Does the RAM Cannula Provide Continuous Positive Airway Pressure as Effectively as the Hudson Prongs in Preterm Neonates?

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Abstract

Objective To compare the level of continuous positive airway pressure (CPAP) delivered by the RAM cannula system (Neotech, Valencia, CA) with that delivered by a traditional CPAP nasal delivery interface (Hudson prongs; Hudson-RCI, Temecula, CA) in preterm infants with respiratory distress.

Methods This was a crossover intervention study in a convenience sample of preterm infants with respiratory distress requiring treatment with CPAP. We measured the mean intraoral (pharyngeal) pressure, which approximates the applied CPAP level, using both the RAM cannula and Hudson prongs. The primary outcome was a comparison of the differences between the set CPAP levels and the measured intraoral pressures of both delivery systems.

Results We analyzed data from 12 preterm infants with mean (standard deviation) birth weight of 1,225 (405) g and gestational age of 28.4 (2.1) weeks at a median postnatal age of 10 days. The mean difference (95% confidence interval) between the set CPAP level and measured intraoral pressure was −2.45 cm H2O (−3.36, −1.55) with the RAM cannula and +0.40 cm H2O (−0.30, 1.12) with Hudson prongs, p = 0.0002.

Conclusion For given set CPAP pressure level in preterm infants, the RAM cannula system consistently delivers lower pharyngeal pressure (effective CPAP) levels than Hudson prongs.

Keywords

► continuous positive airway pressure
► nasal interface
► preterm

Continuous positive airway pressure (CPAP) has gained popularity as a means to provide noninvasive respiratory support in neonates to reduce ventilator-induced lung injury.1–4 However, providing effective CPAP in preterm infants has been challenging, often related to problems associated with the nasal interface. Most neonatal intensive care units (NICUs) use short binasal prongs to deliver supplemental oxygen and CPAP in neonates.5,6 These prongs are effective and safe but have the potential to cause nasal septal pressure injury and pressure leak around the nares.

The RAM cannula (Neotech, Valencia, CA) was approved by the Food and Drug Administration as a Class I medical device for providing supplemental oxygen with 60 to 80% nasal occlusion. It was soon adopted by clinicians to provide CPAP, largely because of its perceived ease of use and less nasal (septal) injury. Compared with the standard nasal interface for CPAP, the RAM cannula is made of softer material with a thin prong wall resulting in a larger caliber and less nasal trauma. However, there is increasing concern that the RAM cannula interface delivers suboptimal pressure compared with the standard nasal prongs, and the high expiratory resistance of the system increases expiratory workload and risk for hypercapnia.7 Importantly, a recent in vitro study reported failure to achieve set CPAP level with
the RAM cannula in comparison with a Drager BabyFlow-1 NCPAP interface. In vitro studies are helpful to study the differences in the physics and dynamics of different CPAP systems, but do not necessarily provide information about effective CPAP pressures achievable with various devices in a clinical environment. To the best of our knowledge, there have been no measurements of effective CPAP pressures delivered by the RAM cannula system in infants and no comparisons between pressures delivered by RAM cannula versus other systems, including the commonly used Hudson prong system (Hudson-RCI, Temecula, CA).

We therefore conducted an in vivo study in preterm neonates with respiratory distress syndrome (RDS) to compare CPAP pressures delivered using the RAM cannula system with pressures delivered using a standard nasal interface (Hudson prongs). We measured the mean intraoral (pharyngeal) pressure to approximate the applied CPAP level with RAM nasal cannula and Hudson prongs as has been done in previous studies. We hypothesized that the RAM cannula system would deliver a mean CPAP level similar to that of the Hudson prongs, and that the intraoral pressure would be lower than set CPAP level due to a variable leak from mouth irrespective of the type of nasal interface.

Methods

We performed a nonblinded, crossover intervention study in convenience sample of 15 preterm infants receiving CPAP for RDS in a Level 3 NICU from October 2016 to April 2017. The Dartmouth College Committee for the Protection of Human Subjects approved the study. Parents of included subjects gave informed consent.

Subjects

Any preterm infant with respiratory distress requiring CPAP but not mechanical ventilation or nasal intermittent positive pressure ventilation was eligible for the study. We recruited subjects when they were stable on CPAP with a fraction of inspired oxygen (FiO₂) requirement of less than 0.30. We excluded infants who were critically ill or had major congenital anomalies, neuromuscular disorders, or upper airway anomalies.

Procedure

It is our current practice in preterm infants with respiratory distress requiring noninvasive respiratory to apply CPAP using a RAM cannula connected to a bubble CPAP system. The cannula or prong size is chosen that best fits the nares with complete nasal occlusion from the four available sizes—micro-preemie (3 mm), preemie (3 mm), newborn (3.5 mm), or infant (4 mm). FiO₂ and the level of CPAP are set as per the provider's instruction and following unit guidelines for CPAP (pressure from 5 to 7 cm of H₂O and flow from 6 to 10 L/min).

After obtaining written consent from the parents, we studied infants in their clinical environment, which remained unchanged during the study period except for the nasal interface used to deliver CPAP. A thermoneutral environment was provided in an Isolette and routine care continued as usual during the study. Since the infant was receiving CPAP with RAM cannula, and we wanted to disturb the infant as little as possible, we elected to first measure the intraoral pressure with RAM cannula and then switch to Hudson prongs. Blinding of the intervention (nasal interface) was not feasible because of the visible differences in the two nasal interfaces. We did not make any changes in the set level of CPAP or flow rate during the measurement period. The FiO₂ was titrated, if necessary, to maintain the oxygen saturation within target range (91–95%).

We measured the intraoral pressure with an air filled tube (2.5 mm ET tube) introduced into the mouth through a hole made in a pacifier and projecting ~1 cm beyond the tip. The ET tube was connected to a differential transducer (Validyne) and the final depth of the tube was adjusted to obtain a stable pressure waveform. The transducer was calibrated before recording for each nasal interface. We started recording data when the infant was calm and quiet, not sucking aggressively on the pacifier and observing a stable pressure waveform. We used sucrose or maternal breast milk on the pacifier to soothe the infant during the procedure. The mouth remained in a passively closed position with the pacifier in place during each data recording.

Because of difficulty in capturing stable waveforms without artifacts, we recorded the intraoral pressure for 2 to 5 minutes with a goal of obtaining at least one stable waveform recordings of at least 30-second duration. After completion of recording pressures with the RAM cannula system, we switched the nasal interface to the Hudson prongs and after calibration and a minimum of a 5-minute acclimatization period and after the infant appeared calm and adjusted to the new prong system, we recorded pressures for 2 to 5 minutes with the Hudson prong system. When this was completed, we placed the infant back on RAM cannula system.

All pressure data were digitized at 50 Hz by using DATAQ Instruments WinDaq, v. 2.95. We selected the first 30 seconds of the longest segment with a stable waveform and without artifacts (from movement or sucking) to minimize selection bias. In addition to the pressure measurements, we also obtained simultaneous measurements of heart rate (HR), respiratory rate (RR), oxyhemoglobin saturation (SpO₂), and FiO₂ from the central monitoring system. The investigator analyzing the data was not blinded.

Statistical Analysis

The primary outcome of the study was a comparison of the difference between the measured intraoral pressure and the set CPAP level for the two nasal interfaces. We analyzed the data using a standard paired Student’s t-test, with p-value < 0.05 considered significant. We similarly compared the difference in other variables with t-tests. We used STATA 12 for statistical analysis.

Results

We recruited 15 subjects for the study, but the data from three were rejected because of unacceptable recordings (interference
from aggressive sucking on pacifier or from movement). We thus included data from 12 infants for analysis. This cohort’s mean (standard deviation [SD]) birth weight was 1,211 (385) g, gestational age 28.4 (2.1) weeks, and postmenstrual age at the time of study was 30.1 (2.3) weeks (∼Table 1).

During the study period, infants were clinically stable and breathing comfortably on CPAP. Three infants were receiving a CPAP set at 6 cm H2O, and the remaining infants were receiving a CPAP set at 5 cm H2O. The FiO2 requirement was minimal, ranging from 0.21 to 0.26. Three infants were fitted with a newborn (3.5 mm) sized RAM cannula and the remainder with the infant size (4 mm). The Hudson prong sizes that were used varied from size 1 to 4 (size 1: two infants, size 2: six infants, size 3: three infants, and size 4: one infant) to achieve complete nasal occlusion. The flow rate varied from 6 to 10 L/min (∼Table 2).

With the RAM cannula, the measured mean (SD) intraoral pressure was 3.15 (1.03) cm H2O at a set CPAP level of 5 cm H2O and 1.89 (1.15) cm H2O at a set CPAP level of 6 cm H2O. In contrast, with the Hudson prongs, the measured mean (SD) intraoral pressure was 5.25 (1.18) cm H2O at a set CPAP level of 5 cm H2O and 6.87 (0.97) cm H2O at a set CPAP level of 6 cm H2O (∼Table 2). The mean difference between set CPAP level and measured intraoral pressure with RAM nasal cannula and Hudson prongs was significantly different for the entire cohort (−2.45 cm H2O [95% confidence interval (CI): −3.36, −1.55]) with RAM cannula and +0.40 cm H2O [95% CI: +0.30, 1.12] with Hudson prongs, p = 0.0002 (∼Fig. 1) and when analyzed separately for set CPAP levels of 5 and 6 cm H2O (∼Table 3). There was no difference in FiO2 requirement, RR, or SpO2 with change in nasal interface. The HR increased slightly from a mean (SD) of 164 (7) beats/min on RAM cannula to 170 (10) beats/min on Hudson prongs during the study period (p = 0.043). In addition, we observed a greater breath-to-breath intraoral pressure variation with RAM cannula compared with Hudson prong (∼Fig. 2).

### Discussion

Our main findings were that the measured intraoral pressures at CPAP levels set at 5 or 6 cm H2O in preterm infants with respiratory distress were consistently lower when using the RAM cannula compared with the differences in measured and set pressures with the Hudson prongs. In a passively closed mouth position, the mean difference between set CPAP level and measured intraoral pressure was −2.45 cm H2O (95% CI: −3.36, −1.55) with the RAM cannula and +0.40 cm H2O (95% CI: +0.30, 1.12) with Hudson prongs. To the best of our knowledge, this is the first in vivo comparison of CPAP delivered with the RAM cannula system with another standard system used to deliver CPAP. Although our study used a bubble CPAP system, rather than a ventilator system to set the CPAP level, our results confirm the results of the in vitro study of Gerdes et al in a clinical setting.

We measured the intraoral (pharyngeal) pressure in a passively closed mouth position to assess delivered CPAP level with RAM cannula with complete nasal occlusion in comparison to Hudson prongs. Similar to the study by Kubicka et al, we were unable to record intraoral pressure in an open mouth position and hence did not evaluate the effect of different mouth positions on delivered pressure. In addition, obtaining highly accurate intraoral pressure for prolonged period in neonates was difficult. However, once the infant was quiet, we were able to obtain satisfactory recordings. Using the Hudson prongs, the delivered pressures were equal to or slightly higher than the set CPAP level in quiet infants with the mouth passively closed using a pacifier. In contrast, the measured intraoral pressure with the RAM cannula was consistently lower than the set CPAP level. With the RAM cannula system, we unexpectedly observed a lower mean measured intraoral pressure at a set CPAP level of 6 cm H2O than at a set CPAP level of 5 cm H2O. Although the reason is unclear, it should be noted that only three infants were studied at higher CPAP level and thus the difference may be related to the small number of measurements. We found no changes in RR, SpO2, and FiO2 associated with a change in the nasal interface. Increase in HR was significant with Hudson prongs, and may have been related to agitation or discomfort from change in nasal cannula or from the nasal irritation from the prongs themselves.

While many binasal prongs/interfaces are available, few studies have evaluated the delivered mean airway pressure with specific CPAP devices. Multiple factors affect the actual delivered pressure when applying CPAP including the CPAP generating device/nasal interface. One in vitro study showed that significant variation in resistance between different nasal interfaces affected the transmitted pressure to the airway. Gerdes et al compared delivered CPAP pressure with RAM cannula and Drager BabyFlow nasal CPAP interface in an in vitro study. The authors reported a 60 ± 17% lower delivered pressure than the set CPAP levels when RAM nasal cannula was applied using the manufacturer recommended 60 to 80% nares occlusion. Bailes et al also reported that RAM cannula delivered less than half of the set pressure across all the pressure setting tested at different flow rates in a test lung model. Our in vivo study showed similar results, even though we used bubble CPAP and measured pressure with complete nasal occlusion. Since we measured the intraoral pressure in a closed mouth position and ensured minimal

### Table 1 Patient characteristics

<table>
<thead>
<tr>
<th>Number of infants</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight, g (mean [SD])</td>
<td>1,121 (385)</td>
</tr>
<tr>
<td>Gestational age, wk (mean [SD])</td>
<td>28.4 (2.1)</td>
</tr>
<tr>
<td>Age at study, d (median [range])</td>
<td>10 (3–46)</td>
</tr>
<tr>
<td>CPAP level (cm H2O) (median [range])</td>
<td>5 (5–6)</td>
</tr>
<tr>
<td>FiO2 (mean [SD])</td>
<td>0.21 (0.02)</td>
</tr>
</tbody>
</table>

Abbreviations: CPAP, continuous positive airway pressure; FiO2, fraction of inspired oxygen; SD, standard deviation.
Table 2  Set CPAP level and measured intraoral pressure with RAM cannula and Hudson prongs

<table>
<thead>
<tr>
<th>SL number</th>
<th>BW (g)</th>
<th>GA at study (wk)</th>
<th>Age at study (d)</th>
<th>Set CPAP level (cm H2O)</th>
<th>Measured intraoral pressure with RAM cannula</th>
<th>Measured intraoral pressure with Hudson prongs cannula</th>
<th>Flow L/min</th>
<th>FiO2</th>
<th>Average SpO2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Median (25–75th percentile)</td>
<td>Median (25–75th percentile)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1,110</td>
<td>30</td>
<td>18</td>
<td>5</td>
<td>2.87 (2.25–3.09)</td>
<td>4.74 (4.4–5.0)</td>
<td>6</td>
<td>0.21</td>
<td>97 (97)</td>
</tr>
<tr>
<td>2</td>
<td>1,230</td>
<td>34</td>
<td>32</td>
<td>5</td>
<td>2.14 (1.49–2.45)</td>
<td>6.66 (6.5–6.79)</td>
<td>6</td>
<td>0.21</td>
<td>91 (92)</td>
</tr>
<tr>
<td>3</td>
<td>710</td>
<td>30</td>
<td>18</td>
<td>6</td>
<td>3.05 (2.55–3.46)</td>
<td>8.07 (7.44–8.46)</td>
<td>6</td>
<td>0.26</td>
<td>93 (98)</td>
</tr>
<tr>
<td>4</td>
<td>1,220</td>
<td>29</td>
<td>10</td>
<td>5</td>
<td>3.23 (2.83–3.52)</td>
<td>6.3 (5.91–6.65)</td>
<td>6</td>
<td>0.21</td>
<td>96 (97)</td>
</tr>
<tr>
<td>5</td>
<td>2,050</td>
<td>31</td>
<td>6</td>
<td>5</td>
<td>3.56 (2.3–4.05)</td>
<td>4.5 (4.02–4.81)</td>
<td>6</td>
<td>0.21</td>
<td>95 (95)</td>
</tr>
<tr>
<td>6</td>
<td>1,200</td>
<td>31</td>
<td>10</td>
<td>5</td>
<td>4.4 (4.32–4.5)</td>
<td>4.68 (3.88–6.12)</td>
<td>6</td>
<td>0.21</td>
<td>99 (96)</td>
</tr>
<tr>
<td>7</td>
<td>1,060</td>
<td>27</td>
<td>3</td>
<td>5</td>
<td>2.81 (2.02–3.6)</td>
<td>3.04 (2.9–3.1)</td>
<td>6</td>
<td>0.21</td>
<td>97 (98)</td>
</tr>
<tr>
<td>8</td>
<td>1,060</td>
<td>30</td>
<td>4</td>
<td>6</td>
<td>1.99 (1.51–2.46)</td>
<td>6.94 (6.24–7.56)</td>
<td>8</td>
<td>0.21</td>
<td>97 (97)</td>
</tr>
<tr>
<td>9</td>
<td>1,850</td>
<td>32</td>
<td>46</td>
<td>6</td>
<td>0.78 (0.25–1.03)</td>
<td>6.47 (5.09–6.99)</td>
<td>10</td>
<td>0.25</td>
<td>a</td>
</tr>
<tr>
<td>10</td>
<td>990</td>
<td>31</td>
<td>38</td>
<td>5</td>
<td>1.93 (1.68–2.25)</td>
<td>5.1 (4.87–5.2)</td>
<td>6</td>
<td>0.21</td>
<td>94 (95)</td>
</tr>
<tr>
<td>11</td>
<td>1,250</td>
<td>32</td>
<td>8</td>
<td>5</td>
<td>2.65 (2.1–3.0)</td>
<td>5.38 (4.89–5.8)</td>
<td>10</td>
<td>0.21</td>
<td>97 (98)</td>
</tr>
<tr>
<td>12</td>
<td>810</td>
<td>25</td>
<td>5</td>
<td>5</td>
<td>5.01 (4.8–5.14)</td>
<td>6.92 (6.17–7.56)</td>
<td>6</td>
<td>0.21</td>
<td>96 (94)</td>
</tr>
</tbody>
</table>

Abbreviations: BW, birth weight; CPAP, continuous positive airway pressure; FiO2, fraction of inspired oxygen; GA, gestational age; IQR, interquartile range.

*Missing data.
Fig. 1 Difference in set CPAP level and measured intraoral pressure for RAM cannula and Hudson prongs. CPAP, continuous positive airway pressure.

Table 3 Intraoral pressure measured with RAM cannula and Hudson prongs

<table>
<thead>
<tr>
<th>Set CPAP level (cm H$_2$O)</th>
<th>Number of patients</th>
<th>Intraoral pressure measured with RAM cannula (cm H$_2$O)</th>
<th>Intraoral pressure measured with Hudson prongs (cm H$_2$O)</th>
<th>Difference in intraoral pressure and set CPAP level between two nasal interfaces Mean (SD), 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>9</td>
<td>3.1 (1.03)</td>
<td>5.25 (1.27)</td>
<td>$-2.15$ (1.43), 95% CI ($-3.25$, $-1.05$), $p = 0.002$</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>1.89 (1.15)</td>
<td>6.87 (0.97)</td>
<td>$-4.98$ (0.22), 95% CI ($-5.54$, $-4.41$), $p = 0.0007$</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; CPAP, continuous positive airway pressure; SD, standard deviation.

Fig. 2 Recording of intraoral pressure from a patient on CPAP of 5 cm H$_2$O with RAM cannula and Hudson prongs. CPAP, continuous positive airway pressure.
leak (with complete nasal occlusion and mouth closed with a pacifier), we can only speculate that the higher resistance of the RAM cannula system results in lower transmitted intraoral pressure.

The crossover study design was useful to compare the intraoral pressure with two nasal interfaces over a short time period. Although a randomized crossover study design would have been preferable, we believe that the risk of carry over effect was low. We used a systematic approach in selecting segments of recording for analysis to minimize selection bias. We also minimized the leaks around the nose, mouth, and along the circuit by using complete nasal occlusion with the cannula and passive closure of mouth with pacifier. Pressure measurements were obtained in the most ideal conditions possible (calm quite infant with passively closed mouth position) and hence may not reflect the real-life scenario where intraoral pressure varies depending on the leak around the nares and mouth position (closed vs. open). We did not assess the effect of flow on transmitted pressure or evaluate the transmitted CPAP level at different set CPAP levels with either the RAM cannula or the Hudson prongs. In addition, we only studied the difference in intraoral pressure delivered by these nasal interfaces and not its effect on gas exchange or long-term outcomes of clinical significance such as days on oxygen, days on respiratory support, or incidence of chronic lung disease.

In conclusion, the RAM nasal cannula system did not provide the desired CPAP level in preterm infants at the set pressures tested in this study. Using higher set CPAP level or flow rate may be able to provide the desired effective CPAP level, but this needs to be systematically evaluated in future studies. We also suggest studying the clinical efficacy of the RAM cannula system in the management of RDS and its effect on clinically important outcomes in preterm infants in clinical trial.

Authors’ Contributions
Dr. Singh conceptualized and designed the study, drafted the initial article, and approved the final article as submitted. Matthew McNally was involved in study design, conducting the study, data collection, and analysis. Dr. Darnall developed the system to measure intraoral pressure, and was involved in designing the study and reviewing the article.

Note
ClinicalTrials.gov. ID: NCT03212508.

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None.

Conflict of Interest
None.

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