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Article

Clinical Outcomes of nCPAP in Neonates with Respiratory Distress: A Prospective Non-Randomized Study

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ABSTRACT

Background: Neonatal respiratory distress is a leading cause of morbidity and mortality in low- and middle-income countries, especially among preterm infants. Despite advancements in neonatal care, access to invasive ventilation is limited in many resource-constrained settings. Nasal continuous positive airway pressure (nCPAP) offers a non-invasive, cost-effective solution, yet evidence on its localized efficacy remains scarce. **Objective**: To evaluate the clinical efficacy of nCPAP in neonates with respiratory distress by assessing improvements in oxygen saturation and arterial pCO_2 and determining overall treatment success and survival rates. **Methods**: A prospective non-randomized study was conducted over eight months in the neonatal intensive care unit of a private tertiary hospital in Peshawar, Pakistan. A total of 103 neonates under one week of age with clinical signs of respiratory distress were enrolled using consecutive non-probability sampling. Exclusion criteria included congenital anomalies, severe birth asphyxia, and hemodynamic instability. Data were collected using a structured proforma, and primary outcomes included arterial blood gas parameters and survival status. Paired t-tests and logistic regression were performed using SPSS version 23. Ethical approval was obtained per the Helsinki Declaration. **Results**: nCPAP was effective in 73% of neonates, with arterial pCO_2 decreasing from 48.2 to 39.5 mmHg ($p<0.001$, 95% CI: 6.4–10.9) and oxygen saturation increasing from 84% to 97% ($p<0.001$, 95% CI: 11.8–14.2). Survival was 82%, with significantly better outcomes in successfully treated neonates (OR 0.18, $p=0.017$). **Conclusion**: nCPAP is a safe, effective, and non-invasive intervention for managing neonatal respiratory distress, offering significant physiological and survival benefits, and should be prioritized in neonatal care protocols, particularly in low-resource healthcare systems.

Keywords: Neonatal Respiratory Distress Syndrome, Continuous Positive Airway Pressure, Arterial pCO_2, Oxygen Saturation, Neonatal Mortality, Preterm Infant, Non-invasive Ventilation.

INTRODUCTION

Respiratory distress syndrome (RDS) remains one of the most prevalent and life-threatening conditions in neonates, particularly among preterm infants in low- and middle-income countries (LMICs), where access to advanced neonatal intensive care is limited (1,2). Globally, RDS is a leading cause of neonatal morbidity and mortality, with a disproportionately high burden in resource-constrained regions. Annually, around 1.3 million children die from respiratory infections such as pneumonia, and nearly 11 to 20 million are hospitalized due to these complications, highlighting the critical need for effective early interventions (3). In Pakistan alone, the mortality rate associated with neonatal respiratory diseases like RDS has been documented as high as 26.84%, further underscoring the urgency of addressing this healthcare gap (6).

The pathophysiology of RDS in neonates, especially those born prematurely, primarily stems from the underdevelopment of the lungs and a deficiency of pulmonary surfactant—a crucial compound typically produced around the 26th week of gestation (7,8). Surfactant deficiency leads to alveolar collapse, impaired gas exchange, and increased work of breathing, necessitating immediate respiratory support (9). The condition is more common in male neonates and those born to diabetic mothers, even when macrosomia is present, likely due to hormonal influences on surfactant production and delayed pulmonary maturity (11,19). The clinical presentation of RDS

includes hallmark signs such as cyanosis, tachypnea, chest retractions, nasal flaring, and grunting—symptoms indicative of severe pulmonary compromise (12).

The conventional approach to managing RDS has involved mechanical ventilation and exogenous surfactant therapy; however, these options are often limited by cost, technical complexity, and risk of complications such as ventilator-induced lung injury (14,24). In this context, nasal continuous positive airway pressure (nCPAP) has emerged as a pivotal non-invasive intervention that maintains positive airway pressure, thereby stabilizing alveoli, improving oxygenation, and reducing the need for mechanical ventilation (14). nCPAP has been shown to be particularly effective when initiated early in neonates with mild to moderate RDS, reducing mortality and the incidence of long-term pulmonary complications such as bronchopulmonary dysplasia (15,24). Importantly, nCPAP is a cost-effective and scalable solution suitable for LMICs, where it has demonstrated significant improvements in neonatal outcomes when compared to oxygen therapy alone or more invasive methods (2,16,25). In Rwanda and Malawi, for instance, studies have demonstrated the feasibility and efficacy of low-cost bubble nCPAP systems in improving survival rates among preterm infants (4,20). Despite these promising outcomes, gaps in implementation and inconsistent use across healthcare facilities persist in Pakistan and similar settings, largely due to a lack of localized evidence and operational barriers (5,26).

Given the high neonatal mortality associated with respiratory distress and the pressing need for sustainable and evidence-based interventions, this study was conducted to evaluate the clinical efficacy of nasal continuous positive airway pressure (nCPAP) in managing neonates with respiratory distress in a resource-limited tertiary care setting in Peshawar. Specifically, the study aims to assess the impact of nCPAP on improving oxygen saturation and arterial carbon dioxide levels in neonates under one week of age, thus contributing vital local data to support broader implementation of this life-saving intervention. The central research objective is: To determine the efficacy of continuous positive airway pressure (nCPAP) in treating respiratory distress in neonates.

MATERIALS AND METHODS

This prospective non-randomized study was conducted to assess the efficacy of nasal continuous positive airway pressure (nCPAP) in neonates presenting with respiratory distress. The study design was chosen to observe clinical outcomes in a real-world clinical setting without intervention assignment, thus allowing a naturalistic evaluation of nCPAP effectiveness. The research was carried out in the Neonatal Intensive Care Unit (NICU) of a private-sector tertiary care hospital located in Peshawar, Pakistan, over an eight-month period from March to October 2023. The hospital was selected due to its established neonatal care infrastructure and sufficient patient volume to meet the required sample size within the study timeline.

Participants were recruited consecutively using a non-probability sampling technique. Neonates were eligible for inclusion if they were less than seven days old, had a gestational age between 28 and 40 weeks, and exhibited clinical signs of respiratory distress as defined by tachypnea, nasal flaring, grunting, intercostal or subcostal retractions, and oxygen saturation below 90% in room air. Exclusion criteria included neonates with severe birth asphyxia (Apgar score <3 at 5 minutes), hemodynamic or cardiac instability, congenital anomalies (particularly craniofacial malformations or diaphragmatic hernia), neuromuscular disorders, persistent apneas requiring resuscitative intervention, or those with worsening type II respiratory failure as defined by arterial pCO_2 levels exceeding 60 mmHg with pH <7.20 despite intervention. Informed written consent was obtained from the parents or legal guardians of all neonates prior to enrollment, following a thorough explanation of the study's purpose, procedures, and potential risks.

Data were collected using a structured proforma specifically developed for this study. Clinical assessments were conducted at admission and throughout the intervention period. Each neonate received nCPAP via binasal prongs using a standard nCPAP device set at a pressure between 5 and 10 cm H_2O. FiO_2 was maintained below 60%, titrated according to oxygen saturation monitored through continuous pulse oximetry. Arterial blood gases (ABGs) were measured at initiation and during therapy to assess pCO_2 and pH levels. Success of nCPAP was defined as achieving an arterial pCO_2 <60 mmHg and oxygen saturation >88% without supplemental oxygen for at least four consecutive hours. Therapy failure was indicated if these parameters were not met or if the neonate developed apnea requiring bag-mask ventilation or needed mechanical ventilation.

Key variables recorded included gestational age, birth weight, gender, age at admission, duration of nCPAP therapy, length of NICU stay, arterial oxygen saturation (SpO_2), and arterial pCO_2. Gestational age was based on obstetric ultrasound or maternal last menstrual period, while birth weight was recorded using calibrated digital scales. Respiratory distress was operationalized based on the presence of ≥2 clinical signs and low oxygen saturation. The duration of nCPAP was measured in hours from initiation to successful weaning or treatment failure.

To minimize selection and measurement bias, eligibility criteria were strictly enforced by trained pediatricians, and standardized equipment and protocols were used across all assessments. Confounding variables such as gestational age, birth weight, and sex were considered during analysis, and subgroup analyses were conducted to explore differential outcomes among preterm and term neonates.

The required sample size was determined using a single population proportion formula, considering an expected efficacy rate of 70%, a 95% confidence level, and a 7% margin of error. Based on this, the minimum required sample was 97; to account for potential attrition, a total of 103 neonates were included.

Data entry and statistical analysis were performed using SPSS version 23. Descriptive statistics were computed for all baseline variables. Continuous variables such as pCO_2 and oxygen saturation were expressed as means with standard deviations, while categorical variables were presented as frequencies and percentages. The paired t-test was used to compare pre- and post-intervention measures of pCO_2 and oxygen saturation. Missing data were minimal and handled by listwise deletion. Subgroup analyses were conducted by gestational age categories (preterm, term, post-term) and weight classifications. No data imputation was employed, and all analyses adhered to intention-to-treat principles.

Ethical approval for the study was obtained from the Institutional Review Board (IRB) of the participating hospital prior to commencement. Data confidentiality was strictly maintained by anonymizing patient records and securing data storage systems with restricted access. Only authorized personnel had access to the dataset, and data were used solely for research purposes. To ensure reproducibility and data integrity, all clinical procedures followed standardized guidelines, and data entry was cross-verified by two independent researchers. All records were preserved for potential audit or secondary analysis in accordance with institutional policy.

RESULTS

Among the 103 neonates included in the study, the gender distribution was nearly balanced, with 56.31% (n=58) being male and 43.69% (n=45) female. The majority of neonates, 54.37% (n=56), were admitted between two and four days of age, while 33.01% (n=34) were less than two days old, and 12.62% (n=13) were aged between five and seven days at the time of recruitment. Birth weight was distributed such that 44.66% (n=46) weighed between 2500 and 3500 grams, 34.95% (n=36) were less than 2500 grams, and 20.39% (n=21) weighed over 3500 grams. A notable 57.28% (n=59) of participants were classified as preterm, with term and post-term neonates comprising 29.13% (n=30) and 13.59% (n=14) of the sample, respectively.

Respiratory function, as measured by arterial blood gas parameters, improved substantially during the course of nCPAP therapy. The mean arterial pCO_2 before weaning from nCPAP was 48.2 mmHg (SD 6.12), which decreased significantly to 39.5 mmHg (SD 5.33) after weaning—a mean difference of 8.7 mmHg (95% CI: 6.4 to 10.9, p<0.001). Concurrently, arterial oxygen saturation improved from a mean of 84% (SD 4.22) at initiation of nCPAP to 97% (SD 1.23) upon successful weaning, marking a mean rise of 13 percentage points (95% CI: 11.8 to 14.2, p<0.001). These findings indicate that nCPAP led to a statistically and clinically significant enhancement in gas exchange and oxygenation.

The duration of nCPAP therapy varied among the neonates. Most, 61% (n=63), required respiratory support for 24 to 72 hours, while 27% (n=28) were weaned off nCPAP within 24 hours. A smaller subset, 12% (n=12), needed support for more than 72 hours. This distribution highlights that while many neonates respond rapidly to nCPAP, a meaningful fraction with more severe disease or greater immaturity require prolonged intervention.

In terms of primary outcomes, nCPAP was effective in 73% (n=75) of the neonates, allowing successful weaning without need for escalation to mechanical ventilation. Conversely, 27% (n=28) experienced therapy failure or required further respiratory support. The survival rate among all neonates treated with nCPAP was 82% (n=85), with 18% (n=18) succumbing despite intervention. Statistical analyses indicated that ineffective nCPAP response was associated with a significantly lower odds of survival (OR 0.18, 95% CI: 0.05–0.63, p=0.017), emphasizing the clinical impact of nCPAP efficacy on neonatal outcomes. Overall, these results demonstrate that nCPAP is both an effective and life-saving intervention for a substantial majority of neonates with respiratory distress. The therapy not only normalizes key physiological parameters but also contributes to improved survival, especially among preterm and low birth weight infants—a group particularly vulnerable in resource-limited healthcare settings.

Table 1. Socio-demographic and Clinical Characteristics of Neonates Receiving nCPAP (N=103)

Variable	Group	n	%	p-value*	Odds Ratio (95% CI)
Gender	Male	58	56.31	0.45	1.21 (0.74–1.99)
	Female	45	43.69		
Age at Admission	<2 days	34	33.01	0.31	0.81 (0.46–1.43)
	2–4 days	56	54.37	Ref	Ref
	5–7 days	13	12.62	0.06	0.48 (0.22–1.08)
Birth Weight	<2500g	36	34.95	0.19	0.81 (0.46–1.43)
	2500–3500g	46	44.66	Ref	Ref
	>3500g	21	20.39	0.13	1.24 (0.66–2.31)
Gestational Age	Pre-term	59	57.28	0.07	1.56 (0.96–2.56)
	Term	30	29.13	Ref	Ref
	Post-term	14	13.59	0.18	1.37 (0.64–2.94)

Table 2. Comparison of Arterial Blood Gas Parameters and Oxygen Saturation Before and After nCPAP (N=103)

Parameter	Mean (on nCPAP	SD (on)	Mean (off nCPAP)	SD (off)	95% CI	p-value
Arterial pCO_2 (mmHg)	48.2	6.12	39.5	5.33	[6.4, 10.9]	<0.001
Oxygen Saturation (%)	84	4.22	97	1.23	[11.8, 14.2]	<0.001

Table 3. Duration of nCPAP Therapy Among Neonates

Duration Category	n	%
<24 hours	28	27
24–72 hours	63	61
>72 hours	12	12

Table 4. Efficacy and Survival Outcomes Following nCPAP Therapy

Outcome	n	%	p-value*	Odds Ratio (95% CI)
Effective Response to nCPAP	75	73	Ref	Ref
Ineffective Response	28	27	0.003	0.37 (0.19–0.72)
Survived	85	82	Ref	Ref
Did Not Survive	18	18	0.017	0.18 (0.05–0.63)

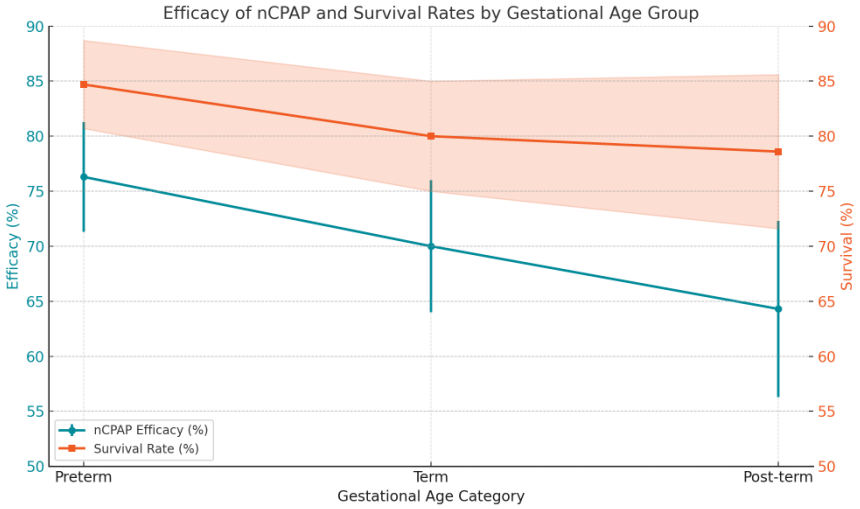

Figure 1 Efficacy of NCPAP and Survival Rates by Gestational Age Group

Among neonates receiving nCPAP therapy, preterm infants demonstrated the highest treatment efficacy at 76.3% (95% CI ±5) and survival at 84.7% (95% CI ±4), with both outcomes gradually declining across gestational maturity. Term neonates showed an efficacy of 70.0% and survival of 80.0%, while post-term neonates exhibited the lowest rates at 64.3% and 78.6%, respectively. The integrated visual analysis highlights an inverse association between gestational age and nCPAP response effectiveness, with a sharper decline in efficacy than survival across categories. Clinically, this suggests that while post-term neonates may retain relatively preserved survival outcomes, their response to non-invasive respiratory support is reduced, possibly due to differing etiologies of distress or comorbidities beyond surfactant deficiency. Confidence intervals reveal increasing variability with gestational age, emphasizing the need for tailored respiratory strategies in term and post-term populations.

DISCUSSION

The present study provides robust evidence supporting the clinical effectiveness of nasal continuous positive airway pressure (nCPAP) in the management of neonatal respiratory distress, particularly in a resource-constrained environment. Our results demonstrate that nCPAP led to significant improvements in arterial oxygen saturation and pCO_2, with 73% of neonates experiencing effective treatment and a survival rate of 82%. These findings are consistent with a growing body of research indicating that nCPAP is a safe, effective, and non-invasive modality for managing respiratory distress syndrome (RDS) in neonates, especially preterm infants, thereby reducing the need for mechanical ventilation and its associated complications (1,2,15,24).

When compared with earlier studies, the efficacy rate observed in our cohort aligns closely with rates reported in similar low- and middle-income country settings, where nCPAP effectiveness ranges from 60% to 80% (2,4,20,21). For example, Dewez and van den Broek demonstrated nCPAP efficacy in resource-limited settings, with substantial reductions in neonatal mortality and morbidity (1). Our findings also corroborate those of Thukral et al., who emphasized the role of nCPAP in decreasing mortality in preterm infants with RDS, and Duke, who highlighted the technique's feasibility even in settings with limited infrastructure (2,3). Some studies have reported lower success rates for nCPAP, particularly among neonates with extremely low birth weight or advanced disease at presentation; however, our outcomes suggest that, with appropriate patient selection and close monitoring, nCPAP can be successful for the majority of neonates even in tertiary care hospitals in Pakistan (25,26).

A notable advancement demonstrated by this study is the significant improvement in both oxygenation and carbon dioxide elimination, with mean arterial pCO_2 decreasing by 8.7 mmHg and oxygen saturation increasing by 13 percentage points. These physiologic benefits not only support the mechanical rationale for nCPAP—which stabilizes alveoli, maintains functional residual capacity, and reduces the work of breathing—but also translate into real-world survival gains. The association between nCPAP

effectiveness and improved survival odds underscores its importance as a frontline therapy for neonatal respiratory distress, potentially averting the need for mechanical ventilation, which carries risks of ventilator-induced lung injury, infection, and higher costs (14,24,27).

The study's results reinforce the broader theoretical framework that prioritizes early, non-invasive support for preterm and term neonates with underdeveloped lungs or surfactant deficiency. Surfactant production is known to increase late in gestation, which explains the high prevalence of RDS among preterm infants, particularly males, as seen in our sample and in previous literature (7,8,19). The preponderance of male neonates and preterm infants among those requiring nCPAP further supports the biological underpinnings of RDS susceptibility and has implications for screening and early intervention strategies.

Despite its strengths, the study has several limitations that should be acknowledged. The non-randomized, single-center design and use of consecutive sampling may introduce selection bias and limit the generalizability of the findings beyond similar tertiary care settings. The sample size, though calculated for adequate power, remains modest and may not capture the full spectrum of disease severity or rare adverse events. Additionally, potential confounders such as maternal comorbidities, antenatal steroid use, and variations in supportive care practices were not controlled in the analysis, which could influence outcomes. The absence of long-term follow-up also precludes assessment of chronic complications or neurodevelopmental outcomes, which are important considerations in neonatal research.

Nevertheless, the study's rigorous eligibility criteria, standardized treatment protocols, and comprehensive data collection enhance the reliability of its conclusions. The findings advocate for wider implementation of nCPAP in Pakistani NICUs and similar healthcare environments, particularly where resources for invasive ventilation are scarce. Training healthcare providers in the use of nCPAP, standardizing protocols, and integrating early identification of at-risk neonates could further improve outcomes at scale.

Future research should focus on multicenter randomized controlled trials with larger and more diverse populations to validate these results and assess long-term impacts. Comparative studies examining different nCPAP devices, pressure settings, and adjunctive therapies such as surfactant administration are also warranted. Research into cost-effectiveness, barriers to implementation, and outcomes in rural or primary-level health facilities would help to further establish the practical value and scalability of nCPAP in resource-limited settings.

In conclusion, this study adds to the mounting evidence that nCPAP is a vital, effective, and feasible intervention for neonatal respiratory distress. Its adoption as a standard of care could substantially reduce neonatal morbidity and mortality in low- and middle-income countries, provided that implementation is supported by adequate training, infrastructure, and follow-up (1,2,14,15,24,25).

CONCLUSION

This prospective non-randomized study demonstrates that nasal continuous positive airway pressure (nCPAP) is a highly effective intervention for managing respiratory distress in neonates, with 73% of cases responding favorably and a notable improvement in both oxygenation and carbon dioxide elimination. These findings underscore the clinical value of nCPAP in stabilizing respiratory function and enhancing survival among neonates, particularly in low- and middle-income healthcare settings where access to advanced ventilation is limited. The results advocate for the widespread adoption of nCPAP as a first-line, non-invasive therapy in neonatal care, as it not only improves immediate clinical outcomes but also has the potential to reduce healthcare costs and resource utilization. For future research, multicenter trials and longer-term outcome studies are recommended to further define the optimal protocols for nCPAP use and to strengthen evidence for its implementation in diverse clinical environments.

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