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Bubble CPAP—Analysis of the Evidence Base

In this Issue...

Bubble continuous positive airway pressure (Bubble CPAP) has become the front-line CPAP device in many high-performing neonatal intensive care units (NICUs) across the nation and it is being adopted by many smaller NICUs concerned about developing best practices for neonatal care. However, because no US Food and Drug Administration–approved bubble CPAP system is available and information from manufacturers is sparse, it has become challenging to prove the safety and superiority of the bubble CPAP device over higher-tech systems on the market.

In this issue, we review several articles from the past 5 years that explore the physiologic function of the bubble CPAP system and compare outcomes with those of other systems in use.

LEARNING OBJECTIVES

At the conclusion of this activity, participants should be better able to:

- Identify how Bubble CPAP performs differently than other nasal CPAP systems
- Describe the challenges encountered in the application of bubble CPAP
- Discuss key differences between bubble CPAP and alternative CPAP devices as they might relate to clinical outcomes

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July 1, 2010

Expiration Date

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- **Christoph U. Lehmann, MD**, has indicated a financial relationship of honoraria from Mead Johnson and Pediatrix. Dr. Lehmann is also the Editor-In-Chief of *Applied Clinical Informatics Journal*. He serves on the Board of Directors for the American Medical Informatics Association.
- **Anthony Bilenki, MA, RRT, Edward E. Lawson, MD, Lawrence M. Nogee, MD and Mary Terhaar, DNSc, RN** indicated they have no relevant financial relationships with any commercial supporters.

Guest Author's Disclosures

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THIS ISSUE

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Guest Faculty Disclosure

Natalie Napolitano, MPH, RRT-NPS has disclosed that she no relevant relationships to disclose.

Unlabeled/Unapproved Uses

The author has indicated that there will be references to unlabelled/unapproved uses of Bubble CPAP.

Program Directors' Disclosures

COMMENTARY

Continuous positive airway pressure (CPAP) is a common therapy used to help open the airways of premature infants, recruiting more alveoli to improve the functional residual capacity of the lungs, and thereby reducing the work of breathing and/or eliminating apneic episodes.[1] The use of CPAP also reduces the need for mechanical ventilation and surfactant administration.[1] Although CPAP is a mainstay therapy that has been shown to decrease the incidence of chronic lung disease, insufficient evidence is available to guide the selection of one form of CPAP therapy over another.

Two types of CPAP are currently available: continuous-flow CPAP and variable-flow CPAP. Bubble CPAP is a form of continuous-flow CPAP used by some best practice centers that have reported low incidence of chronic lung disease. It is also a simple system that can be applied with relatively low cost in just about every type of care setting.[2]

Several theories have attempted to explain why additional benefits are observed with bubble CPAP that are not seen with other forms of noninvasive CPAP. Some studies support the theory that bubble CPAP assists in ventilation through the amplitude generated by vigorous bubbling,[2,3] extrapolating from the action of ventilation reported with high-frequency oscillation.[2,3] However, other studies are unable to confirm this theory with clinical results, as shown in 2 of the articles reviewed in this issue (Morley et al, 2005; Kahn et al, 2008).

A growing body of literature attempts to address the many questions posed by clinicians with respect to the various types of CPAP, in particular: Which system is the best, and how do we use it to achieve the most favorable outcomes?

The articles in this review explore the reliability of bubble CPAP and the differences, or lack thereof, in the outcomes associated with bubble CPAP vs. ventilator-generated CPAP and/or variable-flow CPAP. In the final analysis, because many of the studies have used very small sample sizes and the results need to be validated in larger study groups, the evidence to determine whether one CPAP device is superior over another remains inconclusive. Concerns also exist regarding the safety of the bubble CPAP system in its

current stripped-down remedial version—in particular, the lack of safety alarms to alert bedside clinicians of potential leaks and/or unsafe overshoots in pressure before the patient becomes negatively affected. The modernization of bubble CPAP via the addition of bells and whistles will increase the cost but provide researchers with the opportunity to further investigate its use for the safety of our most vulnerable patients.

Commentary References

1. Christensen DiBlasi RM. Nasal continuous positive airway pressure (CPAP) for the respiratory care of the newborn infant. *Respir Care*. 2009;54(9):1209-1235.
2. Pillow JJ, Hillman N, Moss TJM, et al. Bubble continuous positive airway pressure enhances lung volume and gas exchange in preterm lambs. *Am J Respir Crit Care Med.* 2007;176(1):63-69.
3. Manilal-Reddy PI, Al-Jumaily AM. Understanding the use of continuous oscillating positive airway pressure (bubble CPAP) to treat neonatal respiratory disease: an engineering approach. *J Med Eng Technol.* 2009;33(3):214-222.

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IMPROVEMENT IN VENTILATION?

Morley CJ, Lau R, De Paoli A, Davis PG. **Nasal continuous positive airway pressure: does bubbling improve gas exchange?** *Arch Dis Child Fetal Neonatal Ed.* 2005;90(4):F343-F344.

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In this study, the authors sought to determine if the pressure oscillations that occur with bubble CPAP assist in ventilation in a manner similar to that occurring with high-frequency oscillation. This randomized, crossover trial evaluated 26 stable preterm infants who were treated with bubble CPAP. The infants were randomized to begin treatment with vigorous or slow bubbling. Vigorous bubbling was defined as 3 liters per minute higher than the flow needed to achieve the lowest possible bubbling. The subjects were placed on the first level of bubbling, monitored for 30 minutes, and then switched to the second setting for an additional 30 minutes. The infants were monitored for changes in their condition with the 2 therapies by comparing transcutaneous carbon dioxide, transcutaneous oxygen, oxygen saturation, heart rate, and respiratory rate.

The median age of the 26 infants studied was 27 weeks; the median birth weight was 1033 grams. All patients were treated with a CPAP of 6 cm H_2O at a baseline gas flow rate of 6 liters per minute and inspired oxygen of 21%. The average CPAP levels recorded were 5.28 cm H_2O at slow bubbling and 5.98 cm H_2O at vigorous bubbling. A statistically significant difference (P <.001) was reported between the 2 treatments with a change in flow rate only. All monitored values with respect to the infant's condition were unchanged when the 2 different flow rates were compared.

The results demonstrate no additional benefit with vigorous vs slow bubbling. Although the authors noted a small reduction in respiratory rate with a higher flow rate and vigorous bubbling, this difference was not statistically significant (P = .66) and could have been associated with the rise in CPAP pressure, not with the increase in ventilation. The study included a small patient cohort, and may not have used a high-enough flow rate and long-enough time frame monitoring the infants at each level of bubbling to observe a change in their condition. In 2003, Blackson and colleagues[1] noted a need for a flow rate >10 liters per minute to generate the amplitude necessary to affect ventilation (increasing the flow by 3 liters per minute from baseline of 6 liters per minute to achieve vigorous bubbling would achieve a flow rate of 9 liters per minute for each infant). It may be necessary to expand the results of this study to gain a true understanding of the capabilities of the amplitude generated by bubbling.

Reference

1. Blackson T, Irwin-Sherman T, Touch SM, et al. Bubble continuous positive airway pressure does not augment ventilation. *Pediatr Res.* 2003;53:360A.

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ACCURACY OF SET VS. DELIVERED CPAP LEVELS

Kahn DJ, Habib RH, Courtney SE. **Effects of flow amplitudes on intraprong pressures during bubble versus ventilator-generated nasal continuous positive airway pressure in premature infants.** *Pediatrics.* 2008;122(5):1009-1013.

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The objective of this crossover study was to compare the set vs. the actual delivered pressure accuracy of bubble CPAP vs. ventilator-generated CPAP. The authors measured the intraprong pressure of 12 premature infants, all weighing <1500 grams and born at <30 weeks' gestational age, at constant pressures with increasing flow rates, and then with set flow rates and increasing pressure settings.

Each infant began on bubble CPAP, and was set at a constant submersion depth of 4 cm H_2O and a flow rate necessary to produce minimal bubbling. The flow setting was then increased by 2 liters per minute, and measurements were recorded after 5 minutes on each of the 3 settings. The infants were then switched to ventilator-generated CPAP, and measurements were recorded at CPAP settings of 3, 5, 7, 4, and 2 cm H_2O. The flow rate with ventilator-generated CPAP is variable but was assumed to be relatively constant for each infant.

The intraprong pressure measurements with the bubble CPAP were consistently higher than the set or submersion depth at all flow rates, at a mean of 1.3 cm H_2O. The largest percentage of overshoot (75%) was measured with the lowest pressures. The ventilator-generated CPAP intraprong pressure measurements were very close to the set CPAP levels.

Based on the results of this study, it appears that set pressures with bubble CPAP are not reliable and are consistently higher than believed. This increased mean CPAP pressure may be the reason that clinicians perceive infants as doing better on bubble CPAP than on ventilator-generated CPAP at the same levels, because they are most likely not making an equal comparison. Use of bubble CPAP systems is also associated with safety concerns, as these devices do not have any pressure alarms to alert the clinician when the actual delivered pressures are higher than those intended.

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BUBBLE CPAP VS. VENTILATOR-DELIVERED CPAP

Kahn DJ, Courtney SE, Steele AM, Habib RH. **Unpredictability of delivered bubble nasal continuous positive airway pressure: role of bias flow magnitude and nares-prong air leaks.** *Pediatr Res.* 2007;62(3):343-347.

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In this comparison of bubble CPAP vs ventilator-delivered CPAP, the authors performed measurements of intraprong, proximal-airway, and distal-airway pressures with both devices at various CPAP and flow settings, as well as differing leak conditions between the nasal prongs and the nares. Using a lung model, they recorded measurements at flow rates of 4, 6, 8, 10, and 12 liters per minute at 3 different CPAP levels (4, 6, and 8 cm H_2O), under simulations of no, small, and large leaks between the nasal prongs and the nares.

At no and small leak simulations, the ventilator-delivered CPAP consistently delivered pressure levels extremely close to the set CPAP levels at all CPAP settings and flow rates. The bubble CPAP measurements showed large differences in set vs delivered CPAP levels, which became systematically greater with increases in flow rates. The authors also reported on the inability to maintain desired CPAP levels when a large leak was present between the nares and the nasal prongs, such as a nares-to-prong ratio of 1:1.5.

The investigators concluded that the ventilator-delivered CPAP device is relatively consistent and accurate, and does not depend on flow rates to deliver accurate

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pressures. They also noted that bubble CPAP is very flow-dependent, and that measured overshoots of pressure are greater at low CPAP levels, and increase with increases in flow at all measured CPAP levels and also with reductions in nasal prong leaks. The authors determined that a smaller leak is necessary with bubble CPAP, in order to be able to deliver more consistent and accurate CPAP levels, and they caution that the unpredictability of leaks can be a safety concern when using higher flow rates and pressures.

Although the effect of amplitude caused by bubbling was not the primary focus of this study, the investigators noted that these perceived oscillations play a minimal, if any, role in ventilation or lung recruitment.

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WORK OF BREATHING WITH BUBBLE CPAP VS. VARIABLE-FLOW CPAP

Liptsen E, Aghai ZH, Pyon KH, et al. **Work of breathing during nasal continuous positive airway pressure in preterm infants: a comparison of bubble vs variable-flow devices.** *J Perinatol.* 2005;25(7):453-458.

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The authors designed this randomized, crossover trial of 18 premature infants to compare the work of breathing and breathing asynchrony with bubble CPAP vs variable-flow CPAP. The objectives of this study were the same as those of the prior 2 studies reviewed—that is, to determine if bubble CPAP aids in improvement in ventilation compared with other types of nasal CPAP devices. Each infant was placed on bubble CPAP and variable-flow CPAP at levels of 8, 6, 4, and 0 cm H_2O. The starting device and CPAP levels were selected randomly, with half of the infants started on bubble CPAP and half started on variable-flow CPAP. At each level, the authors monitored the infant's work of breathing, changes in compliance, tidal volume, and respiratory rate.

Nasal CPAP levels of 8, 6, and 4 cm H_2O showed statistically significant improvements in inspiratory work of breathing and tidal volumes (P. <.05), as well as minute ventilation (P <.01), compared with CPAP levels of 0 cm H_2O, with both CPAP delivery devices studied. Variable-flow CPAP was associated with an increase in work of breathing in all variables when comparing any CPAP level set to 0 cm H_2O (P <.01)—an improvement that was not observed with bubble CPAP. No difference was observed between the devices at all levels when comparing inspiratory work of breathing, compliance, tidal volume/kg, and minute ventilation. The authors did note a statistically significant improvement with bubble CPAP in terms of resistive work of breathing (P =.01), respiratory rate (P =0.03), and phase angle (P =.002).

The investigators of this study concluded that there is an improvement observed in breathing asynchrony and resistive work of breathing with bubble CPAP vs variable-flow CPAP in preterm infants with mild respiratory distress. They also determined that larger, lengthier trials are warranted to confirm these results. With this study, the question that still remains is whether the comparison between these 2 CPAP devices was a true comparison, bearing in mind the fact that bubble CPAP levels delivered are routinely greater than the intended pressure levels. The authors did note that variable-flow CPAP was more constant and reliable relative to set and delivered pressures, but they did not report the actual pressure levels of the bubble CPAP delivered at each level studied. When referring to the 2008 publication (our second review) conducted by many of the same authors (published at a later date than this article), the bubble CPAP level is greater by an average of 1.3 cm H_2O. This can be associated with significant changes for a preterm infant, which is likely the cause of the positive results reported with bubble CPAP.

Reference

1. Kahn DJ, Habib RH, Courtney SE. Effects of flow amplitudes on intraprong pressures durig bubble versus ventilator-generated nasal continuous positive airway pressure in premature infants. *Pediatrics.* 2008;122(5):1009-1013.

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EFFICACY AND SAFETY OF BUBBLE CPAP VS. VARIABLE-FLOW CPAP

Gupta S, Sinha SK, Tin W, Donn SM. **A randomized controlled trial of post-extubation bubble continuous positive airway pressure versus infant flow driver continuous positive airway pressure in preterm infants with respiratory distress syndrome.** *J Pediatr.* 2009;154(5):645-650.

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In this study, 140 preterm infants of 24 to 29 weeks' gestational age and 600 to 1500 grams were enrolled to compare the efficacy and safety of bubble CPAP vs variable-flow CPAP for the management of respiratory distress syndrome following extubation. At birth, the infants were randomized to receive bubble CPAP or variable-flow CPAP delivered via the Infant Flow Driver system. The primary outcome of the study was successful extubation for at least 72 hours; the secondary outcomes were successful extubation maintained for 7 days, total duration of CPAP support, and complications of prematurity, including a diagnosis of chronic lung disease.

Once an infant was assigned to a CPAP group, the type of CPAP device was used for the infant throughout his or her admission, and the medical management of each device (CPAP level and flow rates) was determined by each physician according to the patient's condition. Strict criteria for intubation and extubation were followed by all physicians for all study patients, since duration of CPAP and reintubation rates were outcome measures of the study.

There were more male infants in the variable-flow CPAP group than in the bubble CPAP group (n=44 vs n=37, respectively). Additionally, more infants failed extubation in the variable-flow group than in the bubble CPAP group (27.5% vs 16.9%, respectively)—a difference that was not statistically significant (*P* =.130). When comparing infants who were ventilated for ≤14 days, a statistically significant difference in failed extubation rates was reported (14% with bubble CPAP vs 28.6% with variable-flow CPAP; *P* =.046). The median days on CPAP in the bubble group was 2 days, compared with 4 days in the variable-flow group (*P* =.031). However, once the authors included deceased infants in these figures, the value in the bubble CPAP group rose to a median of 3 days, rendering this result no longer significant (*P* =.754). The incidence of chronic lung disease and other complications of prematurity did not differ significantly between the 2 groups.

The authors concluded that there was no difference in the success of extubation with the use of bubble CPAP or variable-flow CPAP. Although not statistically significant, they did note a reduction in days on CPAP, chronic lung disease, and extubation failure with bubble CPAP vs variable-flow CPAP. Some might say that these results may be skewed, because there were more males placed on variable-flow CPAP, and males statistically have poorer outcomes compared with females. There was also minimal mention of deaths, which occurred only in the bubble CPAP group. In fact, there is no documentation of the cause of death in these infants, and whether some of the effects might be associated with complications from respiratory distress and CPAP.

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USE OF BUBBLE CPAP IN VERY LOW BIRTH WEIGHT INFANTS WITH RESPIRATORY DISTRESS SYNDROME

Nowadzky T, Pantoja A, Britton JR. **Bubble continuous positive airway pressure, a potentially better practice, reduces the use of mechanical ventilation among very low birth weight infants with respiratory distress syndrome.** *Pediatrics.* 2009;123(6):1534-1540.

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This publication is the result of a quality improvement initiative conducted by the authors in an effort to reduce chronic lung disease rates among very low birth weight infants. The project was designed to implement the use of bubble CPAP in their NICU, in order to adopt the best practices of another center that has achieved low rates of chronic lung

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disease in the same population. The investigators compared their new outcomes data (March 2005 to October 2007) with historical outcomes data (January 2003 to February 2005). The pulmonary data evaluated included incidence of mechanical ventilation, length of ventilation, incidence of pneumothorax, and incidence of bronchopulmonary dysplasia. During the study time frame, the authors used bubble CPAP instead of mechanical ventilation in very low birth weight infants with respiratory distress syndrome. It also appears that the NICU utilized other best practices that could reduce the rates of chronic lung disease, such as maintaining oxygen saturations of 85% to 92%, tolerated hypercapnia, and use of vitamin A supplements.

There was a statistically significant reduction in the use of mechanical ventilation in the study period (*P* =.001) and in the duration of mechanical ventilation that would exceed 6 days (P=.004). In addition, an unexplained statistically significant increase in stage I and II retinopathy of prematurity (ROP) was reported in the study phase compared with the historical data. All the other results analyzed did not show a significant difference between the 2 groups. The authors also noted an increase in cardiorespiratory lability, including apnea, which may have contributed to the increased rates of ROP.

The investigators concluded that there was a correlation between the reduction in use of mechanical ventilation and the implementation of bubble CPAP, with no significant difference in the rates of chronic lung disease reported. This reduction in the need for mechanical ventilation in the study period can likely indicate a pattern of overuse in the historical period. Bubble CPAP has not been proven to increase ventilation and requires that infants be spontaneously breathing adequately enough to be maintained on CPAP without the need for additional support. Thus, it is difficult to believe that the implementation of bubble CPAP caused this reduction. With all the other practices that were initiated along with the reduction in mechanical ventilation, it is interesting to note that there was no significant reduction in the incidence of chronic lung disease, thus raising the question of whether the use of bubble CPAP, rather than another form of CPAP, could have contributed to this reduction.

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