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Original Research Article

# A Randomized Controlled Comparative Assessment of the of Incidence and Severity of Nasal Complications While using Nasal Prongs and Nasal Mask as CPAP Interface in Preterm Neonates

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**Conflict of interest: Nil**

**Aim:** This study was conducted to compare the outcome of nasal prong and nasal mask interfaces in preterm infants on CPAP support due to respiratory distress.

**Methods:** A randomized controlled trial was performed at Department of Pediatrics, Nalanda Medical College and hospital Patna, Bihar, India for the period of six months.

**Results:** A total of 148 preterm infants were assessed for eligibility to the study of which 28 newborns were excluded from the study as they did not meet the inclusion criteria. A total of 120 babies were enrolled in the study, of which 12 babies were ventilated due to CPAP failure and 8 babies left against medical advice before the study could be completed and hence were excluded. Finally, 100 participants completed the study. 50 participants were enrolled in Group A (nasal prongs) and 50 in Group B (nasal masks). The mean duration of CPAP administration in Group A (nasal prongs) was 4.536 ± 0.86 days and in Group B (nasal masks) was 5.205 ± 0.614 days (P = 0.0778). Babies in Group A had an average hospital stay of 21.36 ± 5.14 days, and babies in Group B had hospital stay of 24.58 ± 7.31 days (P = 0.7900). CPAP failure was seen in 10 (20%) babies in Group A and 11 (22%) babies in Group B (P = 0.7395).

**Conclusion:** Based on our study, we concluded that the use of binasal prongs and nasal masks as interface during CPAP therapy makes no difference in overall outcome of nasal trauma in the patient. Both were found equally effective and comparable to each other.

**Keywords:** Continuous Positive Airway Pressure, Nasal Mask, Nasal Prongs, Nasal Trauma.



## Introduction

Non-invasive respiratory support in the neonatal intensive care unit (NICU) has been used for more than 35 years as a means to reduce complications of invasive mechanical ventilation. Specific types of non-invasive support have been implicated in preventing respiratory failure in spontaneously breathing infants, especially those with Respiratory Distress Syndrome (RDS). Technological progress, along with a better understanding of the applications of equipments, advances in the care of the neonates, and documented favourable patient outcomes have translated into trends that continue to promote non-

invasive respiratory support for care of the neonates. [1]

Respiratory support in the neonatal intensive care unit (NICU) is a mainstay to reduce complications of invasive mechanical ventilation. Nasal Continuous Positive Airway Pressure (CPAP) in infants is used for situations such as respiratory distress syndrome, apnea of prematurity, bronchomalacia with terminal airway collapse, and in other conditions that require positive pressure. Types of CPAP used in neonates include continuous low CPAP, variable flow CPAP, bubble or underwater seal CPAP, bi-level CPAP, synchronized non-invasive positive pressure ventilation, high flow nasal cannula, and nasal high frequency ventilation (NHFV). To apply CPAP, three components are essential required continuous flow of a heated and humidified gas mixture (compressed air and oxygen); a system connecting the device to the patient's airway such as facial masks, nasal prongs, nasopharyngeal or endotracheal tubes and a mechanism of positive pressure generation in the system. [1]

The local pressure of CPAP devices to the nasal area tends to develop decubitus lesions in the newborn due to its cutaneous vulnerability and anatomical factors such as end vascularisation of the columella and nostrils. [2,3] Nasal trauma represent a source of discomfort for patients, possible site of infection and a risk of long term functional or cosmetic sequelae. [4-6] Respiratory distress in newborn babies is one of the commonest causes of neonatal intensive care unit(NICU) admissions (30-40%). [7] Bubble CPAP is a simple, cost effective and non-invasive method of ventilating sick newborns. [8] It is a well-established mode of respiratory support in preterm babies. Early use of CPAP for stabilization of at-risk preterm infants reduces ventilator needs. Nasal prongs and nasal masks are being frequently used as interface between patients.

This study was conducted to compare the outcome of nasal prong and nasal mask interfaces in preterm infants on CPAP support due to respiratory distress.

## Methods

A randomized controlled trial was performed at Department of Pediatrics,Nalanda Medical College and hospital Patna, Bihar, India for the period of six months. A total of 148 preterm infants were assessed for eligibility to the study of which 28 newborns were excluded from the study as they did not meet the inclusion criteria. A total of 120 babies were enrolled in the study, of which 12 babies were ventilated due to CPAP failure and 8 babies left against medical advice before the study could be completed and hence were excluded.

Preterm infants of gestational age 28–34 weeks with moderate respiratory distress (according to Silverman score) admitted within 6 hours of life, requiring CPAP, were enrolled in the study after getting informed written consent. Babies with 5-min Apgar scores <5, major congenital malformation/anomalies, and severe sepsis/meningitis/ metabolic disorders were excluded from the study. The study protocol was approved by the Ethics Committee of the institute.

After initial stabilization, the treatment plan was delineated. Babies requiring bubble CPAP support were randomized using Tippett's random number table to one of the two groups according to the interface used to provide CPAP (Group A: binasal prongs and Group B: nasal masks). Scoring for severity of respiratory distress in preterm infants was done using the Silverman–Anderson score. [9] Outcomes were measured in different parameters. Nasal trauma was assessed when the interface was transiently removed for suctioning or cleaning.

Data were collected on structured pro forma and managed using MS Excel software. Statistical analysis was

performed using one-way ANOVA F-test at 1% level of significance. Statistical significance was considered if P < 0.01. The quantitative data were expressed in mean ± standard deviation (SD), and qualitative data were expressed in terms of frequency distribution.

## Results

**Table 1: Comparison of general characteristics of study participants**

| | Nasal prongs (n=50) | Nasal masks (n=50) | P |
|---|---|---|---|
| Gestational age (weeks), mean±SD | 30.475±2.018 | 30.245±2.021 | 0.8950 |
| Birth weight (g) | 1180±0.22 | 1182±0.21 | 0.7554 |
| **Gender** | | | |
| Male | 38 (76) | 34 (68) | 0.0984 |
| Female | 12 (24) | 16 (32) | 0.2334 |
| **Mode of delivery** | | | |
| Vaginal | 39 (78) | 35 (70) | 0.4221 |
| Cesarean | 11 (22) | 15 (30) | 0.4996 |
| **Place of delivery** | | | |
| Home | 12 (24) | 15 (30) | - |
| Institutional | 38 (76) | 35 (70) | - |
| **Assessment of respiratory distress/Silverman score** | | | |
| 4 | 15 (30) | 15 (30) | - |
| 5 | 15 (30) | 16 (32) | - |
| 6 | 20 (40) | 19 (38) | - |
| **Surfactant instillation** | | | |
| Surfactant received | 26 (52) | 29 (58) | 0.781 |
| Surfactant not received | 24 (48) | 21 (42) | 0.720 |
| **Administration of antenatal steroids** | | | |
| Given | 17 (34) | 23 (46) | - |
| Not given | 33 (66) | 27 (54) | - |

A total of 148 preterm infants were assessed for eligibility to the study of which 28 newborns were excluded from the study as they did not meet the inclusion criteria. A total of 120 babies were enrolled in the study, of which 12 babies were ventilated due to CPAP failure and 8 babies left against medical advice before the study could be completed and hence were excluded. Finally, 100 participants completed the study. 50 participants were enrolled in Group A (nasal prongs) and 50 in Group B (nasal masks). The baseline characteristics of both groups were comparable to each other.

**Table 2: Comparison of outcomes during continuous positive airway pressure therapy**

| Parameters | Nasal prongs (n=50) | Nasal masks (n=50) | P |
|---|---|---|---|
| Mean duration of CPAP (days)±SD | 4.536±0.86 | 5.205±0.614 | 0.0778 |
| Duration of hospital stay (days)±SD | 21.36±5.14 | 24.58±7.31 | 0.7900 |
| CPAP failure | 10 (20) | 11 (22) | 0.7395 |
| ROP | 4 (8) | 5 (10) | 0.1384 |
| NEC | 4 (8) | 5 (10) | 0.1384 |
| PDA | 3 (6) | 3 (6) | 0.1248 |
| Nasal trauma | 23 (46) | 22 (44) | 0.5372 |

The mean duration of CPAP administration in Group A (nasal prongs) was 4.536 ± 0.86 days and in Group B (nasal masks) was 5.205 ± 0.614 days (P = 0.0778). Babies in Group A had an average hospital stay of 21.36 ± 5.14 days, and babies in Group B had hospital stay of 24.58 ± 7.31 days (P = 0.7900). CPAP failure was seen in 10 (20%) babies in Group A and 11 (22%) babies in Group B (P = 0.7395). About 8% (4) babies in Group A and 10% (5) babies in Group B developed retinopathy of prematurity (ROP) (P = 0.1384). Four (8%) babies in Group A and 5 (10%) babies in Group B developed necrotizing enterocolitis (NEC) during CPAP therapy (P = 0.1384). The development of patent ductus arteriosus (PDA) was observed in 3 (6%) babies in Group A and 3 (6%) babies in Group B (P = 0.1248). Nasal trauma was observed in 46% (23) babies in Group A and 44% (22) babies in Group B during CPAP therapy (P = 0.537).

## Discussion

Nasal continuous positive airway pressure is the primary mode of therapy in preterm neonates especially in hyaline membrane disease. It reduces the need of ventilator, surfactant and invasive ventilation associated risks. [10] Use of continuous positive airway pressure (CPAP) in preterm neonates with respiratory distress reduces mortality by 66%. [11] Success rate of CPAP therapy is variable across the neonatal units.

Based on our study, we observed that there is no significant difference in efficacy of binasal prongs and nasal masks in terms of mean duration of hospital stay, mean duration of CPAP therapy, CPAP failure, overall incidence of nasal trauma, development of PDA, NEC, and ROP in premature neonates. Studies by Kieran et al., [12] Singh et al. [13] concluded that the overall rate of trauma, in the nasal prong group, was comparatively more than in the nasal mask group but was not statistically significant. Our study also supports the same fact.

The types of injury were similar in the two groups, the sites of injury differed. In the nasal mask group, injuries occurred primarily at the base of the nasal septum at the junction between the nasal septum and the philtrum. This suggests that this is the area at which the mask exerts the greatest pressure, as prolonged pressure leads to impairment of tissue perfusion with resultant skin trauma. Injuries in the nasal prong group were confined primarily to the medial aspect of the nostrils on the nasal septum, indicating this to be the site of maximum pressure exerted by the prong. The lateral part of the nostrils may expand outwards when the prong are applied; the medial parts, being less mobile, are exposed to greater persistent pressure from the prong with resultant trauma. The mean birth weight in nasal mask and nasal prongs were 1180±0.22 and 1182±0.21respectively while in Yong et al [14] mean birth weight were 1085(232) and 1105(228) mean weight in gm, less weight patient were in Yong et al study, in nasal mask and nasal prongs respectively.

Kumar G et al [15] found that failure of NCPAP was noticed in 11 (36.7%) patients in nasal prong group, while in nasal mask group NCPAP failure was noticed in 5(16.7%) patients. There was no statistically significant difference found in failure rate between the two groups (P=0.080). Median duration (IQR) in hrs on NCPAP support was 42.5hrs (25-55) in nasal prong group, while in nasal mask group median duration (IQR) was 47.25hrs (36-72) with a P value of 0.181.Goel S et al [16] also concluded that nasal continuous positive airway pressure failure occurred in 8 (13%) of Mask group and 14 (25%) of Prongs group but was statistically not significant (RR 0.53, 95% CI 0.24-1.17) (P=0.15). The rate of pulmonary interstitial emphysema was significantly less in the mask group (4.9%

vs. 17.5%; RR 0.28, 95% CI 0.08-0.96; P= 0.03). Incidence of moderate nasal trauma (6.5% vs 21%) (P=0.03) and overall nasal trauma (36% vs 58%) (P=0.02) were significantly lower in mask group than in the prongs group.

Our study also supports Chandrasekaran et al. [15] who found severe nasal trauma to be more common (31% vs. 0%) among neonates in the nasal prong group.Kumar et al. [17] found that local nasal complications were detected in 33.3% in nasal prong group and 20% in nasal mask group (P = 0.136). [18]

## Conclusion

Based on our study, we concluded that the use of binasal prongs and nasal masks as interface during CPAP therapy makes no difference in overall outcome of nasal trauma in the patient. Both were found equally effective and comparable to each other.

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