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# Non-invasive ventilation using RAM'S cannula in neonates-what difference does it make?

**Anjuri Sharma[1], Monica Lazarus[2], Asha Tiwari[3], Lalit M Malviya[4], Vidya K Saurabh[5]**

*[1]Junior Resident, [2]Professor, [3,5]Assistant Professor, Department of Paediatrics, NSCB Medical College, [4]Assistant Professor, Department of Neonatology, SSH NSCB Medical College, Jabalpur, Madhya Pradesh, India*

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## ABSTRACT

**Background:** Neonates undergo transition at birth from breathing fluid to breathing air. If this change is not tolerated by neonate, need of assisted ventilation arises. Non-invasive ventilation (NIV) refers to any mode of respiratory support provided through nasal airway. Using RAM'S cannula as an interface, complications of invasive ventilation can be prevented, and therefore it can be impactful in improving respiratory care in neonates. **Aims and Objectives:** The aim of the study was to find the association of clinicoetiological factors and the outcome of NIV using RAMS's cannula in neonates. **Materials and Methods:** This prospective observational study was done from March 1, 2021 to August 31, 2022 at Neonatal Intensive Care Unit of a Tertiary care center in Central India. Neonates given NIV through Ram's cannula were enrolled. Primary diagnosis of subjects and clinical parameters - birth weight, gestational age, duration of NIV given, and severity of respiratory distress were recorded and analyzed to find an association with the outcomes. Informed consent was obtained from parents. **Results:** 100 neonates (62 male) were given NIV. 78 neonates were weaned off from NIV and 22 needed intubation. Duration of NIV, gestational age, severity of respiratory distress, and birth weight were found to be statistically significant. Weaning was more in gestation >34 weeks, weight >1 kg, duration of NIV given <3 days, and neonate having mild respiratory distress. **Conclusion:** NIV through RAM's cannula is useful in both respiratory and non-respiratory illness. Higher rates of NIV failure were seen in the duration of NIV >7 days, weight <1 kg, and gestation <34 weeks.

**Key words:** Noninvasive ventilation; Neonates; Rams' cannula; Outcome

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## INTRODUCTION

In a developing country like India, drastic advances in perinatal and neonatal care among various levels of health care have significantly reduced neonatal morbidity and mortality rates (national family health survey 5- NMR from 45 to 35).[1] Advances in the field of neonatal ventilation are one such stepping stone.

Respiratory muscles in infants are more susceptible to exertion than those of adults.[2] The neurochemical control of the breathing in neonates is not well known. Central neural control and response of chemoreceptors to hypoxemia are not completely developed; hence, it is more subject to failure (apnea).[3-5] Maturity of lung and growth of the fetus depend on gestational age at which a baby is born, which will further decide the course of survival and the chance of complications.

Non-invasive ventilation (NIV) refers to the use of methods to deliver artificial respiration to lungs without the need for endotracheal intubation. It is used to provide breathing support from outside the airway through an interface like a mask or a nasal prong. NIV is advantageous as it improves respiratory unloading with a decrease in the work of breathing.[6] NIV also augments spontaneous breathing efforts. RAM's cannula (named after the physician-scientist Dr. Ramanathan) is an indigenously made cannula that can deliver NIV and avoid the trauma caused by endotracheal intubation.

**Address for Correspondence:**
Dr. Lalit M Malviya, Assistant Professor, Department of Neonatology, SSH NSCB Medical College, Jabalpur, Madhya Pradesh, India.
**Mobile:** +91-9005433408. **E-mail:** malviyalalit@yahoo.com

Common indications of NIV are apnea of prematurity, following extubation, primary mode of ventilation in preterm infants with respiratory distress syndrome (RDS), transient tachypnea of the newborn, and prevention of bronchopulmonary dysplasia. Certain conditions where plugging of alveoli occurs leading to a decrease in exchange area are also indications for the use of NIV such as meconium aspiration syndrome (MAS) and congenital pPneumonia.[7] NIV can be used either to bridge apneic episodes or for severe apnea - bradycardia syndrome.[8] Neonatal NIV is used in situations, in which it is primary, as preventive measure and secondary respiratory support following extubation.[9]

NIV failure or indications for mechanical ventilation includes hypoxia ($FiO_2$ requirement ≥40%), acidosis (pH ≤7.20), hypercarbia (PCo2 ≥65 mmHg), and apnea of 4 episodes/h or the need for bag-mask ventilation 2 times/h.[7]

### Aims and objectives

The primary objective of this study was to find the immediate outcome of NIV through RAM'S cannula in neonates and secondary objective was to find the association of outcomes of NIV through RAM'S cannula with clinicoetiological parameters such as birth weight, gestational age, duration of NIV given, severity of respiratory distress, duration of hospital stay, and primary diagnosis for the use of NIV.

## MATERIALS AND METHODS

This prospective observational study was done from March 01, 2021 to August 31, 2022 (18 months) at Neonatal Intensive Care Unit of a Tertiary care center in Central India. All neonates (aged 0–28 days) who were given NIV through RAM'S cannula as first-line management or as post-extubation support were included in the study. Informed consent was obtained from parents/caregivers. Attendants not willing to participate in the study were excluded from the study.

Clearance was obtained from the Institute Ethical Committee (IEC/2020/87). A total of 100 neonates were enrolled. For each ventilated neonate, information including age, sex, birth weight (recorded by electronic weighing machine), gestational age (by modified Ballard's scoring), primary diagnosis for the use of NIV, hospital stay, duration of NIV given, and severity of respiratory distress (by Downe's and Silverman Anderson score) was recorded in a pre-defined pro forma. Severity of respiratory distress was also labeled on the basis of Respiratory rate (mild distress RR <60/min, moderate distress RR 60/min to 80/min, and severe distress RR >80/min).

Data were collected, and entry was done in the Microsoft excel spreadsheet. Presentation of categorical variables was done in the form of number and percentage (%). Quantitative data were presented as means±SD and as median with 25$^{th}$ and 75$^{th}$ percentiles (interquartile range). Data normality was checked using Kolmogorov–Smirnov test. Cases in which data were not normal, we used non-parametric tests. The association of variables which were quantitative and not normally distributed in nature were analyzed using Mann–Whitney Test (for two groups) and Kruskal–Wallis test (for more than two groups). The association of variables which were qualitative in nature was analyzed using the Chi-square test. If any cell had an expected value of <5, then Fisher's exact test was used.

Final analysis was done with the use of Statistical Package for the Social Sciences, IBM manufacturer, Chicago, USA, version 25.0. P<0.05 was considered statistically significant.

## RESULTS

During the study, 100 neonates were included. Males were 62 (62%) and females were 38 (38%). 78 (78%) were weaned off and 22 (22%) needed intubation. Table 1 shows the association of outcome with clinical parameter, and Table 2 shows the association of indication for NIV through RAM'S cannula with outcome.

Birth weight has a P=0.03 and therefore is significantly associated. 1–1.5 kg subjects showed 87.5% weaning and 14.2% intubated and minimum weaning off is seen in <1 kg (25%). Association with gestational age (GA) has a P=0.009, so it is statistically significant. Gestation >37 weeks have better outcomes as compared to the other two groups, i.e., 34–37 weeks and <34 weeks.

Severity of respiratory distress has a P=0.03 showing significance. Mild distress (RR ≤60/min) has a better outcome than moderate (60–80 breaths/min) and severe distress (RR ≥80/min). Duration of NIV given has a P=0.03 and is significant. Neonates given NIV for <3 days showed minimum rates of intubation as compared to those given for 3–7 days or >7 days.

P-value for this association is 0.539 and is statistically insignificant. 100% weaning off is seen with TTN, apnea, and CHD. RDS, MAS, and BA are the most common indications for the use of NIV with a greater percentage of weaning off. Subjects with pneumonia had the highest

**Table 1: Association of outcomes with clinical parameters**

| Parameter | Total subjects | Outcomes | | P-value |
|---|---|---|---|---|
| | n=100 | Weaned off n=78 (%) | Needed intubation n=22 (%) | |
| Birth weight | | | | |
| <1 kg | 8 | 2 (25) | 6 (75) | 0.03* |
| 1–1.5 kg | 32 | 28 (87.5) | 4 (14.2) | |
| 1.5–2.5 kg | 43 | 35 (81.39) | 8 (18.6) | |
| >2.5 kg | 17 | 13 (76.74) | 4 (23.5) | |
| Gestational age | | | | |
| <34 weeks | 12 | 5 (41.66) | 7 (58.33) | 0.009* |
| 34–37 weeks | 41 | 33 (80.48) | 8 (19.5) | |
| >37 weeks | 47 | 40 (85.10) | 7 (14.8) | |
| Severity of respiratory distress (RR=respiratory rate) | | | | |
| RR<60/min | 23 | 21 (91.3) | 2 (8.6) | 0.036* |
| 60–80/min | 64 | 50 (78) | 14 (21) | |
| >80/min | 13 | 7 (53) | 6 (46) | |
| Duration of NIV given | | | | |
| <3 days | 49 | 42 (85.71) | 7 (14.29) | 0.031* |
| 3–7 days | 44 | 33 (75) | 11 (25) | |
| >7 days | 7 | 3 (42.86) | 4 (57.14) | |

**Table 2: Association of Indicators for the use of non-invasive ventilation through RAM'S cannula with the outcomes**

| Indication for NIV use | Number of subjects | Outcomes | | P-value |
|---|---|---|---|---|
| | n=100 | Weaned off n=78 (%) | Need Intubation n=22 (%) | |
| RDS | 29 | 22 (75.86) | 7 (24.14) | 0.539 |
| Pneumonia | 10 | 7 (70) | 3 (30) | |
| BA | 19 | 14 (73.68) | 5 (26.32) | |
| MAS | 20 | 14 (70) | 6 (30) | |
| Apnoea | 2 | 2 (100) | 0 (0) | |
| CHD | 5 | 5 (100) | 0 (0) | |
| TTN | 10 | 10 (100) | 0 (0) | |
| NNH | 5 | 4 (80) | 1 (20) | |

RDS: Respiratory distress syndrome, BA: Birth asphyxia, MAS: Meconium aspiration syndrome, CHD: Congenital heart disease, TTN: Transient tachypnea of newborn, NNH: Neonatal Hyperbilirubinemia

rate of intubation, i.e. 30% comparable to those with MAS.

## DISCUSSION

This study is focused on evaluating various indications of NIV, clinical parameters of neonates, and their outcomes in terms of weaning off and need for intubation. Out of 100 neonates 62 (62%) were males. Birth weight, gestation age, and duration of NIV received were found to be statistically significant with the outcome. NIV failure was maximum in MAS and pneumonia (30%).

In this study, majority of neonates 78% were weaned off and 22% needed intubation. Yimer et al. found rate of failure of NIV to be 20%, which is similar to the present study.[10]

In this study, in <1 kg group, 75% needed intubation, 1–1.5 kg had best outcome with only 12.5% requiring intubation, followed by 1.5–2.5 kg (18.6%) and >2.5 kg (23.5%). It was also found that neonates in <34 weeks GA had poor outcome with 58.33% requiring intubation, followed by 34–37-week GA group 19.65% and >37 weeks GA has better outcome with only 14.89% requiring intubation. Dargaville et al., also have similar higher failure rate in extreme preterm (43%).[11] Biniwale and Wertheimer showed successful use of RAM nasal cannula for the resuscitation of very low birth weight infants and decreased need for intubation even among lower gestational age infants (mean 27 weeks).[12]

In this study, NIV failure was maximum in MAS, and pneumonia, i.e., 30%, while in RDS, it was 24.14%, and in birth asphyxia, it was 26.3%. In apnea, TTN, and CHD, 100% neonates were weaned off from NIV. These results are in concordance with the severity of disease

and preceding condition of lung. In a study done by Petrillo et al.,[13] the use of NIV in apnea of prematurity is emphasized.

In the current study, it was found that mild distress has a better outcome than moderate and severe distress. As severity of distress increases, there is an increase in the respiratory rate, which will put burden on lungs along with the supporting muscle, in turn increasing the work of breathing hence pushing the system toward impending failure and need for mechanical ventilation Zhang et al.,[14] also had similar result in their study.

In this study, neonates given NIV for <3 days, had maximum weaning off, this shows that the risk of intubation increases as duration of NIV increases. The 2017 Cochrane review demonstrated the efficacy of NIV to prevent extubation failure when NIV was used immediately after extubation only.[15] This study has an advantage as we have included neonates requiring NIV as primary mode of ventilation as well as secondary, i.e., post-extubation.

### Limitations of the study

It is a single-center study which is not sufficient to establish the efficacy of RAM'S cannula for various indications. Further multicenter trials with larger sample size are required to make more robust implications.

## CONCLUSION

This study concludes that NIV through RAM'S cannula is an effective means of ventilation for respiratory causes such as RDS, MAS, apnea of prematurity, transient tachypnea of newborn, pneumonia, and non-respiratory causes such as Birth Asphyxia. For all gestational age neonates, the benefits of NIV overpower the risk of failure and need for intubation. The number of days for which NIV is to be given can be molded according to the severity and clinical condition of the neonate. With a better understanding and results obtained, we emphasize that NIV can be a primary ventilation mode for various indications, as well as secondary, i.e., post extubation. Additional benefit of NIV is early discharge and better mother–baby bonding. Thus, the use of NIV should be encouraged and can be a stepping stone for further advances in the ventilation of neonates.

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**Authors' Contributions:**
**AS-** Literature survey, prepared first draft of manuscript, implementation of study protocol, data collection; **ML-** Definition of intellectual content, concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **AT-** Data analysis and review manuscript; **LMM-** Manuscript preparation and submission of article, coordination and manuscript revision; **VKS-** Review manuscript, literature survey and preparation of tables.

**Work attributed to:**
Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India.

**Orcid ID:**
Anjuri Sharma- https://orcid.org/0009-0004-1576-7789
Monica Lazarus- https://orcid.org/0009-0008-6786-2920
Asha Tiwari- https://orcid.org/0000-0001-6372-1006
Lalit M Malviya- https://orcid.org/0000-0003-4938-8432
Vidya K Saurabh- https://orcid.org/0000-0003-3561-905X

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