

# RAM Cannula Versus Bi-Nasal Prongs as Respiratory Device Interfaces in Neonates of Thirty-Two or More Weeks of Gestation With Respiratory Distress: The First “ProRAM” Randomized Trial Report

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## Abstract

**Background:** Using bilateral short nasal prongs as an interface for noninvasive respiratory support is challenging, and it is associated with nasal injury. We aimed to compare RAM cannula with nasal prongs in delivering noninvasive ventilation to newborn infants.

**Methods:** This is a single-center randomized trial (trial registry: IS-RCTN10561691). The setting involves a tertiary neonatal unit with a capacity of 30 beds and more than 13 years of experience in neonatal noninvasive ventilation. We included 50 infants born at  $\geq 32$  weeks of gestation, who had respiratory distress at birth. We excluded those with major congenital anomalies and those who required intubation in the delivery room. Primary outcomes were intubation rate and use of noninvasive positive-pressure ventilation (NIPPV); other outcomes included air leak and nasal injury rate. The infants were assigned using randomly generated numbers into bi-nasal prong and RAM cannula groups in a 1:1 ratio.

**Results:** Two and four babies in the RAM and prong groups, respectively, were upgraded to NIPPV ( $P = 0.600$ ). One versus no baby in the RAM vs. prong groups was intubated ( $P = 1.000$ ). Newborns in the prong group required oxygen support for a longer period (mean duration:  $154.6 \pm 255.2$  h) than those in the RAM group ( $40.7 \pm 72.6$  h,  $P = 0.030$ ). None of the patients in the RAM group had traumatic nasal injury compared to five babies in the prong group ( $P = 0.050$ ). Four babies in our study developed air leaks, with two in each group.

**Conclusions:** The use of RAM cannula in delivering noninvasive

ventilation to newborns  $\geq 32$  weeks of age did not affect the noninvasive ventilation failure rate or incidence of air leak. The use was associated with a shorter duration of respiratory support and a reduced risk of nasal septal injury.

**Keywords:** Neonates; RAM cannula; Nasal prongs; Respiratory distress; Noninvasive ventilation

## Introduction

Respiratory distress in the neonatal period has been described as any sign of breathing difficulty in the newborn. These signs would include tachypnea, grunting, retraction, nasal flaring, and cyanosis [1, 2]. It is a very common entity that occurs in up to 7% of newborn infants, comprising a high percentage of neonatal intensive care unit (NICU) admissions worldwide [3, 4]. Many conditions can present with respiratory symptoms, including transient tachypnea of the newborn, respiratory distress syndrome, congenital pneumonia, meconium aspiration, airway malformations, sepsis, congenital heart disease, and other less common etiologies [5].

Regardless of the cause, respiratory support should be provided to infants using invasive or noninvasive methods of ventilation according to their condition. Noninvasive ventilation has been increasingly used in NICU since the 1970s [6-8]. The use of nasal continuous positive airway pressure (CPAP) and nasal intermittent positive pressure ventilation (NIPPV) to treat different neonatal respiratory diseases has been successful, decreasing the need for intubation and invasive mechanical ventilation and their associated complications [9-12].

Respiratory support to neonates using noninvasive ventilation has traditionally been provided using bilateral short nasal prongs [13]. The use of this interface is challenging and requires significant nursing experience, with nasal septal injury being the most common side effect [12-14]. Several trials have been conducted to investigate the use of a different, more user-friendly, and less traumatizing interface to deliver CPAP to newborns with respiratory distress [15, 16]. The main alternative interface is the RAM cannula. It is

Manuscript submitted December 1, 2023, accepted December 28, 2023  
Published online January 10, 2024

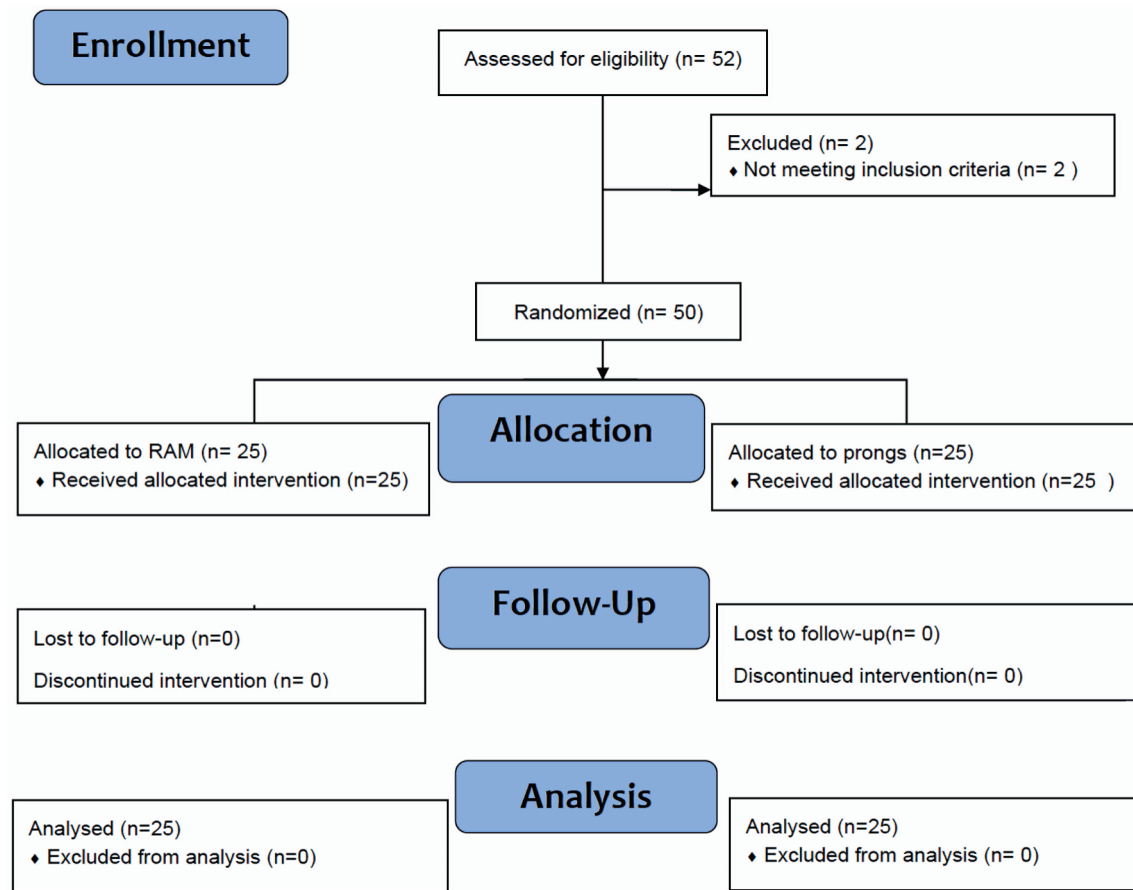
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doi: <https://doi.org/10.14740/jocmr5077>



**Figure 1.** “ProRAM” randomized trial flow diagram for neonates  $\geq 32$  weeks of gestation.

easier to use, and potentially less traumatic to the nasal septum. However, there is a considerable concern of delivering suboptimal pressure.

In this randomized study, we aimed to compare RAM cannulas with traditional nasal prongs in delivering noninvasive ventilation to newborn infants.

## Materials and Methods

This study was conducted at Jordan University Hospital NICU, Amman, Jordan, a tertiary care center with a 30-bed capacity. The study protocol was prospectively registered in the Clinical Trial Registry (registration number: ISRCTN10561691). This study was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration. The study was approved by the Jordan University Hospital Institutional Review Board (approval number: 10/2021/109/9). No changes were made to the study protocol or the outcomes after registration.

All admitted neonates diagnosed with respiratory distress were included in the study, and neonates with major congenital malformations were excluded. Neonates who were intubated in the delivery room or transferred to our unit from other hospitals were also excluded.

According to the gestational age, the admitted neonates were classified into two groups: born at  $< 32$  weeks or  $\geq 32$  weeks. Each group was randomized separately. This paper reports the outcomes of infants born at  $\geq 32$  weeks of gestation. The investigators used random letters generated using an on-line tool to assign the included infants to each study arm in a 1:1 ratio. Randomized letters were kept in serially numbered sealed opaque envelopes and were used to assign the newborn to bi-nasal prongs or RAM cannula use (Neotech RAM cannula®). The target was to randomize 50 infants. Regarding multifetal gestation, each infant was randomly assigned to one group. Each infant received the same assigned interface for respiratory support until weaned off, or the decision to change the interface was determined by the lead investigator (see the CONSORT flow chart in Figure 1).

All neonates received bubble CPAP with positive end-expiratory pressure (PEEP) of 6 cm H<sub>2</sub>O as the primary mode of respiratory support. Our institute’s respiratory bundle for CPAP introduction, titration, upgrading, and weaning was followed (Figs. 2, 3). ACORN score was used to determine the severity of respiratory distress [17].

The size of the interface was selected according to the manufacturer’s recommendations. The short nasal prongs were fixed with gentle skin tape to reduce leaks around the nostrils and produce proper CPAP pressures. Interface fixation and sta-

Breathing Spontaneously	Not Breathing
Apply CPAP (PEEP 6 via T-Piece)	Intubate (If not yet)
Transport to NICU ASAP	Use T-Piece to deliver PEEP & PIP
@ NICU start bubble CPAP PEEP 6	PEEP 6, PIP 20 (Discuss with attending before titrating pressures up)
Avoid pressure on septum	Use preductal Pulse ox
Use preductal Pulse ox	Target O2 90-95
Target O2 90-95	CXR ASAP
Towel under shoulder	
Consider Prone Position	
Minimal Handling	
If less than 34 weeks CXR ASAP	
If > 34 weeks -CXR ASAP if severe distress -At 6 hours if still on respiratory support	

**Figure 2.** Post resuscitation respiratory care bundle. PEEP: positive end-expiratory pressure; ASAP: as soon as possible; CPAP: continuous positive airway pressure; NICU: neonatal intensive care unit; CXR: chest X-ray; PIP: peak inspiratory pressure.

bility in the infant nostrils were monitored by bedside nurses. The data, which were collected prospectively, included maternal and neonatal demographics including risk factors, initial neonatal presenting respiratory symptoms and signs, and the clinical course, including different management interventions and complications. Respiratory rate at admission was stratified into the following categories according to the severity of tachypnea: respiratory rate  $\leq 60$ , 61 - 70, 71 - 80, > 80. The neonatal nasal septum was observed daily by a senior neonatologist and staged according to the degree of injury as follows: I: hyperemia, and hemorrhage; II: disruption of skin integrity and superficial ulceration; and III: nasal deformity. The most severe state was recorded.

We aimed to compare the use of RAM cannula to the traditional nasal prongs in delivering noninvasive ventilation to newborns with respiratory distress, with the need for respiratory support escalation to NIPPV, mechanical ventilation, or other measures such as surfactant administration, as our primary outcome along with the extent of nasal injury at each interface.

**Statistical analysis**

The sample size was calculated based on our unit’s CPAP failure rate (6%) [12], and an expected failure rate of 40% when

Arm 1	Arm 2
-Preductal pulse ox 90-95 & -Fio2 is < 60% or you can wean down by 10% each 15 minutes	-Preductal pulse ox < 90 despite 100% O2 Or -Preductal Fio2 90-95 with Fio2 is > 60%, & You are unable to wean
If yes; Observe, reassess at 2 hours of age	Check if the machine is bubbling
If not or worsen switch to arm 2	Consider repositioning of neck
	Prone position (if not yet)
	Check air entry
	Calculate ACoRN score
ACoRN Score > 8*	
Yes	No
Upgrade to NIPPV (PIP 16, PEEP 6 RR 14) (consult attending for higher PEEPS)	Observe
If < 30 weeks give surfactant (INSURE) ASAP, better < 2 hours	

**Figure 3.** CPAP care bundle of neonates with respiratory distress. CPAP: continuous positive airway pressure; Fio<sub>2</sub>: fraction of inspired oxygen.

**Table 1.** Demographic and Perinatal Characteristics of Newborn Randomized to Both Study Groups

Characteristics	RAM (n = 25)	Prong (n = 25)	P value
Gestational age (weeks), mean ± SD	36 ± 2	36 ± 2	1.000
Birth weight (g), mean ± SD	2,600 ± 600	2,500 ± 670	0.600
Small for age	5 (20%)	3 (12%)	0.702
Male sex	10 (4%)	14(6%)	0.396
Cesarean section	20 (80%)	22 (88%)	0.700
Maternal diseases (hypertension, diabetes, hypothyroidism, pre-eclampsia)	3	8	0.170
Maternal infectious risk factor (PROM, UTI, GBS <sup>a</sup> , COVID-19 infection <sup>b</sup> )	12	9	0.567
Antenatal steroids	18 (72%)	16 (64%)	0.800
Apgar scores (mean ± SD)			
1st min	7 ± 1.6	7 ± 1.9	1.000
5th min	9 ± 0.28	9 ± 0.6	1.000
Low Apgar score < 6			
1st min	3	4	1.000
5th min	0	0	1.000

<sup>a</sup>Group B streptococcus (GBS)-positive screen or positive urine culture during current pregnancy. <sup>b</sup>Coronavirus disease 2019 (COVID-19) positive mothers at time of delivery. SD: standard deviation; PROM: premature rupture of membrane; UTI: urinary tract infection; Apgar: appearance, pulse, grimace, activity, and respiration.

using the RAM canula. This was based on theoretical difficulty of building enough pressure while using an interface with a leak. A sample size of 23 per group was required at 5% alpha error and 80% power.

Microsoft Excel 2010 was used to analyze the results. Continuous variables are presented as mean and standard deviation. Categorical variables are presented as numbers and percentages. Categorical variables were compared using the two-tailed Chi-square test (two-tailed). Continuous variables were compared using Student's *t*-test. Statistical significance was set at  $P < 0.05$ .

## Results

Fifty neonates born at  $\geq 32$  weeks of gestation and admitted to our NICU with respiratory distress after birth were included. The neonates were randomized into two groups according to the allocated nasal airway interface: RAM and prong groups. The neonates in both groups had no significant differences in mean gestational ages, birth weights, antenatal maternal illnesses, and infectious risk factors (Table 1).

All babies were started on bubble CPAP as an initial mode of respiratory support. Neonates in both groups were almost similar in their respiratory rates at admission, with a mean of 61 breaths/min, as well as similar initial fraction of inspired oxygen (FiO<sub>2</sub>) requirement with a mean of 23% in both groups (Table 2). Two babies in the RAM group and four in the prong group were upgraded to NIPPV due to worsening respiratory status ( $P = 0.667$ ). Only one infant in the prong group was intubated ( $P = 1.000$ ). Most newborns in both groups were diagnosed with transient tachypnea (68% vs. 64% in RAM and prong groups, respectively). Newborns in the prong group re-

quired oxygen support for a longer period (mean duration of support,  $154.6 \pm 255.2$  h) than those in the RAM group ( $40.7 \pm 72.6$  h,  $P = 0.030$ ).

Of the babies who received RAM cannulas, none had traumatic nasal injury compared to five babies in the prong group who had a nasal injury value of 0.050. Only four babies in our study developed air leak syndrome, with two cases of pneumomediastinum in the RAM group and one case of pneumothorax and pneumomediastinum in the prong group ( $P = 1.000$ ). None of the infants in either group died before hospital discharge (Table 2).

## Discussion

Respiratory distress is one of the major indications of newborn admission to intensive care units [18]. Noninvasive ventilation remains the main source of respiratory support in such neonates [19]. Choosing the most practical nasal interface that delivers oxygen to babies with the highest efficacy and lowest complications remains controversial [20]. In our institute, prongs are the most used interfaces. However, the availability of RAM cannulas has raised the question of their comparability to nasal prongs: whether they deliver the same support without adding more risks, or even whether they decrease some of the commonly faced complications.

Both groups of neonates who were randomly assigned to receive either a nasal prong or RAM cannula as a respiratory support interface upon admission, had similar demographic and perinatal characteristics (Table 1), with comparable mean gestational age, mean birth weight, and similar rates of maternal infections, antenatal steroids, and Apgar scores. The included infants in both groups had similar severity of respiratory dis-

**Table 2.** Respiratory Characteristics and Clinical Outcome for Included Infants

	RAM (25)	Prong (25)	P value
Average respiratory rate (RR) at admission, mean $\pm$ (SD)	61 (41)	61 (41)	
RR $\leq$ 60	13	13	
RR 60 - 70	8	7	
RR 70 - 80	3	4	
RR > 80	1	1	
Average FiO <sub>2</sub> at admission, mean $\pm$ (SD)	23% (29%)	23% (29%)	
FiO <sub>2</sub> at admission 21% (n)	20	21	
FiO <sub>2</sub> at admission 21-40% (n)	4	4	
FiO <sub>2</sub> at admission > 40% (n)	1	0	
Mean duration of O <sub>2</sub> support hours (SD)	40.7 (72.6)	154.6 (255)	0.037
Total O <sub>2</sub> support < 6 h	8	9	
Total O <sub>2</sub> support 6 - 72 h	14	8	
Total O <sub>2</sub> support 73 h - $\leq$ 1 week	1	2	
Total O <sub>2</sub> support > 1 week	2	6	
Need for upgrade of respiratory support (to NIPPV)	2 (8%)	4 (16%)	0.667
Need for intubation	0	1 (4%)	1
Received surfactant	0	1 (4%)	1
Received antibiotics (%)	7 (28%)	8 (32%)	1
Mean duration of antibiotics, days $\pm$ (SD)	4 (3)	7 (6)	1
Final diagnosis			
Prolonged transition	8 (32%)	9 (36%)	
Transient tachypnea of the newborn (TTN)	15 (60%)	12 (48%)	
Respiratory distress syndrome	2 (8%)	4 (16%)	
Nasal injury (total)	0	5 (20%)	0.05
Nasal mucosal edema	0	1 (4%)	
Nasal septal injury	0	3 (12%)	
Nasal bridge injury	0	1 (4%)	
Pneumomediastinum	2 (8%)	1 (4%)	1
Pneumothorax	0	1 (4%)	1
Mortality	0	0	

SD: standard deviation; FiO<sub>2</sub>: fraction of inspired oxygen.

stress, evident by similar rates of tachypnea and FiO<sub>2</sub> needs on admission (Table 1). One major concern about using the RAM cannula as a respiratory interface is the suboptimal pressure delivery, and consequently, increases in the CPAP failure rate. The basis of this concern was an *in vitro* study that failed to achieve a set CPAP level with the RAM cannula in comparison with other CPAP interfaces [21]. This study is useful in demonstrating the physics and dynamics of CPAP interfaces but does not necessarily report the clinical implications. Regarding clinical studies, results vary in demonstrating the clinical differences between RAM cannulas and bi-nasal prongs, with most of these studies exploring these differences in premature neonates. Drescher et al demonstrated a need for high settings in the RAM cannula group compared to the control group, but

no significant difference in invasive ventilation rates. However, there was a significant reduction in the duration of respiratory support and a trend towards reduction of bronchopulmonary dysplasia in the RAM group [22]. In a randomized controlled trial by Gokce et al, more neonates on RAM cannula required invasive ventilation in the first 72 h and surfactant administration in comparison to bi-nasal prongs. However, there was no increase in the duration of respiratory support or bronchopulmonary dysplasia [23]. Moreover, Hochwald et al showed the noninferiority of the RAM cannula compared to the short nasal prong in providing intermittent positive pressure ventilation in preterm infants born between 24 weeks and 33 weeks and 6 days' gestation [24]. Studies that include late preterm and term infants are lacking in literature.

In our study, requiring NIPPV or mechanical ventilation was considered failure of the treatment in both groups. Adding more pressure to the baseline CPAP is potentially more injurious to the lungs and indicates either a more serious respiratory illness or failure to achieve the intended CAPAP pressure. The RAM cannula showed noninferiority compared to the short nasal prong, as there was no significant difference between the two groups in the need to upgrade the respiratory support or further treatments (Table 2). Adherence to strict respiratory care bundles may also be attributed to this result.

In contrast, our groups showed a significant difference in the mean duration of oxygen support despite the similarities between the final respiratory distress diagnoses. The mean duration of support in the prong group was 154.6 h compared to 40.7 h in the RAM group ( $P < 0.05$ ). This was similar to the findings of Drescher et al, who demonstrated reduced days of noninvasive respiratory support when using the RAM system [22]. In our study, the respiratory support duration difference was mainly due to the continued need of oxygen support in the four babies in the prong group for more than 1 week compared to those in the RAM group, during which the allocated nasal interface was kept the same.

This prolonged need for oxygen therapy was independent of the initial respiratory diagnosis and was mainly caused by persistent desaturation, leading to weaning failure in these neonates. All four infants developed nasal septal injury during their stay. Nasal septal injury, causing nasal blockage and discomfort, can be attributed to the persistent need for respiratory support. Furthermore, there was no difference in the rate of air leak syndrome between the two groups. Some previous studies showed a similar incidence of air leak [23], and others showed a higher but insignificant incidence in the RAM group [20].

This study showed that the rates of all forms of nasal injuries were lower in the RAM group than in the prong group, as none of the neonates who were randomized to the RAM cannula group developed nasal injury. Despite the study outcome  $P$  value of 0.05, it was considered significant because the randomized sample was relatively small, and all nasal injuries occurred in the prong group. A reduced risk of nasal injury has also been reported in previous studies [22, 24]. In contrast, Gokce et al studied the efficacy of RAM and prong as a means of noninvasive ventilation interface and found no difference in the incidence of nasal injury or other morbidities [23]. To our knowledge, no previous studies have been conducted to demonstrate this difference between the late preterm and full-term neonates, which comprises of most NICU admissions at our institute. Ten percent of our studied neonates developed nasal septal injury, which, in general, has a low risk of nasal injuries compared to premature and very low birth weight [14, 25]. This reduced nasal injury in the RAM cannula group could be attributed to the softness of the device, ease of fixation and stabilization, simplicity of nursing care, and better access to the neonate.

The use of RAM cannulas in delivering noninvasive ventilation to newborns  $\geq 32$  weeks did not affect noninvasive ventilation failure rates, and there was no significant difference in the incidence of air leak and other complications. This was associated with a shorter duration of  $O_2$  support and a reduced

risk of nasal septal injury. RAM cannulas can be used as the primary method for delivering noninvasive ventilation to neonates.

## Acknowledgments

The authors acknowledge the efforts of our unit nursing staff in providing neonatal care.

## Financial Disclosure

This study did not receive any funding.

## Conflict of Interest

The authors declare no conflict of interest.

## Informed Consent

Written consent was not taken from the parents since nasal CPAP is the standard of care and our nurses use both interfaces on babies interchangeably before the study, and the parents were informed of the choice of treatment upon admission, and they approved it.

## Author Contributions

MA: conceptualization, design, supervising, analysis, and writing. BA: supervising and conducting, analysis, writing, approving final manuscript. MAZ, IA, HH, AA, LA, and SJ: analysis, writing, and approving final manuscript.

## Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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