



COMPERATIVE SUDY OF OUTCOME OF HIGH FLOW NASAL VIA NASALMASK IN PRETERM NEONATES WITH NON INVASIVE POSITIVE PRESSURE VENTILATION IN PATIENT WITH RESPIRATORY DISTRESS SYNDROME

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ABSTRACT

Introduction: 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. 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. Nasal CPAP is the standard respiratory therapy for preterm neonates with respiratory distress. Respiratory support in the neonatal intensive care unit (NICU) is a mainstay to reduce complications of invasive mechanical ventilation. Nasal Continuous 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.

Objective: To compare effectiveness of NIPPV and CPAP WITH NASAL MASK in reducing the need for higher respiratory support when applied as a non-invasive respiratory support mode for preterm neonates with respiratory distress syndrome.

Methodology: This study is observational study where effectiveness in income of both group Noninvasive positive pressure ventilation NIPPV and Group cpap with nasal mask was compared 100 patiens (50 in each groups) which am included in study according to inclusion criteria.

Results: NIPPV appears to have similar efficacy as CPAP WITH NASAL MASK when applied as a primary mode of respiratory support in preterm with respiratory distress syndrome. NIPPV cases less nasal trauma then CPAP WITH NASAL MASK. So, NIPPV appears to be as effective as CPAP WITH NASAL MASK an invasive modality of respiratory support in neonates.

KEYWORDS : NIPPV, CPAP WITH NASAL MASK, RDS.

INTRODUCTION

Respiratory Distress Syndrome (RDS) is common in preterm newborn infants. The pathogenesis of RDS in very preterm infants is multifactorial, but ventilator induced lung injury plays a major contributing role. In the recent years, there is a growing trend toward avoidance of intubation and mechanical ventilation for preterm neonates, which may reduce lung injury in preterm infants. The primary supportive treatment in patients who are hypoxemic is oxygen therapy, which is commonly delivered by using nasal prongs or masks. New devices have recently been made available to deliver oxygen via Noninvasive positive pressure ventilation (NIPPV). NIPPV delivers heated and humidified gas up to 60 L/min, with an FIO₂ that ranges from 0.21 to 1.0 via a wide-bore soft nasal prong. In a healthy patient during spontaneous unassisted breathing, end expiratory pharyngeal pressure is 0.3 and 0.8 cm H₂O with open and closed mouth respectively. Compared with unassisted spontaneous breathing, NIPPV generates greater pharyngeal pressure during expiration, whereas, in the course of inspiration, it drops to zero, which limits the effectiveness of NIPPV in patients with lung edema and/or collapse. By recruiting atelectatic regions, reducing venous admixture, and decreasing the inspiratory effort, CPAP is likely more effective in these instances. Compared with noninvasive ventilation by application of inspiratory pressure support, CPAP offers several advantages, which include ease of use and lack of patient-ventilator asynchrony. CPAP may be applied either through a mask or a helmet. The latter is better tolerated than face masks and allows more continuous CPAP application. When applying CPAP by using a MASK, however, heating and humidification of the inhaled gas is problematic because of condensation of water inside the interface, the so called fog effect. Therefore, this study was conducted to compare the efficacy and safety of NIPPV and nasal CPAP in respiratory support after surfactant administration in preterm newborn infants with respiratory distress syndrome.

Objectives

- To compare effectiveness of NIPPV and CPAP WITH NASALMASK in reducing the need for higher respiratory support when applied as a non-invasive respiratory support mode for preterm neonates with respiratory distress syndrome
- To evaluate incidence and severity of nasal injury by Noninvasive positive pressure ventilation and nasal Continuous positive airway pressure mask.

MATERIAL AND METHOD

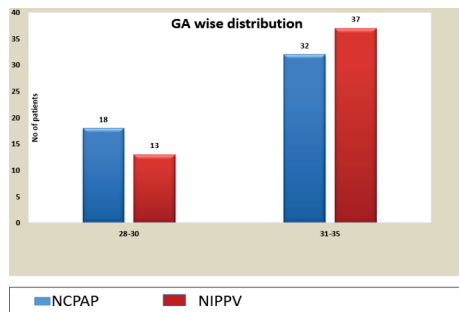
A hospital based prospective randomized control trial was conducted in pediatric department. Study population is all inside born preterm neonate of <37 week. Preterm infant with gestation < 37 weeks with RDS within the first 6 hours of birth are included in study population while Patients with perinatal depression (5-minute Apgar score of <3), major malformations and intubated at admission to the NICU and Patients with meconium stained liquor are excluded from study. Informed written consent was obtained from parents at admission at NICU. Neonates with onset of respiratory distress in the delivery room will be transferred to the NICU on a T piece RESUSCITATOR and randomization to Noninvasive positive pressure ventilation or nasal mask will be done at admission to NICU by random number sequence generator (www.randomization.com). Separate person not involved in the study generated the random sequence. Each patient was eligible for 1 randomization at enrolment (1:1 allocation for CPAP with nasal mask and NIPPV). Each patient will be eligible for 1 randomization at enrolment (1:1 allocation for mask vs. Cannula). The nature of the intervention was prevent us from blinding of the intervention from the investigators as well as the treating team. Attempts were made to minimize the bias by maintaining a strict study protocol. A protocol for titration, weaning and removal of respiratory support was uniform in both groups. The gas delivered in both the devices was heated

and humidified to attain a gas temperature of 37-degree C at the level of the nostrils. The humidifier used in both the groups had a flow-based servo-humidification control mechanism to ensure appropriate humidification.

RESULTS

In present study due to gender of babies wise distribution, it was found that male were predominantly higher in both group as 26(56%) vs 36(72%) then female 22(44%) vs 14(28%) with no any statically significance found between both group CPAP with nasal mask and group NIPPV respectively (P=0.0955)

GENDER	GROUP CPAP WITH NASAL MASK (n=50)	GROUP NIPPV (n=50)
MALE	25(56%)	36(72%)
FEMALE	22(44%)	14(28%)
TOTAL	50(100%)	50(100%)
Pvalue	0.095	



In the present study, due to gestational age wise distribution, it was found that higher of the GA were found of 31-35 weeks in (32 (64%) vs 37 (74%)) both the group NCPAP and Group NIPPV. Moreover, there was no any statistically significant found (31.04 ± 1.67 weeks vs 31.46 ± 1.65 weeks: p=0.2089) between both the group NCPAP and Group NIPPV

MODE	Group NCPAP (n=50)	Group NIPPV (n=50)
LSCS	34 (68%)	36 (72%)
Vaginal	16 (32%)	14 (28%)
Total	50 (100%)	50 (100%)
P value	0.6629	

In the present study, due to mode of delivery wise distribution, it was found that most of the patients have LSCS as (34 (68%) vs 36 (72%)) then normal vaginal delivery (16(32%) vs 14 (28%)) with no any statistically significance found between both the group NCPAP and Group NIPPV. (p=0.6629)

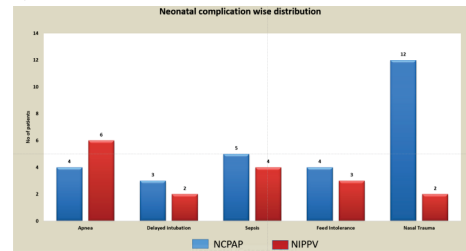
Baseline Characteristics For Infant

Baseline characteristics	Group NCPAP (n=50)	Group NIPPV (n=50)	P value
Silverman Anderson Score	4.48 ± 0.50	4.45 ± 0.53	0.3342
Antenatal Steroid	6 (12%)	5 (10%)	0.7494
Resuscitated at birth	20 (40%)	18 (36%)	0.6801
Surfactant administered	16 (32%)	15 (30%)	0.8283
Days of NIV	3.46 ± 1.16	3.74 ± 1.19	0.2364

In the present study, baseline characteristics such as Silverman Anderson Score (4.48 ± 0.50 vs 4.45 ± 0.53; p=0.3342), Antenatal Steroid (6(12%) vs 5(10%);p=0.7494), Resuscitated at birth (20(40%) vs 18(36%);p=0.6801), Surfactant administered (16 (32%) vs 15 (30%); p=0.8283), Days of NIV (3.46 ± 1.16 vs 3.74 ± 1.19;p=0.2364) with no any statistically significance found between both the group NCPAP and Group NIPPV respectively.

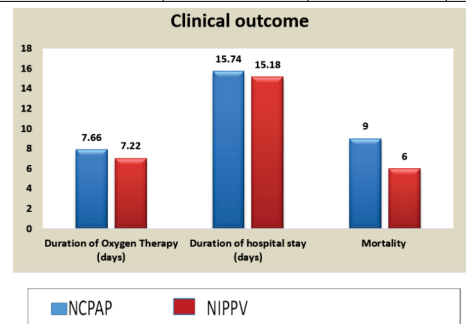
In the present study, due to complication of infant, it was found that nasal trauma was found significantly higher in group

NCPAP as 12 (24%) patients then group NIPPV 2 (4%) patients.(p=0.0039) whereas other complication such as Apnea(4 (12%) vs 6 (12%)), Delayed intubation (3 (6%) vs 2 (4%)),Sepsis (5 (10%) vs 4 (8%)), Feed Intolerance (4 (8%) vs 3 (6%)) of the both groups were mentioned in table above. (p>0.05)



Clinical Outcome Of Infant

Clinical outcome	Group NCPAP (n=50)	Group NIPPV (n=50)	P value
Duration of Oxygen Therapy (days)	7.66 ± 1.31	7.22 ± 1.31	0.0963
Duration of hospital stay (days)	15.74 ± 2.11	15.18 ± 2.02	0.1783
Mortality	9 (18%)	6 (12%)	0.4007



In the present study, clinical outcome of infant, it was found that Duration of Oxygen Therapy (days) was higher in mean days as 7.66 ± 1.31 in group CPAP compared to group NIPPV (7.22 ± 1.31 days) but statistically significant. (p=0.0963). In addition, duration of hospital stay (15.74 ± 2.11 days vs 15.18 ± 2.02;p=0.1783) and mortality (9 (18%) vs 6 (12%); p=0.4007) was no more effective in both the group.

DISCUSSION

CPAP WITH NASAL MASK is the most prevalent and widely accepted noninvasive respiratory support for post-extubation. 12 CPAP WITH NASAL MASK results in progressive recruitment of alveoli, inflates collapsed alveoli and reduces intrapulmonary shunt. It increases the final residual capacity (FRC) and in turn gaseous exchange. It reduces inspiratory resistance by dilating the airways. This permits a larger tidal volume for a given pressure, so reducing the work of breathing. It regularizes and slows the respiratory rate. It increases the mean airway pressure and improves ventilation perfusion mismatch. In contrast, the physiologic mechanism of NIPPV by which it is effective to include: flushing the upper airway dead space of CO₂, allowing for better alveolar gas exchange; providing a flow adequate to support inspiration, thereby reducing inspiratory work of breathing (WOB); effects of drying/cooling are improved by eliminating lung and airway mechanics; decreasing the metabolic cost of gas conditioning, and dispensing end distending pressure.

In the present study, due to gestational age wise distribution, it was found that higher of the GA were found of 31-35 weeks in (64% vs 74%) with no any statistically significant found (31.04 ± 1.67 weeks vs 31.46 ± 1.65 weeks: p=0.2089) between both the group CPAP WITH NASAL MASK and Group NIPPV. Similarly studies by such as Gosai M et al 1, Hedge D et al 2, Sharma PK et al 3, Osman M et al 4 and Lavizzari A et al 5 have

found more than 31-35 weeks (pre-term) of gestational age insignificantly in both the groups. Newborn respiratory distress syndrome (NRDS) occurs in premature babies, because lungs are not fully developed and cannot provide enough oxygen, causing breathing difficulties. Most of the patients have LSCS (68% vs 72%) with no any statistically significance found between both the group CPAP WITH NASAL MASK and Group NIPPV ($p=0.6629$) which was correlates with Shin J et al 6, Sharma PK et al 3, Osman M et al 4 and Lavizzari A et al 5 respectively with higher of patients suffering from LSCS . baseline characteristics such as Silverman Anderson Score (4.48 ± 0.50 vs 4.45 ± 0.53 ; $p=0.3342$), Antenatal Steroid (12% vs 10%; $p=0.7494$), Resuscitated at birth (40% vs 36%; $p=0.6801$), Surfactant administered (32% vs 30%; $p=0.8283$), Days of NIV (3.46 ± 1.16 vs 3.74 ± 1.19 ; $p=0.2364$) with no any statistically significance found between both the group CPAP WITH NASAL MASK and Group NIPPV respectively. Similarly, Gosai M et al 1 have found that baseline characteristics such as Antenatal Steroid (11% vs 11%; $p=1.0000$), Resuscitated at birth (20% vs 22.8%; $p=0.77$), Surfactant administered (31.4% vs 28.5%; $p=0.79$), Days of NIV (3.14 ± 1.76 vs 2.97 ± 1.33 ; $p=0.648$) with no any statistically significance found between both the group CPAP WITH NASAL MASK and Group NIPPV respectively. Another study by Sharma HK et al 7 have found that Silverman Anderson Score (4.05 ± 0.872 vs 4.36 ± 0.942 ; $p=0.144$), Antenatal Steroid (83.7% vs 75%; $p=0.46$), Resuscitated at birth (4.7% vs 11.4%; $p=0.449$), Surfactant administered (34.9% vs 25%; $p=0.44$), duration of NIV (69.1 ± 37.75 h vs 67.57 ± 45.48 ; $p=0.867$) with no any statistically significance found between both the group CPAP WITH NASAL MASK and Group NIPPV respectively. Moreover, the study by Hedge D et al 2 have found that Silverman Anderson Score (5(4-5) vs 4 (4-5); $p=0.08$), Antenatal Steroid (31% vs 28%; $p=0.78$), Resuscitated at birth (33% vs 33%; $p=1.0000$), Surfactant administered (71% vs 54%; $p=0.12$), duration of NIV (66.9 ± 36.1 hrs vs 67.15 ± 40.69 hrs; $p=0.98$) with no any statistically significance found between both the group CPAP WITH NASAL MASK and Group NIPPV respectively. , it was found that nasal trauma was found significantly higher in group CPAP WITH NASAL MASK as (24%) patients then group NIPPV (4%) patients. ($p=0.0039$) whereas other complication such as Apnea (12% vs 12%), Delayed intubation (6% vs 4%), Sepsis (10% vs 8%), Feed Intolerance (8% vs 6%) of the both group CPAP WITH NASAL MASK and Group NIPPV respectively. ($p>0.05$) Similarly, Gosai M et al 1 it was found that nasal trauma was found significantly higher in group CPAP WITH NASAL MASK as (31.42%) patients then group NIPPV (5.71%) patients. ($p=0.013$) whereas other complication such as Apnea (20% vs 8.57%), Delayed intubation (5.71% vs 8.57%), Sepsis (11.42% vs 14.28%), Feed Intolerance (8.57% vs 11.42%) of the both group CPAP WITH NASAL MASK and Group NIPPV respectively. ($p>0.05$) Moreover, the study by Hedge D et al 2 have found that nasal trauma was found significantly higher in group CPAP WITH NASAL MASK as (82%) patients then group NIPPV (41%) patients. ($p<0.0001$) whereas other complication such as Bronchopulmonary dysplasia (2.3% vs 4.3%), Patent ductus arteriosus (24% vs 26%), Sepsis (33% vs 41%), Feed Intolerance (21% vs 22%) and Retinopathy of prematurity (4.7% vs 4.3%) of the both group CPAP WITH NASAL MASK and Group NIPPV respectively. ($p>0.05$). Another study by Sharma HK et al 7 have found that the overall incidence of nasal trauma was more in CPAP WITH NASAL MASK group in comparison to NIPPV group in our study. About 34.9% of infants in CPAP WITH NASAL MASK group and 11.4% of infants in NIPPV group had some form of nasal trauma ($P = 0.019$). Incidences of other complications such as PDA, BPD, ROP, and air leak were similar in both groups. Moreover, the study by Chen J et al 8 found that the incidence rates of nasal injury (6.25 vs. 36.96%) and NEC (10.42 vs. 28.26%) in the HHNIPPV group were significantly lower than those in the CPAP WITH NASAL MASK group. The difference between the two groups was statistically significant ($P < 0.05$). There were no significant differences in the

incidence rates of BPD, ROP, intracranial hemorrhage, PVL, and PDA between the two groups ($P > 0.05$). In the present study, Duration of Oxygen Therapy (days) was found higher in mean days as 7.9 ± 1.46 in group CPAP compared to group NIPPV (7.06 ± 1.26 days) with statistically significant. ($p=0.0027$). In addition, duration of hospital stay (15.74 ± 2.11 days vs 15.18 ± 2.02 ; $p=0.1783$) and mortality (18% vs 12%; $p=0.4007$) was no more effective in both the group. Similarly Sharma HK et al 7 found that the mean durations of total oxygen supplementation in CPAP WITH NASAL MASK and HHNIPPV groups were 96.88 ± 100 and 83.73 ± 107 h, respectively. The total duration of oxygen supplementation was slightly less in NIPPV group as compared to CPAP WITH NASAL MASK group, but the difference was not statistically significant ($P = 0.062$). Therefore, in this study, both CPAP WITH NASAL MASK and HHNIPPV groups were found equally efficacious in view of total duration of oxygen support required. Similar results were obtained in the studies by Hedge D et al 2, Yoder BA et al 9 and Kadaver M et al 10 where the mean durations of oxygen supplementation were similar in both the study groups with $P = 0.62$, 0.357 , and 0.545 , respectively. In contrast, the study DR et al 11 by Gangu Duration of oxygen supplementation in the NIPPV group was significantly reduced compared to the CPAP WITH NASAL MASK group, which was statistically significant ($p<0.05$). Duration to reach full enteral feeds (31.24 ± 11.30 vs. 34.21 ± 14.09 days) in the NIPPV group is earlier compared to CPAP WITH NASAL MASK in our study which was statistically significant ($p<0.05$). Average weight gain before discharge (16.07 ± 3.10 vs. 13.74 ± 4.21 ; grams/day) was increased, the duration of hospitalization (73.45 ± 18.84 vs. 79.24 ± 19.75 days) was less.

CONCLUSION

In a conclusion, NIPPV appears to have similar efficacy and safety to CPAP WITH NASAL MASK when applied as a primary mode of respiratory support to preterm infants between 28 and 34 weeks of gestation with mild to moderate respiratory distress. HHNIPPV causes less nasal trauma than CPAP WITH NASAL MASK. So, HHNIPPV appears to be as effective as CPAP as non-invasive modality of respiratory support in neonates.

Conflict of Interest: Not available

Financial Support: Not available

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