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Original Research Article

Comparison of nasal masks or binasal prongs for delivering continuous positive airway pressure in preterm neonates of gestational age less than 32 weeks

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ABSTRACT

Background: Aim was to compare the efficacy and safety of continuous positive airway pressure (CPAP) delivered by nasal masks vs binasal prongs.
Methods: This was observational trial where preterm infants less than 32 weeks of gestation with respiratory distress were enrolled after parental consent. Participants: 145 neonates less than 32 weeks gestation requiring nasal CPAP (NCPAP) as a primary mode for respiratory distress, who were treated with either nasal mask (n=45) or nasal prongs (n=99) as interface. Primary outcome: Was the incidence of CPAP failure (need for mechanical ventilation at less than 72 hours).
Results: Failure rate in nasal mask group was 13% vs nasal prongs group was 39.4% and the difference was statistically significant. Secondary outcomes were mean FiO_2 requirement at 6 hours, duration of CPAP therapy, hospital stay and nasal trauma. There was 3.7±5.78% reduction in oxygen requirement at 6 hours of CPAP initiation with nasal mask as compared to nasal prongs and the difference was statistically significant ($p<0.05$). the CPAP duration in nasal mask group was 3.4± 4.04 days vs nasal prongs group was 4.5±3.52 days and duration of hospital stay in nasal mask group was 15.4±14.19 vs in nasal prongs group was 20.2±13.86 and the both differences were also statistically significant($p<0.05$). Nasal mask had no nasal injury (0%) as compared to infants on nasal prongs (23.2%) and the difference was statistically significant ($p<0.05$).
Conclusions: NCPAP with mask as interface is as effective as prongs but causes less nasal trauma and less CPAP duration and hospital stay.

Keywords: Preterm, Respiratory distress, NCPAP, Mechanical ventilator, Nasal mask, Nasal prongs

INTRODUCTION

Respiratory distress syndrome (RDS) also called neonatal RDS, RDS of newborn, or increasingly surfactant deficiency disorder (SDD) and previously called hyaline membrane disease (HMD) is an acute lung disease caused by pulmonary surfactant deficiency.[1,2] It is caused by developmental insufficiency of surfactant production or structural immaturity in lungs. It can also result from a genetic problem with the production of surfactant associated protein.[3]

RDS affects 1% of new born infants and is leading cause of death in preterm infants.[4] In developed countries, RDS occurs in 60-80% of infants <28 weeks of gestational age, 25% of those born between 30 and 31 weeks and 15-30% of those born between 32 and 36 weeks.[5] Data from India is limited, hospital-based studies have shown incidence of 8.5 to 10.4% among NICU admissions.[6] One study has

shown a prevalence in India of 2, 00,000 infants per year.[7]

NCPAP is a simple, low cost and noninvasive method of ventilating a sick newborn. Bubble CPAP is the most commonly used modality for delivery of NCPAP. Traditionally, short bi-nasal prongs have remained the standard of care for delivery of NCPAP. The limitations of delivering NCPAP with prongs include 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. Nasal masks are increasing being used for delivering CPAP in recent times due to their ease of application. A randomized trial in neonates comparing nasal mask with binasal prongs showed less intubation rate within 72 hours for the treatment of RDS or in post extubation setting with nasal mask.

Figure 1: Different sizes of nasal mask (left side) and nasal prongs (right side).

Aims and objectives

The objective of this study was to compare the efficacy and safety of CPAP delivered using nasal masks with binasal prongs.

Primary outcome measures: Need for intubation and mechanical ventilation at 72 hours of life (Failure of the primary modality of treatment).

Secondary outcome measures: FiO_2 at 6 hours, duration of CPAP, duration of hospitalization and nasal trauma incidence

METHODS

The study was conducted at level neonatal intensive care unit of department of pediatrics GS medical college and hospital Pilakhwa Hapur, Uttar Pradesh, a tertiary care hospital in northern India between December 2020 to march 2022, after taking the ethical clearance from institutional ethical committee. This was observational trial where preterm infants less than 32 weeks of gestation with respiratory distress were enrolled after parental consent. These neonates were put on nasal CPAP immediately after birth. NCPAP was given either by nasal prong or by nasal mask. NCPAP was given by Fisher and Paykel Nasal CPAP (BC161, New Zealand and UK) which includes a source of gas flow (6-8 L/min), an air oxygen blender (Biomed Devices Blender, USA), humidifier (MR 410, Fisher and Paykel health care, New Zealand), a respiratory circuit and expiratory hose inserted in a bottle of water. CPAP level delivered is equivalent to the distance that the distal end of expiratory tubing is under water (when sub merged to 5 cm of water gives a CPAP of 5 cm of water). Subjects in the CPAP group were initiated on 5 cm of water and flow 6-7 litres/min. The maximum permissible settings were CPAP 7 cm and fraction of inspired oxygen (FiO_2) 0.6 targeted saturation was 91-93%. Nasal CPAP was given either by nasal prong or nasal mask. Infants in the mask group were delivered NCPAP using Fisher and Paykel infant nasal mask in small (BC800), medium (BC801) and large (BC802) sizes based on best estimate using the nasal mask scale provided by the company. Masks were connected to Fisher and Paykel 'bubble CPAP system'(BC151) using Fisher and Paykel 'flexi trunk midline interface' (BC191-70 mm) and appropriately sized 'Infant Bonnet' depending on head circumference (BC300-small, BC303-medium, BC306-large). Infants in the Prong group were delivered NCPAP using appropriately sized Hudson RCI infant nasal prong CPAP cannula system (size 0 and 1). The prongs were connected to Fisher and Paykel 'bubble CPAP system'(BC151) directly using pins and rubber bands over appropriately sized bonnet provided with the Hudson Nasal prong CPAP cannula system.

Those infants who did not maintained on nCPAP was given surfactant if they met any of the following criteria:[8] A fraction of inspired oxygen (FiO_2) greater than 0.50 with gestational age less than 26 weeks and greater than 0.60 with gestation age more than 26 weeks required for maintaining an indicated saturation of peripheral oxygen (SpO_2) at or above 87% for 1 hour. Arterial $PaCO_2$ greater than 65 mm Hg, documented by a single measurement of blood gases within one hour. Hemodynamic instability, defined as a blood pressure that was low for gestational age, poor perfusion, or both, requiring volume or pressor support for a period of 4 hours or more.

Surfactant if needed was delivered by ensure technique (intubation-surfactant-extubation) followed by CPAP or mechanical ventilation as per the need.

Inclusion criteria

Preterm infants less than 32 weeks of gestation were included in the study. RDS was diagnosed by classical symptoms such as need for oxygen supplementation, tachypnea, inter costal retractions and grunting and exclusion of other causes of respiratory failure

supplemented by typical radiographic pattern with reduced air content and a reticulogranular pattern of lung and air bronchograms. Gestational age was calculated by prenatal ultrasonography, expected date of delivery, last menstrual period and new Ballard score.[9]

Exclusion criteria

Infants with following conditions were excluded: Structural cyanotic congenital heart diseases, severe congenital malformations including congenital diaphragmatic hernia, tracheoesophageal fistula, cleft lip and palate. Pulmonary hypoplasia, pneumothorax, severe intraventricular hemorrhage

CPAP protocols

Infants were started on CPAP of 4-6 cm H_2O and FiO_2 of 0.3. Subsequently CPAP and FiO_2 were adjusted to maintain SPO_2 between 87-93% and PO_2 between 60-80torr. CPAP was considered successful if there was no deterioration and infant maintains saturation between 91-93%. CPAP was increased in steps of 1 cm of H_2O up to 8cm of H_2O if saturation didn't improve, FiO2 Was increased in steps of 0.05-0.1 up to 0.6.

Criteria for mechanical ventilation following failure of CPAP

Mechanical ventilation was considered for failure of CPAP i.e. in babies with PaO_2<50 mmHg or PcO_2> 60 mmHg, pH <7.25 with FiO_2> 0.6 or those with clinical deterioration including severe retraction on CPAP>7 cm or prolonged (>20 seconds) or recurrent apneas (>2 episodes within 24 hour associated with bradycardia or desaturation) requiring bag and mask ventilation.

Criteria for weaning off from ventilator

Weaning strategies for CPAP was absence of respiratory distress (minimal or no retractions and respiratory rate<60 per minute), SpO_2>90% on FiO_2<40% and PEEP <5 cm of water.

NICU care

Careful temperature control was provided in all infants to minimize metabolic demands and oxygen consumption. An incubator or radiant warmer was utilized to maintain a thermo neutral environment. Nasal toilet was provided every 4 hourly and the nursing staff evaluated for nasal trauma daily in each shift. Nasal trauma was classified at point of CPAP removal as: Mild trauma: erythema/tenderness; Moderate trauma-excoriation/crusting/bleeding; and Severe trauma-narrowing of the passage. Repositioning of the interface and external massage was given for mildnasal trauma. Mupirocin ointment was applied for moderate/severe trauma to prevent it from further worsening. Saturation by pulse oximetery, respiratory rate and heart rate were continuously monitored; mean airway pressure (MAP) recorded at each change in ventilatory settings; blood pressure measured at least every 6 h; abdominal girth measured prefeed and at least every 6 h; ABG was performed after 30 min of starting respiratory support; then, at least every 6 h in first 24 h and every 8 h in next 24 h and as indicated. Neonates received prophylactic caffeine if the birth weight was 1000 gm. Hematocrit was maintained >35% if MAP was >6 cm of water or FiO_2>35%; and maintained >30% if MAP was <6 cm or FiO_2<35%.

Statistical methods

The recorded data was compiled and entered in a spreadsheet (Microsoft excel) and then exported to data editor of SPSS version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were summarized in the form of means and standard deviations and categorical variables were expressed as frequencies and percentages. Graphically the data was presented by bar and pie diagrams. Student's independent t test was employed for comparing continuous variables. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparing categorical variables. A p value of less than 0.05 was considered statistically significant. All p values were two tailed.

RESULTS

A total of 145 preterm infants less than 32 weeks of gestational age were enrolled in the study over a period of 18 months.

Distribution of study on the basis of nasal mask/prongs

Nasal masks were used in 31.7% of patients (46/145) and Nasal prongs were used in 68.3% of patients (99/145) (Table 1). Table 2 showing various basic characters in 2 groups.

Table 1: Distribution of study patients on the basis of nasal mask/prongs.

Variables	N	Percentage (%)
Nasal mask	46	31.7
Nasal prongs	99	68.3
Total	145	100

Success rate of nasal masks and nasal prongs in cpap group

There was 87.0% success rate in patients in whom nasal masks were used i.e. 6 out of 46 patients required mechanical ventilation while there was 60.6% success rate in patients where nasal prongs were used i.e. 39 out of 99 patients required mechanical ventilation and the difference was statistically significant (p=0.002).The mean FiO_2 at 6 hours in nasal mask group was 33.9 versus 37.6 in patients where nasal prongs were used and

the difference was statistically significant (p<0.001) (Table 3).

Table 2: Baseline characteristic of 2 groups.

Baseline characteristic	Nasal prongs, (n=99)	Nasal mask, (n=46)
Gestational age (in weeks)	30.1	29.7
Birth weight (in grams)	1602	1553
Females, N (%)	49 (49%)	22 (48%)
Apgar score (5 minutes)	7.53	7.50
Age at respiratory support (hours)	2.14	2.57
Downes score	5.01	5.05
Resuscitation (N)	3	2
PROM (N)	10	7

FIO_2 at six hours, duration of CPAP and duration of hospital stay

The mean FiO_2 at six hours in nasal mask group was 33.9 versus 37.6 in patients where nasal prongs were used and the difference was statistically significant (p<0.001). The mean duration of CPAP in nasal mask group was 3.4 days while in nasal prongs group the mean duration of CPAP was 4.5 days and the difference was statistically significant (p=0.017). The mean duration of hospital stay in nasal mask group of patients was 15.4 days versus 20.2 days of hospital stay in nasal prongs group of patients and the difference was statistically significant (p=0.041) (Table 4).

Table 3: Success rate of nasal mask/prongs in CPAP group.

Variables	N	MV requirement	Success rate	P value
Nasal mask	46	6	87.0	0.002
Nasal prongs	99	39	60.6	

*Statistically significant difference (p<0.05)

The columella necrosis

None of patients in nasal mask group developed columella necrosis while 23.2% (23/99) patients of nasal prongs group developed columella necrosis and difference statistically significant (p<0.001) (Table 5).

Table 4: FiO_2 at 6 hours, CPAP duration and hospital stay (days) as per nasal mask/prongs in CPAP group.

Parameters	Nasal mask		Nasal prongs		P value
	Mean	SD	Mean	SD	
FiO_2 at 6 hours	33.9	5.26	37.6	11.04	<0.001*
CPAP duration (days)	3.4	4.04	4.5	3.52	0.017*
Hospital stays (days)	15.4	14.19	20.2	13.86	0.041*

*Statistically significant difference (p<0.05).

Table 5: Columella necrosis as per nasal mask/prongs in CPAP group.

Columella necrosis	Nasal mask		Nasal prongs		P value
	N	%	N	%	
Yes	0	0.0	23	23.2	<0.001*
No	46	100.0	76	76.8	
Total	46	100.0	99	100	

*Statistically significant difference (p<0.05).

DISCUSSION

In our study in CPAP group enrolled infants received either nasal mask or nasal prongs as a mode of NCPAP delivery interface. The 31.7% received nasal mask and 68.3% received nasal prongs.

Nasal mask was successful in 87% patients and nasal prongs in 60.6% and the difference was statistically significant (p=0.002). Failure rate in nasal mask group was 13% vs nasal prongs group was 39.4% and the difference was statistically significant. Failure of CPAP was defined need for intubation and mechanical ventilation in <72 hrs. In the study by Kieran et al failure of CPAP in nasal mask group was seen in 16.1% vs in nasal prongs group was seen in 57.1% and the difference statistically significant (p=0.007) similar to our study.[10] Similar results were seen the study by Chandrasekaran, et al CPAP failure was seen in 13% infants on nasal mask and in 25% infants on nasal prongs, but failed to reach statistical significance (p=0.15).[11] Our overall CPAP failure rate was comparable to the previously done studies.[12,13]

In our study there was 3.7±5.78% reduction in oxygen requirement at 6 hours of CPAP initiation with nasal mask as compared to nasal prongs and the difference was statistically significant (p<0.001). In a recent RCT from

India, Chandrasekaran et al reported a 6% reduction in the oxygen requirement at 2 hours of CPAP initiation with nasal mask as compared to nasal prongs, similar to our study.[11]

In our study the CPAP duration in nasal mask group was 3.4±4.04 days vs nasal prongs group was 4.5±3.52 days and the difference were statistically significant (p=0.017). The duration of hospital stay in nasal mask group was 15.4±14.19 vs in nasal prongs group was 20.2±13.86 and the difference was also statistically significant (p=0.041). Similar results were seen in RCT study by Chandrasekaran et al although in CPAP duration (in days) (6.1 (3.0) VS 5.3 (2.3), RR (95 % CI) 1.15 (0.97-1.37), p=0.09) and hospital stay duration (in days) (22 (15,27) VS 19 (15,28) RR (95% CI) 1.08 (0.65-1.77), p=0.95) was not statistically significant in two groups but duration of CPAP and hospital stay was decreased in CPAP initiation with nasal mask as compared to nasal prongs.[11]

In our study infants on nasal mask had no nasal injury (0%) as compared to infants on nasal prongs (23.2%) and the difference was statistically significant (p<0.001). Similar results were seen in RCT study by Chandrasekaran et al infants on nasal mask had no nasal injury as compared to infants on nasal prongs (0% vs 31.3%; p<0.01).[11] Similar results were seen in previous study.[14]

The major limitation of our study was it has potential for bias in particular with assessment of nasal trauma due to the very nature of the intervention. Another limitation of our study was it being a single center study, as NCPAP failure rates may vary in other units.

CONCLUSION

In preterm neonates less than 32 weeks, CPAP by nasal mask appears to be as efficacious as that by binasal prongs in terms of oxygen requirement in the first 6 h of initiation of CPAP. Use of masks may be associated with lower risk of nasal trauma; less hospital stays duration and CPAP duration.

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