

A COMPARATIVE STUDY OF NASAL PRONGS AND FACEMASKS FOR PROVIDING NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE AMONG NEWBORNS SUFFERING FROM RESPIRATORY DISTRESS SYNDROME IN A TERTIARY CARE CENTRE

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ABSTRACT

A study comparing the efficacy of nasal masks and prongs and adverse effect associated with them. A randomized controlled trial was conducted in the neonatal intensive care unit of Burdwan Medical College in between January 2016 to June 2017. 352 newborns were taken and divided into two groups- A (received CPAP with prongs) and B (received CPAP with masks). Shapiro Wilk test, Chi square test, Student t test, Mann Whitney U test, Pearson's product moment correlation and binary logistic regression were used. $P < 0.05$ was taken as statistically significant. Mean age of study population was 29.5 ± 3.2 weeks and mean birth weight was 1.417 ± 0.214 kg. CPAP failure, duration of CPAP, duration of oxygen dependency, hospital stay and mortality were significantly less among mask group. Complications and nasal injury were higher among the prong group.

KEYWORDS: Nasal Prong, Face Mask, NCPAP, RDS

Nasal continuous airway pressure (nCPAP) is an effective mode of therapy in all newborns suffering from respiratory distress irrespective of cause (Morley *et al.*, 2008). If it is started early in the labour room, it will reduce the need of mechanical ventilation and complication associated with it (Davis and Henderson-Smart, 2003). nCPAP failure occurs in nearly $1/4^{\text{th}}$ of newborn supported by it (Hough *et al.*, 2012). Apart from neonatal conditions, nCPAP is also found useful in infantile age group for treatment of bronchiolitis. It is also useful for making extubation easier (Sandri *et al.*, 2010). Long term endotracheal intubation is associated with different complications like subglottic stenosis, bronchopulmonary dysplasia etc. (De Paoli *et al.*, 2002). Hence use of nCPAP is gradually rising in the neonatal intensive care units (NICU). Literature suggests that use of CPAP increased from 60% at early part of this century to more than 80% in 2015 (Rojas *et al.*, 2009). Nasal prongs are most commonly used interfaces for delivering CPAP. Few authors already reported injuries (septal and collumelar) associated with use of CPAP & such incidents are increasing gradually (Robertson *et al.*, 1996) (Fischer *et al.*, 2010). It is also difficult to maintain the position of nasal prongs. These injuries may be extranasal which are identified by meticulous examination using overhead lighting & intranasal which were identified by endoscopy. Intranasal injuries are more grievous, because the newborns are obligatory nasal breathers. Use of facemask is now increasing because of ease of use (Kieran *et al.*, 2011). Very few studies were found regarding comparison of nasal

prongs & facemask for delivery of CPAP. A randomized trial revealed lesser intubation with nasal mask in comparison to binasal prongs (Kieran *et al.*, 2011). Two other studies from Northern part of India revealed less oxygen requirement and less CPAP failure when facemasks are used in comparison to nasal prongs (Chandrasekaran *et al.*, 2014) (Goel *et al.*, 2015). Results of them are also not confirmatory because of small sample size.

Hence this study was conducted to find out the efficacy of nasal prongs and facemasks for delivering CPAP & adverse effects associated with use of both.

MATERIALS AND METHODS

A randomized control trial was conducted in the Neonatal Intensive Care Unit of Burdwan Medical College in between January 2016 to June 2017 after taking necessary permission from Institution Ethics Committee (IEC). All the newborns admitted in the NICU in the above-mentioned time-period with respiratory distress syndrome (identified by clinical and radiological examination) and required nCPAP were included in our study. (CPAP was administered when Downe's score > 3). Those who have major congenital anomalies, critically ill and likely to be expired by clinical judgment and parents of whom denied consent were excluded from the study. 377 newborns were admitted with respiratory distress syndrome requiring CPAP in the mentioned time-period. 25 were excluded from the study. (9-congenital anomaly, 8- parents denied consent, 8-critically ill and likely to be expired) So, 352

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newborn constitute our study population and complete enumeration method is thus followed. But the sample size is appropriate enough to assure 80% power and 95% confidence level of study. They were divided into two groups. Group A received CPAP by nasal prongs (appropriate size prongs made by Fisher and Paykel Healthcare Ltd.) and group B received the same by facemask (appropriate size masks made by Fisher and Paykel Healthcare Ltd.). Randomization was done by using computer-generated randomized number and using sealed opaque envelopes. But blinding cannot be possible because of the nature of study. Data were collected by pre-designed, pre-tested schedule by trained personnel, mainly the resident doctors. Newborns were examined in follow-up to look for development of any extranasal/intranasal complications. Nasal examination was done by otolaryngologists using overhead lighting and endoscopy, if required. All newborns during the study received appropriate nursing care, surfactant and caffeine citrate. F_iO_2 and PEEP were regulated in such a way that SpO_2 is maintained between 88%-93%.

CPAP failure (Kieran *et al.*, 2011) was defined as requirement of intubation/ventilation due to:-

- Worsening of clinical signs of respiratory distress
- Apnea needing positive pressure ventilation ≥ 2 episodes in one hour
- $F_iO_2 > 0.60$ for maintaining $SpO_2 > 88\%$ for 30 minutes
- $pH < 7.2$ on two arterial blood gas (ABG) done 30 minute apart
- $pCO_2 > 60$ mm Hg on two ABGs done 30 minutes apart

Patent ductus arteriosus (PDA) and intraventricular hemorrhage (IVH) were diagnosed by echocardiography and ultrasonography respectively (Papile *et al.*, 1978). Bronchopulmonary dysplasia (BPD) was diagnosed according to National Institute of Health definition (Bancalari and Jobe, 2001). International classification of retinopathy of prematurity (ROP) and modified Bell's criteria were used for diagnosing ROP and Necrotizing Enterocolitis (NEC) respectively (Kliegman and Walsh, 1987) (International Committee for the Classification of Retinopathy of Prematurity, 2005).

Collected data were entered into MS excel worksheet after double-checking (Microsoft, Redwoods, US) Shapiro-Wilk test was used for checking the skewness

of data. Categorical data were expressed in proportion, whereas Mean & standard deviation were used for normally distributed data. For expression of skewed data median and interquartile range was used. Chi-square test was used to check association between variables in contingency tables. Student's t test & Mann Whitney U test were used for checking the significance of difference between two means & medians respectively. Pearson's product moment correlation coefficient was used for calculating the degree and direction of relationship between two variables. Finally a binary logistic regression model was used for calculating the adjusted odds ratio. $P < 0.05$ was taken as statistically significant. Data were analyzed using SPSS software version 19.0. (Statistical Packages for the Social Sciences Inc., Chicago, US).

RESULTS

A total 352 newborns were included in our study with a mean gestational age of 29.5 ± 3.2 weeks and mean birth weight of 1.417 ± 0.214 kg. There were no significant difference between group A and group B in terms of gestational age, birth weight, sex, mode of delivery, receiving antenatal steroids, APGAR score at 5th minutes, receiving of surfactant and risk factors of sepsis. (Table 1)

Proportion of CPAP failure was significantly higher among group A than group B. (33.0% vs 23.3%) Mean duration of CPAP (14.1 ± 2.2 days vs 9.2 ± 2.3 days) & requirement of supplementary oxygen (9.3 ± 0.7 days vs 7.8 ± 0.5 days) were also significantly higher among group A. Oral/ nasogastric feed can be started early in group B (7.7 ± 1.6 days vs 9.8 ± 2.1 days, $P < 0.05$) & they also achieved full oral feed early (11.2 ± 2.3 days vs 14.5 ± 2.7 days, $P < 0.05$). Mean hospital stay was also significantly lower among the newborns of group B. (18.7 ± 2.9 days vs 21.2 ± 2.5 days, $P < 0.05$) Mortality was also higher among newborns of group A, but not significant statistically. (11.9% vs 8.0%, $P > 0.05$) (Table 2) Use of nasal prong is significantly and positively correlated with CPAP failure ($r = 0.73$), duration of CPAP ($r = 0.72$), duration of supplemental oxygen ($r = 0.79$), time taken to start oral feed ($r = 0.67$), time taken to achieve full feed ($r = 0.70$) & hospital stay ($r = 0.58$). Risk of CPAP failure is 2.9 times (95% CI: 2.2-3.6) more among newborns of group A. Duration of CPAP for > 14 days & requirement of supplemental oxygen for > 7 days is 3.6 times (95% CI: 2.8-4.4) & 2.3 times (95% CI: 1.9-2.8) more common among newborns of group A.

Starting of feed after 7 days & achievement of full oral/nasogastric feed after 14 days is 3.7 (95% CI: 3.0-4.3) & 5.9 (95% CI: 4.9-7.0) times more common among members of group A. Newborns of group A were also 4.6 times (95% CI: 4.2-5.1) more likely to stay in hospital for more than 14 days.

Incidence of nasal injury (27.3% vs 12.5%, $P=0.005$), pulmonary air leak syndrome (17.6% vs 6.8%, $P<0.05$), retinopathy of prematurity (17.6% vs 9.7%, $P=0.03$), bronchopulmonary dysplasia (26.1% vs 12.5%, $P=0.001$) and necrotizing enterocolitis (7.4% vs 2.3%,

$P=0.03$) were significantly higher among newborns of group A. Incidence of late-onset sepsis (6.3% vs 5.1%, $P=0.64$), patent ductus arteriosus (6.3% vs 3.4%, $P=0.21$) and intraventricular hemorrhage (5.1% vs 4.0%, $P=0.60$) were higher among members of group A but, this difference was not significant statistically. (Table 3) Use of nasal prongs were significantly and positively correlated with nasal injury ($r=0.76$) and bronchopulmonary dysplasia ($r=0.72$). Newborns of group A were 3.5 times (95% CI: 3.1-4.0) & 4.1 times (95% CI: 3.0-5.1) more likely to suffer from nasal injury and bronchopulmonary dysplasia respectively.

Table 1: Baseline characteristics of group A and group B (n=352)

Variables	Group A	Group B	Significance
Gestational age* (week)	29.3±3.2	29.7±3.1	Student's $t=1.2$, $P=0.23$
Birth weight*(kg)	1.410±0.212	1.425±0.217	Student's $t=0.67$, $P=0.51$
Sex:#			
Male	92 (52.3)	91 (51.7)	$\chi^2=0.01$
Female	84 (41.7)	85 (48.3)	$P=0.91$
Mode of delivery:#			
NVD	101 (57.4)	104 (59.1)	
AVD	3 (1.7)	2 (1.1)	$\chi^2=0.27$
CS	72 (40.9)	70 (39.8)	$P=0.87$
Antenatal Steroid:#			
Given	172 (97.7)	171 (97.2)	$\chi^2=0.11$
Not Given	4 (2.3)	5 (2.8)	$P=0.74$
APGAR score at 5 minute ^S	9 (7-9)	9 (7-9)	Z score=1.57, $P=0.14$
Downe's score*	5.7±1.3	5.5±1.2	Student's $t=1.4$ $P=0.13$
Surfactant#			
Administered	153 (86.9)	155 (88.1)	$\chi^2=0.10$
Not administered	23 (13.1)	21 (11.9)	$P=0.74$
Risk factors of sepsis#			
Present	25 (14.2)	29 (16.5)	$\chi^2=0.35$
Absent	151 (85.8)	147 (83.5)	$P=0.55$
*Mean± SD, #No(Percent), \$ Median (Interquartile range), NVD-Normal vaginal delivery, AVD- Assisted vaginal delivery, CS- Cesarean section			

Table 2: Efficacy of nasal prongs and masks in delivering CPAP (n=352)

Variables	Group A	Group B	Significance
CPAP Failure [#]	58(33.0%)	41 (23.3%)	$\chi^2 = 4.06$, P=0.04
Duration of CPAP* (day)	14.1±2.2	9.2±2.3	Student's t=20.4, P<0.05
Duration of oxygen*	9.3±0.7	7.8±0.5	Student's t=23.1, P<0.05
Time to start feed*	9.8±2.1	7.7±1.6	Student's t=10.5, P<0.05
Time to achieve full feed*	14.5±2.7	11.2±2.3	Student's t=12.1, P<0.05
Hospital stay* (day)	21.2±2.5	18.7±2.9	Student's t=8.66, P<0.05
Mortality [#]	21 (11.9%)	14(8.0%)	$\chi^2 = 1.55$, P=0.21
*Mean±SD		# No (Percent)	

Table 3: Complications observed in group A and group B (n=352)

Variables	Group A	Group B	Significance
Nasal Injury	48 (27.3%)	22 (12.5%)	$\chi^2 = 12.05$, P=0.0015
Pulmonary Air Leak	31(17.6%)	12(6.8%)	$\chi^2 = 9.56$, P<0.05
BPD	46 (26.1%)	22(12.5%)	$\chi^2 = 5.0$, P=0.001
NEC	13 (7.4%)	4 (2.3%)	$\chi^2 = 5.0$, P=0.03
ROP	31(17.6%)	17(9.7%)	$\chi^2 = 4.7$, P=0.03
IVH	9(5.1%)	7 (4.0%)	$\chi^2 = 0.26$, P=0.60
PDA	11 (6.3%)	6 (3.4%)	$\chi^2 = 1.55$, P=0.21
LOS	11 (6.3%)	9 (5.1%)	$\chi^2 = 0.212$, P=0.64

DISCUSSION

In our study we found less CPAP failure, less hospital stay and less mortality among mask group. Complications were also less among them compared to nasal prongs. In our study we found CPAP failure rate was 33.0% 23.3% in nasal prong and nasal mask group, respectively. This rate is comparable to other similar kind of studies. Goel *et al.*, also observed a lesser failure rate when facemasks are used, but they failed to achieve statistical significance. But Kieran *et al.*, noted that CPAP failure rate is significantly higher among newborns in whom prongs are used (Papile *et al.*, 1978). Similar to us, Goel *et al.*, also noted a decrease in hospital stay, oxygen dependency and mortality among newborn of mask group, but their result was not significant statistically. We found

that incidence of nasal injury, pulmonary air leak, BPD, NEC, ROP, PDA, IVH and LOS was higher in prong group. But out of them only the first five were significant statistically. Smilar finding was noted by Kieran *et al.* But their result was not significant statistically. Goel *et al.*, also noticed the same except they observed higher incidence of BPD among mask group. But their result was also not significant.

We can conclude that nasal mask is better than nasal prongs because it is associated with less CPAP failure and less trauma. This is because of decrease in diameter of nasal cavity by nasal prongs which increase the resistance and pressure delivered to airway. Major limitation of the study is lack of blinding that may lead to bias. We used bubble CPAP in our study thus our findings will be better

reflected in resource-limited settings and should not be generalized. Further studies, preferably multicentric studies should be undertaken.

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