www.jmscr.igmpublication.org
Impact Factor 5.84
Index Copernicus Value: 83.27
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v5i5.32

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Research Articles

To Study Effectiveness of Nasal Prong and Nasal Mask in Nasal Continuous Positive Airway Pressure in Preterm Neonates with Respiratory Distress

Authors
Dr Gaurav Kumar, Dr Ajay Kumar Tiwari, Dr Amlin Shukla, Dr Manish Chopra
Department of Pediatrics, Mata Chanan Devi Hospital, C-1 Janakpuri, New Delhi, Pin- 110058
Corresponding Author
Dr Ajay Kumar Tiwari
Senior Consultant, Department of Pediatrics, Mata Chanan Devi Hospital,
C-1, Janakpuri, New Delhi, PIN- 110058
Mobile number: +919810045660 Email: *ajaytiwari06@yahoo.com*

Abstract

Objective: *To analyse whether nasal continuous positive airway pressure (NCPAP) given with nasal prongs compared with nasal mask reduces the rate of intubation and mechanical ventilation in preterm infants within 72 hours of starting therapy. To compare the effect of both kinds of NCPAP on total duration of NICU stay and the outcome in terms of discharge, death, LAMA or abscond. To compare the profile of side effects caused by both kinds of CPAP interfaces.*

Methods: *Preterm neonates weighing between 1000gms and 2500gms (at birth) fulfilling the inclusion criteria were included in this study. Both preterm neonates, who were given NCPAP as primary treatment of respiratory distress (primary candidate), and neonates who were given NCPAP post-extubation (secondary candidate) were included. The primary outcome of our study was to observe the number of patients requiring intubation and ventilation within 72 hours of starting NCPAP. Infants were intubated and ventilated if they meet 2 or more of 5 failure criteria and it were taken as failure of NCPAP method. Final outcome and total duration of hospital stay and side effects if any also compared between two study groups.*

Results: *In our study we enrolled 60 preterm neonate of birth weight between 1000gms to 2500 gms, 30 in each group of nasal prong and nasal mask. 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. Median duration (IQR) of total hospital stay was 216hrs (112.5-354) in nasal prong group whereas nasal mask group median duration (IQR) of total hospital stay was 264 hrs (186-456). There was a significant difference found in total duration of hospital stay between both interfaces as nasal prong group was better in terms of total hospital stay(P =0.036). Localised nasal complications were detected in 10 (33.3%) patients in nasal prong, while in nasal mask group they were reported in 6 (20%) patients. There was no significant difference (P=0.136).*

Conclusions: *NCPAP support in preterm newborn given with nasal mask as well as with nasal prong was found equally effective in terms of primary objective. Significant difference was found in the total duration of stay in nursery between both the groups, as in nasal prong group median duration of total stay in nursery was less in comparison to nasal mask, but there was no difference observed in terms of outcome (discharge, death and LAMA). Complications were observed in the groups, nasal prong as well as nasal mask, but there was no significant difference observed in the frequency of complications between both the groups.*

Keywords: *NCPAP, Nasal Mask, Nasal Prong, Preterm Neonate, Respiratory Distress.*

INTRODUCTION

Continuous positive airway pressure (CPAP) is a form of non-invasive ventilation that is becoming increasingly popular as a method of respiratory support in sick neonates. CPAP as the term implies, refers to the application of positive pressure to the airways of a spontaneously breathing infant throughout the respiratory cycle.

Continuous Positive Airway Pressure (CPAP) is primarily indicated for use in treating respiratory distress. CPAP was adapted for infants in the 1970's as an alternative to the more invasive mechanical ventilation [1]. Its primary function is to establish an open airway. The circuit is structured such that a continuous flow of humidified oxygen in combination with other compressed gases is delivered. The gases usually meet with the infant at the nasal area [1]. CPAP is accomplished by a variety of methods. In one of these, nasopharyngeal prongs that span from the nares to the nasopharynx are used. Due to their long length, the airway resistance is higher when compared to other methods. Additionally, they are difficult to insert. The most popular method utilizes either nasal prongs or a mask. The nasal prongs consist of short dual prongs that rest at the base of the nose. The mask covers only the nose. Masks that fit over the nose were developed many years ago[2,3] and are commonly used today. Nasal trauma has been reported with the use of both nasal masks and prongs [4,5] occurs equally often with each interface[6]. The effectiveness of NCPAP given with these interfaces has not been extensively studied in India and worldwide. Neither is there enough studies confirming the efficacy of nasal mask vs nasal prong CPAP in neonates. The present study aimed to compare the effectiveness and side effects caused by nasal mask and by nasal prong during NCPAP treatment. Our study was approved by scientific and ethical committee of our hospital.

METHODS

It was a prospective observational study, conducted in the Nursery, Department of Paediatrics, Mata Chanan Devi Hospital, New Delhi. A written informed consent was taken from the parents prior to enrolment of newborn, after explaining the study. During the study, 60 preterm newborns between birth weight 1000gms to 2500gms were enrolled and in whom we had applied CPAP as primary treatment of respiratory distress or to facilitate weaning from ventilatory support, according to inclusion and exclusion criteria on or before 28 days of postnatal age. Each newborn randomly allocated to either nasal prong or nasal mask for giving NCPAP by a computerized random number generator. There were 30 newborn in each group of nasal mask and nasal prong. Since the study was time bound, all consecutive patients meeting the eligibility criteria during the study period were enrolled. Surgical problems causing respiratory distress were excluded from the study such as congenital malformations affecting respiratory tract, congenital heart disease, persistent pulmonary hypertension, esophageal Artesia, congenital diaphragmatic hernia etc.

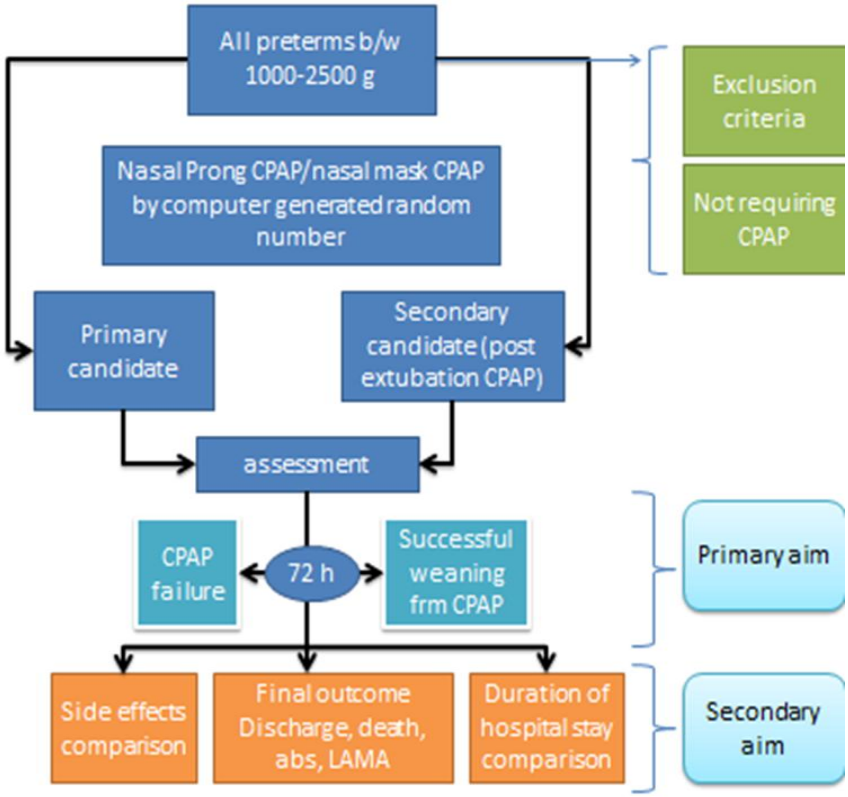
The primary outcome of the study was to observe the number of patients requiring intubation and ventilation within 72 hours of starting NCPAP. Infants were intubated and ventilated if they met 2 or more of 5 failure criteria and were viewed as having failed CPAP treatment.

FAILURE CRITERIA

1) Worsening clinical signs of respiratory distress (increasing tachypnea, expiratory grunting; intercostal, subcostal, and/or sternal recession).
2) Apnea treated with positive pressure ventilation (PPV) by mask on 2 or more occasions in 1 hour.
3) Fraction of inspired oxygen (FiO2) >0.5 to maintain pulse oxygen saturations >88% for 30 minutes.
4) PH<7.2 on 2 arterial or capillary blood gases taken 30 minute apart.

5) PaCO2 >60 mm Hg on 2 arterial or capillary blood gases taken 30 minutes apart.

We also compared the total duration of nursery stay and compared the outcome in terms of discharge, death, LAMA or abscond and side effect profile of both kinds of NCPAP methods. The data of all babies, as per criteria, was collected on a preformed and structured proforma. Respiratory rate was recorded for at least one minute. Silverman Anderson scoring was done for evaluating severity of respiratory distress, and SPO2 monitoring was done by cardiac monitor. Arterial blood gas analysis was performed before and half hour after starting NCPAP support. Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean SD or median if the data was unevenly distributed. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-square test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a P value less than 0.05 was taken to indicate a significant difference



STUDY DESIGN

RESULTS

In our study in nasal prongs group, out of the 30 cases, 26 (86.7%) were primary candidates, in which we provided NCPAP support for respiratory distress and only 4 (13.3%) cases were secondary candidates, in which we used NCPAP support to wean off ventilatory support. While in nasal mask group out of the 30 cases, 24 (80%) cases were primary candidates, and 6(20%) cases were secondary candidates.

In nasal prongs group out of 30 cases , 22 (73.3%) were male and 8 (26.7%) cases were female, while in nasal mask category 21 (70%) cases were male, and 9 (30%) cases were female. The nasal prong group comprised 19 (63.3%) neonates delivered inside the hospital while 11 (36.7%) in

this group were born outside the hospital. The mask group comprised of 22 (73.3%) patients being delivered inside the hospital while rest 8 (26.7%) were born outside. In the nasal prongs group the children delivered vaginally were 7 (23.3%), and those delivered by LSCS were 23 (76.7%). In the nasal mask group the babies delivered vaginally were 9 (30%), and those delivered by LSCS were 21 (70%). There was no use of forceps, ventouse or any other mode of deliveries.

A comparison of gestational age in the two groups reveals that there was one patient each in both the groups in 26-28 wk and 28-30 wk categories while there were 5 patients in each group in 30-32 wk category. In 32-34 wk category there were 9 patients in nasal prong group and 8 patients in nasal mask group. In 34-36 wk category there were 10 patients in nasal prong group and 9 patients in nasal mask group, 36 wk or more category had 4 patients in nasal prong group and 6 patients in nasal mask group. It was observed that in nasal prong group 46.7% of the patients weighed between 1500-2000 gms followed by 40% who weighed above 2000 gms while the rest were below 1500 gms. In nasal mask group 53.3% of the patients weighed between 1500-2000 gms followed by 26.7% who weighed above 2000 gms while the rest were below 1500 gms. These baseline features were found to be similar in both groups as there was no statistically significant difference found in these attributes between the two groups.

In nasal prong group, the mean value of SA Score before and after application of NCPAP stood at 6.73 ± 0.785 and 5.60 ± 1.250 respectively. While for nasal mask group this value was 6.60 ± 0.675 and 5.50 ± 1.009 respectively. It was found that there was no significant difference in mean SA score before and that after between nasal prong and nasal mask application (P=0.483, P=0.734 respectively), but it was observed that in nasal prong group, the mean reduction in SA score stood at 1.133 ± 0.681 while for nasal mask group, the mean reduction stood at 1.100 ± 0.803. Thus there was significant decrease in SA score within the groups (P<0.001, P<0.001) respectively. It was concluded that NCPAP support significantly causes reduction in respiratory distress with both kind of interfaces. We did not find any difference between two interfaces in the degree of reduction of SA score comparatively.

There was no statistically significant difference found in failure rate between the two groups within primary and secondary candidates. In primary candidates failure was observed in 10(38.5%) patients of nasal prong group and in 4(16.7%) patients of nasal mask group (P=0.119). Among the secondary candidates one patient each in both groups had NCPAP failure (p=1.00).

We did not find any significant difference between the final outcomes of the patient in both groups. 23 (76.7%) patients in nasal prong group were discharged, while 26 (86.7%) patients in nasal mask group were discharged. Six (20%) patient died in nasal prong group and 2 (6.7%) patient died in nasal mask group. One patient of nasal prong group and two patients of nasal mask group went LAMA. Median duration of stay on CPAP was 42.5hrs in nasal prong group and 47.25hrs in nasal mask group (P=0.181). Median duration of total stay in nursery was 216hrs in nasal prong group and 264 hrs in nasal mask group (P=0.036). Thus there was a statistically significant difference between median duration of stay in nasal mask group vs nasal prong group.

We had observed that in nasal prongs group localised nasal complications were found in 10 (33.3%) patients, with flaring of nostrils found in 8 patients and nasal septal necrosis found in 2 patients, while in nasal mask group 6 (20%) patients got localised nasal complications as nasal bridge contusion. Pneumothorax was detected in 3 (10%) patients of nasal mask group only. There was no statistically significant difference between occurrence of localized nasal complications in both groups (P = 0.371).

DISCUSSION

In our study we tried to find out the most suitable interface for applying nasal CPAP in preterm neonate in terms of effectiveness as well as safety profile. CPAP nowadays commonly used for treatment of respiratory distress, for facilitation of extubation and weaning ventilatory support, also CPAP has been recommended in neonatal resuscitation protocol for persistent cyanosis and laboured breathing after initial steps. Nasal prong and nasal mask has been commonly used for providing nasal CPAP in neonate. Recently this comparison between these two interfaces had been done by Emily A. Kieranet al [7].

In our study we found that in nasal prong group CPAP support failure was detected in 11 patients (36.7%), and in rest 19 patients (63.3%) CPAP was successful. In nasal mask group, failure was seen in 5 patients (16.7%), and in rest 25 patients there was no CPAP failure. There was no statistically significant difference with p value of 0.080. In study done by Emily A. Kieran et al [7], the investigators found that thirty-two of the 62 (52%) infants randomly assigned to nasal prong group were intubated and ventilated within 72 hours of starting NCPAP compared with 16/58 (28%) infants randomly assigned to nasal mask group (P=.007). They concluded that CPAP support with nasal mask was better than CPAP support with nasal prong, as within 72 hrs of starting CPAP support less number of patients were intubated and ventilated in nasal mask group, while in our study we did not observe any such difference between nasal mask and nasal prong group.

On comparing our study with the study done by Emily A. Kieran et al [7], we found that in our study primary candidates were 50 (83.33%) and secondary candidates were 10 (16.7%), while in their study primary candidates were 57(47.5%) and secondary candidates were 63 (52.5%), so in their study more than 50% patients were those in whom they applied CPAP to wean off ventilatory support (secondary candidate), in comparison to our study in which a majority were primary candidates. In their study failure was observed in 19(63%) out of 30 primary candidates in nasal prong group, and in nasal mask group failure was observed in 11(41%) out of 27 primary candidates. There was no statistically significant difference observed in failure frequencies between the primary candidates of the two groups with a P value of 0.088. Most common failure criterion was worsening of respiratory distress with frequency of 36.7% and 16.7% in nasal prong group and nasal mask group respectively, while second most common criteria was apnea treated with PPV in nasal prongs group, with a frequency of 26.7%, but in nasal mask group it was FiO2>50%, which was the second most common contributory factor for CPAP failure with frequency of 10.0%. This result was quite comparable with the study done by Emily A. Kieran et al[7], as they found that the most common reasons that infants reached failure criteria were clinical signs of respiratory distress and Fio2>40%.

Median duration of stay on CPAP was 42.5hrs in nasal prong group and 47.25 hrs in mask group (P=0.181). Median duration of total stay in nursery was 216 hrs in nasal prong group and 264 hrs in nasal mask group (P=0.036). Thus there was a statistically significant difference between median duration of stay in nasal mask group vs nasal prong group. Therefore, in our study we observed that applying CPAP support with nasal prong resulted in lesser duration of total stay in nursery.

We had observed that in nasal prongs group localised nasal complications were found in 10 (33.3%) patients, while in nasal mask group 6 (20%) patients got localised nasal complications. These findings were comparable with a study done by S C Yong et al[6] to compare the incidence of nasal trauma associated with mask and prong. In their study, they found presence of nasal trauma in 12 (29%) patients in nasal mask group and 17 (35%) patients in nasal prong group. In a study done by N J Robertsonet al [4], it was found that, there was a complication rate of 20%

in the babies who required CPAP support with nasal prong. But our complication rates were higher than this study, and comparable to the study done by S C Yonget al [6]. Our study agreed with a previous study that revealed that nasal trauma had been observed in a small proportion of infants with equal frequency with nasal mask and nasal prong. We also agree with other studies that revealed that trauma related to nasal prongs tends to be maximum around the medial aspect of the nasal septum and the columella, whereas trauma related to nasal masks is more often seen at the junction of the nasal septum and philtrum and at the glabella as observed in our study.

The major weakness of our study was the unblinded nature of the intervention and the consequent potential for the bias of either or both caregivers and/or outcome assessors to influence our results. Our sample size was not large as it was a time bound study.

CONCLUSIONS

Based on our results we conclude that NCPAP support was found to be an effective method for treatment of respiratory distress in a preterm neonate. CPAP support for respiratory distress in preterm newborn given with nasal mask as well as with nasal prong was found to be equally effective in terms of primary objective. There was a significant difference found in the total duration of stay in nursery between both the groups, as in nasal prong group median duration of total stay in nursery was less in comparison to nasal mask, but there was no difference observed in terms of outcome (discharge, death and LAMA). Complications were observed in the groups, nasal prong as well as nasal mask, but there was no significant difference observed in the frequency of complications between both the groups. Localised nasal complications were reported in both groups. Primary site of trauma was at the nasal bridge as contusion in the nasal mask group whereas walls of the nasal septum in the nasal prong group showed flaring of nostrils. Irrespective of the type of interface used, nasal trauma was common during NCPAP treatment.

Acknowledgements – funding none.

Disclosure - The authors declare no conflict of interest.

Author Contribution- AKT contributed to conception and design of this study. GK performed and collected the data. AKT, GK, AS and MC drafted and analysed the manuscript. AKT critically reviewed and supervised the whole study. All authors read and approved the final manuscript.

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