"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"

By

Dr. PADALA TRISALI

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTER, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

PEDIATRICS

Under the Guidance of

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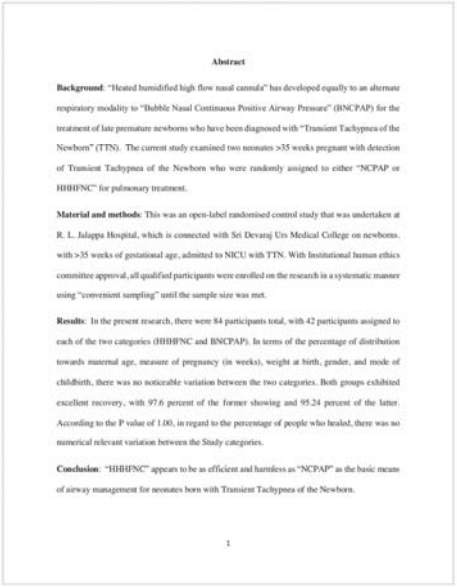

Abstract

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Dr. PADALA TRISALI

ABBREVATIONS

GLOSSARY	ABBREVIATIONS
BNCPAP	Bubble Nasal Continuous Positive Airway Pressure
TTN	Transient Tachypnoea of the New born
HHHFNC	Heated humidified high-flow nasal cannula
NCPAP	Nasal Continuous Positive Airway Pressure
NICU	Neonate intensive care unit
RD	Respiratory distress
AIIMS	All India Institutes of Medical Science
CPAP	Continuous positive airway pressure
HOFV	High-frequency oscillatory ventilation
FRC	Functional residual capacity
FiO2	Fraction of inspired oxygen
RDS	Respiratory distress syndrome
CLD	Chronic lung disease
BPD	Broncho-pulmonary dysplasia
PPHN	Persistent pulmonary hypertension
PVR	Pulmonary vascular resistance
PDA	Patent ductus arteriosus
FO	Foramen ovale
MAS	Meconium aspiration syndrome
ENaC	Expression of The Epithelial Sodium Channel
LMICs	Low- and middle-income countries
LSCS	Lower segment caesarean section
AS	Apgar score

ABG	Arterial blood gas
MV	Mechanical Ventilation
PEEP	Positive end-expiratory pressure
AH	Absolute humidity
RH	Relative humidity
EDP	End-distending pressure
dB	Decibels
BCPAP	Bubble Continuous Positive Airway Pressure
VLBW	Very low birth weight
ELBW	Extreme low birth weight
IVH	Intraventricular hemorrhage
NIMV	Non Invasive Mechanical Ventilation
GA	Gestational age
SAS	Silverman Anderson score
RCT	Randomized controlled trial
HFNC	High Flow Nasal Cannula
HR	Heart rate
RR	Respiratory rate
SPO2	Oxygen saturation
SD	Saturation deviation
NVD	Normal vaginal delivery
IDM	Infant of diabetic mother
NC	Nasal cannula
GDM	Gestational diabetes mellitus
BiPAP	Bilevel Positive Airway Pressure
IQR	Interquartile range

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ABSTRACT

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Key words: Transient tachpnea 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”, 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] In order to make a smooth transition to life outside the womb, the fetus must go through a series of complicated and dynamic changes before birth. After being cut off from the placenta, a newborn infant must rely on their lungs to facilitate breathing. A number of processes work together to help the lungs get the air and oxygen they need: This includes steps one (breathing on one's own), two (alveolar distension), three (removal of lung fluid), four (surfactant secretion), five (“decrease in pulmonary vascular resistance”) and six (“termination of right-to-left shunting at the atrial and ductal levels, followed by closure of the ductus arteriosus”).

RD from retained foetal lung fluid, or Transient Tachypnea of Infant (TTN) because tachypnea is the most frequent clinical sign, may occur if the newborn does not discharge the fluid quickly after delivery. The majority of cases with TTN resolve spontaneously, without therapy. Notwithstanding 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]

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]

Symptoms of TTN, which may include “tachypnea, grunting, nasal flaring, retractions, and even cyanosis,” usually appear during the initial hours of birth. Although the regular breathing rate ranges from sixty to eighty breaths per minute, severe cases of tachypnea may cause rates of breathing to increase to 100 or more breaths per minute. 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 and HHHFNC. [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. HHFNC has been hypothesised to operate by (1) removing "dead space", (2) reducing the effort required to breathe, (3) enhancing "lung compliance" at increased flow rates, and (4) providing "some CPAP". Compared to alternative oxygen supplements, CPAP may reduce the need for more intensive care, decrease the hospitalization, and improve long-term outcomes. and decrease the "maximal fraction of inspired oxygen" (FiO2) in term infants with TTN without raising the risk of "pneumothorax", according to published research. 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.

Need for the study

Newborns delivered at full term often need admission to newborn critical management settings because of TTN, making it the most prevalent cause of respiratory distress. There is a need for reducing the morbidity in the new born with respiratory distress especially with TTN. CPAP is already a modality of treatment for TTN. HHHFNC is a recent modality and oxygen is humidified, temperature is at optimal level and less adverse effects are seen with HHHFNC. The present format of treatment involves employing BNCPAP or HHFNC as a pulmonary technique to help neonates in "respiratory distress". In TTN, utilization of HHHFNC as a respiratory modality is not established. Most of the studies available are done on preterm neonates born <30 weeks' measue of pregnancy. The current research will 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.

AIMS AND OBJECTIVES

OBJECTIVES OF THE STUDY:

1. To monitor the use and complications of HHHFNC in neonates with TTN.
2. To monitor the use and complications of BNCPAP in neonates with TTN.
3. To compare the effect of HHHFNC versus BNCPAP in the management of TTN.

REVIEW OF LITERATURE:

Respiratory Disorders in Neonates

Upon birth, a baby must be able to adjust to life outside the womb in order to have any chance of survival. At the moment of birth, the body undergoes a series of crucial physiological changes that affect every system, lungs being the most crucial adaptation.[10]

The placenta and umbilical veins provide the foetus with oxygen and nutrition while in the womb, while the maternal circulatory system handles the fetus's carbon dioxide expulsion. The respiratory epithelium secretes fluid, which fills the lungs. [11] With its first breath after delivery, a baby takes in enough air to begin exchanging gases with the outside world (also known as "extra-uterine gas exchange"). [12] While doing so, pulmonary vascular pressure is lowered and there is an increase lungs perfusion[13]; and reabsorption of the fetal lung fluid occurs.[14] Babies born prematurely, "before 37 weeks of gestation", have a greater difficulty in adjusting to their new environments because of their immature lungs.

Causes of neonatal respiratory problems include delayed or maladaptive transition to life outside the womb, preexisting disorders including structural or developmental abnormalities, and acquired illnesses such lung infections that may occur before or after birth. Lack of "surfactant" in the lungs causes "respiratory distress syndrome" (RDS), which is particularly prevalent in infants delivered prematurely. A more precise diagnosis would be "hyaline membrane disease" a term used when referring to the structure of the affected tissue. Most occurrences of RDS are seen in children born prematurely, however, 6.4% to 7.8% of instances are detected in children born at 37 weeks of pregnancy, the majority of whom are born through cesarean delivery. In terms of respiratory complications, the most prevalent long-term effect of premature

birth is “chronic lung disease” (CLD), also known as “broncho-pulmonary dysplasia” (BPD). [15]

Newborns with persistent pulmonary hypertension (PPHN) have pulmonary arteries that have not yet adapted to the outside world. Primary pulmonary hypertension of the newborn may occur on its own or as a complication of another lung disorder. About one in every thousand newborns will have PPHN. [16] “Pulmonary vascular resistance” (PVR) limits lungs perfurion during gestation, diverting bloodline instead via the “patent ductus arteriosus” (PDA) and the “foramen ovale” (FO) into the remainder of the body's circulatory system. After being exposed to oxygen and beginning to breathe, the PVR naturally decreases.[17] A failure in this transition leads to persistently high PVR, which triggers “right-to-left shunting” at the rank of the pulmonary veins and FO, following in “pulmonary hypo-perfusion, hypoxia, and acidosis”. [18]

Normal foetal meconium passage is rare. During labour, foetal discomfort may cause meconium to enter the amniotic fluid. As foetal discomfort worsens, it gasps for air and may ingest meconium-stained liquid. Mechanical blockage of the airways from inhaled meconium may cause “ventilation/perfusion mismatch”, which can cause lung damage. Toxic pneumonitis, bacterial infection. PPHN develops as a consequence of an inflammatory response that promotes swelling, which in turn may clog tiny airways, lead to malfunction in surfactant, and reduce gaseous exchange. Post term gestational age, a low Apgar score, low amniotic fluid levels, and a male fetus are all risk factors for meconium aspiration syndrome (MAS). [19]

Similar to newborn sepsis, pneumonia may have an early or a late start. Congenital, or early onset, pneumonia manifests in infants less than 48 hours of life and is linked to trans-placental infection. [20] “Group B streptococcus” is the most prevalent causative

organism in cases of congenital pneumonia, while other viruses, bacteria, and fungi have also been associated with this condition.[21] Fetal pneumonia may arise from chorioamnionitis, which is caused by the inhalation of contaminated uterine fluid. [20]

Sometimes, surgery is needed to fix congenital abnormalities in the lungs and airways. Diaphragmatic hernias, tracheoesophageal fistulas, and pulmonary airway malformations are the most frequent birth defects. [22]

When it comes to respiratory problems in full-term newborns, TTN is by far the most prevalent diagnosis. [23]

Transient tachypnoea of newborn

Wet lung syndrome, or TTN, is a self-limiting respiratory condition that often manifests itself occurring during the first several hours after birth and continuing throughout the next few days. TTN often affects infants born at full term (37–39 weeks) or in the delayed premature range (34–36+6 weeks). [24] Delay in clearing foetal lung fluid was first documented clinically as TTN in 1966. [25] Breathing acceleration and the emergence of additional TTN clinical symptoms result from inadequate minute ventilation from insufficient evacuation of foetal lung fluid, which reduces compliance, functional residual capacity, and tidal volume. [24] The most characteristic clinical indicators, for diagnosis of TTN, are tachypnea and unique radiological findings.

Pathophysiology

The fetal “pulmonary epithelium” produce “alveolar fluid” at roughly six weeks of pregnancy. [26] “Interstitial chloride ions” are actively transported into the “pulmonary epithelial cell” by the “sodium, potassium, and chloride transporter”, and are then released into the alveolus via different “chloride channels”. Para-cellular routes carry chloride ions together with sodium, while aquaporin carries water across cell

membranes. [27] The larynx functions as a one-way valve, enabling fluid to exclusively leave the foetal lung. While starling forces and thoracic pressure play a little part in clearing, it is widely thought that passive flow of sodium via "epithelial sodium channels" is the important process through which lung fluid is reabsorbed. Pneumocytes of "type 1 alveoli express aquaporin 4 and 5", which are water channels are in charge of the vast bulk of water movement throughout the "apical membrane of alveolar epithelia".[28] Most type 1 alveolar cells have a water channel called AQP5. The endothelium of pulmonary capillaries is rich in AQP1. [29] Patients with TTN have higher AQP5 expression than controls. It is not known if the increased expression of "APQ5" is a causal role in the onset of TTN or an adaptive response that helps drain alveolar lung fluid. [30]

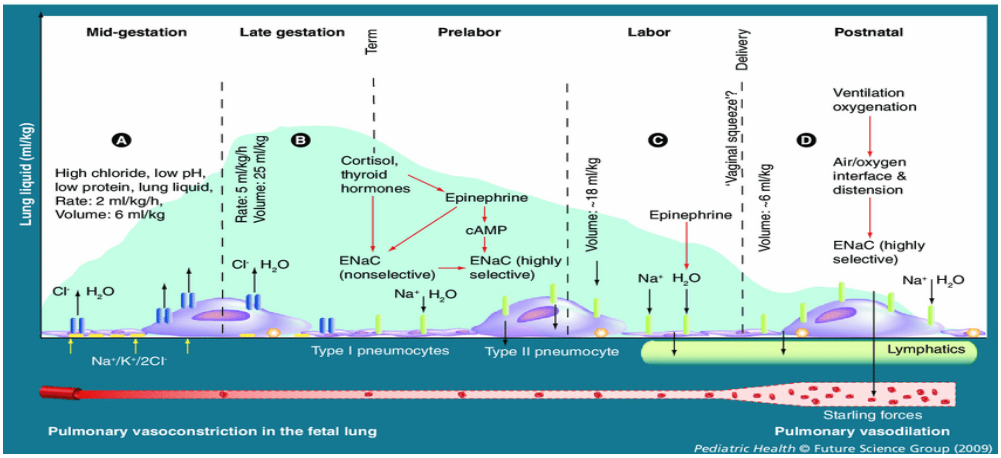


Figure 1: Fluid secretion and reabsorption in the lungs throughout development and labor/delivery/the postpartum period.

Description of figure as follows

(A) Background light blue indicates the volume of lung fluid. There is a concentration gradient in the pulmonary circulation, and water moves down this gradient into the alveolar lumen (light arrows). Liquid production from the lungs rises from 2 ml/kg/h at midgestation to 5 ml/kg/h at full term. During mid-pregnancy, the total lung liquid capacity is 4-6 ml/kg, but by full term, it has increased to 25-30 ml/kg.

(B) During late gestation there is an increase in epithelial sodium (light) channels (ENaC) on type I and type II cells. The respiratory epithelium changes from a chloride-secreting membrane to a mainly sodium-absorbing membrane when cortisol and thyroxine levels rise and catecholamine levels rise during pregnancy. At this point, it's possible that the nonselective cation channels give way to the more selective sodium channels. Sodium is pumped out of the epithelial cells by sodium-potassium ATPase (hexagons) (hexagons).

(C) During labour, lung fluid is absorbed more quickly. Lung liquid capacity is lowered to around 6 ml/kg during birth. Minimal clearance of lung fluids may result from thoracic compression caused by vaginal squeezing.

(D) When exposed to postnatal ventilation and oxygen, the highly selective ENaC channels in the lungs are able to remove more liquid from the lungs. The pulmonary lymphatics and capillaries clean the interstitial space of any fluid that has made its way in. After delivery, pulmonary vascular pressure drops, which may aid fluid evacuation through Starling's forces.

Labor begins when the “ENaC” on the “apical membranes” of type II pneumocytes is activated by maternal epinephrine, and glucocorticoids. “Alveolar sodium” is passively carried through ENaC proteins, and then the Na+/K+-ATPase pump actively transports the sodium back to the interstitium.[32] Chloride and water are able to enter the bloodstream through the lungs and the lymphatic system because to the osmotic gradient that is established. The mechanical pressure experienced by the foetus after vaginal birth aids in the release of lung fluid, although to lower amount. [33]

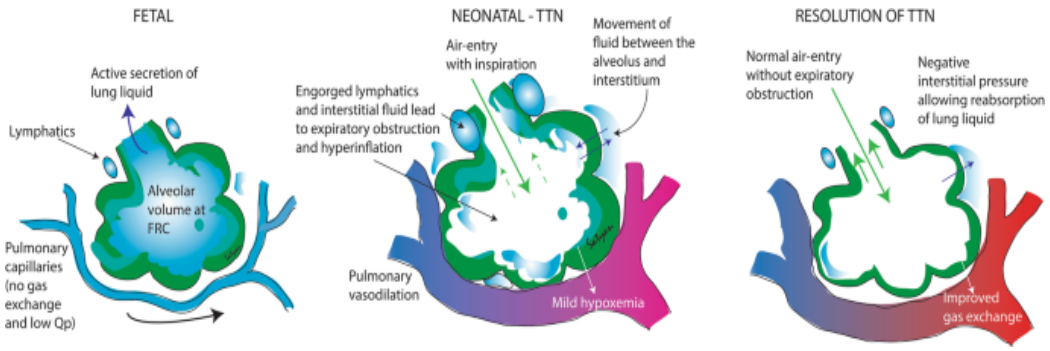


Figure 2 :

Description of figure as follows:

The function of breathing and the retention of fluids in the airways. Although the lungs of a foetus filled with fluid do not take part in gas exchange, their volume is similar to the FRC of a lung filled with air. After the baby's head has been delivered, the interstitial pressure may rise because of the pressure created by inspiration, which pushes liquid from the airways into the lung tissue. End-expiratory interstitial pressure elevation may cause a redistribution of fluid away from the alveoli and back into the alveoli. [34]

Newborns with increased liquid contents in their airways have associated pathophysiology, which has been confirmed in recent investigations. These include:

1. Neonates have a harder time breathing because their chests expand and their diaphragms flatten when they breathe for the first time. [35]

2. The decrease in lung volume at the conclusion of inspiration (functional residual capacity, FRC) [33,35] Since the decreased FRC can be pinpointed to specific areas of the lung that have an abundance of liquid, this strongly suggests that the process of liquids being cleared out of lung tissue locally is the key factor in the diminished FRC. [36]

3. There is a significant decrease in lung compliance, which inhibits inspiration and contributes to the lower FRC. [35]

4. Reduced lung capacity means more oxygen therapy is needed to compensate for low blood oxygen levels. Causes decreased "pulmonary blood flow" and elevated "pulmonary vascular resistance", which may develop into life-threatening chronic pulmonary hypertension in infants. .[37]

5. brings on the physical symptoms of "tachypnea, grunting, and expiratory braking" in infants who are breathing on their own for the first time. .[35]

Epidemiology

Despite a thorough search of the literature, no summary exists that deals specifically with neonatal respiratory distress, a potentially fatal neonatal emergency that continues to plague "low- and middle-income countries" (LMICs), especially where it serves as an important function in the overall infant fatality rate [38] It hinders LMICs'

efforts to achieve Sustainable Development Goal 3, which aims to "fewer than 10 deaths per 1000 live births by 2035".[39]

According to a study conducted in Iraq by Fadhil et al., RDS accounted for 67.1% of neonatal deaths associated with respiratory distress, followed by "perinatal asphyxia (18.4%), congenital abnormalities (6.6%), sepsis (4.6%), and MAS (3%). (3.3 percent)". [40] It was the TTN that caused the most cases of newborn RD. A fatality rate of 26.84 percent was found for infants diagnosed with RDS at birth. [41] The incidence of TTN was estimated to be 16 per 1000 newborns in prospective research conducted at a specialized consultative health care hospital in western India between August 2019 and July 2021. Babies born late in the womb, those delivered via LSCS, and males were shown to be at increased risk for TTN.[42]

Risk factors

Premature birth (birth before 39 weeks), foetal distress, maternal drowsiness, and gestational diabetes are all common risk factors for TTN. [19] Multiple pregnancies, birth weights more than 4 kg, premature delivery, and birth via scheduled "caesarean section" in the non-appearance of contractions are all related to higher threat of TTN. "Birth asphyxia", "excessive maternal sedation and analgesia", "exposure to B-mimetic agents", "prolonged labour", and "polycythemia" are all less common risk factors for TTN.[43] The following are other potential risk factors in term infants: while using medically-assisted conception and delivery (i.e., "forceps or vacuum extraction") and when the newborn's "Apgar score" (AS) at 5 minutes is < 8.[44]

Course

Reportedly harmless and self-limiting, TTN often resolves within a few days after birth. However, some term infants who are first detected with TTN proceed to expand a "progressive and severe respiratory disease course" that requires "prolonged mechanical ventilation, oxygen therapy, or additional intervention" (for example, "surfactant replacement therapy, inhaled nitric oxide, or thoracentesis"), and as a result, a prolonged stay in the NICU. Reasons for the delay in foetal lung fluid reabsorption include abnormalities in "active pulmonary epithelial sodium transport", "moderate immaturity of the surfactant system", and "myocardial left-sided heart failure" caused by hypoxia.[45] Newborns with infections are evaluated with a chest scan, blood testing, and careful cardiorespiratory monitoring. Even while TTN usually resolves on its own, a large retrospective study has established a connection between TTN and wheezing issues in late infancy.[46]

Clinical presentation

Clinical manifestations of TTN in newborns include "tachypnea, expiratory grunting, nasal flaring, and intercostal retraction", all of which may be heard during or soon after delivery. These signs and symptoms often fade within 2 to 3 days following delivery, however they might persist for up to 5 days. [47] Early signs of this condition sometimes mimic those of infant RDS, "pneumonia", and "chronic pulmonary hypertension". Therefore, until there is clarification about blood culture findings, antibiotics are often given to these babies in addition to conservative care. [48]

Diagnosis

The main factor used to diagnose TTN is the length of the respiratory distress. Distress might be classified as "delayed transition" if it goes away within the first few hours of birth. The duration between "delayed transition" and TTN is arbitrarily set at six hours because by then the baby could be having feeding problems and may need additional interventions. TTN is usually diagnosed after other causes of RD are excluded, thus any tachypnea lasting longer than 6 hours requires further testing. These components are often part of the workup: Differential cyanosis may be ruled out with pre- and post-ductal saturations; neonatal sepsis can be ruled out with a "complete blood count, blood culture, C-reactive protein, and lactate"; Hypercapnia indicates weariness or air leak, whereas hypoxemia and hypocapnia may be shown on an ABG study if tachypnea is present. Hyperinflation, conspicuous perihilar vascular marks, edoema of "interlobar septae", or fluid in the "fissures" can be seen on a chest x-ray. 49

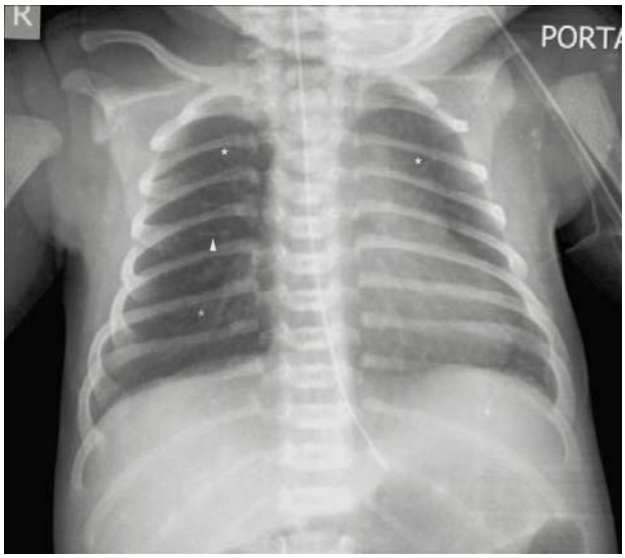


Figure 3: Chest radiograph in transient tachypnea of the newborn[42]

Indicators of TTN are seen on the radiograph. Mild hyperinflation of the lungs causes the rib cage to become more upright and the intercostal gap to widen. Fluid in horizontal lung fissures (white arrow), streaky infiltrates (white asterisk), and perihilar streaking (Sunburst)

“Diffuse streaky pulmonary interstitial opacities”, edema of the “interlobar septae”, and fluid in the “fissures” are all X-ray findings indicative of lung fluid retention. On a chest X-ray, a "sunburst" pattern may be seen if there are noticeable vascular patterns around the hilar region of the lungs. Widening of the intercostal gaps may be accompanied by some “hyperinflation” and fluid that can be observed at the “costophrenic angles”. While complete erasure of radiographic evidence may take up to 7 days, improvement seen on images at regular intervals in 48–72 hours is one of the important features of TTN.,27

Management

Since TTN resolves on its own, supportive care is the primary method of therapy. If a newborn's health has not improved or has deteriorated two hours after the commencement of respiratory distress, or if the fraction of inspired oxygen necessary is >0.4, or if the chest film shows abnormalities, the baby has to be sent to a hospital that provides a better level of newborn care as soon as possible. 50 Continuous cardiac monitoring, maintaining a neutral temperature environment, obtaining “intravenous (IV) access, checking blood glucose levels, and monitoring for sepsis” are all examples of routine NICU care that should be performed. Non-invasive oxygen (O2) therapy is the mainstay of treating TTN; however, invasive respiratory support, such as nasal CPAP and “mechanical ventilation” (MV), can be an assistance in certain cases. “Persistent pulmonary hypertension” (PPHN) and “air leak

syndrome"are TTN consequences that may result from the subject's inability to manage their tachypnea and the subsequent extended need supplementary oxygen. [51]

Role of oxygen delivery devices in TTN

The oxygen delivery technologies used should be risk-free, easy to implement, productive, and reasonably priced. Non-invasive ways include using a face mask or keeping the tubing near to the infant's face, whereas semi-invasive procedures include making small incisions in the skin ("insertion of prongs or catheters into the upper airway"). The following are some of the devices that may be used to supply oxygen:[52]

1. "Blow by method or free flow oxygen"
2. "Oxygen by hood"
3. "Nasal mask"
4. "Nasal cannula" ("low flow")
5. "Nasal or nasopharyngeal catheters".

"**Free flow oxygen":** Although "free flow" oxygen administration, also known as blow-by oxygen delivery, is the quickest and easiest way for administering oxygen treatment, it also has the lowest reliability in terms of maintaining a constant FiO2. Large diameter "oxygen tubing" with a flow meter set to 3–4 L/min is often used to supply oxygen to a patient, with the other end held only a few centimetres (5 mm) from the patient's face. It seems that a flow rate of 3 L/min is optimum, since this is the rate at which the neonate is certain to get a FiO of 36% or higher. There is only around 18 centimetres of space in the oxygen chamber, and that could not be enough for a lively newborn. These oxygen tanks are ideal for premature infants who have trouble breathing, newborns who need less oxygen, and for short-term usage during feeding or neonatal resuscitation. [52]

Oxygen Hood: A plastic hood (cube) is placed over the newborn's head, and a constant supply of "humidified oxygen" is piped in either an "air entrainment device or an air-oxygen blender". A minimum of 7 L/min of "oxygen flow into the hood" is required to maintain oxygen concentrations of 0.21 to 1.0 at constant levels. It is possible to treat patients who need "higher FIO2" under a hood, although doing so becomes more challenging owing to the large neck opening and a "less-than-optimal seal" around the edges. 53

Nasal prongs are a medical device having two thin tubes (approximately 1 cm long) angled such that they rest within the nostrils. These devices are sometimes referred to as nasal cannulae. Newborns typically get 0.5-1 L/min by nasal prongs, babies receive 1-2 L/min, and older children receive 1-4 L/min.

Low-Flow Nasal Cannula: The "low-flow nasal cannula" is still routinely used to supply oxygen to neonates. This low-flow device contains 2 pliable prongs that rest in the nasal passages up front and give a fractional concentration of oxygen. A flow metre for pure oxygen or an air-oxygen blender are connected to the end of the cannula tube. Research by Finer et al. indicated that the highest flow rate of oxygen using a nasal cannula for a newborn was 2 litres per minute (L/min), with a concentration ranging from 22% to 95%. 54 The actual concentration of oxygen provided to the patient might vary, but a nasal cannula is still a reliable and effective way to provide oxygen treatment to a newborn.

High-Flow Nasal Cannula: Using a "nasal cannula" to provide oxygen therapy is the norm, and it is constantly being modernized to improve patient convenience, adherence, and results. Nasal cannulas with high air flow and humidity are a novel concept, though, brought to the respiratory care community for the first time by Vapotherm in the spring of 2002 after getting 510K approval from the "Food and

Drug Administration" in the autumn of 2001. [53] An air-oxygen blender enables direct manipulation of FIO2, and the device's "nasal cannula-style prongs" sit comfortably in the patient's anterior nares to supply "heated, humidified oxygen" at flow rates of 1.0 to 8.0 litres per minute. [55] Most NICUs now use, and it is becoming the standard in many to use high-flow nasal cannulas because of how well they are tolerated by patients. It is also employed because its oxygen concentrations and inspiratory flows surpass those of the previously mentioned devices, allowing it to give the neonate with a greater degree of oxygenation assistance. "Positive end-expiratory pressure" (PEEP) may contribute to the oxygenation benefits of using a "high-flow nasal cannula". "High-flow nasal cannula" has been demonstrated to greatly boost "esophageal pressure" [56] and "pharyngeal pressure"[57] in newborns.

Positive pressure created in a group of preterm newborns was shown to vary with both flow rate and cannula size, according to research by Locke et al., who found that a larger cannula size resulted in a "mean pressure of 9.8 cm H2O at a flow rate of 2 L/min". [56] At flow rates of 1-2.5 L/min, Sreenan et al. determined that positive distending pressure could be reliably provided using a "high-flow nasal cannula", and that this method was just as effective as nasal CPAP in reducing apnea, bradycardia, and oxygen desaturations.[58]

CPAP consists of providing moderate air pressure to maintain open airways. Maintaining lung volume during expiration is made possible by CPAP, which provides PEEP administered to a patient who is independently breathing with a titratable dose of oxygen. With CPAP, oxygenation is increased while atelectasis (the collapse of alveoli and lung segments) is reduced, as are the effects of respiratory exhaustion. [59] For babies who are not improving with oxygen therapy and have severe respiratory distress, hypoxemia, or apnea, this device may be helpful.[60]

It is also possible to administer CPAP by connecting the breathing circuit's expiratory leg to a column submerged in water (bubble CPAP). There are referral hospitals in underdeveloped nations where bubble CPAP has been utilised well. Typically, a gas flow rate of "5-10 L/min" is used to create CPAP. The FiO2 of 21 percent is enough to produce CPAP on its own, but many newborns need extra oxygen. Therefore, an oxygen blender is often included in the setup, which links the system's continuous airflow to an oxygen source ("cylinder or concentrator"), in order to boost the FiO2. [60] "High-flow nasal cannula" oxygen (HHHFNC) is a new, easy procedure of giving patients the benefit of positive pressure. The gas flow rate may reach up to 2 L/kg/min. Depending on the child's clinical condition, the gas supply may be either an air/oxygen mixture (provided by "concentrators or cylinders z/2 a blender") or a "flow generator" with variable air pressure to accommodate infants of varying weights. The use of oxygen mixtures is optional. [60]

Effectiveness of HHHFNC in TTN >35 weeks

Supplemental oxygen administration is a crucial aspect in treating hypoxemic respiratory failure. The use of nasal cannulae to provide oxygen treatment is well-established; however, the quantity of oxygen that may be administered has generally been restricted due to the inability of youngsters to tolerate flow rates greater than 2 L/min. When oxygen and air mixes are warmed to body temperature and humidified to more than 99.5 percent relative humidity, they may be delivered comfortably at flow rates that are equal to or greater than the patient's "inspiratory flow rate", reducing the likelihood of entrainment with ambient air. Treatment with an HHHFNC (heated, humidified, "high-flow nasal cannula") is the term for this method. "High-flow nasal cannula" treatment sets sold commercially are open devices that allow air to escape via the mouth and nose.[61] In order to deliver "positive distending pressure"

to a baby in RD, the HHHFNC system has become part of the repertoire of newborn respiratory therapy. When administered using a regular newborn nasal cannula, heated and humidified gas flow (>=1 L/minute) is used in HHHFNC treatment to increase patient tolerance. Evidence suggests that HHHFNC, which employs "positive distending pressure" to facilitate breathing, is equally effective as non-invasive continuous positive airway pressure (NCPAP). [62] Clinically appropriate amounts of CPAP may be produced using HHHFNC devices in addition to the benefits of heated and humidified breathing gases.

Physiology

Heated humidified HFNC oxygen treatment is the full name of HFNC. Avoiding mucosal irritation and pain from the dry, chilly air is possible with adjustable (FiO2 21 percent -100 percent), heated (34°C-37°C), oxygen. Warm mist humidifiers may help loosen mucus and cleanse the airways, making breathing easier. For HFNC to work, the oxygen flow must be regulated to be greater than the inspiratory demand flow, which might vary from case to case. A reduction in nasal resistance and a smaller dead space in the nose might result from this. [63] Washing out anatomic "dead space" and mixing gases better in big airways are just two of the many effects on respiratory mechanics that HHHFNC has that contribute to its positive clinical outcomes. Other effects include increasing the "end-expiratory lung volume" and the "alveolar partial pressure of oxygen". [64] High-flow non-invasive ventilation (HFNC) systems are less likely to allow entrainment of ambient air during patient inspiration because they produce greater flow rates. These processes, together with the natural clearing of the upper airway during expiration, help to ensure consistent distribution of greater fraction of inspired oxygen concentrations. Emptying the upper airway of

"dead space" also increases ventilation efficiency and lessens the effort required to breathe. PEEP is also produced by HHHFNC, which may counteract auto-PEEP to further decrease "ventilator effort, boost oxygenation, and give back pressure to increase airway patency" during expiration and allow for more thorough emptying. [65]

A total of three components makes up the HHHFNC system:

1. "Fixed oxygen concentration system": A "venturi system" or "oxygen blender" is needed to give a consistent amount of inspired oxygen (FiO2). Complications from oxygen treatment, as well as the danger of oxygen poisoning, may be mitigated by administering oxygen at the precise amounts suggested by a doctor. [66]
2. Humidification system: The temperature of the gas being circulated should be 37 degrees Celsius, and it should be humidified ["absolute humidity (AH) of 44 mg/L, relative humidity (RH) of 100 percent"]. The inhalation process heats the inner lining of the airways to 37 degrees Celsius, the AH will be increased to 44 micrograms per litre, and the relative humidity will increase to 100 percent from the baseline value of 50 percent. [67]
3. High-flow system: The "high-flow system" allows for the distribution of a flow rate in excess of the subject's highest "inspiratory" need. Infants need a "high-flow rate" of at least 2 L/min and often 2-8 L/min. "Nasopharyngeal pressure" produced by a high-flow system may decrease airway resistance and labour of breathing, provide end-distending pressure (EDP), boost FRC, and enhance lung compliance. Nasopharyngeal wash out aids in better alveolar ventilation and gas exchange.[67]

While it was first developed as an alternative to CPAP and a tool to facilitate extubation, HFNC is now utilized for a variety of additional purposes. The belief that HFNC is easier to use, more pleasant to wear, and less likely to cause nasal injury is a major factor in its popularity among parents. [68] Increasing clinical data suggests that

nHF might well be employed safely to provide airway management for preterm babies in a range of clinical scenarios, and this popularity is likely to only rise in the future. Compared to CPAP, nHF has the most supporting data for use after extubation for preterm babies in the NICU exists now in the neonatal population, however caution is urged in severely preterm infants where limited data is available. [69]

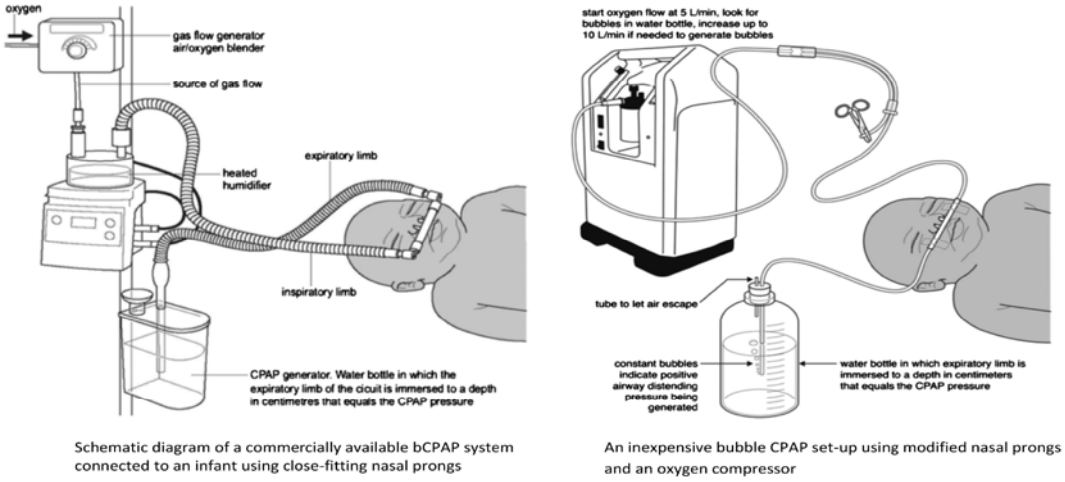
Variable distending pressures may induce progressive atelectasis, according to a hypothesis put out in a cohort analysis of patients who required respiratory assistance after the advent of HFNC,[70] while more recent research has shown an increased chance of mortality or "chronic lung disease/bronchopulmonary dysplasia, respiratory morbidities, delayed oral feeding, and length of stay".[71] Cochrane study data also indicated the need for more respiratory assistance, but found no correlation with an increase in chronic lung disease. When it comes to protecting premature newborns from treatment failure, mortality, and CLD, HFNC usage has a success rate on par with that of other non-invasive respiratory support methods. The majority of research on HFNC focuses on its effectiveness as a post-extubation lifeline. In comparison to nasal CPAP, HFNC usage after extubation is related with reduced risk of nose injury and perhaps pulmonary air leakage. [72]

Avoiding environments with noise levels more than 45 decibels (dB) was suggested by the "American Academy of Pediatrics", and sustained exposure to sounds greater than 90 dB was cautioned to cause hearing damage. [73] Recently, the background commotion that comes with using bubble CPAP (BCPAP) machines were examined in an observational research. In HHHFNC, there was a correlation between increasing noise and gas flow, however in BCPAP, there was no such correlation. [74] According to parent reports, HHHFNC treatment led to considerable improvements in their children's happiness, communication, and capacity to participate in caring.

Infants who underwent HHHFNC treatment after extubation had a substantially decreased incidence of nasal injuries (39.5% vs 54.3%, p=0.01) compared to babies who received CPAP. [75] Three children, all of whom were having HHHFNC treatment, recently had air leakage (pneumothoraces in two of the kids, and pneumomediastinum in the third) reported as a case series. An unexpected increase in positive airway pressure is cited as a probable cause by the authors. [76]

Effectiveness of BNCPAP in TTN >35 weeks

Nearly half a century ago, Gregory and colleagues created the first CPAP equipment made exclusively for neonates, ushering in a new era in neonatal care. An "endotracheal tube, a sealed head chamber (Gregory box), or a face mask" were first used to deliver CPAP.[77] An "air compressor, an air-oxygen blender, a humidifier chamber, and tubing" with a patient interface make up the bare minimum of a bNCPAP system. [78] Because of its cheap price, ease of construction, and possible independence from power and wall-oxygen, bubble-CPAP (bCPAP) is particularly well-suited for LMICs. Low-tech and high-tech bCPAP systems are available at varying costs, and both oxygen concentrators and cylinders may be utilised. Nasal prongs and clear plastic bottles, both readily accessible and inexpensive, may be used in their construction. The PEEP is produced by connecting the breathing circuit's "expiratory limb" to a tube immersed in water. Depending on how far the tube is inserted into the water bottle, different pressures will be produced. The bottle has a vent so that air may escape. [79]



Schematic diagram of a commercially available bCPAP system connected to an infant using close-fitting nasal prongs

An inexpensive bubble CPAP set-up using modified nasal prongs and an oxygen compressor

Figure: 4 A fabricated bCPAP machine [60]

In the beginning, a FiO2 of 0.30 is utilised for newborns delivered <28 weeks of pregnancy, "0.21-0.30" for those born at 28-31 weeks, and "0.21" for those born at more than 32 weeks. [80] If oxygenation is still a problem, the FiO2 is raised from 0.5 to 0.8 in 0.05 increments. [81] Starting PEEP in a newborn is typically between "4-6 cm H2O" and may be altered according on the infant's "clinical status, oxygenation, and perfusion". "PEEP" is raised by "1–2 cm H2O", and highest of "7–8 cm H2O", if there is no sign of improvement. [80]

Modified low-resistance binasal prongs are used in conjunction with an oxygen concentrator or cylinder to create the bNCPAP. The tube is cut in half with one end becoming the "expiratory limb" and the other end being sealed up in some way (by being tied off, cemented, or clamped) so that no air can escape. The tube connected to the opposite end of the "prong is the inspiratory limb". [82] However, there are two primary limitations to using locally produced circuits. Titrating oxygen is not an option since they do not have access to an air-oxygen mixer. A concentrator that mixes air and oxygen may, however, be the answer. [83] Second, the diameter of conventional nasal prongs may not be suitable for the gas flow rate needed to generate

CPAP, often between 5 and 10 L/min of oxygen. This might result in too much resistance and an insufficient pressure being generated. [79]

NCPAP helps infants who are breathing on their own by constantly increasing the pressure at their mouth and nose above the surrounding air. As a consequence, the patient's oxygen consumption drops, their functional residual capacity (FRC) rises, their alveolar recruitment and lung compliance improve, their ventilation and perfusion are enhanced, and their oxygen resistance decreases. NCPAP works by splinting the "airways and diaphragm", which reduces the pace of breathing and helps stabilise the chest wall. In addition to these benefits, NCPAP also facilitates lung development by enhancing surfactant generation and conservation on the "alveolar surface" and decreasing "alveolar oedema". [84]

Table 1: "Indications and contraindications for NCPAP" [85 86 81]

"Indications"	**"Contraindications"**
"Respiratory distress syndrome" "Apnea of prematurity" ("obstructive apnea") TTN "Respiratory distress due to perinatal asphyxia" "Meconium aspiration syndrome" "Congenital pneumonia" Post extubation in preterm "VLBW infant" "Laryngomalacia/tracheomalacia/bronchomalacia"	"Progressive respiratory failure" (pH < 7:2, PCO2> 65 mmHg) CPAP failed to alleviate symptoms of poor respiratory drive, including recurrent apnea or bradycardia. Severe cardiovascular instability (hypotension) Congenital malformations "(choanal atresia, cleft lip and palate, Pierre Robin sequence, congenital diaphragmatic hernia, and tracheoesophageal fistula)"

However, there are some widespread clinical restrictions with NCPAP. As a first point, the mechanical challenges of keeping the nasal prong equipment properly positioned inside the tiny newborn nose are an intrinsic part of administering NCPAP. The nasal prongs used to administer NCPAP have been linked to septal damage. Lastly, the NCPAP device requires a tight seal around the nose and face, which some premature newborns are unable to endure. [87]

Survival rates for neonates treated with bCPAP were 71% compared to 44% for controls in a non-randomized convenience sample investigation investigating the effectiveness of bCPAP in treating babies in acute RD. Contrasted with control category, 65.5% of ELBW newborns were given bCPAP made it to discharge. With bCPAP, the survival rate for newborns with RDS was 64.6% compared to 23.5% for controls. In comparison to the newborns with sepsis in the control group, all of the neonates treated with bCPAP lived until discharge (61.5%). Researchers found that treating infant RD with a basic CPAP device increased survival by 27%. [88] Seventy-three percent of the babies treated for respiratory distress with home-based CPAP improved, 21 percent required further mechanical ventilation, and 6 percent were released against medical recommendation. Comorbidities such as sepsis, congenital heart disease, PPHN, and IVH were linked to CPAP failure. [89]

Effectiveness of HHHFNC vs BNCPAP in TTN >35 weeks

Recently, HHHFNC devices have been introduced in several units as an alternative to NCPAP as a noninvasive method of aiding premature infants' breathing. HHFNC may be more convenient for caregivers and more successful in treating certain infant respiratory problems than traditional CPAP, although it delivers variable and

unexpected positive airway pressure. [90] Comparing BNCPAP and HHHFNC as early noninvasive respiratory treatment for TTN in neonates delivered at 34 weeks of pregnancy: a retrospective cohort study. Infants in the BNCPAP group were found to have considerably lower maximal FiO2 without having a increased pace of pneumothorax. Babies in the BNCPAP category also spent 32% less time on oxygen than those in the HHHFNC group, but this difference was numerically insignificant. [91] When given as the first line of defence to premature neonates with "RDS" whose gestational ages range from 29 weeks 0 days to 36 weeks 6 days, HHHFNC was as effective as regular NCPAP or BiPAP in lowering the likelihood of requiring ventilator support within 72 hours after starting respiratory support. There was also no variation in the rate of failure to breathe without assistance between the various GA groups. Additional secondary respiratory and non-respiratory outcomes were also evaluated, and discovered no significant distinctions between the categories. [92]

Roughly 10% more preterm children randomised to HHFNC than nCPAP had treatment failure due to respiratory distress ("Risk difference 17.17 [1.90-36.23]; P = 0.099"). As a contributing factor to treatment failure, hypoxia occurred more often in the "HHFNC" category compared to "nCPAP" category. (P = 0.020). Upon comparing "respiratory and clinical" outcomes and complications between the two groups, there was no discernible difference. It is not yet known whether HHFNC is effective as a primary airway management for premature neonates experiencing respiratory distress, despite the fact that its safety is comparable to that of nCPAP. [93] Significantly higher risks of treatment failure were seen in the "HFNC" category than the "CPAP" category ("HFNC, n = 35, 26.3% vs CPAP, n = 11, 7.9%; risk difference 18.4%, 95% CI 9.7-27"). Mechanized breathing was used almost equally often in both groups throughout the first three and seven days of life. Neonates with moderate

("Silverman Anderson score", SAS 5) or severe (SAS score, >5) RD were more likely to have a failed therapy in the HFNC cohort according to protocol. [94]

Relevant studies concerned with effect of HHHFNC Versus BNCPAP in neonates with TTN:

Chiruvolu et al. (2021)[91] examined the effectiveness of BNCPAP vs HHHFNC as main noninvasive respiratory treatment in hypoxic newborns for TTN in a "retrospective cohort" of babies born at 34 Weeks gestation. They determined that the maximal FiO2 in the BNCPAP group of babies was considerably lower than in the control group, and this was the case despite the fact that the rate of pneumothorax did not rise.

Liew et al. (2020)[95] studied how HFNC affected the pulmonary physiology of premature babies of varying birth weights. PEEP produced in "open vs. closed" mouth situations differed significantly for all HFNC flows ("difference 0.6-2.3 cm H2O"). When comparing newborns with weights more than 1000 g, PEEP was increased for those weighing less than 1000 g while maintaining the same HFNC flow. PEEP variability was higher than NCPAP variability at HFNC flows of "6-8 L/min" ("2.4-13.5 vs 3.5-9.9 cm H2O"). Clinically substantial PEEP is produced with HFNC treatment, however there is a lot of variation at higher flow rates, according to the research. Infants with birth weights of less than one thousand grammes were shown to experience the highest stresses.

Chen et al. (2020)[96] in their research showed that HHHFNC, as compared to NCPAP, was more successful in prevention of extubation complications in preterm babies with exceptionally low birth weights who are receiving mechanical ventilation. Data showed that HHHFNC decreased the need for oxygen, decreased the number of cases of nasal damage and necrotizing enterocolitis, and reduced hospital stays and expenses.

Colleti Junior et al. (2020)[97] conducted a "meta-analysis of randomised controlled trials" to evaluate the safety and efficacy of "high-flow nasal cannulas" for use with post-extubation CPAP in premature infants. As supplemental respiratory assistance after extubation in premature newborns between 32 and 28 weeks of pregnancy, they found that the "high-flow nasal cannula" was not inferior to CPAP and resulted in reduced nasal injuries.

Sharma et al. (2019)[98] studied infants between 26 and 34 weeks of gestation in a major hospital in Jaipur, India admitted with mild to severe RD over the first 6 hours following childbirth in a prospective, double-blind, randomised controlled study. For preterm neonates with moderate to severe RD, they found that HHHFNC was equally beneficial as NCPAP.

Armanian et al. (2019)[99] analysed the "efficacy of noninvasive respiratory support" strategies (NCPAP, NIMV, and HHHFNC) for the treatment of RDS in premature neonates. NCPAP and NIMV are preferred over HHHFNC as the first line of therapy for RDS because of the lower likelihood of treatment failure associated with these two alternatives, respectively.

Fleeman et al. (2019)[100] in a "meta-analysis and systematic review" comparing the success rate of HHHFNC to that of other therapies for premature newborns. Evidence is weak for children born prematurely (with a GA 28 weeks), however HHHFNC shows promise as a safe and effective alternative to NCPAP for certain newborns.

Diana Grace et al. (2019)[101] claimed that level III units are effectively using bNCPAP therapy for a variety of respiratory illnesses with little adverse effects. 44% of infants with RD had transient tachypnea, 24% had RDS, and 6% had delayed respiratory transition (18 percent). Treatment was effective in 86% of cases. Thirty-five infants were the only ones who did not counter to CPAP. The most often mentioned side effect was puffy eyes (19 percent). Use in very premature infants and after a delay of 6 hours are both controversial.

Murki et al. (2018)[94] reported that in preterm infants with RD, HFNC has been shown to be less efficient than nCPAP in preventing the demand for a "higher mode of respiratory support in the first 72 h of life". Neonates with moderate ("Silverman Anderson score, SAS <=5") or severe (SAS score, >5) RD were more likely to have treatment failure in the HFNC group according to protocol.

Yadav et al. (2018)[102] Treatment for RD in infants with 30% TTN included 2 hours of humidified oxygen, then warm (36°C-38°C) and humidified oxygen, and finally the opposite treatment for the other scheme. High flow nasal cannulas with a separate humidifier that also warms the air have been shown to be effective in treating RD by increasing PA pressure in the airway.

Konda et al. (2018)[103] in their study randomly assigned 64 newborns to receive either nCPAP or HHHFNC after tracheostomy. Babies in the HHHFNC group were 36.7% less likely to improve than those in the nCPAP group ("P=0.043"). The occurrence and intensity of nasal injuries were both greater in the "nCPAP group" than in the "HHHFNC group" ("nCPAP: 58.6 vs. HHHFNC: 15.7; P=0.001"). Although HHHFNC is gentler on preterm newborns and less damaging to the nasal passages, it is not as effective as nCPAP in relieving RD.

Al-lawama et al. (2018)[104] A prospective observational research found that bCPAP was effective in managing babies with respiratory distress in 93.7 percent of cases, with just nine infants failing to respond to treatment with the device. TTN was the leading cause of RD in newborns (42%), followed by PRTF (15%). (34 percent). Only nine babies (3.3%) did not respond to bCPAP treatment, for a success rate of 93.7 percent. Facial injuries was the most frequent adverse event reported.

Shin et al. (2017)[93] stated that early care of RD in children born at 30–35 weeks gestational age with HHHFNC is not non-inferior to using NCPAP. Further randomised controlled trials are needed to evaluate the efficacy and safety of HHFNC as a first therapy in premature babies with respiratory distress since the lack of an increase in the incidence of complications renders any change in failure rate insignificant.

Lavizzari et al. (2016)[92] examined the efficacy of HHHFNC, NCPAP, and BiPAP as the main treatment for mild to moderate RDS in premature infants delivered at or after 28 weeks of gestation. In a comparison of intubation rates within 72 hours after

beginning life-support, HHHFNC and NCPAP/BiPAP, showed equivalent effectiveness.

Hegde et al. (2016)[105] in a prospective observational research of 88 infants born between 28 and 34 weeks of gestation who experienced mild to moderate RD within 6 hours of birth, reported that the outcomes for the HHFNC group were better than those of the NCPAP group. When comparing HHHFNC (10.9%) to NCPAP (40.5%; P= 0.004), the lower risk of moderate or severe nasal damage was attributable to the former.

Soonsawad et al. (2016)[106] neonates with a GA 32 weeks were compared for how long it took to wean straight off CPAP vs how long it took to wean utilising HHHFNC. The research found that HHHFNC resulted in the same amount of time needed to wean off CPAP as straight weaning. **Taha et al. (2018)**[71] reported that when compared to CPAP, HFNC is associated with a higher risk of death or "bronchopulmonary dysplasia", more "respiratory morbidities", a "delay in oral feeding", and a longer hospital stay. BPD or mortality was greater in the HFNC group ("56.8%") than the CPAP group ("50.4%, P<0.05"). HFNC had a higher adjusted risk of BPD or mortality than CPAP (OR 1.085, 95% CI 1.035-1.137, P =0.001).

Mostafa-Gharehbaghi et al. (2015)[107] in a RCT found that HFNC was equivalent to NCPAP for respiratory support in preterm infants after surfactant administration and extubation. While the NCPAP group did have a greater incidence of "re-intubation, pneumothorax, intraventricular haemorrhage, and bronchopulmonary dysplasia", these differences were not statistically significant. NCPAP users were found to have

a substantially greater risk of nasal mucosa injury (62.8%) than HFNC users (33.3%) (P = 0.007). Reductions in nasal mucosal injury were seen in the HFNC group. More extensive studies with larger patient samples are required before HFNC may be used frequently in post-extubated preterm neonates.

Yoder et al. (2013)[69] stated that when used right after "extubation or as first noninvasive support for respiratory failure", HHHFNC seems to be just as "effective and safe" as NCPAP. Despite no differences between the study groups in terms of days on "supplemental oxygen (median: 10 vs 8 days), bronchopulmonary dysplasia (20% vs 16%), or hospital discharge on oxygen", HHHFNC newborns stayed on the study mode for longer than nCPAP infants ("median: 4 vs 2 days, respectively; P < 0.01). (19 percent vs 18 percent").

Collins et al. (2013)[108] studied the effect of providing post-extubation respiratory support with HHHFNC on the success rate of endotracheal intubation in newborns less than 32 weeks of gestation. Fifteen patients in the HHHFNC group (22% success rate) were unable to successfully extubate, whereas this happened to 22 patients in the NCPAP group (34%). In the first week, there was no change in the rate at which babies required reintubation. The nasal trauma score decreased by 3.1 (SD 7.2) points after HHHFNC treatment compared to 11.8 (SD 10.7) points after using NCPAP (P .001 for both). They discovered that HHHFNC and NCPAP had equal rates of extubation failure.

Manley et al. (2013)[75] **i**n a "multicenter, randomized, noninferiority trial", researchers discovered that high-flow nasal cannulae (5 to 6 litres per minute) provided respiratory support for very preterm neonates after extubation on par with CPAP. HFNC was shown to be non-inferior to nasal CPAP, with treatment failure occurring in "52 of 152 babies (34.2%)" in the nasal-cannulae group and in "39 of 151 infants (24.8%)" in the CPAP group ("risk difference, 8.4 percentage points; 95 percent confidence range, 1.9 to 18.7").

Ironpour et al. (2012)[109] tested how well HHHFNC performed compared to BNCPAP for premature babies. (those born at 30–35 weeks). Examining the nasal mucosa of research participants on HFNC revealed more normal results (P0.0001). Neonatal nurses said that HFNC was simpler to use than NCPAP for newborns (P0.0001). "After receiving NCPAP for the first 24 hours after birth, HHHFNC is equally as effective as NCPAP for controlling RDS in preterm neonates delivered at more than 30 weeks gestation". Furthermore, HFNC was more effective than NCPAP in protecting the nasal mucosa from damage.

LACUNAE IN LITERATURE:

Although many NICUs have begun using HHHFNC systems, there is a lack of data to support their usage, especially as the predominant modality of respiratory support, in the new-born population. The little amount of study that has been done on the topic has mostly focused on premature babies (defined as those born before a GA of 30 weeks). The present research aims to fill a gap in the literature by investigating TTN in neonates born at or after 35 weeks of gestation.

MATERIALS AND METHODS:

Study site: This study was conducted in R . L. Jalappa hospital affiliated to "Sri Devaraj Urs Medical College, a constituent of Sri Devaraj Urs Academy of Higher Education and Research".

Study population: All neonates (>35 weeks) born in R L Jalappa hospital and admitted to NICU with TTN were considered as study population.

Study design: The current study was a Open Label Randomized Control Trial

Sample size: Sample size has been estimated based on the difference in proportion of reintubation between NCPAP and HFNC groups. Proportion of reintubation in NCPAP was 14.8% and in HFNC was 51.8% from the study by Kadivar M et al[3]. Using these values in the below mentioned formula

$$N = \frac{2 (Z_{\alpha/2} + Z_{\beta})^2 P (1-P)}{(p_1 - p_2)^2}$$

Where ,

$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ at type 1 error of 5%

$Z_{\beta} = Z_{0.20} = 0.842$= At 90% power

$p_1 - p_2$= Difference in proportion in the two different groups = 37%

P= Pooled prevalence = [Proportion in NCPAP (p_1) + Proportion in HFNC Group (p_2)]/2 = [51.8 + 14.8]/2 = 59.2

N = 38 in each group

Considering 10% dropouts , 38 + 3.8 = 41.8 ≈ 42 patients will be included in each group.[2]

Sampling method: All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

Study duration: The data collection for the study was done between January 2021 to December 2021 for a period of 1 year.

Inclusion Criteria:

All neonates >35 weeks with respiratory distress

Exclusion criteria:

"Infants with 5 minutes Apgar scores < 5"

"Nasopharyngeal pathology (eg: choanal atresia , cleft lip / palate)"

"Congenital malformation"

"Meconium aspiration syndrome"

"Major congenital pulmonary or cardiac anomalies"

Ethical considerations: Study was approved by institutional human ethics committee. Informed written consent was obtained from all the parents /guardians of the study 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.

Data collection tools: 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 Computerised 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 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.

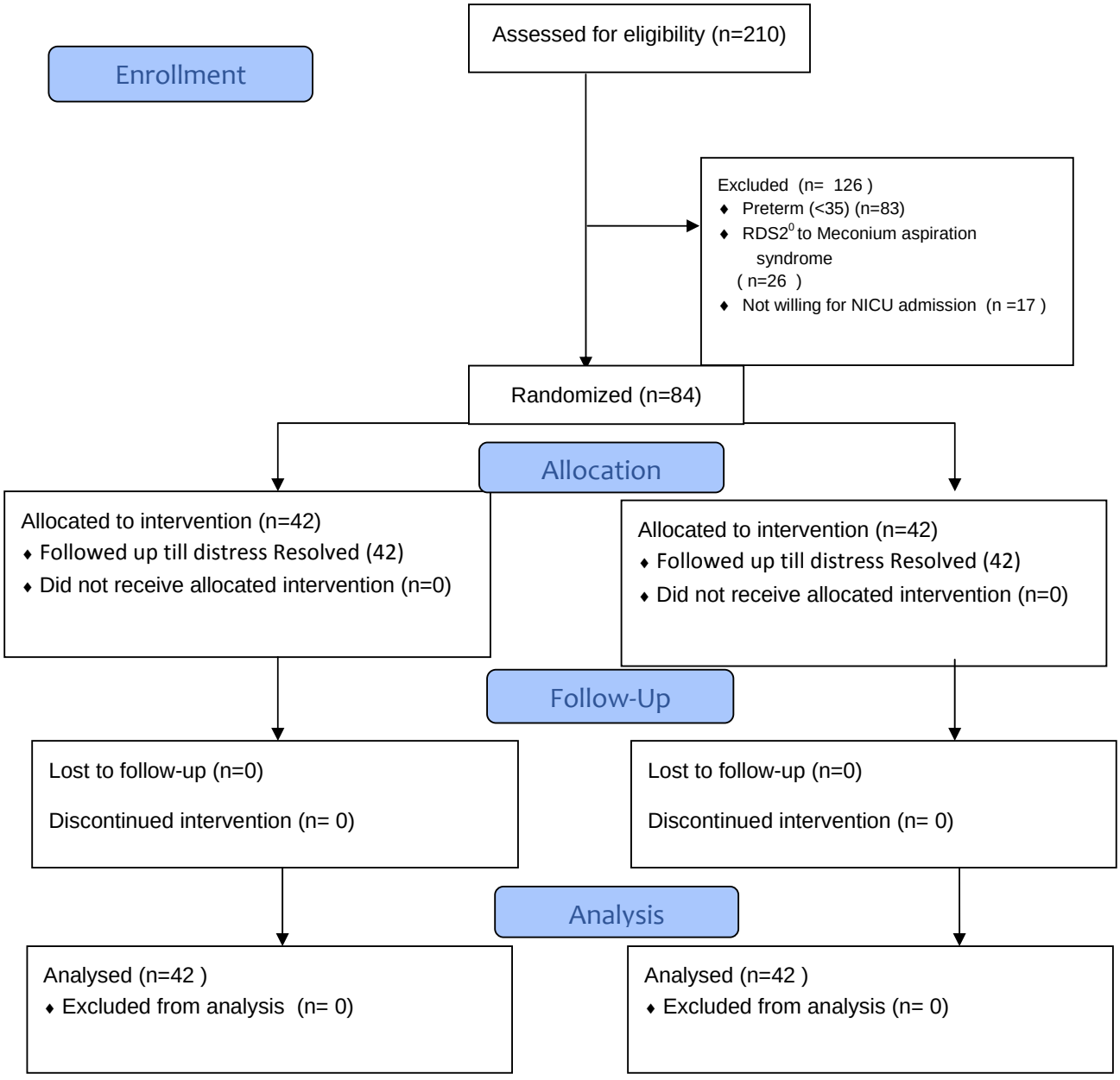
Basic summary stats denoted as count and % for categorical and mean with SD values for continuous parameters. Relevant graphs also provided.

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.


Enrollment
Assessed for eligibility (n=210)
Excluded (n= 126)
♦ Preterm (<35) (n=83)
♦ RDS2^{0} to Meconium aspiration syndrome (n=26)
♦ Not willing for NICU admission (n =17)
Randomized (n=84)
Allocation
Allocated to intervention (n=42)
♦ Followed up till distress Resolved (42)
♦ Did not receive allocated intervention (n=0)
Allocated to intervention (n=42)
♦ Followed up till distress Resolved (42)
♦ Did not receive allocated intervention (n=0)
Follow-Up
Lost to follow-up (n=0)
Discontinued intervention (n= 0)
Lost to follow-up (n=0)
Discontinued intervention (n= 0)
Analysis
Analysed (n=42)
♦ Excluded from analysis (n= 0)
Analysed (n=42)
♦ Excluded from analysis (n= 0)

RESULTS:

The overall result comprised 84 participants, 42 in the "HHHFNC group" and 42 in the "BNCPAP group."

Table 2: Baseline parameters 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

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 3: Effect of HHHFNC Group (N=42) on Heart rate (Bpm)

Parameter	Mean ± SD	Median	Minimum	Maximum
HR (1Hr) (N=42)	140.38 ± 11.52	142.0	120.0	164.0
HR (2Hrs) (N=37)	137.3 ± 7.85	138.0	118.0	156.0
HR (3Hrs) (N=33)	135.76 ± 7.43	136.0	124.0	152.0
HR (6Hrs) (N=20)	132.8 ± 7.8	132.0	118.0	152.0
HR (12Hrs) (N=8)	141.75 ± 6.36	141.0	132.0	152.0
HR (24Hrs) (N=4)	131.5 ± 7.19	129.0	126.0	142.0
HR (36 HRS) (N=2)	143 ± 707	143.0	138.0	148.0
HR (48Hrs) (N=1)	138± 0	138.0	138.0	138.0

The mean HR (1Hr), HR (2Hr), HR (3Hr), HR (6Hr), HR (12Hr), HR (24Hr), HR (36Hr), HR (48Hr) were 140.38 ± 11.52, 137.3 ± 7.85, 135.76 ± 7.43, 132.8 ± 7.8, 141.75 ± 6.36, 131.5 ± 7.19, 143 ± 707 and 138 ± 0 in HHHFNC Group. (Table 3)

Table 4: Effect of HHHFNC Group (N=42) on Respiratory rate (Cpm)

Parameter	Mean ± SD	Median	Minimum	Maximum
RR (1Hr) (N=42)	62.95 ± 3.75	62.0	54.0	74.0
RR (2Hrs) (N=37)	62.27 ± 4.5	62.0	48.0	74.0
RR (3Hrs) (N=33)	59.45 ± 5.66	62.0	48.0	72.0
RR (6Hrs) (N=20)	57.3 ± 6.75	56.0	42.0	70.0
RR (12Hrs) (N=8)	59.5 ± 7.69	59.0	48.0	70.0
RR (24Hrs) (N=4)	59.5 ± 7.55	60.0	52.0	66.0
RR (36Hrs) (N=2)	59 ± 7.07	59.0	54.0	64.0
RR (48Hrs) (N=1)	56 ± 0	56.0	56.0	56.0

The mean RR (1Hr), RR (2Hr), RR (3Hr), RR (6Hr), RR (12Hr), RR (24Hr), RR (36Hr), RR (48Hr) were 62.95 ± 3.75, 62.27 ± 4.5, 59.45 ± 5.66, 57.3 ± 6.75, 59.5 ± 7.69, 59.5 ± 7.55, 59 ± 7.07 and 56 ± 0 in HHHFNC Group. (Table 4)

Table 5: Effect of HHHFNC Group (N=42) on SPO2 (%)

Parameter	Mean ± SD	Median	Minimum	Maximum
SPO2(1Hr) (N=42)	95.81 ± 1.21	96.0	94.0	98.0
SPO2 (2Hrs) (N=37)	95.62 ± 1.32	96.0	92.0	98.0
SPO2 (3Hrs) (N=33)	95.39 ± 1.95	96.0	87.0	99.0
SPO2 (6Hrs) (N=20)	96.3 ± 1.26	96.0	94.0	98.0
SPO2 (12Hrs) (N=8)	95.75 ± 1.75	96.5	92.0	97.0
SPO2 (24Hrs) (N=4)	96.25 ± 2.06	96.0	94.0	99.0
SPO2 (36Hrs) (N=2)	96.0 ± 0	96.0	96.0	96.0
SPO2 (48Hrs) (N=1)	95 ± 0	95.0	95.0	95.0

The mean SPO2 (1Hr), SPO2 (2Hr), SPO2 (3Hr), SPO2 (6Hr), SPO2 (12Hr), SPO2 (24Hr), SPO2 (36Hr), SPO2 (48Hr) were 95.81 ± 1.21, 95.62 ± 1.32, 95.39 ± 1.95, 96.3 ± 1.26, 95.75 ± 1.75, 96.25 ± 2.06, 96.0 ± 0 and 95 ± 0 in HHHFNCA Group (Table 5)

Table 6: Effect of HHHFNC Group (N=42) on Downe's score

Parameter	Mean ± SD	Median	Minimum	Maximum
Downes score (1Hr) (N=42)	1.31±0.75	1.00	0.00	3.00
Downes score (2Hrs) (N=37)	1.16±0.65	1.00	0.00	3.00
Downes score (3Hrs) (N=33)	0.76±0.75	1.00	0.00	3.00
Downes score (6Hrs) (N=20)	0.55±0.83	0.00	0.00	3.00
S Downes score (12Hrs) (N=8)	0.88±1.13	0.50	0.00	3.00
Downes score (24Hrs) (N=4)	1.00±1.15	1.00	0.00	2.00
Downes score (36Hrs) (N=2)	0.50±0.71	0.50	0.00	1.00
Downes score (48Hrs) (N=1)	0.00± 0	0.00	0.00	0.00

The mean Downes score (1Hr), Downes score (2Hr), Downes score (3Hr), Downes score (6Hr), Downes score (12Hr), Downes score (24Hr), Downes score (36Hr), Downes score (48Hr) were 1.31±0.75, 1.16±0.65, 0.76±0.75, 0.55±0.83, 0.88±1.13, 1.00±1.15, 0.50±0.71 and 0.00± 0 in HHHFNCA Group. (Table 6)

Table 7: Outcomes and Complications of the HHHFNC Group (N=42)

Outcomes & Complications	Summary
Duration of oxygen therapy (in hours)	7.36±7.972
Recovery	
Recovered (not intubated)	41 (97.6%)
Not recovered (intubated)	1 (2.4%)
Nasal Trauma	
Yes	2 (4.76%)
No	40 (95.24%)
Air leak syndrome	
No	42 (100.0%)
Intubation	
Yes	1 (2.4%)
No	41 (97.6%)

The mean Duration (in hours) of oxygen therapy was 7.36±7.972 in HHHFNC Group.

In HHHFNC Group, 2 participants had Nasal trauma and 1 (2.4%) participant required endotracheal- intubation.

In HHHFNC Group, none had air leak syndrome.

In HHHFNC Group, 41 (97.6%) participants had recovered and 1 (2.4%) had not recovered and required endotracheal-intubation. (Table 7)

Table 8: Effect of BNCPAP Group (N=42) on Heart Rate (Bpm)

Parameter	Mean ± SD	Median	Minimum	Maximum
HR (1Hr) (N=41)	138.73 ± 10.38	138.0	120.0	164.0
HR (2Hrs) (N=41)	136.34 ± 7.86	138.0	124.0	154.0
HR (3Hrs) (N=33)	133.24 ± 7.41	132.0	122.0	150.0
HR (6Hrs) (N=23)	135.65 ± 7.74	136.0	124.0	152.0
HR (12Hrs) (N=13)	134.31 ± 7.11	134.0	124.0	146.0
HR (24Hrs) (N=6)	135 ± 9.19	132.0	126.0	150.0
HR (36Hrs) (N=3)	135.33 ±3.05	136.0	132.0	138.0

The mean HR (1Hr), HR (2Hr), HR (3Hr), HR (6Hr), HR (12Hr), HR (24Hr), HR (36Hr) were 138.73 ± 10.38, 136.34 ± 7.86, 133.24 ± 7.41, 135.65 ± 7.74, 134.31 ± 7.11, 135 ± 9.19 and 135.33 ±3.05 in BNCPAP Group. (Table 8)

Table 9: Effect of BNCPAP Group (N=42) on Respiratory Rate (RR)

Parameter	Mean ± SD	Median	Minimum	Maximum
RR (1Hr) (N=42)	63.67 ± 3.18	62.0	58.0	72.0
RR (2Hrs) (N=41)	61.37 ± 5.49	62.0	46.0	72.0
RR (3Hrs) (N=33)	60 ± 5.72	62.0	46.0	68.0
RR (6Hrs) (N=23)	59.13 ± 6.6	62.0	48.0	70.0
RR (12Hrs) (N=13)	60 ± 6.06	62.0	48.0	68.0
RR (24Hrs) (N=6)	60 ± 4.38	60.0	56.0	64.0
RR (36Hrs) (N=3)	55.33 ± 3.06	56.0	52.0	58.0

The mean RR (1Hr), RR (2Hr), RR (3Hr), RR (6Hr), RR (12Hr), RR (24Hr), RR (36Hr) were 63.67 ± 3.18, 61.37 ± 5.49, 60 ± 5.72, 59.13 ± 6.6, 60 ± 6.06, 60 ± 4.38 and 55.33 ± 3.06 in BNCPAP Group. (Table 9)

Table 10: Effect of BNCPAP Group (N=42) on SPO2(%)

Parameter	Mean ± SD	Median	Minimum	Maximum
SPO2 (1Hr) (N=42)	95.76 ± 1.46	96.0	92.0	98.0
SPO2 (2Hrs) (N=41)	95.73 ± 1.28	96.0	92.0	99.0
SPO2 (3Hrs) (N=33)	95.67 ± 1.14	96.0	93.0	98.0
SPO2 (6Hrs) (N=23)	96.26 ± 1.6	96.0	92.0	99.0
SPO2 (12Hrs) (N=13)	96.31 ± 1.32	96.0	94.0	98.0
SPO2 (24Hrs) (N=6)	96.17 ± 0.75	96.0	95.0	97.0
SPO2 (36Hrs) (N=3)	95.33 ± 0.58	95.0	95.0	96.0

The mean SPO2 (1Hr), SPO2 (2Hr), SPO2 (3Hr), SPO2 (6Hr), SPO2 (12Hr), SPO2 (24Hr), SPO2 (36Hr) were 95.76 ± 1.46, 95.73 ± 1.28, 95.67 ± 1.14, 96.26 ± 1.6, 96.31 ± 1.32, 96.17 ± 0.75 and 95.33 ± 0.58 in BNCPAP Group. (Table 10)

Table 11: Effect of BNCPAP Group (N=42) on Downe's score

Parameter	Mean ± SD	Median	Minimum	Maximum
Downes score (1Hr) (N=42)	1.50±0.74	1.00	0.00	3.00
Downes score (2Hrs) (N=41)	1.15±0.79	1.00	0.00	3.00
Downes score (3Hrs) (N=33)	1.00±0.83	1.00	0.00	3.00
Downes score (6Hrs) (N=23)	0.78±0.85	1.00	0.00	3.00
S Downes score (12Hrs) (N=13)	0.69±0.85	0.00	0.00	2.00
Downes score (24Hrs) (N=6)	0.67±0.82	0.50	0.00	2.00
Downes score (36Hrs) (N=3)	0.00±0.00	0.00	0.00	0.00

The mean Downes score (1Hr), Downes score (2Hr), Downes score (3Hr), Downes score (6Hr), Downes score (12Hr), Downes score (24Hr), Downes score (36Hr) were 1.50±0.74, 1.15±0.79, 1.00±0.83, 0.78±0.85, 0.69±0.85, 0.67±0.82 and 0.00± 0 in BNCPAP Group. (Table 11)

Table 12: Outcomes & Complications of the BNCPAP Group (N=42)

Outcomes & Complications	Summary
Duration (in hours)	8.21±7.569
Recovery	
Recovered (not intubated)	40 (95.2%)
Not recovered (intubated)	2 (4.8%)
Nasal Trauma	
Yes	6 (14.29%)
No	36 (85.71%)
Air leak syndrome	
No	42 (100.0%)
Intubation	
Yes	2 (4.8%)
No	40 (95.2%)

The mean Duration (in hours) of oxygen therapy was 8.21±7.569 in BNCPAP Group.

In BNCPAP Group, 6 participants had Nasal trauma and 2 (4.8%) participants required endotracheal- intubation.

In BNCPAP Group, none had air leak syndrome.

In BNCPAP Group, 40 (95.2%) participants had recovered and 2 (4.8%) had not recovered and required endotracheal-intubation. (Table 12)

Table 13: Comparison of Heart Rate (bpm) between Study Groups at different time periods in the study population (N=84)

Heart Rate (bpm)	Study Group (Mean± SD)		P value (IST)
	HHHFNC Group (N=42)	BNCPAP Group (N=42)	
HR (1HR) (N=83)	140.38 ± 11.52	138.73 ± 10.38	0.496
HR (2HRS) (N=78)	137.3 ± 7.85	136.34 ± 7.86	0.593
HR (3HRS) (N=66)	135.76 ± 7.43	133.24 ± 7.41	0.173
HR (6HRS) (N=43)	132.8 ± 7.8	135.65 ± 7.74	0.237
HR (12HRS) (N=21)	141.75 ± 6.36	134.31 ± 7.11	0.026
HR (24HRS) (N=10)	131.5 ± 7.19	135 ± 9.19	0.541
HR (36HRS) (N=5)	143 ± 7.07	135.33 ± 3.06	0.177
HR (48HRS) (N=1)	138 ± 0	--	--

In HR, the mean difference between study groups (HHHFNC Group and BNCPAP Group) was statistically not significant at "1 Hr, 2 Hrs, 3 Hrs, 6 Hrs", 24 Hrs and after 36 Hrs. But it was statistically at 12 hours of duration with p value of 0.026. The value of mean HR was high in HHHFNC cluster at 12 Hrs compared to BNCPAP Group (Table 13 & Figure 6)

"Figure 6 : Line chart of comparison of Heart Rate (bpm) between Study group at different time periods in the study population (N=84)"

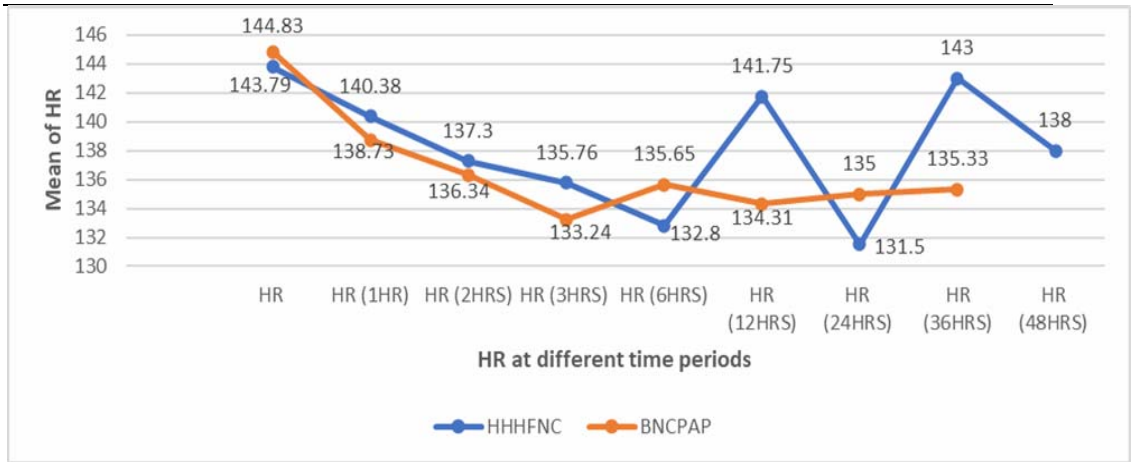


Table 14: Comparison of Respiratory rate (cpm) between Study Groups at different time periods in the study population (N=84)

Respiratory rate (cpm)	Study Group (Mean± SD)		P value (IST)
	HHHFNC (N=42)	BNCPAP (N=42)	
RR (1HR) (N=84)	62.95 ± 3.75	63.67 ± 3.18	0.350
RR (2HRS) (N=78)	62.27 ± 4.5	61.37 ± 5.49	0.431
RR (3HRS) (N=66)	59.45 ± 5.66	60 ± 5.72	0.698
RR (6HRS) (N=43)	57.3 ± 6.75	59.13 ± 6.6	0.375
RR (12HRS) (N=21)	59.5 ± 7.69	60 ± 6.06	0.870
RR (24HRS) (N=10)	59.5 ± 7.55	60 ± 4.38	0.897
RR (36HRS) (N=5)	59 ± 7.07	55.33 ± 3.06	0.463
RR (48HRS) (N=1)	56 ± 0	--	--

In RR, the mean difference between study group (HHHFNC Group and BNCPAP Group) was statistically not significant at all time periods. The mean of RR was high in HHHFNC Group at 36 Hrs compared to BNCPAP Group (Table 14 & Figure 7)

Figure 7: Line chart of comparison of Respiratory rate (Cpm) between Study group at different time periods in the study population (N=84)

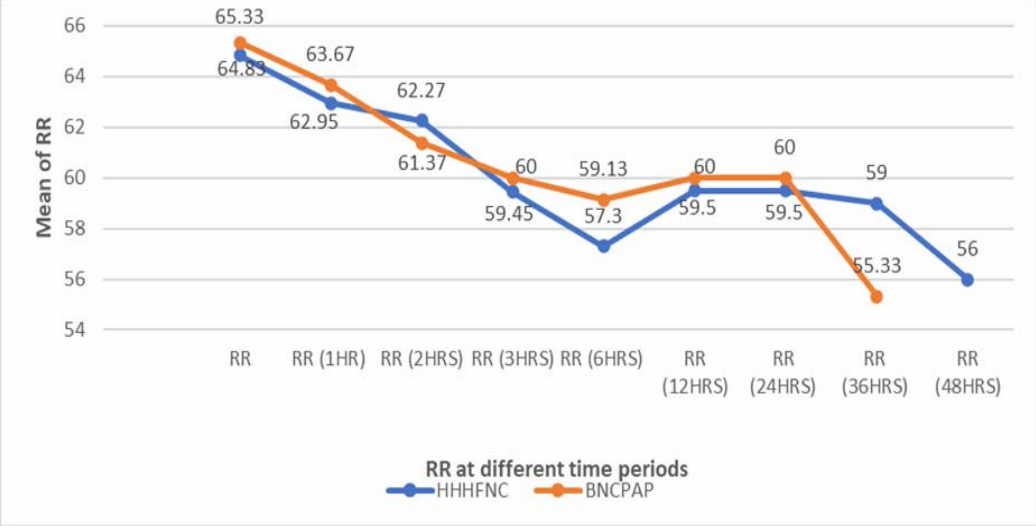


Table 15: Comparison of SPO2 (%) between Study Groups at different time periods in the study population (N=84)

SPO2 (%)	Study Group (Mean± SD)		P value (IST)
	HHHFNC (N=42)	BNCPAP (N=42)	
SPO2 (1HR) (N=84)	95.81 ± 1.21	95.76 ± 1.46	0.871
SPO2 (2HRS) (N=78)	95.62 ± 1.32	95.73 ± 1.28	0.710
SPO2 (3HRS) (N=66)	95.39 ± 1.95	95.67 ± 1.14	0.490
SPO2 (6HRS) (N=43)	96.3 ± 1.26	96.26 ± 1.6	0.930
SPO2 (12HRS) (N=21)	95.75 ± 1.75	96.31 ± 1.32	0.416
SPO2 (24HRS) (N=10)	96.25 ± 2.06	96.17 ± 0.75	0.929
SPO2 (36HRS) (N=5)	96 ± 0	95.33 ± 0.58	0.219

In SPO2 (%), the mean difference between study group (HHHFNC Group and BNCPAP Group) was statistically not significant at all time periods. The mean of SPO2 (%) was slightly high in BNCPAP Group compared to HHHFNC Group at 2 Hrs duration. (Table 15 & Figure 7)

Figure 8: Line chart indicating trend of SPO2 (%) between Study sample at various time units (N=84)

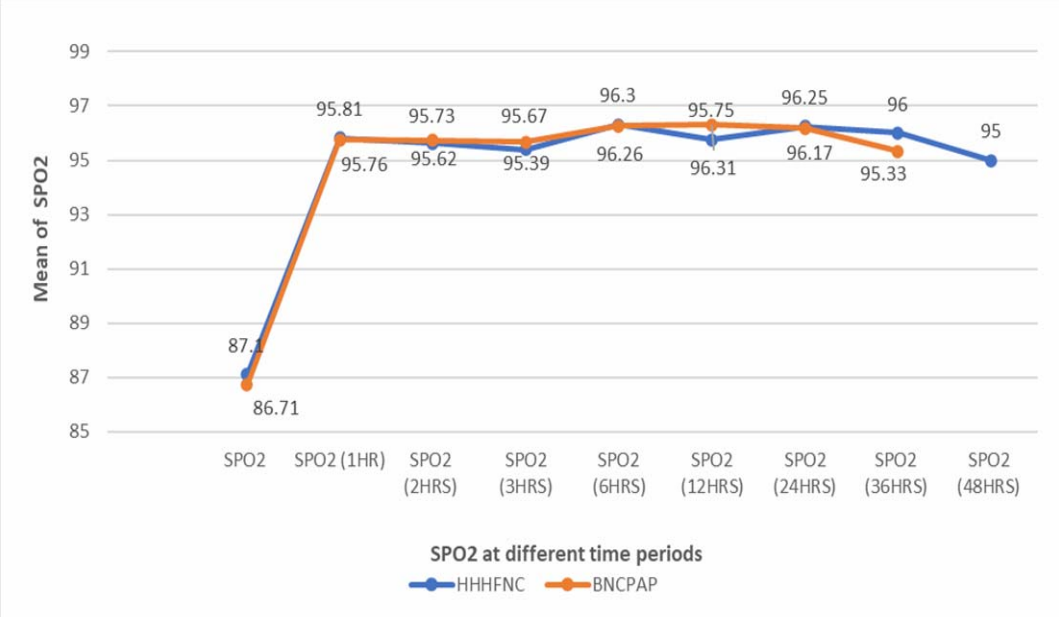


Table 16: Comparison of Downes score between Study Groups at different time periods in the study population (N=84)

Downes score	Study Group (Mean± SD)		P value (IST)
	HHHFNC (N=42)	BNCPAP (N=42)	
Downes score (1HR) (N=84)	1.31 ± 0.75	1.5 ± 0.74	0.245
Downes score (2HRS) (N=78)	1.16 ± 0.65	1.15 ± 0.79	0.924
Downes score (3HRS) (N=66)	0.76 ± 0.75	1 ± 0.83	0.218
Downes score (6HRS) (N=43)	0.55 ± 0.83	0.78 ± 0.85	0.370
Downes score (12HRS) (N=21)	0.88 ± 1.13	0.69 ± 0.85	0.678
Downes score (24HRS) (N=10)	1 ± 1.15	0.67 ± 0.82	0.604
Downes score (36HRS) (N=5)	0.5 ± 0.71	0 ± 0	0.272

In Downes score, the mean difference between study groups (HHHFNC Group and BNCPAP Group) was statistically not significant at all time periods. The high Downes scores reported in HHHFNC at 12 Hrs with respect to BNCPAP cluster. (Table 16)

Figure 9: Line graph for Downes score trend in each Study group at different time periods in the study population (N=84)

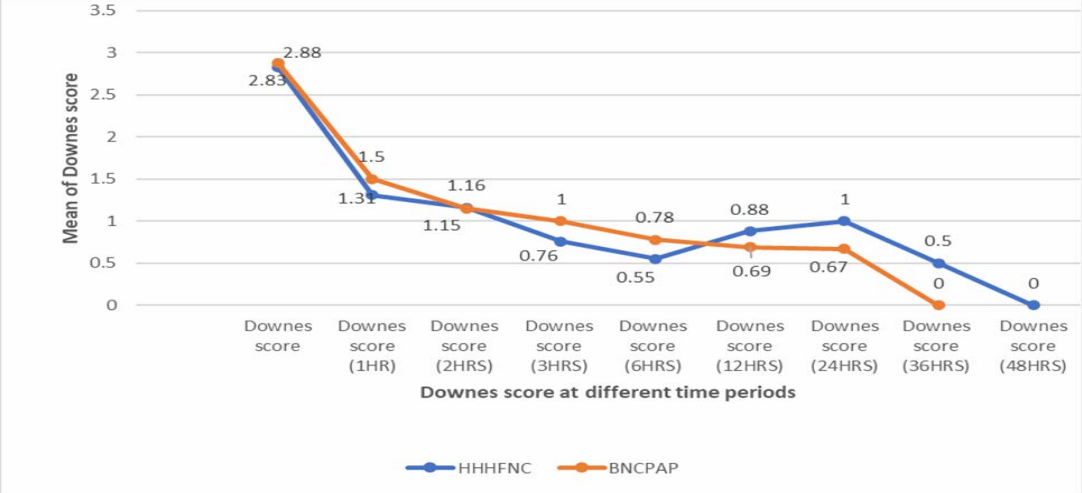


Table 17: Comparison of Outcomes & Complications between the HHHFNC and BNCPAP groups (N=84)

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. (Table 17)

Figure 10: Duration of oxygen support between Study Groups (N=84)

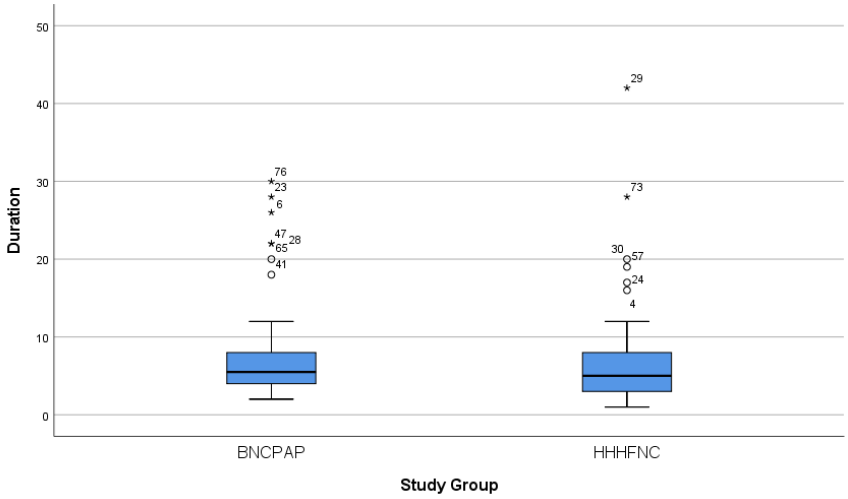


Figure 11: Nasal trauma comparison indication by clustered bars in each Group in the study population (N=84)

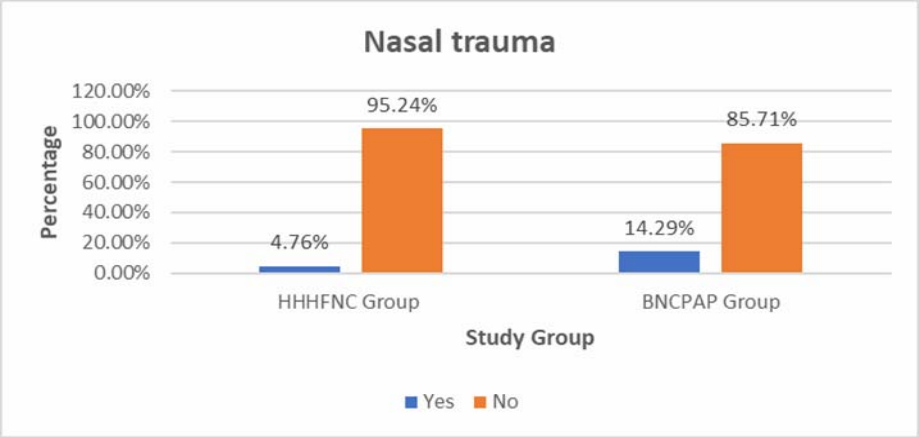


Figure 12: Cluster Bars denoting Comparison of Intubation as per group of study (N=84)

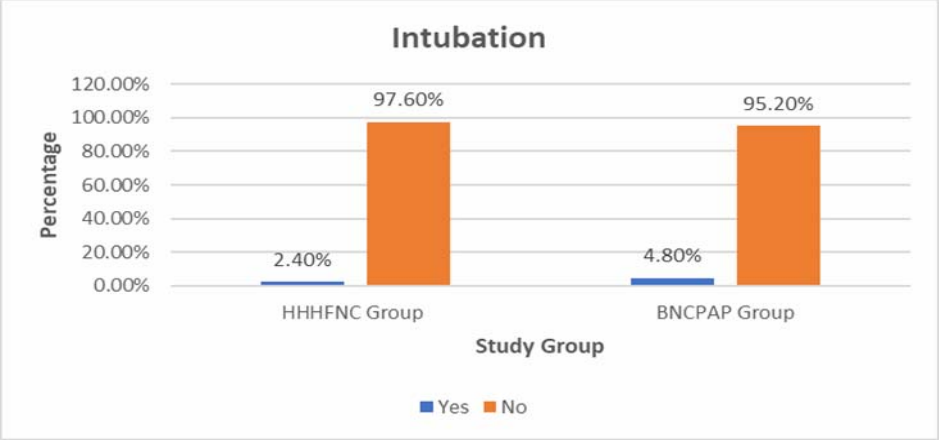
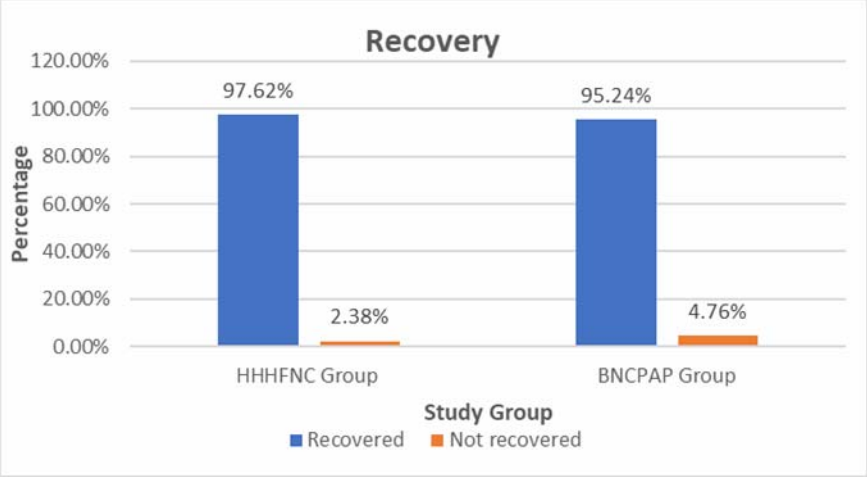


Figure 13: Recovery distribution in Study Groups picturised by clustered bars (N=84)



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.

Patient characteristics

The current study involved 84 subjects with 42 subjects each in HHHFNC and in BNCPAP

group. Both the groups found no notable variation in the ratio of distribution towards "maternal age, gestational age, birth weight, gender and mode of delivery". Mean Maternal age (23.07 ± 2.18 VS 23.83 ± 2.16), gestational age (37.46 ± 1.46 VS 36.71 ±1.12), birth weight in kg (2.95 ± 0.59 VS 2.75 ± 0.54), gender (M/F: 45.24%/54.76% VS 47.62%/52.38%), mode of delivery (LSCS/ NVD: 90.48%/9.52% VS 83.33%/16.67%).

In current study demographic characteristics were found similar in both groups , including parameters which have been studied before start of intervention proves that randomization is successful .

Table 18: Comparing the patient characteristics among study population across various studies to present study

Study	**Design**	**Population**	**Number of infants**	**Gestational age**
Current study	**Open Label Randomised Control Trial**	**neonates >35 weeks**	**HHHFNC 42 BNCPAP 42**	**37.46 ± 1.46 36.71 ± 1.12**
Chen et al.[96]	prospective randomized clinical trial	<32 weeks	HHHFNC 48 BNCPAP 46	27.2±2.8 27.5±3.2
Sharma et al.[98]	prospective, double-blinded, randomized controlled trial	between 26 and 34 weeks	HHHFNC 50 BNCPAP 50	31.77±2.21 31.67±1.89
Murki et al.[94]	"open-label, multicenter, 2-arm parallel, stratified RCT".	≥28 weeks	HHHFNC 133 BNCPAP 139	31.8±1.9 31.6±2.2
Konda et al.[103]	prospective observational study	27-34 weeks	HHHFNC 30 NCPAP 34	29.6 ± 1.7 30 ± 1.6

Table 19: Comparing the antenatal steroid treatment among the study population across various studies to current study

Studies	HHFNC	BNCPAP
Current study	11.9%	21.4%
Sharma et al.[98]	75%	83.7%
Chen, J et al[110]	79.17%	78.26%

In Sharma et al.'s study, 75% of mothers received antenatal steroids in the "HHFNC group and 83.7% in the BNCPAP group".[98] Whereas in contrast to other studies , a very minor percentage of mothers received antenatal steroids in our study with 11.9% in the "HHFNC group and 21.4% in the BNCPAP group". The probable reason for this could be, many maternal cases being unbooked and in our hospital , as mothers come to labour room at eleventh hour where antenatal interventions become difficult to be done in all antenatal women .

Risk factors

The risk factors involved in HHHFNC Group, the majority of 11.9% participants were GDM, followed by 9.5% participants had risk factors like foetal distress & Severe PE & 4.8% participants had maternal Hypothyroidism, one was a twin gestation (2.4%) respectively.

In BNCPAP Group, the majority of 14.3% participants had risk factors like Severe PE, followed by 11.9% had Foetal distress, & 9.5% participants had maternal Hypothyroidism and one was a twin gestation (2.4%) respectively. Hence in BNCPAP group the study population with severe eclampsia where in majority and in HHHFNC group, gestational diabetes was the most frequent risk factor.

Chiruvolu, A et al[111] study compared NC with CPAP as the main "non-invasive respiratory treatment" for hypoxic newborns with TTN. The risk factors in CPAP group reported were as follows: multiple gestation in 28.3%, Intrauterine growth restriction in1.9%, pregnancy induced hypertensive disorders in 26.4%, diabetes 13.2% and asthma in 5.7%, Chorioamnionitis in 3.8%. Among NC group multiple gestation in 5.7%, Intrauterine growth restriction in11.3%, pregnancy induced hypertensive disorders in 28.3%, diabetes 9.4% and asthma in 5.7%, Chorioamnionitis in 3.8%.[111]

In the current study, comparison of risk factors between two groups had not shown effect on outcomes.

Vital parameters

In the current study, vital parameters including HR, RR, SPO2 and Downes score compared between the two groups had shown that mean of the above mentioned parameters is slightly higher in HHHFNC group compared to BNCPAP group. This proves that effect of use of HHFNC versus BNCPAP in treatment of TTN i.e., the HHHFNC group was not superior or inferior to BNCPAP group in terms of vital parameters which were considered as primary outcome variables in this study. Results of both the groups were equivocal pertaining to vital parameters. There are no studies available comparing compare HHHFNC and CPAP in terms of vital parameters.

Nasal trauma

The current study found decreased frequency of nasal damage in subjects participating in HHHFNC technique (4.76% VS 14.29%), While, the group BNCPAP found an increased nasal injury compared to HHHFNC technique. Infants may have

"nasal mucosa oedema, congestion", and other complications as a consequence of the pressure generated by the thick, cumbersome NCPAP dressing of the head and face. Congestion in the nose may irritate the nasal passages and lead to an increase in secretions, which can then lead to secondary infections in the nose and elsewhere in the body, particularly in "extremely low birth weight infants" as noted in Chen et al.[110] study. The right NC of the HHHFNC is inserted directly into the nasal cavity, eliminating the need for any external force on the head and face. This removes the risk of nasal injury and prevents any deformation of the skull. [112] Significantly less nasal injuries occurred in the HHHFNC group (6.25 vs. 36.96%) than the "NCPAP group". A numerically relevant($P < 0.05$) distinction may be seen between the two sets of data. [110]

There were no low birth weight infants in our study and as such occurrence of nasal trauma encountered was very minimal. Since Shin et al. addressed the early stages of RD and provided support for a shorter amount of time, they did not find an instance of nose damage in either group. Babies in both our research and the study by Shin et al. were born at a later gestational age than those in the majority of prior investigations. [93] Similarly, in Lavizzari et alresearch, .'s the incidence of nasal damage related to "nCPAP/BiPAP" has been exceedingly low, and no "macroscopic trauma" was observed in either group at any point in the investigation. [113]

Sharma et al. found that the overall occurrence of nasal trauma was more in NCPAP category than in HHHFNC category with about 34.9% of neonates in NCPAP category and 11.4% of neonates in HHHFNC category sustaining some form of nasal trauma ($P = 0.019$). [98] Nasal trauma was highly prevalent and severe in the nCPAP

group compared to HHHFNC group, according to a study by Konda et al. ("nCPAP: 58.6 percent vs. HHHFNC: 15.7 percent ; P=0.001").[103]

The greater prevalence of nasal damage in the BNCPAP group than the HHHFNC group is constant to the findings of previous research, suggesting that HHHFNC is a safer modality than CPAP in newborns experiencing respiratory distress.

Table 20 : Incidence of nasal trauma between groups across studies:

Study	**HHHFNC**	**BNCPAP**
Current study	**4.76%**	**14.29%**
Konda et al.[103]	15.7%	58.6%
Sharma et al.[98]	11.4%	34.9%
Chen et al.[96]	6.25 %	36.96%
Yoder et al.[69]	9%	16%

Need for Endo- tracheal intubation

The HHFNC group found only 2.4% requiring endotracheal-intubation and in BNCPAP group, 4.76% required endo-tracheal intubation. Relative to a value of 1.00, there was no "statistically significant" variation in the percentage of Recovery across the Study Groups. The requirement for intubation was observed to be decreased in HHHFNC-treated neonates compared to those receiving NCPAP, although this variation was numerically insignificant.[99] In terms of intubation frequency, there was no discernible variation among the "HHHFNC and NCPAP groups" ("10.8% vs. 9.5%") in a major clinical study comparing the two methods, as reported by Lavizzari et al. 95% confidence interval ("CI = -6.0%, 8.6%, P= 0.71"). [113] Treatment results,

such as intubation, were found to be comparable across the two methods, as noted by Yoder et al.[69]

Kadivar et al.[8] from their study reported the "rate of reintubation" was higher in the HHHFNC group ("14 vs. 4, P<0.004"), it may be because the pressure created in newborns managed with HFNC varies depending on the flow rate and the infant's weight.[114]

Majority of studies including this study have shown that need for intubation rates were lesser in HFNC group when compared to CPAP group without any statistical significance , though some studies have shown the opposite results. Therefore large multicentric studies with a bigger sample size are required to know the effect of HHHFNC or BNCPAP in terms of intubation.

Oxygen therapy

The mean Duration (in hours) of O2 therapy was 8.21±7.569 in BNCPAP Group. The average time (in hours) of O2 treatment was 7.36±7.972 in HHHFNC Group. 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 statistically not significant (P Value 0.1941)". The average time that patients on NCPAP and HHHFNC received NIV assistance was 69.1 ± 37.75 h and 67.57 ± 45.48 h, respectively, according to the research of Sharma et al. Total oxygen supplementation time was marginally shorter in the "HHHFNC group compared to the NCPAP group", but the variation was numerically insignificant (P = 0.062), as reported by Sharma et al.[98] This is comparable with our observations where the frequency of oxygen use throughout treatment was equivocal in both BNCPAP and HHHFNC groups .Similar results were

obtained in the reasearche by Hegde et al.,[105] Yoder et al.,[69] and Kadivar et al.[8] where the groups did not vary significantly from one another with regards to the mean periods of oxygen supplementation (P = 0.62, 0.357, and 0.545). "Median primary NIV support (nCPAP: 9.2 vs. HHHFNC: 11) and total NIV support (nCPAP: 11 vs. HHHFNC: 12)" were both shorter for the "nCPAP group than for the HHHFNC group" in the study by Konda et al., but the P-value was still not statistically significant.[103]

Air leak syndrome

The secret to preventing air leak syndrome is gentle ventilation. In addition, it's crucial to do mild resuscitation in the delivery room to lessen the likelihood that high-risk neonates will develop air leak syndrome.[115,116]In both groups, none of the babies had air leak syndrome. In HHHFNC Group, none had air leak syndrome. In BNCPAP Group, none had air leak syndrome. By combining early surfactant treatment with short breathing (rapid extubation to NCPAP), air leak syndrome may be reduced according to Steven et al meta-analysis's of six studies and 664 participants ("RR = 0.52; 95% CI = 0.28–0.96"). [117] In our study the use on ventilation in gentle way in both the groups achieved no complication of air leak syndrome.

Recovery

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". [96] 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. [98] 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. [99] Based on their findings, Konda et al. concluded that HHHFNC therapy is less beneficial than NCPAP therapy in facilitating extubation in preterm newborns. [103] 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.[93] 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. [113] 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. [105] 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. [69]

CONCLUSION

- The mean of Maternal Age was 23.07 ± 2.18 in HHHFNC Group and it was 23.83 ± 2.16 in BNCPAP Group.
- The mean 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, 45.24% participants were male and 54.76% were female. In BNCPAP Group, 47.62% participants were male and 52.38% were female.
- In HHHFNC Group, 90.48% women had LSCS mode of delivery and 9.52% had NVD and in BNCPAP Group, 83.33% women had LSCS and 16.67% had NVD.
- In BNCPAP Group more number of mothers received antenatal steroids (21.4%) compared to HHFNC group (11.9%).
- With regards to HR, RR, SPO2 and Downes score, the mean difference between study groups (HHHFNC Group and BNCPAP Group) was statistically not significant at 1 Hr, 2 Hrs, 3 Hrs, 6 Hrs, 24 Hrs and after 36 Hrs.
- There was a numerically relevant variations in heart rate between the two groups at 12 hours of period with p value of 0.026. The mean of HR was high in HHHFNC Group (141.75 ± 6.36) at 12 Hrs compared to BNCPAP Group (134.31 ± 7.11).
- The mean of RR was high in HHHFNC Group at 36 Hrs compared to BNCPAP Group, though not statistically significant difference was noted (p 0.463).
- The HHFNC group found only 2.4% requiring endotracheal-intubation and in BNCPAP group, 4.76% required endo-tracheal intubation. “The difference in the proportion of Recovery between the Study Groups was statistically not significant with P value 1.00”.

- The average time (in hours) of supplementation oxygenation was 8.21±7.569 in BNCPAP Group. The mean Duration (in hours) of supplementation oxygenation was 7.36±7.972 in HHHFNC Group. 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) among the research subjects numerically insignificant (P Value 0.1941).

  It was observed that both the groups showed good recovery, thus both the techniques found to be effective (97.6% VS 95.24%). "The difference in the proportion of Recovery between the Study Groups was statistically not significant with P value 1.00".

LIMITATIONS AND RECOMMENDATIONS

- This research may not be sufficiently powered to compare the efficacy of the two devices because of the limited number of patients included.
- No standardised method was employed to assess nasal trauma, however we found that it is minimal in our study.
- Additional research in the form of well-designed randomized controlled trials with sufficient sample size is needed before HHHFNC may be used as a main treatment for TTN.

SUMMARY

A randomised open label research intended to assess and parallel the effectiveness of HHFNC with BNCPAP prime therapy of TTN in infants with >35 weeks' gestational age. All neonates (>35 weeks) born in R L Jalappa Hospital and admitted to NICU with TTN during the period Jan 2021 to Dec 2021 are recruited in the study until the sample size is reached. The infants are randomly allocated by computerised randomised allocation in to HHHFNC group or BNCPAP group and monitored for a duration of 48 hours. The current study involved 84 subjects with 42 subjects each in HHHFNC and in BNCPAP group. Both the groups found insignificant variation in the ratio of distribution towards maternal age, measure of pregnancy, weight at birth, gender and modality of childbirth. With regards to HR, RR, SPO2 and Downes score, the mean difference between study groups (HHHFNC Group and BNCPAP Group) was statistically not significant at 1 Hr, 2 Hrs, 3 Hrs, 6 Hrs, 24 Hrs and after 36 Hrs except for HR at 12 hours was relevantly greater in the "HHHFNC group" with probability value of 0.026. In our study, both the groups showed good recovery, showing that both the techniques are effective (97.6% VS 95.24%). "The difference in the proportion of recovery between the Study Groups was statistically not significant with P value 1.00."

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ANNEXURE-I

PROFORMA

SL NO: **DATE:**

NAME OF MOTHER:

AGE OF MOTHER:

NAME OF FATHER:

ADDRESS:

GESTATIONAL AGE :

DATE OF BIRTH:

TIME OF BIRTH:

MODE OF DELIVERY:

INDICATION OF LSCS:

USE OF ANTENATAL STEROIDS:

ANTENATAL RISK FACTORS:

FOETAL DISTRESS

GESTATIONAL DIABETES

LATE PRETRRM

MECONIUM STAINED AMNIOTIC FLUID:

PRE ECLAMPSIA

TWIN GESTATION

DATE OF ADMISSION:

REASON FOR ADMISSION:

Mode Of Respiratory Support	Heated Humidified High Flow Nasal Canula	Bubble Nasal Continuous Positive Airway Pressure
Mode of Respiratory Support used for Baby		

CLINICAL PARAMETERS

Parameter	BNCPAP/ HHHFNC At Birth	1 Hour	2 Hours	3 Hours	6 Hours	12 Hours	24 Hours	36 Hours	48 Hours
Heart rate									
Respiratory rate									
Peripheral pulses									
Capillary refilling time									
Saturation									
Downes score									

Duration of oxygen support	
Nasal trauma	
Air leak syndrome	
Baby requiring intubation	
Recovery	

DOWNE'S SCORE:

SCORE	RESPIRATORY RATE	CYANOSIS	AIR ENTRY	GRUNT	RETRACTION
0	<60/min	Nil	Normal	None	Nil
1	60-80/min	In room air	Mild?	Audible with stethoscope	Mild
2	>80/min	In>_40%	Marked?	Audible with naked ear	Moderate

- A score of >6 is indicative of impending respiratory failure

ANNEXURE-II

PATIENT INFORMATION SHEET

Principal investigator: **Dr TRISALI .P /Dr. KNV . PRASAD**

I Dr. TRISALI. P , Post graduate student in Department at Sri Devraj Urs Medical College, will be conducting a study titled..... **"EFFECT OF HEATED HUMIDIFIED HIGH FLOW NASAL CANULA (HHHFNC) VERSUS BUBBLE NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE(BNCPAP) IN TRANSIENT TACHYPNOEA OF NEWBORN(TTN) – AN OPEN LABEL RCT "** for my dissertation under the guidance of Dr. KNV PRASAD Professor of Department of Paediatrics. The participants of this study i.e., include 84 neonates among which 42 in each group of neonates requiring HHHFNC AND BNCPAP admitted in NEONATAL INTENSIVE CARE UNIT at RL JALAPPA hospital. You will not be paid any financial compensation for the participation of your child in this research project.

All the data will be kept confidential and will be used only for research purpose by this institution. You are free to provide consent for the participation of your child in this study. You can also withdraw your child from the study at any point of time without giving any reasons whatsoever. Your refusal to participate will not prejudice you to any present or future care at this institution.

Name and Signature of the Principal Investigator

Date-

ANNEXURE -III

INFORMED CONSENT

Date:

I, Mr/Mrs _____ ,have been explained in my own vernacular language that my child will be included in the **"EFFECT OF HEATED HUMIDIFIED HIGH FLOW NASAL CANULA (HHFNC) VERSUS BUBBLE NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE(BNCPAP) IN TRANSIENT TACHYPNOEA OF NEWBORN(TTN) (>35 WEEKS) – AN OPEN LABEL RCT"** hereby I give my valid written informed consent without any force or prejudice for recording the observations of haematological and clinical parameters . The nature and risks involved have been explained to me, to my satisfaction. I have been explained in detail about the study being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I provide consent voluntarily to allow my child as a participant in this research. I hereby give consent to provide history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc to the doctor / institute etc. For academic and scientific purpose the operation / procedure, etc may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc responsible for any untoward consequences during the procedure / study.

_____ _____

(Signature & Name of Pt. Attendant) (Signature/Thumb impression & Name of Patient/Guardian)

(Relation with patient)

Witness:

_____

(Signature & Name of Research person/doctor)

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ: ಡಾ ತ್ರಿಸಾಲಿ .ಪಿ / ಡಾ. ಕೆ.ಎನ್.ವಿ. ಪ್ರಸಾದ್

ನಾನು **ಡಾ. ತ್ರಿಸಾಲಿ. ಪಿ** , ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನಲ್ಲಿ ವಿಭಾಗದ ಸ್ನಾತಕೋತ್ತರ ವಿದ್ಯಾರ್ಥಿ, ಶೀರ್ಷಿಕೆಯ ಅಧ್ಯಯನವನ್ನು ನಡೆಸುತ್ತಿದ್ದಾರೆ ..... "**ಬಿಸಿಯಾದ ಆರ್ದ್ರಗೊಳಿಸಿದ ಹೆಚ್ಚಿನ ಹರಿವಿನ ನಾಸಲ್ ಕ್ಯಾನುಲಾ (HHHFNC) ವಿರುದ್ಧ ಗುಳ್ಳೆ ಮೂಗಿನ ನಿರಂತರ ಧನಾತ್ಮಕ ಗಾಳಿಮಾರ್ಗದ ಪರಿಣಾಮ ನವಜಾತ ಶಿಶುವಿನ (TTN)** - **ಡಾ. ಕೆ.ಎನ್.ವಿ. ಪ್ರಸಾದ್**, ಮಕ್ಕಳ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ನನ್ನ ಪ್ರಬಂಧಕ್ಕಾಗಿ ತೆರೆದ ಲೇಬಲ್ RCT. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದವರು ಅಂದರೆ, 84 ನವಜಾತ ಶಿಶುಗಳು ಸೇರಿದ್ದಾರೆ, ಅವುಗಳಲ್ಲಿ 42 ನವಜಾತ ಶಿಶುಗಳ ಪ್ರತಿ ಗುಂಪಿನಲ್ಲಿ HHHFNC ಮತ್ತು BNCPAP ಅಗತ್ಯವಿರುವ ನವಜಾತ ಶಿಶುಗಳ ತೀವ್ರ ನಿಗಾ ಘಟಕದಲ್ಲಿ RL ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ದಾಖಲಾಗಿದ್ದಾರೆ. ಈ ಸಂಶೋಧನಾ ಯೋಜನೆಯಲ್ಲಿ ನಿಮ್ಮ ಮಗುವಿನ ಭಾಗವಹಿಸುವಿಕೆಗಾಗಿ ನಿಮಗೆ ಯಾವುದೇ ಹಣಕಾಸಿನ ಪರಿಹಾರವನ್ನು ಪಾವತಿಸಲಾಗುವುದಿಲ್ಲ.

ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಈ ಸಂಸ್ಥೆಯಿಂದ ಸಂಶೋಧನಾ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಮಗುವಿನ ಭಾಗವಹಿಸುವಿಕೆಗೆ ಒಪ್ಪಿಗೆ ನೀಡಲು ನೀವು ಸ್ವತಂತ್ರರಾಗಿದ್ದೀರಿ. ಯಾವುದೇ ಕಾರಣಗಳನ್ನು ನೀಡದೆ ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಮಗುವನ್ನು ಅಧ್ಯಯನದಿಂದ ಹಿಂಪಡೆಯಬಹುದು. ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ನಿರಾಕರಣೆಯು ಈ ಸಂಸ್ಥೆಯಲ್ಲಿ ಯಾವುದೇ ಪ್ರಸ್ತುತ ಅಥವಾ ಭವಿಷ್ಯದ ಕಾಳಜಿಗೆ ನಿಮ್ಮನ್ನು ಪೂರ್ವಾಗ್ರಹ ಮಾಡುವುದಿಲ್ಲ.

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ

ದಿನಾಂಕ-

ಮಾಹಿತಿ ಸಮ್ಮತಿ ನಮೂನೆ

ನನು, ನನನ ಸವಾಂತ ಪ್ರಾದೇಶಿಕ ಭಾಷೆಯಲ್ಲಿ ನನನ ಮ್ಗುವು ಬಿಸಿಯಾದ ಹಮಿಫೈಡ್ ಹೈ ಫ್ಲೋ ನಾಸ್ನಲ್ (HHFNC) ಪರಿಣಾಮದ ಹೋಲಿಕೆಯ ಮೇಲೆ ಒಂದು ಯಾದೃಚ್ಛಿಕ ನಿಯಂತ್ರಣ ಪರಯೋಗದಲಿಲ ಸೇರಿಸಲಾಗುವುದು

ನಾನು, ಶ್ರೀ/ಶ್ರೀಮತಿ _____, ನನ್ನ ಮಗುವನ್ನು "ಬಿಸಿಯಾದ ಆರ್ದ್ರವಾದ ಹೈ ಫ್ಲೋ ಮೂಗಿನ ಕ್ಯಾನುಲಾ (ಎಚ್‌ಎಚ್‌ಎಫ್‌ಎನ್‌ಸಿ) ಮತ್ತು ಬಬಲ್ ಮೂಗಿನ ನಿರಂತರ ನಿರಂತರ ಧನಾತ್ಮಕ ವಾಯುಮಾರ್ಗ ಒತ್ತಡ (ಬಿಎನ್‌ಸಿಪಿಎಪಿ) ಯಲ್ಲಿ ಸೇರಿಸಲಾಗುವುದು ಎಂದು ನನ್ನ ಸ್ವಂತ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ. (ಟಿಟಿಎನ್) (> 35 ವಾರಗಳು) - ತೆರೆದ ಲೇಬಲ್ RCT" ಈ ಮೂಲಕ ನಾನು ಹೆಮಟೊಲಾಜಿಕಲ್ ಮತ್ತು ಕ್ಲಿನಿಕಲ್ ನಿಯತಾಂಕಗಳ ಅವಲೋಕನಗಳನ್ನು ದಾಖಲಿಸಲು ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡುತ್ತೇನೆ. ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳನ್ನು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ಸಂತೃಪ್ತಿ.ನನಗೆ ನಡೆಸುತ್ತಿರುವ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ.ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ.ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ.ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ ನನ್ನ ಮಗುವನ್ನು ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಅನುಮತಿಸಲು ನಾನು ಈ ಮೂಲಕ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ಡಾಕ್ಯುಮೆಂಟ್‌ಗಳು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಇನ್‌ಸ್ಟಿಟ್ಯೂಟ್ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸಿ. ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ, ಇತ್ಯಾದಿಗಳನ್ನು ವೀಡಿಯೊ ಗ್ರಾಫ್ ಅಥವಾ ಛಾಯಾಚಿತ್ರ ಮಾಡಬಹುದು. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಹೊಣೆಗಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ.

ದಿನಾಂಕ-

(ಸಹಿ ಮತ್ತು ಪಂ. ಪರಿಚಾರಕರ ಹೆಸರು) **(ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತು ಮತ್ತು ರೋಗಿಯ/ರಕ್ಷಕರ ಹೆಸರು)**

(ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ)

ಸಾಕ್ಷಿ:

(ಸಂಶೋಧಕ/ವೈದ್ಯರ ಸಹಿ ಮತ್ತು ಹೆಸರು)

KEYS TO MASTER CHART

Variable Name	
Gender	1=Male, 2=Female
Mode of delivery	1=LSCS, 2=NVD
Antenatal steroids	1=Given, 2=Not given
Risk factor	1=Foetal distress, 2=Hypothyroidism, 3=IDM, 4=IUGR, 5=Preeclampsia, 6=Severe pe, 7=Twin gestation, 8=No
Study Group	G1=HHHFNC, G2=BNCPAP
PP	1=Positive
CFT	1=<3 sec
Chest x-ray	1=Done, 2=Not done
Nasal trauma	1=Yes, 2=No
Intubation	1=Yes, 2=No
Recovery	1=Recovered, 2=Not recovered
Air leak syndrome	1=No

MASTER CHART

SI No	AGE	GESTATIONAL AGE	GENDER	B.wt	MODE OF DELIVERY	ANTENATAL STEROIDS	RISK FACTORS	HHHFNC	BNCPAP	HR	PP	CFT	SPO2	DOWNES SCORE	FiO2	PEEP	CHEST X-RAY	NASAL TRAUMA	INTUBATION	AIR LEAK SYNDROME	DURATION	OUTCOME	RR	HR(1HR)	RR(1HR)	SPO2(1HR)	DOWNES(1HR)	HR(2HRS)	RR(2HRS)	SPO2(2HRS)	DOWNES(2HRS)	HR(3HRS)	RR(3HRS)	SPO2(3HRS)	DOWNES(3HRS)	HR(6HRS)	RR(6HRS)	SPO2(6HRS)	DOWNES(6HRS)	HR(12HRS)	RR(12HRS)	SPO2(12HRS)	DOWNES(12HRS)	HR(24HRS)	RR(24HRS)	SPO2(24HRS)	DOWNES(24HRS)	HR(36HRS)	RR(36HRS)	SPO2(36HRS)	DOWNES(36HRS)	HR(48HRS)	RR(48HRS)	SPO2(48HRS)	DOWNES(48HRS)
1	26	36	M	2.4	LSCS	YES	NO		YES	148	+	< 3 SEC	84	2	30	5	NO	NO	NO	NO	3 HRS	DISCAHRGE	64	152	62	92	2	142	60	96	1	132	54	98	0																								
2	24	37	M	2.04	LSCS	YES	NO		YES	164	+	< 3 SEC	82	3	40	5	NO	NO	NO	NO	6 HRS	DISCAHRGE	66	150	64	95	3	132	64	95	2	134	60	95	2	128	52	97	0																								
3	22	36	F	2.12	LSCS	NO	SEVERE PE	YES		132	+	< 3 SEC	88	2	40		NO	NO	NO	NO	3 HRS	DISCAHRGE	64	148	62	94	1	144	62	94	1	128	56	96	0																								
4	25	39+2	F	2.82	LSCS	NO	NO	YES		138	+	< 3 SEC	84	2	40		NO	NO	NO	NO	24HRS	DISCAHRGE	68	132	70	94	2	148	68	95	2	136	66	94	2	132	64	96	1	152	62	97	1	128	52	96	0												
5	24	39+4	M	2.44	NVD	NO	NO	YES		130	+	< 3 SEC	84	3	30		NO	NO	NO	NO	3HRS	DISCAHRGE	64	146	62	96	1	138	60	96	1	146	56	96	0																								
6	23	35+1	F	2.18	LSCS	YES	SEVERE PE		YES	148	+	< 3 SEC	80	4	30	7	YES	YES(CP AP)	NO	NO	36 HRS	DISCAHRGE	70	158	72	97	3	142	68	96	3	146	68	96	3	138	70	96	3	146	66	98	2	128	64	95	1	132	58	96	0				
7	24	40	M	2.2	LSCS	NO	FETAL DISTRESS		YES	164	+	< 3 SEC	82	3	30	6	NO	NO	NO	NO	6HRS	DISCAHRGE	64	158	62	96	2	148	62	95	1	132	58	97	1	126	50	95	0																								
8	25	35+4	F	2.65	NVD	YES	NO		YES	128	+	<3 SEC	82	3	30	5	NO	NO	NO	NO	2HRS	DISCAHRGE	62	130	60	98	1	124	52	96	0																																				
9	27	36	F	2.88	LSCS	NO	NO		YES	136	+	<3SEC	88	3	30	5	YES	NO	NO	NO	6HRS	DISCAHRGE	64	136	66	94	2	138	64	94	2	126	62	96	1	136	48	96	0																								
10	22	38+2	F	2.9	LSCS	NO	NO	YES		172	+	< 3 SEC	86	2	30		YES	NO	NO	NO	3HRS	DISCAHRGE	64	164	62	96	1	152	60	97	1	144	52	96	0																								
11	22	35	M	2.76	LSCS	YES	HYPOTHYROIDISM	YES		162	+	<3SEC	87	3	30		YES	NO	NO	NO	6HRS	DISCAHRGE	65	158	64	96	2	138	60	96	2	152	62	95	1	142	56	97	0																								
12	20	36+2	M	3.04	LSCS	NO	NO	YES		148	+	< 3 SEC	88	2	40		NO	NO	NO	NO	6HRS	DISCAHRGE	64	152	62	98	2	142	62	95	1	146	62	96	1	152	52	95	0																								
13	26	37+2	M	3.2	LSCS	NO	NO		YES	144	+	< 3 SEC	90	2	30	5	YES	NO	NO	NO	12HRS	DAMA	70	142	68	94	2	132	66	97	1	126	64	96	1	152	62	95	1	124	54	96	0												
14	25	37	M	3.12	LSCS	NO	FETAL DISTRESS	YES		134	+	<3SEC	86	3	30		YES	NO	NO	NO	6HRS	DISCAHRGE	66	128	64	94	2	144	64	95	2	132	62	92	1	128	48	97	0																								
15	23	37+6	F	2.92	LSCS	NO	NO	YES		132	+	< 3 SEC	84	3	30		NO	NO	NO	NO	3 HRS	DISCAHRGE	62	146	64	95	1	136	62	94	1	132	58	96	0																								
16	25	36	F	2.16	LSCS	NO	SEVERE PE		YES	156	+	<3SEC	88	5	30	6	YES	NO	NO	NO	12HRS	DISCAHRGE	72	164	68	94	3	140	66	92	2	142	66	94	2	146	64	94	1	132	56	98	0												
17	22	35+2	F	2.65	LSCS	YES	NO	YES		162	+	< 3 SEC	86	3	40		NO	NO	NO	NO	6HRS	DISCAHRGE	64	156	62	95	2	136	64	96	1	130	62	95	1	138	52	98	0																								
18	24	36	M	2.78	LSCS	NO	FETAL DISTRESS		YES	158	+	<3SEC	84	3	30	5	NO	YES(CP AP)	NO	NO	3HRS	DISCAHRGE	62	134	62	94	2	126	60	95	1	128	50	96	0																								
19	26	35+3	M	3.1	NVD	YES	NO		YES	154	+	< 3 SEC	88	3	30	5	YES	NO	NO	NO	12HRS	DISCAHRGE	66	126	64	95	2	142	62	96	2	146	64	95	2	146	62	96	1	128	54	96	0												
20	19	36+2	M	4.02	LSCS	YES	IDM	YES		142	+	< 3 SEC	88	3	40		NO	NO	NO	NO	6 HRS	DISCAHRGE	64	146	64	96	2	136	64	95	1	136	62	96	1	130	42	98	0																								
21	24	36+6	M	2.76	LSCS	NO	NO	YES		140	+	< 3 SEC	90	3	30		YES	NO	NO	NO	3HRS	DISCAHRGE	66	154	64	96	2	132	64	94	2	146	56	96	0																								
22	26	35+2	F	2.89	LSCS	YES	HYPOTHYROIDSM		YES	152	+	< 3 SEC	85	3	30	6	YES	NO	NO	NO	6HRS	DISCAHRGE	62	148	62	95	1	146	62	94	1	128	60	95	1	144	48	99	0																								
23	23	35+5	M	3.05	LSCS	NO	NO		YES	136	+	< 3 SEC	87	3	40	7	NO	YES(CP AP)	NO	NO	24HRS	DISCAHRGE	68	136	66	94	2	138	64	96	2	130	64	94	2	128	66	98	2	138	64	96	2	142	56	96	0								
24	21	36+4	F	2.4	LSCS	NO	TWIN GESTATION	YES		128	+	< 3 SEC	88	4	40		YES	NO	NO	NO	12HRS	DISCAHRGE	66	146	62	95	2	132	64	92	2	132	64	95	1	126	62	96	1	140	54	96	0												
25	27	36+5	F	4.34	LSCS	NO	IDM	YES		152	+	< 3 SEC	86	4	50		YES	NO	NO	NO	12 HRS	DISCAHRGE	64	124	64	96	2	118	64	96	2	130	62	94	2	118	60	94	1	136	48	97	0												
26	28	36+2	F	2.97	LSCS	NO	NO		YES	162	+	< 3 SEC	84	3	30	5	YES	NO	NO	NO	12HRS	DISCAHRGE	64	132	66	98	3	124	64	96	2	128	62	95	2	140	60	98	1	136	58	96	0												
27	22	35+6	F	2.34	LSCS	NO	SEVERE PE		YES	147	+	< 3 SEC	88	3	30	5	YES	NO	NO	NO	12 HRS	DISCAHRGE	68	126	66	96	2	124	64	96	2	132	62	95	1	126	62	96	1	134	64	94	0												
28	23	38	M	2.54	NVD	NO	HYPOTHYROIDISM		YES	148	+	<3SEC	88	3	30	7	YES	NO	NO	NO	36HRS	DISCAHRGE	76	142	72	93	2	154	68	94	2	140	66	95	2	140	68	92	2	142	68	94	2	150	64	96	2	138	56	95	0				
29	25	39+2	F	1.62	LSCS	NO	SEVERE PE	YES		132	+	< 3 SEC	88	4	30		YES	NO	YES AT 48 HRS	NO	48HRS	DAMA	78	152	74	94	3	156	74	96	3	138	72	96	3	136	70	95	3	148	70	92	3	130	66	94	2	148	64	96	1	138	56	95	0
30	21	40	M	3.2	LSCS	NO	NO	YES		130	+	<4SEC	88	3	40		YES	NO	NO	NO	24HRS	DISCAHRGE	64	136	62	96	1	142	62	95	1	144	64	95	1	146	62	96	1	140	64	95	1	142	54	96	0								
31	21	37+2	F	3.5	LSCS	NO	IDM	YES		146	+	< 3 SEC	86	2	30		YES	NO	NO	NO	12HRS	DISCAHRGE	66	146	66	95	1	130	64	94	1	138	62	96	1	136	64	94	1	132	54	95	0												
32	20	37+4	M	3.06	LSCS	NO	NO		YES	162	+	< 3 SEC	87	3	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	128	60	96	1	134	52	96	0																								
33	26	36+4	F	3.42	LSCS	NO	NO		YES	152	+	< 3 SEC	88	2	30	5	NO	NO	NO	NO	3HRS	DISCAHRGE	64	124	62	98	1	142	62	97	1	126	50	96	0																								
34	24	37+2	F	2.87	LSCS	NO	FETAL DISTRESS		YES	150	+	< 3 SEC	89	2	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	126	62	97	1	138	54	96	0																								
35	23	38	F	2.9	LSCS	NO	NO	YES		164	+	<3SEC	90	3	30		NO	NO	NO	NO	3 HRS	DISCAHRGE	62	146	60	95	1	130	62	97	1	124	48	95	0																								

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36	22	39+1	M	2.96	LSCS	NO	FETAL DISTRESS	YES		155	+	< 3 SEC	86	3	30		NO	NO	NO	NO	3HRS	DISCAHRGE	66	152	66	96	2	140	64	98	1	132	48	94	0																				
37	26	38	F	2.96	LSCS	NO	NO	YES		146	+	<3SEC	88	2	30		NO	NO	NO	NO	2HRS	DISCAHRGE	62	144	62	97	1	128	58	96	0																								
38	25	37+2	M	2.76	LSCS	NO	NO	YES		152	+	< 3 SEC	88	2	30		YES	NO	NO	NO	6HRS	DISCAHRGE	66	146	62	94	1	140	62	95	1	126	60	95	1	132	56	96	0																
39	22	37+4	M	3.09	LSCS	NO	NO	YES		160	+	< 3 SEC	86	2	30		YES	NO	NO	NO	6 HRS	DISCAHRGE	64	154	64	95	1	138	62	97	1	136	62	96	1	126	54	97	0																
40	24	36+3	M	4.02	LSCS	YES	HYPOTHYROIDSM		YES	150	+	< 3 SEC	88	2	30	5	NO	NO	NO	NO	3HRS	DISCAHRGE	64	138	62	97	1	148	62	96	1	126	54	96	0																				
41	24	36+5	M	2.76	NVD	NO	NO		YES	142	+	< 3 SEC	87	3	30	5	NO	YES(CPAP)	NO	NO	12HRS	DAMA	68	146	64	94	1	134	66	97	1	128	64	95	1	126	64	98	1	142	48	97	0												
42	20	37+2	F	2	LSCS	NO	IUGR		YES	132	+	< 3 SEC	86	3	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	120	62	97	1	142	54	95	0																								
43	21	36+2	F	2.74	LSCS	NO	NO	YES		134	+	< 3 SEC	88	4	40		NO	NO	NO	NO	2HRS	DISCAHRGE	62	138	64	94	2	132	48	97	0																								
44	20	37+4	M	2.77	NVD	NO	NO	YES		136	+	< 3 SEC	89	3	30		NO	NO	NO	NO	3 HRS	DISCAHRGE	66	120	62	96	1	138	62	95	1	130	48	98	0																				
45	26	36+4	F	3.07	LSCS	NO	FETAL DISTRESS		YES	132	+	< 3 SEC	88	3	30	5	NO	NO	NO	NO	3HRS	DISCAHRGE	62	134	62	98	1	126	60	96	1	144	46	97	0																				
46	22	35+4	M	3.14	LSCS	YES	NO		YES	128	+	< 3 SEC	86	3	30	5	NO	NO	NO	NO	6 HRS	DISCAHRGE	64	140	62	96	2	134	62	97	2	138	62	95	1	124	52	96	0																
47	25	37+6	F	1.76	LSCS	NO	SEVERE PE		YES	128	+	< 3 SEC	88	4	50	6	YES	YES(CPAP)	YES AT 12 HRS	NO	24HRS	DISCAHRGE	68	138	70	95	3	140	68	96	3	150	66	97	2	130	64	98	2	128	62	96	1	132	56	97	0								
48	24	35+2	M	4.24	LSCS	NO	IDM	YES		126	+	< 3 SEC	88	3	30		NO	NO	NO	NO	6HRS	DISCAHRGE	62	126	62	98	2	144	62	97	2	140	64	95	1	136	56	97	0																
49	23	36+4	F	2.56	LSCS	NO	NO		YES	132	+	< 3 SEC	89	3	30	5	NO	NO	NO	NO	3HRS	DISCAHRGE	62	138	62	96	1	146	62	96	1	132	56	95	0																				
50	21	37+4	M	3.04	LSCS	NO	NO	YES		130	+	< 3 SEC	88	2	30		NO	NO	NO	NO	1 HOUR	DISCAHRGE	62	128	54	95	0																												
51	23	38+5	F	3.12	LSCS	NO	FETAL DISTRESS	YES		154	+	< 3 SEC	86	3	30		NO	NO	NO	NO	3 HRS	DISCAHRGE	66	140	62	94	1	138	62	97	1	142	52	96	0																				
52	25	36+4	F	3.02	LSCS	NO	NO		YES	132	+	< 3 SEC	88	5	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	154	60	96	1	142	48	98	0																								
53	24	35+4	F	2.18	LSCS	YES	PRE ECLAMPSIA		YES	158	+	< 3 SEC	86	3	30	5	YES	NO	NO	NO	6HRS	DISCAHRGE	64	148	62	96	1	138	62	96	1	140	62	95	1	132	56	96	0																
54	28	36+6	F	2.65	LSCS	NO	NO	YES		147	+	< 3 SEC	84	3	30		NO	NO	NO	NO	3HRS	DISCAHRGE	62	154	62	98	1	144	64	96	1	134	58	96	0																				
55	22	35+4	M	3.04	NVD	NO	NO		YES	152	+	< 3 SEC	88	3	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	144	62	97	1	138	54	96	0																								
56	20	36+2	M	4.04	LSCS	NO	IDM		YES	162	+	< 3 SEC	88	3	40	5	NO	NO	NO	NO	1HR	DISCAHRGE	64	142	58	98	0																												
57	24	37+6	M	3.9	LSCS	NO	NO	YES		174	+	< 3 SEC	89	2	30		NO	YES(CHHFNC)	NO	NO	12HRS	DISCAHRGE	68	124	66	96	1	122	64	98	1	124	60	99	1	126	62	98	1	142	56	97	0												
58	23	36+4	M	3.78	LSCS	NO	NO		YES	138	+	< 3 SEC	87	3	30	5	NO	NO	NO	NO	3 HRS	DISCAHRGE	62	144	62	96	1	142	62	96	1	132	52	97	0																				
59	23	35+3	F	3.34	LSCS	YES	NO	YES		130	+	< 3 SEC	86	5	40		NO	NO	NO	NO	3HRS	DISCAHRGE	66	136	64	96	2	130	66	95	1	142	56	97	0																				
60	21	36+6	F	4.52	LSCS	NO	IDM	YES		132	+	< 3 SEC	84	3	30		NO	NO	NO	NO	3HRS	DISCAHRGE	64	128	62	95	1	140	62	94	1	132	54	95	0																				
61	24	39	F	2.67	LSCS	NO	HYPOTHYROIDISM	YES		144	+	<3SEC	88	3	30		YES	NO	NO	NO	6 HRS	DISCAHRGE	64	148	62	96	1	136	62	96	1	140	56	97	1	136	56	96	0																
62	25	37+4	F	2.89	NVD	NO	NO		YES	142	+	< 3 SEC	89	3	30	5	NO	NO	NO	NO	2HRS	DISCAHRGE	64	132	62	95	1	148	54	97	0																								
63	26	39+2	F	2.64	LSCS	NO	FETAL DISTRESS	YES		164	+	< 3 SEC	89	2	30		NO	NO	NO	NO	2 HRS	DISCAHRGE	62	128	60	97	1	136	56	96	0																								
64	24	41	F	2.54	LSCS	NO	NO	YES		135	+	<4SEC	90	2	30		NO	NO	NO	NO	6HRS	DISCAHRGE	66	138	66	98	1	148	64	95	1	128	62	95	1	128	54	97	0																
65	22	37+4	F	1.87	LSCS	NO	SEVERE PE		YES	122	+	< 3 SEC	90	2	50	6	YES	NO	YES AT 20 HRS	NO	24HRS	DISCAHRGE	68	128	64	96	1	132	64	94	1	122	64	96	1	132	62	96	1	124	64	98	1	132	56	97	0								
66	25	36+5	M	2.88	LSCS	NO	NO	YES		118	+	< 3 SEC	87	2	30		NO	NO	NO	NO	1 HOUR	DISCAHRGE	62	126	56	97	0																												
67	25	35+4	M	2.64	LSCS	YES	NO	YES		126	+	< 3 SEC	88	5	30		NO	NO	NO	NO	1 HOUR	DISCAHRGE	62	122	58	96	0																												
68	21	35+2	M	2.54	LSCS	NO	HYPOTHYROIDISM		YES	128	+	< 3 SEC	88	2	30	5	NO	NO	NO	NO	3HRS	DISCAHRGE	64	126	62	97	1	134	64	94	1	146	54	96	0																				
69	20	36+5	M	2.22	LSCS	NO	TWIN GESTATION		YES	138	+	< 3 SEC	89	2	30	5	NO	NO	NO	NO	2 HRS	DISCAHRGE	62	142	60	96	1	126	46	97	0																								
70	18	36+2	M	2.06	LSCS	NO	SEVERE PE	YES		130	+	< 3 SEC	89	3	30		NO	NO	NO	NO	2 HRS	DISCAHRGE	62	128	62	97	1	134	48	96	0																								
71	25	38+3	M	1.84	LSCS	NO	IUGR		YES	140	+	< 3 SEC	88	2	30	5	YES	NO	NO	NO	12HRS	DISCAHRGE	66	148	64	94	1	138	64	97	1	136	62	95	1	140	62	96	1	140	56	97	0												
72	26	37	F	2.2	LSCS	NO	NO	YES		136	+	<3 SEC	87	3	30		YES	NO	NO	NO	6 HRS	DISCHARGE	64	150	62	96	1	144	62	96	1	128	62	96	1	128	54	98	0																
73	25	35+ 3	F	2.56	LSCS	NO	SEVERE PE	YES		162	+	< 3 SEC	88	4	30		YES	YES(HHFNC)	NO	NO	36HRS	DAMA	74	132	72	98	3	128	66	95	2	142	68	87	2	132	68	95	2	144	68	97	2	126	66	99	2	138	54	96	0				
74	24	37+6	F	2.67	LSCS	NO	NO		YES	122	+	< 3SEC	86	3	40	5	YES	NO	NO	NO	6 HRS	DISCHARGE	66	126	64	98	1	132	64	96	1	126	64	98	1	142	56	97	0																
75	22	38	M	2.84	NVD	NO	NO	YES		144	+	<3SEC	85	3	40		YES	NO	NO	NO	6HRS	DICHARGE	68	152	66	96	2	138	64	98	1	144	62	96	1	128	54	96	0																

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76	23	39	F	2.9	LSCS	NO	FETAL DISTRESS		YES	168	+	< 3SEC	89	2	30	5	NO	YES(CPAP)	NO	NO	36HRS	DICHARGE	74		70	96	2	126	72	96	2	128	68	96	2	138	68	94	1	132	66	96	1	126	64	96	1	136	52	95	0				
77	22	40	F	3.08	NVD	NO	NO	YES		156	+	<3SEC	90	2	30		YES	NO	NO	NO	3HRS	DICHARGE	68	134	66	97	1	128	66	94	1	126	64	97	0																				
78	21	37+6	F	3.06	LSCS	NO	NO		YES	142	+	< 3SEC	84	2	40	5	NO	NO	NO	NO	6 HRS	DISCHARGE	66	140	64	96	1	126	64	95	1	132	62	96	1	142	52	98	0																
79	27	36+2	F	2.88	NVD	NO	NO		YES	136	+	< 3SEC	84	2	50	5	YES	NO	NO	NO	6HRS	DISCHARGE	68	136	62	95	1	136	62	94	1	130	64	93	1	132	56	96	0																
80	28	38+6	M	3.09	LSCS	NO	NO		YES	122	+	< 3SEC	88	3	30	5	YES	NO	NO	NO	3 HRS	DISCHARGE	62	142	62	96	1	142	62	99	1	125	56	94	0																				
81	24	37+5	F	3.12	LSCS	NO	NO	YES		136	+	<3SEC	86	2	40		YES	NO	NO	NO	1 HRS	DISCHARGE	62	136	58	95	0																												
82	22	37+2	M	3.16	LSCS	NO	NO	YES		168	+	<3SEC	84	2	50		NO	NO	NO	NO	1 HRS	DISCHARGE	62	132	56	96	0																												
83	21	36+2	F	2.87	LSCS	NO	NO		YES	166	+	< 3SEC	88	4	30	5	NO	NO	NO	NO	3HRS	DISCHARGE	66	128	64	95	1	126	62	96	1	128	52	97	0																				
84	24	36+6	M	2.56	LSCS	NO	SEVERE PE		YES	162	+	< 3SEC	86	3	40	5	NO	NO	NO	NO	6HRS	DISCHARGE	68	142	64	96	2	128	64	94	1	138	62	96	1	132	56	97	0																