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Research Article

Heated Humidified High-Flow Nasal Cannula versus Nasal Continuous Positive Airway Pressure as an Initial Non-Invasive Respiratory Support in Preterm Neonates with Respiratory Distress

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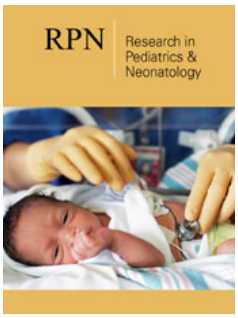

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Abstract

Background: Preterm neonates with respiratory distress are usually managed by either non-invasive or invasive respiratory support. Among non-invasive respiratory supports, continuous positive airway pressure (CPAP) is used as the common modality of treatment in preterm neonates. Evidence for heated humidified high-flow nasal cannula (HHHFNC) as an alternative mode of non-invasive respiratory support is inconclusive.

Objective of the study: To compare the efficacy of heated humidified high-flow nasal cannula (HHHFNC) with continuous positive airway pressure (CPAP) as an initial non-invasive respiratory support in preterm neonates with respiratory distress.

Methodology: This randomized clinical trial was carried out on 56 inborn preterm neonates, in the Department of Neonatology, BSMMU, Dhaka from October 2020 to September 2021. Inborn preterm neonates with respiratory distress required non-invasive respiratory support were enrolled for the study. Out of 64 neonates, 8 neonates were excluded and finally 56 neonates were included for the study. After satisfying the inclusion criteria, computer-based randomization was done with 28 neonates in the HHHFNC group received HHHFNC support and another 28 neonates in the CPAP group received CPAP support after taking informed written consent from the parents/guardians. After initiation of assigned treatment, the incidence of treatment failure within 72 hours and also complications of both CPAP and HHHFNC groups were collected, analyzed and compared. All data were recorded in a preformed questionnaire and data were analyzed by statistical package for social sciences (SPSS) version 22. Quantitative variables were compared by unpaired t-test and categorical variables by Chi-square test/ Fisher's exact test. p-value <0.05 was considered as significant.

Result: A total of 56 neonates were studied, the incidence of treatment failure within 72 hours was 10.7% and 14.3% in the HHHFNC and CPAP group respectively and was not statistically significant (P=1.00). Nasal trauma occurred 3.6% in the HHHFNC group in comparison to 28.6% in the CPAP group which was statistically significant (P=0.02).

Conclusion: HHHFNC is equally efficacious to nasal CPAP when applied as an initial mode of non-invasive respiratory support for respiratory distress in preterm neonates. Furthermore, HHHFNC is a safer modality than CPAP in terms of nasal trauma.

Keywords: Heated humidified high-flow nasal cannula; Nasal continuous positive airways pressure; Initial non-invasive respiratory support; Respiratory distress in preterm neonate

Introduction

Bangladesh has achieved the Millennium Development Goal (MDG) target-4 for reduction of under 5 mortalities ahead of time but unfortunately, neonatal mortality is still significantly

high (30/1000 live birth) which accounts for 66.66% of all under 5 deaths [1]. Respiratory disorders are the leading cause of early neonatal mortality (0-7 days) [2] and morbidity [3] in newborns and are the most frequent cause of admission to the special care nursery [4]. Neonates with respiratory distress are 2-4 times more likely to die than neonates without respiratory distress [5]. Respiratory distress in the neonate is diagnosed when one or more of the following is present; tachypnoea or respiratory rate of more than 60/minute, retractions or increased chest in drawings on respirations (subcostal, intercostal, sternal, suprasternal) and noisy respiration in the form of a grunt, stridor or wheeze [6]. The optimal approach to the early respiratory management of the preterm infant remains controversial [7,8]. Most of the newborns with respiratory distress are managed by either non-invasive or invasive respiratory support [9]. In the past decade, there is a dramatic change in the respiratory care of preterm infants with the implementation of non-invasive respiratory supports such as nasal continuous positive airway pressure (CPAP) and heated humidified high flow nasal cannula (HHHFNC) with the objective to minimize ventilator-induced lung injury [10]. Nasal continuous positive airway pressure (CPAP) is the current standard care of non-invasive respiratory support for preterm infants [11] based on the provision of a continuous distending pressure [12]. But nasal CPAP is associated with complicated fixation techniques, positional problems, frequent nasal trauma, and experienced medical and nursing specialists are required in order to provide CPAP safely and effectively [13]. Heated humidified high-flow nasal cannula (HHHFNC) is an alternative mode of non-invasive respiratory support which deliver heated, humidified, blended oxygen into nose through a loose fitting short binasal prong at a flow rate of >1liters/min. HHHFNC work with several potential modes of action including washout of the nasopharyngeal dead space, generation of distending airway pressure, reduction of work of breathing, and optimum gas conditioning [12]. HHHFNC has several potential advantages over CPAP such as reduced nasal trauma, ease of use, better infant tolerance with improved feeding and bonding which has led to its rapid adoption into neonatal intensive care units [12]. HHHFNC is gaining popularity in clinical practice owing to its technical ease of use without sealing. A recent Cochrane review of HHHFNC use in preterm infants [14] concluded that HHHFNC is as effective as other forms of non-invasive respiratory support in preterm infants for preventing treatment failure, death, and chronic lung disease. But these results were from the evidence for the use of HHHFNC as post-extubation support. Although some randomized trials [15,16] support the notion that HHHFNC is as effective as CPAP in the early stages of respiratory distress in newborns but the evidence for HHHFNC as the primary treatment of respiratory distress is still insufficient. Therefore, the aim of this study is to assess the efficacy and safety of HHHFNC compared to CPAP as non-invasive respiratory support for the initial management of respiratory distress in preterm neonates.

Method and Materials

This randomized clinical trial was conducted in the Department of Neonatology, BSMMU, Dhaka from October 2020 to September 2021 over one year period after approval by Institutional Review Board (IRB). Total 56 inborn preterm neonates with gestational age<37 weeks having moderate respiratory distress characterized by Silverman Anderson Score (SAS) of 4-7 were included in the study after taking informed written consent from the parents/guardians. Neonates requiring early intubation for resuscitation, having major congenital anomalies or metabolic abnormalities were excluded from the study. Randomization was done before the initiation of non-invasive respiratory support. The enrolled neonates were randomly assigned with computer generated random number tables via software named 'Random Allocation Software' into two groups. The heated humidified high-flow nasal cannula (HHHFNC) group received HHHFNC support and nasal continuous positive airway pressure (CPAP) group received CPAP support.

Neonates were transferred to the neonatal intensive care unit (NICU) after delivery room management. On the first day of hospitalization, details of maternal and perinatal medical history were taken and physical examination was done. Gestational age was determined by the New Ballard score [17]. All required information for each neonate was recorded in a data collection form. The questionnaire was developed by reviewing evidence from books and scientific articles. Maternal use of antenatal corticosteroid, GDM, PIH, multiple gestation, risk factors for sepsis, and newborns gestational age, mode of delivery (vaginal/caesarean), gender, birth weight, Apgar score at 5th minute, Silverman Anderson score, resuscitation, surfactant administration and mode of respiratory support was recorded.

Infants in the HHHFNC group were treated with the Opti-flow device which includes the MR850 humidifier and bi-nasal infant cannula (Fisher & Paykel Healthcare). The initial flow rate was 4-6L/min, FiO_2 0.5, and prong size to occupy <50% of the nares internal diameter. FiO_2 adjustment based on maintaining SpO_2 90-95%. The flow rate was increased in increments of 1L/min up to 8L/min in response to the severity of respiratory distress evidenced by increased chest retractions, tachypnea, or increased O_2 requirements. Weaning from HHHFNC was achieved initially by stepwise reduction of FiO_2 down to 0.3 and flow rate in decrements of 1L/min for every 12 or 24 hourly guided by infant's clinical improvement or arterial blood gas (ABG) analysis values. Once a flow rate of 3L/min was reached with a fraction of inspired oxygen <0.3 for at least 6 hours then HHHFNC was discontinued.

Infants in the CPAP group were initiated at a pressure of 5cm of H_2O, FiO_2 0.5 and flow 5L/min with nasal mask depending on the practice in the individual unit. Nasal CPAP was generated with the use of an underwater "bubble" system. The pressure was altered at the physician's discretion within limits of 5 to 8cm of water. CPAP pressure and FiO_2 were titrated according to the baby's requirements as per the NICU protocol of BSMMU. The flow was adjusted between 5-8liters/min to maintain adequate bubbling. Weaning from CPAP was achieved initially by stepwise reduction of FiO_2 down to 0.3 and then the pressure was decreased gradually to 5cm of water. Decrement in CPAP parameters was guided by the infant's clinical improvement or arterial blood gas (ABG) analysis

values. Once infants were weaned to a nasal CPAP pressure of 4cm of water with a fraction of inspired oxygen <0.3 for at least 6 hours then nasal CPAP was discontinued.

All babies on HHHFNC or CPAP had inserted an orogastric tube (5/6Fr) placed open to the atmosphere to avoid distension of the stomach. All relevant laboratory investigations, including pulse oximetry, septic work up, X-ray chest, ABG were done. Newborn babies were monitored as per standard nursing protocols and once babies became hemodynamically stable feeding was given as per NICU protocol of BSMMU. Infants with treatment failure received CPAP or mechanical ventilator support in case of the HHHFNC group and mechanical ventilator support in case of the CPAP group. The primary outcome was treatment failure within 72 hours from the beginning of non-invasive respiratory. Secondary outcomes include incidence of invasive ventilation, the incidence of nasal trauma, pneumothorax after trial entry, Patent ductus arteriosus (PDA), Necrotizing enterocolitis (NEC), Retinopathy of prematurity (ROP), Bronchopulmonary dysplasia (BPD), Culture-proven sepsis, in-hospital mortality, duration of respiratory support and duration of hospital stay.

Data Analysis

Data entry and analysis were carried out by using the statistical package of social science (SPSS) version 22. Quantitative variables were expressed as mean ±SD. Qualitative or categorical variables were presented as numbers and percentages. All quantitative variables (between HHHFNC group and CPAP group) were compared by unpaired t-test. Categorical variables were compared by the Chi-square test and Fisher's exact test. p-value <0.05 was considered statistically significant.

Results

A total of 126 inborn newborns were admitted with respiratory distress during the study period. According to the inclusion criteria, 64 babies were eligible for this study. Among 64 cases, 8 were excluded from this study, 4 cases had congenital anomalies (2=Congenital diaphragmatic hernia, 2= Ante-natally diagnosed complex congenital heart disease) and 4 cases were excluded as parents/guardians did not give consent. So, the remaining 56 neonates with respiratory distress who were a candidate for non-invasive respiratory support were randomly assigned into two groups, 28 neonates were allocated in the heated humidified high-flow nasal cannula (HHHFNC) group received HHHFC support and the remaining 28 were allocated in the continuous positive airway pressure (CPAP) group received CPAP support as initial management for respiratory distress. The primary and secondary outcomes were followed up, analyzed, and compared between the two groups. Outcomes were available for all the patients until discharge from neonatal intensive care unit.

Baseline demographic and perinatal characteristics of the studied neonates were presented. Mean gestational age was 32.46±2.01 weeks in the HHHFNC group and 32.79±2.36 weeks in the CPAP group which was almost similar in both the groups (p=0.59). Most of the newborns belonged to the gestational age 32-34 weeks category, 50% in both HHHFNC and CPAP groups. Mean birth weight was 1625.71±563.10 g in the HHHFNC group & 1689.45±549.69 g in the CPAP group. Very low birth weight infants were more common in the CPAP group (53.6%) than the HHHFNC group (46.4%). All of them were inborn and cesarean section was the mode of delivery for more than two-thirds of the enrolled neonates.

Regarding maternal characteristics, most of the mothers were multiparous and most of them did not receive even a single dose of antenatal corticosteroid that was 46.4% and 50% in the HHHFNC and CPAP groups respectively. Common maternal problems demonstrated during pregnancy were GDM, PIH, and risk factors for sepsis. Multiple births occurred in 21.4% and 17.9% in HHHFNC and CPAP groups respectively. Two patients in the HHHFNC group and three patients in the CPAP group needed bag and mask ventilation after delivery. One patient in the CPAP group got a single dose of surfactant therapy. Concerning the causes of respiratory distress in both groups, respiratory distress syndrome (RDS) was the most common cause. In the HHHFNC group 13(46.4%), 11(39.3%), and 4(14.3%) neonates were suffering from RDS, TTN and congenital pneumonia respectively, on the other hand, it was 12(42.9%), 11(39.3%) and 5(17.9%) respectively in CPAP group.

Regarding primary outcome, the incidence of treatment failure within 72 hours of the initially assigned modality of respiratory support were comparable between two groups. The failure rate in the HHHFNC group was 10.7% and the failure rate in the CPAP group was 14.3% (p=1.00). Among three treatment failure patients in the HHHFNC group, two of them required MV support (7.1%) and one patient was switched to the CPAP. On the other hand, all four treatment failure patients in the CPAP group were managed by MV support (14.3%).

HHHFNC group required less duration of respiratory support and hospital stay than CPAP group but the total duration of required NIV support was less in CPAP group compared to HHHFNC group. There were no significant differences between the two groups regarding secondary outcomes including the incidence of PDA, NEC, BPD, ROP, culture-proven sepsis, and in-hospital mortality. None of the infants in either group developed pneumothorax. Nasal trauma occurred significantly higher in the CPAP group (28.6%) in comparison to the HHHFNC group (3.6%) (p=0.02).

Discussion

A total of 56 inborn preterm neonates having respiratory distress required non-invasive respiratory support were included in this study and divided into the HHHFNC group (28 neonates) and CPAP group (28 neonates). The mean gestational age was 32.46±2.01 and 32.79±2.36 weeks in the HHHFNC and CPAP group respectively in this study which is close to the previous study done by Murki et al. [11]. where the mean gestational age was 31.8±1.9 and 31.6±2.2 weeks [11]. In the present study, the mean birth weight was 1625.71±563.10 and 1689.45±549.69g in the HHHFNC and CPAP group respectively which was lower than the previous study done by Shin et al. [18]. Where the mean birth

weight was 2058±371 and 1996±374g in the HHHFNC and CPAP group respectively [18]. Only 14.3% mothers in the HHHFNC group and 28.6% mothers in the CPAP group received antenatal steroids which differed from the study conducted by Sharma P [19] that revealed 83.7% and 75% mothers in the HHHFNC and CPAP group received antennal steroids respectively [19]. In this study, LUCS was needed in 92.9% and 85.7% cases in the HHHFNC and CPAP group respectively which was quite higher than the previous study done by Shin et al. [18] where LUCS was needed in 71.4% and 60.5% in the HHHFNC and CPAP group respectively [18]. This higher percentage of the LUCS may be explained by the fact, this study was conducted in a tertiary care hospital where most of the complicated pregnancies are dealt with necessitating LUCS. Respiratory distress syndrome (RDS) was the most common cause of respiratory distress in preterm neonates in this study that was 46.4% and 42.9% in the HHHFNC and CPAP groups respectively. The study was done by Murki et al. [11] also showed a similar result in which RDS was the cause of respiratory distress in 54% and 42% cases of HHHFNC and CPAP groups respectively [11]. In this clinical trial, the frequency of treatment failure was 3(10.7%) in the HHHFNC group and 4(14.3%) in the CPAP group and was not statistically significant (p=1.00). A similar result was obtained in the study done by Hegde et al. [16], included 88 preterm neonates between 28 to 34 weeks gestation in which the frequency of treatment failure was slightly lesser in the HHHFNC group (19.5%) in compared to the CPAP group (26.2%) and the difference was not statistically significant (p=0.46) [16]. In this study treatment failure was considered when the infant received maximum support (flow rate of ≥8L/min in the HHHFNC group or pressure ≥8cm of H_2O in the CPAP group) and had one of the following: Persistent or increased respiratory distress, pH<7.20 and $PaCO_2$>60mm Hg, FiO_2 >0.60 to a target SpO_2 of 90-95% and recurrent apnea (≥3 episodes/h or apnea requiring bag and mask ventilation). A large randomized controlled trial conducted by Lavizzari et al. [12] on HHHFNC versus CPAP in 316 preterm infants between 29 to 36 weeks gestational age as primary therapy to mild to moderate RDS. In their study, HHHFNC showed efficacy and safety similar to those of CPAP when applied as a primary approach to mild to moderate RDS in preterm infants older than 28 weeks [12]. Some other randomized controlled trials [15,19-22] also support the notion that the HHHFNC is equally efficacious to the CPAP as a primary mode of respiratory support for respiratory distress in preterm infants. A recent systematic meta-analysis [23] of 21 randomized controlled trials involving 2886 preterm infants concluded that the HHHFNC has similar rates of effect to those of CPAP when used for primary respiratory support in premature infants. Opposite to these studies, some studies were reported showing HHHFNC to be inferior to CPAP. In a trial done by Roberts et al. [10] where HHHFNC was compared with CPAP as an initial treatment method in 564 preterm infants of ≥28 weeks of gestational age. They concluded that treatment failure was significantly higher in the HHHFNC group compared with the CPAP group when used as a primary mode of respiratory support [10]. Another study conducted by Murki et al. [11] compared HFNC with CPAP for primary respiratory support in preterm infants of ≥28 weeks of gestational age with respiratory distress. During their study period, 139 and 133 infants were randomized to the CPAP and HHHFNC groups, respectively and the treatment failure was significantly higher in the HHHFNC group compared to the CPAP group [11]. The incidence of nasal trauma was more in the CPAP group (28.6%) compared to the HHHFNC group (3.6%) and this difference was statistically significant (p=0.02) in this present study. This finding was similar to the observations by Hegde et al. [16] where the incidence of nasal trauma is higher in CPAP group than HHHFNC group (p=0.01) [16]. Other secondary outcomes parameters such as total duration of respiratory support, duration of hospital stay, the incidence of pneumothorax, BPD, ROP, PDA, culture-proven sepsis and in-hospital mortality showed no statistically significant difference between the HHHFNC and CPAP groups. These findings were similar to the observations by Hegde D et al. [16] and Murki et al. [11]. For determination of ROP, neonates were screened as per our protocol on 20th or 30th day according to gestational age and birth weight. NEC were assessed by using Modified Bell's criteria and PDA was determined by echocardiographic measurements. Based on this study results and before mentioned trial findings, it demonstrated that HHHFNC is equally efficacious to CPAP as an initial mode of respiratory support in preterm infants with respiratory distress. HHHFNC causes less nasal trauma than CPAP.

Conclusion

HHHFNC is equally efficacious to nasal CPAP when applied as an initial mode of non-invasive respiratory support for respiratory distress in preterm neonates. Furthermore, HHHFNC is a safer modality than CPAP in terms of nasal trauma.

Limitation of the Study

A. Single center analysis.

B. The sample size was small.

C. HHHFNC was a newer modality of respiratory support used in the study place, so it was challenging to convince the health care worker to implement it as initial respiratory support.

D. It was difficult to convince the parents/guardians as it was a newer and costly intervention.

Recommendation

HHHFNC can be used as an initial mode of non-invasive respiratory support to treat preterm neonates with respiratory distress. Further studies involving multiple centers with large sample size are needed to evaluate the efficacy and safety of HHHFNC.

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b) Source of Funding: Nil.

c) Writing-Review& Editing: Shimul Mandal, Baisakhi Biswas, MA Mannan, All authors contributed to the final version of the manuscript.

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