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Comparison of Treatment Outcomes of High-Flow Nasal Cannula and Nasal Continuous Positive Airway Pressure in Preterm Neonates with Respiratory Distress Syndrome in the NICU of Shahid Sadoughi Hospital in Yazd

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ABSTRACT

Background: Neonatal respiratory distress syndrome (RDS) is a common and urgent condition in newborns, caused by a lack of surfactant production and secretion. This study aimed to compare two non-invasive methods, nasal continuous positive airway pressure (nCPAP) and high-flow nasal cannula (HFNC), for managing RDS.

Methods: The study was conducted in the Neonatal Intensive Care Unit (NICU) of Shahid Sadoughi Hospital between 2020 and 2021 and included 49 premature neonates (with gestation ≤34 weeks and birth weight ≤2,000 g) diagnosed with RDS. The neonates were randomly assigned to either the HFNC group (n = 24) or the nCPAP group (n = 25).

Results: No significant differences in demographic features were observed between the two groups. The HFNC group had lower rates of intubation, shorter hospitalization duration, and less need for full nutritional support and oxygen therapy compared to the nCPAP group, but these differences were not statistically significant. Additionally, there were no significant differences in complications such as traumatic nasal injury, apnea, necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD), pneumothorax, pulmonary hemorrhage, and mortality between the two groups.

Conclusion: The results of this study suggest that both HFNC and nCPAP are equally effective in treating premature neonates with RDS, with no significant differences in clinical outcomes. Given the cost-effectiveness of HFNC, medical staff expertise, and equipment accessibility, this approach could be considered a viable alternative to nCPAP.

Introduction

Premature birth contributes to 10.6% of total live births globally, with around 15 million newborns delivered prematurely annually, a growing trend worldwide.[1,2] The survival rate and incidence of morbidities in preterm newborns are key indicators of healthcare quality in medical facilities.[2] Neonatal Respiratory Distress Syndrome (RDS) often leads to breathing issues in newborns, appearing shortly after birth, sometimes immediately after delivery.[3] Diagnosis of neonatal RDS is based on the need for additional oxygen within the first 24 hours after birth, significantly increasing the risk of morbidity and mortality in infants, posing a major public health concern.[4,5] Managing RDS in preterm newborns is a significant challenge in the Neonatal Intensive Care Unit (NICU). Heated, humidified High Flow Nasal Cannula (HFNC) and NCPAP are commonly used treatment options.[6] Understanding the comparative treatment outcomes of these methods is crucial to improving care for preterm infants with RDS.[7] While premature infants are surviving at higher rates, there remains a significant prevalence of chronic pulmonary issues, mainly linked to lung damage from ventilation.[8,9] Non-invasive ventilation (NIV) can help reduce the negative effects of mechanical ventilation.[10] Despite being recognized as a beneficial treatment, NIV using NCPAP can lead to complications such as intestinal distention, nasal trauma, nasal deformity, and other issues that may require surgery. Recently, HFNC has gained popularity as a respiratory support method for neonates, thanks to its ease of use and improved patient comfort.[11,12] HFNC has shown effectiveness in treating specific respiratory disorders in newborns, offering caregivers a more convenient option compared to traditional NCPAP therapy.[13,14]

In Iran, Shirvani et al. conducted a study to assess the clinical effectiveness of NCPAP compared to humidified high-flow nasal cannula (HHFNC) for managing RDS in premature neonates. Their results showed no significant differences in primary and secondary outcome measures, indicating equivalent efficacy between HHFNC and NCPAP for treating RDS in newborns.[15] Lavizzari et al. also compared HHFNC and NCPAP for managing RDS in premature infants, finding HHFNC to be as effective and safe as NCPAP as initial treatment for mild to moderate RDS in preterm infants born after 28 weeks of gestation.[7] Yuan et al. evaluated NIV modes post-extubation in premature neonates with severe RDS, suggesting that non-invasive positive pressure ventilation (NIPPV) and nasal high-frequency oscillation (NHFO) were more cost-effective than NCPAP, especially for infants under 32 weeks, with similar clinical outcomes and complications in infants over 32 weeks.[16] Kostekci et al. compared the efficacy of NCPAP and heated HHFNC as initial treatments for extremely premature infants with RDS, finding nasal intermittent positive pressure ventilation to be as effective as NCPAP, highlighting the need for further research on NIPPV synchronization.[17] However, evidence on the functionality, effectiveness, and safety of HFNC therapy in neonates, and its comparative effectiveness with NCPAP in Yazd, remains limited. This study aimed to evaluate the effectiveness of HFNC versus NCPAP in premature neonates as non-invasive approaches for RDS treatment by assessing clinical outcomes and comparing the safety and potential complications of both methods.

Materials and Methods

The research protocol was thoroughly evaluated and approved by the ethics committee at Shahid Sadoughi University of Yazd (IR.SSU.MEDICINE.REC.1399.260). Before being included in this study, explicit written consent was obtained from the patient's guardians within the first hour of their existence.

Study Population: This cross-sectional study was conducted over one year in the

NICU at Shahid Sadoughi Hospital in Yazd, from March 20, 2020, to March 19, 2021. Infants meeting specific inclusion criteria and without exclusion criteria were randomly assigned to two study groups. The sample size was determined based on a 60% surfactant utilization rate in the NCPAP group and 80% in the HFNC group, with a 95% confidence level and 80% test power. All neonates meeting the inclusion criteria and not meeting the exclusion criteria were included in the analysis. Inclusion criteria included gestational age <34 weeks or birth weight <2 kg, mild to moderate respiratory distress, oxygen requirement <60%, no cardiac, pulmonary, or gastrointestinal abnormalities, no coagulation abnormalities at birth, and no Apgar score < 5 at 5 minutes post-birth. Exclusion criteria included positive culture at hospitalization initiation indicating sepsis and guardians declining participation. Data on infant and maternal records were collected from the NICU and women's division of the hospital. After parental consent, infants were randomly assigned to the HFNC or CPAP groups by NICU medical staff.

Procedures: The initial cohort received nCPAP from birth at a pressure of 4 to 6 cm H_2O until resolution of respiratory distress and oxygen dependency (CPAP group). In contrast, the subsequent cohort was treated with warm and humid HFNC at a flow rate of 2 to 5 liters per minute until resolving respiratory distress and oxygen dependency (HFNC group). Both groups were then thoroughly evaluated and compared based on clinical parameters and associated complications. Cessation of respiratory support with HFNC and CPAP was determined by the absence of respiratory distress symptoms, tachypnea, and oxygen needs ≤ 21%. Treatment failure leading to intubation (pH<7.25 - $PaCO_2$>60mmHg - PaO_2<50mmHg - oxygen saturation<90% at an oxygen concentration of 40-70%) and increased oxygen requirement within 96 hours postpartum was also considered; (Extubation failure was defined as needing reintubation within 2-7 days after extubation).

A research questionnaire for infants meeting specified criteria was completed by a pediatric assistant while ensuring adherence to inclusion and exclusion criteria. The questionnaire was administered after obtaining informed consent for study participation, utilizing information from the vaccination card, maternal history, and medical records from obstetrics and gynecology, as well as the operating room. Following questionnaire collection, data entry into EXCEL software was performed manually. To maintain blinding, a separate researcher inputted the data into the SPSS file, followed by statistical analysis.

Statistical Analysis: The outcomes related to a quantitative factor were presented as the mean and standard deviation (SD ± mean), while for a qualitative factor, they were described in terms of frequency and percentage. Comparisons of the quantitative factors were performed using the Mann-Whitney U test. Contrasts among qualitative factors were analyzed using the Chi-square test and Fisher's exact test. The statistical analysis was conducted using SPSS 26 software.

Results

Demographic and Clinical Characteristics: In the present study, CPAP treatment was administered to 25 infants, while HFNC treatment was provided to 24 infants. The initial demographic characteristics of the enrolled infants were similar across both groups in terms of gender, birth status, presence of multiple pregnancies, mode of delivery, maternal age, gestational age, birth weight, head circumference at birth, height at birth, and Apgar scores at 1 and 5 minutes (Table 1). The average gestational age was 31.32 ± 1.84 weeks in the CPAP group and 32 ± 0.92 weeks in the HFNC group, with no statistically significant difference between the two groups (P = 0.1). The average neonatal head circumference at birth was 29.6 ± 1.5 cm

Table 1. Comparison of Demographic Characteristics between the Two Groups

Characteristics	HFNC (n = 24)	nCPAP (n = 25)	P- value
Gender			
Male	12 (50%)	12 (48%)	0.88
Female	12 (50%)	13 (52%)	
Birth Type			
Singletons	13 (54.2%)	11 (44%)	0.07
Twins	3 (12.5%)	10 (40%)	
Triplets	8 (33.3%)	4 (16%)	
Mode of delivery			
Normal vaginal delivery	3 (12.5%)	2 (8%)	0.67
Caesarean section	21 (87.5%)	23 (92%)	
Mother's age (years)	28.17 ± 6.99	27.72 ± 7.36	0.50
Gestational age (week)	32 ± 0.92	31.32 ± 1.84	0.10
Birth weight(g)	1637.5 ± 260.81	1566.92± 305.95	0.55
Head circumference at birth (cm)	30.25 ± 1.53	29.6 ± 1.5	0.68
Height at birth (cm)	42.5 ± 2.91	42.4 ± 3.85	0.19
Apgar score (first min)	8.17 ± 0.86	7.72 ± 1.33	0.25
Apgar score (5 min)	9.67 ± 0.56	9.56 ± 0.82	0.18

in the CPAP group and 30.25 ± 1.53 cm in the HFNC group, indicating no discernible distinction between the groups (P = 0.68). The mean maternal age at delivery was 27.72 ± 7.36 years in the CPAP group and 28.17 ± 6.99 years in the HFNC group, with no notable difference detected between the two cohorts (P = 0.5).

Clinical Outcomes: About the administration of surfactants, the prescription requirement rate stood at 14 cases (56%) in the nCPAP cohort and 18 cases (75%) in the HFNC cohort. Conversely, the incidence of no prescription necessity was 11 cases (44%) for the nCPAP group and 6 cases (25%) for the HFNC group. However, the difference between these two cohorts was not statistically significant (P = 0.16). The need for intubation was observed in 3 patients (12%) in the nCPAP group, while none in the HFNC group required intubation. The absence of intubation was seen in 22 cases (88%) for the nCPAP group and 24 cases (100%) for the HFNC group. The difference between the two cohorts was not statistically significant (P = 0.23). The duration of mid-day hospitalization was similar between the nCPAP group (15.76 ± 10.61 days) and the HFNC group (11.04 ± 5.71 days), with no statistically significant variance (P = 0.48). The time to achieve full infant feeding was also comparable, with the nCPAP group requiring 8.88 ± 6.16 days and the HFNC group 5 ± 3.31 days, showing no significant difference (P = 0.1). Similarly, the length of oxygen therapy did not display significant variance between the nCPAP group (6.28 ± 6.19 days) and the HFNC group (3.04 ± 1.68 days) (P = 0.48) (Table 2).

Table 2. Determining and Comparing the Frequency of Clinical Outcomes in Two Groups

Variables	HFNC (n = 24)	nCPAP (n = 25)	P-value
Surfactant administration			
Yes	18 (75%)	14 (56%)	0.16
No	6 (25%)	11 (44%)	
Intubation			
Yes	0	3 (12%)	0.23
No	24 (100%)	22 (88%)	
Mean of Hospitalization days	11.04 ± 5.71	15.76 ± 10.61	0.48
Mean of Complete nutrition days	5 ± 3.31	8.88 ± 6.16	0.10
Mean of Oxygen therapy days	3.04 ± 1.68	6.28 ± 6.19	0.48

Table 3. Comparison of the Frequency of Complications in the Two Study Groups

Variables	HFNC (n = 24)	NCPAP (n = 25)	P
PDA, n (%)	0	1 (4.5%)	0.48
IVH, n (%)	0	3 (13.6%)	0.10
Traumatic nasal, n (%)	0	1 (4.5%)	0.48
Apnea, n (%)	0	1 (4.5%)	0.48
NEC, n (%)	3 (12.5%)	3 (13.6%)	0.10
BPD, n (%)	0	0 (0%)	NA
Pneumothorax, n (%)	0	0 (0%)	NA
pulmonary hemorrhage, n (%)	0	0 (0%)	NA
Mortality, n (%)	0	0 (0%)	NA

PDA: patent ductus arteriosus; IVH: intraventricular hemorrhage; NEC: necrotizing enterocolitis; BPD: bronchopulmonary dysplasia.

Complications: Pulmonary ductus arteriosus (PDA) was not found in either group, with one case (4.5%) in the NCPAP cohort and none in the HFNC group, indicating no significant difference between the two cohorts (P = 0.48). Intraventricular hemorrhage (IVH) occurred in three cases (13.6%) in the nCPAP group and none in the HFNC group, showing no statistically significant variance between the groups (P = 0.1). Traumatic nasal trauma was seen in one case (4.5%) in the nCPAP group and none in the HFNC group, with no significant difference between them (P = 0.48). Regarding apnea, one case (4.5%) was noted in the nCPAP group, while none were found in the HFNC group, indicating no significant distinction between the two (P = 0.48). Necrotizing enterocolitis (NEC) was observed in three cases (13.6%) in the nCPAP group and three cases (12.5%) in the HFNC group, with no statistically significant difference between the two cohorts (P = 0.1). Pneumothorax, pulmonary hemorrhage, mortality, and bronchopulmonary dysplasia (BPD) were not reported in either group, showing no observable variation between the cohorts (Table 3).

Discussion

The management of RDS in premature neonates is a critical aspect of neonatal healthcare. Among the respiratory support modalities available, HFNC and NCPAP are commonly used techniques. Various studies have compared these methods to determine their effectiveness and safety in treating RDS in preterm infants.[18] This study compared clinical outcomes between CPAP and HFNC, including mortality rates, hospitalization duration, intubation incidences, length of oxygen therapy, and time to initiate oral feeding in neonates in the NICU. Adverse effects such as nasal mucosa damage or bleeding from these techniques were also evaluated. The study found no significant difference in outcomes between CPAP and HFNC. Additionally, the combined use of budesonide and surfactant for RDS treatment, as well as the impact of Iranian surfactant (Beraksurf) on managing RDS in premature neonates, showed no significant differences in complications.[19,20] Birth parameters and clinical outcomes, including nasal trauma, apnea, intraventricular hemorrhage (IVH), PDA, NEC, BPD, pneumothorax, pulmonary hemorrhage, and mortality, did not show statistically significant variances between the two techniques. Therefore, based on medical expertise, both HFNC and CPAP can be used in treating premature neonates with RDS. Our study, compared to other research, found both similar and different results. In a study by Vitaliti et al., both CPAP and HFNC were effective in improving the clinical condition of infants with mild to moderate RDS, with those receiving both methods having shorter hospital stays, fewer days of intravenous therapy, and reduced medication administration time. However, CPAP showed a quicker and more pronounced clinical response compared to HFNC, suggesting a preference for the

former.[21] Our study did not find any differences, although the duration of intravenous therapy was not specifically mentioned. Research by Shoemaker also showed no disparities in mortality rates, occurrences of BPD, need for ventilation, sepsis rates, and other clinical outcomes.[22]

In the Kadivar study, no differences were found in the incidence of IVH or ROP between the two groups under investigation. Hospital stay duration and oxygen requirement were similar in both cohorts.[23] However, the main distinction between the results of the study and our research was the higher rate of intubation cases in the HFNC group. A randomized clinical trial by Lavizzari et al. aimed to establish the noninferiority of HHFNC compared to NCPAP in preterm infants with RDS. The study showed that HHFNC was as effective and safe as NCPAP when used as the primary strategy for managing mild to moderate RDS in infants over 28 weeks of gestational age.[7] Similarly, a separate randomized controlled trial by Yengkhom et al. compared HHFNC with NCPAP for respiratory support post-extubation in preterm infants. The results indicated that HHFNC was as effective as NCPAP in preventing extubation failure while causing less nasal trauma.[24] On the other hand, a study by Iranpour et al. explored Nasal High-Frequency Oscillatory Ventilation (nHFOV) versus NCPAP as the initial intervention for RDS in preterm infants. The findings showed that nHFOV reduced the duration of non-invasive respiratory support, decreased the need for intubation, and lowered the incidence of IVH without increasing other complications compared to NCPAP.[25] Additionally, a study protocol outlined by Cresi et al. described the Enteral Nutrition Tolerance and Respiratory Support (ENTARES) trial, which aimed to determine the most suitable respiratory support modality (NCPAP vs. HHFNC) for preterm infants with feeding intolerance. The main goal of the trial was to improve clinical outcomes and reduce healthcare costs by identifying the optimal respiratory support technique. Overall, the comparison between HHFNC and NCPAP in the management of RDS in preterm infants is crucial for enhancing neonatal care and improving outcomes.[26]

The comparison of two common methods, HFNC and NCPAP, in treating premature infants with RDS has attracted significant attention in neonatal healthcare. Shirvani et al. conducted a study comparing HFNC and NCPAP for managing RDS in preterm neonates. Results showed both methods to be equally effective in treating RDS, suggesting either can be used as the primary therapy for premature neonates.[15] Similarly, Wang et al. performed a meta-analysis to evaluate the effectiveness and safety of HFNC and NCPAP in neonates with RDS. This analysis supports the notion that both HFNC and NCPAP have similar effectiveness and safety profiles for neonates with RDS.[27] Therefore, the choice between HFNC and NCPAP for treating preterm infants with RDS may depend on factors like accessibility, cost, and individual patient characteristics.

Conclusion

The study suggests that HFNC and NCPAP are equally effective in treating RDS in preterm infants, with no significant differences in outcomes. Given the cost-effectiveness of HFNC and medical staff proficiency, it could serve as a viable alternative to NCPAP. Treatment outcomes, including mortality rates, hospital stay duration, oxygen therapy needs, and various complications, indicate that the choice between CPAP and HFNC should rely on expert medical advice. Physician expertise, resource availability, and nursing staff proficiency play crucial roles in determining the preferred treatment method.

Conflict of Interest

The authors declare no conflicts of interest.

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Ethical Considerations

The present study was approved by Shahid Sadoughi University Ethics Committee (IR.SSU.MEDICINE.REC.1399.260).

Author's Contribution

Conceptualization, S.R.M., M.H.L. and M.N.; methodology, S.R.M. and M.H.M.; formal analysis, A.M. and S.R.M.; investigation, A.M., S.R.M., M.N. and M.H.L.; resources, A.M. and S.R.M.; data curation, A.M and S.R.M.; writing— original draft preparation, A.M.; writing— review and editing, M.N., M.H.L. and S.R.M.; supervision, M.N. and M.H.L. All authors have read and agreed to the published version of the manuscript.

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