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ORIGINAL ARTICLE

Comparison of short-term outcomes between Nasal Continuous Positive Airway Pressure and Nasal Intermittent Positive Pressure Ventilation in preterm neonates with respiratory distress syndrome.

Syed Hassan Ahmed[1], Ather Razzaq[2], Wasif Ijaz[3], Sidra Saleem[4], Meh Jabeen[5]

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ABSTRACT… Objective: To compare the safety and effectiveness of nasal continuous positive airway pressure (NCPAP) versus nasal intermittent positive pressure ventilation (NIPPV) as initial respiratory therapy among preterm neonates with respiratory distress syndrome (RDS). **Study Design:** Randomized Controlled Trial. **Setting:** The Neonatal Intensive Care Unit (NICU) of Indus Hospital and Health Network, Muzaffargarh, Pakistan. **Period:** January 2024 to June 2024. **Methods:** A total of 118 preterm neonates with 26-34 weeks gestation and admitted to NICU with RDS were randomly allocated to either NCPAP or NIPPV. Success respiratory support, along with complications, and mortality were noted. **Results:** In a total of 118 newborns, 64 (54.2%) were girls. The mean gestational age, and birth weight were 30.94±1.43 weeks, and 1479.07±310.69 grams. In NIPPV group, 49 (83.1%) babies showed successful outcome versus 29 (49.2%) in NCPAP group ($p<0.001$). Necessitation of intubation within 7 days (40.7% vs. 22.0%, $p=0.029$). Surfactant requirement (37.3% vs. 16.9%, $p=0.013$), and bronco pulmonary dysplasia (BDP) (11.9% vs. 0%, $p=0.006$) were significantly more in NCPAP group. Pneumothorax was significantly more prevalent in NIPPV group (18.6% vs. 3.4%, $p=0.008$). Duration of non-invasive support was significantly more in NCPAP group (10.58±6.07 vs. 8.15±3.58 days, $p=0.009$). **Conclusion:** NIPPV significantly outperformed NCPAP in terms of successful outcomes, as measured by reduced rates of intubation, surfactant requirement, and the incidence of BPD.

Key words: Gestational Age, Intubation, Pneumothorax, Respiratory Distress Syndrome, Surfactant.

INTRODUCTION

Around 1% newborns develop “respiratory distress syndrome (RDS)” and its incidence increases with decreasing gestational age.[1] Infants with RDS may require various levels of respiratory support ranging from noninvasive to invasive ventilation. Invasive ventilation strategy and prolonged tracheal intubation are associated with various complications like ventilation associated pneumonia, air leak syndromes and bronchopulmonary dysplasia (BPD) particularly in VLBW.[2,3]

“Nasal continuous positive airway pressure (NCPAP)” and “”nasal intermittent positive pressure ventilation (NIPPV)” are the primary non-invasive respiratory support strategies used for managing RDS.[4-8] A study done by Skariah et al revealed that failure rates were relatively similar among infants who were given NIPPV and NCPAP as found in 13.5% and 15.0% infants respectively (p value 0.80).[9] Another study by Kishore MS et al noted failure rates of 13.5% with early NIPPV versus 35.9% with CPAP ($p=0.024$).[10] The contemporary literature reports NIPPV shows superiority over NCPAP in RDS perterms.[11,12]

Although different studies showed that NIPPV is superior to NCPAP but there is no consensus that which one is the preferred mode for NIV in preterm with RDS and especially local literature is deficient in this aspect. According to best of my knowledge no comparative study has been done in Pakistan on these two noninvasive modes of

1. MBBS, FCPS (Pediatric Medicine), Fellow in Neonatology, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan.
2. MBBS, FCPS (Pediatric Medicine), FCPS (Neonatology), Consultant Neonatologist, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan.
3. MBBS, FCPS (Pediatric Medicine), Fellow in Neonatology, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan.
4. MBBS, FCPS (Pediatric Medicine), Fellow in Neonatology, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan.
5. MBBS, FCPS (Pediatrics), Fellow in Neonatology, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan.

Correspondence Address:
Dr. Syed Hassan Ahmed
Department of Neonatology
Recep Tayyip Erdogan Hospital,
Muzaffargarh, Pakistan.
shassaan28@yahoo.com

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respiratory support. This study was aimed to compare the safety and effectiveness of NCPAP versus NIPPV as initial respiratory therapy among preterm neonates with RDS.

METHODS

This open label, randomized controlled trial was conducted at the neonatal intensive care unit (NICU) of Indus hospital and health network, Muzaffargarh, Pakistan, From January 2024 to June 2024. A sample size of 118 was calculate taking 2-sided significance level 95%, power 80%, success rate of NIPPV 86.5%, and CPAP as 64.1%.[10] Inclusion criteria were preterm neonates, 26-34 weeks gestation admitted to NICU with diagnosis of RDS and Downes score between 4-7. Exclusion criteria were preterms requiring endotracheal intubation within 1st hour of life. Newborns having congenital pneumonia, pleural effusion, congenital malformations, congenital heart defects, or craniofacial abnormalities were excluded. RDS[12,13] was labeled according to Downe's scoring system along with x-ray findings. Signs of respiratory distress[14] included increase respiratory rate (> 60breath/min), nasal flaring, grunting: which is sound created during inspiration that can be audible with or without stethoscope, and chest in drawing (suprasternal/ intercostal/subcostal).

Approval from Institutional Ethical Committee was acquired (letter: IHHN-IRB-2023-09-010, dated 1st April 2024). After explaining about the aims of this research, parents/guardians were asked for written consent. At the time of enrollment, demographic information like gestational age, post natal age, birth weight, length, Head circumference, Mode of delivery, delivery room resuscitation required (yes/no) and use of antenatal steroids before delivery were noted. Antenatal steroid treatment was considered adequate when two doses of dexamethasone 12 mg were administered intramuscularly, 24 hours apart, at least seven days before preterm delivery. Neonates were randomly assigned to either the NCPAP or NIPPV group using a lottery method.

In the NCPAP group, infants were connected to a CPAP device with initial settings of 5 cm H2O and FIO2 of 30%. Adjustments were made based on respiratory distress and SpO2 levels, with a maximum CPAP of 8 cm H2O and FIO2 of 40%. The target oxygen saturation was 90%-95% in the right upper limb, with alarms set at 89% and 95%. In the NIPPV group, SIMV (PCV) PSV mode was used with initial settings of 40 breaths per minute, inspiratory time of 0.3 to 0.4 seconds, PEEP of 5 cm H2O, PIP of 15 cm H2O, and maximum pressure of 25 cm H2O, delivered via nasal prongs. Respiratory support in both groups was tapered based on target SpO2 levels and improvement in respiratory distress and respiratory rate. NIPPV group patients were shifted to heated humidified high flow nasal cannula when respiratory rate was less than 60 and fio2 requirement was 30% or less and PEEP is <5 cmH_2O and after that flow was decreased gradually and when flow was less than 1 liter/min and fio2 is 30% baby was shifted to low flow nasal canula and tapperd from oxygen therapy. NCPAP group was tapperd directly from NCPAP with continuous spo2 monitoring and clinical examination for respiratory distress, oxygen free trial was given when PEEP was <5 cmH_2O and FiO^2 requirement was less than 25%. Need for surfactant requirement was also noted. Surfactant administration was indicated when PEEP exceeded 8 cm H2O and FiO2 was greater than 40% in either group to maintain target SpO2 levels.

The main outcome was categorized as either the success or failure of non-invasive respiratory support. Failure, leading to intubation, was determined by specific criteria: PaCO2 exceeding 65 mmHg, pH dropping below 7.2, experiencing three or more apnea episodes within a single hour, or requiring more than one instance of intermittent positive pressure ventilation (IPPV). Additionally, an FiO2 greater than 40% needed to maintain SpO2 at or above 88% also indicated failure.[9] The secondary outcome focused on the necessity of intubation and mechanical ventilation within seven days of beginning non-invasive ventilatory support. Complications such as pneumothorax, "intraventricular hemorrhage (IVH)", "bronchopulmonary dysplasia (BPD)", "retinopathy of prematurity (ROP)", "necrotizing enterocolitis (NEC)", or sepsis were recorded in both study groups throughout the study period. Pneumothorax was labeled as rupture of lung resulting in free air in pleural cavity that may be spontaneous or due to inspiratory pressure and weak lung tissues. BPD was characterized by the requirement for oxygen supplementation (>21%) at 36 weeks postmenstrual age in infants born before 32 weeks of gestation. For those born after 32 weeks, BPD was defined by the need for supplemental oxygen for a duration exceeding 28 days but less than 56 days after birth. Neonatal sepsis was diagnosed clinically with evidence of laboratory findings. IVH was defined as bleeding in lateral ventricles characterized by hyperechoic fluid typically seen within the ventricles by cranial ultrasonography. NEC was labeled as per Modified Bell's scoring. Need for surfactant requirement was also be noted according to set criteria for surfactant administration. Duration of non-invasive support, oxygen therapy and NICU stay were recorded. All study data will be noted a pre-designed proforma.

The data were analyzed using "IBM-SPSS Statistics, version 26.0". Qualitative data were summarized as frequencies and percentages, while quantitative data were reported as mean and standard deviation. The Chi-square test or Fisher's Exact test was utilized for comparing qualitative data, and the independent sample t-test was applied for quantitative data comparisons. Pearson's correlation coefficient was calculated to evaluate the relationship between quantitative variables. A p-value of less than 0.05 was regarded as statistically significant.

RESULTS

In a total of 118 newborns, 64 (54.2%) were girls. The distribution of gestational age showed that 79 (66.7%) were very preterm, 31 (26.3%) moderately preterm, and 8 (6.8%) late preterm. The mean gestational age was 30.94±1.43 weeks, ranging between 28 to 34 weeks. The birth weight was 1479.07±310.69 grams, ranging between 850 to 2100 grams. Mode of delivery was cesarean section, noted in 66 (55.9%) cases. Delivery room resuscitation was need in 30 (25.4%) newborns. Comparison of baseline demographical and clinical characteristics in both study groups is shown in Table-I.

Overall, successful outcome was reported in 78 (66.1%) babies. In NIPPV group, 49 (83.1%) babies showed successful outcome versus 29 (49.2%) in NCPAP group ($p<0.001$), as shown in Figure-1.

Necessitation of intubation within 7 days was significantly more in NCPAP group versus NIPPV group (40.7% vs. 22.0%, $p=0.029$). Surfactant requirement was significantly more in NCPAP group versus NIPPV group (37.3% vs. 16.9%, $p=0.013$). Broncopulmonary dysplasia was reported in 7 babies and all were from NCPAP group ($p=0.006$). Table-II is showing comparison of secondary outcomes in both study groups.

Bivariate correlation analysis revealed that moderately negative but statistically significant relationship was noted between birth weight and duration of NICU stay (r=-0.314, p=0.001), as shown in Figure-2(a). Gestational age also showed moderately negative but statistically significant relationship with duration of NICU (r=0.-223, p=0.015), as shown in Figure-2(b).

Demographical and Clinical Characteristics		Total (N=118)	NIPPV (n=59)	NCPAP (n=59)	P-Value
Gender	Boy	54 (45.8%)	24 (40.7%)	30 (50.8%)	0.268
	Girl	64 (54.2%)	35 (59.3%)	29 (49.2%)	
Gestational age (weeks)		30.94±1.43	31.02±1.37	30.86±1.50	0.566
Birth weight (grams), Mean±SD		1479.07±310.69	1492.37±318.92	1465.76±304.38	0.644
Length (cm)		41.92±1.93	42.03±1.97	41.81±1.90	0.538
Antenatal steroids given to mother		98 (83.1%)	46 (78.0%)	52 (88.1%)	0.141
Mode of delivery	Vaginal delivery	52 (44.1%)	29 (49.2%)	23 (39.0%)	0.266
	Cesaren section	66 (55.9%)	30 (50.8%)	36 (61.0%)	
Apgar score		6.87±0.82	6.78±0.79	6.97±0.85	0.220
Delivery room resuscitation required		30 (25.4%)	12 (20.3%)	18 (30.5%)	0.205

Table-I. Comparison of baseline characteristics

Secondary Outcomes		Total (N=118)	NIPPV (n=59)	NCPAP (n=59)	P-Value
Necessitation of intubation within 7 days		37 (31.4%)	13 (22.0%)	24 (40.7%)	0.029
Surfactant required		32 (27.1%)	10 (16.9%)	22 (37.3%)	0.013
Frequency of complications	Intraventricular hemorrhage	15 (12.7%)	5 (8.5%)	10 (16.9%)	0.167
	Bronchopulmonary dysplasia	7 (5.9%)	-	7 (11.9%)	0.006
	Pneumothorax	13 (11.0%)	11 (18.6%)	2 (3.4%)	0.008
	Lung collapse	10 (8.5%)	3 (5.1%)	7 (11.9%)	0.186
	Necrotizing enterocolitis	7 (5.9%)	3 (5.1%)	4 (6.8%)	0.697
	Sepsis	33 (28.0%)	17 (28.8%)	16 (27.1%)	0.837
Duration of non-invasive support (days), Mean±SD		9.36±5.11	8.15±3.58	10.58±6.07	0.009
Duration of NICU stay (days), Mean±SD		12.24±6.72	11.08±5.18	13.39±7.84	0.062
Mortality		8 (6.8%)	3 (5.1%)	5 (8.5%)	0.464

Table-II. Comparison of secondary outcomes

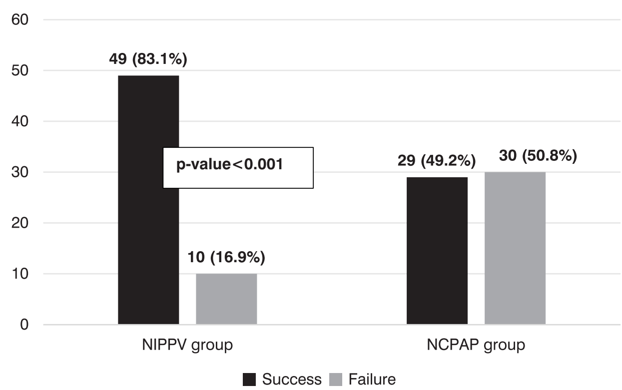

Figure-1. Comparison of success/failure of NIPPV and NCPAP (n=118)

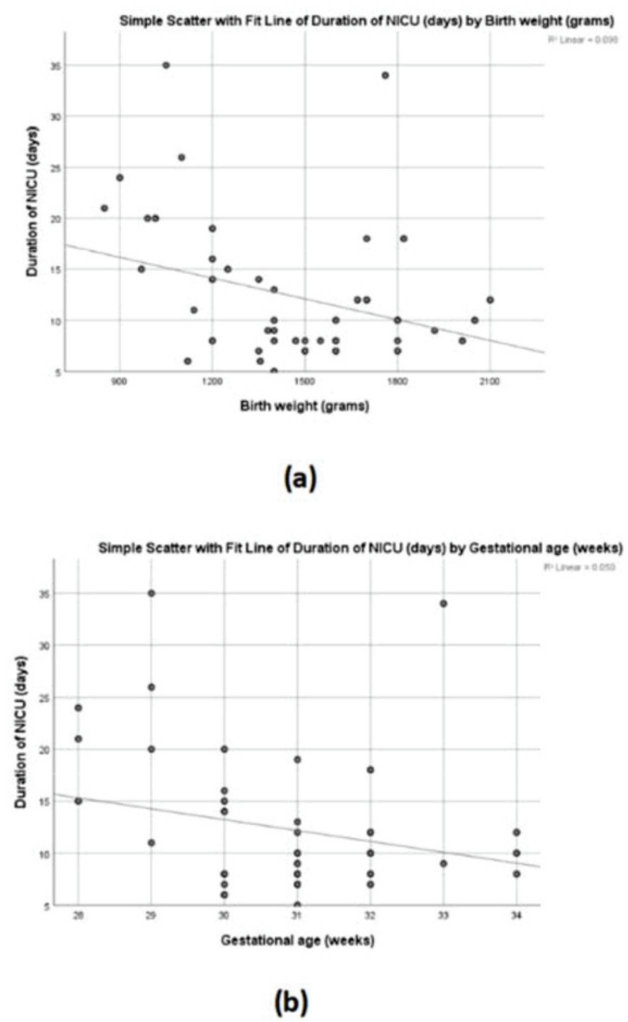

Figure-2. Relationship of duration of NICU with birth weight (a), and gestational age (b)

DISCUSSION

The success rate of NIPPV was notably higher than that of NCPAP, with 83.1% of neonates in the NIPPV group achieving successful outcomes, compared to 49.2% in the NCPAP group. Supporting these findings, Lemyre et al. reported that NIPPV significantly reduced the risk of respiratory failure and decreased the need for intubation in preterm infants with RDS.[12] Ramanathan et al. found that early extubation to NIPPV, rather than NCPAP, lowered the requirement for mechanical ventilation via an endotracheal tube.[15] In contrast, Kostekci et al. did not observe a significant difference in the need for intubation within 72 hours between the NIPPV and NCPAP groups.[10] This inconsistency may stem from differences in study populations, particularly the inclusion of extremely preterm infants (<29 weeks' gestation) in Kostekci et al study, which could have impacted the overall effectiveness of NIPPV.

Our study showed a significantly higher surfactant requirement in the NCPAP group (37.3%)

compared to the NIPPV group (16.9%). Malakian et al.[16] found that the NIPPV group required fewer multiple doses of surfactant than the NCPAP group. The reduced surfactant requirement in NIPPV-treated infants could be attributed to the more stable and efficient delivery of positive airway pressure, which may help maintain alveolar recruitment and reduce the need for additional surfactant therapy.[17] The meta-analysis by Li et al. also supports this observation, showing that NIPPV significantly decreased the need for invasive ventilation and, consequently, surfactant administration in preterm infants with RDS.[18]

In the present study, BPD was reported exclusively in the NCPAP group, with no cases observed in the NIPPV group. This outcome is particularly significant given that BPD is a major complication associated with preterm birth and prolonged mechanical ventilation.[19] Kostekci et al[10], and Meneses et al[20] found no significant differences. This variation in outcomes may reflect differences in study designs, patient populations, and definitions of BPD used across studies. Nevertheless, the current study's findings suggest that NIPPV may offer a protective effect against the development of BPD, which warrants further investigation in larger, multicenter trials. One of the notable adverse outcomes in the NIPPV group was the significantly higher incidence of pneumothorax (18.6%) compared to the NCPAP group (3.4%). This finding is consistent with concerns raised in the literature regarding the potential risks associated with higher airway pressures used in NIPPV.[21] The higher pneumothorax rate in our study suggests that careful monitoring and adjustment of NIPPV settings are essential to minimize the risk of this serious complication. The literature reports similar mortality rates between the two approaches.[22,23] The low mortality in both groups reflect the overall effectiveness of non-invasive respiratory support in managing RDS among preterm infants, reducing the need for more invasive interventions that carry higher risks. The study by Li et al. also reported no significant differences in mortality between NIPPV and NCPAP groups.[18]

Bivariate correlation analysis in our study revealed moderately negative but statistically significant relationships between birth weight, gestational age, and the duration of NICU stay. This finding is expected, as higher birth weights and more advanced gestational age are associated with more stable clinical conditions and faster recovery, leading to shorter hospital stays. These correlations highlight the importance of early gestational age and birth weight as critical determinants of neonatal outcomes, consistent with existing literature on the subject.

Single center with a relatively small sample size were some of the limitations of this study that can limit the generalizability. The lack of long-term follow-up means that we cannot assess the lasting impact of NIPPV versus NCPAP on neurodevelopmental outcomes.

CONCLUSION

NIPPV significantly outperformed NCPAP in terms of successful outcomes, as measured by reduced rates of intubation, surfactant requirement, and the incidence of BPD. However, NIPPV was associated with a higher incidence of pneumothorax, highlighting the trade-offs involved in selecting the most appropriate respiratory support strategy for preterm infants.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Syed Hassan Ahmed	Data collection, Drafting, Responsible for Data, Approved for publication.	
2	Ather Razzaq	Concept and Designing, Proof reading, Critical revision, Approved for publication.	
3	Wasif Ijaz	Data synthesis, Data analysis, Proof reading, Approved for publication.	
4	Sidra Saleem	Data synthesis, Data analysis, Proof reading, Approved for publication.	
5	Meh Jabeen	Data synthesis, Data analysis, Proof reading, Approved for publication.	