

# Clinical performance and safety profile of the RAM cannula as an interface for post-extubation noninvasive ventilation: an observational study in preterm newborns

## Desempeño clínico y perfil de seguridad de la cánula RAM como interfaz de ventilación no invasiva post-extubación: estudio observacional en recién nacidos pretérmino

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### ABSTRACT

**Introduction:** Noninvasive ventilation (NIV) is a fundamental strategy in the respiratory management of preterm infants. The RAM cannula is a binasal interface designed for the delivery of positive pressure; its flexible, wide-bore design allows for effective support with a potentially lower risk of nasal injury. Despite its growing use, evidence regarding its efficacy and safety in very low birth weight preterm infants remains limited. **Objective:** To describe the clinical performance and safety profile of the RAM cannula used as a post-extubation ventilatory support strategy in preterm infants, and to analyze the clinical and demographic factors associated with failure of the technique in our population. **Methods:** An observational, analytical, and retrospective study that included preterm infants who used the RAM cannula as post-extubation ventilatory support during their hospital stay. NIV failure was defined as the need for reintubation and return to invasive mechanical ventilation within the first 48 hours. Perinatal, respiratory, and safety variables were analyzed. Statistical analysis included chi-square or Fisher's exact tests for categorical variables and Student's t-test for continuous variables ( $p < 0.05$ ). **Results:** Thirty-two newborns were included, with a mean gestational age of  $28.1 \pm 1.9$  weeks and a birth weight of  $1063 \pm 179$  g. The success rate of extubation using the RAM cannula was 81% (26/32). No significant differences were found in weight, gestational age, or Apgar score between the success and failure groups. However, bivariate analysis revealed a statistically significant association between NIV failure and the presence of nasal injuries (33% in the failure group vs. 0% in the success group;  $p=0.002$ ), intraventricular hemorrhage (33% vs. 0%;  $p=0.002$ ), and premature rupture of membranes  $\geq 18$  h (32% vs. 0%;  $p=0.003$ ). The overall incidence of nasal injuries was low (6%). **Conclusions:** With a failure rate of 19% and a nasal injury rate of 6%, the RAM cannula could be a viable alternative among NIV interfaces, to be considered for specific patients in settings with high rates of reintubation due to nasal trauma.

**Keywords:** RAM cannula; Noninvasive ventilation; Preterm infant; Respiratory distress syndrome; Nasal injury; Ventilatory failure; Neonatal respiratory support.

### RESUMEN

**Introducción:** La ventilación no invasiva (VNI) constituye una estrategia fundamental en el manejo respiratorio del recién nacido prematuro. La cánula RAM es una interfaz binasal diseñada para la administración de presión positiva, cuyo diseño flexible y de amplio calibre permite un soporte eficaz con potencial menor riesgo de lesión nasal. A pesar de su uso creciente, la evidencia sobre su eficacia y seguridad en prematuros de muy bajo peso sigue siendo limitada. **Objetivo:** Describir el desempeño clínico y el perfil de seguridad de la cánula RAM utilizada como estrategia de soporte ventilatorio post-extubación en recién nacidos prematuros, y analizar los factores clínicos y demográficos asociados al fracaso de la técnica en nuestra población. **Métodos:** Estudio observacional, analítico y retrospectivo que incluyó recién nacidos prematuros que utilizaron cánula RAM como soporte ventilatorio post-extubación durante su internación. El fracaso de la VNI se definió como la necesidad de reintubación y vuelta a la asistencia respiratoria mecánica invasiva dentro de las primeras 48 horas. Se analizaron variables perinatales, respiratorias y de seguridad. El análisis estadístico incluyó pruebas de Chi cuadrado o exacto de Fisher para variables categóricas y t de Student para continuas ( $p < 0,05$ ). **Resultados:** Se incluyeron 32 recién nacidos con una edad gestacional media de  $28,1 \pm 1,9$  semanas y peso al nacer de  $1063 \pm 179$  g. La tasa de éxito de la extubación con cánula RAM fue del 81% (26/32). No se encontraron diferencias significativas en peso, edad gestacional o puntaje de Apgar entre el grupo de éxito y el de fracaso. Sin embargo, el análisis bivariado reveló una asociación estadísticamente significativa entre el fracaso de la VNI y la presencia de lesiones nasales (33% en el grupo fracaso vs. 0% en éxito;  $p=0,002$ ), hemorragia intraventricular (33% vs. 0%;  $p=0,002$ ) y Ruptura Prematura de Membranas  $\geq 18$  h (32% vs 0%;  $p=0,003$ ). La incidencia global de lesiones nasales fue baja (6%). **Conclusiones:** Con un fracaso del 19% y lesión nasal del 6%, la cánula RAM podría ser una alternativa dentro de las interfaces de VNI, a considerar en pacientes puntuales en servicios con altas tasas de reintubación por trauma nasal.

**Palabras clave:** Cánula RAM; Ventilación no invasiva; Recién nacido prematuro; Síndrome de dificultad respiratoria; Lesión nasal; Fracaso ventilatorio; Soporte respiratorio neonatal.

## Introduction

Preterm newborns frequently present with hyaline membrane disease due to immaturity and surfactant deficiency, which leads to respiratory failure. The incidence of respiratory distress syndrome is inversely related to gestational age and is highest among preterm infants born at less than 29 weeks of gestation, with the consequent need for endotracheal intubation and surfactant administration. Avoiding mechanical ventilation in these patients results in a reduction in lung injury, bronchopulmonary dysplasia, hypoxia, and brain damage, as well as airway injuries and infections associated with mechanical ventilation.

The RAM cannula is a binasal interface with a larger-than-usual internal diameter. It is designed specifically for the early application of continuous positive airway pressure. Owing to its unique design, it allows for the delivery of sufficient flow and pressure according to the requirements of the newborn. The objective of this study was to describe the clinical performance and safety profile of noninvasive ventilation with a RAM cannula in preterm infants with respiratory distress and to analyze its relationship with the clinical outcomes observed in our population, specifically ventilation failure and the occurrence of associated nasal injury. We also evaluated the incidence of nasal injuries linked to the use of the RAM cannula compared with that reported in the literature.

Despite the resistance observed in some neonatal units to adopting the RAM cannula as a noninvasive ventilation interface, the available evidence suggests that, by optimizing ventilatory parameters, its effectiveness could be comparable to that of conventional interfaces.

### Objective

To describe the clinical performance and safety profile of the RAM cannula used as a postextubation ventilatory support strategy in preterm infants and to analyze the clinical and demographic factors associated with failure of the technique in our population.

## Materials and Methods

An observational, analytical, and retrospective study was conducted in a Level IIIB maternity ward. The data collection period was from May 2023 to May 2025 and included 32 newborns weighing less than 1500 g who used postextubation ventilatory support with the RAM cannula interface during their hospitalization.

The ventilatory support protocol was initiated using a resistance-compensating strategy, with parameters set to 2 to 3 cmH<sub>2</sub>O higher than the standard levels. Specifically, a peak inspiratory pressure of 17/18 cmH<sub>2</sub>O and an end-expiratory positive pressure of 7/8 cmH<sub>2</sub>O were set, with the aim of ensuring an effective distal pressure equivalent to a 15/5 cmH<sub>2</sub>O setting in conventional noninvasive ventilation.

Under these conditions, the effectiveness and complications associated with the use of the RAM cannula were evaluated, and associations with adverse clinical outcomes were established. Special attention was given to skin integrity, and the severity of nasal septum lesions was classified through standardized clinical inspection for erosions, ulcerations, or deformities attributable to the interface.

Failure of RAM cannula use was defined as the need for therapeutic escalation to invasive mechanical ventilation within the first 48 hours. This outcome was determined by the presence of gasometric failure—defined as respiratory acidosis with a pH less than 7.20 and hypercapnia with a partial pressure of carbon dioxide greater than 60 mmHg—persistent requirements for an inspired oxygen fraction greater than or equal to 0.40 or significant clinical deterioration.

Maternal variables (hypertension, diabetes, cholestasis, and preterm birth), perinatal variables (delivery mode and antenatal corticosteroid treatment), and neonatal variables (gestational age, birth weight, sex, and Apgar score) were collected. With respect to clinical variables, the need for surfactant, days of cRAM use, total days of mechanical ventilation, and maximum values of PCO<sub>2</sub> and FiO<sub>2</sub> were recorded. Continuous variables are expressed as the mean  $\pm$  standard deviation. Comparisons were performed using the  $\chi^2$  test or Fisher's exact test for categorical variables and Student's t test for continuous variables. A p value < 0.05 was considered to indicate statistical significance.

## Results

A total of 32 preterm newborns who met the inclusion criteria during the study period were included in the analysis. The population had a mean gestational age of  $28.06 \pm 1.9$  weeks and a mean birth weight of  $1063 \pm 178$  g.

With respect to perinatal history, 59% of the births were by cesarean section, and 69% received full lung maturation with antenatal corticosteroids. The need for exogenous surfactant was high, with 91% of the cohort receiving it. The baseline demographic and clinical characteristics of the population are detailed in Table 1.

### Clinical outcomes and NIV failure

The RAM cannula was used as a postextubation support interface, with a mean duration of use of  $11.7 \pm 8.9$  days. The failure rate, defined as the need for reintubation and escalation to invasive mechanical ventilation within the first 48 hours, was 19% (6/32 patients). The remaining 81% (26/32) successfully maintained noninvasive ventilation.

### Analysis of Factors Associated with Failure

When the baseline demographic variables, such as birth weight (978 g vs 1083 g;  $p=0.20$ ) and gestational age (28.1 weeks vs 28.0 weeks;  $p=0.88$ ), did not significantly differ between the groups of patients who experienced NIV failure ( $n=6$ ) and the group of patients who did not experience NIV failure ( $n=26$ ). No significant differences were found in the Apgar scores or in the incidence of maternal conditions (hypertension, diabetes, and cholestasis) (Table 2).

Bivariate analysis revealed significant associations between perinatal history and developmental complications. First, a history of premature rupture of membranes (PROM  $\geq 18$  h) was significantly more frequent in the successful group (32% vs. 0%;  $p=0.003$ ) and was associated with tolerance of extubation.

The group in which NIV failed had a significantly higher incidence of intraventricular hemorrhage (IVH) than the group in which NIV was successful (33% vs. 0%;  $p=0.002$ ). Similarly, a strong association was found between method failure and the presence of nasal injuries: 33% of patients who required reintubation had some degree of injury, while no such events were recorded in the group that successfully continued with the RAM cannula ( $p=0.002$ ).

Finally, although it did not reach statistical significance ( $p=0.11$ ), a clinically relevant percentage difference was observed in retinopathy of prematurity (ROP), which was more prevalent in the failure group (67%) than in the success group (31%).

### Safety profile

The overall incidence of nasal injuries in the total cohort was low, occurring in only 2 of the 32 patients (6%). No serious adverse events directly attributable to interface malfunction were recorded.

**Table 1. Demographic and perinatal characteristics of the population (n=32)**

| Variable                                       | Mean $\pm$ SD/%    | Range (Min - Max) |
|------------------------------------------------|--------------------|-------------------|
| Demographic Data                               |                    |                   |
| Gestational age (weeks)                        | $28.06 \pm 1.92$   | 25–33             |
| Birth weight (g)                               | $1063.6 \pm 178.8$ | 730–1410          |
| Gender (Male)                                  | 47%                | -                 |
| 1-minute Apgar score*                          | $6.26 \pm 1.79$    | 2–9               |
| Apgar at 5 min*                                | $8.13 \pm 0.92$    | 5–10              |
| Maternal and Perinatal History                 |                    |                   |
| Vaginal Delivery                               | 59%                | -                 |
| Lung Maturity (Full)                           | 69%                | -                 |
| Premature Rupture of Membranes ( $\geq 18$ h)* | 26%                | -                 |
| Maternal hypertension                          | 22%                | -                 |

| Variable                                       | Mean $\pm$ SD/%   | Range (Min - Max) |
|------------------------------------------------|-------------------|-------------------|
| Maternal diabetes                              | 3%                | -                 |
| Cholestasis                                    | 3%                | -                 |
| Respiratory Management and Course              |                   |                   |
| Use of Surfactant                              | 91%               | -                 |
| Days on Mechanical Ventilation                 | 12.78 $\pm$ 12.94 | 1–57              |
| Days of RAM cannula use                        | 11.69 $\pm$ 8.93  | 2–38              |
| Average FiO <sub>2</sub> (%)                   | 28.78 $\pm$ 4.98  | 21–40             |
| Mean PCO <sub>2</sub> (mmHg)                   | 39.88 $\pm$ 7.55  | 29–58             |
| Outcomes and Comorbidities                     |                   |                   |
| NIV failure (return to mechanical ventilation) | 19%               | -                 |
| Nasal Injuries                                 | 6%                | -                 |
| Bronchopulmonary Dysplasia (BPD)               | 59%               | -                 |
| Retinopathy of Prematurity (ROP)               | 38%               | -                 |
| Intraventricular hemorrhage (IVH)              | 6%                | -                 |

**Table 2. Comparative analysis between the NIV success and failure groups using a RAM cannula**

| Variable                             | Failure (n=6)     | Success (n=26)    | p value |
|--------------------------------------|-------------------|-------------------|---------|
| Demographic Data                     |                   |                   |         |
| Birth weight (g)                     | 978 $\pm$ 249     | 1083 $\pm$ 158    | 0.20    |
| Gestational age (weeks)              | 28.17 $\pm$ 2.56  | 28.04 $\pm$ 1.80  | 0.88    |
| Male gender (%)                      | 50%               | 46%               | 0.87    |
| Apgar at 1 min                       | 6.33 $\pm$ 1.51   | 6.24 $\pm$ 1.88   | 0.91    |
| Apgar at 5 min                       | 8.33 $\pm$ 0.52   | 8.08 $\pm$ 1.00   | 0.55    |
| Maternal and Perinatal History       |                   |                   |         |
| Vaginal delivery (%)                 | 50%               | 62%               | 0.62    |
| RPM $\geq$ 18 h (%)                  | 0%                | 32%               | 0.003   |
| Lung maturity (%)                    | 67%               | 69%               | 0.91    |
| Maternal hypertension (%)            | 33%               | 19%               | 0.47    |
| Maternal diabetes (%)                | 0%                | 4%                | 0.64    |
| Cholestasis (%)                      | 0%                | 4%                | 0.64    |
| Respiratory Variables                |                   |                   |         |
| Surfactant Use (%)                   | 83%               | 92%               | 0.51    |
| Total Days of Mechanical Ventilation | 11.17 $\pm$ 10.98 | 13.15 $\pm$ 13.51 | 0.74    |
| Maximum FiO <sub>2</sub> (%)         | 29.17 $\pm$ 3.76  | 28.69 $\pm$ 5.28  | 0.84    |
| Maximum PCO <sub>2</sub> (mmHg)      | 40.0 $\pm$ 10.2   | 39.9 $\pm$ 7.0    | 0.97    |

| Variable                              | Failure (n=6) | Success (n=26) | p value |
|---------------------------------------|---------------|----------------|---------|
| Comorbidities and Complications       |               |                |         |
| Nasal Lesions (%)                     | 33%           | 0%             | 0.002   |
| Intraventricular Hemorrhage (IVH) (%) | 33%           | 0%             | 0.002   |
| Bronchopulmonary Dysplasia (BPD) (%)  | 67%           | 58%            | 0.70    |
| Retinopathy of Prematurity (ROP) (%)  | 67%           | 31%            | 0.11    |

\*Statistical significance determined using Fisher's exact test.

Study limitations: The retrospective, single-center design, along with the small sample size, limits the generalizability of the results and causal inference. The absence of a control group, the lack of an internationally validated scale for injury grading, and the reliance on ventilatory settings based on local clinical practice constitute potential sources of bias.

## Discussion

In this retrospective observational study, the use of the RAM cannula as a postextubation noninvasive ventilation interface was associated with a failure rate of 19%, which is comparable to the failure rate reported in the literature for CPAP in preterm infants, which ranges from 12% to 25% depending on the series [5, 7].

After the perinatal history was analyzed, a statistically significant difference in the incidence of premature rupture of membranes (PROM  $\geq$  18 h) ( $p=0.003$ ) was observed. Interestingly, this history was exclusive to the success group (32% vs. 0%), which could suggest a possible effect of stress-induced pulmonary maturation in these patients, favoring tolerance to extubation.

On the other hand, with regard to morbidities, the pattern of retinopathy of prematurity (ROP) stands out. Although the difference did not reach statistical significance ( $p=0.11$ ), likely because of the small sample size of the failure group ( $n=6$ ), a clinically relevant percentage difference was observed: 67% of patients in the failure group had ROP, compared with only 31% in the success group. These findings suggest that the failure group consists of patients with greater systemic instability and greater exposure to oxygen fluctuations, although a larger sample size is needed to confirm the statistical association.

The most relevant finding and the main strength of this interface in our study lies in its favorable safety profile, particularly regarding the low incidence of nasal injury observed. The incidence of nasal injury was 6%. This figure is notably lower than that historically reported for short binasal prongs or masks, which can reach 40–50% in some reports [8]. Our findings are consistent with those of a recent meta-analysis by Kumar et al. [9] and a clinical trial by Al-Lawama et al. [2], who described the RAM cannula as a significantly less traumatic interface (RR 0.34 for nasal injury). Although we observed a significant association between the presence of nasal injury and NIV failure ( $p=0.002$ ), the low overall event rate suggests that this interface effectively protects the integrity of the nasal septum.

From a physiological standpoint, we acknowledge that the RAM cannula is not the “gold standard” because of its high-flow-resistance design, which can result in lower-than-programmed distal pressure delivery [1]. However, our results suggest that this mechanical limitation can be successfully overcome in clinical practice by adjusting respiratory parameters in a compensatory manner.

The need to use higher set pressures (PIP 18/PEEP 8) in our cohort is due to the intrinsic mechanical properties of the interface. As demonstrated by Claassen et al. (2020), compared with a set value, a RAM cannula acts as a high-resistance interface that can attenuate distal pressure transmission by up to 35% [10]. In their in vitro and clinical trials, these authors concluded that a compensatory increase in set pressure is essential for achieving effective lung inflation and reducing the failure rate of noninvasive ventilation, a finding that aligns with the high success rate observed in our study when this compensation strategy was applied.

This strategy could allow the RAM cannula to offer clinical performance comparable to that of other interfaces in daily practice but with the critical advantage of causing less nasal injury. This position makes it a potentially useful tool within the therapeutic arsenal, especially in settings with a high incidence of readmission to the ICU due to severe nasal trauma caused by rigid devices.

Finally, this combination of a low injury rate and ease of placement positions the RAM cannula as a pragmatic and valuable alternative for healthcare settings with limited resources or a low nurse-to-patient ratio. In these settings, where the continuous and meticulous monitoring required by stiffer interfaces to prevent septal necrosis is difficult to sustain, the RAM cannula offers a safe option that could facilitate nursing care, without showing an increase in ventilatory failure in our cohort.

## Conclusion

In this cohort of preterm infants, the use of the RAM cannula as a postextubation noninvasive ventilation interface was associated with a failure rate of 19%, comparable to that reported in the literature, and with a very low incidence of nasal injury (6%).

Although the resistance of the cannula is greater than that of traditional interfaces, our findings suggest that, with appropriate parameter adjustment, the RAM cannula may constitute an effective alternative for postextubation ventilatory support, with a low risk of nasal injury.

Its ease of use makes it a potentially useful alternative, especially in healthcare settings with limited resources or understaffing, where minimizing care-related trauma is a priority for treatment success.

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