# Effects of Condensate in the Exhalation Limb of Neonatal Circuits on Airway Pressure During Bubble Continuous Positive Airway Pressure

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Data in this manuscript were presented in an Open Forum at the 2012 AARC Congress in New Orleans, LA on Tuesday, November 13, 2012.

The authors have no conflict of interest to disclose.

## **Abstract**

**Background.** Bubble continuous positive airway pressure (B-CPAP) is frequently used in spontaneously breathing infants with lung disease. Often, the B-CPAP systems lack pressure alarms and pressure release valves. We observed a large volume of condensate in the exhalation limb of a patient circuit and conducted a series of experiments to test the hypothesis that accumulated condensate could affect delivered pressures. **Methods.** An anatomically accurate nasal airway model of a preterm infant was attached to a spontaneously breathing lung model. A Fisher & Paykel B-CPAP system was attached to the nasal airway with bi-nasal short prongs and the rate of fluid condensation was measured. Next, tracheal pressures were monitored digitally to detect changes in airway pressure related to condensate accumulation. Measurements were obtained with volumes of 0, 5, 10, 15, and 20 mL of water in the exhalation limb at flow rates of 4, 6, 8, and 10 L/min. Measurements with 20 mL in the exhalation limb were recorded with and without an F&P pop-off valve in the circuit. **Results.** The rate of condensate accumulation was 3.8 mL/hour. At volumes of  $\geq$ 10 mL, noticeable alterations in the airway pressure waveforms and significant increases in mean tracheal pressure were observed. The popoff valve effectively attenuated peak tracheal pressures but only decreased mean pressures by 0.5-1.5 cmH<sub>2</sub>O. **Discussion/Conclusion**. Condensate in the exhalation limb of the patient circuit during B-CPAP can significantly increase pressure delivered to the patient. The back and forth movement of this fluid causes oscillations in airway pressure that are much greater than the oscillations created by gas bubbling out the exhalation tube into the water bath. We recommend continuously monitoring pressure at the nasal airway interface, placing an adjustable pop-off valve in the circuit set to 5 cmH<sub>2</sub>O above desired mean pressure, and emptying fluid from the exhalation limb every 2-3 hours.

Keywords: B-CPAP, condensate, added resistance, patient safety, airway pressure, neonatal intensive care, maintenance, lung protection, noninvasive ventilation

# Introduction

Nasal bubble continuous positive airway pressure (B-CPAP) is a form of noninvasive respiratory support used in spontaneously breathing infants with lung disease. Its popularity in the NICU has been on the rise since a multi-center randomized controlled trial<sup>1</sup> showed no differences in the rate of complications between infants supported by B-CPAP or ventilator-derived CPAP, as well as a lower incidence of reintubation in the B-CPAP group. Clinicians prescribe the level of airway pressure desired for the infant and frequently use the depth of the expiratory tube in water (the water pressure seal) as an estimate of the pressure delivered to the patient.

When applying B-CPAP to infants, many institutions construct their own homemade systems. Unlike ventilator-derived CPAP, the homemade systems described in literature frequently lack safety alarms and high pressure pop-off valves.<sup>2-7</sup> The commercially available B-CPAP system manufactured by Fisher & Paykel (F&P) includes a pressure release valve which opens at pressures above 17 cmH<sub>2</sub>O. This valve effectively responds to high pressures that could result from a kink in the exhalation circuit; however, it would be unresponsive to a mean airway pressure of 16 cmH<sub>2</sub>O.

Kahn et al.<sup>8,9</sup> have shown that the bias flow coursing through the circuit can lead to an underestimation of the delivered pressure. The present investigation pursues an additional clinical event that may also contribute to the disparity between tube depth setting and the actual pressure delivered to the patient. The aim of this study was to test the hypothesis that increases in condensate levels within the expiratory tubing of a B-CPAP system would result in greater pressure levels than a dry circuit.

#### Methods/Materials

# Lung Model

We modeled lung mechanics using a neonatal test lung (ASL5000, Ingmar Medical, Pittsburgh, Pennsylvania). The lung was configured to represent the pulmonary mechanics of an extremely-low-birth-weight infant with respiratory distress syndrome: lung compliance 0.5 mL/cmH<sub>2</sub>O, resistance 100 cmH<sub>2</sub>O/L/s. The lung model was made to breathe spontaneously by setting a simulated pleural pressure profile ( $P_{musc}$ ): 10 cm H<sub>2</sub>O (yielding  $V_T \sim 5$  mL), and Rate 50 breaths/min.<sup>10</sup>

## Nasal Airway Model

A head CT scan from a 26-week gestation age infant was loaded into Vworks<sup>TM</sup> 4.0 (ver. 4.0, CyberMed, Centreville, VA), upper airway anatomy was cropped out of each image, and relevant files were exported in a stereolithography format. Files were then loaded into a rapid prototyping system and a 3D model of the upper airway was printed (V-Flash). The model was then glued to a 15mm adapter to attach to the lung model.

# **B-CPAP System**

All testing was conducted using a commercially available B-CPAP system (Fisher & Paykel, Auckland, New Zealand). A standard oxygen flow rotameter provided fresh gas to the dry side of the humidifier via the pressure manifold.

#### Instrumentation

Micro-machined piezoresistive silicon pressure transducers (All Sensors, range 0 to 100 cmH<sub>2</sub>O), for measuring airway pressure, were calibrated using two point calibrations with a pre-calibrated manometer (Digitron Model PM-23). Analog signals

from the pressure transducer were sampled at 1,024 kHz with a 16-bit analog-to-digital converter (DT BNC Box USB 9804, Data Translation, Waltham, Massachusetts) and recorded on a laptop computer. Pressure signals were recorded digitally and calculations of mean airway pressure, amplitude of oscillations in airway pressure, and peak frequency of oscillations were made using custom software written in Visual Basic (Microsoft, Redmond, WA).

### **Experimental Protocol**

#### **Rate of Condensate Accumulation**

The average rate of condensate accumulation in the exhalation limb during B-CPAP was determined so that approximate volumes could be used in a controlled fashion for the second phase of testing. The nasal airway model was attached to the spontaneously breathing lung model. The expiratory circuit was removed from the B-CPAP system and the mass (g) of the dry circuit was measured on a scale (n=3) and reattached to the B-CPAP system. The expiratory hose was placed into a 27 cm fixed "U-shaped" configuration<sup>11</sup> and the position was secured by taping the hose to the table (Figure 1). The CPAP level was set at 5 cmH<sub>2</sub>O with flow 6 L/min. The nasal prongs were attached to the nasal airway openings and secured by a bonnet fixation. Continuous bubbling during the entire respiratory cycle indicated a good seal at the prongs. The humidifier was set at 37°C in the Invasive Mode and the internal components of the lung model were held at 37 °C using an integrated warmer. Ambient temperature was controlled in the room (~21 °C) with a pre-set thermostat, and an oscillating fan set on "medium" was placed eight feet away from the B-CPAP system to simulate drafts from

ceiling vents or excessive movement around the circuit, which are encountered in the clinical setting.

The study began following a 20-minute temperature stabilization period with the system running. Every two hours, the volume of accumulated fluid in the expiratory hose was assessed by removing and weighing the tubing and comparing the measurement to the mass of the dry circuit. Tubing was reattached to the B-CPAP system after each measurement without removing fluid. The lung model breathed for a total of eight hours during B-CPAP and the experiment was conducted three times with a new dry circuit.

#### **Effect of Condensate on Delivered Pressure**

Nasal prongs were inserted into a nasal airway model and a tight seal (no leak) was made by forming medical-grade Silly Putty around the interface. The nasal airway model was connected to the test lung, and tracheal pressure ( $P_{TR}$ ) was monitored between the nasal airway model and test lung in a simulated trachea consisting of small plastic 15 mm OD adapters (Figure 1).

The initial measurements were recorded using a dry circuit with no pressure manifold in the system, and P<sub>TR</sub> was collected for 8 seconds at flows of 4, 6, 8, and 10 L/min. The expiratory hose was disconnected and water was added in 5 mL increments to the "U" in the exhalation circuit though a feeding catheter attached to a glass syringe. P<sub>TR</sub> measurements were obtained for 8 seconds at each flow setting with volumes of 5, 10, 15, and 20 mL of water in the circuit. Three separate pressure measurements were recorded for each set of conditions.

## Effectiveness of a "Pop-Off" Valve at Attenuating Pressure

Following the final measurement (20 mL water), the Fisher & Paykel B-CPAP pressure manifold (pop-off valve) was introduced into the circuit. Tracheal pressure measurements were obtained for 8 seconds at each flow rate (4, 6, 8, and 10 L/min) with CPAP set to 5 cmH<sub>2</sub>O.

# **Data Analysis**

Data from the study that assessed rate of condensate accumulation were saved in an Excel (Microsoft, Redmond, WA) Spreadsheet, and the rate was calculated from a linear regression using the least squared method.

Mean tracheal pressure ( $P_{TR}$ ) was calculated for each 8 s run (n=3). The mean  $\pm$ SD of the amplitudes of oscillations in tracheal pressure ( $\Delta P_{TR}$ ) were then calculated from the  $P_{TR}$  signals using an algorithm (described elsewhere<sup>12</sup>) that determines the amplitude of individual oscillations. The peak frequency was calculated using spectral power analysis to define frequencies with the maximum power observed in each testing condition.

For data collected without a pop-off valve in the system, a one-way analysis of variance (ANOVA) was used with a Tukey test for post hoc analysis to compare the  $P_{\overline{TR}}$  and  $\Delta P_{TR}$  at each volume of condensate at similar flows. Data collected with 20 mL of condensate in the circuit while the pop-off valve was in place were compared to data collected with the same volume of condensate in a circuit without a pop-off valve using a paired t-test. Statistical significance was set *a priori* at p<0.05.

#### Results

The rate of fluid accumulation in the exhalation limb of the B-CPAP system remained constant ( $R^2 = 0.9929$ ) at 3.8 mL/hour over the 8-hour period. The condensate formed a pool in the low point of the expiratory circuit that became intermittent at large volumes (15 and 20 mL) as the air pushed past the occlusion.

There were no differences in the  $P_{\overline{TR}}$  (Figure 2) or  $\Delta P_{TR}$  (Figure 3) between 0 and 5 mL at similar flows during B-CPAP. However, the addition of larger volumes of fluid (>5 mL) to the exhalation limb of the B-CPAP system resulted in increases in both sets of pressure measurements at each flow rate (p<0.05).

Figure 4 shows a graphical representation of  $\Delta P_{TR}$  measured over an 8 s period at each volume during 5 cmH<sub>2</sub>O CPAP and flow 8 L/min. There were noticeable changes in pressure waveform characteristics at volumes greater than 5 mL. The P  $_{\overline{TR}}$  was 5.01±0.01, 5.09±0.01, 6.14±0.06, 8.84±0.01, and 11.85±0.22 cmH<sub>2</sub>O for volumes of 0, 5, 10, 15, 20 mL, respectively. The  $\Delta P_{TR}$  was 2.60±0.28, 2.08±0.15, 5.01±0.20, 7.60±0.21, and 9.90±0.57 cmH<sub>2</sub>O for volumes of 0, 5, 10, 15, 20 mL, respectively. The peak frequencies were 10.29±0.32, 10.50±0.32, 4.17±0.07, 3.37±0.21, and 1.67±0.70 Hz for volumes of 0, 5, 10, 15, 20 mL, respectively.

The use of a preset pressure manifold (pop-off valve) in the B-CPAP circuit significantly decreased the  $P_{\overline{TR}}$  and  $\Delta P_{TR}$  (Figures 5 and 6, respectively; p<0.05), when compared within each flow rate, with the exception of  $P_{\overline{TR}}$  at a flow of 8 L/min. This component had a greater influence on  $\Delta P_{TR}$  than on  $P_{\overline{TR}}$ . Figure 7 compares two pressure waveforms with and without a pop-off valve in the circuit. The frequency of the  $\Delta P_{TR}$ 

9

was higher when no pop-off valve was used, and peak  $P_{TR}$  was well above 17 cm $H_2O$ . However, when the pop-off valve was incorporated into the circuit, the peak  $P_{TR}$  was blunted to 13-14 cm $H_2O$ , and the consequent lower frequencies resulted in a longer duration at the peak  $\Delta P_{TR}$ , which in turn resulted in only minor decreases in the  $P_{\overline{TR}}$ .

## Discussion

The major finding of this study was that condensate in the exhalation limb of the patient circuit during B-CPAP can result in  $P_{\overline{TR}}$  significantly higher than the CPAP depth setting. Additionally, the flow-induced movement of accumulated condensate and the patient's spontaneous respiratory efforts cause oscillations in  $P_{TR}$  that are greater than the oscillations created solely by gas bubbling out of the expiratory tubing. The combination of increases in both  $P_{\overline{TR}}$  and  $\Delta P_{TR}$  results in airway pressures that may surpass safe levels.

To discuss this point in detail, at volumes of 10 mL,  $P_{\overline{IR}}$  is noticeably increased from dry circuit measurements but might still appear to be relatively benign. However, when combined with the increased pressure oscillations, it is evident that the peak pressures reaching the infant are cause for concern. For example, at a flow of 6 L/min, a dry circuit delivers a peak pressure of 7.5 cmH<sub>2</sub>O ( $P_{\overline{IR}}$ : 4.9,  $\Delta P_{TR}$ : 2.6) while a wet circuit containing 10 mL of condensate delivers peak a pressure of 10.4 cmH<sub>2</sub>O ( $P_{\overline{IR}}$ : 5.8,  $\Delta P_{TR}$ : 4.6), which is twice the set CPAP level. Taking into account our measured rate of fluid accumulation of 3.8 mL/h, and using 10 mL as an arbitrary marker for the onset of unwarranted pressure spikes, an unattended B-CPAP system in conditions similar to our experimental setup can reach potentially unsafe pressures (>12 cmH<sub>2</sub>O) in less than 3 hours.

Allowing delivered pressures to reach pressures significantly higher than those intended can result in serious physical consequences such as air leaks, overdistension, and gastric distension. <sup>13</sup> Physiological consequences may include increased PaCO<sub>2</sub>, reduction in venous return, and compromised cardiac output. <sup>14, 15</sup>

The additional resistive loading of the infant respiratory system from excessive fluid accumulation in the B-CPAP circuit could potentially add to respiratory failure by superimposing large airway pressure oscillations that are out-of-phase with the patient's intrinsic respiratory efforts. Imposed resistance through any or all of the airways during exhalation can produce alveolar hyperinflation, uneven regional ventilation, and excessive respiratory muscle loading, leading to increased work of breathing (WOB), impaired gas exchange, <sup>16</sup> and failure to wean <sup>17-22</sup>.

As expected, the placement of the F&P pressure-relief valve had an appreciable effect on the magnitude and frequency of the  $\Delta P_{TR}$  (Figures 6 & 7) but did little to decrease  $P_{\overline{TR}}$  (Figure 5) to levels considered safe for some preterm neonates. Thus, an adjustable pressure-relief may provide better control over excessive pressure transmission when unwarranted condensate levels build within the B-CPAP system. Further, high-pressure audio alarms may be useful in warning clinicians of rising pressure levels.

Our suggestion that circuits be emptied every 2-3 hours to avoid potentially unsafe pressure increases is based on our accumulation rate and pressure data, which have inherent limitations. We conducted the accumulation rate study at a single flow (6 L/min); it may be reasonable to suspect that higher flow rates will result in greater fluid accumulation rates due to the increased volume of humidified air flowing through the circuit. The test lung, though heated to 37°C and programmed to simulate breaths, cannot predict how the physiology of an infant's lung contributes to condensate formation in the expiratory circuit. However, since the exhaled gas is at body temperature and is saturated, it is likely that infants will add moisture to the air, in which case our results may somewhat underestimate the actual rate of condensate formation. By having a completely

airtight system, our measurements may overestimate the pressures that an infant actually receives. Small leaks around the prongs or at the mouth are commonplace in the NICU, especially if chinstraps or pacifiers are not being used. Additionally, if a chinstrap is not in place, the mouth may serve as a natural pressure-relief valve should an obstruction in the circuit cause pressures to drastically increase.

Substitutions for, or alterations in, the proprietary non-heated exhalation circuit used with the F&P B-CPAP system may decrease the rate of condensate accumulation. An exhalation circuit with a heated wire may allow water to remain in vapor form; the extent to which a heated expiratory circuit affects condensate formation is an area for further study. Fisher & Paykel's novel Evaqua 2<sup>TM</sup> circuit allows water vapor to diffuse out of the tubing wall, which drastically decreases the amount of fluid condensate and circuit maintenance required. However, the added expense of the Evaqua 2<sup>TM</sup> may make it inaccessible to many clinicians, particularly those in resource limited settings. Water traps have also been integrated into exhalation circuits to catch condensate and keep the circuit clear, but they are not well suited for use with B-CPAP because the volume they add to the circuit may increase overall compliance and result in a dampening of the pressure oscillations that are both characteristic and desirable of B-CPAP.

## **Conclusions**

The presence of condensate in the expiratory limb of a B-CPAP circuit will lead to unintended increases in delivered pressure if permitted to accumulate. We recommend that the operators of basic (i.e. commercial systems without specialized circuits) or homemade B-CPAP systems monitor pressure continuously at the nasal airway interface to ensure that the pressure delivered to the infant matches the pressure that was intended by the CPAP depth setting. In order to avoid potential complications related to inadvertent pressure increases, we encourage frequent emptying of condensate from the circuit, the verification of proper heated humidifier settings, and the incorporation of an adjustable high-pressure pop-off valve set to 5 cmH<sub>2</sub>O above the desired mean pressure.

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RESPIRATORY CARE Paper in Press. Published on March 12, 2013 as DOI: 10.4187/respcare.02322

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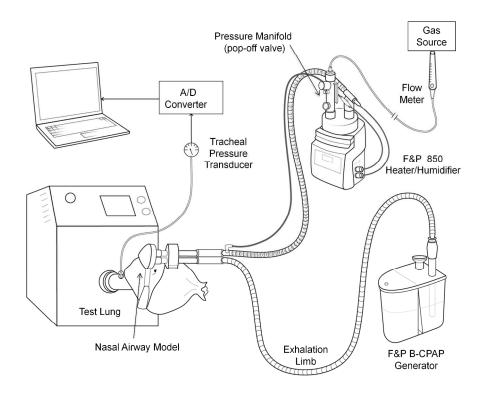
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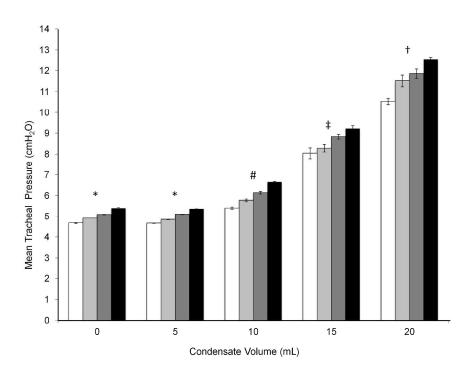
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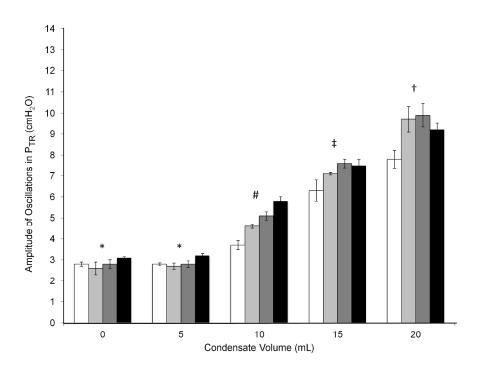
- Figure 1 Schematic of experimental setup.
- **Figure 2** Mean tracheal pressure measurements with varying volumes of condensate in the exhalation limb. Flow rates of 4, 6, 8, and 10 L/min are represented as white, light gray, dark gray and black columns, respectively. Groups not sharing similar symbols are different (p < 0.05).
- **Figure 3** Amplitude of oscillations in tracheal pressure measurements with varying volumes of condensate in the exhalation limb. Flow rates of 4, 6, 8, and 10 L/min are represented as white, light gray, dark gray and black columns, respectively. Groups not sharing similar symbols are different (p < 0.05).
- **Figure 4** Tracheal pressure waveforms are shown for condensate volumes of 0, 5, 10, 15, and 20 mL at a CPAP depth setting of 5 cmH<sub>2</sub>O and a flow rate of 8 L/min. Pressure signals were sampled at 1,024 kHz for 8 s.
- **Figure 5** Comparison of mean tracheal pressures with and without a pressure manifold (pop-off valve) in the circuit over a range of flows with 20 mL of condensate in the circuit and a CPAP depth setting of 5 cm $H_2O$ . \* p < 0.05.
- **Figure 6** Comparison of amplitude of oscillations in tracheal pressure with and without a pressure manifold (pop-off valve) in the circuit over a range of flows with 20 mL of condensate in the circuit and a CPAP depth setting of 5 cm $H_2O$ . \* p < 0.05.
- **Figure 7** Comparison of pressure waveforms with (A) and without (B) a pop-off valve in the circuit. Pressure signals were sampled at 1,024 kHz for 8 s; CPAP depth 5 cmH<sub>2</sub>O, flow 10 L/min, condensate volume 20 mL.



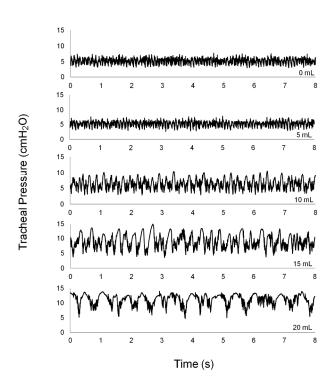
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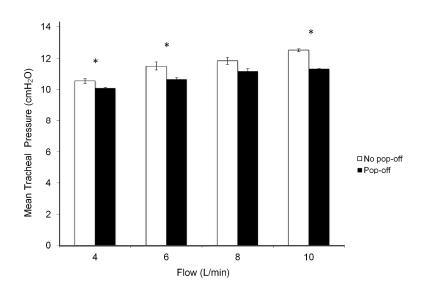
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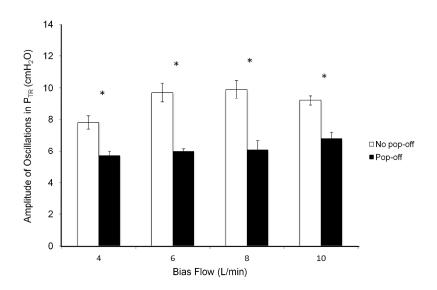
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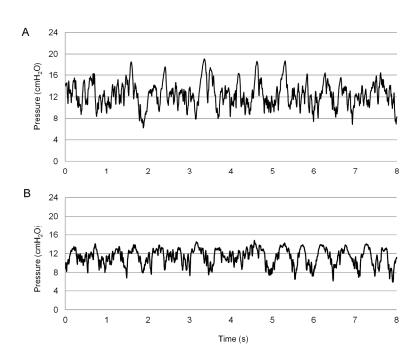
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