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Effect of heated humidified high flow nasal cannula vs bubble nasal continuous positive airway pressure in transient tachypnoea of newborn (>35 weeks)- an open label rct

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Abstract

"Heated humidified high flow nasal cannula" has developed equally to an alternate respiratory modality to "Bubble Nasal Continuous Positive Airway Pressure" (BNCPAP) for the treatment of late premature newborns who have been diagnosed with "Transient Tachypnea of the Newborn" (TTN). The current study examined neonates >35 weeks gestation diagnosed of Transient Tachypnea of the New-born who were randomly assigned to either "NCPAP or HHHFNC" for treatment. This was an open-label randomised control study that was undertaken at R. L. Jalappa Hospital, which is connected with Sri Devaraj Urs Medical College on new-borns. with >35 weeks of gestational age, admitted to NICU with TTN. With Institutional human ethics committee approval, all qualified participants were enrolled on the research in a systematic manner using "convenient sampling" until the sample size was met. In the present research, there were 84 participants total, with 42 participants assigned to each of the two categories (HHHFNC and BNCPAP). In terms of the percentage of distribution towards maternal age, measure of pregnancy (in weeks), weight at birth, gender, and mode of childbirth, there was no noticeable variation between the two categories. Both groups exhibited excellent recovery, with 97.6 percent of the former and 95.24 percent of the latter. According to the P value of 1.00, in regard to the percentage of people who cured, there was no numerical relevant variation between the Study categories. "HHHFNC" appears to be as efficient and harmless as "BNCPAP" as the basic means of airway management for neonates born with Transient Tachypnea of the Newborn.

Key words: Transient tachypnea of the newborn, TTN, "Heated humidified high flow nasal cannula, HHHFNC", "Bubble Nasal Continuous Positive Airway Pressure", BNCPAP, "respiratory distress (RD)", oxygen support, gestational age.

INTRODUCTION

While premature newborns are more prone to suffer from "respiratory distress" [RD], a rising number of term-born infants are now demonstrating indications of respiratory distress during the initial hours of birth, necessitating admittance to critical management for medical intervention.[1]

RD from retained foetal lung fluid, or Transient Tachypnea of Infant (TTN) occurs if the newborn does not discharge the fluid quickly after delivery. The majority of cases with TTN resolve spontaneously, without therapy. Not with standing this, TTN is clearly the most prevalent trigger of RD in term babies admitted to a to a newborn critical care setting.[2] TTN may cause a rare but significant consequence known as prolonged tachypnea, which is defined as RD of a duration of more than five to six days. This condition can lead to respiratory failure ("characterized by a triad of hypoxia, respiratory fatigue, and acidosis").[3]

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According to “NICU research” on the Indian scenario for TTN, the incidence of TTN decreases with increasing gestational age, affecting about 10% of neonates delivered between 33 and 34 weeks of pregnancy, about 5% of neonates born between 35 and 36 weeks of gestation, and <1% of infants born at due date.[4] The frequency of TTN has been estimated to be as high as “46.6 per 1000 live births”, according to an examination of an unreleased five-year (2010-2016) record from "All India Institutes of Medical Science,”.[5]

If the newborn has TTN, his or her chest may seem like a barrel because the lungs have expanded too much.[6] If the patient's condition deteriorates, supplemental oxygen or respiratory support may be required to maintain oxyhemoglobin saturations at 90 to 95 percent. Newborns with chronic respiratory distress need constant monitoring of oxyhemoglobin saturation to determine whether they require supplementary oxygen. Standard treatment with supplementary oxygen will be enough for the management of TTN. To lessen the severity of respiratory distress, however, non-invasive respiratory assistance may be used during TTN.[7] Nasal prongs, an oxygen hood, a “continuous positive airway pressure” (CPAP) machine, a bubble nasal CPAP machine, a HHHF nasal cannula, “high frequency oscillatory ventilation” (HOFV), and a mechanical ventilator are all instances of oxygen delivery equipment. Most newborn care facilities in India have access to BNCPAP (bubble nasal continuous positive airway pressure) and HHHFNC (Heated humified high-flow nasal cannula).[8]

When used, NCPAP may boost “functional residual capacity” (FRC) and restore alveolar inflation. Improved gas exchange is the result of the combination of reduced intrapulmonary shunt and increased lung compliance.[9] HHHFNC involves the administration of HFT oxygen at frequency ranging from 1 to 8 L/min. Even though HHHFNC is equally efficient as BNCPAP for post-extubation respiratory support, it is not often used as the predominant way of breathing assistance, especially for newborns born with TTN. The current study is designed to assess the impact of HHHFNC with BNCPAP in the therapy of TTN in newborns with measure of pregnancy >35 weeks, as well as monitor the usage and complications of BNCPAP and HHHFNC in neonates with TTN.

Materials and methods:

This was an open label randomized controlled trail conducted in R . L. Jalappa hospital during January to December 2021. All the neonates (>35 weeks) born in R L Jalappa hospital and admitted to NICU with TTN were considered as study population. All neonates >35 weeks with respiratory distress were included in the study. “Infants with 5 minutes Apgar scores < 5” , “Nasopharyngeal pathology, Congenital malformation, Meconium aspiration syndrome and major congenital pulmonary or cardiac anomalies were excluded from the study. Study was approved by institutional human ethics committee. Informed written consent was obtained from all the parents /guardians of the participants and only those participants whose parents/ guardians willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of participation were explained to the parents/guardians of the participants before obtaining consent. Confidentiality of the study participants was maintained. All the relevant parameters were documented in a structured study proforma.

Methodology:

Babies whose parents consent for being included in this study were randomly allocated by Computerized Randomized allocation in to HHHFNC group or BNCPAP group.

Neonates > 35 weeks born with TTN were monitored for a duration of 48 hours or till distress was resolved whichever is earlier.

HHHFNC therapy: HHHFNC therapy (Fisher and paykel health care) was delivered by using “binasal prongs” . “The size of the nasal prongs should not exceed more than 50 % of the size of the nares . HHHFNC was initiated at a flow of 3 L/min with a Fio2 titrated to a maximum of 50 % to maintain spo2 between 88 to 93 % . Changes in flow was made by increments of 1L/min to a max flow 6 L/min if distress persists. Weaning was done by stepwise reduction of FiO2 to 21% and flow to 1L/min, followed by removal of HHHFNC at 1L/min and 21% oxygen”. [7]

NCPAP therapy: “NCPAP was delivered by bubble CPAP system (BC 151, Fisher and Paykel Healthcare, Inc.) with MR850 humidifier using short binasal prongs as interface (Hudson RCI Infant Nasal Prong CPAP cannula

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system). NCPAP was initiated at 5 cm H2O and flow of 6L/min with FiO2 to maintain SpO2 between 88-93%. CPAP pressure and FiO2 were titrated to a maximum of 7 cm H2O and 60%, respectively. A maximum of 8L/min of flow is allowed to ensure adequate bubbling in the water chamber". [7]

Demographic data and baseline vital parameters including HR,RR , SPO2 and Downes score were recorded . After intervention, primary outcome variables considered and compared in this study were vital parameters (HR,RR, SPO2(%) etc.) with respect to time duration till 48 hours or till distress was resolved , whichever was earlier. Whereas "Nasal trauma , Air leak syndrome , Duration of oxygen support and Recovery" were considered as secondary outcome variables and compared between two groups.

Statistical methods : Nasal Trauma, intubation and duration reported as primary outcomes and study group (HHHFNC Group Vs BNCPAP Group) was indicated as primary exposure. Basic summary stats denoted as count and % for categorical and mean with SD values for continuous parameters. Relevant graphs also provided. Normal distribution verification was done with the statistical test called "Shapiro-Wilk test" and visual method as histograms in each group of study. "Independent sample t-test (2 groups)" and "Mann Whitney u test (2 groups)" was employed as per the criteria fulfilment for the distribution of normality as parametric and non-parametric test. Outcomes measured in categories comparison done by "Chi square test". The P value < 0.05 indicates statistical significance.

RESULTS

The study overall result comprised 84 participants who were categorized into two groups of 42 in the "HHHFNC group" and 42 in the "BNCPAP group."

Table 1: Comparison of HHHFNC Group (N=42) and BNCPAP Group (N=42)

Parameters	**HHHFNCA group**	**BNCPAP Group**
Maternal Age (years)	23.07 ± 2.18	23.83 ± 2.16
Gestational age (in weeks)	37.46 ± 1.46	36.71 ± 1.12
"Birth weight (in kg)"	2.95 ± 0.59	2.75 ± 0.54
Gender		
Male	19 (45.24%)	20 (47.62%)
Female	23 (54.76%)	22 (52.38%)
Mode of delivery		
LSCS	38 (90.48%)	35 (83.33%)
NVD	4 (9.52%)	7 (16.67%)
Antenatal steroids		
Received	5 (11.9%)	9 (21.4%)
Not received	37 (88.1%)	33 (78.6%)
Risk factors		
Foetal distress	4 (9.5%)	5 (11.9%)
Hypothyroidism	2 (4.8%)	4 (9.5%)
IDM	5 (11.9%)	1 (2.4%)
IUGR	-	2 (4.8%)
Preeclampsia	-	1 (2.4%)
Severe PE	4 (9.5%)	6 (14.3%)
Twin gestation	1 (2.4%)	1 (2.4%)
No Risk factors	26 (61.9%)	22 (52.4%)
Vital parameters		
Heart rate (Bpm)	143.79 ± 14.38	144.83 ± 13.46
Respiratory rate (Cpm)	64.83 ± 3.22	65.33 ± 3.47
SPO2(%)	87.1 ± 1.81	86.71 ± 2.36
Downe's score	2.83 ± 0.82	2.88 ± 0.74

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The mean of Maternal Age was 23.07 ± 2.18 in HHHFNC Group and 23.83 ± 2.16 in BNCPAP Group. The mean of Gestational age (in weeks) was 37.46 ± 1.46 in HHHFNC Group and 36.71 ± 1.12 in BNCPAP Group. The mean of Birth weight (in kg) was 2.95 ± 0.59 in HHHFNC Group and 2.75 ± 0.54 in BNCPAP Group. In HHHFNC Group, 19 (45.24%) participants were male & remaining 23 (54.76%) were female. In BNCPAP Group, 20 (47.62%) participants were male & remaining 22(52.38%) were female . In HHHFNC Group, 38 (90.48%) women had LSCS mode of delivery and 4 (9.52%) had NVD. In BNCPAP Group, 35 (83.33%) women had LSCS mode of delivery and 7 (16.67%) had NVD. In HHHFNC Group, the proportion of subjects, who had received Antenatal steroids were 5 (11.9%) and 37 (88.1%) hadn't received Antenatal steroids. In BNCPAP Group, the proportion of subjects, who had received Antenatal steroids were 9 (21.4%) and 33 (78.6%) hadn't received Antenatal steroids.In HHHFNC Group, the majority of 5 (11.9%) participants were IDM, followed by 4 (9.5%) participants had risk factors like foetal distress & Severe PE & 2 (4.8%) participants had maternal Hypothyroidism, one was a twin gestation (2.4%) respectively. In BNCPAP Group, the majority of 6 (14.3%) participants had risk factors like Severe PE, followed by 5 (11.9%) had Foetal distress, & 4 (9.5%) participants had maternal Hypothyroidism and one was a twin gestation (2.4%) respectively. The mean of baseline Heart rate (bpm) was 143.79 ± 14.38 in HHHFNC Group and 144.83 ± 13.46 in BNCPAP Group. In Both Groups, all the neonates had CFT <3 sec and peripheral pulses were well felt. The mean of baseline SPO2(%) was 87.10 ± 1.81 in HHHFNC Group and 86.71 ± 2.36 in BNCPAP Group. The mean of baseline Downes score was 2.83 ± 0.82 in HHHFNC Group and 2.88 ± 0.74 in BNCPAP Group.

Table 2: Comparison of Outcomes & Complications between the HHHFNC and BNCPAP groups (N=84)

Parameter	**Study Group**		**P value**
	HHHFNC Group	**BNCPAP Group**	
Duration (in hours)	5.00 (3.0 to 8.0)	5.50 (4.0 to 8.0)	0.1941†
Recovery			
Recovered (not intubated)	41 (97.62%)	40 (95.24%)	1.000§
Not recovered (intubated)	1 (2.38%)	2 (4.76%)	
Complications			
Nasal Trauma			
• Yes	2 (4.76%)	6 (14.29%)	2.21§
• No	40 (95.24%)	36 (85.71%)	
Need for intubation			
Yes	1 (2.4%)	2 (4.8%)	0.557§
No	41 (97.6%)	40 (95.2%)	
Air Leak syndrome	**None**	**None**	

"*=IST P-value; †= Mann Whitney U test P-value; ‡="No Test is Applicable due to the nature of the data; §= Chisq test P-value

In HHHFNC Group, median duration of oxygen therapy was 5 hours (IQR 3.0 to 8.0) of duration and 5.50 (IQR 4.0 to 8.0) in BNCPAP Group, the median difference in the duration (in hours) between study groups was of no significance with value of P as 0.1941.

In both groups, none of the babies had air leak syndrome.

In HHHFNC Group, 41 (97.62%) participants had recovered and 1 (2.38%) baby hadn't recovered and required endo-tracheal intubation.

In BNCPAP Group, 40 (95.24%) participants had recovered and 2 (4.76%) hadn't recovered and required endo-tracheal intubation.

The ratio of Recovery between the research subjects was not significantly differed since the P value was1.00.

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DISCUSSION

In newborns, TTN is a leading cause of RD. Some newborns with TTN may need "noninvasive respiratory assistance" like NC or CPAP with supplementary oxygen, despite the fact that TTN is often a self-limiting condition. Among premature newborns, BNCPAP has become the standard non-invasive ventilation technique. [1] Nasal injuries and nerve damage are among the problems that might arise.[2] When it comes to preventing extubation failure in premature newborns, HHHFNC is another non-invasive respiratory support approach that has gained widespread acceptance throughout the world.[3] Infants with inadequate respiratory function may benefit from its usage since it reduces breathing effort, improves ventilation efficiency, and reduces the need for intubation. [4] The current randomized control trial intended to contrast the impact of HHFNC with BNCPAP device, for establishing the best possible respiratory modality for the treatment of TTN. Primary outcome variables considered in this study were vital parameters (HR, RR, SPO2(%) etc.) and complications like "Nasal trauma , Air leak syndrome , Duration of oxygen support and Recovery" were considered as Secondary outcome variables.

The current research was regarded that both the groups showed good recovery, thus both the techniques found to be effective ("97.6% VS 95.24%"). The proportion of recovered infants after receiving treatment did not vary significantly across the Study Groups (P = 1.00). In their research, Chen et al. found that HHHFNC dramatically decreased the need for reintubation within 7 days, shortened the duration of oxygen administration, and decreased the occurrence of issues such "nasal damage and NEC compared to NCPAP".[10] For premature newborns with mild to severe respiratory distress, Sharma et al. found that HHHFNC is just as effective as non-invasive positive airway pressure (NCPAP). When compared to NCPAP, HHHFNC is a less traumatic modality for the nasal passages. [11]Study results by Armanian et al. demonstrated that the "HHHFNC" approach revealed no suitable effectiveness in the therapy of babies detected "RDS", despite the HHHFNC group having a greater gestational age and birth weight than the NIMV and NCPAP groups.[12] Based on their findings, Konda et al. concluded that HHHFNC therapy is less beneficial than NCPAP therapy in facilitating extubation in preterm newborns. [13] When comparing the two groups, Shin et al. discovered no difference in terms of "respiratory and clinical outcomes" and sequelae. Although "HHFNC is non-inferior to NCPAP" in terms of safety, the researchers found that it is uncertain whether or not it is beneficial as a prime "respiratory support" in preterm neonates with RD.[14] When used as a main treatment for mild to moderate RDS in premature babies >28 weeks, HHHFNC has been shown to have effectiveness and safety comparable to those of nCPAP/BiPAP, according to research by Lavizzari et al.[15]From these investigations, Hegde et al. concluded that HHHFNC seems to have equal effectiveness and safety to NCPAP when used as the main method of respiratory support for preterm babies between "28 and 34 weeks of gestation" with mild to moderate RD.[16] Yoder et al. reported that HHHFNC appears to be as "effective and as safe" as NCPAP as the "major modality of respiratory support in neonates born" with TTN, and our results corroborate their findings. [17]

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DECLARATIONS

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