Performance Evaluation of Nasal Prong Interface for CPAP Delivery on a Critical Care Ventilator: A Bench Experiment

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BACKGROUND: The RAM cannula (Neotech, Valencia, CA) has become a commonly used interface for CPAP in neonatal intensive care. Performance characteristics of this interface used with a critical care ventilator are not well described. METHODS: This was a bench study utilizing a lung simulator configured as an actively breathing infant (weights of 800 g, 1.5 kg, and 3 kg) with moderate lung disease and a critical care ventilator in CPAP mode with leak compensation on. Three sizes of the RAM cannulae (preemie, newborn, and infant) were compared to 3 BabyFlow nasal prongs (Dräger Medical, Lübeck, Germany) (medium, large, and extra-large). Fabricated nasal models produced a 70% occlusive fit for the RAM cannula and an occlusive fit with the Dräger prongs. Delivered flow and pressure levels were recorded at 9 CPAP levels between 5 and 20 cm H_2O. RESULTS: The Dräger prongs produced a mean airway pressure ($\overline{P}_{aw}$) within 0.20 cm H_2O (range –0.10 to 0.35) of the set CPAP across all evaluated prong sizes and CPAP levels. In contrast, the RAM cannula produced $\overline{P}_{aw}$ values that averaged 8.5 cm H_2O (range –15 to –3.5) below the set CPAP levels. The deficit in delivered versus target CPAP level for the RAM cannula increased with greater set CPAP. Set CPAP of 5 cm H_2O delivered $\overline{P}_{aw}$ values that ranged from 0.6 to 1.5 cm H_2O (difference of 3.5–4.4 cm H_2O). Set CPAP of 20 cm H_2O delivered $\overline{P}_{aw}$ values that ranged from 5.0 to 8.4 cm H_2O (difference of 11.7–15 cm H_2O). Inspiratory flow required to achieve set CPAP levels did not differ between interfaces, suggesting high resistance in the RAM cannula device masks the delivered CPAP levels. CONCLUSIONS: Use of the RAM cannula with a 30% leak on a critical care ventilator delivered $\overline{P}_{aw}$ values lower than set CPAP. This may be clinically meaningful and should be considered when choosing a nasal interface. *Key words: CPAP; high-flow nasal cannula; PEEP; infant; bench study..* [Respir Care 2021;66(10):1514–1520. © 2021 Daedalus Enterprises]

Introduction

Administration of nasal CPAP is an evidence-based approach to reduce exposure to invasive mechanical ventilation in very preterm infants and decrease the risk of lung injury and subsequent development of chronic lung disease.[1,2] The physiologic goal of nasal CPAP is to maintain a consistent distending pressure within the airways to maintain patency of the respiratory system, reduce work of breathing, and improve oxygenation and ventilation, without the use of an endotracheal tube.[3,4] Nasal CPAP interfaces typically use nasal prongs or masks that produce an occlusive seal around the external airway. Unfortunately, these devices may contribute to patient discomfort and facial injury in some infants. High-flow nasal cannula (HFNC), which utilizes binasal prongs with a 60–80% occlusive fit, has been studied as an alternative, potentially more comfortable and less injurious means to provide noninvasive respiratory support to premature infants. However, several studies raise concern that HFNC may not be as effective as nasal CPAP, particularly when used in extremely preterm newborns.[5-8]

The RAM cannula (Neotech, Valencia, California) was introduced in November 2011 as a new nasal cannula interface. The device is composed of softer materials than traditional nasal CPAP prongs (eg, Hudson prongs), uses a larger prong diameter than other short nasal cannula, and, unlike HFNC, can be attached to a ventilator or nasal CPAP circuit without additional adaptors.[9,10] The manufacturer of the RAM cannula recommends a 60–80% occlusive

fit to allow for exhalation. Although this device may combine the potential benefits of the HFNC interface with the therapeutic goals of nasal CPAP, the limited existing data raise concern that the RAM cannula may not adequately deliver goal pressure levels to the airway with prong sizes that facilitate the recommended nasal leak.[10,11] However, an important unanswered question is how the interface performs when used in conjunction with a critical care ventilator that augments flow to compensate for leak.

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The purpose of this bench study was to compare set PEEP and measure mean airway pressure ($\overline{P}_{aw}$) levels between a conventional nasal CPAP prong interface with an occlusive fit and the Neotech RAM cannula using a critical care ventilator. We also examined the flows generated by the ventilator in an attempt to deliver goal PEEP levels with the 2 devices.

QUICK LOOK

Current knowledge

There are many interfaces used to deliver noninvasive respiratory support to infants. The fit and quality of the interface can affect the pressure delivered to the patient.

What this paper contributes to our knowledge

After comparing set versus delivered pressures with RAM cannula to the same parameters with classic occlusive nasal prongs, our results indicate that the RAM cannula did not achieve set pressures with all sizes and all set pressure ranges.

Methods

Study Design and Setup

We performed a series of bench experiments with a lung simulator and custom, plastic infant nasal models. The nasal models were designed with nares diameters that produced 70% occlusive fit for 3 different Neotech RAM cannulae: preemie (3.4 mm), newborn (4.0 mm), and infant (4.6 mm). The models were produced by Hans Rudolph (Shawnee, Kansas) with a standard 22–15 mm connection to attach to the lung simulator and a side port with a male lure connector enabling connection of a pressure sensor (Fig. 1). The BabyFlow system (Dräger Medical, Lübeck, Germany) with nasal prongs sized for an occlusive fit was used as the control interface. An actively breathing infant lung model was produced with the ASL 5000 lung simulator (version 3.6, IngMar Medical, Pittsburgh, Pennsylvania) using the pre-set scripts for premature (800 g), newborn (2,000 g), and infant (3,000 g) models with respiratory distress. The following alterations to the pre-set scripts were made for this study: for the preemie and newborn models, compliance was set at 0.5 mL/cm H_2O, resistance was set at 100 cm H_2O/L/s, and breathing frequency was set at 40 breaths/min; for the infant model, compliance was set at 1.5 mL/cm H_2O, resistance was set at 50 cm H_2O/L/s, and breathing frequency was set at 30 breaths/min.[12,13]

A Dräger V500 ventilator (Dräger Medical) was set in CPAP mode with leak compensation turned on. Nine PEEP levels (5, 6, 8, 10, 12, 14, 16, 18, and 20 cm H_2O) were tested for 3 min each to allow for system equilibration. Data abstracted from the last 5 breaths were utilized for the analyses. High PEEP levels were tested to determine whether leveling off or a reduction in flow occurred, which may indicate back pressure from resistance in the cannulae.

Pressure and Flow Measurements

The $\overline{P}_{aw}$ was measured at 3 locations: at the ventilator, at the circuit Y-piece, and at the nasal model (Fig. 2). Pressure transducers (Hans Rudolph) were connected at the ventilator Y-piece and at the nasal model to measure the $\overline{P}_{aw}$ in these locations. Flow values were recorded with a flow sensor (Hans Rudolph) placed between the nasal model and the ASL 5000 to measure the flow during the entire breath

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cycle (Fig. 2). The continuous sinusoidal pressure and flow waveforms were captured with Power Lab software (ADInstruments, Colorado Springs, Colorado) (Fig. 3).

Critical care ventilators increase inspiratory flow to compensate for detected airway leak and achieve target pressure levels. In this study, the peak inspiratory flow was measured at each PEEP level to assess the level of leak compensation among the various nasal prong devices. The peak inspiratory flow at the nasal model was measured from the sinusoidal waveforms captured with Power Lab software. Peak inspiratory flow was measured at each PEEP level to determine the actual flow delivered to compensate for the leak and attempt to maintain set PEEP.

Statistical Analysis

Data from the last 5 breaths of each experiment were abstracted from the ventilator and sinusoidal waveforms recorded by the Power Lab software and summarized with standard descriptive statistics. Differences in the set versus delivered measures were calculated by subtracting the average delivered $\overline{P}_{aw}$ from the set CPAP level. Linear regression examined the association between the set and achieved $\overline{P}_{aw}$ values across the range of studied CPAP levels.

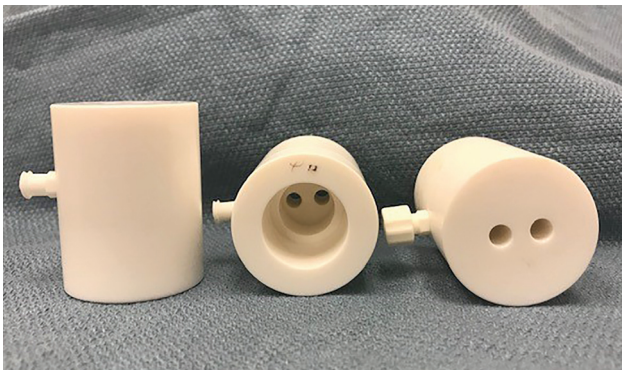

Fig. 1. Nasal models.

Results

A total of 3,780 breaths were captured, and values from 210 breaths were analyzed. When these data were summarized across all nasal interfaces, the average $\overline{P}_{aw}$ measured at the Y-piece prior to CPAP cannula equipment approximated the set CPAP levels (mean difference –0.12 cm H_2O, range –0.66 to 0.40). Similar results were obtained when stratifying by nasal interface and across the range of studied CPAP levels (Table 1). These data confirm adequate

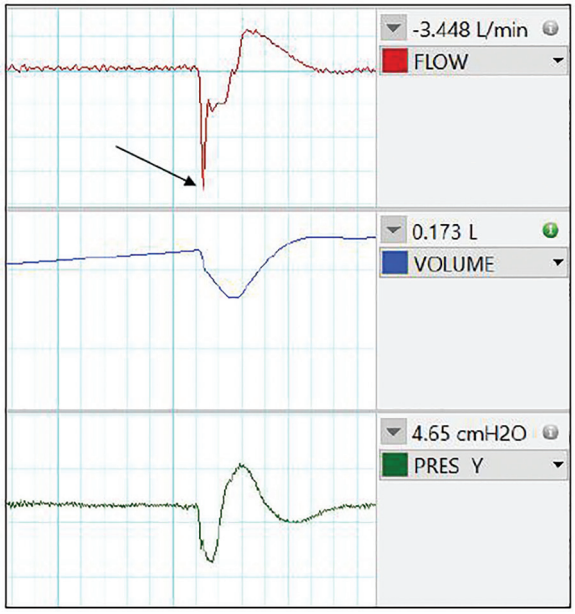

Fig. 3. Sinusoidal flow waveform. Inspiration is indicated by negative flow as the arrow indicates placement for peak inspiratory flow measurements.

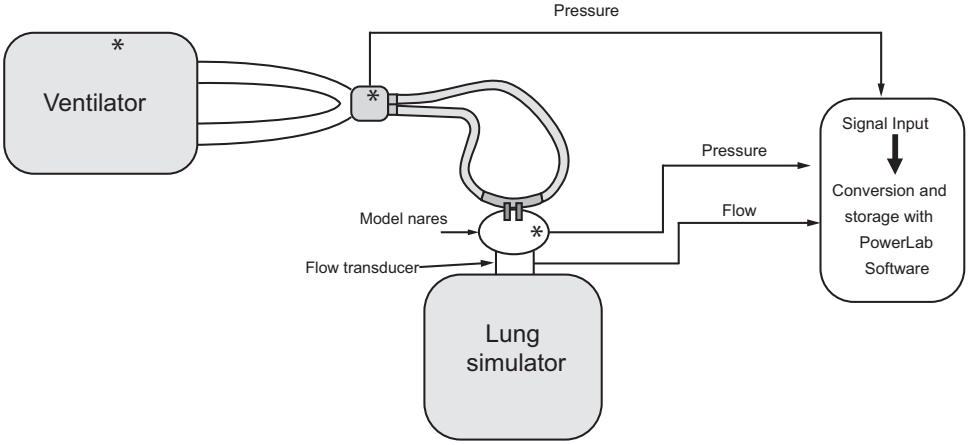

Fig. 2. Experiment model setup. *Indicate all the locations of pressure measurements.

Table 1. Measured Pressures Prior to Interface for Different Set PEEP Levels

	Set PEEP, cm H_2O									Linear Regression		
Interface	5	6	8	10	12	14	16	18	20	Slope	Intercept	R^2
RAM Cannula												
Preemie	5.01	5.97	7.97	9.72	11.86	13.77	15.73	17.76	19.79	0.98 (0.97–1.00)	0.04 (–0.12 to 0.20)	.999
Newborn	4.98	5.97	7.77	9.74	11.78	13.74	15.79	17.86	19.71	0.99 (0.98–1.00)	–0.05 (–0.22 to 0.13)	.999
Infant	5.16	5.78	7.71	9.60	11.76	13.68	15.71	17.77	19.73	0.99 (0.96–1.01)	–0.07 (–0.38 to 0.24)	.999
Dräger BabyFlow												
Medium	5.25	6.28	8.34	10.37	12.41	14.44	16.49	18.52	20.54	1.02 (1.01–1.02)	0.17 (0.15–0.20)	1
Large	5.32	6.11	8.35	10.40	12.44	14.47	16.20	18.22	20.24	1.03 (1.02–1.04)	0.09 (–0.05 to 0.23)	.999
Extra Large	5.31	6.35	8.42	10.40	12.46	14.51	16.54	18.59	20.33	1.02 (1.02–1.02)	0.22 (0.19–0.26)	1

Table 2. Measured Pressures at Nare Model for Different Set PEEP Levels

	Set PEEP, cm H_2O									Linear Regression		
Interface	5	6	8	10	12	14	16	18	20	Slope	Intercept	R^2
RAM Cannula												
Preemie	14.5	1.91	2.81	3.54	4.59	5.47	6.41	7.36	8.38	0.46 (0.44–0.47)	–0.87 (–1.05 to –0.70)	.998
Newborn	0.63	0.85	1.28	1.83	2.41	2.95	3.64	4.43	5.05	0.30 (0.27–0.32)	–1.02 (–1.32 to –0.73)	.993
Infant	1.21	1.78	1.85	2.53	2.96	3.69	4.39	5.03	5.62	0.30 (0.29–0.32)	–0.50 (–0.74 to –0.27)	.995
Dräger BabyFlow												
Medium	5.11	6.14	8.18	10.20	12.26	14.27	16.30	19.36	20.35	1.02 (1.01–1.02)	0.04 (0.02–0.07)	1
Large	5.10	5.80	8.09	10.12	12.16	14.15	16.20	18.22	20.24	1.02 (1.02–1.03)	–0.06 (–0.19 to 0.07)	.999
Extra Large	5.12	6.14	8.15	10.17	12.22	14.26	16.33	18.30	20.33	1.01 (1.01–1.02)	0.05 (0.01–0.10)	1

delivery of the target CPAP level directly proximal to the nasal interface equipment.

Table 2 shows the average $\overline{P}_{aw}$values measured at the test nares chamber versus the set CPAP level for each nasal prong interface. Across the studied prong sizes and CPAP levels, the Dräger prongs produced average $\overline{P}_{aw}$ values that were within 0.20 cm H_2O (range –0.10 to 0.35) of the set CPAP levels. In contrast, the $\overline{P}_{aw}$ values produced with the RAM cannulae were, on average, 8.5 cm H_2O (range –15 to –3.5) below the set CPAP level. This equated to an average CPAP delivery of only 27% (range 13% to 42%) of the set target. With each of the RAM cannulae, the absolute difference between the desired and delivered $\overline{P}_{aw}$ increased with greater set CPAP level (Fig. 4). For instance, with the CPAP set to 5 cm H_2O, the 3 RAM cannulae achieved average delivered $\overline{P}_{aw}$ values at the test nares chamber of 0.6–1.5 cm H_2O (3.5–4.4 cm H_2O below target level). With the ventilator set to a CPAP of 20 cm H_2O, the RAM cannulae achieved average delivered $\overline{P}_{aw}$ values of 5–8.4 cm H_2O (11.7–15 cm H_2O below target level). To generate an average delivered $\overline{P}_{aw}$ of ≥ 5 cm H_2O required a set CPAP level of 14 cm H_2O with the preemie RAM interface and 18–20 cm H_2O with the newborn and infant RAM devices (Fig. 4).

Table 3 shows the maximum inspiratory flow measured between the nasal model and the lung simulator for each set CPAP level. There were minimal differences in the

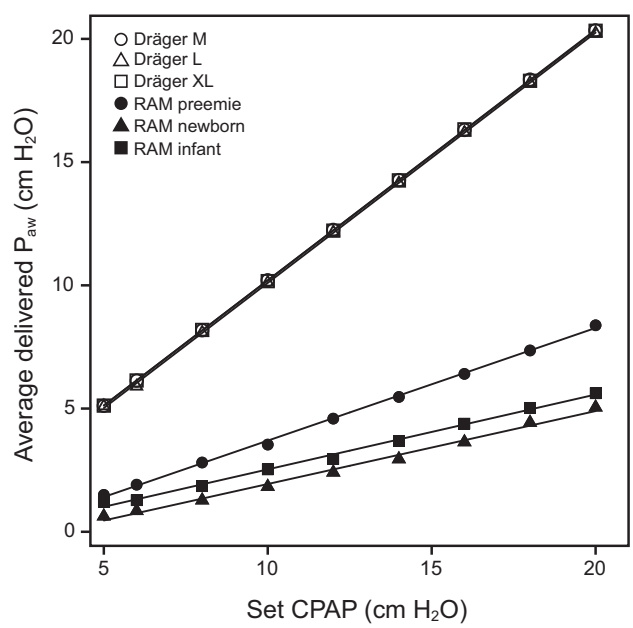

Fig. 4. Set CPAP versus delivered mean airway pressure ($\overline{P}_{aw}$) at the nares. The mean observed pressure level recorded within the test nare is plotted for each nasal interface device. Best fit lines were estimated using linear regression. Regression line equations and R^2 values are available in table 2.

Table 3. Comparison of Set PEEP and Maximum Inspiratory Flows

Set PEEP, cm H_2O	Maximum Inspiratory Flow, L/min					
	RAM Cannula			Dräger BabyFlow		
	Preemie	Newborn	Infant	Medium	Large	Extra Large
5	1.81	1.91	1.21	2.06	1.83	1.21
6	1.77	1.88	1.39	2.02	1.79	1.15
8	1.81	1.93	1.36	1.99	1.82	1.08
10	1.86	1.92	1.33	2.08	1.86	1.20
12	1.92	2.03	1.29	2.01	1.81	1.20
14	1.85	2.00	1.33	1.95	1.87	1.20
16	2.08	2.05	1.20	1.98	1.82	1.18
18	1.90	2.01	1.18	1.93	1.86	1.24
20	2.02	2.01	1.26	1.93	1.86	1.21

measured flows between the BabyFlow and the RAM cannula, despite the nonocclusive fit of the RAM cannula and lower delivered airway pressure.

Discussion

Nasal CPAP is employed in the neonatal ICU for a range of clinical reasons, including for the treatment of respiratory distress syndrome and to mitigate the risk of developing bronchopulmonary dysplasia.[1] From a physiologic perspective, the goals of nasal CPAP are to relieve work of breathing and reverse or prevent airway collapse and atelectasis. Understanding the advantages and limitations of respiratory support equipment is essential to achieve the best possible patient outcomes. This series of bench experiments compared delivered pressure levels between the Dräger BabyFlow nasal prongs and Neotech RAM cannula for 3 different interface sizes that are commonly used in the neonatal ICU. The study data indicate that the Dräger prongs, with the recommended occlusive fit at the nares, enabled reliable delivery of goal CPAP levels. In contrast, the RAM cannula, sized with the manufacturer recommended fit, delivered $\overline{P}_{aw}$ levels that are likely to be below clinically acceptable goals.

Some prior experiments explored the performance of the RAM cannula with delivery devices that rely on set flows such as bubble CPAP.[14-16] These studies may not be generalizable to CPAP delivered with critical care ventilators, which utilize variable flows to overcome mechanical system leak. A small number of previous bench studies have appraised the performance of the RAM cannula with a critical care ventilator.[10,11,17] Each demonstrated significant discrepancy between the set and delivered CPAP levels when the RAM cannula was used with the manufacturer's recommended level of nasal occlusion.[10,11,17] In a study of 3 different RAM cannula sizes with 60–80% nasal occlusion, Gerdes et al[10] observed delivered $\overline{P}_{aw}$ values that averaged 60% of the set level of CPAP. Similarly, Iyer and Chatburn[11] recorded pressure transmissions of 60–70% of the set CPAP level when using the RAM cannula with 70% naris occlusion in 3 simulated continuous mandatory ventilation infant models. These investigators advised that the use of cannula that are too small for the patient may further reduce pressure transmission and that delivered CPAP may reach clinically insignificant levels.[11] Fernandes et al[17] evaluated all currently available RAM cannula sizes using the Servo-i ventilator for delivery of CPAP within 7 simulated patient models that ranged between 0.5 kg and 20 kg in weight. The results of that study suggest that CPAP delivery with the RAM cannula is highly dependent upon the level of nasal leak, but that goal CPAP levels may not be delivered even in the presence of minimal leak.[17]

Our results agree with reports of prior bench experiments, which demonstrated significant loss of pressure delivery with the RAM cannula. However, our study also differs from these prior works in several regards. The CPAP levels delivered with the RAM cannula in this series of experiments ranged between 13% and 42% of goal levels. These values are far lower than those observed in previous studies.[10,11,17] Accordingly, we tested an expanded range of CPAP levels to assess what set CPAP levels may be required to deliver commonly desired clinical $\overline{P}_{aw}$ levels.[10,11,17] The reliable CPAP delivery with a classic noninvasive interface serves as an important validating control in these experiments. Lastly, our novel measurement of flows required to achieve set CPAP levels with the evaluated interfaces suggests a mechanistic hypothesis as to why the RAM cannulae were unable to achieve target CPAP levels in this study.

In the clinical setting, Singh et al[18] performed a crossover interventional study in 12 preterm infants utilizing the RAM cannula and the Hudson prongs through a CPAP system with a set flow of 6–10 L/min. Intraoral pressure was measured with each device after a 5-min stabilization time frame. The RAM cannula consistently delivered lower intraoral pressures with a mean difference of $\sim$ 2–5 cm H_2O with set CPAP levels of 5–6 cm H_2O.[18] In a moderately sized randomized trial of infants enrolled within the first hour of life ($N = 126$ subjects), Gokce et al[19] reported that use of the RAM cannula, as compared to short binasal (ie,Hudson) prongs, with the specialized laboratory equipment ventilator led to an increased need for invasive ventilation and surfactant therapy. Lastly, a prospective observational study examining respiratory support characteristics before and after introduction of the RAM cannula as the preferred interface to deliver CPAP indicated that greater RAM use was

associated with higher set CPAP levels.[20] This finding may reflect clinician up-titration of set CPAP levels to achieve the desired clinical effects.

We hypothesized that leak compensation by the critical care ventilator would lead to increased peak inspiratory flows with prongs that do not provide an occlusive fit at the nares. With the $\overline{P}_{aw}$ measured at the circuit Y-piece, prior to both interfaces, and the discordance of pressures measured at the nares, after the interface, we expected the flows to increase as the delivered $\overline{P}_{aw}$ decreased. We did not see this expected increase in flow and suspect that high resistance within the cannula may cause the ventilator to detect adequate $\overline{P}_{aw}$ in the equipment circuitry, even though this pressure is not transmitted to the nares. Green et al[16] reported on the resistance within 6 interfaces that deliver nasal CPAP at 3 flows (6, 8, and 10 L/min). Of the tested nasal prong interfaces, the RAM cannula had the highest resistance at all sizes and at all flow settings.

We acknowledge limitations to this study. Our use of a bench model represents a highly controlled, best case scenario. Even with an actively breathing lung model, we cannot fully simulate an infant in varying degrees of distress to determine actual flow and pressure delivery in true clinical settings. We are also unable to comment on the $\overline{P}_{aw}$ levels that may be delivered with set CPAP values that fall outside of range tested in this series of experiments. We did not measure the flows within the circuit prior to the prong interface connection on both devices to determine any resistance that may occur within this portion of the circuitry. Such data may assist in explaining the variability in delivered pressures despite similar flows. This study does however give us more information than explored in previous bench studies with the RAM cannula while confirming others. Clinicians need to be aware of the performance of respiratory support devices and the adequacy of pressure delivery relative to the target therapy. Inefficient pressure delivery may lead to worsening of clinical status. More research is needed to determine the clinical safety and efficacy of the RAM cannula for delivery of nasal CPAP in very preterm infants.

Conclusions

In this bench investigation, we measured set nasal CPAP and the delivered $\overline{P}_{aw}$ with on a critical care ventilator using both a traditional occlusive fit nasal interface and the RAM cannula with manufacturer recommended 70% occlusive fit. Our data show that, while the traditional occlusive fit device reliably delivered goal CPAP, the paired RAM cannula used with a critical care ventilator produced $\overline{P}_{aw}$ values that averaged 8.5 cm H_2O (range –15 to –3.5) below the set CPAP levels. The deficit in delivered versus target CPAP level for the RAM cannula increased with greater target CPAP. Our study data raise concern that the clinical use of RAM cannula in small infants with moderate lung disease may not achieve the target distending airway pressures. These data may help clinicians when selecting nasal CPAP interface devices in this patient population.

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