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[1]Hasani A et al. *Chron Respir Dis*. 2008;5(2):81-86. [2] Roca O et al. *Respir Care*. 2010;55(4):408-413.

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Cover: Landscape, Bridge, Huntingdon Valley. Artist: H. Lyman Saÿen, born Philadelphia, PA 1875-died Philadelphia, PA 1918.

Editorial Advisory Board

Letter to the Editor

Dear Dr Campbell:

I am writing to you regarding your analysis of the study that was originally published by Khoury R et al. in the November 2020 issue of the *Journal of Perinatology*.[1,2] In this study, Khoury R et al. analyzed the performance of two pulse oximeters in a normal cohort of newborn infants during their transition period. Pulse oximetry heart-rate stability was recorded "qualitatively" by manually identifying when the oximeter achieved stability as identified by the observer.[1]

There were multiple concerns with the study, including the fact that this study was conducted only in healthy newborns, those least likely to require extensive resuscitation. As a consequence of the restatement of the AAP guidance regarding resuscitation in the delivery room in 2015, Masimo developed a sensor that was specifically designed to operate in this environment.[3] The sensor provided better performance, especially in pulse-rate stability, than that which was used in the study. Further, this sensor was optimized to automatically transition the monitor to a 2-second averaging time and maximal sensitivity. Neither of these refinements was incorporated into the study. Studying this pulse oximeter without the benefit of these modes completely invalidates the findings. When comparing oximetry technologies, it is critically important that the latest technologies from each manufacturer be used.[4]

Moreover, the study attempted to clarify pulse rate using heart rate as a gold standard for comparison. It is well known that not all ECG electrical activity translates to a heartbeat, and thus a pulse. Pulseless electrical activity (PEA) is a well-recognized phenomenon in the neonatal population. ECG signals can provide a reliable indication of electrical heart activity but cannot predict with absolute certainty the presence of a heartbeat in association with each waveform. Further, an algorithm predicated on the generation of a stable heart rate as opposed to one that genuinely identifies "missed" beats may be closer to the ECG rate but not accurately reflect the presence of a pulse. The bradycardia reported by Masimo may have accurately reflected actual pulsatile activity.[5-7]

The authors of the study generalized their concern about their findings and the presence of false bradycardia in resuscitation. The need for resuscitation is typically associated with decreased perfusion, unstable heart rate, and abrupt changes in oximetry. PR stability is an inferior metric during these situations. These are areas where Masimo SET technology has been shown to have superior performance in myriad studies. For a pulse oximeter to prove its mettle, it is inappropriate to suggest that "fair weather" conditions in normal transitioning neonates are in any way similar to those encountered during a full-on resuscitation.[8]

These concerns were also addressed in a letter to the editor that appeared in the March 2021 *Neonatology Today* authored by Dr Latorre and corroborated by the response. "Speed of response, notwithstanding, the technology is not just about speed alone. Accuracy, precision, and reproducibility are a *sine qua non*."[9]

Sincerely,
Mitchell Goldstein, MD, MBA, CML
Professor of Pediatrics
Division of Neonatology
Loma Linda University Children's Hospital
Editor in Chief
Neonatology Today

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News

FDA Authorizes Booster Shot for Immunocompromised Americans

The US Food and Drug Administration has authorized a third dose of COVID-19 vaccines by Pfizer Inc (PFE.N)-BioNTech and Moderna Inc (MRNA.O) for people with compromised immune systems. The amended emergency use authorization paves the way for people who have had an organ transplant, or those with a similar level of weakened immune system, to get an extra dose of the same shot they have initially received. Mixing of mRNA vaccines is permitted for the third shot if their original vaccine is not available. An advisory panel to the US Centers for Disease Control and Prevention (CDC) on Friday voted to recommend the additional doses, an important step before the policy is implemented. Patients will not need a prescription or the sign off of a health care provider in order to prove they

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are immunocompromised and receive the additional dose, according to CDC officials. "It will be a patient's attestation, and there will be no requirement for proof or prescription or a recommendation from an individual's health care provider," CDC official Dr Amanda Cohn said, speaking before the Advisory Committee on Immunization Practice vote. The vulnerable group makes up less than 3% of U.S. adults, Rochelle Walensky, director of the CDC, had said before the authorization. "After a thorough review of the available data, the FDA determined that this small, vulnerable group may benefit from a third dose of the Pfizer-BioNTech or Moderna vaccines," Janet Woodcock, US FDA's acting commissioner, said in a tweet. Woodcock said that others who are fully vaccinated do not need an additional vaccine dose right now.

Tachycardia Syndrome May Be a Distinct Marker for Long COVID

Tachycardia is commonly reported in patients with post-acute COVID-19 syndrome (PACS), also known as long COVID, authors report in a new article. The researchers say tachycardia syndrome should be considered a distinct phenotype. The study by Marcus Ståhlberg, MD, PhD, of Karolinska University Hospital, Stockholm, Sweden, and colleagues was published online August 11 in The American Journal of Medicine. Ståhlberg said that although much attention has been paid to cases of clotting and perimyocarditis in patients after COVID, relatively little attention has been paid to tachycardia, despite case reports that show that palpitations are a common complaint.

"We have diagnosed a large number of patients with postural orthostatic tachycardia syndrome [POTS] and other forms of COVID-related tachycardia at our post-COVID outpatient clinic at Karolinska University Hospital and wanted to highlight this phenomenon," he said. Between 25% and 50% of patients at the clinic report tachycardia and/or palpitations that last 12 weeks or longer, the authors report. "Systematic investigations suggest that 9% of Post-acute Covid-19 syndrome patients report palpitations at six months," the authors write. The findings also shed light on potential tests and treatments, he said. "Physicians should be liberal in performing a basic cardiological workup, including an ECG [electrocardiogram], echocardiography, and Holter ECG monitoring in patients complaining of palpitations and/or chest pain," Ståhlberg said.

Biologics for Asthma Also Improve Chronic Rhinosinusitis

Biologics used as an asthma treatment also appear to improve symptoms of coexisting chronic rhinosinusitis in some patients, according to results from a real-world study published in the International Forum of Allergy & Rhinology. Although patients with asthma commonly have coexisting chronic rhinosinusitis (CRS) with nasal polyps (CRSwNP) or without nasal polyps (CRSsNP), research on the effect of biologics has focused on CRSwNP, according to Devyani Lal, MD, of the Department of Otolaryngology, Division of Rhinology, Mayo Clinic, Phoenix, Arizona, and colleagues. The researchers evaluated how the use of omalizumab, mepolizumab, benralizumab, reslizumab, and dupilumab affected a group of 181 patients with asthma and CRSwNP and 66 patients with asthma and CRSsNP in a retrospective review of electronic health records at the Mayo Clinic. Over a period of at least 12 months, most patients in the study received omalizumab (51%), mepolizumab (46.6%), benralizumab (10.5%) or a combination of omalizumab and mepolizumab (6.9%). Of the 247 patients studied, 206 (84.1%) underwent endoscopic sinus surgery (ESS) and 189 of those patients had the surgery performed prior to receiving biologic therapy. Matched-pair analyses were performed to identify changes from baseline in Lund-Mackay CT scores, SNOT-22 scores, serum eosinophil counts, and serum immunoglobulin E (IgE) levels. Lal and colleagues found treatment with an anti-interleukin-5 (anti-IL-5) biologic such as mepolizumab, benralizumab, or reslizumab significantly improved Lund-Mackay CT scores when analyzing the proportion of patients with both CRSwNP and CRSsNP, and SNOT-22 scores for patients with CRS overall and CRSwNP. Patients who received the anti-IgE biologic omalizumab had improved Lund-Mackay CT scores, but SNOT-22 scores did not significantly improve at any follow-up time, including the longest follow-up at mean 23.7 months. Aaron N Pearlman, MD, an otolaryngologist at Weill Cornell Medicine and NewYork-Presbyterian in New York City, said the finding of objective and subjective improvement in a real-world study is important. "It shows you that these monoclonal antibodies are having a positive effect on diffuse chronic inflammatory conditions," said Pearlman,

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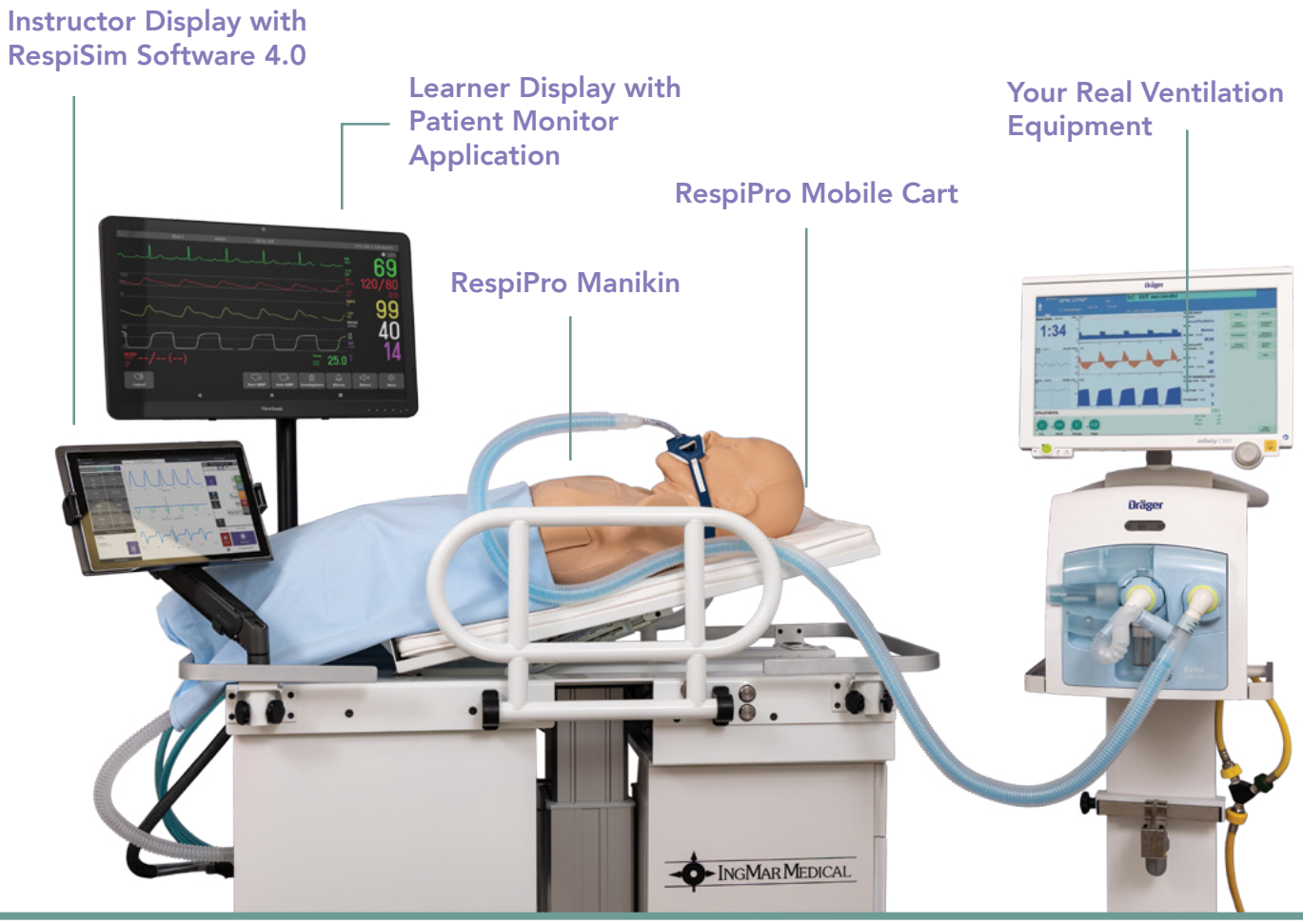

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was not involved in the study. "Where asthma and chronic sinusitis with nasal polyps in many patients have a similar inflammatory pathway, we think that these medications would work on both systems. With this retrospective data, they've shown that there is some improvement even in patients [where] the indicated use was not for nasal polyps."

New Solution to Impact the Future of Respiratory Simulation

IngMar Medical, LLC, a leading global provider of respiratory simulation solutions, launched their next generation solution for respiratory and ventilation training, RespiPro. With RespiPro, educators can train all levels of learners across multiple disciplines on the full scope of respiratory techniques using their own real ventilators and respiratory devices. The solution includes the most realistic breathing simulator, the ASL 5000, as well as easy-to-use software, a true-to-life patient monitor, and a respiratory-focused manikin on a compact ICU bed. IngMar Medical President, Brian Linn, explains, "We have spent years talking to customers about how we can help them achieve better training outcomes, ultimately leading to better patient care. We understand that our customers want to immerse their learners in an environment that is indistinguishable from real life, while controlling the simulation with easy-to-use software. These are the key elements of our new RespiPro, and that is why we are thrilled to share it with respiratory educators all over the world." While the concept of RespiPro is the same as IngMar Medical's legacy RespiSim System solutions, this launch is particularly monumental due to the overhaul of both the software and hardware components. IngMar Medical worked closely with educators throughout the entire development process to ensure RespiPro meets their respiratory and ventilation training needs. "The launch of RespiPro marks a major step on our journey, and we couldn't be more excited to continue working with the respiratory simulation community to build off of this new foundation," stated Linn.

CPAP Device is Available for Acute Care Use and Surge Capacity Planning

The FDA issued recent guidelines indicating that Bilevel and CPAP devices can be used to effectively help treat COVID-19 patients in Respiratory Distress potentially avoiding mechanical ventilation. The patented Flow-Safe II+ is the first and only Disposable Bilevel CPAP ventilatory assist device available in the global market. This disposable Bilevel CPAP system includes a mask and manometer and optional filter that provides hospital and emergency clinicians with the components required to quickly set up the device and connect to an oxygen source for delivering verifiable Bilevel and CPAP therapies to patients in respiratory distress. A recent article published in the American Journal of Emergency Medicine supports the use of the Flow-Safe product line concluding, "The Flow-Safe Disposable CPAP system can be as effective as NIMV in patients with Acute Cardiogenic Pulmonary Oedema (ACPO). Considering the overall improvement observed in the physiological blood gas and other parameters as well as the mortality and cost-related considerations, FSD-CPAP-S can be preferred in emergency services if there are insufficient NIMV devices." The disposable advantage reduces the need for costly capital equipment and is the clinical solution for situations where backup Bilevel / CPAP equipment is scarce or unavailable. Flow-Safe II+ has been used extensively in pre-hospital EMS environments and in acute care emergency rooms. The disposable feature has the added advantage of assisting in preventing potential cross contamination. These advantages make it an ideal solution when planning surge capacity for pandemics or natural disasters. Flow-Safe II+ was introduced to the market in 2018 and has been awarded two prestigious industry awards, the 2018 EMS World Innovation Award and the 2019 JEMS Hot Products Award. This novel device was selected for both awards from over hundreds of submissions after a thorough review by panel of judges consisting of emergency medical services (EMS) product specialists, physicians, educators, managers and paramedics. The United States Patent and Trademark Office (USPTO) has issued Flow-Safe II+ US Patent No.10,258,759 in 2019. In March 2020, the USPTO issued two new utility patents, US Patent No. 10,583,266 and 10,583,262 for the award-winning Flow-Safe II+ Disposable Bilevel CPAP device. John Gargaro MD, President and CEO at Mercury Medical, states: "Mercury Medical believes that Flow-Safe II+ is a unique superior solution designed to quickly improve patients in respiratory distress with a cost-efficient device. The disposable feature assists in reducing hospital infection rates that are associated with reusable equipment, Mercury Medical has a rich experience in introducing innovative, clinically differentiated medical devices to market. We are extremely pleased to extend this device to the acute care market where there is a need for Disposable Bilevel CPAP equipment."

Benralizumab Promising for Severe, Chronic Rhinosinusitis With Nasal Polyps

Benralizumab (Fasenra) significantly reduced nasal polyp score (NPS) and average nasal blockage score (NBS) compared with placebo for patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) in a phase 3 trial. The randomized, multicenter, double-blind, placebo-controlled OSTRO study, sponsored by AstraZeneca, enrolled 413 patients in Europe and North America with severe CRSwNP. The patients generally had high rates of comorbid asthma (68%); prior NP surgeries (73%); and elevated Sino-Nasal Outcome Test (SNOT-22) scores. They were randomly assigned in a 1:1 ratio to receive either benralizumab 30 mg or placebo. NPS and NBS (scored by patients from 0 [no blockage] to 3) were co-primary endpoints. Improvements in both were statistically significant compared with placebo at week 40 ($P < .005$). Improvements were maintained through week 56 ($P < .05$). Results were presented on July 11 at the European Academy of Allergy and Clinical Immunology (EAACI) Meeting 2021 by principal investigator Claus Bachert, MD, PhD, head of the Department of Oto-Rhino-Laryngology and chair of the Upper Airway Research Laboratory, University Hospital Ghent, Ghent, Belgium. He said, "It's clear that there is a significant difference from placebo." On the NPS, the difference from placebo was -0.57 ($P = .0001$) from week 40 to week 56. On the NBS, the difference from placebo was -0.27 ($P = .005$) at week 40. Patients with CRSwNP typically endure sleep disruptions, nasal congestion, loss of smell, and rhinorrhea, which lower physical and mental health-related quality of life. Current pharmacologic therapies, including intranasal and systemic corticosteroids, are often inadequate for managing symptoms, and symptoms frequently recur after surgery, he said.

In the OSTRO trial, enhanced treatment effects were seen in some groups, including patients with comorbid asthma and/or higher baseline blood eosinophil counts.

Short-Acting Beta Agonist Overuse 'a Global Public Health Issue'

About one third of asthma patients have high use of short-acting beta agonists (SABAs) in Europe across all severity levels, said

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Santiago Quirce, MD, PhD, with Hospital Universitario in Madrid, Spain.

High use — defined as three or more canisters dispensed per year — "is a global public health issue," and is associated with increased risk of asthma exacerbations and death, he said, along with increased healthcare costs. Asthma patients tend to rely too heavily on SABAs and too little on inhaled corticosteroids (ICS), he said Saturday at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress 2021, adding that SABA use continues to increase globally. Quirce is a co-author on the SABINA study, the largest real-world study on SABA use. It included 1 million people with asthma across five European countries. Among the findings were that overuse varied greatly by country. Overuse was 9% in Italy; 16% in Germany; 29% in Spain; 30% in Sweden; and 38% in the United Kingdom. In the UK, SABA overuse was greater for people with moderate-to-severe asthma compared with those who had mild asthma (58% vs 27%, respectively.) Quirce also pointed to a 2012 study in the *Annals of Allergy, Asthma & Immunology* of more than 33,000 patients that identified values of SABA that predicted exacerbations in children in adults. For adults, "use of 2 or more SABA canisters was found as the critical value with shorter optimal assessment periods of 3 and 6 months," the 2012 study found. "Each additional SABA canister resulted in an 8% to 14%" increase in the risk for asthma-related exacerbation in children and "a 14% to 18%" increase in that risk in adults. Patients become overreliant on the SABA inhalers, which have been in use for more than 50 years, for many reasons, Quirce said, despite the increased risk of exacerbations.

COPD worsens COVID-19 by altering epithelial cell genes

New findings shed light on why chronic obstructive pulmonary diseases increase patients' risks for severe COVID-19. The diseases cause genetic changes in the epithelial cells that line the airways, making the cells more vulnerable to attack from the coronavirus, researchers reported in Nature Communications. Laboratory studies of these cells found changes in their molecular makeup that likely make it easier for the virus to enter the body, make copies of itself, and trigger out-of-control immune responses that fill the lungs with fluid and cause severe organ damage. The researchers, led by Nicholas Banovich at Translational Genomics Research Institute in Phoenix, were only able to examine cells from lung-disease patients without COVID-19 but said their "study highlights crucial areas for future research."

How Intranasal COVID Vaccines Could Be 'Holy Grail' of Vaccination

Beyond the obvious advantage for the needle-phobic, the seven intranasal COVID-19 vaccines in development could offer two additional layers of protection against SARS-CoV-2 infection, experts say. First, intranasal vaccines could produce antibodies and attract other components of the immune system to the nose and upper respiratory tract, forming a first line of defense against infection. Second, if infection does occur, a local response in the nose can be faster than a systemic one, giving SARS-CoV-2 less of a chance to replicate, shed, and be transmitted to others. At least that's the idea. "We'll see how they fare in clinical trials, but research suggests that these types of vaccines should trigger a specialized immune response in the nasal passages that can help stop SARS-CoV-2 at the site of infection and reduce transmission," Troy D. Randall, PhD, said. Randall and co-author Frances Lund, PhD, analyzed the promise of intranasal COVID-19 vaccines in a perspective article published online July 22 in *Science*. Applying the vaccine directly to the inside or mucosa of the nose could be an advantage, agreed Deborah H. Fuller, PhD. "Mucosal immunity, especially for respiratory diseases, is a relatively untapped gold mine for vaccines," she said when asked to comment. Recent research from Fuller and colleagues, as well as others, suggests that immune responses on the mucosa can limit viral replication better than immune responses localized in the blood.

"And this makes sense. If you have immune cells localized at the initial site where the virus infects, it could shut down the virus before it gets a chance to replicate," added Fuller, professor of microbiology at the University of Washington School of Medicine and chief of the Division of Infectious Diseases and Translational Medicine at the Washington National Primate Research Center, Seattle, Washington.

An active lifestyle may reduce the risk of sleep apnea

Getting off the couch and into activities that get your body moving is linked to a decreased risk of obstructive sleep apnea (OSA), according to a wide-scale study that highlights the hazards of leading a sedentary life. The study, published in the European Respiratory Journal, tracked around 130,000 men and women in the US over a period of 10 to 18 years and found that more movement and less sedentary behaviour were associated with a lower likelihood of OSA. "In our study, higher levels of physical activity and fewer hours of TV watching and sitting either at work or away from home were associated with lower OSA incidence after accounting for potential confounders," said Tianyi Huang, an associate epidemiologist at Brigham and Women's Hospital, a teaching hospital affiliated with Harvard University. "Our results suggest that promoting an active lifestyle may have substantial benefits for both prevention and treatment of OSA." A 2014 study estimated that around 5.4 million Canadians have either been diagnosed with sleep apnea or are at high risk of the disorder. OSA, the most common type of sleep apnea, occurs when the upper airways become blocked, often because the soft tissue at the back of the throat collapses and obstructs the flow of oxygen to the lungs. This passage can also become comprised in people with large tongues, relaxed throat muscles or narrow airways. Family members are usually aware of the issue before those with the actual disorder, largely because obstructed airways can result in loud snoring followed by choking or gasping for breath during sleep. Many of the symptoms of OSA are felt the next day, including a morning headache, fatigue, irritability or mood changes, poor concentration, memory loss or a lowered sex drive. Serious cases of OSA can increase the risk of heart issues, including heart failure. Researchers used statistical modelling to compare physical activity and sedentary hours to OSA diagnoses. Moderate and vigorous physical activity were looked at separately and both were found to be strongly tied a lower risk of OSA, with no real difference detected between the intensity of the activity. The correlation was strongest for women, adults over the age of 65 and those with a BMI greater or equal to 25 kg/m2.

Virtual Space Created for Clinicians

Dale Medical Products, Inc. has created a virtual space to allow clinicians, patients and purchasing/value analysis professionals the opportunity to learn about Dale products in a simulated setting. When visiting the Virtual Dale Medical Center, users can enter rooms by specialty to see products that are available for clinicians and their patients. Users can move around the room to view product videos and other information relevant to each

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care setting, select product(s) on the patient which enables contextual information, view 3-D product renderings and video presentations. There are other options to bring viewers to the Dale website, links to request samples, contact Customer Service or find local Sales Representatives. "Dale is proud to be among the leaders in the medical device manufacturing industry to deploy this technology. The Virtual Dale Medical Center will enable users to view and handle our products in simulated care settings," states John Brezack, President of Dale. "The Virtual Dale Medical Center will empower our customers to see how our products can help care for patients and contribute to improved clinical outcomes. They can also view 3-D models of the products and request additional training and information." The Virtual Dale Medical Center will continue to expand capabilities in the future, including a training center, "C-Suite" and other features.

Dräger Celebrates Legacy of Robert Kacmarek Through Ventilator Donation

To help advance education in the respiratory therapy (RT) profession and honor the life's work of Robert Kacmarek, PhD, RRT, FCCM, FCCP, FAARC, Dräger is donating a Babylog VN500 ventilator to each RT school throughout the Commonwealth of Massachusetts. This marks the seventh year of Dräger's RT school donation program, which began in 2014. Dr Robert Kacmarek, professor of Anesthesiology at Harvard Medical School and the director of Respiratory Care at Massachusetts General Hospital, dedicated his career to the growth of the respiratory profession, serving as a member of the American Association for Respiratory Care (AARC) for more than 50 years, writing 19 textbooks, authoring or co-authoring over 300 articles, and presenting more than 700 lectures at respiratory care and medical conferences nationally and worldwide. He passed away on April 1, 2021. Jason Moury, MPH, RRT, president of the Massachusetts Society for Respiratory Care (MSRC), comments on Dr Kacmarek's work and Dräger's donation in his honor: "Bob was a humble giant who advocated for the profession and was world-renowned for his teaching. Words cannot express the loss that this profession will feel with his passing. We cannot thank Dräger enough for its donation. We appreciate all that the company has done in support of the RT profession and schools, including this latest contribution to Massachusetts RT programs."" Robert Kacmarek was a driving force in furthering the RT profession, championing the advancement of higher education in the field, conducting decades of research on respiratory care interventions and training hundreds of students," said Dräger Senior Vice President of Sales, Hospital Solutions, Steve Menet. "Through our donation of Babylog VN500 ventilators, we honor his legacy and support education of the next generation of respiratory care professionals by enabling them to train on advanced ventilation technology."

Highlighting the Effectiveness of the COVID-19 Vaccines Could Convert Doubters

Informing people about how well the new COVID-19 vaccines work could boost uptake among doubters substantially, according to new research. The study, led by the University of Bristol and published in the *British Journal of Health Psychology*, shows the importance of raising awareness of vaccine efficacy, especially if it compares very favourably to another well-established vaccine. The research focused on adults who were unsure about being vaccinated against COVID-19. Those who were given information about the vaccine's efficacy scored 20 per cent higher on a measure of willingness to be vaccinated, compared to those who received no information. This improved receptivity increased by as much as double among survey respondents who were also given information about how COVID-19 vaccines perform in comparison to the annual flu vaccine. Lead author Professor Colin Davis, Chair in Cognitive Psychology at the university's School of Psychological Science, said: "The general positive effect of providing key information is not surprising, as we knew already that people's perception of the effectiveness of a vaccine is an important factor in their vaccination intentions. But the extra benefit of providing comparative information is a novel finding which underscores the vital role of communication in improving vaccine uptake." The findings come from two surveys of UK adults, aged between 18 and 85, last December. The first survey of 2,400 people revealed that 65 per cent agreed or strongly agreed they would have the COVID-19 vaccine, which at the time wasn't widely available. A further 12 per cent were equally sure that they would not take the vaccine. However, in the middle

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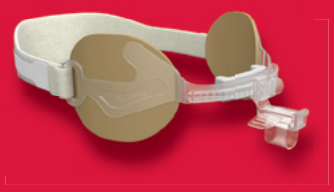

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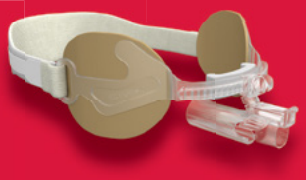

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range were around a quarter (23 per cent) of respondents who expressed reservations and uncertainty about whether they would be vaccinated. A second survey of 481 of those fence-sitters followed, which aimed to discover whether providing certain relevant information might nudge them to overcome their hesitancy and be more inclined to be vaccinated. When no information was given, the majority of the participants were unsure about having the vaccine. Confidence levels grew by some 20 per cent when they were told of the overwhelming efficacy of the Pfizer and Moderna vaccines, 95 per cent and 94 per cent respectively at the time. Their likelihood of being vaccinated grew by a similar margin again, when the information about the COVID-19 vaccine also stated the effectiveness of the flu vaccine over the past 15 years, according to the US Centers for Disease Control, which stands at some 40 per cent. "The findings show the positive potential of the contrast effect. Pointing out factual comparisons can be helpful when making a decision, particularly about something new. People value evidence-based information and this can provide affirmation and reassurance for cautious groups," Professor Davis said. "It's also important to note the information we provided about the lower effectiveness of the flu jab did not change people's intention to have the flu vaccine. Perception of the flu vaccine benefits from its familiarity and an established sense of safety and efficacy. By positively associating the COVID-19 vaccine with the well-known flu jab, people are reminded that vaccines work and they are safe." The latest figures show vaccine uptake is slowing. Over the last two months the average number of vaccine doses being administered daily has dropped from over half a million doses a day to just under a third of a million. This reflects a much lower rate of uptake among younger groups. In England while at least 95 per cent of 55 to 79-year-olds have had their first dose and at least 80 per cent of those aged 35 and above, the figure drops to some 76 per cent among 30 to 35-year-olds, 65 per cent for 25 to 29-year-olds, and just 57 per cent of 18 to 24-year-olds, according to latest NHS England data. Professor Davis said: "Younger people perhaps perceive themselves to be less vulnerable to COVID-19 virus. While mortality rates are fortunately much lower in this age group, exposure to the virus carries the danger of long-COVID in people of all ages. By getting vaccinated young people can protect themselves and also reduce transmission levels in the population as a whole. The vaccination campaign is by no means over and this study shows the importance of informed and targeted communication."

Company Launches Telehealth Solution

CAIRE Inc., pioneers of the portable oxygen concentrator and the only global manufacturer covering the entire continuum of care for the oxygen patient, announced the US launch of its next-generation telehealth solution — myCAIRE — at its corporate headquarters and Respiratory Center of Excellence. Designed to increase the efficiency of administering delivery and improve patient care, the application connects to CAIRE's leading concentrators via the patient's smart device and simplifies remote data collection through a secure, cloud-based technology in real-time — easily accessible via the medical equipment provider's desktop. "It was important to us to have a telehealth solution that connected to CAIRE's premier oxygen concentrators in the portable, transportable and stationary categories — the full spectrum of oxygen care for patients. Because of this, CAIRE is the only oxygen manufacturer that offers its provider partners a holistic approach to serving the complex healthcare needs of oxygen users during activity or when they are at home," said Earl Lawson, President and CEO. The myCAIRE application is available through Android, iOS and Surface platforms, and the portal provides customizable views, filtering and search options to view oxygen usage, flow rates, device notifications, equipment location, and requests sent directly from patients to the provider through the app. The timing of the launch supports the needs of providers who administer care to oxygen patients with respiratory conditions, like Chronic Obstructive Pulmonary Disease (COPD), but also the growth in the population of users who have been prescribed oxygen as a therapeutic component to their recovery from the novel coronavirus, COVID-19. The development of telehealth solutions received a giant push during the pandemic according to global consulting firm McKinsey & Company who estimates the market size up to $250 billion. They predict the shift to these platforms will continue to evolve with step-change improvements that impact a variety of providers ultimately resulting in better patient care and outcomes. "We see the use of telehealth as it applies to oxygen therapy equipment to only expand as adoption increases and access opens up," said Barry Hassett, Vice President of Global Marketing. "This remote visibility to patient data allows the provider to engage with those patients who require more frequent touchpoints in their case management through personal contact and educational resources — the end result is improved care for patients." In developing this next-generation telehealth solution, the CAIRE team prioritized improvements in functionality and usability while listening to the voice of customers — medical equipment providers who needed something that would help them remotely review data and troubleshoot devices efficiently during a time of increased oxygen demand in the treatment of COVID-19. "Streamlining oxygen patient management can assist in easing

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up on an already stretched bandwidth for our providers and their teams," Hassett added. myCAIRE can connect wirelessly to the FreeStyle Comfort portable oxygen concentrator, the Eclipse 5 transportable oxygen concentrator, and the Companion 5 stationary oxygen concentrator. Most newly-prescribed oxygen users utilize a portable or transportable oxygen device to maintain their targeted saturation rate during their daily activities, and an at-home oxygen source—a stationary oxygen concentrator for when they are inside the home—particularly for use while they are at rest. myCAIRE setup is quick, and users will find the free application easy to use with features allowing them to view settings and notifications, share access with a caregiver, request service from their provider, and access the device user manual.

Company Signs Agreement with University

Neotech Products has entered into a mutually beneficial agreement with Wichita State University. This exciting collaboration will provide Neotech with the resources of an institution well known for advanced research, including clinical work through their partners. Wichita State, a national leader in aerospace research, will benefit from the experience of a well-established and innovative medical device company as it expands research in the area of medical products. They will work closely with Neotech's new product development team to explore product ideas that will impact the end user. "Wichita State is committed to using our aviation expertise for expanding research in other industries," said Rick Muma, President of Wichita State University. "As a clinician in internal medicine and infectious diseases and a public health practitioner, I understand the need to continually innovate through collaboration in the healthcare sector. Partnerships with companies like Neotech Products do just that." With this partnership, Neotech will have access to advanced facilities and technologies, including: Labs for materials and adhesive testing and research; Electron microscopes; CT scanning (for materials); Pull and compression testing; A wide array of 3D printing and scanning; VR visual design space. The partnerships' first collaboration is a locking mechanism for the NeoBar ET Tube Holder. The idea originated with Dr Mohammed Ansari, a neonatologist with ties to the Wichita area. Wichita State teamed up with Dr Ansari and brought the idea to Neotech to drive the project forward. We're extremely excited to see where it leads. Overall, the purpose of the partnership between Neotech and Wichita State is to utilize the combined expertise of both institutions to bring medical products to market that will truly make a difference.

Diagnostic Product Range Updated to Spirometry Standards

NDD Medical Technologies (NDD), a leading provider of diagnostic technology enabling healthcare professionals the early detection of COPD and other chronic lung diseases, has updated the entire EasyOne product range, including the EasyOne Air, Easy on-PC, EasyOne Pro, and EasyOne Pro LAB, to be compliant with the ATS/ERS Standardization of Spirometry 2019. Spirometry is widely used in the assessment of lung function to provide objective information used in the diagnosis of lung disease and monitoring lung health. The updated guidelines aim to improve the quality of the spirometric measurements and improve the patient experience. Committed to usability since the very first EasyOne spirometer, NDD continues this tradition during the implementation of the spirometry 2019 update. The user interface across the product line has seen a major update to help the user navigate through the changes. This is particularly noticeable in the quality assessment of the measured FEV1 and FVC parameters, and the overall quality grading of a test session. As obtaining a high-quality result is essential to the accurate interpretation of the spirometry test outcome, each quality-related criterion proposed by the ATS/ERS standard is analyzed. The user is presented with clear messages on which quality criteria have not been fulfilled, and most importantly, how to coach the patient in order to meet the criteria. The implementation of the ATS/ERS Standardization of Spirometry 2019 update across the entire EasyOne product line is indeed a milestone moment in NDD's mission of offering reliable, innovative, and easy-to-use products for physicians and patients to combat respiratory disease. However, the journey does not end here, as NDD continues to improve and expand the capabilities of its products and services. The software update with the ATS/ERS spirometry standard 2019 content can be downloaded free-of-charge for EasyOne Air, Easy on-PC, EasyOne Pro and EasyOne Pro LAB at www.nddmed.com/pulmonary-resources/library/download/software.

Study Investigates the Ability of Masimo PVi to Predict Preload Responsiveness in Patients On Nasal High-Flow Therapy

Masimo announced the findings of a study published in the *Journal of Applied Physiology* in which Dr Marina García-de-Acilu and colleagues at the Vall d'Hebron University Hospital in Barcelona evaluated the utility of Masimo PVi as a noninvasive method of predicting preload responsiveness in patients treated with nasal high-flow (NHF) therapy. They

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The Benefits of Personalized Lung Protection and Weaning Solutions

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Eric Honroth, Getinge President, North America.

Can you tell us about the recent clearances your company has received?
In April of this year, we received FDA Class II 510(k) clearance for 4.1 software upgrades for the Servo-u and Servo-n ventilator systems and clearance to introduce the next generation of the Servo-u MR ventilator system into the US market.

Mechanical Ventilation—why is this important?
Mechanical ventilation is a well-established life supporting treatment for the lung-compromised patient. In the United States, it is estimated that over 300,000 patients receive mechanical ventilation each year (excluding COVID-19 in 2020/21). Mechanical ventilation is a life supporting treatment delivered to patients who suffer from a wide spectrum of acute respiratory failure (ARF). The ventilator functions to allow the patient to heal and recover. Over time, we have come to understand that life supporting, mechanical ventilation over extended periods of time can have an adverse effect on the lungs. Ultimately, the goal is to assist the patient when needed and to help improve clinical care.

What are the challenges in the ICU and, in particular, mechanical ventilation?
Mechanical ventilation is life supporting in patients with respiratory failure but may lead to lung injury.

Lung injury can be impacted by the settings of the mechanical ventilator resulting in potential consequences including:
- Ventilator acquired pneumonia (VAP)
- Ventilator induced lung injury (VILI) including atelectrauma, volutrauma, barotrauma, and biotrauma
- Ventilator induced diaphragmatic dysfunction (VIDD)
- Myotrauma

Recent clinical studies suggest that many ventilators lack effective bedside decision support tools. It is a problem that results in protective strategies being delayed or inconsistently applied. Ultimately, this can harm the patient and worsen the outcome.[1,2,3]

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net

Can you tell us about the benefits of personalized lung protection and weaning solutions? How does this help patients?
Getinge is a leader when it comes to high acuity patients and mechanical ventilation.

Our Servo family is tailored to the acute care segment. We constantly strive to innovate our products and advance the markets that we serve. Servo-u, Servo-n, and Servo-u MR with system version 4.1 give clinicians many options for personalized lung protection and weaning.

Our goal is that clinicians can deliver the right protection, for each patient, at the right time with a comprehensive toolkit for clinicians to make decisions and plan of care. The main toolkit includes:
- **Servo Compass** for easy-to-see plateau driving pressure or tidal volume per predicted body weight (VT/PBW) monitoring.
- **Transpulmonary pressure monitoring** to provide guidance on the relationship between airway and transpulmonary pressure.
- **Open Lung Tool** to assess lung mechanics and gas exchange.
- Finally, **Automatic recruitment maneuvers Auto SRM** and **Auto RM**. Auto SRM is an automatic workflow for Stepwise recruitment maneuvers based on the Open Lung approach and is unique to Getinge.

In terms of weaning support, most clinicians are familiar with NAVA/ Edi monitoring and its potential to activate the diaphragm and protect the lungs. In addition to PRVC and High Flow Therapy, clinicians can now have access to Heliox therapy to help reduce the work of breathing for patients with obstructed asthma.

Do the software upgrades have any benefits for the clinician?
The 4.1 software integrates major respiratory therapy enhancements for all patient categories—adults, pediatrics, and neonates. We have a legacy of more than 50 years of close collaboration with intensive care clinicians worldwide, working together to develop ways to improve the software offerings of the Servo ventilators. We always ensure we are updating the base software with new features and then layering in additional purchasable upgrades like the Automatic Recruitment maneuvers, transpulmonary pressure monitoring, and Heliox therapy.

One of the software options includes Automatic Stepwise Recruitment maneuver—why is this important for patients and clinicians?

The Open Lung Tools includes three new and different tools: Automatic Stepwise Recruitment maneuvers (Auto SRM), Automatic Recruitment maneuvers (Auto RM), and open lung trends, a manual recruitment maneuver tool. We are very excited about the Automatic Stepwise Recruitment maneuvers, automatic lung recruitment with PEEP titration. Auto SRM was designed to create a standardized workflow that optimally divides the workload between the clinician and the ventilator. Pressures are incrementally increased to reduce the occurrence of hemodynamic compromise, and alarm limits are automatically adapted. The tool guides the clinician through recruitment, decremental PEEP titration, re-recruitment, and post-recruitment. With Auto SRM, the clinician will find the right PEEP and right driving pressure, and all of this is automatic.

The Automatic recruitment maneuver allows for quick recruitment after patient disconnection, suction, or surgery, keeps recruitment settings used in Auto SRM. It also provides an opportunity to delegate recruitment when few physicians are available (during night shifts), a post-recruitment summary with color-coded results, and a shortcut to open lung tool trends.

We see the clearance includes Heliox therapy. Can you tell us more about what Heliox therapy is and how it benefits patients?

Servo-i users will be familiar with Heliox, and we are excited to offer Heliox now as part of the Servo u/n ventilators. It is yet another tool that clinicians can use to support advanced personalized ventilation. Heliox has long been used as an adjunctive therapy to overcome airflow-obstruction disorders. In combination with Servo's integrated Aerogen nebulizer, it is often used as an adjuvant treatment while waiting for the onset of conventional pharmacological treatments. It provides a smoother airflow for patients with obstructive lung disease such as exacerbated asthma and COPD, reduces airway resistance due to laminar flow, cost-efficient due to low gas consumption, can be combined with all ventilator modes, invasive to NIV, High Flow therapy, and nebulization. It is easy to switch from Heliox to air and back.

What other kinds of lung protection functionality does the new software have?

Transpulmonary pressure monitoring, including key parameters for assessment of lung stress during controlled and spontaneous ventilation, complements the lung protective toolkit, which was designed to optimally divide the cognitive workload between the clinician and the ventilator. Transpulmonary pressure monitoring validates balloon positioning and includes a diagnostic view including esophageal (Pes) and transpulmonary (PL) pressure waveforms. We wanted clinicians to have an intuitive tool that provides guidance on the relationship between airway and transpulmonary pressure. It is one additional tool for clinicians to use as part of a personalized and lung protection strategy.

What about the base software—any enhancements there?

There have been several additional enhancements to the Servo base software, version 4.1, including the addition of the Stress index for lung mechanics monitoring (Servo-u & Servo-u MR only) and the inclusion of PEEP 0 (ZEEP), and several enhancements to the user interface.

Can you tell us more about the Servo-u MR system and how it might make it easier to monitor patients on ventilators?

The Servo-u MR is the newest member of the Servo family. It has been designed to provide all the key features of a Servo-u with special adaptations for the MR room. Positioning the ventilator in an MRI room can be a real challenge. We have included a magnetic field indicator with visual and audible alerts to help guide the unit to a safe position. In addition, the Servo-u MR features a visible auto-lock handle. When depressed, the wheels unlock, allowing the unit to be moved. As soon as your hand leaves the handle, it will automatically lock up all four wheels, stopping the unit.

We have also enhanced[4] some existing features. Our software interface, a key feature, is now housed in a large 15" screen that can be tilted and rotated for a flexible view from any angle.

Now, with Distance view with Servo Compass, the operator can see at a glance from the control room all the important parameters, and the system will alert you of any deviation from set targets.

Can you tell us more about the Servo Family Range?

With the introduction of Servo-air last year and Servo-u MR to the Servo Family, you can be confident, no matter where in the hospital you are, that you have access to the trusted Servo technology. The **Servo-u** was designed to enhance user confidence in tailoring treatments to the individual patient's condition. This means more patients in all phases of ventilation—controlled, supported, non-invasive, and during spontaneous breathing trials—can benefit from advanced lung protective strategies.

The **Servo-n** is our neonatal/pediatric ventilator created to help provide vulnerable patients with the support they need while protecting the lungs, brain, and other developing organs. Sensitive and responsive, Servo-n compensates for variable leakage in both invasive and non-invasive modes of ventilation. Servo-n can deliver tidal volumes as low as 2ml in patients as small as 0.3kg and includes optional hot-wire flow sensor technology to both trigger and measure pressure and flow at the patient interface.

The recently introduced **Servo-air** launched in Oct 2020 is a turbine-driven ventilator with a hot-swappable battery backup, making it perfect for intra-hospital transport without requiring wall gas or power outlets. It can be easily lifted and moved with patients within the facility. Finally, rounding out the family offerings is the **NEW conditional, Servo-u MR,** designed to ventilate all patient categories during MR scanning, from invasive and non-invasive ventilation to high-flow therapy.

It has been quite a year for mechanical ventilation.

Yes, it really has. In addition to the introduction of the Servo-air, Servo-u MR, and the updated SW 4.1, there have also been a few very impactful studies around NAVA. We have additional information about those on our website, www.getinge.com. We are celebrating 50 years as a leader in the mechanical ventilation market globally and are proud of our legacy of driving innovation within the space. We are really looking forward to many more years of helping to shape the future of mechanical ventilation through continued collaboration with intensive care clinicians and further innovation.

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4 Vs. Servo-i

News…continued from page 16

found that PVi may identify preload responders and noted that PVi may therefore be used in the "day-to-day clinical decision-making process in critically ill patients treated with NHF, helping to provide adequate resuscitation volume." More than 100 independent studies have demonstrated the utility of PVi as an indicator of fluid responsiveness. This is the first time PVi has been evaluated in patients treated with NHF therapy. Noting the potential convenience of a noninvasive method of predicting fluid responsiveness in NHF patients, the researchers sought to evaluate whether PVi, which is noninvasive and easy to use, could play such a role. To do so, they compared PVi to reference measurements—stroke volume (SV) and cardiac output (CO)—in 20 adult ICU patients with acute respiratory failure (ARF) supported by NHF (flow ≥ 30 L/min). SV and CO were measured using transthoracic echocardiography (TTE) using a portable echocardiogram. PVi was measured using a Masimo Radical-7 Pulse CO-Oximeter with a pulse oximetry sensor attached to the finger. Within the first 24 hours of NHF support, the patients' SV/CO and PVi were assessed. Passive leg raising (PLR) was performed and SV/CO and PVi were then reassessed. Preload responsiveness was defined as a ≥ 10% increase in SV after PLR. A fluid challenge was then conducted by administering a 250-mL saline solution to patients who were found to be preload responders (12 of the 20 patients). SV/CO and PVi were measured again after the fluid challenge in these patients. The researchers found that preload responders showed higher baseline PVi values and ΔPVi after PLR. PVi and ΔPVi after PLR showed "excellent diagnostic accuracy for predicting preload responsiveness." At a baseline cut-off value of 16%, PVi had sensitivity of 91.7% and specificity of 87.8% for discriminating between preload responders and non-responders; a change of 2% or more in PVi allowed for discrimination between the two groups with 100% sensitivity and specificity. Additionally, the researchers found that ΔPVi after PLR and after fluid challenge were strongly correlated ($r = 0.84$, $p < 0.001$). The researchers concluded, "This physiological study suggests that PVi might predict preload responsiveness in hypoxemic ARF patients treated with NHF. Further research should focus on validating these results and analyze whether PVi-guided fluid administration can improve outcomes in NHF patients." The researchers also noted that PVi may not be sufficient to identify preload responders in all patients using NHF, hypothesizing that the intrathoracic pressures delivered by NHF are lower than those generated during invasive mechanical ventilation and that therefore a certain degree of hypoperfusion might potentially be required to effect changes in baseline PVi. The accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure, and device-related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi. In the US, PVi is cleared as a noninvasive, dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients.

OxyGo Acquires Maker of Portable Emergency Oxygen Devices

OxyGo LLC, a leader in lightweight portable oxygen concentrators, has acquired LIFE Corporation, a manufacturer of medical devices that specializes in portable Emergency Oxygen and CPR administration equipment. Founded in 1985,

Continued on page 28…

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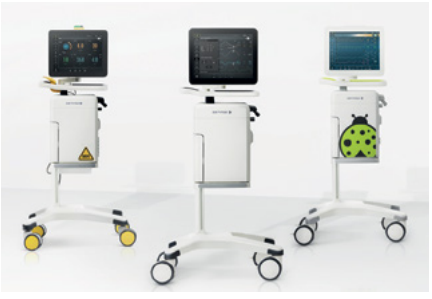

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Using Technology to Handle 'Serious Reportable Events'

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with John Zaleski, PhD, NREMT, CAP, CPHIMS, head of clinical informatics at Capsule, a Philips company

Why do "serious reportable events" (i.e., undetected compensation leading to respiratory failure and arrest) as described by the National Quality Forum continue to vex hospitals?

Patients are increasingly complex. Nearly one-third of the US population has three or more chronic conditions. When hospitalized, many of these higher-risk patients may not require admission to the ICU but are nonetheless more challenging to manage. Away from the ICU, clinicians may not have the information or tools to detect the onset of a serious reportable event because they are only periodically checking on the patient instead of continuously surveilling them. Clinicians must often cognitively prioritize device alerts without the benefit of broad, comprehensive, and contextual data collected from continuous surveillance. Periodic checks, limited insight from isolated monitoring devices, and fewer available clinicians per the lower acuity care settings can result in later detection of more serious reportable events (such as somnolence related to opioid induced respiratory depression).

What progress have health systems made with monitoring patients in non-critical care environments?

Early warning scoring systems (EWSS) used in many hospitals are helping clinicians measure patients' risk upon admission, enabling them to respond to alerts appropriately and with greater preparation. Upon responding to an alert, or during their rounds, clinicians in general care units also have checklists to identify early signs of decompensation or other potential health issues that may be contributing to the alert. A key factor for improving care in these non-critical environments has been medical device integration (MDI) so that clinicians do not need to respond to alerts in isolation, but rather are better informed about the patient's health status from multiple other device outputs. Checklists, including STOP-BANG type criteria for identifying the likelihood that a patient will be susceptible to central or obstructive sleep apnea, have been shown to be marginally reliable in predicting dangerous hypoxaemia.[1]

How does technology address these monitoring challenges?

MDI combines multiple device outputs and the electronic health record (EHR) to enable clinicians to have a more comprehensive perspective of their patients' health status and vital signs trajectories. As a result, MDI offers greater context to the clinician into why the alert may be triggering and if any action is required. When device outputs can be viewed through a centralized workstation, clinicians can be better prepared before entering the patient's room and address the alert appropriately. These efficiencies are important for non-critical care environments due to the higher patient-to-clinician ratios compared to the ICU. Not only does MDI reduce clinician documentation burden, but when the collected data are analyzed through predictive algorithms, clinicians can be forewarned as to devolving patient conditions, such as increasing episodes of sleep apnea, desaturation, and cardiac events.

Why is it important to monitor patients in general care settings—aside from just ICUs and postoperative ones?

Patients in general care can have numerous respiratory risk factors, such as sleep apnea, obesity, diabetes, asthma/COPD, older age and others. Often, patients in general care settings have more than one comorbidity that increases their risk of respiratory failure. An underutilized tool in general care settings is capnography, which could help clinicians in these units better monitor these higher-risk patients. When combined with pulse oximetry, capnography helps clinicians recognize the onset or occurrence of respiratory depression. Proactive response to the decompensating patient can save a life.

Sepsis continues to be an issue that hospitals grapple with. To what extent do additional data points from medical devices help clinicians mitigate patients succumbing to sepsis?

Regular capture of all vital signs, including pulse, respiration, blood pressure, oxygen saturation, and axial or oral temperature, together with lactate or glucose measurements, can help to identify a patient with sepsis. The early warning score can be calculated and displayed at the bedside so that it can be acted upon immediately.

Clinician burnout is an issue that continues to plague hospitals and care teams. What progress has been made to reduce the number of alarms that nurses and other care team members confront on a daily basis which often adds to their stress levels?

Clinicians are over-alerted, but underinformed. Faced with a barrage of alerts from disconnected monitoring devices, clinicians are daily required to respond to the patient's bedside only to discover that the alert requires no action, and the patient is at no risk of harm. This level of response, however, is needed to protect patient safety. Hospitals, however, are

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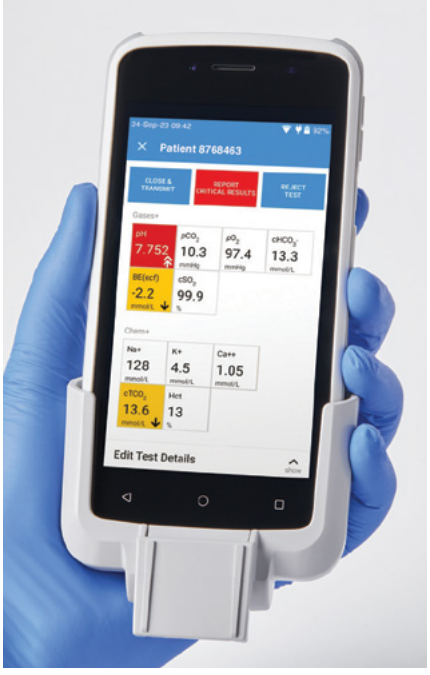

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using alarm management solutions to reduce the alert fatigue that contributes to clinician burnout. These solutions enable clinicians to build smart alert notifications outside of medical devices, using data from multiple medical device sources associated with a patient, such as the patient's physiological monitor and mechanical ventilator, to indicate interventional events. The result is fewer unnecessary interruptions and more efficient patient care delivery.

How can tailored smart alerts improve care?

Physiologic decompensation can be expressed in different forms, from respiratory distress to shock and cardiac events, including cardiac arrest. Physiologic monitors communicate emergent events through alarms that are intended to alert caregivers as to the immediate need to intervene in the case of life-threatening or potentially life-threatening arrhythmias, respiratory behavior, oxygen desaturation, or similar. Unfortunately, most physiologic monitoring alarms are not clinically actionable due to the fact that they are indicative of the behavior of single parameters and lack patient context, or are related to measurement or machine artifact.[2,3] Yet, by studying the behavior of the cardiovascular and respiratory measurements together in concert with other types of indications, such as medical device disconnects, calibration errors, battery alarms, etc., it is possible to identify more clinically beneficial notifications that carry a higher likelihood of true interventional action, simply because they incorporate more relevance into the mathematical rule underlying the alert or alarm. By monitoring and assessing changes in multiple measurements, it is possible to create notifications, or smart alerts, that provide more information on physiologic status.

During the pandemic, you developed a Ventilated Patient Surveillance workstation to reduce the risk of clinical exposure to COVID-19 and preserve scarce PPE. Do you envision such a workstation having application after the pandemic subsides?

Absolutely. In fact, we expect such remote monitoring solutions both within and outside of hospitals to increase in adoption. The VPS usage during COVID-19 has demonstrated to our clients that clinical surveillance can include fewer bedside visits. Even without the risk of exposure to a pathogen, remote clinical surveillance delivers patient care and operational efficiency benefits through alerting providers to potential indicators of decompensation based on an analysis of multiple device data points. This enables the clinician to prevent serious reportable events only when there is an actual risk as opposed to responding to the bedside at every device alert.

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Study Finds BAL Safer, More Effective with Closed-Loop System

June Arney

Bronchoalveolar lavage (BAL) is a common, but cumbersome, procedure for collecting fluid samples from the lungs, often done in the ICU.

In new research, Dr. Suveer Singh of the Royal Brompton and Chelsea & Westminster hospitals in the UK, found a unique closed-loop sampling system reduced the risk of sample loss or contamination during BAL.

The independent research, published in Respiration, included 20 bronchoalveolar lavage (BAL) and bronchial washing (BW) procedures. Singh reported the Ambu aScope BronchoSampler simplified sampling in 95 percent of procedures. He also wrote that in 80 percent of the study's 20 procedures, the BronchoSampler made it "much easier to collect and protect a sample from start to finish" compared with traditional (BAL) sampling techniques. Clinicians rated the device "easier" in another 15 percent and noted "no difference" in 5 percent of the cases.Singh disclosed a financial relationship with Ambu in his report. The study is limited in that it is a single-operator case series.

The History of BAL

First popularized by Dr. H.Y. Reynolds and Dr. H.H. Newball in Maryland in 1974, BAL has largely become a diagnostic tool for evaluating lower respiratory tract issues. It sometimes also has therapeutic value. Despite the procedure's common utility for collecting samples, BAL remains a challenging process, from setup to post-procedure waste disposal. The procedure involves putting a saline solution through a bronchoscope to wash the airways and capture a fluid sample. Typically, two healthcare providers are involved in obtaining the sample which requires switching between suctioning and sampling, without contaminating the open container holding the sample or spilling it. The laboratory of Dr. Ronald G. Crystal in the Pulmonary Branch of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH) in Bethesda, Maryland, was an original site for lung studies using BAL. Many of the medical staff and trainees who worked in that lab returned to their own centers or relocated to other pulmonary groups to become modern leaders in lung medicine. Although there have been many innovations in bronchoscope and imaging technology, little has changed in the realm of BAL and BW since the procedures were first introduced in the 1970s.

In new research, Dr. Suveer Singh of the Royal Brompton and Chelsea & Westminster hospitals in the UK, found a unique closed-loop sampling system reduced the risk of sample loss or contamination during BAL.

Challenges of BAL

One of the challenges that physicians have long reported with BAL is that it's easy to lose these samples that are so vital for diagnosis and treatment, either because of awkward workflows or due to contaminated tools and accessories. BAL samples may also be spoiled by inadequately reprocessed flexible bronchoscopes that can harbor infectious organisms. Those lost samples can in turn delay diagnosis and treatment. Another BAL workflow challenge includes the potential for a long wait time for a reprocessed flexible bronchoscope. During the procedure itself, switching between suction and sampling can also leave open containers exposed to surrounding elements and contaminants. That can compromise the integrity of the samples collected. Approximately 500,000 bronchoscopy procedures are performed in the U.S. each year, according to the U.S. Food and Drug Administration. COVID-19 presented additional BAL challenges in the ICU because aerosolizing procedures can put healthcare workers at increased risk of infection. The disconnection of suction tubing, as well as splashing from specimen containers, are particular areas of concern. Recommendations from a variety of U.S. and international professional associations issued earlier in the pandemic included using leak-proof specimen collection for suspected COVID-19 patients when bronchoscopy sampling is deemed necessary.

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Are You 'Flying Blind' with NIV Pressures?

Greg Spratt BS RRT CPFT

Introduction

Noninvasive Ventilation (NIV) has become an increasingly utilized tool for ventilatory support in neonates with two primary goals: 1) preventing intubation in a newborn requiring increasing ventilatory support due to evolving respiratory failure, and 2) continued ventilatory support to avoid reintubation after extubation. The potential benefits of avoiding endotracheal intubation or reintubation and the accompanying trauma and negative sequelae from the ventilation via endotracheal tube placement are evident.[1-3]

As with any form of ventilatory support, settings optimized to the patient's needs are critical for a successful outcome. Clinicians typically use NIV settings for peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP) similar to those used during intubated ventilation, assuming that these settings will deliver a relatively similar level of ventilatory support using a non-invasive interface compared to use while intubated.[4] **Evidence presented below shows that this is a poor assumption which may lead to unnecessary intubation or reintubation due to an overestimation of the true level of support being provided.**

In fact, the pressure readings on the ventilator may dramatically misrepresent the pressure (and consequently ventilatory support) truly being delivered to the airway. Not only may it misrepresent the true airway pressure, the degree of error can be highly variable based on two factors: 1) added resistance from the non-invasive interface being used and 2) leak at the patient interface. As different interfaces have different levels of resistance and leak, the level of pressure reduction is highly variable and difficult to predict when transitioning from one interface type or size to another.

During the routine, pre-use check, ventilators typically auto-calibrate to the breathing circuit characteristics so that during ventilation, the monitored PIP and PEEP values accurately represent what is measured at the patient connection port of the circuit. However, when you add a NIV interface to the circuit, the resistance and compliance of the breathing circuit change. Depending on the amount of resistance added, pressures applied to the patient may be significantly lower than the displayed values. Added resistance is primarily created by the small openings in the non-invasive interface.

Let me illustrate with a simple analogy. If you blow out forcefully through a large tube (say one inch in diameter), the pressure inside your mouth will not be appreciably different to the pressure inside of the tube. However, how would that change if you blew with the same force into a very small tube, like a coffee straw? Your cheeks would puff out and significant back pressure would be created inside of your mouth, much higher than the actual pressure inside the distal end of the straw.

The ventilator is displaying pressures for PIP and PEEP based on the pressure in the ventilator circuit (in our analogy, inside the mouth). When increased resistance is introduced with the NIV interface (in our analogy, the coffee straw), this significantly affects the pressure reading inside the ventilator circuit proximal to the restriction compared to the actual pressure distal to the restriction (ie, at the interface). The resistance may be dramatically increased because of the small diameter of the non-invasive interface ports (eg, the nasal prongs). Poiseuille's law teaches us that decreasing the diameter of the tubing by half creates a 16-fold increase in resistance (and thus a reciprocal *decrease* in the true airflow to the patient).[5]

Secondly, some level of leak is expected from these systems as the interface is typically not fully sealed to the infant's airway (ie, nose, face) and due to open-mouth leaks intrinsic to nasal interfaces. For example, a properly fitted RAM cannula is suggested to create ~70% occlusion of the nares allowing for a significant leak even when properly fitted.[6] Movement of the infant may also result in additional leak due to partial and variable dislodgement of the interface from the infant's face.

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These two factors can result in significant and highly variable dampening of the interface pressure at the patient when compared to the set pressures on the ventilator, in essence causing clinicians to be 'flying blind' when it comes to the actual pressures being provided to the patient as demonstrated in the studies below.

Evidence Demonstrating Errors in PIP and PEEP Displays

In an observational study by Owens et al, median delivered PIP (ie, interface pressure) was about 80% (15.9 cmH_2O) of the set PIP when set at 20 cmH_2O. More than a third of all inflations (ie, 'breaths') were delivered at least 5 cmH_2O below the set PIP. In infants with PIP set at 25 cmH_2O, the error was even higher with only 69% of the pressure being delivered at the interface (median PIP of 17.2 cmH_2O). When viewing breath by breath, 83% of inflations were delivered at least 5 cmH_2O below the set PIP.[7]

In a simulated neonatal lung model, Iyer et al explored pressure transmission using the small caliber nasal RAM cannula. Using a leak within manufacturer guidelines (30%), there was a 25-37% reduction of peak airway pressure and 10-30% reduction of PEEP transmitted across the nasal interface compared to the ventilator settings. During a 50% leak (ie, 'worst-case scenario'), there was a much higher 92% reduction in delivery of peak airway pressure and PEEP.[6]

Also using a simulated neonatal lung model comparing the short binasal prongs (SBP) interface with the small caliber nasal cannula (RAM) interface, Mukerji et al found significant decrease in the interface pressure compared to ventilator settings and high variability between the effect of the two devices tested. When measured at the lung level of the model, the transmitted pressure dampening was even greater with the fraction of operator-set pressure that was transmitted to the lung being significantly lower with the RAM cannula (only 2.8% of set pressure transmitted), as compared with the SBP interface (still only 11.9% of set pressure transmitted). Carbon dioxide elimination, also measured in the model, was directly proportional to delivered PIP level, and better preserved by the SBP interface where pressure dampening of PIP was less than with RAM. Pursuant to the earlier discussion of the impact of resistance, the resistance of the smallest ('preterm') RAM cannula was 400% higher when compared with the SBP interface.[4]

In bench testing, Gerdes et al looked at the impact of the RAM cannula on nasal CPAP levels between four and eight cmH_2O. Using varying nasal occlusion levels, prong depth insertion, and mouth leakage, mean airway pressure (MAP) decreased progressively with decreasing nares occlusion (ie, increasing leak). The simulated open-mouth condition (additional leak) resulted in significantly lower MAPs to < 1.7 cmH_2O. The one-half prong insertion depth condition, with closed mouth, yielded MAPs approximately 35 ±9% less than full insertion pressures ($P<0.001$). They concluded that in their testing, the RAM interface failed to deliver set CPAP levels when applied using the manufacturer recommended 60–80% nares occlusion, even with closed-mouth and full nasal prong insertion conditions.[8]

How do I know what pressure I'm truly delivering?

An optimal method would be to actually measure true delivery pressures on the patient side of the interface or within the airways. While this may be possible in research situations or in simulated models, the specialized and invasive equipment required simply isn't practical for everyday practice.

A new release by one manufacturer (Medtronic) is attempting to take the impact of resistance and leak into account. The NIV+™ software[9] option on the Puritan Bennett 980™ ventilator calibrates to the specific neonatal NIV interface in use, thereby enabling the monitoring of two additional data values: 1) interface end-inspiratory pressure and 2) interface end-expiratory pressure. By calibrating based on the resistance of the individual circuit and type/size of interface being used, these two new measurements provide a more representative reading of the true pressures being delivered to the patient.[10] Bench testing with three popular interfaces: 1) Fisher & Paykel Healthcare™ Infant Nasal Prongs, 2) Hudson RCI™ Infant Nasal Prongs, and 3) Neotech™ RAM Cannula), showed very high correlation between the new values displayed by the software on the ventilator and measured values using an independent manometer at the patient interface (R^2 – 0.992, 0.9925, and 0.9989 respectively) (See Figure 1). An R^2 of 1.0 represents a 'perfect' correlation. Any change in the type or size of the interface being used would require a new calibration.[11,12,13]

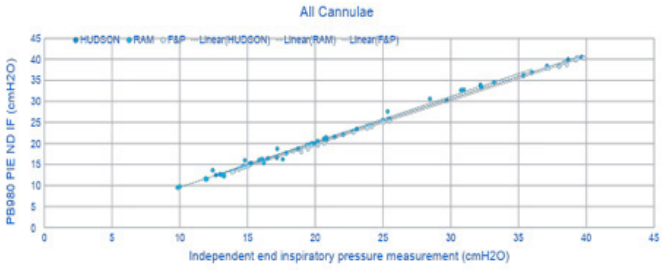

Figure 1. Agreement of PB980 End-Inspiratory Pressure at the Patient Interface ($P_{I\,END\,IF}$) Displayed Value & Independent Measurement by Manometer at Patient Interface.

Test setup with NIV+ in use with physiological model of neonatal patient nares and lungs. Independent pressure gauge connected to the physiological model shows end inspiratory pressure experienced by the "patient."

Summary

Increased resistance and leaks inherent to noninvasive interfaces frequently lead to significant misrepresentation of true delivery pressures at the patient compared to the settings on the ventilator. This makes it difficult for the clinician to know what PIP and PEEP pressures are truly being transmitted to the patient. Recent product developments may enable clinicians to better understand what level of ventilatory support is being delivered, thus potentially increasing the chances of a favorable outcome.

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News…continued from page 20

LIFE Corporation specializes in AED companions to provide supplemental oxygen to a breathing victim before the onset of fibrillation, oxygen enriched CPR to a non-breathing victim, or continued supplemental oxygen after successful defibrillation. LIFE also provides a complete line of medical oxygen regulators and cylinders for LIFE products and separately for EMTs, hospitals, and the home care market. "Acquiring LIFE Corporation is an exciting and logical next step in offering proactive gas solutions to the medical and industrial markets," said V.E. Marquard-Schultz, Esq., "and continues our mission to help our customers and communities grow." The acquisition of LIFE Corporation fits into OxyGo's strategy to offer high quality and market leading service to compressed gas users and the home healthcare market. By purchasing LIFE Corporation, OxyGo can expand their oxygen expertise even further, providing the best product and service. OxyGo is noted for providing high quality home healthcare oxygen products and has been rated as the industry's best POC—ahead of all competitors the last four years in a row and established itself as a leader of portable oxygen concentrators in North America.

Company Unveils New Website

Vitalograph (USA) Inc. is inviting visitors to explore their new website www.vitalograph.com. The new website allows customers to see the full range of Vitalograph products and services, through a more user-friendly experience with improved navigation and functionality. Created with the customer in mind, the site includes many new features and information on respiratory diagnostic devices, medical equipment, clinical trial services and medical research papers for the respiratory community.

New features include: Website split into Healthcare and Clinical Trials to suit the customer journey. Rapid response functionality allowing compatibility with various browsers and mobile devices. Reference Paper Resource area. Clinical Practise Guidelines area. Reimbursement codes information. Product filters to easily narrow down the product portfolio. Online shopping with new cart functionality to streamline the purchasing process. Full information on Vitalograph's Clinical Trial product solutions and services. Look ahead navigation which reduces the number of clicks to navigate the site. 5 Year-Product Registration and Spirotutor Online Training. In addition, the new product filters allow Vitalograph to place their complete portfolio on the site while still allowing the user to easily navigate through the line. The new Resources section allows visitors to stay informed with the latest industry news, guidelines, and references. The user is always just one click away from useful and pertinent respiratory research, clinical practice guidelines and other spirometry information. Vitalograph is a world-leading provider of the highest quality respiratory diagnostic devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning over half a century, Vitalograph continues to make valuable contributions to effective medical care and enhanced quality of life.

Company Launches New Software into the UK

Vitalograph is excited to launch the next generation Spirotrac 6 software into UK. Healthcare and Occupational Health. Spirotrac 6 PC software provides a powerful respiratory diagnostic platform. This redesigned software is compliant with 2019 ATS/ERS spirometry guidelines, meeting international guidelines

Continued on page 34…

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Monitoring Passive Robotic Stepping with Volumetric Capnography: A Case Report

Charles J Gutierrez, PhD, RRT, CPFT, FAARC, William H Haven, DPT, NCS and John L Merritt, MD

Abstract

Volumetric capnography (VCap) is a valuable tool for measuring physiologic variables in patients who may or may not require mechanical ventilation. We report changes in physiologic variables including alveolar minute volume (MValv) and carbon dioxide elimination ($\dot{V}CO_2$) as measured by VCap, in a high cervical spinal cord injury (high CSCI) patient who received a diaphragm pacer (DP) and later underwent transplantation of nasal olfactory ensheathing cells (OECs) followed by passive robotic stepping on an Erigo dynamic tilt-table. An N-of-1 study revealed that engaging patient's DP during robotic stepping, led to increases in MValv, $\dot{V}CO_2$ and systolic blood pressure (SBP). These indicators reflected the patient's ability to tolerate passive robotic stepping, a key to obtaining enhanced neurological function following OEC transplantation. Given that VCap is underutilized, we encourage rehab teams to adopt it to routinely monitor physiologic variables in ventilator dependent, high CSCI patients undergoing rehab and weaning.

Key words: abdominal binder; alveolar minute volume; carbon dioxide elimination; cervical spinal cord injury; chest optimization; diaphragm pacer; Erigo tilt-table; olfactory ensheathing cell; passive robotic stepping; pneumatic calf compressor; rehabilitation; tetraplegia; volumetric capnography.

Introduction

Approximately 11,000 spinal cord injury (SCI) cases occur annually in the United States, and about 50% present with a cervical spinal cord injury (CSCI).[1] While many of these acute patients develop ventilatory failure and require mechanical ventilation, most may eventually be weaned. Some may require long-term mechanical ventilation and chronic, clinically complex care at rehab centers with transdisciplinary rehab teams that employ multiple rehabilitation modalities aimed at weaning the patient from mechanical ventilation.[2] Unlike most other patients with ventilatory failure, ventilator-dependent patients with high CSCI generally present with lungs, chest and ventilatory muscles that are physiologically normal.[1] Nevertheless, the estimated life expectancy for a 20-year-old tetraplegic who needs long-term mechanical ventilation typically declines from approximately 59 years to 17 years.[3] The quality of life for these patients is markedly diminished while their care needs are compounded. Hence, reducing dependence on mechanical ventilation is a critical clinical objective for the patient, his/her rehab team and for society.

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Methods

This is the case report of a 32-year-old man who sustained a traumatic, high CSCI (C3, AIS A) and was admitted to a regional SCI center for comprehensive rehabilitation and weaning from mechanical ventilation. He had been quite athletic prior to injury and on presentation was medically stable, nutritionally repleted and free from major infections including pneumonia. Nevertheless, he periodically exhibited episodes of atelectasis and/or mucus plugging and/or airway constriction, that necessitated administration of chest optimization, a protocolized neurorespiratory intervention designed to enhance lung function.[4] The patient was mechanically ventilated using the following settings: synchronous intermittent mandatory ventilation (SIMV), SCI-associated tidal volume (TV) = 1000 ml,[5] ventilatory rate (RR) = 6-8 bpm, fractional inspired oxygen (FiO_2) = 21%, pressure support ventilation (PSV) = 15 cm H_2O and positive end-expiratory pressure (PEEP) = 5 cm H_2O.

Volumetric Capnography

Volume-based capnography, also known as volumetric capnography (VCap), can play a key role in monitoring a wide range of physiologic variables, including alveolar minute volume (MValv) and carbon dioxide elimination ($\dot{V}CO_2$), during rehab and weaning of patients with CSCI.[6] Alveolar minute volume (MValv) is the amount of gas delivered to alveoli in ml/minute, minus dead space ventilation. The primary objective of respiratory therapy interventions is to optimize MValv to improve alveolar gas exchange. MValv varies with delivered tidal volume and may normally range from 4 to 9 L/minute. Carbon dioxide elimination ($\dot{V}CO_2$) is the amount of carbon dioxide (CO_2) that is transported to the lungs by the systemic circulation and then eliminated by ventilatory excursions and may normally range from 200 to 250 ml/min.

Unlike time-based capnography (TCap) which measures exhaled CO_2 concentration plotted against time, and is mostly used in critical care environments, VCap integrates CO_2 concentration with exhaled volume.[7] Integrating CO_2 with volume enables VCap to provide real-time monitoring of numerous physiologic variables that may include airway resistance (Raw), static chest compliance (Cstat), and cardiac output (CO), in addition to

$\dot{V}CO_2$ and MValv. The NM3 VCap monitor (Phillips Respironics, Murrysville, Pennsylvania) (see Figure 1), has been used for rehabilitation and weaning of ventilator-dependent adults with CSCI[4] as well as with mechanically ventilated children.[8]

Figure 1. NM3 VCap Monitor

Rehab – Strength Training & SBTs

After admission clinical evaluations, the patient commenced rehabilitation that consisted of daily, protocolized ventilatory muscle strength training and spontaneous breathing trials (SBTs) with continuous VCap monitoring. One year of comprehensive rehabilitation resulted in some gains in ventilatory function, enabling the patient to spend a few minutes (5 to10) off the mechanical ventilator. However, patient desired further improvement in ventilatory function and possible liberation from mechanical ventilation. Hence, after reviewing risks and benefits, the patient, in consultation with his family and his transdisciplinary rehab team, elected to undergo implantation of diaphragm pacer (DP) (Synapse Biomedical, Oberlin, OH). After review by the university institutional review board (IRB), and hospital ethics committee, the subject gave informed consent, and subsequently underwent this procedure.

Diaphragm Pacer

DP implantation via laparoscopy has been well documented in the literature[3] and involves identifying motor points on the abdominal side of each hemidiaphragm and then implanting two pacer wires (Peterson Electrode, Synapse Biomedical, Oberlin, OH) per hemidiaphragm. All wires are connected to the DP via a cable (see Figure 2).

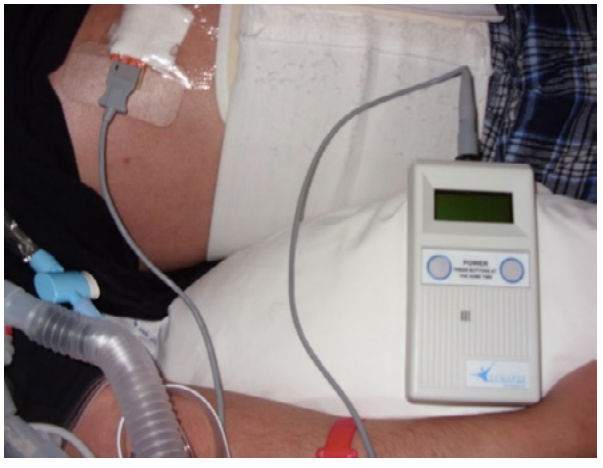

Figure 2. Diaphragm Pacer (DP)

Additionally, an abdominal binder was applied to improve the mechanical efficiency of diaphragm motion, support blood pressure and improve venous return.[9] Studies maintain that judicious use of DP potentially increases the proportion of slow twitch muscle fibers in the diaphragm which may also progressively improve a patient's ventilatory function.[3] As diaphragm conditioning and rehab proceeded, the patient was able to ventilate with DP for longer periods, eventually remaining off mechanical ventilation for 1-2 hours at a time.

Two years after DP implantation, patient sought even further improvement in ventilatory function and possible further liberation from mechanical ventilation. Hence, after discussions involving risks and benefits, the patient, in consultation with his family and his transdisciplinary rehab team, elected to undergo transplantation of autologous olfactory neural tissue also known as olfactory ensheathing cells (OECs). OECs are a type of neuronal glial cell that has been shown to guide and support elongation of axons after neurological injury thus facilitating neural regeneration.[11] After review by the university IRB, and the hospital ethics committee, the subject gave informed consent, and subsequently underwent this procedure.

Olfactory Tissue Transplantation

Transplantation of olfactory tissue is a well-documented procedure[12] which involves surgical resection of scar tissue from the CSCI site followed by surgical harvesting and subsequent transplanting of autologous OECs and associated olfactory tissues into the spinal cord injury tissue cavity. Accumulating evidence suggests that transplantation of autologous OECs may promote neurogenesis with consequent improvements in functional outcomes including enhanced ventilatory function.[13]

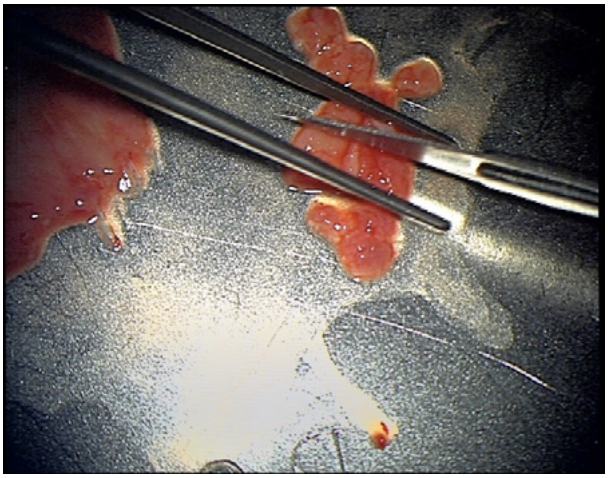

Figure 3. Preparing OECs for Transplantation

Rehab – Passive Robotic Stepping with Erigo Tilt-table

The patient had been using DP for two years prior to OEC transplantation. As there were no guidelines specifying whether DP should or should not be engaged during the intensive exercise required to augment neural regeneration, the transdisciplinary rehab team conducted an N-of-1 evaluation[14] in which DP was either engaged or not during the initial six-week period of rehab, to evaluate the effects of DP engagement on the patient's ability to tolerate intensive Erigo exercise. DP frequency, amplitude, and pulse width remained constant throughout the initial six weeks of Erigo exercise.

Previous studies describing transplantation of autologous OECs have stressed the critical importance of daily, intensive exercise in helping CSCI patients to realize the benefits of

improved neural function.[12,13] Consequently, after recovering from transplantation surgery, patient commenced an intensive, customized exercise program that included daily, passive, robotic stepping with the Erigo dynamic tilt-table (Erigo, Hocoma AG, Switzerland). The Erigo is a mobile, robotic stepping tilt-table that allows a patient to be placed in supine position with his body secured to the tilt-table with buckles and straps. Robotic stepping begins while patient is in supine position after which the patient is slowly raised to an upright position. Because pulmonary secretions and airway constriction periodically increased airway resistance and decreased lung compliance prior to passive robotic stepping, the patient received chest optimization protocol[4] which consisted of body positioning, lung hyperinflation, tracheal suctioning and aerosolization of bronchodilators immediately prior to beginning passive robotic stepping. CSCI patients undergoing rehab must be monitored via pulse oximetry and end tidal CO_2 measurements to assess adequacy of oxygenation and ventilation respectively.[1] VCap is an ideal tool for monitoring such physiologic variables.

While in supine position (see Figure 4) and prior to beginning a 30-minute Erigo exercise session, patient was instrumented with BP cuff, and intermittent pneumatic calf compressors (PCC)[9,10] (see Figure 5). Intermittent PCC uses air pressure to compress the gastrocnemius muscles bilaterally. Pressure up to 60 mm Hg was intermittently applied during passive robotic walking to augment venous return. The patient was then removed from mechanical ventilation and connected to DP which was randomly engaged (turned on) or not engaged (turned off). The NM3 VCap monitor was calibrated per manufacturer's recommendations, and the mouthpiece was inserted while patient was still in supine position.

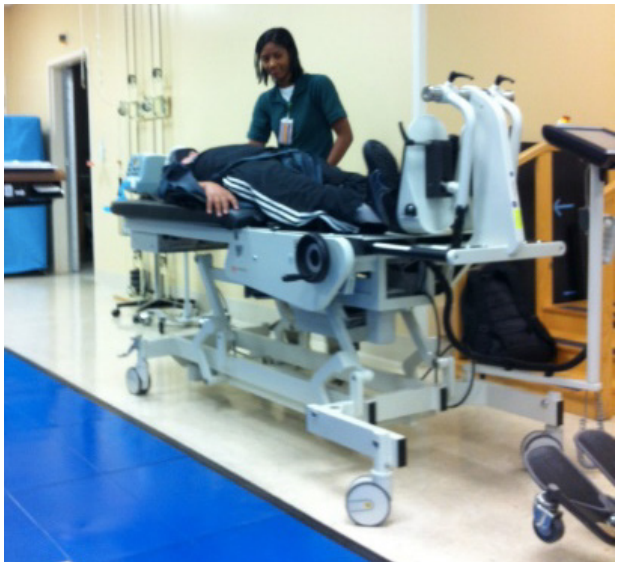

Figure 4. Erigo Tilt-table in Supine Position

All rehab sessions were conducted between 0900 - 1400 hours in a clinical gym with ambient temperature maintained between 19-21°C. Exercise was continuously monitored with VCap and consisted of 30 minutes of passive robotic stepping performed with actuators attached to the patient's thighs and PCC delivered to patient's gastrocnemius muscles. The passive stepping motion and PCC commenced shortly after the Erigo tilt-table reached the upright position. After the 30-minute exercise session, the patient was returned to supine position, at which point buckles, straps, PCCs, BP cuff and NM3 mouthpiece were removed.

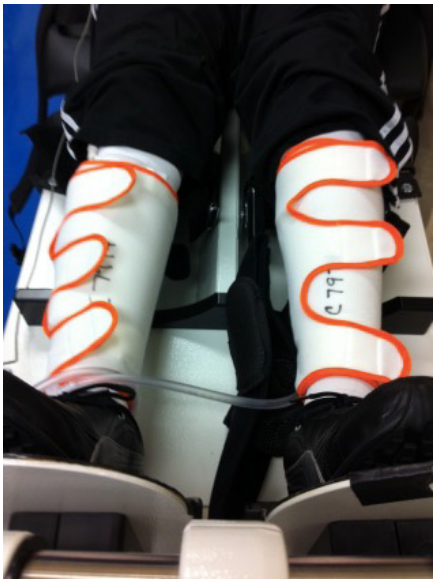

Figure 5. Intermittent Pneumatic Calf Compression

Results

Statistical modeling of physiologic data measured by VCap was carried out by analysis of variance (ANOVA) using an SPSS data spreadsheet. Statistical significance was established at $p < 0.05$. Graphs of MValv and $\dot{V}CO_2$ measurements, shown in Figure 6 and Figure 7 respectively, were created by averaging the first six weeks of daily MValv and $\dot{V}CO_2$ measurements with and without DP engagement. DP engagement during Erigo exercise was associated with significant improvement ($p < 0.01$) in MValv and clinical improvement in $\dot{V}CO_2$. Similar clinical improvements were also noted in systolic blood pressure (SBP) measurements (see Figure 8).

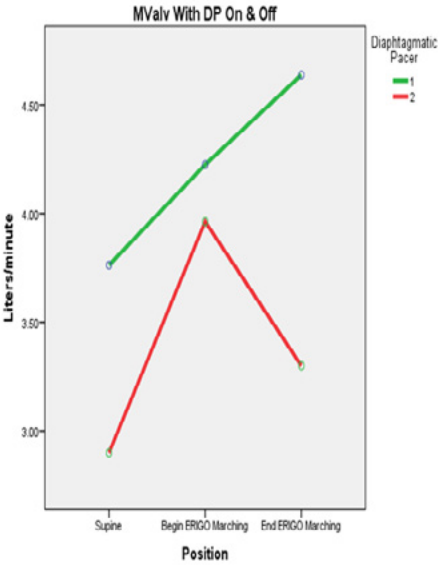

Figure 6. MValv with Engaged (green) versus non-Engaged (red) DP

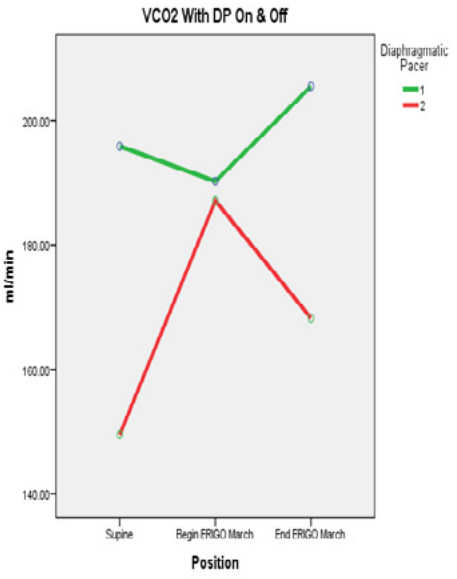

Figure 7. $\dot{V}CO_2$ with Engaged (green) versus non-Engaged (red) DP

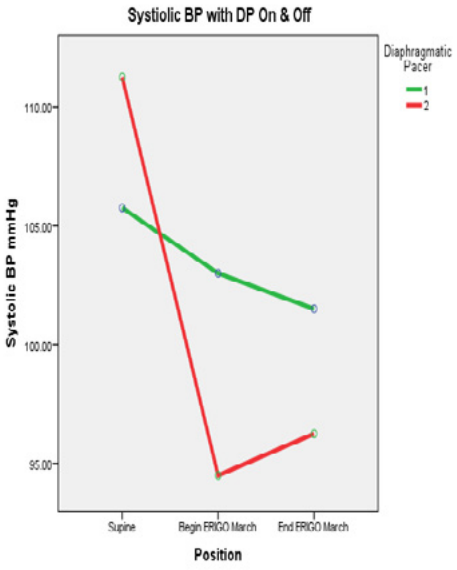

Figure 8. SBP with Engaged (green) versus non-Engaged (red) DP

Discussion

Patients with CSCI exhibit varying degrees of sympathetic nervous system dysfunction and may develop parasympathetic predominance which can manifest as increased airway secretions and bronchoconstriction, both of which complicate airway management for ventilator dependent patients.[15] During changes in body position, sympathetic nervous system dysfunction may also manifest as orthostatic hypotension (OH), a clinical condition that results in decreased venous return with concomitant decrease in cardiac output.[16] These patients may experience dizziness or loss of consciousness[17] which can interfere with their ability to participate in intensive rehab sessions needed to promote recovery of neural function and attain important clinical outcomes.[18]

Improved venous return has been found to mitigate OH and may help patients tolerate rehab sessions. During these sessions, sequential application of diverse rehab modalities, each of which improves venous return, may result in synergistic effects. Previous research has shown that administering protocolized chest optimization to high CSCI patients undergoing conventional rehab and weaning is associated with short-term improvements in cardiac output and an increased ability to perform longer SBTs.[4] Similarly, venous return can be improved by application of an abdominal binder,[19] administration of passive, robotic stepping with Erigo tilt-table,[16] and delivery of PCC[20] during a given session of synergistic rehabilitation (see Figure 9). Scientific findings suggest that DP engagement augments venous return;[21] we noted evidence of this in the form of higher systolic blood pressure (SBP) measurements during DP engagement.

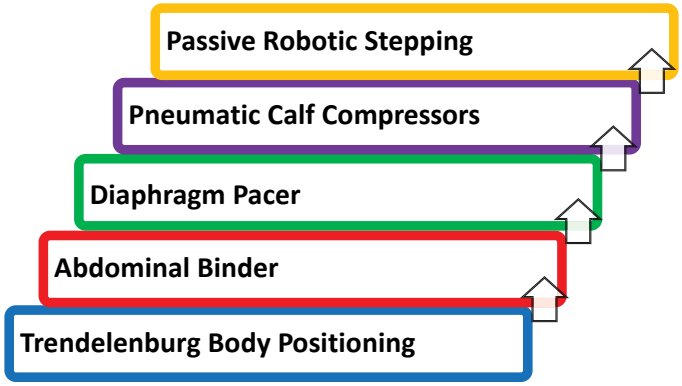

Figure 9. Synergistic Rehabilitation

This N-of-1 study revealed that using DP in concert with the rehab modalities described earlier, improved MValv, $\dot{V}CO_2$, and SBP, by augmenting venous return and thus mitigating OH. We posit that augmenting the patient's venous return, enhanced his ability to tolerate an intensive exercise regimen intended to facilitate post-OEC neurogenesis and neuroplasticity.[10] Declines in MValv, $\dot{V}CO_2$ and SBP that occurred when DP was turned off, reflected the baseline physiological status of the patient during passive robotic stepping. After the six-week acclimation period, patient continued to perform all Erigo exercises with DP engaged.

Conclusion

The patient successfully completed the prescribed course of intensive inpatient rehab and has since entered long-term outpatient rehab. He maintains a robust, daily schedule and receives ventilatory assistance from DP throughout the day and returns to mechanical ventilation at night. The ability of VCap to monitor multiple physiologic variables was key to understanding the role that the DP played in helping a ventilator dependent CSCI patient achieve important clinical milestones. We encourage rehab teams to consider increasing their adoption of VCap as a routine tool for monitoring physiologic variables in high CSCI patients undergoing rehab and weaning from mechanical ventilation.

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News…continued from page 28
on accuracy and reporting. The software includes a 12-lead electrocardiogram (ECG) option with detailed results based on the University of Glasgow interpretation algorithm. A brand-new user interface provides advanced quality control feedback for rapid and easy testing. Filing and storing results could not be simpler with fast connection to your electronic medical record (EMR) system, streamlining your clinical workflow. Five Key Benefits: supports full-feature spirometry testing and bronchodilator responsiveness testing with over 50 available parameters; rovides instant quality feedback using the latest 2019 ATS/ERS spirometry grading, test/session acceptability, usability, and repeatability criteria; uses latest global lung function initiative (GLI) predicted equations with lower limit of normal (LLN), Pred and Z-scores for accurate assessment of abnormality; saves time and ensures consistency with Standardised Operator Comments to quickly add comments to the subject record; ombines spirometry and ECG into one comprehensive patient record. The integrated Glasgow Algorithm provides a computer-generated analysis of potential cardiac abnormalities, a full range of parameters, interpretation, and rhythm analysis.

Company Launches New Device

Vitalograph are excited to launch the next generation Pneumotrac spirometer into the UK market. The next-generation Vitalograph Pneumotrac Spirometer, combined with Spirotrac PC software, is a powerful tool for respiratory diagnosis of both adults and pediatrics. Capture reliable test results immediately with Pneumotrac's precise and durable measuring technology which is extremely accurate and stable over time. Connects instantly to your PC by USB, delivering results through the new, improved Spirotrac 6 software. Compliance with the 2019 ATS/ERS spirometry update ensures your service meets international guidelines on accuracy and reporting. The Vitalograph Pneumotrac Spirometer easily connects to your Electronic Medical Records (EMR) system to streamline your clinical workflow. Features include: Highly accurate, robust, and stable Fleisch flow measuring technology with no moving parts; supports full-feature spirometry testing and bronchodilator responsiveness testing with over 50 available parameters; instant quality feedback using the latest 2019 ATS/ERS grading, test/session acceptability, usability, and repeatability criteria; low running costs and environmentally friendly: no need for costly disposable sensors, turbines, adaptors, or flow tubes. Plus free online training and a five-year warranty.

Getinge Gets FDA Clearance

Getinge announces clearance from the US FDA of several new software options for the Servo-u and Servo-n ventilators. In addition to the latest software upgrades, Getinge also received clearance for the new Servo-u MR ventilator for the MRI room. "The COVID-19 pandemic and the heightened awareness of respiratory health has driven the need for personalized ventilation solutions for critically ill patients. Now more than ever, options for personalized lung protection and personalized weaning solutions are at the forefront of respiratory patient health. Getinge strives to support clinicians and patients by optimizing lung protection and delivering solutions for personalized ventilation," said Eric Honroth, President, Getinge North America. With this software upgrade for the Servo-u and Servo-n combined, Getinge adds several new functionalities and options across all patient categories—adult, pediatric and
Continued on page 45…

Lung Function Testing in Patients Who Can't Seal Their Lips

Alex Stenzler

Introduction

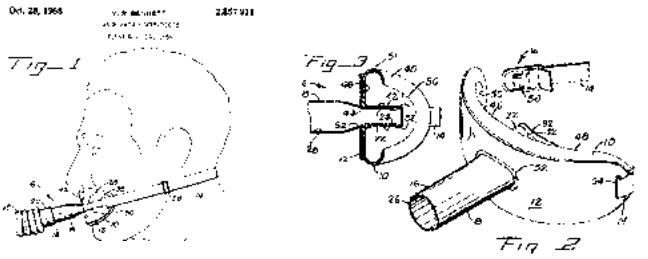
Pulmonary function tests that measure the volume and flow rate of air a patient inhales or exhales requires that there no air leaks from the nose or mouth. Specifically stated in the 2019 ATS/ERS standard on lung function testing is the requirement that "There must be no leak at the mouth". This can be a challenging aspect of lung function testing when collecting spirometry data from patients who can't seal their lips around the mouthpiece to get a tight seal without a leak. This inability may be due to neurological diseases such as ALS or in patients with residual effects from a stroke, patients with scleroderma, or patients with oral malformations that prevent them from sealing their lips.

The most common approach for testing patients who cannot seal their lips around a mouthpiece, is the use of a "snorkel" mouthpiece. These typically have a flange that fits between the teeth and the patient's lips to create seal. For some patients, this works well. However, for patients who can't open their mouths wide enough to fit the flange in their mouths, or when it doesn't seal sufficiently for spirometry maneuvers or gas dilution measurements, an alternative method is required.

When flanged mouthpieces don't work, pulmonary function laboratories frequently go to a mask for sealing the face in connection with a spirometer. While masks can usually provide an effective seal, they need to be held to the face with either straps or are hand held to the face. For a patient performing tests at home, use of head straps can be difficult to place by themselves, and holding a mask tight to their own face brings their upper arms close to their chest, which may alter chest wall mechanics, reduce chest wall expansion and therefore artificially alter lung volume measurements.

Masks also add significant dead space to the airway, which within seconds, will alter the patient's breathing pattern. For patients with long time constants, such as in obstructive lung disease, the effect of increased deadspace and the required increased compensatory ventilation, will frequently cause the patient to breathe at a higher lung volume and artificially raise the patient's Functional Residual Capacity and reduce the measured Inspiratory Capacity. The additional ventilation volume to clear the higher deadspace, will also increase the work of breathing, which for some patients and particularly those with restrictive diseases, may exceed their comfort level.

A new concept for addressing this problem is the use of a mouth seal for pulmonary function testing. Mouth seals have been used for more than 65 years for respiratory applications. Vivian Ray Bennett patented a mouth seal for the Bennett IPPB machines in 1956 (Figure 1).[1,2] This was a silicone shaped seal that was held close to the face with a plastic backing flange and a strap around the head.



As IPPB therapy lost favor as a therapeutic modality and a need for prolonged non-invasive ventilation generated new nasal and full-face mask patient interfaces, the use of mouth seals nearly vanished from respiratory use, with the exception of some use for aerosol treatments.

One of the limitations of existing aerosol mouth seals is the size of the mouthpiece opening, as it is too small for pulmonary function mouthpieces or PFT filters. Therefore, there was a need for a mouth seal that is designed specifically for pulmonary function testing applications.

PFT Mouth Seal Development

To address this need, we designed a silicone mouth seal that slips over the mouthpiece of the GoSpiro® spirometer or most oval PFT filters. This seal surrounds the mouth and has a Velcro® style backing plate. A narrow Velcro® style strap around the back of the patient's head can seal the mouthpiece and prevent leaks

Alex Stenzler is the president of 12th Man Technologies, Inc. He was a Registered Pulmonary Function Technologist and has been working in the field of pulmonary function testing since 1968. He spent half of his career managing Respiratory Care Departments, COPD Clinics and Pulmonary Function Laboratories, or teaching pulmonary function technology as an Assistant Professor at the State University of New York at Stony Brook and twelve years at the Graduate School of Adelphi University. He has been the PI for two NIH and one DARPA grant and has extensive research experience. He has co-authored 18 peer-reviewed papers and one book chapter on pulmonary function testing. He holds 53 patents, most of which are related to pulmonary medicine.

during measurements. Figures 1 to 4 show different views of the mouth seal used with spirometer mouth pieces and PFT filters.

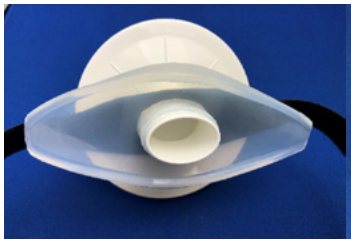


Figure 1

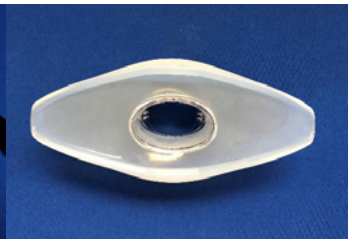


Figure 2

Figure 3

Figure 4

To test the performance of the mouth seal, we had five participants test the mouth seal while performing both Forced Vital Capacity and Slow Vital Capacity measurements. Triplicate measurements were performed without use of the mouth seal (Standard), wearing the mouth seal but the lips tight around the mouthpiece, and wearing the mouth seal, but with the lips intentionally loose around the mouthpiece, which would cause a leak without the seal.

The order of measurements for each participant was randomized. Each participant was limited to three attempts at each configuration. The analysis explored the correlation between measurements using the mouth seal with lips tight or loose and the standard measurement technique separately for Forced and Slow Vital Capacity measurements. Additionally, we explored whether the individual sets of 3 measurements for each participant met ATS/ERS requirements for repeatability.

Results

Thirty (30) measurements of vital capacity (FVC and SVC) were collected with each mouth piece configuration (Standard, Loose, Tight) resulting in a total of ninety (90) measurements. Table 1 below shows a high correlation for all measurements using the mouth seal with standard measurements and R-values ranging from 0.992 to 0.998.

Table 1. Table below shows a high correlation for all measurements using the mouth seal with standard measurements and R-values ranging from 0.992 to 0.998.

	Mean Difference	Correlation R-value
FVC Standard vs Loose	0.098L	0.994
FVC Standard vs Tight	0.096L	0.992
SVC Standard vs Loose	0.172	0.994
SVC Standard vs Tight	0.016	0.998

Table 2. below shows the repeatability of measurements for each configuration. Recognizing that the ATS/ERS standard for repeatability for the largest 2 measurements is 0.150 L, all participants were able to perform measurements that met this standard.

	Repeatability 1st vs 2nd Best	Std Deviation
FVC Standard	0.062 L	0.040 L
FVC Tight	0.090 L	0.060 L
FVC Loose	0.140 L	0.060 L
SVC Standard	0.100 L	0.111 L
SVC Tight	0.052 L	0.031 L
SVC Loose	0.038 L	0.041 L

Discussion

Performing pulmonary function tests in patients who can't seal their lips around a mouthpiece presents laboratory technologists with a challenging situation. While some patients can attain a seal with a "snorkel type" mouthpiece, and some patients can be tested with use of a face sealing mask, particularly for tests of short duration, for some patients or for some procedures, these options are not ideal.

A mouth seal that fits over pulmonary function filters or mouthpieces can solve that problem and enable quality testing in patients where snorkel mouthpieces or masks limit test performance. We explored the use of a mouth seal that provides more flexibility for obtaining a seal and without any increase in dead space to determine if it enabled ATS/ERS repeatable testing. We found that a silicone mouth seal can enable repeatable measurements, meeting ATS/ERS requirements.

Conclusion

We conclude that a mouth seal can be used for performing spirometry in patients who are unable to seal their lips around a mouthpiece without adding external dead space or altering chest wall mechanics.

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Updating Evidence and Defining Aerosol Generation in Respiratory Health OLE Therapies and Procedures: Evaluation of the MetaNeb® and Volara® Systems

The 2019 global SARS-CoV-2 pandemic had profound impacts on healthcare resources and exposed significant gaps in current literature of what is and is not an aerosol generating procedure (AGP) during respiratory health therapies. Early into the pandemic many professional organizations like the American Thoracic Society (ATS), Society of Critical Care Medicine (SCCM), and American College of Chest Physicians (CHEST) warned that certain therapies such as intubation, bronchoscopy, high frequency chest wall oscillation (HFCWO), Oscillation Lung Expansion (OLE), non-invasive positive pressure ventilation (NIPPV) are or may cause dispersion of aerosolized particles, placing healthcare workers at increased risk of infection.[1,2,3]

While intubation and bronchoscopy have been well studied and defined as aerosol generating procedures, HFCWO, OLE, and other routine respiratory health therapies have limited evidence. Some position statements early in the 2019 pandemic from health organizations suggested HFCWO and OLE are an AGP citing studies done during a 2003 SARS outbreak. However, it was hard to substantiate if OLE and HFCWO were true AGPs due to small sample size and design limitations. It is important to note that avoiding HFCWO and OLE therapies is considered a 'weak recommendation' due to low-level evidence.[2] Another issue that complicates this matter is rapid advances in medical device technology, HFCWO and OLE systems are no exception.

Several research papers on aerosol generation during respiratory health therapies have recently been published. Gaeckle et al. (2020) found that some non-invasive therapy modalities themselves did not increase aerosols, rather environmental conditions, individual physiology and specific activities (ex/coughing) seemed to play a bigger role in particle dispersion dynamics.[4] Of course, the mechanism of action within a therapy group can differ from one manufacturer to the next. For this reason, medical device manufacturers can use existing data and laboratory bench tests to measure aerosol dispersion to better inform healthcare workers of their risk when using therapies to treat infectious patients.

Evaluation of the MetaNeb® and Volara™ Systems

An evaluation of OLE systems was conducted at a University Medical Institution. Bench tests were conducted by trained medical staff and mechanical engineers specializing in aerosol research. Four cases applied both the Volara and the MetaNeb systems. For case 4, nebulized aerosol was not introduced via exhalation from the patient simulator, and instead was applied via a nebulizer mimicking nebulization based therapy. (Figure 1)

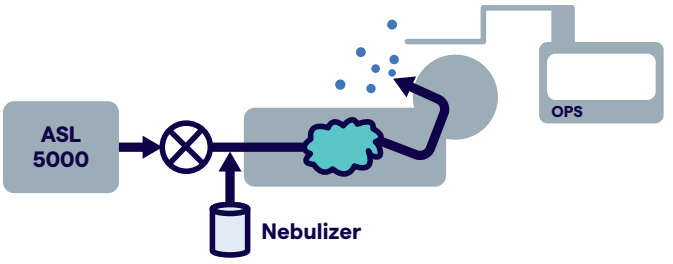

Figure 1. Schematic diagram of the combined breathing simulator-aerosol source-SimMan 3G®.

The bench model utilized an ASL 5000™ breathing simulator, a custom made aerosolization source and a SimMan 3G® patient simulator. Aerosol was generated within the system and was exhaled into the test room during exhalation.

The aerosol dispersion during exhalation simulated that which occurs during spontaneous patient breathing. With the SimMan 3G/Aerosol system in operation, particles were then measured at two locations 11.8 inches and 19.7 inches from the mouth respectively, (Figure 3) within the room (using a TSI optical particle spectrometer (OPS) 3330) to determine the dispersion of aerosol during simulated patient breathing (Figure 1).

After collecting baseline measures, OLE therapy was added to the SimMan 3G/Aerosol system and measurements were repeated with the Volara System and then with the MetaNeb System. Evaluation of aerosol dispersion during therapy was conducted using a number of circuit configurations. Four cases applied both the Volara and the MetaNeb systems. For case 4, nebulized aerosol was not introduced via exhalation from the patient simulator, and instead was applied via a nebulizer mimicking nebulization based therapy. (Figure 1).

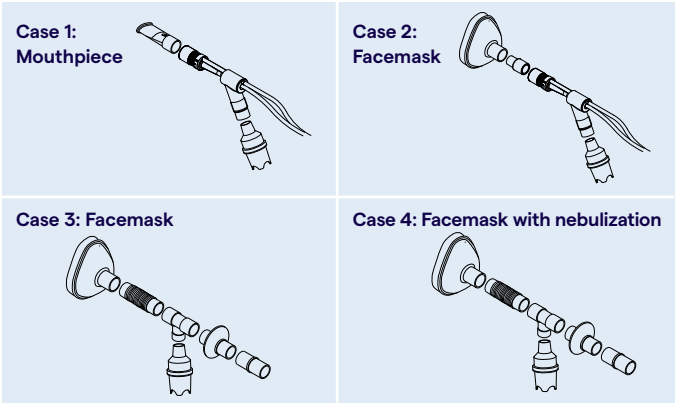

Figure 2. A summary of the four cases applied with both OLE Therapies.

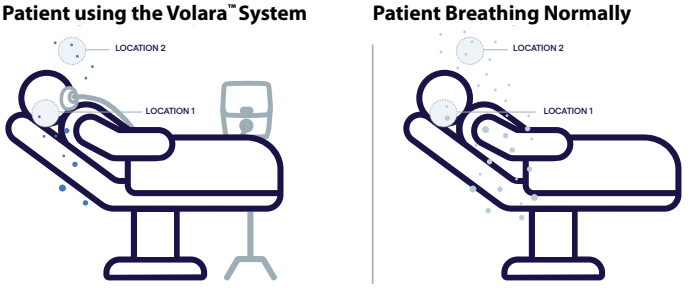

Figure 3. Visual Representation of Exhaled Aerosol Concentration Ratios (OLE Therapy with Volara vs. Normal Unassisted Breathing)

Note: Data drawn from Case 3 of bench test study. Mask was not removed during cough.

Results

Aerosol concentrations were evaluated at selected locations at the patient simulator mouth and at a bedside location. Particle dispersion during therapy with OLE therapy, with either the Volara System or the MetaNeb® System, was generally found to be near or lower than baseline (measurements with simulated patient breathing alone) (Figure 4 & Figure 5). An increase in particles was noted during a simulated cough in both the OLE therapy tests and was also observed during simulated breathing alone. This increase was, in most instances, near the patient cheek. Our study results suggest that application of OLE therapy does not increase aerosol dispersion.

Measuring Aerosol Particles > 0.7 µm: MetaNeb OLE w/HEPA Filter vs. Normal Breathing Patient

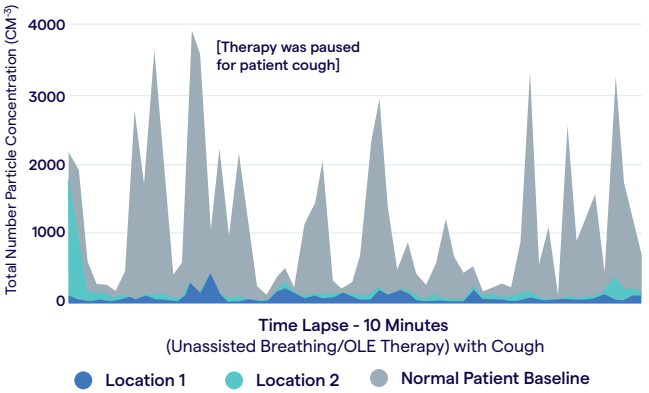

Figure 4. MetaNeb system results from Case 3: face mask with HEPA filter placed in-line.

Measuring Aerosol Particles > 0.7 µm: Volara OLE w/HEPA Filter vs. Normal Breathing Patient

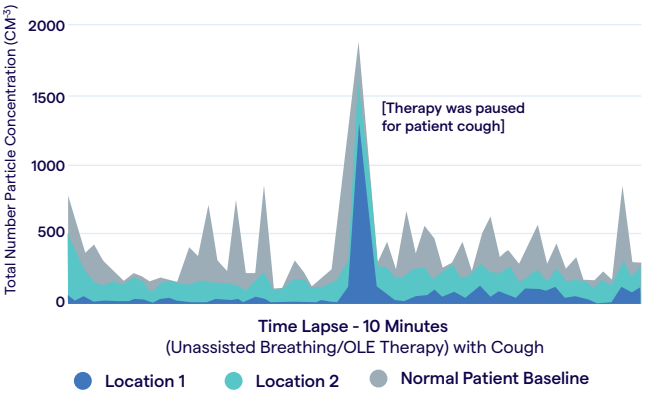

Figure 5. Volara system results from Case 3: face mask with HEPA filter placed in-line.

For more information or to place an order, please contact your local Hillrom sales representative or call Hillrom Customer Service at 1-800-426-4224.

References

1 Pasnick, S. et al. (2020). SARS-CoV-2 Transmission and the Risk of Aerosol-Generating Procedures. Am J Respir Crit Care Med Vol. 202, P13-P14, 2020. https:// doi.org/10.1164/rccm.2024P13

2 Alhazzani, W. et al. (2020) Surviving Sepsis Campaign: Guidelines on the Management of Critically Ill Adults with Coronavirus Disease 2019 (COVID-19), Critical Care Medicine: June 2020 - Volume 48 - Issue 6 - p e440-e469 doi: 10.1097/CCM.0000000000004363.

3 https://www.chestnet.org/Guidelines-and-Resources/COVID-19/Guidelines-and-Statements

4 Gaeckle, N. T., Lee, J., Park, Y., Kreykes, G., Evans, M. D. & Hogan, C. J. (2020). Aerosol Generation from the Respiratory Tract with Various Modes of Oxygen Delivery. American Journal of Respiratory and Critical Care Medicine 202:1115-1124.

Updating Evidence and Defining Aerosol Generation in Respiratory Health NIPPV Therapies and Procedures: An Evaluation of the Life2000® System

Background and Rationale

The 2019 global SARS-CoV-2 pandemic had profound impacts on healthcare resources and exposed significant gaps in current literature of what is and is not an aerosol generating procedure (AGP) during respiratory health therapies. Early into the pandemic many professional organizations like the American Thoracic Society (ATS), Society of Critical Care Medicine (SCCM), and American College of Chest Physicians (CHEST) warned that certain therapies such as intubation, bronchoscopy, high frequency chest wall oscillation (HFCWO), Oscillation Lung Expansion (OLE), non-invasive positive pressure ventilation (NIPPV) are or may cause dispersion of aerosolized particles, placing healthcare workers at increased risk of infection.[1,2,3]

While intubation and bronchoscopy have been well studied and defined as aerosol generating procedures, NIPPV and other routine respiratory health therapies have limited evidence. Some position statements early in the pandemic from health organizations called NIPPV an AGP citing data from a 2003 SARS outbreak in which several healthcare workers may have contracted the virus during NIPPV use on patients. However, this was hard to substantiate due to PPE being used incorrectly. It is important to note that avoiding NIPPV therapies was considered a 'weak recommendation' due to low-level evidence.[2] Another issue that complicates this matter is rapid advances in medical device technology, NIPPV systems are no exception.

Several research papers on aerosol generation during respiratory health therapies have recently been published. Gaeckle et al. (2020) suggested that oxygen modalities: high flow nasal cannula (HFNC) and NIPPV themselves do not increase aerosols, rather environmental conditions, individual physiology and specific activities (ex/coughing) seemed to play a bigger role in particle dispersion dynamics.[4] Of course, the mechanism of action within a therapy group can differ from one manufacturer to the next. For this reason, medical device manufacturers can use existing data and laboratory bench tests to measure aerosol dispersion to better inform healthcare workers of their risk when using therapies to treat infectious patients.

Evaluation of the Life2000 Device

An evaluation of NIPPV using the Life2000 proportional open ventilation (POV) system was conducted at a University Medical Institution. Bench tests were conducted by trained medical staff and mechanical engineers specializing in aerosol research.

The bench model utilized an ASL 5000™ breathing simulator, a custom made aerosolization source and a SimMan 3G patient simulator. Aerosol was generated within the system and was exhaled into the test room during exhalation. The aerosol dispersion during exhalation simulated that which occurs during patient breathing (Figure 1). With the SimMan 3G/Aerosol system in operation, particles were then measured at three locations within the room to determine the dispersion of aerosol during simulated patient breathing, 11.8 inches, 11.8 inches, and 19.7 inches from the mouth, respectively. (Figure 2). After collecting baseline measures, the Life2000 System was added to provide NIPPV support to the SimMan 3G/Aerosol system and measurements were repeated. Evaluation of aerosol dispersion during NIPPV therapy was conducted at a number of different therapeutic settings (Table 1).

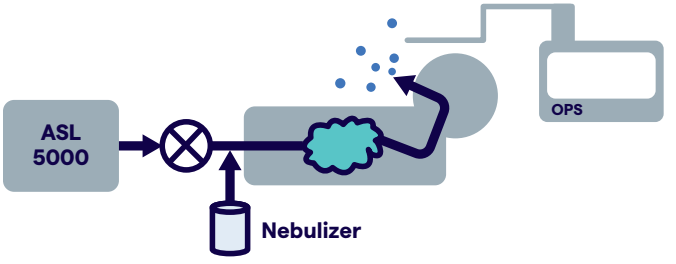

Figure 1. Schematic diagram of the combined breathing simulator-aerosol source-SimMan 3G®.

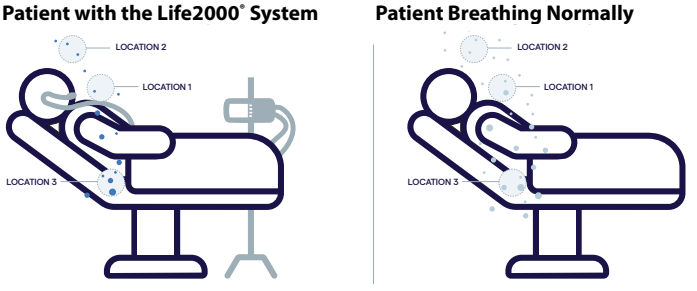

Figure 2. Visual Representation of Exhaled Aerosol Concentration Ratios (Life2000 POV vs. Normal Unassisted Breathing)

Note: Surgical mask was placed in-line with nasal pillows.

Table 1. A summary of Life2000 system settings applied for the 12 cases, with color used to denote the ASL 5000™ settings applied.

TEST CASE SCENARIOS	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8	CASE 9	CASE 10	CASE 11	CASE 12
Volume (mL)	180	180	180	180	230	230	230	230	250	250	250	250
Time (s)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
BR (BPM)	12	25	25	30	12	25	25	30	12	25	25	30
PEEP (cm H_20)	0	3	5	10	0	3	5	10	0	3	5	10

Mild ARDS 12 bpm Mild ARDS 25 bpm Moderate ARDS 30 bpm

Results

When evaluating aerosol concentrations at selected locations within 1 m from the patient simulator mouth and at nasal passages, similar particle dispersion patterns were found during simulation patient breathing alone and with simulation patient breathing with the addition of NIPPV using the Life2000 System. Results suggest that application of Life2000 does not increase aerosol dispersion (Figure 3).

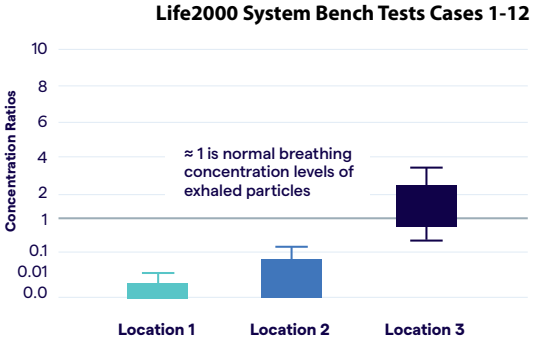

Figure 3. Summary of Life2000 system aerosol bench tests 1-12

For more information or to place an order, please contact your local Hillrom sales representative or call Hillrom Customer Service at 1-800-426-4224.

References

1 Pasnick, S. et al. (2020). SARS-CoV-2 Transmission and the Risk of Aerosol-Generating Procedures. Am J Respir Crit Care Med Vol. 202, P13-P14, 2020. https:// doi.org/10.1164/rccm.2024P13

2 Alhazzani, W. et al. (2020) Surviving Sepsis Campaign: Guidelines on the Management of Critically Ill Adults with Coronavirus Disease 2019 (COVID-19), Critical Care Medicine: June 2020 - Volume 48 - Issue 6 - p e440-e469 doi: 10.1097/CCM.0000000000004363.

3 https://www.chestnet.org/Guidelines-and-Resources/COVID-19/Guidelines-and-Statements

4 Gaeckle, N. T., Lee, J., Park, Y., Kreykes, G., Evans, M. D. & Hogan, C. J. (2020). Aerosol Generation from the Respiratory Tract with Various Modes of Oxygen Delivery. American Journal of Respiratory and Critical Care Medicine 202:1115-1124.

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Noxivent is contraindicated in neonates dependent on right-to-left shunting of blood.

Warnings and Precautions
Rebound: Abrupt discontinuation of Noxivent may lead to worsening oxygenation and increasing pulmonary artery pressure.

Methemoglobinemia: Methemoglobin levels increase with the dose of Noxivent; it can take 8 hours or more before steadystate methemoglobin levels are attained. If methemoglobin levels do not resolve with decrease in dose or discontinuation of Noxivent, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide: Monitor nitrogen dioxide (NO2) levels. Nitrogen dioxide may cause airway inflammation and damage to lung tissue.

Heart Failure: In patients with pre-existing left ventricular dysfunction, Noxivent may increase pulmonary capillary wedge pressure leading to pulmonary edema.

Adverse Reactions

The most common adverse reaction of Noxivent is hypotension.

Drug Interactions

Nitric Oxide donor compounds may increase the risk of developing methemoglobinemia.

Administration

Use only with a calibrated, FDA-cleared NOxBOXi® Nitric Oxide Delivery System (NODS). Refer to the NODS labeling for needed information on training and technical support for users of this drug product with the NODS.

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The Importance of Monitoring SpO_2: Methods, Limitations, and Best Practices

Sydnie Aldrich, Snr. Marketing Communications Specialist, Masimo

SpO_2 Matters

Breathing brings oxygen into the lungs, from where it travels to the rest of the body via the hemoglobin in blood. Maintaining adequate oxygen delivery throughout the body is vital to healthy body function. Oxygen saturation, or SpO_2, is a measure of the percentage of oxygen-carrying hemoglobin in the blood. Without oxygen delivery, hypoxemia (low blood oxygen) and hypoxia (lack of oxygen in tissue) can occur—both of which can be life threatening and cause irreversible harm if not acted upon quickly. That's why measuring SpO_2 can be important when assembling a full picture of a patient's status and assessing care needs.

Pulse oximetry is commonly used to measure SpO_2 levels: it's accurate, noninvasive, and easy to use. Pulse oximeters can either provide continuous monitoring or spot-checking. Both types of measurement are useful, although continuous monitoring offers additional benefits that may help inform clinical assessments.

Know the Difference: Spot-checking vs Continuous Monitoring Spot-checking

Spot-checking SpO_2 provides caretakers with a snapshot of a patient's blood oxygen status at the precise moment the measurement is made. This may be more convenient in situations where a patient may not need continued surveillance, such as with stable, low-acuity, or ambulatory patients. Many spot-check devices are portable and handheld, making them convenient for use on the go. However, through recent innovations, **continuous** monitoring is now available in wireless and tetherless forms that allow patients to ambulate freely while still being monitored—offering the best of both worlds.

Continuous Monitoring

With more data comes the potential for more effective clinical assessment. Continuous monitoring offers trended data and configurable alarms, helping caretakers stay aware of patient progress and providing early indications that further intervention may be needed. Timely warnings or notifications about patient status are key to early intervention, which helps support better patient outcomes. For example, a high-risk, chronic care patient taking one or more medications can experience unexpected adverse events. With continuous monitoring, caretakers have greater visibility of their patient's condition and—with the aid of continuous, high-fidelity data—can make effective clinical judgements and care decisions.

Remote continuous SpO_2 monitoring is growing in popularity. Driven by the COVID-19 pandemic and the need for telemedicine solutions, there is an increased demand for SpO_2 monitoring that conveys trended data from patients convalescing at home to clinicians at the hospital or other off-site locations. Remote monitoring solutions combine continuous SpO_2 measurements with a secure patient surveillance platform, allowing physicians to review a patient's trended data remotely and communicate with them through a secure application in the event a return to the hospital is necessary.

Recommending the Right Pulse Oximeter

Especially when monitoring patients at home, it's important to use a pulse oximetry solution that is light, comfortable, easy to use, durable, and portable—keeping in mind that, as mentioned above, technological advancements have now made it possible to provide the benefits of continuous monitoring in a device that promotes patient comfort and allows freedom of movement as readily as fingertip spot-check devices.

But even when narrowing your selection to pulse oximeters with these *physical* attributes, there are many *technological* differences that separate good pulse oximeters from bad, reliable from unreliable. To maximize the health and safety of patients, be wary of inexpensive, unproven, non-hospital-grade devices that trade a low price for lack of accuracy and reliability—and equally so, avoid smartwatches and other fitness-focused consumer devices that may claim to measure SpO_2 but aren't actually medical devices.

Instead, consider these criteria when recommending a pulse oximeter:

- Pulse oximeters that have received **FDA clearance** for reading (accurately measuring) through **challenging conditions** like patient motion and low perfusion (decreases in arterial blood flow). This is especially important for neonatal patients, who are often prone to involuntary movement. Low perfusion is also common, for example in elderly patients with vascular or cardiac conditions. Many of the cheap fingertip devices found readily online do not have such capabilities, lacking the advanced algorithms and signal processing that allow more sophisticated devices to separate noise from true arterial signal. Unreliable SpO_2 readings under these common

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Sydnie is a healthcare copywriter specializing in noninvasive medical devices. She has been with Masimo for the past two years. Prior to that she worked in supplements and medical foods.

conditions can lead to excessive false alarms and inaccurate data, delayed notifications, and an inability to obtain timely information about high-acuity patients.
- Pulse oximeters whose technology has been validated by a substantive body of **clinical evidence** drawn from objective, peer-reviewed studies.
- Pulse oximeters whose performance has been proven in **hospital** environments, used on the sickest of patients, such as those in the ICU or NICU.
- Pulse oximeters with validated **accuracy specifications** of ±2% or less, even during challenging conditions.
- Pulse oximetry technology which was developed and has been shown to measure accurately on a variety of **skin pigmentations**. Because pulse oximeters depend on the passage of light through the skin, older technologies and those not developed or tested on a variety of pigmentations are often unable to accurately measure the SpO_2 of patients with darker skin tones.

To sum up, it's important to seek out a pulse oximeter that can perform even when the patient is in motion, has cold hands, has darker skin, or in the presence of sunlight.

Another key takeaway: the less direct clinician involvement in a patient's care—the less time a patient spends being actively supervised—the more the patient and caregiver are reliant on the pulse oximeter to do its job accurately and reliably, with timely notifications and alarms when it matters most.

Keys to Success When Measuring SpO_2

Proper patient preparation and sensor application are crucial for obtaining accurate readings. The ideal monitoring site is selected based on the perfusion of the digit or extremity. Perfusion readings are available on some pulse oximeters to help select a site with a strong signal. Before applying a sensor, prepare the monitoring site by making sure the skin is clean and dry.

Pulse oximetry sensors use an emitter to shine light through the application site and measure light that passes through the site using a detector. Upon sensor application, ensure that the optical components (emitter and detector) are aligned. Misapplied sensors or sensors that are not securely placed, with gaps where extraneous light might enter, can lead to inaccurate readings and, in some cases, false alarms. Also, because sensors are designed for specific application sites and patient populations (eg, adult vs pediatric), ensure the appropriate sensor is being used. Proper application can also vary depending on the type of sensor being used; for example, when using a neonatal wrap sensor, it should be spiral-wrapped *down* the digit rather than wrapped around itself to help prevent pressure necrosis and ensure adequate blood flow.

Sensor sites should also be checked periodically, or per clinical protocol, to ensure adequate adhesion, circulation, skin integrity, and correct optical alignment. Remember to be especially cautious in the case of poor perfusion; skin erosion and pressure necrosis can result if a sensor is not moved or readjusted regularly. To maximize sensor life, replacement tapes that replace only the adhesive components of the sensor can be extremely convenient, and make rechecking and readjusting sensor sites relatively simple.

News…continued from page 34
neonatal. Getinge broadens its portfolio of lung-protective tools, including Automatic Stepwise Recruitment maneuver (Auto SRM), a standardized and automated workflow that guides lung recruitment and helps clinicians identify a personalized PEEP that provides the lowest driving pressure, which is a variable strongly associated with patient survival in ARDS1. Stress index and Transpulmonary pressure monitoring, including key parameters for assessment of lung stress during controlled and spontaneous ventilation, complements the lung protective toolkit, which was designed to optimally divide the cognitive workload between the clinician and the ventilator. Additionally, the clearance includes Heliox therapy. Heliox is a mixture of helium and oxygen that facilitates laminar flow and minimizes airway pressure due to its low density. This helps reduce the work of breathing (WoB) of patients suffering from obstructive lung diseases. Getinge also received clearance to introduce the Servo-u MR to the US market, a complement to the Servo Family, expanding Getinge's platform of ventilators into the MRI room. Designed to guide the ventilator into a safe position, the Servo-u MR includes a magnetic field indicator with visual and audible alerts and an auto-lock handle that locks all four wheels as soon as the clinician releases the ventilator. "We are seeing a transformation in the way healthcare providers view respiratory health," said Eric Honroth. "With this clearance, we are excited to be part of driving this transformation, working hand in hand with experts and clinicians." Getinge remains committed to innovation in ventilation platforms. With its rich legacy of firsts, Getinge is proud to bring innovative products and solutions to clinicians through this most recent 510k clearance. The new options and the Servo-u MR ventilator are expected to be available in the US in July 2021.

Masimo Announces FDA Clearance of Radius PCG

Masimo announced that Radius PCG, a portable real-time capnograph with wireless Bluetooth connectivity, has received FDA 510(k) clearance. Radius PCG connects with the Root Patient Monitoring and Connectivity Platform to provide seamless, tetherless mainstream capnography for patients of all ages. Radius PCG joins the growing family of tetherless Masimo technologies that includes Radius PPG, which offers Masimo SET Measure-through Motion and Low Perfusion pulse oximetry, and Radius T, which provides continuous temperature measurements. Radius PCG requires no routine calibration, with accurate end-tidal carbon dioxide ($EtCO_2$) and respiration rate measurements and continuous $EtCO_2$ waveforms displayed within 15 seconds—all in a small, portable package that can fit in the palm of a hand. "Radius PCG has been a game changer for our clinical team," commented Joseph DiMartino, MSN RN, NE-BC, CCRN-K, Associate Vice President of Nursing at Temple University Hospital in Philadelphia. "It provides us with a portable and rapid measure of capnography for confirming airway placement in accordance with AHA guidelines." Wirelessly connected to Root, Radius PCG presents a compelling mainstream capnography solution, offering: *Cable-free Capnography:* High-quality capnography without a tethered connection to Root reduces the possibility of an interruption in capnography monitoring by minimizing tugging on the breathing circuit. In busy operating rooms, where space is already at a premium, and where capnography cables can easily be pulled and dropped on the floor—potentially damaging the fragile and expensive capnography sensor head—the reduction in clutter may be especially welcome. *Automated Documentation:* Root,
Continued on page 61…

Evaluation of the GEM® Premier™ 5000 with iQM®2 at Albert Einstein Israelita Hospital, São Paulo, Brazil

Carlos Eduardo dos Santos Ferreira[1], Adriana Caschera Leme[1], Fernanda Donde Menegat[1], JoAnn Conant[2], Nicki Raymond[2], José Cervera[2]

Introduction

The GEM Premier 5000 with Intelligent Quality Management 2 (iQM2) (Werfen) is a blood gas analyzer providing rapid analysis (29 samples/hour) of heparinized whole blood samples at the point of care or in the lab. Its all-in-one, multi-use GEM cartridge (PAK) contains all components required for quality management and quantitative measurements of blood gas, electrolytes, metabolites, CO-Oximetry and total Bilirubin.

The GEM Premier 5000 system was evaluated at Albert Einstein Hospital and compared to the ABL800 FLEX system (Radiometer) in terms of clinical performance and operational usability.

Methods and Materials

Two hundred and fifty-two de-identified whole blood patient samples were tested on the GEM Premier 5000 system and the ABL800 FLEX, from Oct 4th to Nov 30th, 2017.

For correlation performance, regression analysis was performed for each measured analyte, according to CLSI EP09-A3. Table 1 summarizes the information collected for usability analysis.

Table 1. Methodology for usability assessment

GEM Premier 5000	ABL800 FLEX
Observation Analyzer logs • iQM2 corrective actions • Process Control Solutions • AutoPAK Validation • Sensor performance	**Observation Analyzer logs** • QC (frequency and repeats) • Activity (maintenance, replacements, service)

Results

Clinical performance

Results in Table 2 demonstrate that the GEM Premier 5000 system correlates well with ABL800 FLEX (the reference analyzer). Minor observed differences, due to system-to-system variability, do not impact clinical outcome.

Table 2. GEM Premier 5000/ABL800 FLEX correlation

Analyte	N*	Slope	Regression Coefficient
pH	215	1.124	0.955
pCO_2	215	1.088	0.978
pO_2	214	1.031	0.995
Na^+	215	0.944	0.935
K^+	215	1.125	0.996
Cl^-	215	(98.7%)**	n/a
Ca^{++}	215	1.095	0.978
Glu	214	1.070	0.992
Lac	213	1.059	0.991
tHb	213	0.959	0.998

*Total of 252 samples run. Some samples were excluded due to test exclusion criteria or data-transcription errors.

**A regression evaluation was not possible, due to the limited sample range acquired. Percent of samples inside the total error allowable was calculated. This value should be >95%.

Operational usability

A key requirement for blood gas analyzers utilized in acute care settings is on-demand result reporting. Delays, due to lack of analyzer availability, can impact the quality of care. Factors that can contribute to downtime, including hands-on troubleshooting or maintenance, consumable replacements, instrument service, performance of quality management processes and other manual corrective actions, were analyzed for each system.

During the study, the GEM Premier 5000 used 3 PAKs, while the ABL800 FLEX required replacement of 115 components (Figure 1).

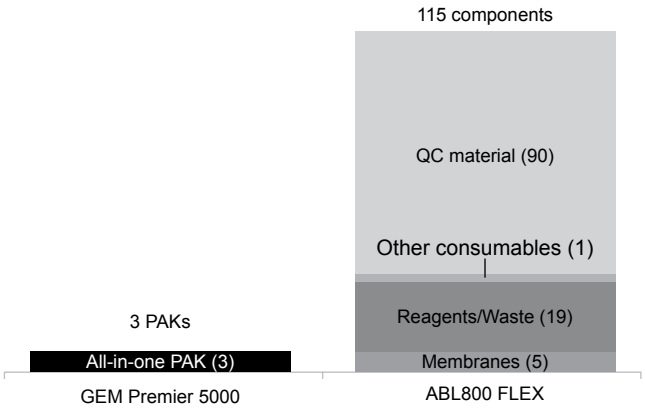

Figure 1. Consumable usage during study

[1]Albert Einstein Israelita Hospital, São Paulo, Brazil; [2]Werfen, Bedford, MA, USA. Presented at the 71st American Association for Clinical Chemistry (AACC) Annual Scientific Meeting and Clinical Lab Expo, August 6th-8th, 2019, Anaheim, CA, USA.

Replacement of the 115 consumables on the ABL800 FLEX required 3.6 hours of operator hands-on management, while the GEM Premier 5000 required 15 minutes to place the 3 GEM PAKs onboard the system (Figure 2).

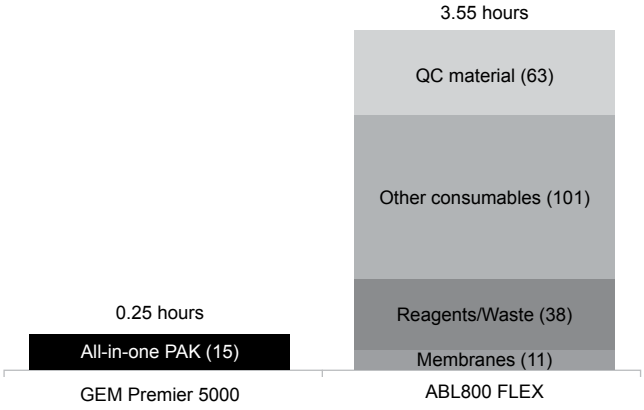

Figure 2. Hands-on replacement and maintenance time (mins)

In total, the ABL800 FLEX was unavailable for patient testing during the study for 15.4 hours, due to consumable replacements, maintenance, error troubleshooting and service. In contrast, the GEM Premier 5000 was unavailable only for 2.82 hours to replace each PAK (3 × 5 minutes) and PAK warm-up time (3 × ~50 minutes). No hands-on maintenance or error troubleshooting is required for operation of the GEM Premier 5000 system (Figure 3).

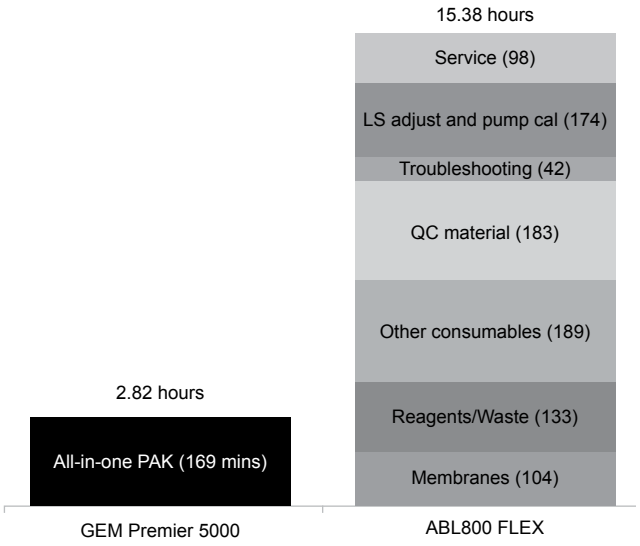

Figure 3. Analyzer unavailability due to component replacement, maintenance, troubleshooting and service

In addition to the operational performance metrics described, the GEM Premier 5000 with iQM2 detected and corrected sample-specific errors in real-time. Specifically, iQM2 performed automated corrective actions for analyte or sample-specific errors: 3 micro-clot patterns in 252 samples, incident rate 1.2%—0.36% of the study duration (cumulative of all 3 GEM PAKs). Actions were automatically documented in the Corrective Action Report.

During the same period, the ABL800 FLEX AutoQC program required repeats in 19% of QC samples with manual troubleshooting in some instances.

Conclusions

The GEM Premier 5000 system with iQM2 demonstrated good analytical performance compared to the ABL800 FLEX. The GEM Premier 5000 system offers marked improvements vs traditional systems in operator usability:

- Easy-to-use, maintenance-free technology enables more efficient blood gas testing
- iQM2 ensures lab-quality results on a single and standardized platform

For more information, contact your local Werfen sales representative or distributor.

Clinical Case: Spinal Muscular Atrophy Type 1 – Vivo 45 LS is a Valid Option for Long-Term Ventilation

Mirella Gaboli, MD, PhD Macarena Borrero Rodríguez, DUE Seville (Spain)

A five-day old newborn with a normal pregnancy but, with decreased foetal movements in the last week of pregnancy was admitted for assessment. Apgar test results were 9/10/10 at birth, and no resuscitation was required. The parents reported hypotonia since birth. Key features on examination were, soft cry, severe hypotonia and poor spontaneous movement, poor feeding with a low weight. Paradoxical breathing with a respiratory rate 70-78 breaths per minute.

At Day14, genetic results confirmed the clinical suspicion of spinal muscular atrophy (SMA) presenting during the neonatal period and the child was diagnosed with SMA type 1.

SMA is a genetically determined, congenital neuromuscular disorder, which presents with the progressive deterioration of the motor neurons in the anterior horn cells of the spinal cord. This leads to progressive muscle wasting including the respiratory muscles. SMA is classified on a functional scale. Type 1 are unable to sit unaided, type 2 are unable to walk unaided and type 3 who can walk unaided. Within the types there is a wide range of weakness. SMA type 1 is the severest form and therefore has the poorest prognosis due to the severe involvement of the respiratory muscles. Those patients that present with respiratory symptoms at birth or close to birth are classified further as SMA type 1a. In recent years, there are some treatments that can change the natural course of the disease but the effect on the bulbar and respiratory symptoms are not fully known. It is for this reason that, despite new medications, ventilation, preferably non-invasive, remains an essential support for these children with SMA type 1.

Due to the severe hypotonia and the bulbar involvement. Non-invasive ventilation (NIV) was indicated to alleviate the symptoms of breathing difficulties, maintain a more stable airway, prevent pectus excavatum, facilitate the drainage of secretions and slow down the progress of the disease to terminal respiratory failure in addition to other therapies previously highlighted.

This patient with SMA type 1a, was offered NIV. However, there were several different challenges:

1) The patient's weight means limited licenced ventilators
2) The patient's high respiratory rate, which results in very short inspiration times
3) The need for very high inspiration and expiration sensitivity to enable in spontaneous triggering
4) High daily usage due to sleep wake pattern of infants.
5) Finally, it would be desirable if the equipment was small, light and resistant.

Table 1. Initiation of NIV with Vivo 45 LS

Ventilation mode	PCV(A+TgV)
Target Volume	50 ml
Breath Rate	40 bpm
Maximum inspiratory pressure	14 cmH2O
Minimum inspiratory pressure	10 cmH2O
PEEP	6 cmH2O
Inspiratory trigger	1
Rise time	2

During sleep the Vivo 45 LS was used with a nasal mask and a 15 mm passive circuit with active humidification. At that time the total RR was around 38-40 and each breath had an estimated Vt of around 40-45 ml. When awake spontaneous triggering was around 30-60% and asynchrony was only present during

Table 2. The course of some of the clinical parameters

	Chest circumference (cm)	Head circumference (cm)	Chest/head circumference	SpO2 (%)	PVCO2	EtCO2	Median HR (beats per minute)	Median RR (breaths per minute)
Day 1 of NIV	30.5	34	0.897	98	50	48	140	70
Day 10 of NIV	32	34.5	0.927	99	47	44	130	60
Day 40 of NIV	37	37	1	100	42	42	120	40

periods of tachypnoea (RR 90bpm). The patient was generally comfortable when sleeping and with SpO2 100% without supplementary oxygen and normal transcutaneous carbon dioxide levels (TcCO2 42 mmHg).

"the sensitivity of the triggers, and the precise measuring systems facilitate the adaptation of the ventilator to the child"

At two months, the patient was discharged home with the Vivo 45 LS, using it for 12 hours a day. However, during the first month at home, the patient was readmitted due to increased bulbar symptoms such as difficulties in swallowing and laryngospasm leading to a respiratory tract infection. On admission, NIV continued with oxygen entrained. The Vivo 45 LS settings were changed, RR increased to 60 bpm and maximum inspiratory pressure to 30cmH2O to achieve the same Vt. However, due to the progressive hypoxaemia and the instability of the airway, the patient required intubation and ventilation. After 21 days of IMV and two failed attempts of extubation, the decision was made to perform a tracheotomy and continue with invasive home mechanical ventilation.

At four months old, the Vivo 45 LS settings were further modified. Current average usage was 18 hours per day. Taking advantage of the programable profiles, three profiles were set: Profile 1, aimed at supportive awake ventilation was pressure support ventilation with target volume (PSV(TgV)). Profile 2, aimed for ventilatory support whilst sleeping and was set to pressure control with target volume (PCV(TgV)). Profile 3, aimed to be used when nebulising was assisted pressure control ventilation PCV(A). All profiles had disconnection and rebreathing alarms set. The family was instructed on how to change from one profile to the other and were given instructions on how and when to use each profile.

The patient remained stable during the following months. When the patient reached the age of one, they continued with invasive respiratory support on average of 10-12 hours a day. Settings were adjusted, in accordance with the patient's change in weight and respiratory pattern being his spontaneous respiratory rate much lower and his respiratory effort more effective. Further adjustments were made but, by 1 year old the child used pressure support mode and only required assist control mode when unwell or extremely fatigued.

Discussion

In infants, the available technology is limited and adapting a ventilator to a small child, both in invasive and non-invasive ventilation, can be challenging. The most significant problem is asynchrony: the device needs to have a high sensitivity of the inspiratory and expiratory triggers to allow synchronisation at high respiratory rates. It is technically challenging to support breathing in a child whose respiratory rate is greater than 40 bpm. Short inspiratory times, in very young children, are often insufficient to activate the inspiratory trigger and do not cycle into expiration appropriately. Also if the trigger is very sensitive it can be activated by any small movement in the circuit (e.g. water), causing auto-triggering and ineffective breathing. To eliminate asynchrony, we used a 15mm active circuit, with a higher back-up respiratory rate and an appropriate Target Volume for the patient. In our case, during an initial period of non-invasive respiratory support in a patient with estimated tidal volume less than 50 ml, the use of a PCV(A+TgV) mode allowed two inspiratory pressure levels to be programmed, which, at times of increased resistance in the airway, enabled ventilation to remain more or less uniform at the expense of small variations in inspiratory pressure.

Secondly, due to the progression of the natural history of the illness, it was necessary to initiate prolonged invasive ventilation, by tracheostomy. Ventilators need to have appropriate modes and alarms for life support. In this case, the presence of fewer leaks, the sensitivity of the triggers, and the precise measuring systems facilitate the adaptation of the ventilator to the child, thus allowing the use of a support mode, PSV(TgV), which is more suited to the spontaneous breathing pattern of the child. All of this possible with the same ventilator the Vivo 45 LS.

Conclusions

In very young children it is essential that a ventilator has the ability to use different circuits, very sensitive inspiratory and expiratory triggers, the possibility to cope with a high respiratory rate (>60 bpm) and the possibility of ensuring a tidal volume of 50 ml. If the progress of the disease results in the need for invasive ventilation, as in the case presented, the possibility of using the same equipment, with multiple programable profiles and with different ventilation modes facilitates the process of adaptation to prolonged respiratory support at home.

Non-Invasive Ventilation with the Vortran GO2VENT During Covid-19: Case Studies of Successes and Failures

Hugo Ricardo Espejo, MD, Dave E Swift, RRT

Objective

In 2020, the COVID-19 pandemic quickly overwhelmed hospital resources around the world. Hospitals including Hospital del IESS Quito Sur in Quito, Ecuador began using the VORTRAN GO_2VENT to supplement a limited supply of mechanical ventilators by providing patients with non-invasive ventilatory support using a full face mask in order to avoid the complications associated with intubation.

Methods

Data were collected for 350 COVID-19 patients who received ventilatory support from the GO_2VENT at Hospital del IESS Quito Sur. The patients were fitted with a non-vented bilevel/CPAP full face mask and connected to the GO_2VENT for a duration of 4 hours. The data collected included vitals, such as heart rate, blood pressure, and respiratory rate, as well as a blood gas analysis. The ROX Index, RASS score, and HACOR score were further used to document the patients' tolerance to the GO_2VENT.

Results

This case study focuses on 4 patients with varying experiences. Patient 1 saw an overall increase in ROX score and made a full recovery after 10 days of care. Patient 2 saw a moderate decrease in ROX score, indicating the need to transfer the patient to mechanical ventilation, which eventually led to death. Patient 3 saw very low ROX scores, which served as a predictor for the patient's severe condition, which eventually led to death. Patient 4 experienced lessening degrees of respiratory distress when on the GO_2VENT and was eventually transferred to a high flow oxygen mask.

Conclusion

The developed protocol proved useful in directing each patient to the proper treatment limb based on their ROX scores, HACOR scores, and ABG analyses. While the GO_2VENT performed its role sufficiently when used non-invasively, some patients with declining ROX scores required a higher level of support via intubation and mechanical ventilation. The protocol can be used as a predictor to determine which patients will benefit from the GO_2VENT, avoiding the complications associated with mechanical ventilation.

Background

Hospital del IESS Quito Sur, one of Ecuador's newest hospitals, opened in December 2017 as a 450 bed (increased to 700 beds during the pandemic) secondary and referral hospital. Starting on February 26, 2020, Dr. Hugo Espejo (the Deputy Director of Critical Care Medicine of the hospital) was faced with managing the quickly evolving COVID-19 outbreak. The Ecuadorian government had predicted an eight-fold increase in fatalities[1] and demand for critical care services. The numbers quickly exceeded these predictions and created a significant shortfall in available mechanical ventilators.

The Quito Sur medical team utilized conventional therapies to manage the rapid influx of COVID-19 patients, but the numbers of critically ill patients soon overwhelmed existing resources. The hospital had purchased GO_2VENT disposable ventilators (VORTRAN Medical[2]) and decided to put them into use providing non-invasive support using non-vented bilevel/CPAP full face masks to avoid patient deterioration to the point of needing mechanical ventilation. Faced with these challenges, Dr. Espejo developed the GO_2VENT COVID-19 Non-invasive Protocol to address their needs.

The protocol considers initial assessment at triage, oxygen saturations, oxygen requirements (utilized in ROX scoring[3]) and arterial blood gases to direct the patient into a treatment limb. Using the HACOR[4] score and P/F ratio, the patient's placement in the protocol was further refined.

ROX Index

The ROX Index is calculated at triage and each hour (ROX Index score = $[SpO_2/FiO_2]$/breath rate). An increasing score reflects success, while a declining score reflects continued decline requiring more aggressive support. A score of ≤4 reflects the need for mechanical ventilation.

HACOR Score

The HACOR score is used once arterial blood gases are drawn. Higher scores are used to predict probable failure in the therapy currently being utilized. A total possible score of 25 points is available. At the 1-hour mark, the score is calculated. A HACOR score of >5 is indicative of probable failure which requires a

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review of the current therapy to prevent deterioration that leads to mechanical ventilation.

Table 1. HACOR Score

Variables	Category	Points
Heart Rate (BPM)	≤120	0
	≥121	1
pH (ABG)	≥7.35	0
	7.30-7.34	2
	7.25-7.29	3
	<7.25	4
Glasgow Coma Scale (GCS)	15	0
	13-14	2
	11-12	5
	≤10	10
PaO_2/FiO_2	≥201	0
	176-200	2
	151-175	3
	126-150	4
	101-125	5
	≤100	6
Respiratory Rate (BPM)	≤30	0
	31-35	1
	36-40	2
	41-45	3
	≥46	4

RASS Scale

The Richmond Agitation-Sedation Scale is a medical scale used to measure sedation effectiveness in patients.[5] Pharmacologic agents are utilized to maintain a RASS score between 0 and 1 while the patient is on the GO_2VENT during non-invasive support, while lower scores are maintained before facilitating mechanical ventilation.

Table 2. RASS Scale

Patient Description	RASS Score
Combative	+4
Very agitated	+3
Agitated	+2
Restless	+1
Alert and calm	0
Drowsy	-1
Light sedation	-2
Moderate sedation	-3
Deep sedation	-4
Unarousable sedation	-5

Case Studies: A total of 350 patients' data were documented as part of the development of the protocol to support the effective use of the GO_2VENT in a non-invasive application. Four patients were chosen for this case study to highlight the successes and failures encountered during the development of the protocol.

During use of the GO_2VENT, the flowmeter is adjusted to supply the device with 30-40 LPM when the entrainment knob is set to 100% FiO_2 (which supplies the patient with the flow indicated on the flowmeter), and 15 LPM when the entrainment knob is set to 50% FiO_2 (which supplies the patient with a combined flow of approximately 40 LPM).

In all cases, the GO_2VENT was set to "assist mode." This mode is intended for patients who are still exerting their own respiratory efforts and will provide them with breathing support. No timed breaths are delivered, as the breath rate depends on the patients' own breathing efforts. To set the GO_2VENT into assist mode, the rate knob is dialed clockwise until it does not automatically cycle but rather triggers when the patient exhales. If more resistance is required to slow down the patients' exhalation, the rate knob can be dialed clockwise even further as needed.

Patient 1

Patient Background: A 54-year-old male was presented to the hospital with COVID-19 symptoms.

Triage Conditions:
- Heart Rate: 120 BPM
- Blood Pressure: 171/85 mm-Hg
- Respiratory Rate: 28 BPM
- O_2 Saturation: 40%
- ROX Score: 6.8

Treatment was initiated immediately by placing the patient on the GO_2VENT with the rate control knob turned into assist mode (no timed breaths delivered, all are spontaneously triggered). The pressure knob was set to approximately 20 cm-H_2O and FiO_2 was set to the 50% setting. Pulse was observed to drop to 105 BPM, blood pressure to 127/82 mm-Hg, respiratory rate to 22 BPM, and an oxygen saturation of 95%. An arterial blood gas sample was immediately drawn resulting in:
- pH: 7.50
- $PaCO_2$: 29.6 mm-Hg
- PaO_2: 74 mm-Hg

Condition at 1 Hour: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 96 BPM
- Blood Pressure: 140/93 mm-Hg
- Respiratory Rate: 20 BPM
- O_2 Saturation: 98%
- pH: 7.47
- $PaCO_2$: 32.4 mm-Hg
- PaO_2: 137.5 mm-Hg
- ROX Score: 9.8

Condition at 2 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 102 BPM
- Blood Pressure: 122/78 mm-Hg
- Respiratory Rate: 25 BPM
- O_2 Saturation: 97%
- ROX Score: 7.8

Condition at 3 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 98 BPM
- Blood Pressure: 129/84 mm-Hg
- Respiratory Rate: 24 BPM
- O_2 Saturation: 96%
- pH: 7.48
- $PaCO_2$: 31.7 mm-Hg
- PaO_2: 91.1 mm-Hg
- ROX Score: 8.0

Condition at 4 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 98 BPM
- Blood Pressure: 126/77 mm-Hg
- Respiratory Rate: 22 BPM
- O_2 Saturation: 96%
- ROX Score: 8.7

The patient was admitted to a medical floor after being removed from the GO_2VENT and recovered before being discharged after 10 days.

Patient 2

Patient Background: A 54-year-old male was presented to the hospital with COVID-19 symptoms.

Triage Conditions:
- Heart Rate: 120 BPM
- Blood Pressure: 152/80 mm-Hg
- Respiratory Rate: 28 BPM
- O_2 Saturation: 76%
- ROX Score: 12.9

Treatment was initiated immediately by placing the patient on the GO_2VENT with the rate control knob turned into assist mode. The pressure knob was set to approximately 20 cm-H_2O and FiO_2 was set to 100%. Pulse was observed to drop to 109 BPM, blood pressure to 132/85 mm-Hg, and respiratory rate to 31 BPM, and an oxygen saturation of 94%. An arterial blood gas sample was immediately drawn resulting in:
- pH: 7.45
- $PaCO_2$: 27 mm-Hg
- PaO_2: 57 mm-Hg

Condition at 1 Hour: The GO_2VENT's FiO_2 was reduced to 50%.
- Heart Rate: 107 BPM
- Blood Pressure: 147/85 mm-Hg
- Respiratory Rate: 32 BPM
- O_2 Saturation: 94%
- pH: 7.36
- $PaCO_2$: 36 mm-Hg
- PaO_2: 96.5 mm-Hg
- ROX Score: 5.9

Condition at 2 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 109 BPM
- Blood Pressure: 154/77 mm-Hg
- Respiratory Rate: 34 BPM
- O_2 Saturation: 92%
- ROX Score: 5.4 (declining)

Condition at 3 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 98 BPM
- Blood Pressure: 142/80 mm-Hg
- Respiratory Rate: 34 BPM
- O_2 Saturation: 92%
- pH: 7.36
- $PaCO_2$: 36 mm-Hg
- PaO_2: 85.3 mm-Hg
- ROX Score: 5.4

Condition at 4 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 99 BPM
- Blood Pressure: 142/80 mm-Hg
- Respiratory Rate: 34 BPM
- O_2 Saturation: 94%
- ROX Score: 5.5

The patient was transferred to the ICU for closer monitoring and mechanical ventilation via intubation. 17 days after being transferred, the patient suffered respiratory failure and died.

Patient 3

Patient Background: A 64-year-old male was presented to the hospital with COVID-19 symptoms.

Triage Conditions:
- Heart Rate: 116 BPM
- Blood Pressure: 112/70 mm-Hg
- Respiratory Rate: 33 BPM
- O_2 Saturation: 40%
- ROX Score: 5.8

Treatment was initiated immediately by placing the patient on the GO_2VENT with the rate control knob turned into assist mode. The pressure knob was set to approximately 30 cm-H_2O and FiO_2 was set to the 100% setting. Pulse was observed to drop to 97 BPM, blood pressure to 101/67 mm-Hg, respiratory rate to 38 BPM, and oxygen saturation of 85%. An arterial blood gas sample was immediately drawn resulting in:
- pH: 7.37
- $PaCO_2$: 26.8 mm-Hg
- PaO_2: 72.5 mm-Hg

Condition at 1 Hour: The GO_2VENT's pressure knob was adjusted to approximately 20 cm-H_2O.
- Heart Rate: 89 BPM
- Blood Pressure: 115/79 mm-Hg
- Respiratory Rate: 36 BPM
- O_2 Saturation: 93%
- pH: 7.37
- $PaCO_2$: 24.3 mm-Hg
- PaO_2: 82.9 mm-Hg
- ROX Score: 2.6 (rapid decline)

Condition at 2 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 102 BPM
- Blood Pressure: 112/77 mm-Hg
- Respiratory Rate: 36 BPM
- O_2 Saturation: 91%
- ROX Score: 2.5

Condition at 3 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 92 BPM
- Blood Pressure: 127/69 mm-Hg
- Respiratory Rate: 30 BPM
- O_2 Saturation: 96%
- pH: 7.37
- $PaCO_2$: 29.8 mm-Hg
- PaO_2: 115.4 mm-Hg
- ROX Score: 3.2

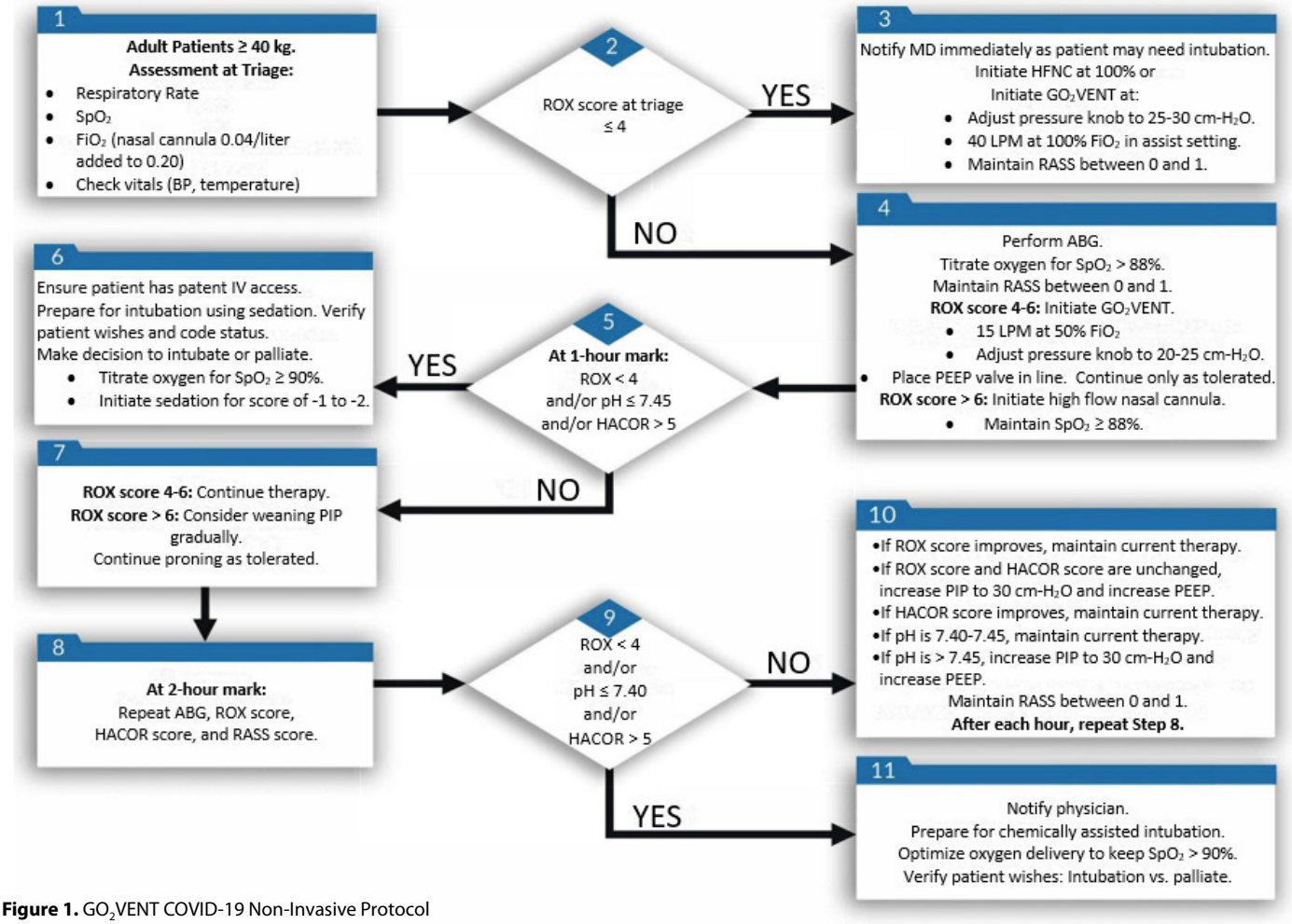

Figure 1. GO_2VENT COVID-19 Non-Invasive Protocol

Condition at 4 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 87 BPM
- Blood Pressure: 121/85 mm-Hg
- Respiratory Rate: 28 BPM
- O_2 Saturation: 95%
- ROX Score: 3.4

Discussions were held with the family surrounding goals of care to clarify that the patient was not a candidate for mechanical ventilation, but aggressive medical treatment would continue.

Despite medical recommendations, the patient was intubated. After 12 days of mechanical ventilation, the patient suffered a cardiopulmonary arrest. The patient did not respond to resuscitative efforts and died.

Patient 4

Patient Background: A 71-year-old male was presented to the hospital with COVID-19 symptoms.

Triage Conditions:
- Heart Rate: 104 BPM
- Blood Pressure: 110/63 mm-Hg
- Respiratory Rate: 20 BPM
- O_2 Saturation: 70%
- ROX Score: 16.7

Treatment was initiated immediately by placing the patient on the GO_2VENT with the rate control knob turned into assist mode. The pressure knob was set to approximately 30 cm-H_2O and FiO_2 was set to the 50% setting. Pulse was observed to drop to 86 BPM, respiratory rate to 30 BPM, and oxygen saturation of 88%. Blood pressure remained at 110/63. An arterial blood gas sample was immediately drawn resulting in:
- pH: 7.49
- $PaCO_2$: 28.2
- PaO_2: 52.4

Condition at 1 Hour: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 74 BPM
- Blood Pressure: 110/70 mm-Hg
- Respiratory Rate: 30 BPM
- O_2 Saturation: 93%
- pH: 7.42
- $PaCO_2$: 35.6 mm-Hg
- PaO_2: 121.4 mm-Hg
- ROX Score: 6.2

Condition at 2 Hours: The patient remained on the GO_2VENT with the established settings.
- Heart Rate: 73 BPM
- Blood Pressure: 119/77 mm-Hg
- Respiratory Rate: 30 BPM
- O_2 Saturation: 96%
- ROX Score: 6.4

Condition at 3 Hours: The patient remained on the GO_2VENT with the established settings.

- Heart Rate: 68 BPM
- Blood Pressure: 104/73 mm-Hg
- Respiratory Rate: 26 BPM
- O_2 Saturation: 97%
- pH: 7.34
- $PaCO_2$: 46 mm-Hg
- PaO_2: 127.6 mm-Hg
- ROX Score: 7.5

Condition at 4 Hours: The patient remained on the GO_2VENT, and the flow was reduced to 15 LPM.

- Heart Rate: 60 BPM
- Blood Pressure: 100/75
- Respiratory Rate: 26 BPM
- O_2 Saturation: 95%
- ROX Score: 7.3

The patient was transitioned to an oxygen mask at 50% FiO_2 and transferred to the in-patient medical ward.

Discussion

The use of the GO_2VENT to provide respiratory assistance in a non-invasive mode, coupled with the developed protocol (Figure 1), provides an effective COVID-19 response in a resource-challenged environment to effectively predict outcomes, sustain patients, and guide clinicians in making treatment decisions. The ROX score provided a demonstrably accurate prediction of the success or failure of the use of the GO_2VENT in its non-invasive mode and allowed clinicians to direct the treatment of the patient into the options of the conventional mechanical ventilation treatment arm, continuing to provide noninvasive support, or transfer the patient to comfort care.

Knowing the documented outcomes associated with mechanical ventilation of the COVID-19 patients encouraged clinicians to use the GO_2VENT in higher support settings (higher PIP and PEEP) to avoid intubations.

When using the protocol, the ROX score is recalculated, along with the HACOR score and arterial blood gas analysis, to direct the clinician to adjust the GO_2VENT or transfer the patient to a different mode of ventilation as needed. Declining ROX scores will eventually lead to a determination of mechanically ventilating the patient, while increasing ROX scores to greater than 6 leads to a justification for weaning the patient off the GO_2VENT.

The use of the COVID-19 non-invasive protocol allows for more judicial use of scarce resources while providing effective support of COVID-19 patients and avoiding the effects associated with intubation and mechanical ventilation.

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The Case for Early Intervention for Excess Sputum in COPD

Gary Hansen, PhD

Since the growth of awareness of bronchiectasis (BE) in the late 1980s, the relationship between chronic obstructive pulmonary disease (COPD) and BE has been elusive. While early studies did not often find an association between COPD and BE,[2] later research increasingly began to describe COPD as a possible etiology of BE.[3] Estimates for the prevalence of COPD within BE varied from 12%[2] to 20%,[4] suggesting a stronger association than was previously known. Conversely, BE was found to be highly prevalent in patients with COPD. In 2013, Martinez-Garcia showed that about half of moderate-severe COPD patients also have BE[5], with the best recent estimate from a meta-analysis at 54.3%.[6] It is established that the presence of BE worsens the clinical and quality of life outcomes of COPD patients.[7]

> "Early detection, diagnosis, and maintenance treatment of COPD, alongside smoking cessation and exercise, may help to provide the best symptom control, disease progression, and outcomes in COPD." —Soriano et al, 2018[8]

However, correlation is not causality. While these diseases are clearly associated with one another and might represent a "COPD/BE Overlap Syndrome",[9] whether COPD is a "cause" of BE has not been firmly established. If symptomatic COPD naturally evolves into BE, it builds support for Cole's "vicious cycle" hypothesis[10] and creates urgency for early treatment of symptoms. Below we will introduce new research that reports just such a progression. Since COPD is estimated to cause over 15 million exacerbations yearly and over $5 billion in direct medical costs,[11] early interventions have the strong potential to improve patient care and lower healthcare costs.[12]

This educational information offers general coverage, coding and payment information for procedures associated with use of HFCWO, which is indicated when external manipulation of the chest is the prescribed treatment to increase the clearance of mucus in patients with pulmonary disorders. This is not legal guidance, nor is it advice about how to code, complete, or submit any particular claim for payment. It is always the provider's responsibility to determine coverage and submit appropriate codes and charges for services rendered. This is based on the medical necessity of the services and supplies provided, the requirements of insurance carriers and any other third-party payers, and any local, state or federal laws that apply to the products and services rendered. Given the rapid and constant change in public and private reimbursement, we cannot guarantee the accuracy or timeliness of this information. Gary Hansen is the Director of Scientific Affairs, Respiratory Technologies, Inc. dba RespirTech, a Philips Company.

Key Points

- COPD is a progressive disease
- Disease progression accelerates with time
- New research findings support the idea that COPD progresses into bronchiectasis
- Bronchiectasis increases the risk of exacerbations and death
- Sputum is a key risk factor for the progression to bronchiectasis

COPD is a progressive disease

COPD is a progressive disease, characterized by chronic airflow obstruction that may sometimes be arrested but not reversed.[13] There is a long preclinical period, perhaps decades-long, before the beginning of actual lung function decline.[14] Once COPD is diagnosed and the loss of lung function begins to accelerate, it is sensible to intervene early before severe and permanent lung damage occurs.[15]

> "To have an impact on the natural history of COPD, it is logical to look at the effects of treatment in the earlier stages." —Lange et al., 2021

The opportunity is large, as the majority of diagnosable COPD cases are in the early stages of the disease. A recent study found that mild COPD accounted for 56% of all patients diagnosed with COPD, and it is important to note that 73% of subjects with COPD remained undiagnosed.[16]

Disease progression accelerates with time

The downward progression of COPD is not consistent, but is characterized by periodic exacerbations, defined as an acute worsening of symptoms that frequently results in hospitalization.[17] There is evidence that exacerbations are more frequent in patients with chronic sputum production,[18] with excess sputum production associated with Forced Expiratory Volume (FEV1) decline[18] and mortality.[19] The focus of treatment becomes managing exacerbations through the treatment of symptoms.[20] Early research showed that exacerbations are not randomly distributed, but rather occur in clusters: after each exacerbation is a high-risk period when another exacerbation is more likely to occur[21] One study found that 20% of patients experience an urgent relapse within 14 days of the last exacerbation.[22] A landmark paper by Suissa[23] determined that COPD exacerbations are more frequent and more severe

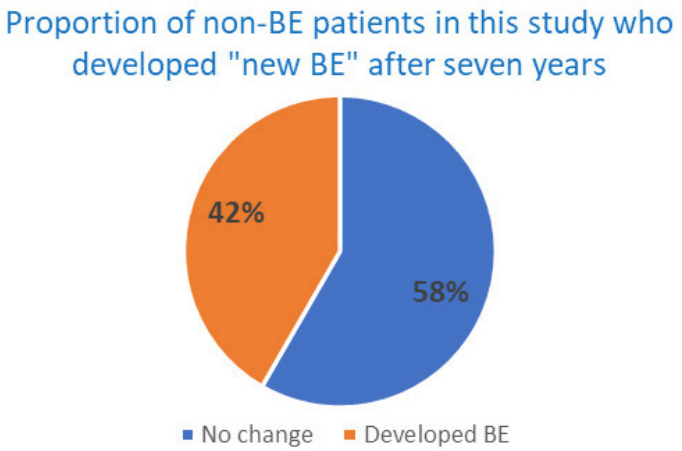

Figure 1. In patients who started with no sign of BE, the proportion who developed BE after seven years compared with the proportion of those who did not. Adapted from Martinez-Garcia et al., 2021.1

after each occurrence. He found a clear pattern where the time between exacerbations decreased for each subsequent exacerbation experienced: the risk of an additional occurrence of a severe exacerbation increased three times after the first exacerbation, and 24 times after the tenth. This finding, along with more recent evidence described below, strongly suggests that addressing early exacerbations is critical to arresting the downward course of the disease.

New evidence that COPD Progresses to BE

A new study by Martinez-Garcia sheds new light on this significant clinical issue.[1] These clinician-scientists have established for the first time that COPD can often progress to BE.[1] In this tour de force study, 201 patients with COPD were assessed for BE, followed for seven years, and then reassessed. By the seventh year, of those who started with BE, 32% were worse; of those who started the study period without BE, 42% went on to develop BE. 73% of all patients who finished the study had BE at the end of the seventh year, compared to only 53% at the start (Figure 1). Moreover, the presence of purulent sputum was the primary independent risk factor, with the development of BE 2.8 times more likely than in patients without sputum. The authors concluded that BE should be detected as early as possible and the main risk factor, purulent sputum, should be addressed to prevent or slow the progression to BE.

> "There has thus been compelling evidence for the relationship between the presence of persistent symptoms and subsequent development of COPD." —Stockley 2021[24]

The critical impact of excess sputum production in the development of BE has been confirmed by Zhang in a recent meta-analysis.[25] The combined results of eight studies showed a highly significant relationship: the presence of purulent mucus sputum increases the risk of developing BE by 7.17 times.

The dangerous combination of BE and COPD

Numerous converging lines of evidence indicate that the combination of BE and COPD adds substantial risk compared to either disease separately, and a heavy symptomatic burden is common in both BE and COPD patients.[26] By analyzing a large commercial claims database (Truven Marketscan), Seifer and colleagues reported the risks of having comorbid COPD and BE compared to having COPD alone.[27] They showed that BE+COPD patients were hospitalized 2.4 times more frequently, had 2.6 times more hospital days, and 2.5 times the total healthcare expenses. To complement this finding, poorer health indicators and higher healthcare utilization were also reported in an analysis of US Medicare enrollees.[28] Another study found that the mortality rate more than doubled after five years in patients with BE+COPD, rising to 55%, compared with 20% in those with bronchiectasis without COPD.[29] A meta-analysis of existing data confirms these findings.[7] These results underscore the substantial risk of comorbid BE+COPD compared to COPD alone: almost two times the risk for exacerbations, over four times the risk for colonization of the lungs, a 30% higher risk of severe airway obstruction, and almost double the risk of death. Collectively, these studies show that the dramatic impact of comorbid BE+COPD is considerably worse than COPD by itself.

Sputum production is a key risk factor for the progression to BE

One common factor in both COPD and BE is the presence of a chronic cough with excess sputum production. These symptoms in persons with COPD are associated with negative patient outcomes such as severe airflow obstruction, limited quality of life, a higher rate of hospitalization, and early mortality.[19,30-34] In such cases. retained secretions can block the normal mechanisms of airway clearance forming a reservoir of infection and inflammation within the lungs, particularly for antibiotic-resistant pathogens.[35]

> "The increased propensity for mucus retention, recurrent inflammation, and infection damage conducting airways and inhibit restoration of mucociliary function." —Volsko et al., 2013[36]

The impact of chronic sputum production is heavy for both COPD and BE,[37] so high that a new study has found that the symptomatic burden is indistinguishable.[26] In general, patients with excess sputum production are more symptomatic, have more episodes of exacerbation, and suffer chronic bronchial infections more often than those who do not.[5,9,38]

Excess sputum production needs to be treated with airway clearance

Purulent sputum is destructive and is an important factor in disease progression.[39] Pharmaceutical treatments exist for COPD that focus on improving FEV1, dyspnea, and exacerbations, but there are limited options specifically for sputum production, and these are often expensive and not well-tolerated.[40] At the same time, recent research suggests that reduction of symptoms is associated with fewer exacerbations in patients with bronchiectasis.[41] Patients with excess sputum production, whether they have COPD or BE, should receive appropriate treatment for their symptoms, including mucoactive therapies,[40,42,43] inhaled corticosteroids,[44] macrolides,[44] bronchodilators,[44] and airway clearance.[44-47]

Airway clearance therapy (ACT) methods directly address the risk factor of retained secretions by removing the sputum accumulation in the lungs that has been colonized by pathogens. ACT has been described as "one of the cornerstones of therapy for the prevention and treatment of pulmonary disease and neurorespiratory dysfunction."[36] ACT methods, including high-frequency chest wall oscillation (HFCWO), improve the effectiveness of sputum clearance, reduce the rate of

exacerbations, and improve the symptom burden of patients with COPD.[48]

> "Symptoms of chronic bronchitis impose a heavy burden on patients and should be treated regardless of the presence or absence of underlying bronchiectasis." —McEvoy 2021[26]

HFCWO effectively addresses excess sputum in COPD alone

Evidence from multiple independent sources demonstrates that initiation of HFCWO therapy is positively associated with improvements in hospitalization rate and quality of life. There is a large and growing body of evidence from different sources including clinical studies, retrospective outcomes studies, and cleared claims data, summarized below.

A recent systematic review and meta-analysis by Daynes and colleagues evaluated 18 randomized controlled trials of airway clearance devices for adult patients with stable COPD and reported that using these devices to support everyday management of the condition reduced future exacerbations by 50%.[48] In 2011, Mahajan found that nearly twice as many patients treated with HFCWO reported a clinically significant improvement in dyspnea than with sham therapy (71% vs. 42%).[49] Rumbak found improvements in COPD patients beginning six-minute walk tests and dyspnea for patients who initiated HFCWO therapy.[45] A recent study of data from the Optum claims database found that respiratory-related hospitalizations were reduced by 17% in the year after receiving an HFCWO vest.[50] Similarly, a 2017 study using MarketScan data showed that all-cause hospitalization was reduced by 40%, ER visits by 27%, and office visits by 12% in the year following initiation of HFCWO therapy.[51]

A series of studies based on patient-reported outcomes also reports the improvement of quality of life following the initiation of HFCWO vest therapy. In these studies, hospitalization rates and changes in quality of life metrics were compared for time intervals before and after initiation of the therapy. The methodology is fully described in a recent peer-reviewed publication.[52] Looking at patients with COPD who were confirmed to be without BE, a recent study (n=219) showed the hospitalization rate dropped 54.4%, while the self-reported ability to clear the lungs improved 51.9%.[53] The response to vest therapy was rapid and sustained for up to two years. (Figure 2.)

HFCWO effectively addresses excess sputum in BE

Concerning bronchiectasis, there is a much larger body of evidence. Several studies of cleared claims found a reduction in hospitalization after initiating vest therapy: a 2017 study by Weycker showed all-cause hospitalizations down by 33%, ER visits down by 25%, and office visits down by 14%.[51] Another study by McEvoy found that mean respiratory-related and all-cause hospitalization rates were lowered by 17.1% and 13.6% respectively.[50] A recent report by Basavaraj and colleagues demonstrated that by the third year following initiation of HFCWO therapy, there was a 25% reduction in all-cause hospitalization median length-of-stay, a 17% reduction in emergency department visits, a 20% reduction in pulmonologist visits, and a 16% reduction in antibiotic use.[54]

The HFCWO outcomes registry maintained by RespirTech also demonstrates similar results for bronchiectasis patients.[52] In an analysis of 2,596 records from a registry of adult bronchiectasis patients using the Philips InCourage system, the yearly rate of hospitalization dropped 54.5%, antibiotic use dropped from 57.7% to 29.9%, and self-reported ability to clear the lungs improved from 13.9% to 76.6%. Updated results for patients with bronchiectasis show a 72% reduction in hospitalization rate in the two years after initiating vest therapy, and this was with a cohort of over 12,000 records.[55]

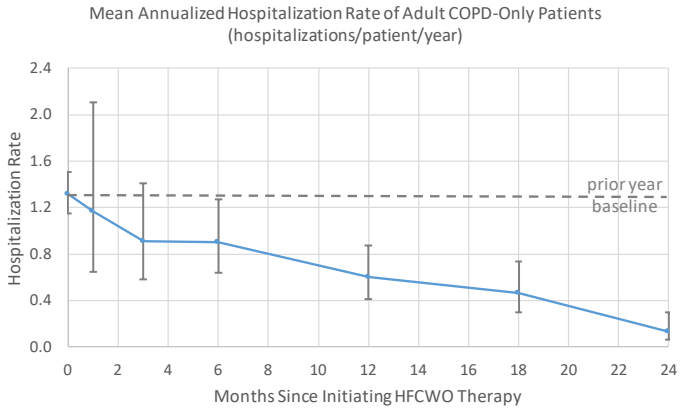

Figure 2. The mean annualized hospitalization rate for patients with COPD-only after starting HFCWO therapy at time zero. Error bars are 95% confidence limits. There is a 54.4% reduction in annualized hospitalization rate.

HFCWO effectively addresses excess sputum in symptomatic pulmonary patients.

In early 2020, in response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services (CMS) temporarily relaxed the enforcement of certain clinical coverage limitations for respiratory devices like vest therapy. This allowed clinicians great flexibility in determining the clinical need for patients who required these devices: RespirTech designated patients covered under this program as "COVID Waiver" — an undifferentiated population of patients needing airway clearance therapy. They most likely did not have an active case of COVID, but rather a blend of diagnoses, predominantly COPD, as well as a wide variety of conditions that resulted in excess mucus production necessitating a prescription for HFCWO therapy. Previously, CMS did not typically allow for coverage of HFCWO for many of these diagnoses; this created a pragmatic opportunity to understand the benefits of HFCWO for these patients. An outcomes-based study of HFCWO vest therapy patients found considerable self-reported improvement among these patients as well: a 70% reduction in hospitalization rate for 812 patients as well as a 15% drop in antibiotic usage.[56]

> "In clinical practice, it is advisable to detect BE in COPD as early as possible and to monitor, prevent, and treat these three risk factors* to prevent or slow BE progression in COPD patients" — Martinez-Garcia 2021
>
> *Chronic purulent sputum production, the number of potentially pathogenic microorganisms found in sputum samples, and the number of hospitalizations due to exacerbations of COPD.

Summary

There is growing evidence to support early intervention for COPD patients with excess sputum production, specifically to treat the presence of pulmonary purulence by reducing the bacterial load.[39] Methods for airway clearance are available that

directly address excess sputum production, the most important risk factor for disease progression from COPD to BE. Recent clinical studies report that symptomatic patients in the early stages of COPD are likely to progress to more severe stages, with a major impact on health-related quality of life; therefore early treatment is needed to slow the progression of the disease.[57] Medications may address purulence, however, the use of airway clearance devices is advised to maintain pulmonary hygiene, to pre-empt exacerbations, and to delay the progression of COPD into more severe disease.

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New Technology That May Help Reduce Unplanned Extubations and Optimize Suctioning Practice in the NICU

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Introduction

Neonatal patients in respiratory distress are frequently intubated and require an endotracheal tube (ETT). Keeping an ETT in place can be challenging in neonates as they are not typically paralyzed and experience movement.[1] Movement can lead to migration of the ETT, which can lead to dislodgement or an unplanned extubation. The presence of an ETT can also stimulate mucus production and impair clearance of secretions. ETT suctioning is then necessary and, although required, the timing and frequency varies from patient to patient.[2,3] This paper will address the risks associated with endotracheal tube movement and obstruction in the neonate and explore the ways a new technology can be used to optimize care.

Unplanned Extubations

Unplanned extubations (UEs) are a significant safety concern for neonates and are defined as any dislodgement of an endotracheal tube from the trachea that is not intentional or ordered by a health care professional.[7] UEs are the most common adverse event during mechanical ventilation in the neonatal intensive care unit (NICU).[4,7] The risk of UEs in neonates is higher when compared to other populations. This is likely due to several factors, such as neonates have a longer duration of intubation, they have a shorter trachea, use of uncuffed ETTs, and skin to skin contact with a parent is encouraged. UEs often result in an emergent reintubation and may cause cardiovascular collapse, leading to an increase in hospital length of stay and costs.[6,7]

Costs

In a retrospective matched cohort study, Hatch et al evaluated the clinical outcomes and costs in very low birth weight infants. In the primary cohort they found that UEs were associated with a one week increase in mechanical ventilation, a ten day increase in length of stay, and a nearly $50,000 increase in total hospital costs.[7]

Prevention Bundles

To address this issue, a multicenter quality improvement initiative was implemented utilizing a bundled care method recommended by the Children's Hospitals Solutions for Patient Safety (SPS). In this study Klugman et al suggested a widely accepted benchmark of 1 UE per 100 vent days. The bundle included several recommendations including the use of two licensed clinicians for procedures such as repositioning and for bedside imaging. The study found that the bundle reduced NICU UEs by 17.6% from 1.55 UE per 100 vent days to 1.282 UE per 100 vent days. Although the NICU bundle did not reach the set benchmark, they concluded that all ICUs should strive for rates at or near zero.[5]

Despite the implementation of prevention bundles, UE rates have been found to initially decline and then plateau at a rate greater than zero. This suggests that there is a need for additional interventions to reduce UEs to acceptable rates. One intervention that is commonly used directs clinicians to focus on the placement of the endotracheal tube tip. The current widely used method to confirm EET tip placement is through chest radiograph or X-ray. Although this procedure helps identify ETT placement it may not be routinely prescribed to avoid radiation exposure in patients that have prolonged intubations.[8]

By measuring the location of the endotracheal tube tip within the trachea, the SonarMed™ airway monitoring system can improve a clinician's ability to manage a patient's airway. The device provides continuous, real-time monitoring of the ETT tip position and can also assist in identifying obstructions, which can help optimize suctioning practices.[9]

Suctioning

Endotracheal tube suction is one of the most common procedures in the NICU. Suction practices are associated with significant risks including hypoxemia, bradycardia, hypotension, changes in cerebral blood flow, and changes in lung volume. Recent literature suggested that ETT suction guidelines may use evidence that is outdated or from adult and animal studies. Often suction practices are performed based on the health care providers personal experience and recognition of clinical finding such as decreased breath sounds on auscultation.[2,3]

New Technology

The SonarMed™ airway monitoring system is a Food and Drug Administration (FDA) cleared technology that has been proven to be a complementary method for the assessment of ETT migration and obstruction.[9] The SonarMed™ airway monitoring system uses acoustic reflectometry to emit sound waves through the ETT and measures them as they return to the sensor. The system analyzes the timing and amplitude of the echoes to estimate the position and integrity of the ETT. Immediate audible alerts then inform clinicians when movement or obstructions

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are detected. This unique technology assists in verifying ETT movement, position, and patency during ventilation.

Conclusion

Through application of the SonarMed™ airway monitoring system, healthcare providers can mitigate some of the risks associated with endotracheal tube movement and obstruction, optimizing the care of the neonatal patient.

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in conjunction with the Masimo Hospital Automation Platform, automates electronic charting of patient data, including the data collected by Radius PCG, in hospital electronic medical record (EMR) systems, to simplify and speed workflows, as well as reduce the likelihood of transcription errors. *Maximized Data Visibility and Manipulation:* Root's large, multi-touch, high-resolution screen provides an easily interpretable secondary display of large, crisp $EtCO_2$ waveforms, improving visibility and assisting clinicians in identifying wave patterns suggestive of airway obstruction or tube dislodgement. Clearly displayed trend data for up to 96 hours helps clinicians review patient progress over time, helping guide ventilation efforts. And the intuitive touch-screen interface allows clinicians to quickly adjust the trend display range and configure alarm settings to meet the needs of each patient. *Hassle-free Connectivity:* Radius PCG quickly and effortlessly pairs with Root via Bluetooth, supporting seamless integration into clinical workflows while providing the benefits of reliable capnography. Tom Friedland, MD, Emergency Medicine Physician, described Radius PCG as "the easiest and most affordable solution to switch your hospital from the unreliable color change CO_2 detector to waveform capnography. #NoTraceWrongPlace." "Radius PCG is indispensable for emergencies, as well as for monitoring the COVID patients in our house," added Kai Schurig, Head of the Biomedical Department at Marien Hospital in Hamburg, Germany. "These handheld devices are very reliable and fail very rarely. The users are very satisfied and treat the device accordingly." Root is a powerful, expandable hub that integrates an array of technologies, devices, and systems to provide multimodal monitoring and connectivity solutions. Root's plug-and-play expansion capabilities allow clinicians to simultaneously monitor with Radius PCG and many other measurements, such as Masimo SET, advanced rainbow Pulse CO-Oximetry measurements, O3 regional oximetry, and SedLine brain function monitoring, for expanded visibility of patient status. Using Root in combination with the Hospital Automation Platform, monitoring data from all connected devices can be automatically charted in EMRs. Joe Kiani, Founder and CEO of Masimo, said, "With its wireless connectivity, Radius PCG is a powerful and useful tool for assessing end-tidal CO_2 in a multitude of clinical scenarios. Masimo continues to make clinically relevant, accurate patient data available, helping clinicians gain the insights they need to make the best decisions and improve patient outcomes."

FDA Approves Xolair (omalizumab) Prefilled Syringe for Self-Injection Across All Indications

Genentech, a member of the Roche Group announced that the US Food and Drug Administration (FDA) has approved the company's supplemental Biologics License Application for Xolair (omalizumab) prefilled syringe for self-injection across all approved US indications. Xolair is the only FDA-approved biologic designed to target and block immunoglobulin E (IgE) for the treatment of moderate to severe persistent allergic asthma, chronic idiopathic urticaria (CIU) and nasal polyps. "Today's approval reflects our commitment to continued innovation with Xolair to address the critical needs of people living with allergic and inflammatory conditions," said Levi Garraway, M.D., Ph.D., chief medical officer and head of Global Product Development. "Appropriate patients will now have the flexibility to administer Xolair from home, which is particularly important for those who are considered high-risk during the COVID-19 pandemic." Before starting self-injection with Xolair prefilled syringe, the

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Comparing the Performance of Two Pulse Oximeters and Electrocardiography During Neonatal Transition

Chris Campbell

When it comes to the resuscitation of full-term infants, the use of a pulse-oximeter is a valuable way to monitor vital signs used for newborn evaluation after birth.

The question for those who deliver babies is: What pulse-oximeter should they use?

Schneider Children's Medical Center of Israel researchers Rasha Khoury and Gil Klinger set out to build on previous "sparse" data on the subject, comparing devices from "two companies that claim a superior performance of their POxs," according to their study, entitled: "Monitoring oxygen saturation and heart rate during neonatal transition. Comparison between two different pulse oximeters and electrocardiography."

They set out to compare the efficacy and reliability of the Masimo Radical-7 and Nellcor™ Oxymax Bedside, as well as evaluate the feasibility of routine ECG monitoring during delivery room transition.

They conducted a prospective observational comparative study and 60 newborns were connected simultaneously to both POxs and ECG monitor. Times to achieve a stable signal were compared. Heart rates were compared to simultaneous ECG.

What they found was the time for the achievement of a stable saturation reading in an uncomplicated resuscitation setting differed significantly between POxs.

Neonatal Resuscitation

According to the authors, the 2010 neonatal resuscitation program (NRP) guidelines of the American Academy of Pediatrics and American Heart Association[1] are what are followed by hospitals. These guidelines say that "resuscitation of full-term infants is initiated using an inspired fraction of oxygen (FiO2) of 21% (room air) and in preterm infants an FiO2 of 30-40%. As assessment of color has been shown to be unreliable,[2] breathing and heart rate (HR) remain important vital signs used for newborn evaluation after birth. The NRP guidelines recommend use of pulse-oximetry (POx) in the delivery room as an accurate method for estimating the FiO2 necessary to reach pre-established oxygen saturation (SpO2) targets over the first 10 min of life. POx contributes to avoid the adverse effects of exposure to low or high concentrations of oxygen.[3-6] As a consequence, POx has become essential for delivery room evaluation and monitoring of the newborn.[7,8] POx is based on photo-plethysmography, displaying pulse waves and HR required by the NRP algorithm for decision making. In 2015 the NRP guidelines were revised suggesting use of electrocardiography (ECG) monitoring for a more accurate and rapid evaluation of HR.[9] However, time to acquisition of a stable and accurate signal may be delayed, especially during critical situations such as low perfusion and motion; occasionally, the signal may even fail to appear."[10,11]

The authors write that the Masimo Radical-7 and Nellcor™ Oxymax Bedside devices have been compared in studies before,[12-14] but added that there is only "sparse data on the duration required to obtain a reliable saturation signal and on the accuracy of the HR reading."[15]

Study Methods

For the study, a convenience sample of newborns (full term and preterm) for whom consent was obtained prior to delivery was eligible for inclusion. The minimal total sample size (two tailed) of 52 subjects was calculated to achieve a power of 80% and a level of significance of 5% (two sided), for detecting an effect size of 0.4 between pairs with p value < 0.05. A resident in pediatrics (RK) approached the parents during admission before delivery in order to explain the study procedure and receive written informed consent; this required that the mother had a pain score below 3 using the (Visual Analogue Scale (VAS),[16] and both parents' emotional condition allowed them to receive the explanations.

Two POxs were simultaneously connected: Masimo Radical-7 (Masimo Corp, Irvine, CA) and Nellcor™ Oximax Bedside SpO2 (Medtronic Parkway, Minneapolis, MN) using Masimo M-LNCS™ Neo and Nellcor Neonatal-Adult SPO2 sensors respectively.

The highest sensitivity setting available was used for each POx: "Max", in the Masimo and "Neonatal" and "Fast" in the Nellcor, said the authors.

"After delivery, as soon as the newborn was placed under a radiant warmer, each of the POxs' sensors was attached to one of the newborn's feet, and then, simultaneously connected to the POxs device that was already turned on. Assignation of the device to the right or left foot was randomized by changing the side of the sensors every other patient. ECG HR was measured with Philips Efficia CM120 patient monitor (Philips, Eindhoven, Netherlands) using Neotrode® neonatal/pediatric

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ECG electrodes, (ConMed, New York, USA). ECG leads were attached to the newborns' skin following the POXs' sensors and connected to the ECG cable outlet immediately after saturation probes were connected to the POx cable outlet."

Results

Data for comparing time duration to obtain a stable signal between both POxs were available in 55 neonates.

"Nellcor POX delivered a stable signal faster than Masimo median (Interquartile range) was 8.5 (6–18) and 12 (9–34) s, respectively ($p < 0.001$)," the authors wrote. "For the Masimo pulse-oximeter, a signal from the device was obtained in 58 of 60 (96%) newborns, however a stable signal was obtained in only 55 newborns (92%). The average time to a stable signal was 27 s. In 51 newborns, simultaneous ECG records were available for comparison. Heart rate was significantly lower in POx vs ECG, Median (IQR) were 156 (121–170) vs 162 (147–172) ($p = 0.001$). In 18 of 51 (35%) newborns there was a mismatch of 12 or more beats per minute between devices, in 16 of 51 (31%) newborns the difference was of 40 or more beats per minute, (POx lower in all newborns). In all of these 18 cases the ECG (reference) showed a HR of above 100, and the baby had normal color and was crying properly."

The authors also determined that the Masimo produced false bradycardia results.

"A signal from the (Masimo) device was obtained in 58 of 60 (96%) newborns, however a stable signal was obtained in only 55 newborns (92%)," they wrote. "The average time to a stable signal was 27 s. In 51 newborns, simultaneous ECG records were available for comparison. Heart rate was significantly lower in POx vs ECG, Median (IQR) were 156 (121–170) vs 162 (147–172) ($p = 0.001$). In 18 of 51 (35%) newborns there was a mismatch of 12 or more beats per minute between devices, in 16 of 51 (31%) newborns the difference was of 40 or more beats per minute, (POx lower in all newborns). In all of these 18 cases the ECG (reference) showed a HR of above 100, and the baby had normal color and was crying properly. The HR delivered by the Pox was below 100 therefore these cases represented false bradycardia (FB)."

For the Nellcor pulse-oximeter, a signal from the device was obtained in 60 of 60 (100%) newborns and a stable value was achieved in all newborns (100%), said the authors.

"The average time to stable signal was 15 s. In 49 newborns, simultaneous ECG records were available for comparison. There was no statistical difference in HR between POx vs ECG; Median (IQR) were 158 (140–170) vs 163 (140–173) (NS) (in two there was not simultaneous ECG record at the time of stable signal reading due to electrode's detachment); in 7 cases (14%) there was a 12 beat per minute difference or higher between the devices, and in 3 of these cases the HR measured by the pulse-oximeter was higher than the HR measured by ECG."

The authors write that the American Academy of Pediatrics NRP guidelines show "ventilation is the single most important step and positive pressure should be administered to all newborns who do not breath effectively or who are apneic;[9] this would be independent of the accuracy of the HR's signal. On the other hand, during resuscitation of critically ill newborns, perfusion may be compromised and using ECG may be the only or best way of obtaining a reliable monitoring of the HR.[17] Therefore, the use of ECG during neonatal resuscitation should be evaluated based on its added value, but it comes at the expense of intervention and treatment of the newborns. An ECG monitor should be available for neonatal resuscitation and is valuable especially for those cases in which a POx does not deliver a reliable HR value. We have shown that attaching a POx does not significantly interfere with the steps of neonatal resuscitation and provides saturation and HR values within a relatively short period of time. One should be aware of the possibility of FB when POx's are used and remember that physical examination has still a crucial role in the evaluation of patients."

Conclusions

When the study authors wrapped up their report, they assessed both devices as having "relatively quick measurements" but gave a distinct edge to one device.

"Our study conclusions can be summarized as follows: Both POxs, Nellcor and Masimo provide relatively quick measurements of HR and saturation, in most cases well before the 'golden first minute' of resuscitation. We showed a statistically significant difference in the time needed to deliver a stable signal between devices in favor of Nellcor. One should be aware of the possibility of occurrence of FB during resuscitation. In general, routine connection of the ECG device to the newborn may consume valuable time (especially in centers with limited resources) without a significant effect on the management of the newborn's resuscitation, but it might be helpful in monitoring and decision making in cases of absence of a signal from a pulse-oximeter. A more user-friendly ECG device should be developed. Until then, we suggest making a selective use of ECG for resuscitation of the newborn."

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patient must have no prior history of anaphylaxis and be closely observed by a healthcare provider for at least three injections with no hypersensitivity (allergic reactions). After Xolair therapy has been initiated and safely established in a healthcare setting, a healthcare provider may determine whether self-injection with Xolair prefilled syringe by the patient or a caregiver is appropriate. The healthcare provider must train the patient or caregiver on the correct subcutaneous injection technique, how to recognize the signs and symptoms of anaphylaxis and how to treat anaphylaxis appropriately, before the first self-injection outside a healthcare setting. "Expanding treatment options for personalized care and self-management is always welcome news for the patient community," said Kenneth Mendez, CEO and President, Asthma and Allergy Foundation of America. "The possibility of administering FDA-approved treatment outside of the healthcare provider's office, but still guided by that healthcare provider, may reduce barriers to care for patients and their caregivers." Approximately 460,000 patients have been treated in the US with Xolair since its initial approval in 2003. The use of Xolair across allergic asthma, CIU and nasal polyps is based on its well-established efficacy and safety profile and supported by a robust clinical development program, including 10 Phase III studies. In the US, Genentech and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

Confront Today's Challenges with Cardiorespiratory Diagnostic Software

The respiratory industry is ever growing and changing. With new studies and trials being conducted, new treatment methods and disease challenges are often discovered. This means that reliable and efficient methods for diagnosing pulmonary disorders are needed. As COVID-19 continues, mild to severe lung damage has been found in some patients post-Covid, which often requires Pulmonary Function Tests to determine the extent of damage, monitor the progress and to create a treatment plan. Add to that the number of patients with Chronic Obstructive Pulmonary Disease (COPD), a progressive and chronic disease. According to the American Lung Association, COPD is the third leading cause of death in the world. It is estimated that over 300 million people worldwide have COPD. As we can see, the need for Pulmonary Function Testing is only going to increase. In the respiratory industry, manufacturers introduce new diagnostic software about once every 15 years. With these thoughts in mind, MGC Diagnostics has a solution to help solve today's challenges. MGC Diagnostics' new Ascent cardiorespiratory diagnostic software for pulmonary function testing has been designed from the ground up to be the most advanced testing software platform available. Their easy-to-use, powerful, and versatile software allows you to obtain the very best data possible so that a diagnosis can be made confidently. It's simple. Improving the diagnosis of patients starts with diagnostic tests done correctly and according to ATS/ERS standards. The ease in which data is collected, accessed, and reviewed helps to ensure an effective patient outcome. The dynamic on-screen instructions within the software walk the technologist through the entire testing process. Ascent software's unique Insight quality control gauge shows if an effort has passed ATS/ERS quality standards in Real-Time while the patient is performing the effort. With enhanced graphics, know at-a-glance if a test effort meets your labs' standards and are acceptable for diagnostic purposes. After the test is complete, data can be reviewed quickly and efficiently.
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The Benefits of Inhaled Nitric Oxide in the Transport of Newborns

Chris Campbell

Imagine how difficult it is for a clinical team to treat a newborn with a rare medical condition like persistent pulmonary hypertension of the newborn (PPHN) in a hospital setting. Now imagine the logistical and safety challenges involved with PPHN during an interhospital transport. That transport just pushes the risks even higher for the infant and increases the challenges for the medical team. A new review, however, highlights transport-friendly equipment that has received new US FDA approval that can facilitate treatment during transport from the moment of departure to the moment of arrival.

The published review, authored by Natalie Mitchell, Robert E. Newmyer, Mary Cominek, Rupa Crite, Heloisa Georgiev and Charles V. Pollack, sums up an advisory board event held in October 2020 and hosted by VERO Biotech, the company that makes the GENOSYL DS device that received the FDA approval. This written summary reflects the key elements and learnings of the discussion that included respiratory therapists, flight nurses, and an air transport physician.

Dealing with PPHN

PPHN is a condition that carries with it great risks, the authors write in their introduction. "The incidence of persistent pulmonary hypertension of the newborn (PPHN) in infants ≥34 weeks gestational age without congenital heart disease, is approximately 0.2% in the United States.[1] A high-risk diagnosis that carries a one-year mortality rate of 7-8% and is often associated with serious congenital anomalies of the respiratory tract (in which patients one-year mortality may exceed 30%),[1] PPHN requires intensive cardiopulmonary care. In severe cases or in those patients who fail to respond to supportive measures and specific treatment of associated lung disease, further interventions include the use of inhaled nitric oxide (iNO), a selective pulmonary vasodilator that reduces the ratio of pulmonary to systemic vascular resistance (PVR/SVR). With iNO, oxygenation improves as vessels are dilated in better-ventilated parts of the lung, and the need for extracorporeal membrane oxygenation (ECMO) to provide adequate tissue oxygenation is diminshed.[2-3]"

Transportation Challenges

The authors wrote about how certain hospitals need to transport infants because they don't have the capacity to handle the specialized, intensive care required by PPHN, saying that "30-40% of newborns with severe hypoxemia due to pulmonary hypertension who show a suboptimal or nonsustained response to iNO[4] must be transported with advanced life support (ALS) capability and ongoing administration of iNO from one hospital to an ECMO-capable center. Abrupt discontinuation of iNO therapy before transport in patients who have not improved oxygenation and hemodynamics can be harmful because of acute deterioration with severe hypoxemia ('rebound' pulmonary hypertension). Therefore, the standard of care is to transport such patients while continuing iNO treatment. In fact, initiation of iNO therapy at the referring hospital is associated with decreased length of hospitalization in those infants not ultimately requiring ECMO.[5] While not part of the labeled indication for iNO, therapy may also be initiated prior to transport in the management of other illness accompanied by pulmonary hypertension, including bronchopulmonary dysplasia, meconium aspiration, pulmonary hemorrhage, pulmonary hypoplasia, tracheoesophageal fistula, transposition of the great vessels or other congenital heart defects, or sepsis with respiratory failure.[4]"

Standards for interhospital transport of patients on iNO are set out by the Association of Critical Care Transport[6] and include blending gas capability including supplemental oxygen and room air; proper administration device that integrates with the ventilator used in transport; sufficient iNO capacity for the maximum duration of transport, plus a 30-minute reserve; and temperature stabilization for the nitric oxide.

"These standards are in addition to special controls set forth by the FDA in a guidance document entitled 'Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer,'" the authors write. "The apparatus must allow reliable maintenance of an approximately constant concentration of iNO during inspiration, regardless of variation in flow rates, as set typically in the range of 0 to 80 parts per million (ppm). It must include a pressure regulator and connectors with fittings which are specific for nitric oxide gas cylinders, and must be designed to limit the time that NO is mixed with oxygen, thus minimizing the production of NO_2 … The Commission on Accreditation of Medical Transport Systems (CAMTS) standards require that teams providing interfacility transport have the capability to deliver out-of-hospital care at a specialty or subspecialty level (eg, comparable to that of a tertiary or quaternary such as an ICU, PICU, NICU, or tertiary perinatal center). This includes the capability to provide blended gases, specifically citing iNO.[7]"

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Logistical Challenges

The authors cite several logistical challenges, including the higher costs associated with using multiple types of ventilators and nitric oxide delivery systems (NODS), from different manufacturers.

"This approach also creates more regular and intensive training requirements in order to keep staff credentialed on and comfortable with two or more NODS, including in the transport setting where working space is severely limited and when there are substantial differences regarding set-up and manual resuscitation process for different devices," the authors write. "This scenario increases the likelihood for error to occur in the transport of a critically ill patient. On the contrary, the potential to improve the quality of care associated with continuity of equipment use across the entire care path for the delivery of iNO via any conventional or high frequency ventilator during neonatal transports would streamline and improve this process. In addition to that, training on multiple types of equipment for the current transport process necessitates that the team overcome important and frequently encountered logistical obstacles. With variable flow modes, for example, potentially wide fluctuations in flow require adjustment from breath to breath. Space restrictions occur in both ground and air transport vehicles, especially if additional support is needed for the patient, or if bagging is required. Bagging with currently used equipment requires a second NO tank with a specialized regulator. Use of other types of tank-based equipment requires reconfiguration of the transport apparatus; the patient must be bagged with an iNO blender, which must itself be mounted along with the delivery system monitor onto the transporter."

The authors also detail issues involving the current transport systems that increase costs for hospitals, increase the training requirements for staff and increase the chances of errors during the transport of critically ill patients.

"Using multiple types of ventilators and NODS, from different manufacturers, results in an increase in costs to the hospital," the authors write. "This approach also creates more regular and intensive training requirements in order to keep staff credentialed on and comfortable with two or more NODS, including in the transport setting where working space is severely limited and when there are substantial differences regarding set-up and manual resuscitation process for different devices. This scenario increases the likelihood for error to occur in the transport of a critically ill patient. On the contrary, the potential to improve the quality of care associated with continuity of equipment use across the entire care path for the delivery of iNO via any conventional or high frequency ventilator during neonatal transports would streamline and improve this process."

The authors also detail more logistical "obstacles" of dealing with multiple types of equipment for the "current" transport process. These include having additional tanks or the need to remove tanks to accommodate the iNO tank; a lack of gas supplies in some transport modes to accommodate the vent or long distance transport; the heavier weight and how that impacts fuel consumption during warmer months; the need for back-up injector modules with tank-based systems which can impact the accuracy of gas delivery without it; and a pre-use check which requires purging, leading to more prep time prior to transport.

"With variable flow modes, for example, potentially wide fluctuations in flow require adjustment from breath to breath," the authors write. "Space restrictions occur in both ground and air transport vehicles, especially if additional support is needed for the patient, or if bagging is required. Bagging with currently used equipment requires a second NO tank with a specialized regulator. Use of other types of tank-based equipment requires reconfiguration of the transport apparatus; the patient must be bagged with an iNO blender, which must itself be mounted along with the delivery system monitor onto the transporter. Both current systems require an additional tank to be added to the transporter configuration, or another tank must be removed for the iNO tank to be added. This can be an issue if ambulance or helicopter does not have onboard gas supplies for the ventilator and during long distance transports. In addition, weight is an issue for neonatal transports; the isolette itself weighs 300 lbs or more before the NODS is added. This total weight makes it more difficult, particularly during the summer months/warmer areas for the flight crew to ensure there is enough fuel for the transport, equipment, and personnel traveling with the patient. With some tank-based systems there is a need for a back-up injector module; accurate electronic gas delivery may not be available without it. Finally, a pre-use checkout which includes a purge procedure is required prior to transport with typical tank-based systems, requiring an additional 10 minutes prior to transport. A tankless system does not have these requirements and therefore can be much lighter in weight. Using other equipment off-label may require the addition of costly proprietary parts and pieces, and special training for respiratory therapist use on that improvised combination. A system approved by FDA and consistent with FAA regulations would be a valuable asset in transport on iNO."

Significance of FDA Approval of the GENOSYL Delivery System

The authors wrote about how clinicians for 30 years have used devices "off-label" that were not approved by the FDA.

But now arrives the GENOSYL DS, the first tankless NODS, supplying iNO from 16-ounce cassettes instead of two six-pound D-cylinder tanks.[8] The device was granted FDA approval on December 14, 2020.

"The approval reflects rigorous testing and a careful design process," the authors write. "The VERO engineering team worked with key opinion leaders and transport experts in the field to design a transport mount that would reduce the overall system weight and footprint as much as possible. The mount was designed to contour to the console geometry with minimal size and weight increase. A strap is utilized to allow easy console removal and replacement for set up. Helical mounts connected to the base of the transport mount provide shock and vibration dampening to allow the console to dose without disruption.

Applicable standards for crash safety, EMI/EMC, shock, and vibration were tested to ensure that the GENOSYL DS and transport mount assembly can withstand the environments of ground, fixed-wing, and rotary-wing intrahospital transport."

The authors wrote that having an "on-label" device is an important step. "First, the indication means that the FDA has evaluated the safety and efficacy of the product for that specific use and found it appropriate for use in patients who have specific treatment needs. It does not mean uses outside the

approved labeling are not safe, it simply provides assurance that the overall approved use has been reviewed specifically by the FDA. Secondly, as alluded to above, it provides guidance and 'guard rails' within which that safety and efficacy are assured. This is particularly beneficial for the inexperienced or only occasional user, to have one process or one dosing regimen approved and explained. Third, it offers consistent information on any monitoring that should be applied when the patient is using the device or drug. Finally, a FDA labeled indication offers a potential pathway to reimbursement for use, so that uninsured, underinsured, and insured patients can all have access to the drug or device, and providers such as hospitals or transport companies do not have to absorb the cost of the therapy. FDA approval of the VERO transport NODS offers a streamlined approach to iNO use in acute care and in various transport settings. For those facilities that have adopted the GENOSYL system, advantages include no need for training on new devices, the reassurance and time-saving of using an approved configuration, and an improved focus on patient safety for these vulnerable neonates as they are transported to higher levels of care."

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Completely customizable comments can be generated to summarize the quality of each effort more quickly and accurately than ever before. And the computerized interpretation can be tailored to the individual physician.

FDA Clears Use of Oscillating Positive Expiratory Pressure Products

D•R Burton Healthcare Products LLC is a leading manufacturer of Oscillating Positive Expiratory Pressure (OPEP) products that treat the symptoms of COVID-19. D•R Burton OPEP products provide supporting treatment of some COVID-19 symptoms, particularly symptoms of respiratory airway infections that can precede pneumonia and further progress to more serious complications. The FDA has cleared the use of Oscillating Positive Expiratory Pressure (OPEP) products which are known to decrease the burden of respiratory pathogens by promoting airway secretion clearance. OPEPs are widely accepted by the medical community for helping to reduce the likelihood that respiratory infections progress to pneumonia and even more serious complications including death. Despite the familiarity in the medical community with these products, OPEPs are largely unknown to the US general public except for patients living with chronic lung diseases such as Cystic Fibrosis, COPD, and Bronchiectasis to name a few. D•R Burton manufactures small hand-held OPEPs that can be easily self-administered in hospitals, nursing homes, and the home setting by most patients. These devices can also be filtered with a common bacteria/viral filter to alleviate concern of droplet transmission. While researchers race for a cure, our country and the world face a public health challenge of treating infected people. OPEP therapy is not a direct treatment for the COVID-19 virus, but it is our hope that increased awareness of OPEP therapy could help in the current health challenge by offering proven and available therapy for symptoms of respiratory tract infections associated with the COVID-19 virus.

Study Investigates the Impact of Automating Respiration Rate Measurement Using this Device

Masimo announced the results of a prospective, observational study published in *Acta Paediatrica* in which researchers from the Hospital for Sick Children in Toronto evaluated the accuracy of plethysmographic respiration rate measurement (RRp) using Masimo Rad-G, a rugged, handheld device, on malnourished, hospitalized children in Nigeria. Noting that in resource-limited environments, respiration rate (RR) measurement is often used to directly inform medical decisions for children with respiratory problems, but that manual RR counting "remains a challenge," Dr Nancy Dale and colleagues investigated whether a technological solution might provide a useful alternative to manual counting. To make the evaluation, the researchers compared simultaneous device measurements and nurse-measured manual RR counts on malnourished children. The device chosen was the Masimo Rad-G, which uses a pulse oximetry sensor to measure both oxygen saturation and RRp, and which has been shown to provide good agreement between RRp and pediatrician-measured RR. They enrolled 514 children, aged 6 to 59 months, who were hospitalized between July 2019 and May 2020, in Borno State, Nigeria. Study nurses were trained to operate Rad-G and also perform manual RR counts as part of twice-daily patient assessment. RR was manually counted for 60 seconds while Rad-G simultaneously measured RRp via a sensor attached to the patient's toe, and both measurements were recorded. Analyzing

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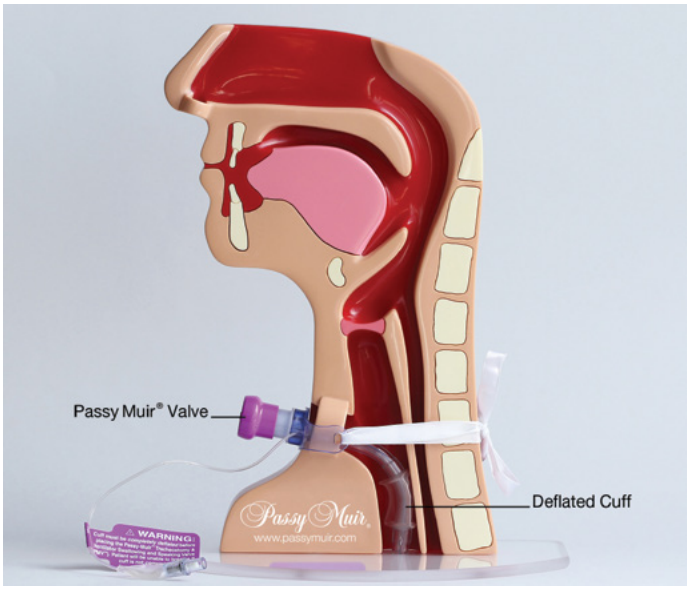
Considerations for Success with Patient Safety and Progression with Cuff Deflation

Tiffany Oakes, MS, CCC-SLP and Gabriela Ortiz, BSRT, RCP

With the number of patients receiving tracheostomies increasing over the last several years and with the increased rate of these patients being discharged to long-term care facilities prior to weaning and decannulation, more clinicians in a variety of settings are participating in the care of patients with tracheostomies (Mehta, 2015). An important part of that care is management of the tracheostomy cuff, and cuff deflation is an important step in the treatment plan for a patient with a tracheostomy (Speed & Harding, 2013). Without clear guidelines, clinicians may question what it means to deflate the cuff and what a successful deflation trial looks like.

Before clinicians start deflating the cuff, it is important to understand why the patient required an artificial airway and the purpose of the cuff. An artificial airway is placed for three reasons: to administer positive-pressure ventilation, to provide a patent airway, or to provide access to the lower airway for secretion clearance. The primary purpose of the tracheostomy cuff is to seal the airway for mechanical ventilation and direct the airflow, allowing the closed ventilator circuit to control and monitor ventilation for the patient (Harrell, 2018). While an inflated cuff does not eliminate aspiration, especially aspiration related to an oral diet, a patient may require cuff inflation to limit the risk of aspiration from gross emesis or reflux (Suiter, 2003). If neither the requirement of mechanical ventilation nor the risk of gross aspiration is present, cuff deflation, or changing to a cuffless tracheostomy tube, is recommended (Harrell, 2018).

Despite the frequency of tracheostomy tube placement in intensive care settings, there is little research to determine criteria for progressing a patient with a tracheostomy towards decannulation. Existing research focuses more on indicators for decannulation, rather than the progression towards decannulation, such as tolerance of cuff deflation (Mitchell et al., 2013).



Clinical indicators for cuff deflation

A study by Pryor et al. (2016) examined clinical indicators that could be associated with successful tracheostomy cuff deflation. Patient characteristics that were considered prior to cuff deflation were:

1. Medical status (stable or improving)
2. Respiratory status (stable or improving)
3. Oxygenation ($FiO_2 \leq 0.4$)
4. Cough strength (≥moderate)
5. Patient alertness (≥eyes open to voice)
6. Sputum color (clear or white)
7. Sputum nature (thin and easy to suction)
8. Tracheal suction frequency (≤1-2 hourly)
9. Above cuff secretions (≤1 ml per hour)

This study revealed that nearly all participants achieved successful cuff deflation on the first attempt, even with some participants not meeting all criteria. Pryor et al. also suggested that requiring patients to meet all nine criteria may not be appropriate. Instead, clinicians should review overall medical and respiratory stability of the patient and the ability to control oral secretions as the primary considerations. In this study, factors that indicated the need for reinflation of the cuff included

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frequent coughing, overt discomfort or distress, increased sputum load, and clinically significant changes from patient baseline.

There is little consensus among clinicians as to duration of the initial cuff deflation trial or necessity of intermittent subsequent trials to determine tolerance of cuff deflation, but this study supports that with use of key selection criteria and clinical judgement, most patients can progress in a single step to continuous cuff deflation, regardless of the reason for tracheostomy insertion.

Considerations for trial length

However, requiring a patient to demonstrate tolerance of cuff deflation over an arbitrarily determined length of time or number of days may only delay the patient's physiological and psychological recovery and return to verbal communication and oral intake (Bach et al., 2014). Deflating the tracheostomy tube cuff is necessary prior to placement of a biased-closed, no-leak Valve. By withholding the placement of a Valve until a patient demonstrates tolerance of continuous cuff deflation over a long period of time, the clinician also is requiring that the patient tolerate the negative effects of an open aerodigestive system, which includes decreased positive pressure in the upper airway. This may increase the patient's work of breathing and be misinterpreted as though the patient is not tolerating cuff deflation. While having a closed system, through use of a no-leak speaking Valve, may improve cuff deflation tolerance due to sustained pressures.

Cuff deflation alone also may impact swallow function by decreasing subglottic pressure, decreasing sensory awareness of airflow and secretions, and diminished airway protection with decreased cough effectiveness to expel secretions. A decrease in these functions may also be misinterpreted as poor cuff deflation tolerance (Suiter et al., 2003). These negative factors may be eliminated by placing a Valve after establishing initial cuff deflation, improving the patient's overall success with and length of cuff deflation tolerance.

With mechanical ventilation

For patients requiring mechanical ventilation, cuff deflation trials may be conducted during ventilator weaning trials. Under the care of a physician and a respiratory therapist, adjustments to the ventilator may be needed to augment or compensate for the leak created by the deflated cuff and to allow more comfortable and efficacious breathing. Sutt at al. (2016) provided evidence that with the cuff deflated and a speaking Valve in place, patients receiving mechanical ventilation demonstrated improved diaphragmatic function, increased lung recruitment, and overall faster weaning times.

Clinicians should also consider other benefits of cuff deflation. Early cuff deflation may potentially avoid the negative consequences related to the inflated cuff, such as increased risk of tracheal injury, disuse atrophy of the upper airway, and restricted laryngeal movement which may negatively affect swallow function (King & Harrell, 2019). Cuff deflation aids in restoring positive airway pressures, by returning the patient to a more normal physiology, and it assists in reducing trachea mucosal damage by allowing the upper airway to filter, warm, and humidify the air. Research also suggests that early cuff deflation may assist in lowering in the risk of respiratory infections.

Risk for infections may increase with cuff inflated as it allows for pooling of oropharyngeal secretions, which may become colonized with pathogenic bacteria (Marik, 2001). The inflated cuff does not form a complete seal against the tracheal wall, and secretions and other material may leak around the cuff into the lower airway, increasing the risk of aspiration and respiratory infection with an inflated cuff (Hernandez et al., 2013).

Cuff deflation tolerance is a necessary step towards ventilator weaning and decannulation but is also important to achieving multiple benefits for those patients whose goals do no include weaning and decannulation. To best serve patients with tracheostomies, clinicians should understand the benefits and risks associated with the tracheostomy cuff and its proper management, developing an evidence-based approach to achieving early cuff deflation tolerance and speaking Valve use.

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the 6,889 paired RR measurements, the researchers found that the mean Rad-G RRp reading was 1.3 bpm (95% confidence interval 1.2-1.4 bpm) higher than the mean manual RR value. The mean absolute difference between the two methods was 4.4 bpm (95% CI 4.3-4.5 bpm). When RR was classified as either "normal" or "fast" breathing (using WHO pneumonia thresholds), the two methods resulted in the same classification 84% of the time. When RR was classified according to BedsidePEWS RR sub-scoring (a 4-point scale), 80% of the scores were the same, and 99.3% were within 1 point. The researchers concluded that their findings "highlight the potential clinical impact of changing practice from manual to automated RR count. Clinical implementation of the device should be carefully monitored to measure impact on patient outcomes." Study co-author Dr Stanley Zlotkin commented, "Technical solutions to improve clinical care are laudable. We look forward to continuing this research." RRp is one of multiple RR monitoring modalities offered by Masimo, which also include acoustic respiration rate (RRa) and NomoLine capnography (RRc), helping clinicians ensure they have the most suitable tool for each patient scenario. First developed in partnership with The Bill & Melinda Gates Foundation, Rad-G is a rugged, handheld device that provides clinically proven Masimo SET pulse oximetry, respiration rate (RRp), and other important parameters. With its long-lasting rechargeable battery, robust rubber casing, and light weight, Rad-G makes it easier for clinicians to quickly assess patients and make informed care decisions anywhere pulse oximetry or vital signs checking is needed in a compact, portable form factor. Coupled with the universal Mini-Clip pulse oximeter sensor to provide the ultimate in handheld versatility, Rad-G can be used in a variety of settings, including limited-resource environments, both indoors and in the field.

Survey Shows Stress Over the Past Year Is Negatively Impacting Quality of Sleep

ResMed, a world-leading digital health company, announced today the results of a nationwide survey of 1,000 adults, which revealed that for half of Americans, stress over the past year is negatively impacting the quality of their sleep—and many are ignoring sleep challenges that could point to a larger underlying health concern. ResMed published the survey in conjunction with National Sleep Awareness Week (March 14-20) and World Sleep Day (March 19), and as part of *Sleep for a Better Tomorrow*, an education and outreach initiative to build awareness of the critical role good sleep plays in physical and mental health—and how to get our best sleep. "COVID-19 has impacted all aspects of our lives, including our sleep health, leading many people to struggle to get the recommended seven to nine hours of sleep at night," said Carlos M. Nunez, M.D., chief medical officer for ResMed. Beyond the pervasive effects of stress, the survey found the impacts on sleep vary across gender and working arrangements: 35% of women reported worse sleep quality in the past year compared to just 26% of men. Women selected stress and anxiety as the most significant impacts on their sleep; more individuals working from home reported improved sleep quality since the pandemic began vs. those who haven't worked from home (39% vs. 21%). Across all respondents, more than one-third say they are having a harder time falling asleep, and nearly one-third say they are sleeping less over the last year, and one-quarter started taking naps more often. While COVID-related stresses are often noticeable, one of the biggest stealers of our sleep might be something we can't easily detect:
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Positioning Changes Affecting Daily LCI

Tom McKarns and TJ Baker

Abstract

Background: Lung Clearance Index (LCI) is an indicator of lung homogeneity and was established 65 years ago. This specific pulmonary function test (PFT) parameter was developed from the multiple-breath washout (MBW) examination. Despite these lung mechanics measurements initially not being widely accepted or utilized, recent study and review has shown an increased interest in LCI as an indicator for respiratory and pulmonary impairment and diseases, such as Asthma, Cystic Fibrosis (CF) and Chronic Obstructive Pulmonary Disease (COPD).

Investigation: The primary purpose of our research was to observe daily changes in LCI based upon subject positioning. Over the course of three-month study, we made measurements in the seated, standing, supine, and prone positions. The authors intended to demonstrate how daily LCI values would vary based on the different positioning.

Method: Data was collected from two subjects in good health and no known existing pulmonary disease or issues. Weekday measurements were made almost daily with the EXHALYZER® D from ECO MEDICS AG. The instrument system utilized SPIROWARE® data acquisition and evaluation software version 3.1.6. The instrument was mounted on a mobile cart and connected to H-size cylinders of medical air (20.94 % oxygen) and 100% oxygen (O_2). Tests were performed according to manufacturer's recommendations from the Operators Manual EXH405 v2.1 from 2017.

Results: The analysis of data from the subjects resulted in minimal LCI differences based on position of the subjects—either sitting, standing, or lying supine or prone.

Conclusions: Recent studies suggest the LCI may be a more useful indicator for many pulmonary illnesses than FEV_1. For example, LCI may also give more useful information for Primary Ciliary Dyskinesia (PCD). Our findings show small differences in daily LCI measurements over time, and that the positioning of the subjects may not cause significant differences in LCI values.

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Speech Development in Children and its Initiation in Children with a Tracheostomy Tube

Nicolin Bähre

Viewed from the outside, speech in a healthy child develops almost by itself. This is partly correct, since scientific evidence shows that the ability to acquire the grammar of a language is universal and therefore genetically determined. However, speech comprehension and speaking, with all their complexities, depend on a communicative environment and interaction. They are embedded in the development of motor skills and cognition. Although every child learns at a slightly different pace, definite developmental steps exist, referred to as milestones in speech development[1].

Crying is the first form of phonetic utterance and has an important function in the further communicative development. Newborns use it to indicate discomfort (hunger, pain, tiredness, etc.). They learn that this elicits a response from their parents to meet their needs. From about the second month of life, infants can produce a kind of "cooing" sound, which is more likely to be heard in states of well-being. This is followed by babble stages of varying complexity and articulatory sophistication. Toddlers explore various articulation positions within the oral cavity, refine their tongue mobility and put their own voice to the test in terms of volume and pitch.

From around the 12th month of life, a child can produce the first proto-words (e.g. "tup" for cup) or simple words. Adults intuitively react appropriately to a child's "speech level" either by imitating the sounds the child produces and/or providing a speech model for words that are still "unfinished" (e.g. child: "tup, tup", mother: "Ah, you want the cup"). This allows the child to experience the purpose of communication and to further develop his/her verbal skills.

Influencing factors of a tracheostomy tube on speech development

Children with a tracheostomy tube (TT) placed from birth usually cannot produce a voice to begin with, as the TT fills the entire tracheal space, thus preventing an airflow from reaching the vocal cords[2].

This means that the child cannot hear itself when crying or screaming. Accordingly, the children stop intentionally crying or screaming as this serves no communicative purpose. Often, only reflexive screaming can be observed (in case of pain or hunger in infancy). Likewise, the babble stage is not initiated without an auditory experience. Thus, the child lacks the experiences and the training of the differentiated use of the entire speech apparatus (mouth, tongue, lips, vocal cords). The parents and other relatives are usually very worried because they cannot communicate with the child in the usual way. The following questions often arise in this context:

- How can we recognize what our child wants and/or what is wrong with him/her when he/she is crying?
- How far forward is my/our child in his/her cognitive development?
- Is it just the TT that is preventing our child from speaking, or does he/she also have other cognitive impairments?

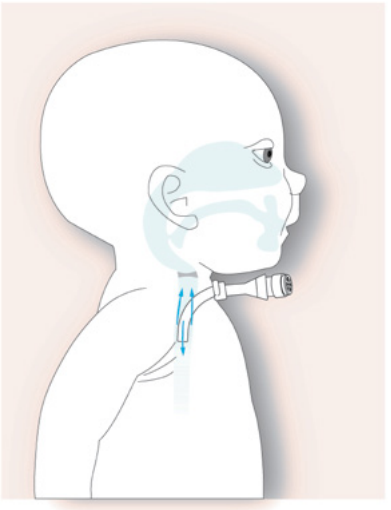

Figure 1. Child with tracheostomy tube and speaking valve.

The great concern of parents is whether their child will ever be able to speak. Although speech production is usually delayed in children with a tracheostomy tube, it can be compensated for with appropriate support – **always provided that there are no other cognitive or motor impairments.**

Promotion of communication skills and speech initiation

In order to make the significance of communication clear to the children and not to leave them alone with their needs, it is important to pay attention to their facial expressions and signs, and to respond to them verbally. This creates a relationship and bond between a child and the person who is most important for the child. The joy and pleasure of communicating are important factors that should be conveyed to the child.

Nicolin Bähre, independent academic Speech and Language Therapist with additional qualification in systemic supervision and coaching.

As a child grows, the diameter of the trachea also increases, so that, while the size of the TT remains the same, air can at some point get past the TT and pass through the vocal cords into the upper airways. This requires the absence of any obstruction above the TT that would impede the passage, and a reliable oxygen supply even with a small TT. As described in the above article 2, the use of a speaking valve as early as possible is an important aspect when promoting speech development in a child.

Figure 2. Regular conversations promote the child's communication skills.

Methods of speech initiation

In order to support a child's development, so-called sound dialogues are conducted, i.e. the sounds produced by the child are imitated. In doing so, one looks at the child while demonstrating the joy of „dialogue" through one's own facial expressions. The aim is to convey that communication is fun. Animals or vehicles are often the first objects of interest that children notice and play with. This offers the opportunity to imitate the animal sounds or vehicle noises. The children can also use this to try out their voice, pitch and volume, because a dog can bark very loudly, a cat can meaow softly, a cow can moo deeply, and a bird or chicken can cheep or caw. Frequent repetitions of the same sound are important.

Figure 3. Learning animal noises while playing promotes language development.

The use of signs supporting the sounds is a very valuable method to give the children a possibility of communicating early on. Supporting sounds with signs means that the corresponding signs are used for objects and actions expressed verbally at the same time. This allows children to communicate even before they can actually pronounce a word or hear their voice. Here, too, it is important to use the signs consistently and in the same manner. Although little children are often not yet capable of performing the signs as precisely as older children or adults, those familiar with the child will recognize his/her individual performance.

When a child uses a sign, the adult will repeat it, both as a sign and phonetically. For example: The child makes the sign for car because he/she sees or hears a car outside. The caregiver looks at the child and repeats the sign while saying at the same time: "Yes, that is a car" or „Did you hear a car right now?" Just as with speech development in healthy children, the introduction of signs must be adapted to the child's level of development. As a first step, signs essential for the child are introduced. These include: Mummy, Daddy, eat, drink, hungry, tired/sleep, etc. These signs are introduced gradually and used consistently so that the child can imitate and adopt them. This method allows the child to learn the following essential aspects of communication:

- It is important to look at each other when conversing
- There are names for objects and actions that are generally used
- I can impart and relate by communicating
- I make contact
- There are names for objects and people, for actions and for characteristics (hot, loud, bright, etc.)

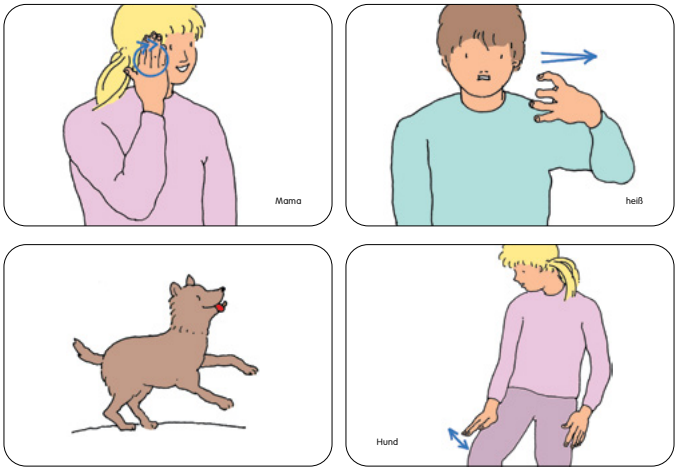

Figure 4. "Sprechen lernen mit GuK [Learning to speak with sign-assisted communication]", developed by Prof. Etta Wilken. With kind approval of the German Down-Syndrom InfoCenter

Once a child no longer needs the sign because he/she can express the word verbally, he/she will automatically drop it. Speech develops much faster if a child has previously communicated using signs, since he/she has already learned the above-mentioned basic principles and rules of speech.

In some cases, spoken communication can be difficult or impeded in its further development because the child, for example:

- suffers from articulatory impairments (impaired tongue function)
- suffers from repeated infections, which make the use of a speaking valve difficult (a lot of secretion, vomiting due to frequent coughing)
- requires a TT that prevents the use of a speaking valve (larger TT due to oxygen supply, blocked TT aspiration pneumonia)

A digital communication device (e.g. Tobii) can be a good addition and/or alternative in these cases.

Figure 5. I110 by TobiiDynavox. With kind approval of Tobii Technology GmbH.

Conclusion

Giving a child the opportunity to communicate with his/her environment in order to participate and integrate socially is of major importance. How this is done and what tools are used is of secondary importance. If spoken communication is possible, it should be chosen and encouraged, as it is shared by most people. However, mixed forms of communication (speech + signs + digital media) are also helpful and can be used, if necessary, even temporarily. **Encouragement and support always focus on a child's social participation.**

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sleep apnea. The survey revealed that more than one in two Americans say they snore, or a bed partner has told them they snore, yet 78% of those who snore aren't concerned it could be related to an underlying health condition, despite snoring being a top symptom of sleep apnea. Additionally, nearly half of survey respondents said their doctor had not asked them about their sleep quality, reinforcing the importance of consumers being aware of the potential health impacts of poor sleep and acting on key sleep apnea symptoms such as snoring. "While data show that stress and worry are key factors impacting many people's sleep, now is an opportunity for everyone to take measure of all of the factors that could be impacting the quality of their sleep, which could include sleep disorders that can have negative long-term impacts to overall health," said Nunez. Everyone experiences a lousy night of sleep once in a while; however, those who experience ongoing sleep issues could be dealing with a more significant underlying health condition. Most survey respondents who snore overwhelmingly discount the potential health impacts, yet snoring is the most prevalent symptom of sleep apnea—one of the most common sleep disorders. Over 54 million adults in the US have sleep apnea, but more than 80% don't know they have it. Undiagnosed and untreated sleep apnea may increase your risk for developing other chronic and life-threatening conditions, including high blood pressure, heart disease, and Type 2 diabetes. "Sleep apnea can impact all types of people from all walks of life, and while some people are more prone to have sleep apnea, it does not discriminate," said Nunez. "If you snore, have been told you stop breathing in your sleep, or feel tired each day despite getting enough hours of sleep, ask your doctor if sleep apnea—which is 100% treatable at home—could be the cause." To learn more about ResMed's sleep surveyor to take a free quiz about your risk for sleep apnea, visit SleepForBetterTomorrow.com.

EMA Launches Review of Clot Risk With AstraZeneca COVID Vaccine

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) is investigating cases of thromboembolic events related to AstraZeneca's COVID-19 vaccine, but says the benefits currently still outweigh risks. As of March 10, 30 cases of thromboembolic events had been reported among nearly 5 million people vaccinated with the AstraZeneca vaccine in the European Economic Area, which includes European Union (EU) countries as well as Iceland, Liechtenstein, and Norway. The Danish Health Authority paused its vaccination campaign with the AstraZeneca vaccine last week as a precautionary measure while they investigate reports of blood clots in people who received the vaccine, including one individual who died, the EMA noted in a statement March 12. Now, several other European countries have temporarily stopped using the AstraZeneca vaccine based on similar reports, including Italy, Germany, France, the Netherlands and Ireland. The EMA issued an update today saying that suspending these vaccination campaigns are "a precaution taken in the light of their national situation while EMA investigates a number of events of blood clots in people who have received the vaccine." Events involving blood clots, some with "unusual features" such as low numbers of platelets, have occurred in a "very small number" of people who received the vaccine, the new statement notes, and the number of events overall in vaccinated people "seems not to be higher than that seen in the general population." The agency is working with AstraZeneca, experts in

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Respiratory Distress and Abnormal CT Scan in a Newborn Infant

Ellen Foster, MD and Shabih Manzar, MD

Summary

We present here an infant born at 34 weeks with abnormal chest CT scan of unknown etiology. At the time of this report, infant remains on 60% oxygen and 1.5 liter per minute of flow to keep the oxygen saturations in the target range of 92-95%. The genetic workup including Surfactant Protein B (SFTP-B) deficiency, Surfactant Protein C (SFTP-C) deficiency, ATP binding cassette protein (ABCA-3) dysfunction and NKX2-1 mutation are pending.

Case

A late preterm 34-2/7 weeks black male infant was delivered via emergency C-section at an outside facility due of fetal decelerations and breech presentation. APGARS were 7 and 9 at 1 and 5 minutes. Maternal prenatal history was significant for drug use (THC, opiates), *E. coli* UTI, trichomonas infection, and poor prenatal care. Perinatal labs were unremarkable. At delivery infant required positive pressure ventilation (PPV) followed by blow-by oxygen. On day 2 of life, patient had spontaneous desaturations while crying. Patient was transferred to the NICU and started on high flow nasal canula. The chest X-ray (CXR) at this time showed minimal bilateral perihilar streaky lung edema. Sepsis workup was collected to rule out infection and patient was started on ampicillin and gentamicin.

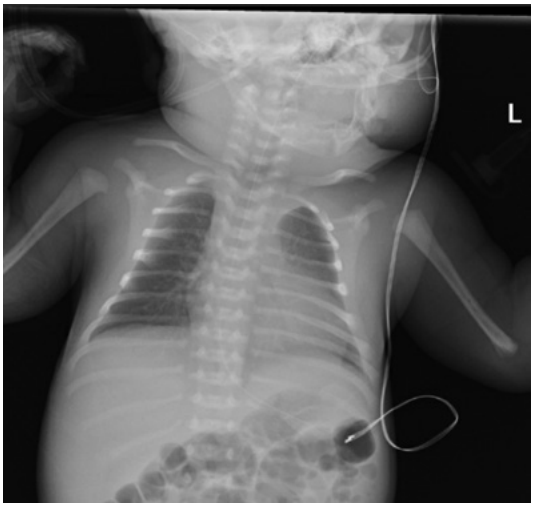

Figure 1. Chest X-ray compatible with RDS

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Sepsis workup remained negative and blood cultures showed no growth, so antibiotics were discontinued after 48 hours. Repeat CXR showed improvements in perihilar markings. However, multiple attempts to wean on high flow nasal cannula failed as patient continued to experience spontaneous desaturations. The blood gas showed pO2 of 50 and then 57 even after FiO2 was increased to 100%; pH remained normal. Echocardiogram showed PFO vs. ASD. Pre- and post-ductal SpO2 difference noted to be >3%. On day 7 of life, patient was transferred to our NICU for further evaluation and higher level of care.

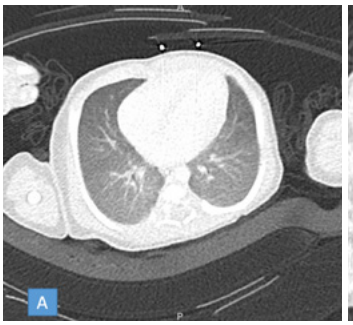

Figure 2 A. Chest CT axial view showing bilateral infiltrates

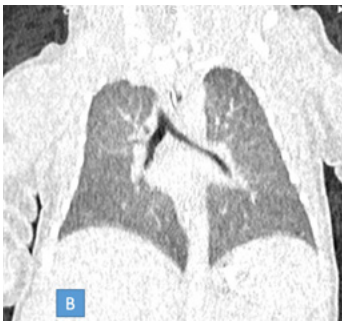

Figure 2 B. Chest CT coronal view showing bilateral infiltrates

Investigation into the cause of patient's hypoxia began with a repeat CXR, which now revealed a fine diffuse granular appearance of the lungs without evidence of consolidation, pneumothorax, or effusion (Figure 1). Repeat echocardiogram was obtained and revealed peripheral branch PAS and PFO. CT chest revealed diffuse ground-glass opacities in both lungs (Figure 2 A and B).Upper airway evaluation revealed excessive nasal secretions and mild laryngomalacia, which was not obstructing the airway and not contributory to patient's symptoms. Upper GI series notable for significant reflux to the lower neck level (Figure 3); modified swallow study was normal with no evidence of aspiration. This points to the possibility of RDS with subsequent chronic lung disease or interstitial lung disease as the cause of this patient's symptoms.

Case Progression

An intensive search for etiology of abnormal chest CT remains unrevealing. Repeat echocardiogram and modified swallow study were normal. Upper GI series showed gastroesophageal reflux. Treatment attempts including furosemide, chlorothiazide, and prednisolone have had little to no effect on the patient's oxygen requirements or respiratory status to date. The genetic workup

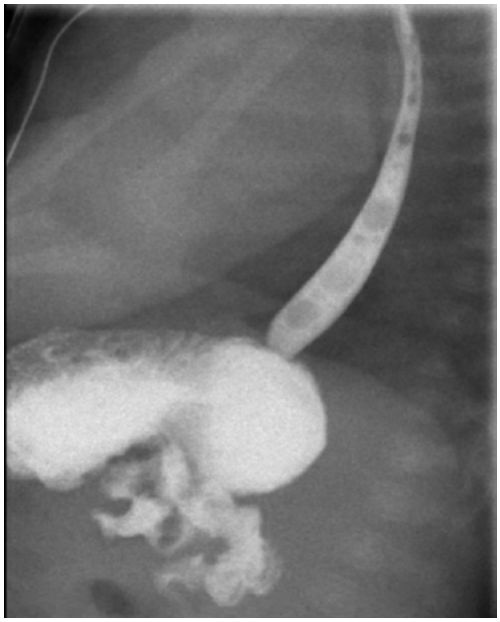

Figure 3. Upper GI showing reflux

including Surfactant Protein B (SFTP-B) deficiency, Surfactant Protein C (SFTP-C) deficiency, ATP binding cassette protein (ABCA-3) dysfunction and NKX2-1 mutation is pending.

The case remains a mystery for now. We are waiting on the results from genetic workup. We plan to send the infant home on oxygen and follow up with pediatric pulmonology.

Discussion

Respiratory distress is a common finding in premature infants and remains the most common cause of admission to the NICU.[1] However, this case presents an interesting challenge in both diagnosis and management. On initial evaluation, the patient exhibited signs of classic respiratory distress syndrome (RDS) on both physical exam and CXR. He was placed on high flow nasal cannula on day 2 of life. While RDS is much more common in patients born < 34 weeks of age, this patient's C-section delivery placed him at higher risk of this common disorder, making this the most likely diagnosis at the time. RDS typically improves by day 4 or 5 of life as surfactant production and diuresis improve.[2] In the case of this patient, he began to clinically deteriorate around day 7 of life with worsening appearance of CXR and continuous need for respiratory support. Increases in FiO2 to 100% produced minimal changes in observed pO2 and multiple attempts to wean support were unsuccessful, prompting workup for causes other than RDS. Evaluation for cardiac, infectious, or aspiration-related causes of symptoms was unrevealing, and the patient's newborn screening was negative for CF, thyroid, or other autoimmune disorders. Ultimately, chest CT was performed and revealed diffuse bilateral ground glass opacities.

While ground glass opacity is nonspecific and not diagnostic of any particular disorder, it is a common finding seen in interstitial lung disease.[3] These disorders are rare in the pediatric population with an estimated prevalence of 0.13-16 cases/100,000 children per year; the incidence in neonates is not known.[4] According to the guidelines devised by the American Thoracic Society, diagnosis is considered in a patient that has 3 of the 4 following criteria — respiratory symptoms, respiratory signs, hypoxemia, and diffuse abnormalities on chest radiography;[5] this patient fits all 4 criteria. As with this patient, initial CXR may appear unremarkable and progressively worsen over time. Beyond the general diagnosis of interstitial lung disease (ILD), the identification of the specific disorder present presents another challenge as radiography is not diagnostic of the specific ILD at hand. In fact, a survey of the European Respiratory Society Pediatric Assembly found that in 10.6% of cases, no specific cause of ILD was found.[6] In preterm infants like this patient, congenital disorders of surfactant production are often the culprit and require genetic testing of surfactant protein B (SFTP-B), surfactant protein C (SFTP-C), ATP binding cassette protein (ABCA-3), and NKX2-1 mutation. While the sensitivity and specificity of these genetic tests is not known, the results are positive for SFTP-C in ~17% and ABCA-3 in ~5-22% in patients with signs and symptoms of ILD beyond 4 weeks of life.[5] Identification of the underlying cause of ILD is essential to tailor the patient's therapy as well as guide parental counseling on the patient's prognosis. If this patient's genetic testing is unrevealing, lung biopsy will be the next step in diagnosis.

As the prevalence of these diseases in the neonatal population is low, there are few current guidelines to the management of these patients. Previous cases report success with immunosuppressives such as corticosteroids and hydroxychloroquine,[5] but management currently relies on case studies/series and clinical judgment. Our patient remains stable on VTH and is growing appropriately. Corticosteroids had little effect on the patient's respiratory status, and he continues to require high flow nasal cannula at 1.5 LPM with FiO2 of 60%. We will continue to adjust nutrition and respiratory support as clinically indicated until genetic testing results become available.

In conclusion, interstitial lung disease is a rare but present disorder in the neonatal population. Diagnosis and management guidelines are limited due to the lack of controlled trials and low disease incidence in the pediatric population. More research is needed in this field of study to better manage newborn infants with signs and symptoms of interstitial lung disease.

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Capnography: A Vital Sign for Improving Care

Lauren Migliore

Capnography has long been used by anesthesiologists to monitor proper ventilation and the condition of patients under sedation, during surgery, or mechanical ventilation. Critical care units, procedural sedation suites, and emergency medical services, among others have also adopted capnography in recent years to enhance patient safety and non-invasively monitor patients with respiratory conditions. But when COVID-19 patients flooded hospitals and experienced high risks of respiratory failure, it drove the need for capnography even further.

Capnography, or End-tidal CO_2 ($EtCO_2$) is a visual, non-invasive display of carbon dioxide concentration present at the end of each breath. It works by monitoring alveolar ventilation and provides a numeric, respiratory rate, and waveform of CO_2 levels as they change during breathing. Not only can capnography indicate if a patient is breathing adequately, but it can also yield key information about a patient's pulmonary and cardiovascular status with more precision than traditional vital sign measurements.

Capnography Goes Beyond Traditional Vitals

$EtCO_2$ is a valuable and sensitive measurement of ventilation that can alert clinicians to early changes in a patient's breathing before hypoventilation, hyperventilation, and other potentially life-threatening conditions occur. For example, when a patient is breathing normally, a sudden decrease in $EtCO_2$ levels indicates a loss of perfusion from a sudden decrease in blood flow to the lungs, suggesting a possible pulmonary embolism, loss of cardiac output, or sudden heart failure in a patient. With the additional data of $EtCO_2$, clinicians can better assess a patient's condition and create effective treatment plans.

A New Standard for Covid-19 Patients

With the high risk of respiratory failure in COVID-19 patients and increased need for critical care support, capnography has become a vital tool for assessing and managing respiratory care. Safely caring for these patients requires meticulous attention to detail, and monitoring specific vital signs — especially capnography's $EtCO_2$ and pulse oximetry's SpO_2 — becomes even more important. The Joint Commission advises the use of both since pulse oximetry will detect changes in oxygen concentration while the $EtCO_2$ values of capnography can identify if a patient's ventilation is compromised. Used together, these devices offer clinicians a more accurate snapshot into a patient's breathing, overall health, and awareness for necessary intervention or possible life-saving treatment decisions.

A Key Tool in Patient Intubation

Proper endotracheal tube placement is key to ensuring successful mechanical ventilation with both COVID-19 and critical care patients. Capnography has proven to be a valuable tool when intubating using laryngoscopy or rapid sequence intubation (RSI). Not only can it help confirm correct endotracheal tube placement, but it can also help identify airway obstruction, issues with a circuit, or a leak in the seal.

Following intubation, monitoring $EtCO_2$ may offer insight into the effectiveness of the breathing circuit. With true breath-to-breath feedback during gentle positive pressure ventilation (PPV) and by bag valve mask (BVM), this information can help overcome the natural tendency to over-ventilate a patient. capnography provides, helping maintain proper ventilation.

With more data comes the potential for more effective clinical assessment, and several organizations, including the AARC (American Association of Respiratory Care), ASA (American Society of Anesthesiology), and ESA (European Society of Anesthesiology), have now issued recommendations on airway management for COVID-19 patients that include the use of waveform capnography prior to and during intubation.

The Gold Standard for Resuscitation

COVID-19 has also changed how Emergency Medical Service (EMS) responders must react, especially when it comes to mitigating transmission risks of the virus during airway management procedures for respiratory distress and failure patients. But one thing that remains consistent is the use of capnography to monitor patients. It helps gives first responders and Rapid Response teams more information to support effective clinical assessments and better patient outcomes.

COVID-19 patients may often present with low blood oxygen (SpO_2) values. However, $EtCO_2$ values will remain accurate and reflective of the patient's ventilation and perfusion status, regardless of SpO_2. It may also detect the return of spontaneous circulation (ROSC), provides continuous, breath-to-breath feedback, assess the quality of chest compressions, and indicate

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when to end resuscitation efforts, making it the gold standard for first responders and monitoring airway management.

Providing Support across the Board

Capnography hosts a range of applications that can be utilized by across the spectrum of patient care. From operating rooms and critical care units to the NICU and long-term care, capnography is a valuable tool that can be used in addition to pulse oximetry to assess and monitor intubated, mechanically ventilated, or spontaneously breathing patients of all sizes. Today, this technology allows us to be much more precise when assessing and monitoring both the pulmonary and cardiovascular status of patients. As a unique measurement, capnography is quickly becoming a staple for evaluating and delivering enhanced patient care.

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blood disorders, and other health authorities, including the UK's Medicines and Healthcare products Regulatory Agency (MHRA), where around 11 million doses have already been administered. "EMA's investigation has been continuing over the weekend, and rigorous analysis of all the data related to thromboembolic events will be carried out in the coming days," the agency notes. "Experts are looking in great detail at all the available data and clinical circumstances surrounding specific cases to determine whether the vaccine might have contributed or if the event is likely to have been due to other causes."

At-Home COVID-19 Testing: Convenience, Cost, and Some Caveats

At-home testing for COVID-19 features great convenience, but pathology experts caution that false positives, false negatives, out-of-pocket costs, and the potential for inadequate sampling from people swabbing their own noses or mouths could compromise results. Experts agree that COVID-19 testing has had its challenges and has evolved over the past year. "It's a very, very significant day," Kisha Mitchell Richards, MD, FCAP, director of pathology and laboratory at Greenwich Hospital, Greenwich, Connecticut, said at a March 11 webinar on COVID-19. The webinar was sponsored by the College of American Pathologists (CAP). "It's 1 year ago today that the World Health Organization declared COVID-19 a pandemic and basically set in stone a year that was going to change our lives probably forever," Richards said. During that time, "PCR testing" became more of a household term, community and preoperative testing changed and expanded, and more at-home tests gained emergency use authorization from the US Food and Drug Administration (FDA). Among them is the first molecular-based at-home test, which was approved earlier. However, the number and nuances of COVID-19 tests have left some people with questions. "People are still having difficulty understanding the tests. This may be due to the shift in focus to the vaccines and/or being overwhelmed and confused by the amount of information available," said Patrick Godbey, MD, FCAP, president of CAP and laboratory director of Southeastern Pathology Associates and Southeast Georgia Health System, Brunswick, Georgia.

Vaccinators Put Squeeze on FDA to Relax Vaccine Handling Advice

President Joe Biden has promised enough covid vaccine to immunize every willing adult by June 1. But the gap between supply and demand has been so dramatic that vaccinators discoveried ways to suck the final drops out of each vaccine vial — if federal regulators will let them. Pharmacists involved in the covid vaccination drive say it's common to have half a dose left in a Pfizer vial after five or even six doses have been administered — and to have half a dose left after 10 doses have been drawn out of a Moderna vial. Combining two half-doses could increase vaccinations by thousands at a time when 2 million or so doses are being administered every day in the country. So, they want to use a single hypodermic needle to withdraw leftover vaccine from two vials from which all full doses already have been removed. The American Society of Health-System Pharmacists asked the Food and Drug Administration consider granting permission to do so in a recent letter. The governors of Colorado and Oregon also have sought permission to allow their pharmacists to pool covid vaccine vials. Federal health regulators, however, have long opposed the reuse of drug vials because of the risk of introducing a bacterial contaminant. From 1998 to 2014 more than 50 outbreaks of

viral or bacterial disease were reported as a result of unsafe injection practices, including injecting multiple patients with a drug from the same vial. The FDA wouldn't comment on the pharmacists' letter but restated to KHN its current policy that "doses not be pooled from different vaccine vials, especially for coronavirus vaccines, which are not formulated with a preservative." On its website, the Centers for Disease Control and Prevention explicitly tells vaccinators to discard vials "when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose." "It's a recipe for disaster," said Ann Marie Pettis, president of the Association for Professionals in Infection Control and Epidemiology. There is always a tiny chance that one of the two vials has previously been contaminated, which would contaminate a shot that combined their contents, she said. Spokespeople for both Moderna and Pfizer said excess portions of their vaccines must be discarded and never pooled. Johnson & Johnson had no comment on the issue.

Fauci Worries About Possible Post-COVID 'Mental Health Pandemic'

Anthony Fauci, MD, says he's concerned about how Americans will react once the coronavirus pandemic is brought under control, CBS News reports. Noting that an American Psychological Association survey showed people reporting high stress levels because of the pandemic, CBS's Norah O'Donnell asked if Fauci was worried about a possible "mental health pandemic." "Very much so," Fauci, director of the National Institute of Allergy and Infectious Diseases and a top White House coronavirus advisor, replied. "That's the reason why I want to get the virological aspect of this pandemic behind us as quickly as we possibly can because the long-term ravages of this are so multifaceted," Fauci said. Some of the problems could include prolonged physical symptoms and the economic effects of the pandemic, he said. "And then the other things: Not only the mental health effects, but many people have put off routine types of medical examinations that they normally would have done," Fauci said. "I hope we don't see an increase in some preventable situations that would not have happened if people had the normal access to medical care, which clearly was interrupted by the shutdown associated with COVID-19." The American Psychological Association released the survey results Thursday in what many people consider the 1-year anniversary of the start of the coronavirus pandemic. "The prolonged stress experienced by adults, especially the high levels of stress reported by Americans directly linked to the pandemic, is seriously affecting mental and physical health, including changes to weight, sleep and alcohol use," the APA said in a news release.

Online COVID-19 Symptom Checkers May Not Catch Severe Illnesses

Digital COVID-19 symptom checkers in the US and the UK may fail to identify severe COVID-19 and other serious illnesses such as bacterial pneumonia or sepsis, according to a group of public-health researchers. The online tools often advise patients to stay home and may prevent them from getting prompt treatment, the team writes in BMJ Health and Care Informatics. "As a frontline COVID doctor myself, I was concerned that the symptom checker was delaying the presentation of patients with severe COVID-19 to the hospital, and this was adding to the pressure on higher-dependency areas, such as" intensive-care units (ICUs), said senior author Dr Daniel Goyal of the Gibraltar Health Authority and Gibraltar's COVID-19 Research Group. "The earlier we can identify pneumonia, the easier it is to facilitate recovery," he told Reuters Health by email. "If patients present late, then they have higher mortality, higher rates of ICU admissions, longer admission, and they take much longer to recover, if they survive." Dr Goyal and his colleagues ran a simulation study in April 2020 on nationwide symptom checkers in the US, UK, Japan and Singapore. They used 52 cases that represented typical COVID-19 presentations, including mild, moderate, severe and critical cases, as well as COVID-19 "mimickers" such as bacterial pneumonia and sepsis. The case scenarios included symptoms such as cough, fever and shortness of breath, along with underlying conditions, immunosuppression, age, symptom severity and symptom duration. They compared the recommendations, including whether patients were advised to seek medical care or stay at home. Overall, the research team found that the Japan and Singapore checkers were twice as likely to recommend medical care. About 88% of the Singapore cases were triaged onward, followed by 77% in Japan, 44% in the UK and 38% in the .S. Both the UK and US tools consistently failed to identify severe COVID-19, bacterial pneumonia and sepsis, often advising patients to stay at home and not seek care. The Singapore and Japan symptom checkers recommended clinical assessment after four days of symptoms, whereas the US and the UK tools didn't change based on the duration of symptoms. Age also didn't appear to affect the recommendations in the US or UK, but all patients in Singapore over age 65 with viral symptoms and all "older adults" in Japan who had viral symptoms for more than two days were advised to seek medical care.

First Pill for COVID-19 Could Be Ready by Year's End

New pills to treat patients with COVID-19 are currently in midstage clinical trials and, if successful, could be ready by the end of the year.

Only one treatment — remdesivir (Veklury) — has been fully approved by the US Food and Drug Administration (FDA) for patients in the hospital and it must be administered intravenously. Hopes for a day when patients with COVID-19 can take a pill to rid their bodies of the virus got a boost over the weekend when early trial results were presented at a medical conference. Interim phase 2 results for the oral experimental COVID-19 drug molnupiravir, designed to do for patients with COVID-19 what oseltamivir (Tamiflu) can do for patients with the flu, were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) 2021 Annual Meeting. In the small study, the pill significantly reduced infectious virus in patients who were symptomatic and had tested positive for COVID-19 during the previous 4 days but were not hospitalized. After 5 days of treatment, no participants who received molnupiravir had detectable virus, whereas 24% who received placebo did. Two other oral agents are being developed by RedHill Biopharma: one for severe COVID-19 infection for hospitalized patients, and one for patients at home with mild infection. The first, opaganib (Yeliva), proceeded to a phase 2/3 global trial for hospitalized patients after the company announced topline safety and efficacy data in December. In phase 2, the drug was shown to be safe in patients requiring oxygen and effectively reduced the need for oxygen by the end of the treatment period.

California Leaders Look to Reopening, Push 1-Shot Vaccine

California officials are contemplating what things will look like in the nation's most populous state once millions of people are vaccinated and they move to phase out restrictions on gatherings

and businesses that have altered life for a year. When officials last summer designed the four-tiered, yellow-to-purple system California now uses to decide whether people can dine indoors, go to the movies or gather with friends, they did not include a green tier — a recognition that a return to normalcy after the pandemic was far off. Now, Gov. Gavin Newsom's administration is preparing to add one. "The likelihood of hitting that green tier is probably sooner than some of us thought when we were looking at the summer and fall," Dr Mark Ghaly, California's health secretary, said. State officials rely on a complicated formula, including virus spread, to determine which activities are restricted in each county. But a green designation won't mean "go" for all things. Ghaly said such a label would still mean wearing masks and staying physically distant. He declined in an interview to offer more specifics on what restrictions would be maintained or to provide a threshold of vaccinations the state hopes to meet to allow such a go-ahead. State Public Health Director Dr Tomas Aragón forecast that California could achieve herd immunity when about 75% of the population has been vaccinated, though that could change as the virus mutates. That officials are optimistic enough to publicly discuss a green tier puts California in a dramatically different place than it was a few weeks ago during the state's worst surge. Now case rates, hospitalizations and deaths are on the decline and vaccinations are on the rise.

CDC's 'Huge Mistake'

Since the start of the pandemic, the most terrifying task in health care was thought to be when a doctor put a breathing tube down the trachea of a critically ill covid patient. Those performing such "aerosol-generating" procedures, often in an intensive care unit, got the best protective gear even if there wasn't enough to go around, per Centers for Disease Control and Prevention guidelines. And for anyone else working with covid patients, until a month ago, a surgical mask was considered sufficient. A new wave of research now shows that several of those procedures were not the most hazardous. Recent studies have determined that a basic cough produces about 20 times more particles than intubation, a procedure one doctor likened to the risk of being next to a nuclear reactor. Other new studies show that patients with covid simply talking or breathing, even in a well-ventilated room, could make workers sick in the CDC-sanctioned surgical masks. The studies suggest that the highest overall risk of infection was among the front-line workers — many of them workers of color — who spent the most time with patients earlier in their illness and in sub-par protective gear, not those working in the covid ICU. "The whole thing is upside down the way it is currently framed," said Dr Michael Klompas, a Harvard Medical School associate professor who called aerosol-generating procedures a "misnomer" in a recent paper in the Journal of the American Medical Association. "It's a huge mistake," he said. The growing body of studies showing aerosol spread of covid-19 during choir practice, on a bus, in a restaurant and at gyms have caught the eye of the public and led to widespread interest in better masks and ventilation. Yet the topic has been highly controversial within the health care industry. For over a year, international and US nurse union leaders have called for health workers caring for possible or confirmed covid patients to have the highest level of protection, including N95 masks. But a widespread group of experts have long insisted that N95s be reserved for those performing aerosol-generating procedures and that it's safe for front-line workers to care for covid patients wearing less-protective surgical masks. Such skepticism about general aerosol exposure within the health care setting have driven CDC guidelines, supported by national and California hospital associations. The guidelines still say a worker would not be considered "exposed" to covid-19 after caring for a sick covid patient while wearing a surgical mask. Yet in recent months, Klompas and researchers in Israel have documented that workers using a surgical mask and face shield have caught covid during routine patient care.

New Study Evaluates the Ability of Masimo EMMA Capnography to Assess the Respiratory Status of Children with Tracheostomy

Masimo announced the findings of an observational, retrospective study published in *Pediatrics International.* In the study, researchers at the Osaka Women's and Children's Hospital in Japan found the Masimo EMMA Portable Capnograph "useful for assessment of the respiratory condition in children with tracheostomy." EMMA provides seamless mainstream capnography for patients of all ages in a compact, easily portable device. The device requires no routine calibration and minimal warm-up time, with accurate end-tidal carbon dioxide ($EtCO_2$) and respiration rate measurements and continuous $EtCO_2$ waveforms displayed within 15 seconds. Noting the potential value of a compact and portable way to monitor changes in respiratory status for patients in scenarios where typical inpatient hospital monitoring equipment is less likely to be available, Dr Masashi Hotta and colleagues sought to evaluate the utility of the EMMA capnograph on children with tracheostomy by comparing $EtCO_2$ values from the EMMA device (which was connected to the distal side of the tracheostomy cannula) to invasively measured partial pressure of venous carbon dioxide ($PvCO_2$). Although partial pressure of arterial carbon dioxide ($PaCO_2$) is considered a gold standard for assessing respiratory condition, the researchers chose $PvCO_2$ because "collection of arterial samples is more invasive than collection of venous samples" and noted that studies have shown a correlation between $PaCO_2$ and $PvCO_2$. They enrolled 9 infants (median age 8 months) and compared 43 paired $EtCO_2$-$PvCO_2$ readings in total. The researchers found a correlation coefficient of 0.87 (95% confidence interval of 0.7-0.93; $p < 0.001$) between $EtCO_2$ and $PvCO_2$ readings. Analysis of the data revealed that $EtCO_2$ readings were, on average, 10.0 mmHg lower than the corresponding paired $PvCO_2$ value (95% limits of agreement of 1.0-19.1 mmHg). The researchers speculated that the tendency for $EtCO_2$ to be lower than $PvCO_2$ may be explained by "gas mixing proximal to the tracheostomy cannula due to the presence of anatomic and physiologic dead space. Because almost all patients used a cannula without a cuff, some air leakage may have occurred. In addition, about two-thirds of the patients had [chronic lung disease or bronchopulmonary dysplasia]," which they noted have been shown to cause lower CO_2 concentrations during exhalation, relative to the partial pressure of CO_2 in the blood. They also found that the median difference in values was significantly greater for readings collected while patients were on mechanical ventilation (28 of the 43 data pairs). With a ventilator, there was a median 11.2 mmHg (6.8-14.3) difference; without a ventilator, there was a median 6.6 mmHg (4.1-9.0) difference ($p = 0.043$). The researchers noted that use of a ventilator was significantly related to the difference in paired readings because patients on ventilators had respiratory or circulatory disease. Noting that, "We demonstrated a strong positive relationship between $PvCO_2$ and $EtCO_2$ and revealed the availability and usefulness of this capnometer for children with tracheostomy," the researchers concluded, "EMMA is useful for assessment of the respiratory

condition in children with tracheostomy. EMMA can be used especially in home-care settings and outpatient departments for such children." They also noted, "The main strength of this study is that we used a portable capnometer to evaluate $EtCO_2$."

Asthma-COPD Overlap Linked to Occupational Pollutants

The development and worsening of overlapping asthma and chronic obstructive pulmonary disease (COPD) can be affected by pollutants found in rural and urban environments, according to a recent presentation at the annual meeting of the American Academy of Allergy, Asthma, and Immunology, held virtually this year. a"Urban-rural-occupational air pollutants or respiratory sensitizers impact asthma and the asthma-COPD overlap features," Jill A. Poole, MD, division chief of allergy and immunology at the University of Nebraska Medical Center, Omaha, said in her presentation. The Global Initiative for Asthma (GINA) first outlined a syndrome in 2015 described as "persistent airflow limitation with several features usually associated with asthma and several features usually associated with COPD" and called asthma-COPD overlap syndrome. In 2017, a joint American Thoracic Society/National Heart, Lung, and Blood Institute workshop outlined knowledge gaps about asthma-COPD overlap, noting it "does not represent a single discrete disease entity." "This is not a single disease and should be thought of as being heterogeneous and used as a descriptive label for patients commonly seen in clinical practice," Dr Poole said. "Both asthma and COPD definitions are not mutually exclusive because each disease includes several phenotypes with different underlining mechanisms." An example of how asthma-COPD overlap might present is through a patient with allergic asthma who has a history of smoking who develops airflow obstruction that isn't fully reversible, or a patient with COPD "with high reversible airflow, obstruction, type 2 inflammation, and perhaps the presence of peripheral blood eosinophils or sputum eosinophils." A patient's interaction with urban, rural, and occupational environments may additionally impact their disease, Dr Poole explained. "The environmental factors of an urban versus rural environment may not be necessarily mutually exclusive," she said. "It's also important to recognize occupational exposures that can be both seen in an urban or rural environment [can] contribute to asthma-COPD overlap." In a study of 6,040 men and women with asthma living in Canada, 630 (10.4%) had asthma-COPD overlap, with increased air pollution raising the likelihood of developing asthma-COPD overlap (odds ratio, 2.78; 95% confidence interval, 1.62-4.78). These people experienced later onset asthma, increased emergency department visits before a diagnosis of COPD, and increased mortality. Another study in Canada of women from Ontario in the Breast Cancer Screening Study found 1,705 of 4,051 women with asthma also had COPD. While air pollution did not increase the risk of developing asthma-COPD overlap, there was an association between body mass index, low level of education, living in a rural area, and smoking status. Among farmers in rural areas, "it has been recognized that there is something called the asthma-like syndrome that's been reported in adult farming communities," Dr. Poole said, which includes "some degree of airflow obstruction and reversibility" that can be worsened by smoking and could be an overlap of asthma and COPD. Farmers can also experience asthma exacerbations while working, and "livestock farmers appear more at risk of developing [chronic bronchitis and/or COPD] than do the crop farmers," she noted. Occupational environments outside of agriculture exposure can cause incident asthma, with high-molecular-weight antigens such as flour cereal, animal dander, latex, psyllium, crab processing products, and enzymes as well as low-molecular-weight antigens such as isocyanates, woods, antibiotics, glues, epoxies colophony products, and dyes presenting a risk. In food processing, main allergen sources can include raw and processed animal and plant products, additives and preservatives, contaminants from microbes or insects, inhaled dust particles or aerosols, which can be "IgE mediated, mixed IgE-mediated and non-lgE mediated." While some studies have been conducted on the prevalence of work-related asthma and asthma-COPD overlap, "in general, the prevalence and clinical features have been scarcely investigated," Dr Poole said. One survey of 23,137 patients found 52.9% of adults with work-related asthma also had COPD, compared with 25.6% of participants whose asthma was not work related. To prevent asthma-COPD overlap, Dr Poole recommended tobacco cessation, reducing indoor biomass fuel use, medical surveillance programs such as preplacement questionnaires, and considering "reducing exposure to the respiratory sensitizers with ideally monitoring the levels to keep the levels below the permissible limits." Dr Poole noted there is currently no unique treatment for asthma-COPD overlap, but it is "important to fully characterize and phenotype your individual patients, looking for eosinophilia or seeing if they have more neutrophil features and whether or not the allergy features are prevalent and can be treated," she said. "[A]wareness is really required such that counseling is encouraged for prevention and or interventional strategies as we move forward." For patients with features of both asthma and COPD where there is a high likelihood of asthma, treat the disease as if it were asthma, Dr Poole said, but clinicians should follow GINA GOLD COPD treatment recommendations, adding on long-acting beta-agonists (LABAs) and long-acting muscarinic antagonists (LAMAs) when needed, but avoiding LABAs and/or LAMAs without use of inhaled corticosteroids, and avoiding oral corticosteroids entirely. Clinicians should be reviewing the treatments of patients with asthma and COPD features "every 2-3 months to see how their response is to it, and what additional therapies could be used," she said. Dr Poole reports receiving grant support from National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, and the Central States Center for Agricultural Safety and Health at the University of Nebraska Medical Center.

COVID-19 Isolation and an Infant's Immune System

Queirra Fenderson, a first-time mom in Fort Washington, MD, gave birth to her daughter, Arya, at the end of December 2019. On the advice of their pediatrician, she and her husband spent the first month of their daughter's life living in a "bubble" with only a few close family and friends seeing their baby to protect her from germs during cold and flu season. Right about the time the new parents were ready to start exposing Arya to more people and germs, the pandemic hit. So a year later, their 14-month-old still remains in that bubble. "There are still people to this day, some are my closest friends, who haven't met her yet. It's crazy," Fenderson says. She says she and her husband have often wondered how this isolation is impacting their daughter's developing immune system. They've even considered day care to boost her immunity, but balancing that against the risk of COVID-19 has led them to still keep her home. "Arya hasn't been sick her whole entire life, and I want her to get more exposure to germs to boost her immunity. But in my gut, I'm afraid of the exposure to COVID, too," Fenderson says. "Pandemic parenting is hard." Simone Christensen of California agrees. She's been very cautious with her 9-week-old daughter, Scout, who has seen only a few family members since

she was born. Christensen has asthma, and their pediatrician has stressed the need to be cautious about COVID-19. But she and her husband also worry how isolation is impacting their daughter's immune system. "Scout hasn't really been exposed to much at this point, which seems crazy because I feel like at this age, I was probably sucking on a table at McDonald's," she says with a laugh. "Anytime you talk to someone who raised their child pre-pandemic, they always tell you how important it is to expose babies to germs so their immune system starts to build up, and I always thought I'd be the kind of mom who does that. But everything is different because of COVID. The risks are so much greater, and trying to figure out what's best in a pandemic is scary and hard." Leana Wen, MD, is an emergency room doctor and a public health expert. She's also a mom whose second child — a 10-month-old girl — was born during the pandemic. She says there's good reason to be cautious with babies and what you expose them to early in life. "Newborns are highly susceptible to illnesses," she says. "They don't have much of an immune system of their own, so even pre-pandemic, we advised people to be very careful to germ exposure with newborns, understanding that they develop more robust immune systems over time." But many others, like B. Brett Finlay, PhD, a Canadian microbiologist and professor of microbiology at the University of British Columbia, also stress that early exposure to microbes has been shown to help a baby's immune system develop well. "We've learned over the last decade or so that the normal development of the immune system absolutely requires the presence of normal microbes," says Finlay, co-author of *Let Them Eat Dirt: Saving Your Child from an Oversanitized World*. "It makes a difference in childhood development, and lack of exposure to these good microbes affects allergies, asthma, eczema, obesity, and more,"

We don't know everything about how the immune system is built, "but we do know the end result is you need these early life microbes to get normal immune system development." This question, often referred to as the hygiene hypothesis, was first raised in 1989, and it has long caused controversy and debate. It argues that the developed world's focus on clean environments through the use of disinfectants, sanitizers, and bleach has a negative impact on the immune system. The FDA points out it is one of many explanations for "for asthma being the most common chronic disease in the developed world." But plenty of others aren't so sure. Researchers who published a study in 2016 found "no good evidence that hygiene, as the public understands, is responsible for the clinically relevant changes to microbial exposures." The study, published in *Perspectives in Public Health*, says a combination of things, including "natural childbirth, breast feeding, increased social exposure through sport, other outdoor activities, less time spent indoors, diet and appropriate antibiotic use, may help restore the microbiome and perhaps reduce risks of allergic disease." The hygiene hypothesis theorizes that cleanliness and lack of exposure to microbes have led to increased allergies, asthma, and other conditions.

Almost All US COVID-19 Deaths Now in the Unvaccinated

If you, a friend or a loved one remain unvaccinated against COVID-19 at this point — for whatever reason — you are at higher risk for dying if you do become infected. That's the conclusion of a new report The Associated Press released looking at COVID-19 deaths during May 2021. Of more than 18,000 people who died from COVID-19, for example, only about 150 were fully vaccinated. That's less than 1%. "Recently I was working in the emergency room [and] I saw a 21-year-old African- American who came in with shortness of breath," says Vino K. Palli, MD, a doctor specializing in emergency medicine, internal medicine and urgent care. The patient deteriorated rapidly and required ventilation. She was transferred to a specialized hospital for in case she needed what's known as ECMO treatment, where blood is pumped outside your body to remove carbon dioxide. "This patient was unvaccinated along with her entire family. This would have been easily preventable," says Palli, who is also founder and CEO of MiDoctor Urgent Care in New York City. "Vaccine misinformation compounded with vaccine inertia and vaccine access has contributed to this," he says. "Even though we have a surplus amount of vaccines at this time we are only seeing 50 to 55% off completely vaccinated patients." The AP report authors also acknowledge that some people who are fully vaccinated can get a "breakthrough infection" of COVID-19. These occurred in fewer than 1,200 of more than 853,000 people hospitalized for COVID-19 in May, or about 0.1%. The AP came up with these numbers using CDC data. The CDC tracks the numbers of cases, hospitalizations and deaths, but does not break down rates by vaccination status. "The fact that only 0.8% of COVID-19 deaths are in the fully vaccinated should persuade those people still hesitant about vaccination," says Hugh Cassiere, MD, medical director of Respiratory Therapy Services at North Shore University Hospital in Manhasset, NY. Stuart C. Ray, MD, professor of Medicine and Oncology in the Division of Infectious Diseases at Johns Hopkins University School of Medicine in Baltimore, says. "It seems compelling, even for skeptics, that unvaccinated people represent 99% of those now dying from COVID-19, when they represent less than 50% of the adult population in the USA." The findings from the study could be more persuasive than previous arguments made in favor of immunization, Ray says. "These recent findings of striking reductions in risk of death in the vaccinated are more directly attributable and harder to ignore or dismiss." Brian Labus, PhD, of the University of Nevada Las Vegas is less convinced. "While this might change some peoples' minds, it probably won't make a major difference. People have many different reasons for not getting vaccinated, and this is only one of the things they consider." ■

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[1] Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB, Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, Journal of the American College of Surgeons (2019)

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