DOI: 103126/JNPS.V4113

Original Article

Efficacy of Nasal Continuous Positive Airway Pressure Delivered by Nasal mask Versus Nasal Prongs in Neonates

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Article History

Received on - 2023 Apr 12
Accepted on - 2023 Oct 16

Keywords:

Continuous positive airway pressure; nasal masks; neonatal Intensive care unit; newborn care; respiratory distress syndrome

Online Access

DOI: https://doi.org/10.60086/jnps544

Abstract

Introduction: Nasal continuous positive airway pressure (CPAP) is the standard therapy for neonatal respiratory distress. It is delivered using nasal mask (NM) or nasal prong (NP), both of which can result in nasal trauma. The type of nasal interface used is an important determinant of nasal injury. The superiority of one over the other is debatable necessitating further research to identify the more efficacious, safe and convenient nasal continuous positive airway pressure (CPAP) interface. This study was conducted to compare the efficacy of NM Nasal continuous positive airway pressure (CPAP) versus NP CPAP.

Methods: Sixty neonates < 37 weeks and having respiratory problems were alternately divided into two groups based on the respiratory support provided: Group A (NM CPAP) and Group B (NP CPAP). They were followed up on a daily basis during their NICU stay and placed on regular recall until three months of age. Between-group comparisons were done using Wilcoxon-Sign-Rank Test and Proportion test. P-value ≤ 0.05 indicated statistical significance.

Results: Patients in Group A (NM CPAP) showed significantly less number of days of CPAP therapy (P = 0.0033) and lesser failure rate (P = 0.0198) compared to those in Group B (NP CPAP). Incidence of complications was also lower in Group A than in Group B.

Conclusion: NM CPAP is more efficacious and safer than NP CPAP for the treatment of respiratory problems in neonates.

Introduction

Respiratory distress syndrome (RDS) is a leading cause of mortality among preterm infants, with the risk being higher for gestational ages < 37 weeks.[1,2] CPAP forms the mainstay for RDS management among neonatal patients since it provides a simple, low cost, non-invasive method for applying constant distending pressure (above atmospheric pressure) during inhalation and exhalation to support spontaneous breathing.[3,4] The clinical goals of CPAP are to maintain the functional residual capacity of lungs and support gas exchange in order to reduce apnea, work of breathing and lung injury.[5]

Traditionally, short bi-nasal prongs (NP) have remained the standard of care for delivery of nasal CPAP. However, they are associated with certain limitations like mechanical difficulties in maintaining the nasal prongs, poor tolerance of the infant to the apparatus, difficulties in positioning the neonate, columella injury and septal deformities.[6-8] Nasal masks (NM) are increasingly being used as effective alternatives to nasal prongs (NP) for CPAP delivery owing to their ease of application, greater

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reduction in oxygen requirement, and lower intubation rate.[9-11] However, nasal trauma has been reported with both NP and NM and occurs with each of these interfaces.[12,13]

The type of nasal interface used is an important determinant of nasal injury and the site of injury is related to the pressure points of the interface.[14] This warrants identification of the most effective, safe and convenient modality for CPAP delivery. In light of lack of consensus regarding which method is superior to the other, the present research aimed to compare the efficacy of NM CPAP versus NP CPAP for the treatment of respiratory problems in neonates.

Methods

This comparative prospective clinical study was conducted at a tertiary care hospital in Kolhapur, Maharashtra, India, from October 2018 to October 2020, after obtaining ethical clearance from the Institutional Review Board. The study enrolled 60 neonates aged < 37 weeks (Preterm infants), irrespective of their gender, including post-extubation neonates, who were suffering from respiratory problems. Written informed consent from their parents / guardians before inclusion. The study excluded patients with cleft lip, cleft palate, choanal atresia, tracheoesophageal fistula, unrepaired diaphragmatic hernia, severe cardiovascular instability, severe impairment (pH < 7.25 and pCO_2 > 60 mmHg), major congenital malformation, and those requiring abdominal surgery (intestinal obstruction, posterior urethral valve). The required sample size was calculated using the following formula:

$$n = \frac{((Z\alpha/2) + Z\beta)^2 \ [p_1(1 - p_1)) + p_2(1 - p_2)]}{(p_1 - p_2)^2}$$

where is the critical value of the Normal distribution at α / 2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), is the critical value of the normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p1 and p2 are the expected sample proportions of the two groups i.e., p1 = 10% and p2 = 31%. The calculated minimum sample size obtained was 54 and the subjects included in the study were 60. The patients were put on either CPAP alternatively.

The respiratory problems were diagnosed based on the findings of history and clinical examination (like increased respiratory rate > 60 cycles / minute, cyanosis, grunting, retraction and nasal flaring). Diagnosis was confirmed by radiologic patterns consisting of reduced air content and a reticulo-granular pattern of lungs with air bronchogram. For this study, respiratory problem at initiation was defined as Silverman Anderson score (SAS) of 3 - 6 with fraction of inspired oxygen (FiO_2) requirement between 21 - 60% to maintain oxygen saturation (SpO_2) between 90 - 95%.[15] The neonates were alternately divided into two groups based on the respiratory support provided: Group A (placed on NM CPAP) (N = 30) and Group B (placed on NP CPAP) (N = 30). These patients were followed up on a daily basis during their NICU stay (criteria for follow up was SpO_2, improvement in nasal trauma complications like excoriation, redness, bleeding, crusting and narrowing of nasal passage) and placed on regular recall until three months of age. Complications, if any, were recorded, including pulmonary interstitial emphysema, pneumothorax, bronchopulmonary dysplasia, feeding intolerance, mortality etc. Criteria for CPAP failure included SpO_2 < 88% on FiO2 > 60% for > 30 minutes with requirement of CPAP > 8 cm of H_2O, blood gas analysis showing pH < 7.20, pCO_2 > 65 mmHg and pO_2 < 50 mmHg on FiO2 > 60%, pathologic apnea, and increasing retractions. Fisher and Paykel CPAP was used and Fisher and Paykel nasal prongs and nasal mask was used of small (BC800), Medium (BC801), and Large (BC802) sizes based on best estimate using the nasal mask and nasal prong scale provided by the company. Weaning criteria for CPAP was when babies had maintained saturation more than 95% on 4 cm of H_20 with FiO_2 of 21% for 24 hours. Data was compiled and analyzed using statistical software Statistical Package for the Social Sciences (SPSS) version 18.0 (SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.) and Microsoft Excel. Continuous variables were expressed in mean ± standard deviation (SD) format. Categorical variables were expressed in a frequency distribution format. Wilcoxon-Sign-Rank Test and Proportion test have been used to assess the significant difference between the two groups. P-value ≤ 0.05 indicates statistical significance.

Results

The study consisted of 60 neonates suffering from respiratory problems, consisting of 30 (50%) males and 30 (50%) females, with a mean age of 32.91 ± 2.55 weeks, M:F ratio of 1:1 and mean birth weight of 1551.31 ± 429.48. Table-1 presents the inter-group comparison of different variables. Patients in Group A (NM CPAP) showed significantly lesser number of days of CPAP therapy (P = 0.0033, by Wilcoxon-Sign-Rank Test) and lesser failure rate (P = 0.0198, by Proportion test) compared to those in Group B (NP CPAP).

Table 1: Demographics and outcomes in Nasal mask group and nasal prongs group.

Variable	Nasal Mask Group		Nasal Prong Group		P-value
	Mean	SD	Mean	SD	
Gestation age (Weeks)	33.02	2.92	33.8	2.13	0.5092
Birth weight (Gm)	1491.4	500.5	1613.3	338.83	0.0811
Initial FiO_2 %	55.67	12.23	58.45	13.3	0.3432
Maximum FiO_2 %	76	18.31	78.79	12.51	0.6167
Maximum Flow (L / Min)	5.13	0.43	5.48	0.63	0.0232
No of days CPAP Required	5.1	0.88	5.9	1.42	0.0033

Table 2: Complications associated with nasal mask CPAP and nasal prongs CPAP

Parameter		Group A (NM)	Group B (NP)	p-value
Mean duration of CPAP (days)		5.1 ± 0.88	5.9 ± 1.42	0.0033*
Failure rate		2 (6.67%)	10 (34.48%)	0.0198*
Complications	Pulmonary Interstitial Emphysema	0%	13.33%	< 0.001*
	Pneumothorax	0%	6.66%	0.0019*
	Bronchopulmonary dysplasia	0%	0%	-
	Feeding intolerance	0%	0%	-
	Mortality	0%	0%	-
	Crusting	0%	20%	< 0.001*
	Excoriation	6.66%	26.66%	< 0.001*
	Narrowing of nasal passage	0%	0%	-
	Redness in nasal mucosa	20%	20%	1.0
	Bleeding	13.33%	20%	0.165

The overall incidence of complications was also lower in Group A than in Group B. By proportion test, the incidences of PIE (P = < 0.001), pneumothorax (P = < 0.0019), crusting (P = < 0.001), and excoriation (P = < 0.001) was significantly less in Group A than Group B as shown in Table 2. The odds ratio could be calculated only for failure rate and it was high [OR 7.38 (CI 1.36-76.54) p value 0.0093.

Discussion

Nasal CPAP therapy is associated with reduction in morbidity and mortality associated with neonatal RDS.[16] The need for identification of the safest and the most efficacious nasal interface for this purpose prompted the present study that compared the efficacy of nasal mask CPAP versus nasal prong CPAP for the treatment of respiratory problems in neonates. NM CPAP was found to be associated with less number of days of CPAP duration as well as lower failure rates and complications compared to NP CPAP.

These findings are resonated in a meta-analysis conducted on preterm infants by King et al, who reported that NM compared to NP, was associated with reductions in failure rates [relative risk (RR) = 0.72, 95% confidence interval (CI) = 0.53-0.97], incidence of nasal injury (RR = 0.71, 95% CI = 0.59-0.85), complications like bronchopulmonary dysplasia (RR = 0.47, 95% CI = 0.23-0.95) as well as need for surfactant administration (RR = 0.78, 95% CI = 0.64-0.96). Hence, they suggested that NM should be preferred over NP for CPAP delivery in preterm infants, given the potential clinical benefit and minimal risk associated with a change in patient interface.[17] Mirroring the observations of the current study, Say et al noted that NM yielded a shorter duration of nasal CPAP (Median = two hours) in comparison to NP (Median = Four hours).[18] The

reduction in the rate of moderate-severe bronchopulmonary dysplasia was also significantly more with NM (2.7%) than with NP (14.6%) ($P < 0.01$).[18] In contrast to the current research, Goel et al and Prakash et al found NM CPAP to be as effective as NP CPAP, with no significant differences noted in their efficacy ($P > 0.05$ in both groups).[13,19] The mean duration of CPAP was 5.20 days in NM group and 4.53 days in NP group ($P > 0.05$).[13] However, the risk of nasal trauma and pulmonary interstitial emphysema was seen to be significantly lower with NM compared to NP ($P = 0.03$ for both groups).[19] Bashir et al also reported that NM CPAP significantly reduced nasal injury compared to NP CPAP ($p<0.0001$).[14] However, they concluded that the type of interface did not affect the nasal CPAP failure rates.[14] Another meta-analysis by Jasani et al reinforced the current findings by concluding that the use of NM significantly decreased CPAP failure rate (RR 0.63, CI 0.45 to 0.88) and nasal injury incidence (10%) (RR 0.41, CI 0.24 to 0.72), as compared to NP (26%).[20]

In this study the number of days CPAP required was more in NP group than NM group. Failure rate was more in NP group than NM group. The short prongs can be difficult to fit, they may get blocked these may be the reasons for failure. Nasal trauma was more in NP group than NM group because nasal prongs exert constant pressure at columella and on the anterior part of nasal septum.

Complications were more in NP group than NM group. PIE is a condition associated with respiratory distress syndrome, prematurity and assisted ventilation. In this study it was more common in nasal prongs group may be due to higher flow rate of oxygen and more duration of CPAP.

Hence, the present study establishes the superiority of NM CPAP over NP CPAP in the respiratory assistance of neonates with respiratory distress. We have to acknowledge the limitation of the study. Here the investigator and treatment team were not blinded, randomization of babies were not performed and the study was single centered, which all together could have led to bias and difficulty in generalizing the results.

Conclusions

NM CPAP is more efficacious and safer than NP CPAP for the treatment of respiratory problems in neonates.

Conflict of interest: None

Acknowledgement: None

Funding source: None

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