

Objective Evaluation of Neonatal Ventilators

Choosing which ventilator to purchase can dramatically affect what type of care patients get, practitioners' working environment, and the hospital's "bottom line." Choosing a ventilator is a complicated process, often confounded by competing stakeholders. Trying to balance the desires of the hospital management, physicians, and respiratory therapists can be tricky. Getting the right equipment for the patient can be even more difficult in the neonatal intensive care unit (NICU), because few ventilators are made especially for premature babies. Objective data and tools are critical for guiding the acquisition of new ventilators, or even deciding to continue on with the existing fleet.¹ Published information on the value and effectiveness of individual devices and features is limited. Improved patient outcomes due to technology innovation are difficult to demonstrate.²

In October 2001, Chatburn and Primiano published in *RESPIRATORY CARE*³ a ventilator-evaluation tool to guide intensive care unit ventilator purchases. They devised a checklist scoring system to objectively evaluate ventilators based on technical features, operator interface, and customer service. That system uses objective data to allow stakeholders to compare devices "head to head" in a data-centered way. The balanced approach to the evaluation includes such important details as the maintenance costs, which might otherwise be overlooked by an evaluation committee. Although slightly limited by the fact that it was not designed specifically for the NICU, and that new ventilator features have become available, Chatburn and Primiano's tool is still highly relevant today. Scores for each device with the desired new features included can be incorporated in the evaluation by adding them to the Optional Functions section.

The ventilator-evaluation tool can provide a score based on the availability of a feature on a ventilator, but it can't help in the evaluation of the clinical effectiveness of features and systems. Issues especially important to clinicians in the NICU, such as the work of breathing imposed by the machine and circuitry, monitoring and accuracy of delivered tidal volumes, and the functioning and effectiveness of the ventilator modes, must be evaluated in the laboratory and with clinical trials. In this issue of the *Journal*,⁴ DiBlasi et al report a laboratory investigation of the ventilator-imposed expiratory resistance of 4 neonatal ventilators. One of the ventilators they tested was a neonatal-only device that was cleared by the United States Food and

Drug Administration in the early 1990s and is in widespread use in NICUs around the world. The other three are so called "cradle-to-grave" ventilators, all of which were cleared by the Food and Drug Administration after 2000. Are the newer devices superior? Are neonatal-only ventilators more effective for infants in the NICU, regardless of the ventilator's release date? These important questions have yet to be answered.

SEE THE ORIGINAL STUDY ON PAGE 1450

There are some important revelations in the extensive laboratory evaluation by DiBlasi et al.⁴ It has long been accepted that the resistance of the endotracheal tube is a factor in gas exchange and work of breathing in neonatal patients.^{5,6} High expiratory resistance in a neonatal breathing system can impair gas exchange, elevate the work of breathing, delay ventilator weaning, and affect lung-mechanics measurements.⁶⁻⁹ Imposed resistance through any or all of the airways can produce alveolar hyperinflation and intrinsic positive end-expiratory pressure (PEEPi).⁹ The common assumption that the small endotracheal tube required for neonatal mechanical ventilation is the largest contributor to expiratory resistance was not supported by the laboratory evaluation by DiBlasi et al. As a matter of fact, the ventilator-imposed expiratory resistance was greater than the expiratory resistance of the endotracheal tube and the external airway flow sensor *combined*, with all 4 ventilator brands. This finding justifies further research into the clinical implications of ventilator-imposed expiratory resistance and the impact of ventilator brand on work of breathing, PEEPi, and time to extubation.

Research by Yoder et al⁹ with 2 brands of neonatal ventilator and extremely-low-birth-weight baboons suggested that one of the ventilators had higher expiratory airway resistance and indices of impaired ventilation and generally required a higher ventilation rate, maximum inspiratory pressure, and mean airway pressure, which could have been the result of PEEPi.

Another important finding by DiBlasi et al⁴ is that the Dräger Babylog 8000plus, which is an earlier-generation ventilator, consistently had the lowest ventilator-imposed expiratory resistance, including during spontaneous breathing, which could be of great interest to clinicians who are considering updating their NICU ventilator fleet. How-

ever, was that finding due to the design of the expiratory valve of the Babylog 8000plus? Another possible explanation is that the neonatal continuous-flow ventilation mode may be superior to the bias flow modes that are primarily used in newer adult-to-infant ventilators. Unfortunately, we can't ascertain from the DiBlasi et al report if the primary cause of the ventilator-imposed expiratory resistance was the ventilator's exhalation system or the ventilator mode, since the Babylog was tested in a continuous-flow mode and the other 3 ventilators were not. Regrettably, the continuous-flow mode is not an option in most cradle-to-grave ventilators. However, the Cardinal/Viasys Avea can provide continuous-flow ventilation, in the pressure-control mode only, and a direct comparison between it and the Babylog 8000plus would be possible and would help to ascertain if the continuous-flow ventilation mode decreases ventilator-imposed expiratory resistance or if the Babylog 8000plus has a superior exhalation system.

Often when performing laboratory evaluations the researchers are hampered by the necessity of using ventilator settings that will work in all testing scenarios. This can limit the applicability of the results and sometimes even prevent the discovery of important results. In the DiBlasi et al study design the relatively short inspiratory time (0.25 s) may have prevented the discovery of PEEP_i that may routinely occur clinically with all these devices, especially in disease conditions commonly found in the NICU. The tendency of clinicians to use different ventilator settings depending on the region of the country in which they practice, rather than settings based on patient pulmonary mechanics, can also impact the clinical effect of identical devices.

Respiratory therapists are accustomed to embracing new technology. We are an equipment-centered profession. The more complex the device, the more we dive into its intricacies and master its details. We are also optimists who believe in the power of technology to transform the patient's outcome. But what if we discover that the older technology was better? Once ventilators reach a certain age, there is pressure to update the fleet. There is a great desire to constantly modernize our technology and stay current. Most, including myself, would argue that such a strategy is good for patients. Old ventilators can be outdated and not have clinically important features. Some of the newer ventilator features may improve patient moni-

toring, make new therapies possible without unapproved user modifications, or add modes desired by respiratory therapists and physicians alike. But what if the newer equipment is not actually superior?¹⁰ What if the old way of doing things was actually better for our patients? Might we lose a valuable tool or mode?

A final issue is the availability of equipment designed specifically for neonates. Is it possible to build a device that will function for all patients and still have it be the best device for each patient subgroup? As we periodically assess our ventilator fleets and discuss the possibility of purchasing new equipment, the question asked should always be: Is there something better available than what we are using now? Chatburn and Primiano's ventilator-assessment tool should be used to objectively evaluate the presence of desired features and calculate other important factors such as maintenance costs. In addition, research, such as the excellent work by DiBlasi et al,⁴ is crucial to objectively evaluate manufacturers' claims of benefits from modes and features and the limitations of individual devices.

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Managing the Patient With Neuromuscular Disease and Respiratory Insufficiency

Though the development of physical limitations associated with neuromuscular disease is often apparent to the clinician, the development of neuromuscular-induced respiratory muscle weakness can be insidious. Respiratory muscle weakness is often overlooked by the clinician, particularly when weakness of the extremities limits physical exertion and no respiratory compensation for exertion is required. Patients with neuromuscular disease are often not found to have respiratory insufficiency until they present in the emergency department with acute respiratory failure secondary to pulmonary congestion resulting from respiratory infection and inadequate cough clearance. Early symptoms of neuromuscular respiratory insufficiency are more often associated with the onset of sleep-disordered breathing.¹ On finding symptoms of neuromuscular weakness the clinician should question the patient about symptoms of sleep-disordered breathing and developing dyspnea when supine or with exertion. A comprehensive neuromuscular respiratory evaluation should also be done as a baseline for serial assessment of chronic progressive insufficiency, to support preventive out-patient respiratory care.^{2,3}

In this issue of *RESPIRATORY CARE*, Kelly et al⁴ describe a rare adult-onset presentation of nemaline myopathy, a muscle disease that can affect the respiratory muscles. In this case the patient was referred by his primary care provider to a respiratory clinic after developing cough and dyspnea on exertion. Although the patient presented with chronic hypercapnic respiratory failure, the immediate use of noninvasive ventilation (NIV) relieved his symptoms and reversed the chronic alveolar hypoventilation, as evidenced by improved arterial blood gas values.

SEE THE CASE REPORT ON PAGE 1490

Though NIV has been more widely used to treat obesity hypoventilation and central and complex sleep-disordered breathing, it could be argued that patients with neuromuscular disease and respiratory insufficiency receive the greatest benefit from NIV. NIV is effective in providing intermittent, often nocturnal, ventilatory support in various

neuromuscular diseases,⁵ and improves survival and quality of life in patients with amyotrophic lateral sclerosis.⁶

The key to effective NIV for respiratory insufficiency is to provide adequate pressure support to augment respiratory-muscle-induced hypoventilation. “Wide-span” bi-level pressure support (ie, in which the difference between the applied inspiratory and expiratory pressures is ≥ 10 cm H₂O) effectively augments ventilation. A minimal expiratory pressure—only that sufficient to flush exhaled gas from the circuit—is better tolerated by patients with neuromuscular disease, and is generally sufficient when neuromuscular weakness does not affect upper-airway patency during sleep. The need for a spontaneous/timed mode with an adequate backup rate is often overlooked when prescribing NIV for nocturnal hypoventilation associated with neuromuscular disease. During rapid-eye-movement (REM) sleep, all of the muscles of ventilation except for the diaphragm develop a state of atonia.⁷ If diaphragm weakness during REM sleep limits the ability to trigger the ventilator, the patient may not receive adequate ventilatory support during REM sleep, so a backup rate provides a necessary bridge of ventilatory support during REM sleep.

Particular attention must be paid to determining the best patient-ventilator interface with regard to fit, comfort, and effectiveness.⁸ A self-directed desensitization protocol can help the patient acclimate to NIV before titrating the inspiratory pressure to achieve optimal pressure support.⁹

Although oronasal masks are not always well tolerated, particularly by patients with neuromuscular disease and therefore unable to remove the mask, oronasal masks may provide the most effective means of limiting air leak, if nasal mask and chin-strap alternatives are not effective, as often occurs in patients with bulbar weakness. A patient with neuromuscular disease who relies on nasal mask as the primary NIV interface should also have an oral-nasal mask alternative in the event of nasal congestion from allergic rhinitis or upper-respiratory infection.

Monitoring and managing mask air leak is particularly important in maximizing the effectiveness of NIV.¹⁰ A data-storage device in a bi-level-pressure ventilator can be very helpful for evaluating ongoing mask leak and monitoring the effectiveness of ventilation and patient adher-

ence to NIV. Most neuromuscular disease processes are chronic and progressive and therefore require increasing pressure support to maintain adequate ventilation. An integrated heated humidifier should be prescribed with the bi-level-pressure ventilator, and the patient can adjust the humidification according to comfort with the increasing pressure support.

In their patient, Kelly et al⁴ observed improved forced vital capacity following initiation of NIV. Although not described in their report, a regimen of hyperinflation therapy, either via pressure pre-set or volume insufflation, can reverse atelectasis, improve lung compliance, and help maintain the respiratory health of patients with neuromuscular disease and chronic hypoventilation.¹¹

Correcting neuromuscular-induced hypoventilation is usually the clinician's primary goal, and providing support to compensate for limited or ineffective cough strength is often overlooked. This is an important component in the overall preventive respiratory care plan for patients with neuromuscular disease. Peak expiratory cough flow (a measure of cough strength) should be evaluated in any comprehensive neuromuscular respiratory assessment.^{12,13} Cough-augmentation techniques, including mechanical in-exsufflation and manual hyperinflation with assisted cough maneuvers, help patients who have inadequate cough clearance.¹⁴⁻¹⁶ In the patient described by Kelly et al there was no evidence of airway-clearance limitation. This is most likely due to the absence of bulbar involvement and relatively well preserved expiratory muscle strength, as indicated by the patient's peak expiratory pressure (86 cm H₂O).

The overall management of neuromuscular respiratory insufficiency, including diagnosis and initiation and management of ventilation and cough-augmentation therapies, is within respiratory therapists' scope of practice. With a strong understanding of neuromuscular respiratory pathophysiology the respiratory therapist is in a unique position to complement the pulmonologist and neurologist in managing the ongoing respiratory care of patients with neuromuscular respiratory insufficiency.

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