



eNeonatal Review

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PROGRAM INFORMATION

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As mechanical ventilation has improved to the point where few infants now die because of acute respiratory failure, early mortality is now predominantly from other complications of extreme prematurity. Consequently, the focus has shifted from reducing mortality to reducing the still unacceptably high incidence of chronic lung disease.

The two modalities of respiratory support that have attracted the most attention in this regard are high-frequency ventilation and synchronized (also known as patient-triggered) ventilation. Even more promising is the advent of volume-targeted modalities of conventional ventilation that, for the first time, allow effective control of delivered tidal volume for neonates. In this month's issue, we summarize the current state of knowledge in synchronized and volume targeted ventilation.

[NOTE: High-frequency ventilation will be addressed in a future issue of e-Neonatal Review.]

Reviews:

Martin Keszler, MD
Kabir M. Abubakar, MD

Commentary:

Martin Keszler, MD

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Guest Editors of the Month

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Guest Faculty Disclosure

Martin Keszler, MD

Faculty Disclosure: Dr. Keszler receives grant and research support from Dräger Medical, Inc

Kabir M. Abubakar, MD

Faculty Disclosure: Dr. Abubakar receives grant and research support from Dräger Medical, Inc

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COMMENTARY

Despite nearly universal acceptance of synchronized mechanical ventilation in newborn intensive care, there is a surprising paucity of information on the impact of this modality on major outcomes such as mortality, chronic lung disease, or length of hospitalization. While a number of small studies have shown improvement in short-term physiologic outcomes, demonstrating the "bottom line" long-term outcome improvement has been elusive.¹ In addition, the only available studies suffer from important design and device limitations, leaving Neonatologists with the unsatisfactory situation of using an "unproven therapy" on a daily basis.

These problems highlight the difficulties involved in conducting ventilator studies where many different devices are used and experience with their use differs among participating centers. The characteristics of the triggering and sensing device are crucial to how well it performs in synchronizing infant and machine breaths, especially in the tiniest infants. Therefore, ventilator studies must be interpreted with caution, and their conclusions should be applied only to the specific devices and strategies employed. While meta-analysis is an important tool in attempting to arrive at evidence-based practice, lumping studies with different devices and approaches to ventilation may obscure these important differences and confuse, rather than clarify, the issues.

Despite years of routine use, there is no consensus regarding the relative merits of the two most widely used modalities of synchronized mechanical ventilation: Synchronized Intermittent Mandatory Ventilation (SIMV) and Assist-Control (AC). SIMV provides a preset number of mechanical breaths as in standard IMV, but these are synchronized with the infant's spontaneous respiratory effort. However, spontaneous breaths in excess of the preset number are not supported, resulting in uneven tidal volumes (V_T) and potentially a high work of breathing, especially during weaning. In AC, every spontaneous breath is supported by the ventilator, providing more uniform tidal volume delivery. A third mode, Pressure Support Ventilation (PSV), supports every spontaneous breath just like AC but also terminates each breath when inspiratory flow declines to a preset threshold, eliminating inspiratory hold and presumably providing more optimal synchrony.

Smaller and less variable V_T , less tachypnea, more rapid weaning from mechanical ventilation, and smaller fluctuations in blood pressure have been documented with AC, as compared to SIMV. However, many clinicians still prefer SIMV, especially for weaning from mechanical ventilation. This preference is apparently based on the assumption (unsupported by data) that fewer mechanical breaths are less damaging, as well as on the belief that weaning of ventilatory rate is necessary prior to extubation. However, drawing on extensive experience with high-frequency ventilation (HFV), it is clear that lowering pressure amplitude and leaving the rate unchanged is an effective way of reducing ventilator support to the point of extubation.

Although we cannot make a direct parallel between AC and HFV, it would be reasonable to accept that a larger number of smaller breaths with AC need not be detrimental. A rate of 60 breaths/min compared to 30 breaths per minute was shown to result in less airleak with un-synchronized IMV,² lending further support to the putative advantage of AC over SIMV. Once again, the definitive large study comparing the two modalities is lacking.

The most recent, and in many ways most promising, advance in neonatal ventilation is the advent of Volume-Targeted Ventilatory modes. The growing recognition that volume, rather than pressure, is the critical determinant of ventilator-induced lung injury,^{3,4} along with mounting evidence that hypocarbia is associated with neonatal brain injury,⁵⁻⁷ has rekindled interest in directly controlling V_T . Because traditional volume-controlled ventilation is impractical in small neonates — due to the unpredictable loss of V_T to gas compression in the circuit, stretching of the tubing, and variable leak around uncuffed endotracheal tubes — a number of modifications of time-cycled, pressure-limited ventilation (designed to target a set tidal volume by microprocessor-directed adjustments of peak pressure or inspiratory time) have been recently developed.

Each of the available modes has advantages and disadvantages. The main problem with the Pressure Regulated Volume Control (PRVC) mode of the Siemens Servo 300 is the major inaccuracy of V_T measurement performed at the ventilator end of the circuit, rather than at the airway opening.^{8,9} The Volume Assured Pressure Support (VAPS) mode on the Bird VIP Gold can only increase the delivered V_T by prolonging the inspiratory time with a passive increase in peak pressure, which may result in a rather prolonged inspiratory time leading to asynchrony. With this device, targeting tidal volume is based on inspiratory V_T and, therefore, is susceptible to error in the presence of significant endotracheal tube leak. Furthermore, there is no provision for automatically lowering inspiratory pressure as lung compliance improves.

The Draeger Babylog Volume Guarantee (VG) option regulates inspiratory pressure in response to changing compliance and patient effort, using exhaled V_T measurement. This approach makes it less susceptible to the effect of leak, but results in some fluctuation of V_T when the patient's respiratory effort is inconsistent. On the other hand, the autoregulation of inspiratory pressure makes VG a self-weaning mode. Because weaning occurs in real-time, rather than intermittently in response to blood gases, VG has the potential to achieve faster weaning from mechanical ventilation. At this point, the only published data are those demonstrating feasibility, greater stability of delivered V_T and less hypocarbia in short-term studies of the VG mode of the Draeger BabyLog. Documentation of the potential major outcome benefits such as shorter duration of ventilation or decreased risk of intraventricular hemorrhage/periventricular leukomalacia will require completion of adequately powered clinical trials.

In conclusion: While a host of new modalities and techniques have been made available for the treatment of respiratory failure, the understanding of how to optimally use these devices, while improving constantly, remains somewhat behind the pace of technological innovation. Improvements in outcomes such as broncho pulmonary dysplasia (BPD) are increasingly difficult to demonstrate, as each incremental improvement leaves "the bar" that much higher. It should be also pointed out that avoidance of mechanical ventilation by means of early continuous positive airway pressure (CPAP), with or without surfactant administration, may still be the most effective way to reduce the risk of chronic lung disease.

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SIMV VS. UN-SYNCHRONIZED CMV (1)

Bernstein G, Mannino FL, Heldt GP, et al. Randomized multicenter trial comparing synchronized and conventional intermittent mandatory ventilation in neonates. J Pediatr 1996;128:453-463.

A multi-center trial highlights some advantages of SIMV.

This study compared SIMV and CMV in a prospective randomized multi-center trial conducted in 6 level III neonatal centers. Infants >500g with respiratory distress syndrome, pneumonia or meconium aspiration syndrome (MAS) at <36 hours of age and on mechanical ventilation for <12 hours at entry were eligible. Outcome measures included acute effect on oxygenation, sedative/analgesic drug requirements, incidence of air-leaks, duration of mechanical ventilation, and bronchopulmonary dysplasia. All infants were ventilated using the Infant Star ventilator with Star Sync module (Graseby capsule abdominal movement sensor). Three hundred and twenty seven infants, stratified by birth weight, were enrolled at a mean age of 7.5 hrs, mean birth weight 1654g, gestational age 30.7 weeks, and mean PIP 23 cm H₂O.

There was no difference in survival, air-leak or overall length of mechanical ventilation. Secondary analyses revealed that, compared to CMV, there was a shorter duration of mechanical ventilation among infants >2000g, less need for sedation for infants 1000-1499g, and a lower mean airway pressure at 1 hour post-entry in all age groups on SIMV. In addition; the SIMV group also demonstrated shorter time to regain birth weight when ventilated for >14 days, less need for oxygen at 36 weeks corrected gestational age (CGA) among infants <1000g, and less need for oxygen at 36 weeks CGA for all infants <2000g.

It is of interest to note that, had the investigators chosen BPD at 36 weeks CGA as their primary outcome, they would have been able to report a significant improvement in their entire study population (reduction from 42% to 28%, p<0.05) [result re-analyzed based on published data].

Bernstein G, Mannino FL, Heldt GP, et al. Randomized multicenter trial comparing synchronized and conventional intermittent mandatory ventilation in neonates. J Pediatr 1996;128:453-463.

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SIMV VS. UN-SYNCHRONIZED CMV (2)

Chen JY, Ling UP, Chen JH. Comparison of synchronized and conventional intermittent

mandatory ventilation in neonates. Acta Paediatr Jpn. 1997 Oct;39(5):578-83.

A single-center trial supports the benefit of SIMV.

A single-center randomized trial by Chen et al enrolled 77 neonates with RDS and MAS requiring mechanical ventilation. Infants on SIMV were ventilated using the Infant Star with Star Sync Module (airflow trigger); CMV was provided using the Bear-Cub ventilator. Primary outcome measures included: duration of ventilation, need for re-intubation, air leaks, patent ductus arteriosus (PDA), intraventricular hemorrhage (IVH); secondary outcomes include BPD, retinopathy of prematurity (ROP) and death.

The authors reported that premature infants on SIMV had significantly shorter duration of ventilation, less need for re-intubation, lower incidence of severe IVH (grades 3 and 4), and a lower incidence of BPD compared those on CMV.

NOTE: This small study has largely been ignored, having been published in a journal that is not widely read; in addition, the small numbers make the study susceptible to Type One error (false positive result).

Chen JY, Ling UP, Chen JH. Comparison of synchronized and conventional intermittent mandatory ventilation in neonates. Acta Paediatr Jpn. 1997 Oct;39(5):578-83.

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ASSIST/CONTROL VS. UNSYNCHRONIZED CMV IN RDS

Baumer JH. International randomized controlled trial of patient triggered ventilation in neonatal respiratory distress syndrome. Arch Dis Child 2000;82:F5-F10.

A large randomized trial compared patient triggered ventilation (known as AC in the USA) with CMV in pre-term infants ventilated for respiratory distress syndrome.

Nine hundred and twenty four infants <32 weeks gestational age were randomized across 22 centers. All were within 72 hours of birth and on mechanical ventilation for <6 hours at randomization. PTV was provided using SLE 2000 (airway pressure trigger) in the large majority of patients, and Draeger Babylog 8000 (airway flow trigger) in the rest; CMV was provided using the SLE 2000, Draeger Babylog and Sechrist. [It should be noted that some centers lacked prior experience with triggered ventilation.]

This trial showed no difference in chronic lung disease, pneumothorax, duration of ventilation, or IVH between the two groups.

While the authors concluded that there was no observed benefit from the use of PTV particularly in infants less than 28 weeks of gestation, it is important to interpret the results in light of the device used in the majority of patients. The SLE 2000 uses airway pressure to sense patient effort. Pressure trigger has been shown to result in failure to trigger in a large proportion of infants < 1000g (see additional references). 27% of infants crossed over from the synchronized group, primarily due to failure to trigger. There was a non-significant trend to higher incidence of airleak in infants <1000g in the triggered group.

Given the long trigger delay of pressure-triggered ventilators, it is tempting to speculate that the airleak resulted from late cycling of the ventilator at a time the infant was already starting to exhale. The authors appropriately stated in their discussion that their results should be applied to this device and the population studied, and should not be generalized to other situations.

Baumer JH. International randomized controlled trial of patient triggered ventilation in neonatal respiratory distress syndrome. Arch Dis Child 2000;82:F5-F10.

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ASSIST/CONTROL VS. UNSYNCHRONIZED CMV IN RDS (2)

Beresford MW, Shaw NJ, Manning D. Randomised controlled trial of patient triggered and conventional fast rate ventilation in neonatal respiratory distress syndrome. Arch Dis Child 2000;82:F14-F18

Comparing patient triggered ventilation with conventional fast rate ventilation in a randomized controlled trial using incidence of chronic lung disease as the primary outcome measure.

Infants were randomized to receive either conventional or trigger ventilation with the SLE 2000 ventilator (pressure trigger). 386 preterm infants with birth weight of 1kg-2kg, who required ventilation for respiratory distress syndrome within 24 hours of birth, were enrolled. Infants in the trigger group were ventilated using AC, then weaned using SIMV; the control group had their ventilator rate adjusted manually to match the infant's own respiratory rate initially, and then weaned.

The authors found no significant differences in the incidence of chronic lung disease (28 day and 36 week definitions), death, pneumothorax, intraventricular hemorrhage, number of ventilator days, or length of oxygen dependency between groups. It could be concluded that careful manual synchronization of ventilator set rate with the infant's breathing is as effective as automatic synchronization by the ventilator. However, how practical manual synchronization might be outside of a study protocol remains an open question. Once again, the issue of the relatively ineffective pressure-triggered device adds further uncertainty regarding interpretation of the data.

Beresford MW, Shaw NJ, Manning D. Randomised controlled trial of patient triggered and conventional fast rate ventilation in neonatal respiratory distress syndrome. Arch Dis Child 2000;82:F14-F18

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AC VS. SIMV

Chan V, Greenough A. Comparison of weaning by patient triggered ventilation or synchronous mandatory intermittent ventilation. Acta Paediatr 1994;83:335-337

Dimitriou G, Greenough A, Giffin FJ, Chan V. Synchronous intermittent mandatory ventilation modes versus patient triggered ventilation during weaning. Arch Dis Child 1995;72:F188-F190

Four studies compare the effect of each method in different circumstances.

The trials of Chan et al and Dimitriou et al compared weaning from mechanical ventilation between SIMV and AC, using the Draeger Babylog ventilator. Both trials showed the duration of weaning to be shorter with AC compared to SIMV, except in the subgroup where the SIMV rate was not decreased below 20/min. The relatively small number of patients limits the confidence in interpreting the data.

The reluctance of many clinicians to accept AC as a weaning mode is unsupported by the available evidence. Even though the small study population precludes a definite conclusion that AC is a better weaning modality, these two studies indicate that it appears to be at least as effective as SIMV.

Hummeler H Gerhardt T, Gonzalez A, Claire N, Everett R, Bancalari E. Influence of different methods of synchronized mechanical ventilation on ventilation, gas exchange, patient effort, and blood pressure fluctuations in premature neonates. *Pediatr Pulmonol* 1996;22:305-313.

This study examined the effects of IMV, SIMV and AC on ventilation, gas exchange, patient effort, and arterial blood pressure (ABP) fluctuations. SIMV and AC were applied in random order in 12 preterm neonates (gestational age: 29.7 +/- 2.3 weeks; birth weight: 1,217 +/- 402 g). Minute ventilation was similar in all three groups by study design. Ventilator VT increased during SIMV and was 31% smaller during AC than during SIMV. Esophageal pressure decreased during SIMV and AC compared with IMV; Paw was higher during AC than during IMV or SIMV. Beat-to-beat ABP fluctuations were reduced during SIMV and further reduced with AC compared with IMV, showing a close positive correlation with esophageal pressure changes.

Mrozek JD, Bendel-Stenzel EM, Meyers PA, Bing DR, Connett JE, Mammel MC. Randomized controlled trial of volume-targeted synchronized ventilation and conventional intermittent mandatory ventilation following initial exogenous surfactant therapy. *Pediatr Pulmonol*. 2000; 29:11-18.

This was a prospective, randomized study of 30 neonates, designed to evaluate the impact of synchronized ventilation and conventional intermittent mandatory ventilation (IMV) on the early physiologic response to surfactant in neonates. Infants with respiratory distress syndrome (RDS) were randomly assigned to IMV (n = 10), SIMV (n = 10), or AC (n = 10), using a strategy of manual adjustment of peak pressure to achieve a target V_T . Infants assigned to each mode of ventilation had similar birth weight, gestational age, and Apgar scores at birth, as well as similar oxygenation indices at randomization. Total respiratory rate was lowest (P <0.05) and variation in V_T was least in the AC group (P <0.05). Minute ventilation, airway pressures, respiratory system mechanics, and hemodynamic parameters were similar in all groups.

Oxygenation and lung mechanics were not improved by synchronization; the authors speculate that this was because the V_T was kept constant. AC ventilation resulted in more consistent tidal volumes and less tachypnea than IMV or SIMV, suggesting that this fully-synchronized mode may be the most efficient method of mechanical ventilation in neonates receiving surfactant for treatment of RDS.

These second two studies suggest that AC offers the advantage of smaller, more stable V_T , lower work of breathing and less fluctuation of blood pressure. The differences are likely to be most dramatic in the micro-preemies with the smallest endotracheal tubes, which have the highest airway resistance. Especially during weaning, SIMV would impose an excessive work of breathing that can be likened to "breathing through a straw".

Chan V, Greenough A. Comparison of weaning by patient triggered ventilation or synchronous mandatory intermittent ventilation. *Acta Paediatr* 1994;83:335-337

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Hummler H Gerhardt T, Gonzalez A, Claire N, Everett R, Bancalari E. Influence of different methods of synchronized mechanical ventilation on ventilation, gas exchange, patient effort, and blood pressure fluctuations in premature neonates. *Pediatr Pulmonol* 1996;22:305-313.

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Mrozek JD, Bendel-Stenzel EM, Meyers PA, Bing DR, Connett JE, Mammel MC. Randomized controlled trial of volume-targeted synchronized ventilation and conventional intermittent mandatory ventilation following initial exogenous surfactant therapy. *Pediatr Pulmonol*. 2000; 29:11-18.

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VOLUME TARGETED VENTILATION (1)

Cheema IU, Ahluwalia JS. Feasibility of tidal volume-guided ventilation in newborn infants: a randomized, crossover trial using the volume guarantee modality. *Pediatrics* 2001 Jun;107(6):1323-8.

Two studies provide new information on this modality.

Cheema and colleagues examined the feasibility and efficacy of VG in 40 premature newborn infants with RDS [mean gestational age was 27.9 (0.3) weeks; birth weight was 1064 (60g)]. In a four-hour crossover trial, they compared AC with and without VG in infants with acute RDS, and SIMV with and without VG during weaning. In both VG groups, patients were able to achieve equivalent gas exchange using lower peak airway pressure. There were fewer excessively large V_T with the VG modes. The authors concluded the VG mode was feasible, and may offer the benefit of lower airway pressures.

Due to the short duration of the study, no major conclusions could be drawn, other than that the ventilator performs as intended and no short-term adverse effects were evident.

Herrera CM, Gerhardt T, Claire N, Everett R, Musante G, Thomas C, Bancalari E. Effects of volume-guaranteed synchronized intermittent mandatory ventilation in preterm infants recovering from respiratory failure. *Pediatrics*. 2002 Sep;110(3):529-33.

Herrera et al compared the effects of SIMV+VG with conventional SIMV on ventilation and gas exchange in a group of very low birth weight infants recovering from acute respiratory failure. They showed that short-term use of SIMV+VG resulted in automatic reduction of the mechanical support and enhancement of the spontaneous respiratory effort, while maintaining gas exchange relatively unchanged (in comparison to conventional SIMV). Further shifting of the work of breathing was achieved when the target V_T was reduced from the normal 4.5 ml/kg target to 3 ml/kg.

This study adds further confirmation of the short-term benefit and potential of VG. It should be pointed out that excessive reduction of target V_T below a physiologically appropriate value is likely to impose a large work of breathing on the infant, and may not be desirable. As long as the target V_T is low enough to stimulate the infant's respiratory drive, self-weaning of inspiratory pressure will occur.

Cheema IU, Ahluwalia JS. Feasibility of tidal volume-guided ventilation in newborn infants: a randomized, crossover trial using the volume guarantee modality. *Pediatrics* 2001 Jun;107(6):1323-8.

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Herrera CM, Gerhardt T, Claire N, Everett R, Musante G, Thomas C, Bancalari E. Effects of volume-guaranteed synchronized intermittent mandatory ventilation in preterm infants recovering from respiratory failure. Pediatrics. 2002 Sep;110(3):529-33.

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Volume targeted Ventilation (2)

Abubakar KM, Keszler M. Patient-ventilator interactions in new modes of patient-triggered ventilation. Pediatr Pulmonol. 2001 Jul;32(1):71-5.

Keszler M, Abubakar K. Volume Guarantee: Stability of Tidal Volume and Incidence of Hypocarbica. Pediatr Pulmonol 2004, in-print.

This month's Guest Editors report on their own studies.

We recently showed in a short-term crossover study that VG combined with AC, SIMV or PSV led to significantly lower variability of V_T with VG (compared to AC or SIMV alone), and that peak inspiratory pressures were similar. In a randomized clinical trial, we demonstrated that, when combined with the AC mode, VG maintained PaCO₂ and V_T within a target range more consistently than assist/control alone during the first 72 hours of life in preterm infants with uncomplicated respiratory distress syndrome.

The first paper documented that the device functions as intended in the clinical setting, with the anticipated reduction of the variability of V_T . The second, reporting a prospective trial, demonstrated that excessively large V_T and hypocarbica could be reduced, though not eliminated, with the use of VG. While these results suggest the potential of VG to reduce many of the important adverse effects of mechanical ventilation, it remains to be seen whether the demonstrated short-term benefits translate into significant reduction in airleak, chronic lung disease, neuroimaging abnormalities, duration of mechanical ventilation, or length of hospitalization.

Abubakar KM, Keszler M. Patient-ventilator interactions in new modes of patient-triggered ventilation. Pediatr Pulmonol. 2001 Jul;32(1):71-5.

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Keszler M, Abubakar K. Volume Guarantee: Stability of Tidal Volume and Incidence of Hypocarbica. Pediatr Pulmonol 2004, in-print.

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- Evaluate the information presented to develop a more complete understanding of the current research in neonatal ventilation.
- Demonstrate a more complete understanding of the advantages/disadvantages of the SIMV, CMV, AC and VG modalities.
- Use the information presented herein as a basis for decision making in determining ventilation methods in your clinical practice.

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- Dr. Noguee has indicated a financial relationship of grant/research support with Forest Laboratories and has received an honorarium from Forest Laboratories.
- Dr. Lawson has indicated a financial relationship of grant/research support from the NIH. He also receives financial/material support from Nature Publishing Group as the Editor of the Journal of Perinatology.

All other faculty have indicated that they have not received financial support for consultation, research, or evaluation, nor have financial interests relevant to this e-Newsletter.

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