battery life • Solid build yet still fairly light • Display/settings are clear and easy to use and protected by fold-down door (which also includes condensed user instructions) • PEEP-controlled internally and solid plastic exhalation valve • I:E ratio constantly displayed	• Designed for transport of critically ill patients • Used by US military and many civilian retrieval services • Compact, sturdy, and light • Protective door over settings	• Solid build • Obvious controls with a protective door and no LED displays to break • Current model for long-term ward ventilation at the RAH

Continued

	Breas PV 403	Pulmonetic LTV 1000	Newport HT50	Uni-Vent 754	Puritan Bennett LP 10
Cons	• Not robust or designed for transport (made for home/long-term ventilation) • Small, dark LCD screen without protective cover • All displays and controls lost if LCD screen damaged • Low pressure alarm sounds only on third breath after disconnection • I:E ratio needs to be calculated or read from Table	• Short internal battery life (although can be attached to pressurized oxy gen supply to extend battery life) • PEEP valve brittle and easily damaged by unfamiliar staff	• Does not measure expired minute volume (c.f. LTV 1000)	• LCD display not as clear as LED alternatives • Moderate battery life • Currently no distributor in Australia	• Large and heavy • Very short internal battery life • No pressure support function • I:E ratio needs to be calculated or read from Table

Table 2

Ventilator Battery Test

Lung	Breas PV 403		Newport HT 50		Pulmonetic LTV 1000		Puritan Bennett LP 10	
Normal	Alarm	Stopped	Alarm	Stopped	Alarm	Stopped	Alarm	Stopped
	11 hrs	14 hrs 20 min	12 hrs 35 min	17 hrs	1 hr 20 min	2 hrs	45 min	50 min
Stiff	7 hrs 20 min	10 hrs 50 min	6 hrs 10 min	8 hrs 10 min	1 hr 15 min	1 hr 45 min	35 min	45 min

patient's VO_2, tidal volume, respiratory rate, and the oxygen flow rate.

As aforementioned, the FiO_2 may be rapidly increased by attaching the oxygen tubing to the emergency cylinder at 10 L/min. The scavenging valve on the CO_2 unit must be partially opened during flushing to avoid delivering excessively large tidal volumes to the patient. To allow the FiO_2 to decrease, the oxygen supply is simply turned down or off while the oxygen analyzer is closely observed.

TIDAL VOLUMES

Tidal volumes set on the ventilator should be used as a guide and adjustments made in relation to the measured end-tidal CO_2. Several factors will render the set tidal volume inaccurate, including expansion of compliant tubing, additional flow from the oxygen supply (i.e., if the oxygen flow rate is increased to improve oxygenation, the tidal volume will need to be decreased slightly to maintain the same CO_2), and altitude effects on ventilator function.

PRESSURE ALARMS

It is important the ventilator's low pressure alarm should be set high enough to compensate for resistance to flow within the circuit. This ensures that the low pressure alarm will sound if a disconnection occurs. (Similarly the ventilator high pressure alarm may be set slightly higher than normal because the pressure at the patient end of the circuit will be less than that recorded by the ventilator.)

VENTILATOR FAILURE

The system design is such that, in the event of ventilator failure, a self-inflating bag can be attached to the circuit in its place and the system will continue to function in the same way. No oxygen supply needs to be attached to the bag, and therefore a reservoir attachment is not needed. A PEEP valve can be fitted to the expiratory valve on the self-inflating bag if required and patient breaths either assisted or controlled as necessary. The only consideration would be avoiding excessive tidal volumes that may increase gas mixing in the dead space tubing.

CHANGING THE CO_2 UNIT

When the CO_2 unit requires changing, the safest and easiest method is to connect a self-inflating bag with reservoir (attached to the emergency oxygen cylinder) directly to the tracheal tube mounting catheter through a heat moisture exchange filter.

SUCTION

Suctioning should be through a closed inline system to reduce oxygen wastage. The circuit FiO_2 inevitably will drop after suctioning; however, standard practice should be to

preoxygenate the patient before any suctioning, so this should not be an issue.

STAFF ISSUES

The modified circle requires a period of familiarization, even for an anesthesiologist/respiratory technician who is familiar with circle systems in the operating theatre setting. Color coordinating connections and a condensed aide-memoire may assist in the safe management of the system during transfer by less experienced staff.

TRANSPORT VENTILATOR REQUIREMENTS

The ventilator should be able to provide a pressure/volume support mode to allow the transfer of patients without additional sedation and muscle relaxation, which is usually necessary with CMV. An electrically powered ventilator that can entrain room air to generate a tidal volume is required for optimal efficiency with the MCS. A pressurized gas supply must not be required. Ideally though, the ventilator should be able to generate a known FiO_2 when connected to an oxygen supply to allow this option for shorter transfers when oxygen conservation is not an issue. (The benefits of simplicity usually outweigh the oxygen-conserving benefits of the system in these situations.) The ventilator should have either an integral PEEP setting or allow an external PEEP valve to be applied to the exhalation valve.

The ideal attributes of the transport ventilator, other than those already mentioned, are:

- Compact, robust, and lightweight
- Easy to understand and use
- Clear display and settings
- Clearly audible and visible alarms
- Display protected from damage
- Settings lockable or protected by cover (to prevent accidental changes)
- Powered by both 12v DC and AC supply with long-lasting internal battery
- Mounting points for securing in aircraft

VENTILATOR SELECTION

The initial criteria we used to narrow the search for a suitable ventilator were electrically powered and the ability to generate a tidal volume without an additional pressurized gas supply. Table 1 summarizes each of the ventilators we considered and compares their specifications.

Although each of the 4 ventilators available for bench testing could be powered by both AC and 12v DC supply, the ability to operate from an internal battery for several hours was considered important. As the internal battery life quoted by the respective manufacturers was not derived using a standard test, we decided to perform our own testing. Each ventilator was fully charged (per the manufacturer's instructions) and then set to ventilate the test lung through the modified circle circuit at 2 separate settings:

Normal lung, 700 mL x 10 bpm (PEEP zero, I:E 1:2)
Stiff lung, 400 mL x 25 (PEEP 10, I:E 1:2)

Table 2 outlines the results. The performance of batteries can deteriorate over time, and the varying ages of the demonstrator ventilators may have affected the results to some extent. Having said this, the differences were considerable and roughly in proportion to the manufacturers' quoted figures. The Breas 403 and Newport HT50 clearly outperformed the other ventilators in this testing.

Several ventilators currently available fulfill the requirements of the ideal transport ventilator to varying degrees. The frequency of long distance transfers, the availability of aircraft power supply during flight (rather than carrying battery packs), and whether the ventilator will be used for shorter transfers need to be considered. Cost will also enter the equation.

Each critical care service has slightly different factors to consider, so a blanket recommendation is not appropriate. Of the ventilators we tried, the Newport HT 50 appears to best fulfill the criteria.

CONCLUSION

The Oxylog 1000 requires large amounts of oxygen to be carried when undertaking long distance transfers of ventilated patients. The use of an electrically powered ventilator will reduce these requirements, and several ventilators can be used in this role.

To allow a more substantial reduction in oxygen requirements, a form of circle circuit must be used. An MCS has been described that is relatively cheap and fairly simple to use. This system, in combination with an electrically powered ventilator, allows a large reduction in the safe oxygen requirements when transferring a ventilated patient over long distances.

Several aspects of the MCS require further investigation, including minimum oxygen flow rates to maintain a range of FiO_2, pressure drop across the circuit, and the time required to increase the FiO_2 in an emergency. This discussion will be presented in a separate article.

Short Communications

RSBI as a Predictor of Weaning Success

Melissa Turner, BA, RRT

Melisa Turner is with Hamilton Medical. This item is reported in the company newsletter.

The Rapid Shallow Breathing Index (RSBI) has been shown to be an accurate predictor of success in weaning from mechanical ventilation. Is there a best time to measure the RSBI? According to Kuo et al,[1] the RSBI measurement taken at termination of a spontaneous breathing trial (SBT) is a better predictor of weaning success than the RSBI measured at the beginning of the SBT. In order to find RSBI, the patient's respiratory rate and minute ventilation are measured for 60 seconds. Minute ventilation is then divided by the rate which results in the average tidal volume (Vt). The respiratory rate is divided by the average Vt to get the RSBI. The study done by Kuo et al[1] measured RSBI during SBT with patients on a T-piece. It is also important to note that Tobin's original RSBI article measured RSBI during a T-piece trial, however; RSBI is commonly measured on the ventilator. Several studies have reported that RSBI results show no significant differences when measured on CPAP with or without low levels of pressure support (<10 cm PS). In the study done by Kuo et al, 172 patients were identified that were recovering from acute respiratory failure. RSBI measurements were done during a SBT once the patients met weaning criteria: (1) partial or complete recovery from acute respiratory failure; (2) adequate gas exchange, as indicated by a ratio of the partial pressure of arterial oxygen (PaO2) to the fraction of inspired oxygen (FiO_2) above 150, with a positive end-expiratory pressure (PEEP) of less than 5 cm H_2O; (3) stable hemodynamics without the need for vasoactive or intravenous sedative agents; and (4) core temperature of 38ºC. Once placed on SBT, the patient's RSBI was measured once at the beginning of the trial (RSBI1), and again 2 hours later at the termination of the trial (RSBI2). At the end of the 2 hour trial all patients that passed the trial were extubated. Mechanical ventilation was reinstituted for those patients that failed. Weaning failure was based on the criteria reported by Chatila et al,[2] which include: respiratory rate >35 breath/min; $PaCO_2$ increment >5 mm Hg; PaO_2 < 60 mm Hg; SpO_2 < 90% on 50% inspired oxygen; subjective distress or diaphoresis; heart rate increment >20 beats/min; systolic blood pressure decrement >20 mm Hg; arrhythmia (an increase in premature ventricular beats >4/min or new onset of sustained supraventricular rhythm)."[1] The physicians did not use the RSBI data collected in determining success or failure from weaning. Patients were considered weaned successfully if they were able to maintain spontaneous breathing for 48 hours post extubation. Any patients that could not maintain spontaneous breathing for 48 hours post extubation, or failed the SBT were considered weaning failures. Of the 172 patients in the study, 106 were categorized as weaning successes and 66 as weaning failures. When the RSBI1 (RSB measured after 1 minute) measurements were compared, it was found that there were no significant differences in the RSBI1 values among the weaning success and weaning failure groups (~69 vs 65). The RSBI1 did not differentiate between the successes and failures. There was, however, a significant difference in the RSBI2 (RSB measured at the end of a 2 hour trial) measurements (82 vs. 96). The RSBI2 values were significantly higher in the weaning failure group as compared to the weaning success group. In regards to correlation of RSBI1 to RSBI2, there was some correlation in the weaning success group and no significant correlation in the weaning failure group. In summary, as pertaining to this study, "RSBI2 was the most significant predictor of weaning outcome in both groups."[1] Also worth mentioning is that respiratory rate and heart rate are also significant in the prediction of successful weaning as there was a significant increase in both at SBT termination in the patients that were classified as weaning failures. As far as the length of time during SBT at which the RSBI measurements are made, it is important to ensure enough time has passed to get an accurate RSBI2 measurement as a prediction of weaning success. Kuo et al chose 2 hours and their results were found to be similar to the results of the study by Chatila et al[2] whereby the RSBI2 was measured at 30 minutes. At whatever time interval is chosen, RSBI[2] is an important

measurement to be evaluated when weaning a patient successfully from mechanical ventilation. Trending RSBI values may be a very valuable tool in helping to predict weaning success in mechanically ventilated patients.

COMMENTARY

In reviewing Melissa's article summary, I'd like to note that the original Tobin RSB study utilized a RSB of 105 as a weaning predictor threshold. I found it of interest that in the current study, the mean RSBs in patients failing extubation were less than the 105 threshold (the physicians responsible for extubation decision were not aware of the RSB values). This might further support serial measurement of RSB in predicting extubation success. In regards to measuring RSB "through the venilator," there are two scenarios where I've observed potential problems. In patients with significant autopeep, the application of CPAP may offset the added work due to the inspiratory threshold load imposed by autopeep. Additionally in patients with signficant/unstable CHF, positive pressure may reduce preload enough to prevent acute CHF. In both these scenarios, it may be of value to challenge the patient by measuring the RSB on a t-piece. If significant deterioration occurs, one might consider applying CPA post extubation. – Paul Garbarini, MS, RRT.

Intelligent Ventilation in Space

When we think of emergencies, we think car crashes, airplane accidents, heart attacks, etc. However, in another industry, emergencies take on another meaning. In space, there are different types of accidents that can occur. Apollo 1, where 3 brave astronauts died in service of their country. Apollo 13, where Jim Lovell, John Swigert, and Fred Haise were trapped and everyone in NASA came together to bring them home. In 1977, fire aboard the Russian Space Station MIR occurred. Each of these accidents provides a realistic example of how medical emergencies can possibly occur. For long spaceflights, equipment and procedures need to be in place in case of medical emergencies. As medical professionals, trauma has many faces. These same scenarios can occur in space. These scenarios include inhalation injuries, burns, decompression sickness, aspiration pneumonia, and trauma. These emergencies could have easily warranted intubation and mechanical ventilation. Like medicine, personnel are chosen based on necessity and unfortunately, budget. Because of financial restraints, NASA has prepared several contingency plans to provide emergency medical care, including respiratory support, in space. It is crucial that the equipment launched be capable of providing adequate support for a variety of scenarios. NASA has a ventilator for space, but it has its limitations. An assessment of current Respiratory Support Pack (RSP) was written by David Kaczka, MD, PhD and George Beck BA, RRT. The current RSP was designed primarily as a short term transport ventilator for use by emergency medical service personnel but not tested as a primary device for ventilating patients longer than 12 hours or used in weaning trials. This is not an ideal piece of equipment given the current status of our space program, the remoteness of the crew from definitive medical care facility, and the amount of time and preparation it takes to get an injured crew member back to earth. The current ventilator may be required to be used for > 48 hours. The ventilator may be called upon to make changes as the patient's status changes, which the current ventilator has no capability of doing. The current RSP has many other limitations such as flow limitations, fixed inspiratory time, no blender to provide variable FIO2, and unable to set PEEP or CPAP. Because of the many limitations of the current RCP, the injured crewman may work harder than necessary or receive sub- optimal ventilation/oxygenation. Dr. Kaczka and Mr. Beck come up with 3 different alternatives to help alleviate some of the problems with the current RCP. 2 of the 3 recommendations require crewmembers to continuously monitor the patient in a time where every crewmember would be needed for preparation to return to earth. Recommendation 2 has a ground based physician make changes through communication with the medical equipment. However, during times of communications blackout, crewmembers would be expected to be the primary caregiver and make adjustments with no guidance from the physician. The 3rd alternative would be an on-board computer with algorithms that would monitor multiple physiological parameters and make adjustments on an as-needed basis. Closed-loop control would provide the answer NASA seeks. Allowing the ventilator to make adjustments according to the changing parameters of the patient frees up the crewmembers from continuously monitoring the patient and allows them to make other necessary interventions or prepare for evacuation. Another advantage in this type of system, the ground based physician or crewmember can make adjustments as necessary and allow the ventilator to take over from there.

NASA's RSP is a first step as preparation for pulmonary emergencies in space. However, with the wide degree of variability in possible injuries, closed-loop ventilation offers a simple yet optimal approach to managing various pulmonary emergencies in orbit. Closed-loop ventilation would be more efficient in terms of crew allocation, cost, and resources and more importantly, clinically for the injured patient in providing the best chance of survival during an emergency. Dr. Kaczka'a article can be found in Respiratory Care Clinics of North America Mechanical Ventilation in Orbit: Emphasis on Closed-Loop Ventilation Respir Care Clin 10 (2004) 369-400

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