HEAD HUMIDIFIED HIGH FLOW NASAL CANNULA VERSUS NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE AS A PRIMARY MODE FOR RESPIRATORY SUPPORT OF NEWBORNS IN GESTATIONAL AGE GROUP OF 30-37WEEKS-PROSPECTIVE OBSERVATION STUDY

BY

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"HEATED HUMIDIFIED HIGH FLOW NASAL CANNULA VERSUS NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE AS A PRIMARY MODE FOR RESPIRATORY SUPPORT OF NEWBORNS IN GESTATIONAL AGE GROUP OF 30-37WEEKS-PROSPECTIVE OBSERVATIONAL STUDY"

DOCTOR IN MEDICINE IN PEDIATRICS

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LIST OF ABBREVATIONS USED

1.ELBW- Extreme Low Birth Weight

2.RDS-Respiratory Distress Syndrome

3.NICU-Neonatal Intensive Care Unit

4.HHHFNC-Heated Humidified High Flow Nasal Cannule

5.PPROM- Preterm Premature Rupture Of Membranes

6.NCPAP-Nasal Continuous Positive Airway Pressure

7.ACST-Antenatal Corticosteroids Therapy

8.NMR-Neonatal Mortality Rate

9.BPD-Bronchopulmonarydysplasia

10.ROP-Retinopathy Of Prematurity

11.CLD-Chronic Lung Disease

12.FRC-Functional Residual Capacity

13. INSURE (Intubation, Surfactant administration, Rapid Extubation).

14.IVH-Intraventricular Hemorrhage

15. NSG-Neurosonogram.

16. TTNB-Transient tacypnea of newborn

17.PPHN-Persistant pulmonary hypertension

18.BPD-Bronchopulmonarydysplasia

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Introduction

The primary indicators of the country's health are the rates of neonatal and perinatal death. In industrialized countries in 2019[1,2], Per 1000 live births, the rates of neonatal and perinatal death are 3-5 and 8-9, respectively. Neonatal and perinatal death rates are remain high in India despite notable urban improvements. In India, there are 21.4 newborn deaths for every 1000 live births in 2019[3]. According to a number of studies, respiratory distress during the newborn era accounts for between 32 and 52 percent of deaths[4,5]. Res.piratory distress, one of the most common newborn situation, affecting 3-7% of all live births worldwide[5-8]. The mortality rate in cases of respiratory distress would be decreased by ensuring adequate and fast rescue, O2 supplementation, maintaining an ideal body temperature, prompt referral, and effective ventilatory support. One of important approaches for managing respiratory distress in neonates is assisted ventilation. A sudden, short-term intervention to help the newborn breathe physically until they are able to do it on their own.

basically two forms of assisted ventilation.

1.Non invasive. ventilation

2.invasiv.e ventilation,

One of the more expensive treatments in newborn critical care, but having the potential

to save lives.

Additionally, related morbidity exists . Non-invasive ventilation necessitates the use of trained medical staff who must operate it and continuously sample the infant's blood (e.g.-ABG monitoring). In addition to equipment costs, the price of healthcare and pulmonary physician services varies from location to area. Many benefits come with gentle non-invasive ventilation, such as Bubble Continuou's positive airway pressure. The bubble Continuous positive airway pressure machine is easy to use and reasonably priced. These neonates can be efficiently handled with the aid of pulse-oximeter monitoring[9]. Without any increase in mortality, Bubble CPAP also had lower long-term morbidity[10].

To satisfy the demands of many newborns in developing countries like India, It can be applied in any hospitals with a secondary level with skilled staff[11,12]. The most effective strategy to reduce the costs of morbidity and mortality is through these low-cost measures. The incidence of BPD and mortality are decreased by using CPAP as a noninvasive breathing method. However, the difficulty of applying CPAP to the nares and the possibility of nasal damage may limit its usage in ELBW newborns.

The use of heated humidified high-flow nasal cannula therapy (HHHFNC), which was first reported as a method of respiratory support in preterm newborns, is growing in the treatment of acute respiratory failure in older children. Gas mixtures can be administered at flow rates that are equal to or higher than the patient's inspiratory flow rate due to heating and humidification. The use of HHHFNC treatment may reduce work of breathing, increase ventilation efficiency, and lessen the need for intubation in children with respiratory insufficiency, according to emerging evidence from observational studies[6].

High-flow nasal cannulae are being used increasingly frequently as an alternative for

nasal continuous positive airway pressure (CPAP) for noninvasive breathing support of early preterm neonates[5]. However there is a lack of information regarding the efficiency or security of such cannulae in the population of late-preterm babies (32–37 weeks). Use of HFNC in babies with ELBW may provide an additional means of noninvasive respiratory support due to its simplicity, improved toleration, and reduced nasal trauma. HFNC can enhance the lung compliance, lessens work of breathing, and deliver some positive airway pressure[8]. Despite limited data, HFNC is commonly used in preterm infants to wean from CPAP or an alternative to CPAP.

Hence, this study we assessed whether HHHFNC is as effective and safe as NCPAP in providing respiratory support in preterm neonates.

AIMS AND OBJECTIVES:

- To assess the **efficacy** of HFNC as compared to CPAP in providing respiratory support in 30 to 37 weeks period of gestation as primary mode.
- To assess the **safety** of HFNC as compared to CPAP in providing respiratory support in 30 to 37 weeks period of gestation as primary mode.

Review of literature:

PREMATURITY:

Preterm babies are those that are born alive before 37 full weeks of pregnancy.

Prematurity has several risks, thus it is best to avoid having a caesarean section or inducing labour before 39 weeks, unless medically necessary[13].

There are many causes for preterm birth. The majority of preterm deliveries are spontaneous, however some are brought on by early caesarean sections or labour inductions.

Preterm delivery-causes

1) Number of pregnancies

2) Infection

3) PROM.

4) diabetes , high blood pressure

5) Poor socioeconomic status

But no major reason has been identified. A better understanding of the mechanisms and causes contributes to the development of premature birth prevention strategies.

Over 60% of preterm births occur in Africa and South Asia, despite being a global problem. 12% of babies in low-income countries have preterm delivery, compared to 9% in high-income countries.

Over 35,19,100 births each year, India is in the top 10 nations with the highest rate of premature births[25]. There are several potential causes of this, including the prevalence of fundamental maternal health conditions like diabetes and high blood pressure, the increased use of infertility treatments that lead to higher rates of multiple pregnancies, better interventions, rising maternal ages, and changes in obstetric practises like more caesarean deliveries performed early in pregnancy to increase baby survival[25].

Depending on where they are born, preterm newborns' chances of surviving are drastically different. For instance, more than 90% of kids born in low-income nations who are severely preterm (less than 28 weeks) pass away within the first few days of life, compared to less than 10% of newborns born in high-income countries who are similarly premature[5].

Preterm birth issues are associated with organ system immaturity and a difficulties adapting to the extrauterine environment.

Respir System

1) Delayed Perinatal adaptation

2) RDS

3) Apnea of prematurity

NEUROLOGICAL COMPLICATIONS

1) Intraventricular bleeding

HEMATOLOGICAL COMPLICATIONS

1) Neonatal Hyperbilirubinemia

2) Anemia of prematurity

NUTRITIONAL REQUIREMENT:

1) caloric requirements

2) feeding problems

3) Volume of feeding

GI COMPLICATIONS

Necrotizing enterocolitis (NEC)

INSTABILITY IN TEMPERATURE

Variations like hypothermia and hyperthermia

COMPLICATIONS

1) Bronchopulmonary dysplasia

2) Failure to thrive

3) Increased childhood morbidity and mortality

More than 1 in 10 babies are thought to be born prematurely each year, or an estimated 15 million preterm births[25]. Additionally, it is estimated that 1 million kids risk their own lives each year from preterm birth-related complications[3]. Among survivors, learning disabilities, problems with the eyes, ears, and other chronic conditions are rather frequent.

The leading cause of death for children under the age of five worldwide is prematurity. And preterm birth rates are rising in almost all nations with reliable data. Low birth weight (LBW), which is caused by early preterm delivery and SGA babies, are also significant indirect causes of neonatal fatalities. 60% to 80% of all newborn deaths are caused by LBW. With a 15.5% prevalence worldwide and 96.5% of LBW newborns being born in underdeveloped nations, there are over 20 million LBW babies born each year.

It is clear that survival rates vary widely over the world. Half of babies delivered at or under 32 weeks in low income settings die because there is a shortage of practical, inexpensive care, such as warmth, breastfeeding support, and fundamental treatment for infections and breathing problems.

Nearly 90% of these infants survive in high income countries because of greater aid and care. Due to substandard technological use in middle-class surroundings, the burden of disability among preterm infants who survive the newborn period is increasing.

It has been demonstrated that proper care of LBW infants, such as feeding, temperature control, hygienic cord and skin care, and early detection and treatment of infections and complications, such as respiratory distress syndrome, significantly lowers mortality in both developed and low- and middle-income countries.

RDS

The primary cause of death in preterm infants is RDS affects about 1% of all infants. According to national neonatal-perinatal database for the years 2002–2003, hyaline membrane disease caused 13.5% of all newborn deaths and affected 1.2% of all live births.

Gestational age has an inverse relationship with the prevalence of HMD. It affects 60–80% of babies born between 28 and 32 weeks of gestation, 15–30% of babies born between 32 and 37 weeks, and hardly ever babies born after 37 weeks.

ETIOPATHOGENESIS:

Lack of pulmonary surfactant in both quantity and quality is the main factor causing RDS. An sufficient level of surface-active material, which is made up of saturated lecithins and phosphatidyl glycerol, must be present in the air gaps

for a newborn to undergo proper postnatal pulmonary adaptation. Because type 2 alveolar cells produce surface active material that lowers surface tension to maintain alveolar stability at low pressures, alveolar collapse at the end of expiration is prevented.

Athelectasis is caused by a lack of surfactant brought on by the lungs' immaturity or by their inability to replace it after being injured by type 2 alveolar cells. Hypoperfusion of the lungs, which causes epithelia.l necrosis and transudation of plasma, appears to be the cause of the development of hyaline membranes and the typical pathological features.

End e xpiratory alveolar collapse, decreased pulmonary compliance, pulmonary underperfusion, and increased capillary exudation all work together to generate CO2 buildup and lower oxygen and pH partial pressures in the blood. By causing pulmonary arterioles to shrink and right-to-left shunts to open, these metabolic changes lengthen hypoxia.

Diffuse alveolar atelectasis, edema, and cell damage are the causes of the disease's symptoms. The alveoli then receive serum proteins that reduce surfactant function. The disease worsens because of the developing lung's small surface area for gas exchange, increased water content, immature fluid-clearing processes, absence of alveolar-capillary apposition, and immature fluid-clearing mechanisms.

PRENATAL PREDICTION

Assessment of fetal lung maturity: Amniotic fluid acquired during amniocentesis can be tested to predict lung maturity before birth.

Lecithin/ sphingomyelin ratio: Thin-layer chromatography is used to carry out this task. Surface-active fluid is secreted from the foetal lung and enters the posterior pharynx. A small portion of it enters the amniotic fluid, but the majority is swallowed. To determine the amount of lecithin and sphingomyelin in an amniotic fluid sample, Following a 3- to 5-minute centrifugation of the material at 1000 rpm, a very thin layer chromatography is performed on the supernatant. While a ratio about less than 1.5 is linked to hyaline membrane illness, one of two or higher indicates good lung maturation. The exceptions include children born to diabetic moms, those who have erythroblastosis fetalis, and those who have suffered from intrapartum hypoxia. Contamination of the data with blood (false low) or meconium makes it difficult to interpret the results (false high).

TDx-FLM II- Fluorescent polarisation technique is used to calculate the surfactant to albumin ratio. Lung maturity is correlated with a value greater than 55 mg surfactant/gm albumin. Meconium or blood contamination affects how this test is interpreted.

Foam stability index : It produces FLM estimates based on the formation of a protective foam following the shaking of amniotic fluid and ethanol in a test tube. To determine the likelihood that RDS may develop in a high-risk infant, a helpful bedside screening test is available. Gastric aspirate that was taken within 15

minutes of delivery was combined with 1.0ml of 95% ethyl alcohol and 0.5ml of normal saline in a clean test tube. After giving it a 15 second, vigorous shaking, it is then let to stand for the following 15. Quantities of froth or bubbles are checked on the surface. According to the test results, which were negative, there is a high risk of developing HMD when bubbles only covers 1/3rd or less of the liquid surface. if the mixture contains at least two thirds froth or bubbles.

Lamella'r body counts : It is simple and cost-effective test. With increasing gestational age, the amniotic fluid contains more lamellar bodies, which are phospholipid-containing packages produced by type two alveolar cells. Lung maturity is predicted by a value of >50,000 lamellar bodies per microliter.

Instead of using gastric aspirate, the Click test evaluates the generation of stable microbubbles in 0.2 millilitres of tracheal aspirate. Meconium or blood contamination affects how this test is interpreted.

Regardless of the L/S ratio, quantitation of phosphatidyl glycerol is the most accurate way to assess lung maturity, and its absence is consistently linked to the emergence of HMD.

ACST medication must be given to expectant mothers between twenty four-thirty four weeks of pregnancy who have intact membranes or preterm membrane rupture without chorioamnionitis and who are at a high risk of giving birth too soon the following week.

It stimulates surfactant synthesis and quickens the development of embryonic tissues, including the lungs.

In order to improve morphological and biochemical lung maturation in newborns, corticosteroids were first administered to pregnant women who were at risk of having an early birth in 1972. It has been demonstrated that using antenatal steroids to prevent premature deliveries lowers the risk of ,IVH,RDS,NEC.

Course of steroids consists of four doses of Dexamethasone (6 mg INTRAMUSCULAR) spaced out over two weeks, or two doses of Betamethasone (12 mg IM) spaced out over two weeks. Incomplete courses can also be effective. Indications for immediate delivery, such as chorioamnionitis, are contraindications. The majority of studies indicate that betamethasone is preferable because dexamethasone may be neurotoxic, although the Betacode Trial comparing the two medications revealed no differences between them, with the exception of a more incidence of Intraventricular hemmorrhage and brain lesions in newborns treated to betamethasone. Antenatal steroids appear to continue to be advantageous in the context of contemporary neonatal care, as shown by the similarity of their favourable effects in trials done in the 1970s and those completed more recently. They improve results when supplied properly. If not, negative effects like obstructed foetal and placental growth, brain apoptosis, and elevated infection risks could take hold. There are few follow-up statistics on term infants who were exposed to prenatal steroids.

The best treatment to delivery interval is more than 24 hours and less than 7 days after the start of steroid treatment; benefits start to wane after 14 days. The World Health Organisation recommends that a single repeat course of steroids

may be indicated if a preterm birth does not occur within 7 days of the initial course and a subsequent assessment reveals that there is a high risk of preterm birth in the 7 days that follow.

Randomized controlled trail from low- to medium-income countries revealed that women who received prenatal steroids had increased rates of infant mortality and maternal infection. Because most babies weighed more than 2 kg at birth, these results highlight the importance of precise timing of pregnancy duration, assessment of the preterm birth risk, and accessibility to neonatal services.

RESPIRATORY DISTRESS

Advanced fetal monitoring, early detection, referral of high-risk pregnancies, connections between referral hospitals and health centres, close monitoring of labour to detect foetal distress, and prompt intervention when necessary, according to recommendations made by the National Neonatology Forum India[13], can reduce the incidence of respiratory distress and subsequent perinatal mortality.

Tachypnea, retractions, and grunting are common signs of respiratory distress in newborns. Lethargy, poor feeding, and central cyanosis. The clinical degree of respiratory distress can be assessed using a variety of grading methods. To evaluate respiratory distress, we employed the Downes score.

DOWNES SCORE

Score	0	1	2
Respiratory rate/min	<60	60-80	>80
Cyanosis	None	At room air	With 40% O2
Retractions	None	Mild	Moderate-severe
Grunting	None	Audible with Stethoscope	Audible without Stethoscope
Air entry	Clear	Decreased	Barely audible

Score <5 - Mild respiratory distress

Score 5-7- Moderate respiratory distress

Score >7- Severe respiratory distress

Respirator,y distress - Causes

medical conditions in India [14]

1. Birth asphxia
2. TTNB

3.Meconium aspiration syndrome

4. Respiratory distress syndrome

5. Bronchopneumonia

6. Aspiration pneumonia

7. PPHN

8. Cardiac conditions

9. Neurologic conditions

10. Metabolic abnormalities.

Surgical. conditions include

1. Pneumothorax

2. Tracheo -Oesophageal fistula

3. Bronchopulmonary dysplasia

Invasive ventilation in respiratory distress- disadvantages

Neonatal survival has certainly increased as a result of traditional mechanical ventilation through an endotracheal tube. However, chronic use of a mechanical ventilator with an endotracheal tube may result in

1. Altered mucociliary flow
2. Upper airway damage
3. BPD
4. Barotrauma
5. Volumtrauma

Non invasive ventilation in respiratory distress- Advantages

CPAP is method for maintaining lung capacity during expiration to prevent atelectasis and increase oxygenation[15,16,17]. It also provides +ve end-expiratory pressure and a changing amount of oxygen to a spontaneously breathing neonate's airway. End-expiratory Volume (FRC) is maintained by CPAP by splinting the chest [18,19,20]. It supports the at-risk-of-fatigue respiratory muscles. Muller and co.

HISTORY

To assist premature newborns with breathing, CPAP was initially utilised in 1971. Gregory et al. reported using CPAP for the first time to treat HMD in 1971. The Bubble CPAP method was developed in the 1970s by dr. JenTien Wung at the Columbian Presbyterian Medical Center in New York using short nasal prongs[21]. Retrospective research on 1625 neonates from eight tertiary hospitals was published in 1987 by Avery et al. [22]. The study found

that the lowest prevalence of chronic lung disease (CLD) and no appreciable change in mortality were found at Columbia University, where nasal CPAP was the most common form of respiratory assistance.

Even in the pre-surfactant era and during the sparse use of prenatal steroids, there has been some evidence that early CPAP usage would avoid later use of artificial breathing and the accompanying unfavourable outcome. The need for aided reventilation owing to respiratory failure decreased in infants who were extubated to nasal CPAP.

CPAP - Benefits[23]

1. lowers upper airway resistance and increases pharyngeal cross sectional area to lessen upper respiratory obstruction.
2. Decreases R to L shunting.
3. Reduces obstructive apnea.
4. increases the FRC.
5. By widening the airways, reduces inspiratory resistance. As a result, the work of breathing is reduced because a greater tidal volume is possible at a given pressure.
6. Increases tidal volume and compliance in lungs with low FRC that are rigid by preventing paradoxical movements and stabilising the chest wall.
7. Decreases the RR.
8. Decreases incidence of apnea.

9. increases the mean airway pressure and improves ventilation perfusion mismatch.

10. Conserving surfactant.

11. Diminishes alveolar edema.

12. CPAP, following extubation reduces the proportion of babies requiring re-ventilation.

13. Alveolar surface area affects oxygenation, and alveolar volume affects carbon dioxide removal. Enhancing oxygenation and carbon dioxide removal through normalising lung volumes.

Delivering continuous positive airway pressure requires 3 components:

1. Flow generation

2. an airway interface

3. positive pressure system.

FLOW GENERATION

Constant flow and variable flow are the two main categories. In most cases, the flowing generator also heats and humidifies the gases that are inhaled. Typically, an infant ventilator provides constant flow. The clinical team is often in charge of determining the flow rate.

Alternatives include the employment of a specific flow generator using variable flow devices. Since the circuit's expiratory limb is exposed to the air in this situation, the baby can use this limb to pull in more gas to aid in the process of inhaling. This device has gained widespread acceptance in Europe and North America. Despite the many advantages of the variable flow device, there are no reliable data demonstrating clinically substantial advantages over constant flow devices over the long term.

The arrays of airway interfaces are in use:

binasal prongs (short and long)

single prongs

et tubes

nasopharyngeal prongs

pressurised plastic bags

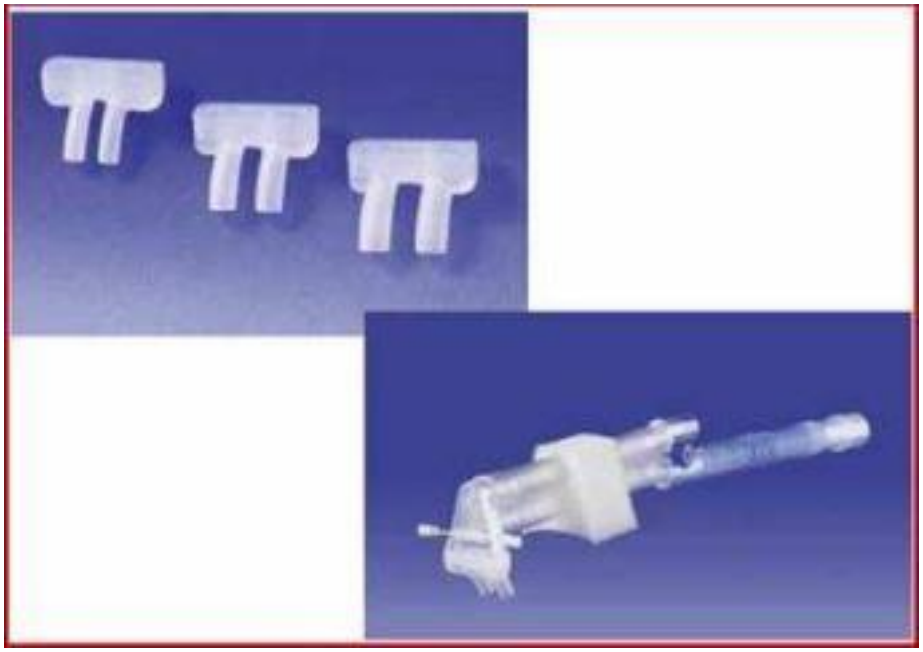
head boxes

face masks and nasal cannulae.

Nasal prongs are quite simple to use and do not obstruct the airways. CPAP can be used continuously when the baby is being handled and nursed. According to a Cochrane Systematic Review, single nasal prongs are less

effective than short binasal prongs at preventing re-intubation in premature newborns. However, NP can result in nasal scarring and excoriation[25,26].

Short nasal prongs (Fisher & Paykel)



A Positive pressure system – of three types

1. Ventilator's expiratory valve is used to modify the expiratory pressure.
2. By adjusting the inspiratory flow or the expiratory resistance, the pressure is produced.
3. By submerging the far end of the expiratory tubing, Bubble CPAP device creates a positive pressure. By adjusting the tube's depth beneath the water's surface, the pressure can be changed.

Bubble continuous positive airway pressure

The bubble continuous positive airway pressure system essentially consists of three parts:

1. Constant flow of gas entering the circuit

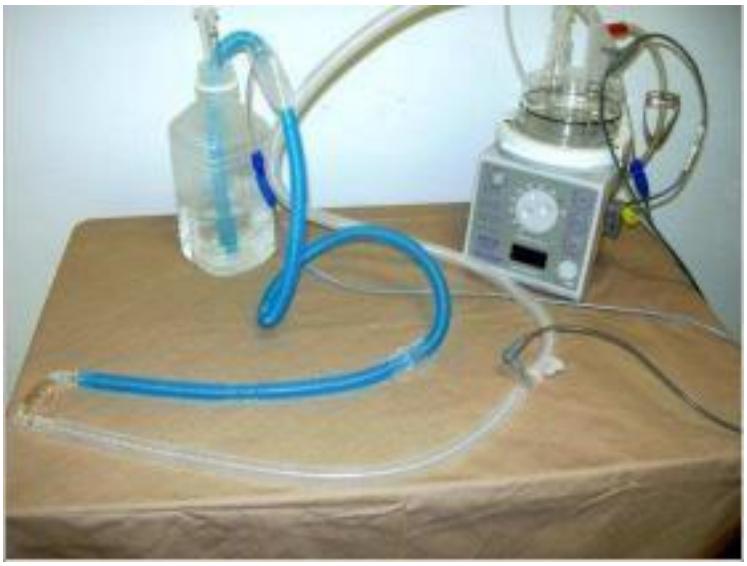
2. expiratory limb used to produce positive end expiratory pressure, with the distal end dipped into a liquid.

3. Nasal interface linking the circuit to the baby's airway.

The gas bubbles as it exits the circuit via the expiratory limb. It is possible to supply the right concentration of inspired oxygen by using an oxygen blender that is coupled to a wall-mounted oxygen and compressed air supply[28,29].

The optimal gas flow is maintained using a flow metre to prevent carbon dioxide rebreathing, make breathing more difficult due to a lack of flow available for inspiration, and take into account CPAP system leaks. A flow rate of 5 to 10 litres per minute is appropriate when administering CPAP to newborns[30,31].

BUBBLE Continuous positive airway pressure



Distal expiratory tubing is submerged in water to provide pressure within the bubble CPAP system. The length of the immersed expiratory limb determines the designated pressure. When the baby receives the pressure without a leak, the pressure in the circuit fluctuates and there is constant bubbling. Leakage is not in ventilator CPAP. Although it was formerly believed that the pressure oscillation might aid in gas exchange, a more recent report[32,33] rejected this idea.

Today, CPAP is utilised to treat a number of newborn disorders. It works well to maintain recently extubated infants and to treat prematurity-related apnea. In the treatment of HMD, it is also increasingly being taken into account as an alternative to intubation and ventilation. Patients with moderate to severe HMD who use CPAP early surfactant delivery of a single dosage, accompanied with brief intubation, and oxygenation are less likely to require mechanical ventilation[34,35].

The INSURE methodology is the name of this strategy (Intubation, Surfactant administration, Rapid Extubation).

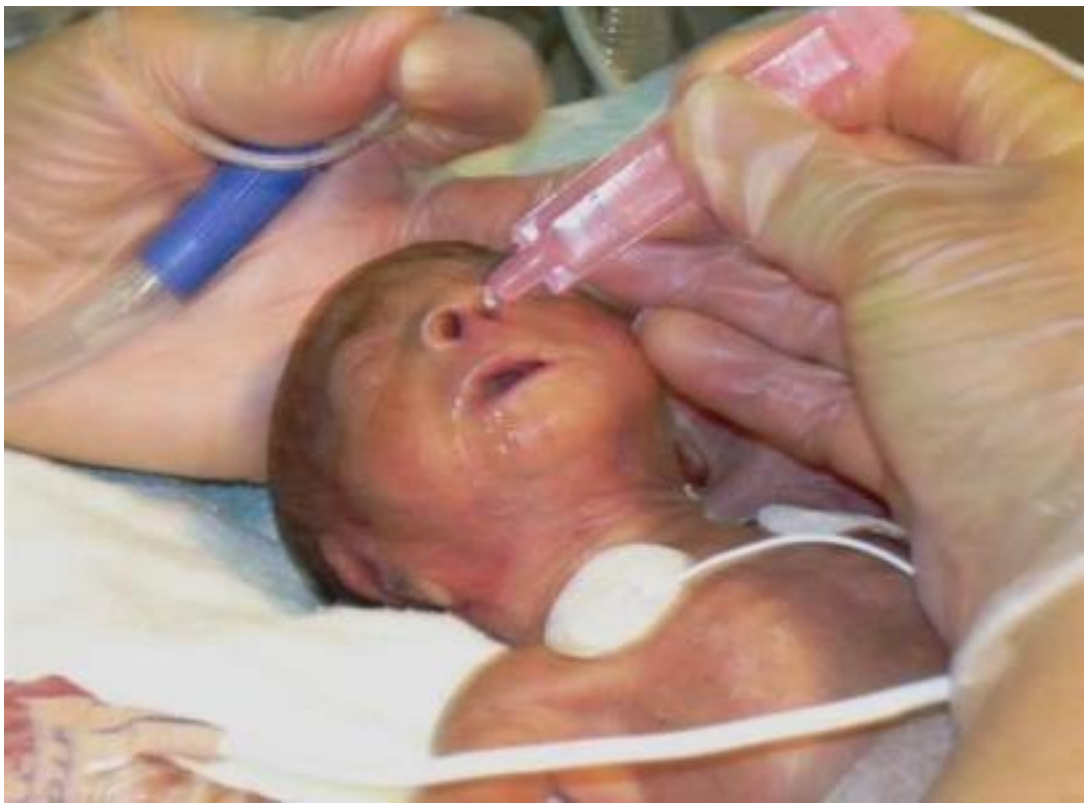
MONITORING:

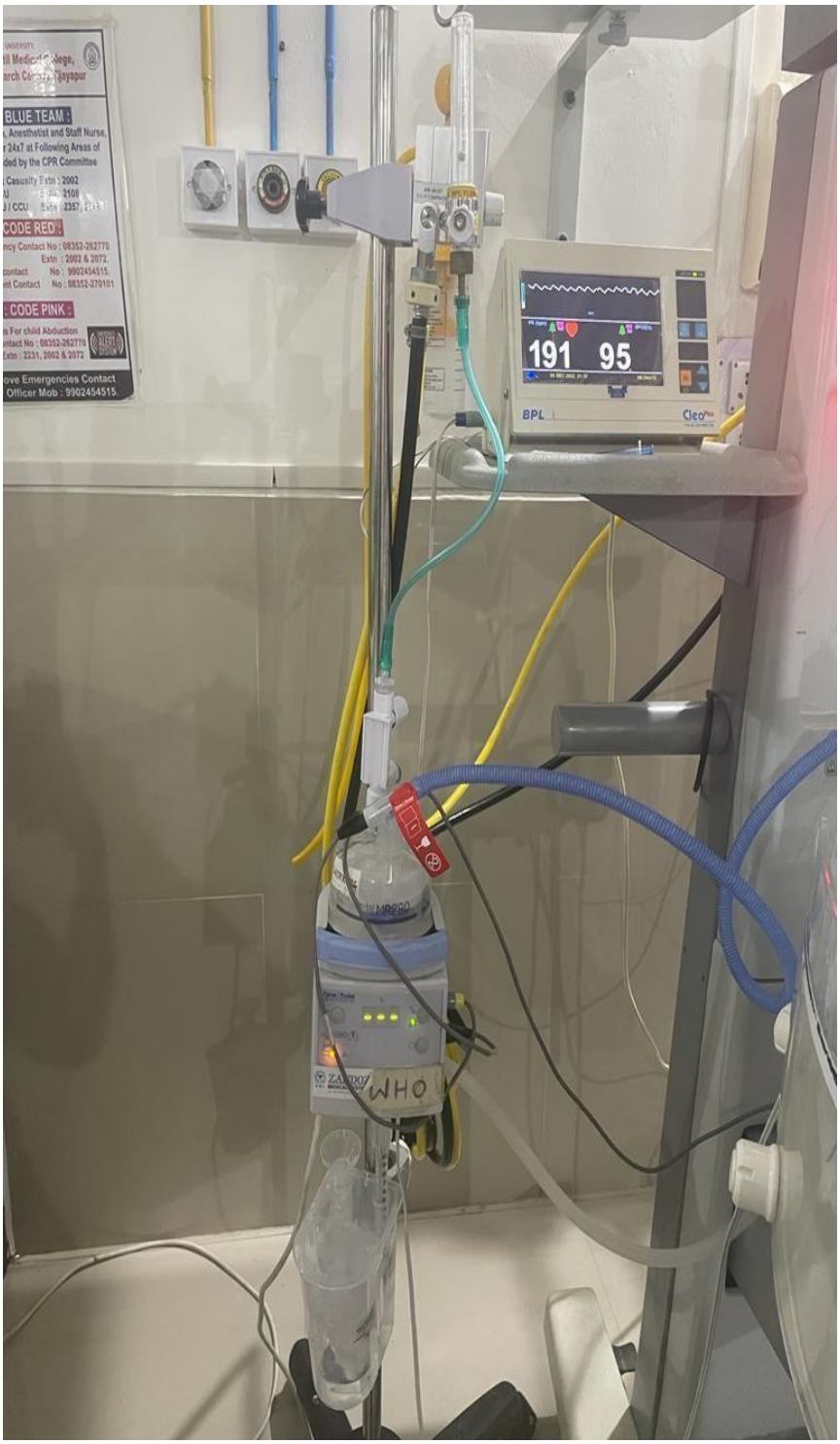
The infant's airway must be properly cared for when using CPAP. To prevent excessive flexion or extension, it's important to use the right prong size and position the baby's neck. The breathed gas should be optimally humidified, and frequent suction is necessary to regularly remove accumulated secretions from the airway. Gaseous bowel distension can be relieved with the aid of an oral gastric tube. According to Robertson et al., 20% of newborns who used CPAP developed nasal problems, including columella necrosis, flared nostrils, and snubbing of the nose. When nursing infants who need nasal CPAP, it's crucial to pay attention to and take care of the nasal area. Clinicians need to be aware that CPAP can cause more severe side effects such pneumothorax and air embolism[37,38]. Therefore, careful monitoring for clinical deterioration is still necessary for all newborns requiring breathing support, whether invasive or non-invasive. In this regard, there should be no compromises for CPAP use, and its use necessitates constant monitoring of breathing patterns as well as standardised and strict training for medical professionals, respiratory practitioners, and nursing personnel.

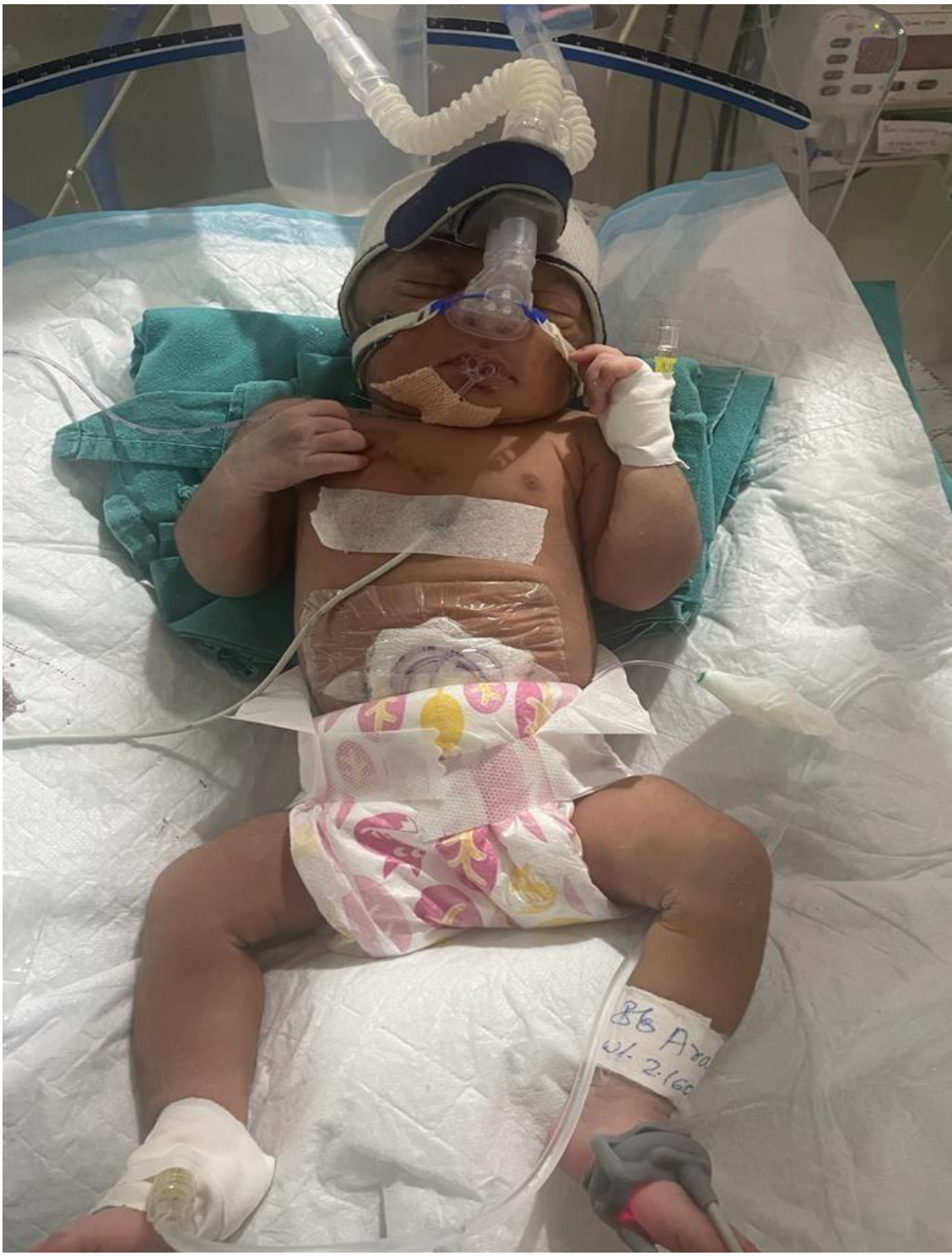
NURSING CARE

The success of Bubble CPAP is critically dependent on comprehensive nurse care. By placing a hat of the right size that crosses the infant's forehead and rests along the lower

portion of his ears with the circuit tied on it, the proper alignment of the prongs may be ensured. It must be placed on the infant's head and be tightly fastened. Otherwise, the motion of the hat will cause the circuit and the prong to move. If the prong could not be kept in the nostrils of an active infant, tissue necrosis was seen.







When the prong rests on the columella or the nasal septum, nasal injuries are frequent. The columella or nasal septum may be accidentally pierced by the prong if it is not applied properly. To maintain a healthy airway without jeopardising the nostrils' tissue integrity, adequate airway humidification and gentle nasal suction are required.

To reduce "rain-out," adjustments can be made to the temperature of the temperature probe, the chamber, and the sample. During the acute stage of respiratory distress, consistent bubbling is necessary to lower airway resistance, increase functional residual capacity, and draw in alveoli. If the bubbling stops, a systemic pressure leak—usually in or close to the nostrils—is probably present. It has been noted that when the infant using CPAP opens his mouth, the pharyngeal pressure significantly decreases. A recent study showed that while not entirely communicated, the prong pressure was more successfully conveyed when the mouth was closed. For effective CPAP support, it has been advised to use a chhin strap or pacifier to reduce mouth leak. It should, however, only be snug enough to stop leakage when the baby is dozing and not too tight to stop the baby from yawning or crying. It is necessary to regularly monitor the infant's respiratory condition in order to determine how well the treatment is working and to make plans for follow-up care. In order to avoid interference, CPAP must be momentarily stopped during chest auscultation.

However, precautions must be taken since when CPAP support is temporarily interrupted, the baby may develop apnea and bradycardia. When a newborn is receiving CPAP assistance, gastric distension is typical (CPAP Belly Syndrome). To provide comfort and avoid the swollen stomach from splinting the diaphragm and impairing respiration, inbetween decompression of the stomach through an Ryles tube is required.

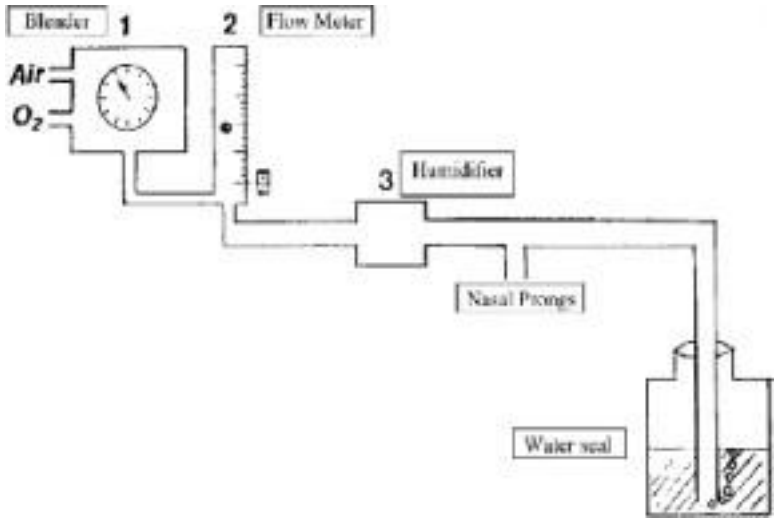
DEVELOPING WORLD AND CPAP

In the developing world, many newborns with higher rates of death and morbidity are excluded from neonatal intensive care because there aren't enough resources to treat them. Pieper et al. conducted a randomised control trial of CPAP for infants with birth weights between 775 and 1160 g in a prospective study from South Africa who were not allowed access to NICU. These babies treated with CPAP had better results than those treated with head box oxygen, which is the conventional therapy.

Although respiratory therapists initially set up the CPAP, nurses who had no prior training with intensive care or CPAP continued to provide the therapy. In these situations, the infants who underwent CPAP had dramatically increased short-term survival (at 24 hours) and showed signs of improving survival[39].

CPAP SYSTEM

The Bubble Continuous Positive Airway Pressure system is the easiest, least expensive nasal CPAP device to set up. 1 requires the equipment shown in *Table*.



equipment for CPAP

10 cm H2O of sterile water is placed into a container with a lid.
column with a graded scale from 0 to 10 cm H2O that can pass through the lid of this container.
O2 sourse, fflow meter with blender, analyzer and oxygen tubing.
Expiratory, Inspiratory circuits.

Heater, humidifier.
Manometer
NP with bonnet.

Place the container below the infant's level and fill it with sterile water to a height of 10 cm H2O. Before being placed in to container through the lid and lowered to the fluid level to the necessary pressure, which is initially 4-6 cm H2O, the column should be connected to the infant's expiratory circuit. A valve and pressure tubing connecting to a calibrated manometer are required for the expiratory circuit. The oxygen supply, flow metre, blender, and analyzer are all connected to the inspiratory circuit via a humidified heater, and the snug-fitting, short, anatomical nasal prongs are shielded by a cap. It is suggested to start with a flow rate of 6L per minute and increase it to create a constant stream of bubbles.

Indications for CPAP

1. newborns experiencing respiratory discomfort.

2. Increased work of breathing manifested by: respiratory rate increase, nasal flare, nasal recession, or grunting.

3. Lung chest x-ray with inadequate expansion or infiltration.

4. Atelectassis

5. Pulmonary hemorrhage.

6. Pulmonary oedema.

7. Recent extubation.

8. Apnea of prematurity.

9. Phrenic nerve palsy.

Contraindications to CPAP

1. Trachro oesophageal fistule

2. Upper airway anomalies (cleft palate, choanal atresia).

3. Severe cardiovascular instability

4. Diaphragmatic hernia.

HHHFNC

HHHFNC is non-invasive respiratory support technique uses a nasal cannula interface to provide conditioned (warm,fully humidified) gas mixtures to patients. The minimum flow rate that defines "high flow" is not a term that is generally acknowledged. Highflow rates of two L/min are considered high in neonates, while flow rates of 4-6 L/min are typically thought of as high in older children. HHHFNC systems have become more widely employed in recent years to help critically ill patients of all ages, from preterm newborns to adults. This is due to their increased popularity over the past ten years.

It is used in the emergency room, paediatric intensive care unit (PICU), medical and surgical intensive care units (ICU), intermediate care units, and neonatal intensive care unit (NICU) (ED). According to a recent randomised controlled trial[40], HFNC may avoid therapy failure in children with bronchiolitis better than conventional low flow oxygen delivery. According to other research, HFNC is comparable to more established non-invasive breathing support techniques like continuous or bi-level positive airway pressure (CPAP or BiPAP).

RATIONALE FOR USING HFNC

Oxygen supplementation, which is typically given by a facemask or a simple nasal cannula, is the basis of treating children with hypoxemia caused by an acute respiratory process. As the oxygen flow rate is increased and less atmospheric air is absorbed during inspiration, the inspired gas's oxygen content increases. Medical gases, including oxygen, are preserved as a dried substance in contrast to atmospheric air, which is rich in vapour.

If humidification is not supplied, prolonged delivery of supplemental oxygen dehydrates and irritates the mucous membranes and impairs mucociliary clearance. A bubble humidifier with sterile water is typically used for this purpose in a hospital setting[41].

The dry medicinal gases are somewhat hydrated by these uncomplicated and inexpensive devices, but for gas fluxes greater than 5 L/m, this humidification is insufficient. When using greater gas flows, the airway mucosa cannot transfer enough heat and humidity on its own at these super physiologic flow rates, thus the gas mixture must be completely saturated with water vapour and heated to a temperature close to body temperature[40].

THE FOUR KEY ASPECTS OF HIGH FLOW THERAPY DELIVERY ARE PREDICATED.

(1) Open system: Gas delivery through a cannula interface that doesn't impede the nostrils is ideal. This is a crucial contrast from pressured nasal breathing techniques like CPAP and BiPAP. As a general rule, the prongs of the nasal cannula shouldn't be more than 50% of the cross-sectional area of each nostril[41]. This ought to give the area around the cannula plenty of room for gas leakage.

(2) Conditioned gas: The gas mixtures administered by HFNC should be adequately heated and humidified to prevent drying out of the respiratory mucosa[41].

(3) High flows: HFNC should deliver higher gas mixture flows than the patient's peak inspiratory flow.

(4) High velocity: By bringing the supply of fresh gas closer to the carina through deep airway entry from high-velocity gas delivery, some respiratory support is given[42].

HHHFNC system - Anatomy

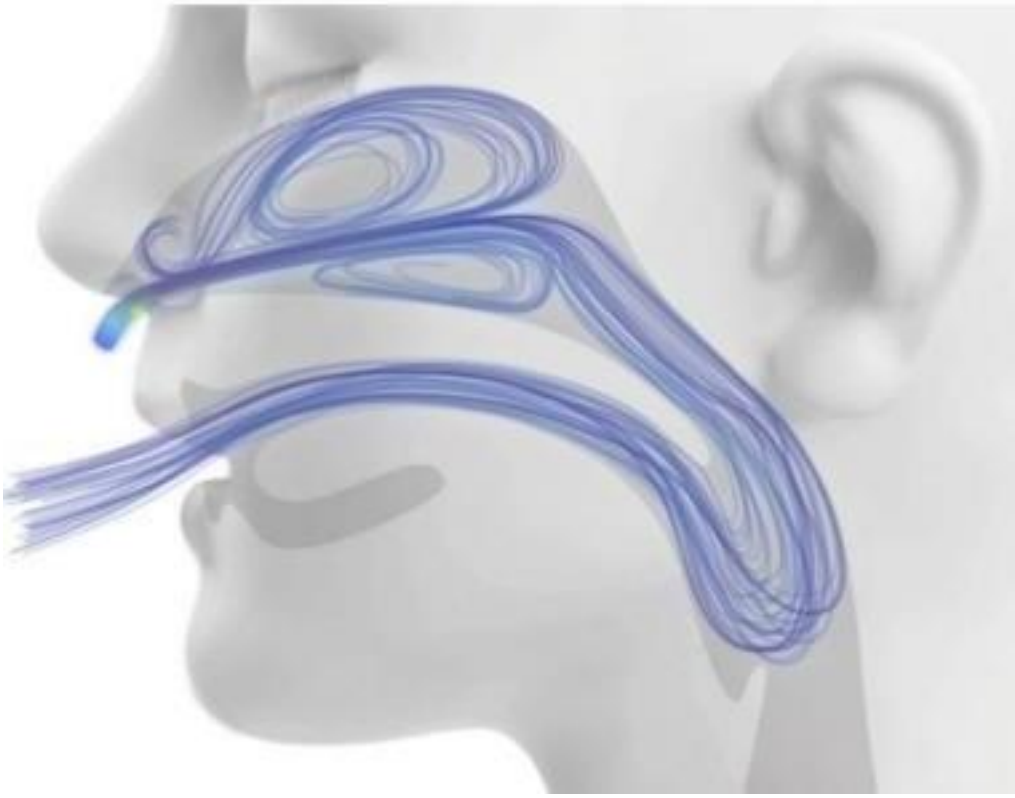
Components of HHHFNC system vary amongst manufacturers of medical equipment, the fundamental setup always consists of the same crucial components.:

(1) a supply of pressured air and oxygen that a flow metre or blender controls;

(2) an effective heater humidifier connected to a reservoir of sterile water;

3) a heated or insulated circuit that controls the conditioned gas's temperature and humidity as it is delivered to the patient; and

(4) non-occlusive cannula interface[43].



Mechanisms of action

Increasing body of research suggests HHHFNC produces advantageous benefits through a variety of pathways, including:

(1) nasopharyngeal anatomical dead space washout,

(2) Decreased inspiratory resistance,

(3) enhanced mucociliary clearance and airway conductance and

(4) decreased metabolic activity associated with gas conditioning,

(5) less level of positive airway pressure[10]

Decreased inspiratory resistance: Parts of the human airway that present the most obstruction are the nostrils and nasal passageways. By simply transferring fresh gas further down the airway and bypassing the area of highest resistance, using a flow that meets or surpasses an individual's inspiratory demand with a properly positioned nasal cannula helps battle that inspiratory resistance and reduces the labour of breathing[44].

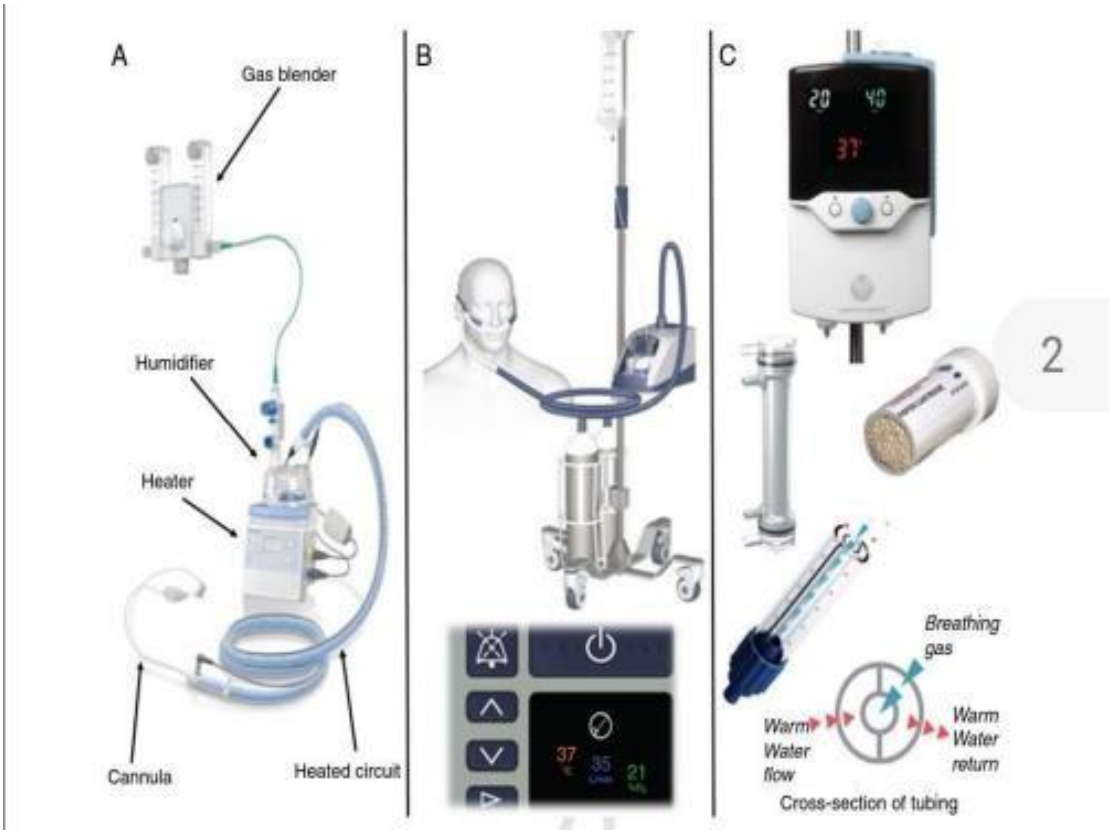


Figure 2: HFNC Unit

Washout of the anatomically dead space in the nasopharynx: End-of-exhalation carbon-dioxide-rich gas is present in the nasopharynx during normal breathing. Due to the fact that gas is then breathed in again during the subsequent respiratory cycle, gas exchange is less effective. Using an HFNC device flushes CO2-rich gas from the nasopharyngeal dead space[40] by rapidly filling the nasal cavity and throat with fresh gas.

Gas conditioning is associated with less metabolic work because it lowers innsensible water losses and the energy needed to heat the inspired gas to body temperature[41]. This is so that the airway can receive properly conditioned gas from HFNC. Improved mucociliary clearance and airway

conductance: According to research, breathing in warm, humidified air can lessen dysnea, the feeling of oropharyngeal dryness, and the drying of respiratory secretions[41].

A limited amount of continous positive airway pressure and low amounts of positive pharyngeal pressure are created by HFNC, which may aid to reduce the dynamic inspiratory airway resistance. Positive airway pressure measurements are site-specific, site-dependent, and inversely correlated with HFNC flow rates. The research supports the idea that, when compared to ordinary nasal cannula, HFNC produces very minor increases in positive end-expiratory pressure; however, the precise amount varies on the HFNC flow and patient size. Independent of the mechanism at work, HFNC has been demonstrated to greatly reduce the effort needed to breathe by attenuating the negative intrathoracic inspiratory pressure as seen by a reduction in esophageal pressure swings and diaphragm electrical activity[41].

When starting HHHFNC therapy, clinician must control three crucial factors: gas temperature, fiO2, and flow rate. To ensure patient comfort, the temperature in this setting is frequently set at 1-2 degrees Celsius below body temperature. Older children and young adults feel uneasy with a slight sense of claustrophobia when the gas temperature is at or above body temperature, such as during breathing in a steam room or on a particularly hot, muggy summer day[43].

If there are no physiologic reasons why using these high doses of supplemental oxygen shouldn't be done, HFNC is often started with a FiiO2 of 0.6 for the hypoxemic patient. Over the next few minutes, FiO2 is swiftly

increased or decreased to obtain the desired oxygen saturation (SPO2), which is normally 92%—-97%10. There are times when patients using HFNC do not receive a gas mixture that has been improved with extra oxygen.

Despite not having hypoxemia, patients with respiratory distress can still benefit from HFNC's effects on respiratory mechanics when breathing conditioned air without additional oxygen[10]. Based on patient size and the estimated level of respiratory support required, the gas flow rate is chosen. In general, patients who are older, bigger, more dyspneic will need higher flows. The ideal HFNC flows are not generally accepted upon.

The flow rate can be increased to 1.5 to 2.0 L/kg/min to further attenuate intrathoracic pressure swings and reduce breathing effort. A flow rate of 0.5 to 1.0 L/kg/min can be employed to provide mild assistance. It's possible that flows higher than 2 L/kg/min are not any more efficient. With this technique, HFNC can be started in a newborn with flows of 4-5 L/min and in an older child with flows of 5-15 L/min.

Materials and Methods

Study setting: Level 3A NICU of BLDEDU'S Shri B.M. Patil Medical College, Hospital & Research Centre, Vijayapura.

Study Population: 108 babies born prematurely and requiring resp. support 54 babies in each group of CPAP and HHFNC.

Study Period: From January 2021 to June 2022

Study Design: Prospective Open label observational study.

Formula for Sample size calculation:

- **Formula used:** $n = \frac{(z_\alpha + z_\beta)^2\ 2\ p*q}{MD^2}$

Where Z= Z statistic at a level of significance

MD= Anticipated difference between two proportions

P=Common Proportion

q= 100-p

Inclusion criteria:

Preterm neonates 30 to 37 weeks of gestation who required respiratory support during first 96 h of life as a primary mode being placed on either HFNC or CPAP .

Exclusion criteria:

1) Antenatally detected life-threatening congenital heart diseases.

2) Babies subsequently discharged against medical advice.(AMA)

Primary Outcomes: 1) Failure of assigned means of respiratory support

2)Death prior to discharge

Secondary Outcomes: Xray abnormality, Neurosonogram findings, Blood culture positivity, Duration of NICU stay, Duration of respiratory support, Nosocomial infection, Air leaks, HSPDA, ROP, NEC, Days to reach Full feeds, Nasal Trauma.

Methods of data collection:

All babies born prematurely and requiring respiratory support, will be placed on one of the respiratory support HFNC OR CPAP by random allocation methodology with consent of parents/attenders. Babies will be admitted in NICU, CPAP OR HFNC modes will be used and standard care of treatment will be given , as per advice of

consultant . Babies would be monitored for improvement or worsening, complications, follow up till discharge or death.

At the end of the study two groups Group 1 and Group 2 for HFNC and CPAP respectively will be compared for maternal factors, Birth weight, Gestational age, Duration of respiratory support, Need for ventilation, Complications, Duration of NICU stay.

Minimum of 108 cases, 54 in each group will be studied to compare safety and efficacy of CPAP OR HFNC. Appropriate statistical method will be used to find p value. Findings would be depicted in tabular form or pie chart.

Statistical Analysis:

- The data obtained will be entered in a Microsoft Excel sheet, and statistical analysis will be performed using statistical package for the social sciences (Verson 20).
- Results would be presented as Mean±SD, counts and percentages and diagrams.
- For normally distributed continuous variables between two groups will be compared using Independent t test For not normally distributed variables Mann Whitney U test would be assessed. Categorical variables between two groups will be assessed using Chi square test.
- .$p<0.05$ will be considered statistically significant. All statistical tests will performed two tailed
- Statistical Analysis
- Categorical data was represented in the form of frequency and percentage.

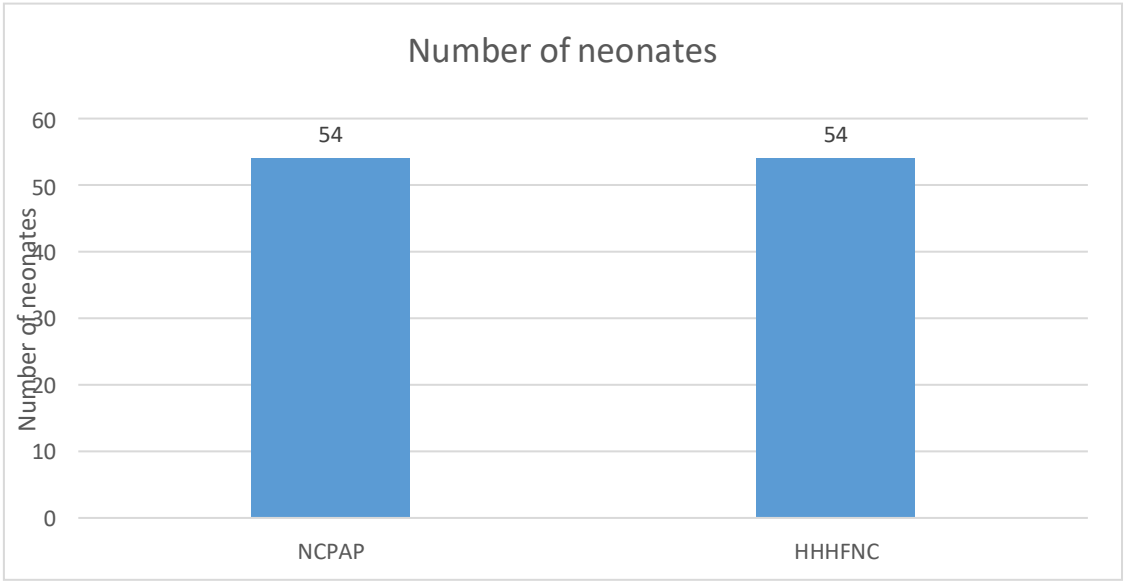
- Association between variables were assessed with Chi Square Test and Fisher's
- Exact test if cell values were small.
- P value of <0.05 was considered statistically significant.
- Data was analyzed with IBM SPSS Version 25 for windows.

RESULTS

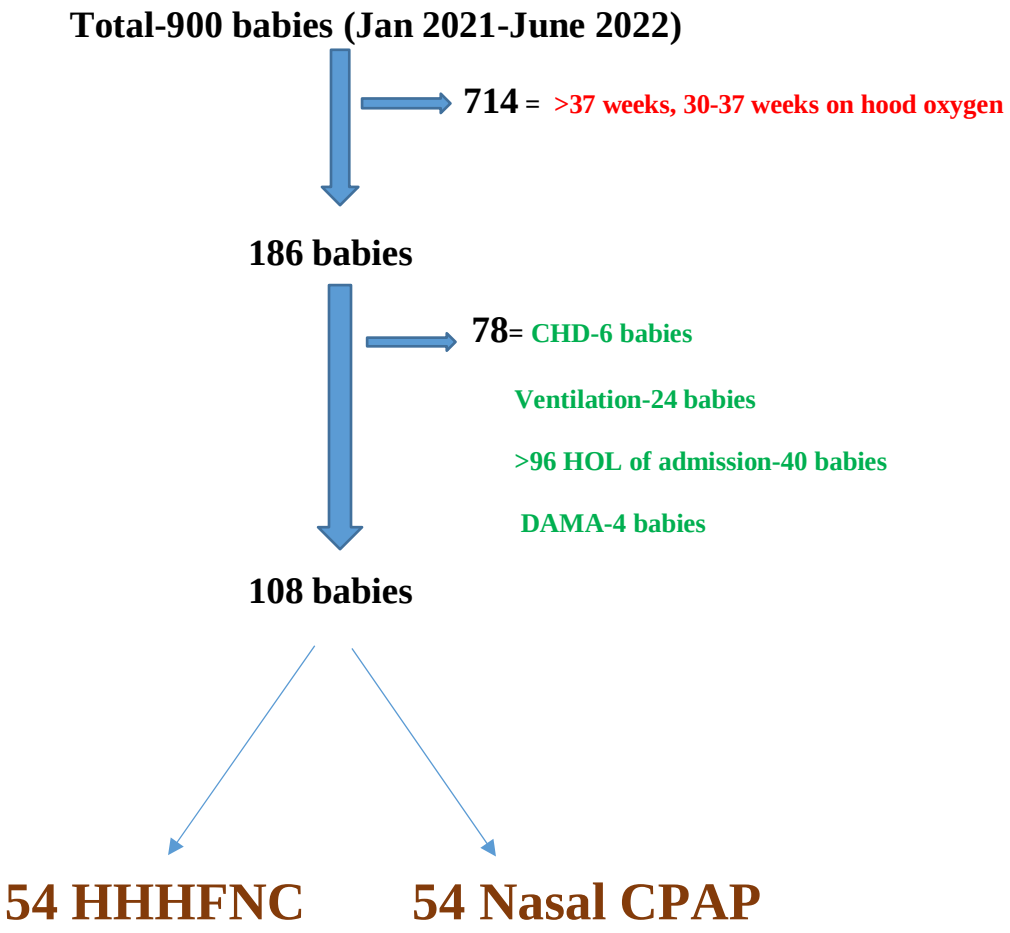
TABLE:1

GROUP	Number of neonates
NCPAP	54
HHHFNC	54

Fig:1: Number of neonates in both groups



Participant flow diagram



Distribution of baseline characterstics of study groups

TABLE 2: Distribution of Gender between Study Groups

Gender	HHHFNC		Nasal CPAP	
	N	%	N	%
Female	21	38.9	26	48.1
Male	33	61.1	28	51.9
Total	54	100.0	54	100.0

In our study groups, 21 female and 33 male babies in HHHFNC and 26 female and 28 male babies in Nasal CPAP.

Fig:2: Distribution of Gender between Study Groups

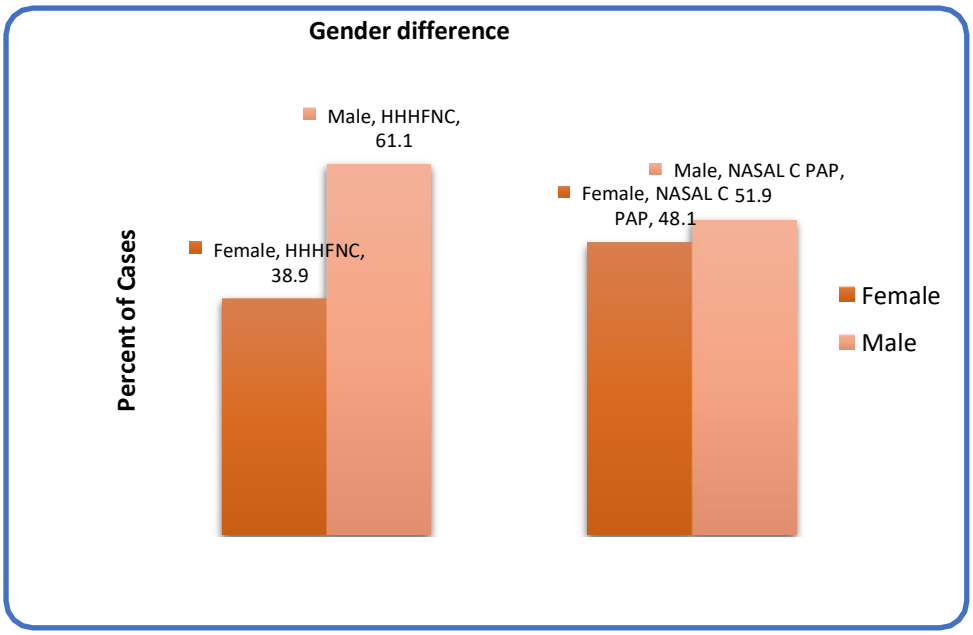


Table 3: Distribution of study population based on primary respiratory support and birth weight

Group	Birth Weight (Mean ±SD)	p value
Nasal CPAP	1768.7±1984.1	0.529
HHHFNC	1945.5±472.4	

*** Unpaired t test- not significant**

In our study, Nasal CPAP babies have Mean birth weight of 1768.7 grams and HHHFNC babies having Mean birth weight of 1945.5 grams which is statistically not significant.

Fig:3: Distribution of study population based on primary respiratory support and birth weight

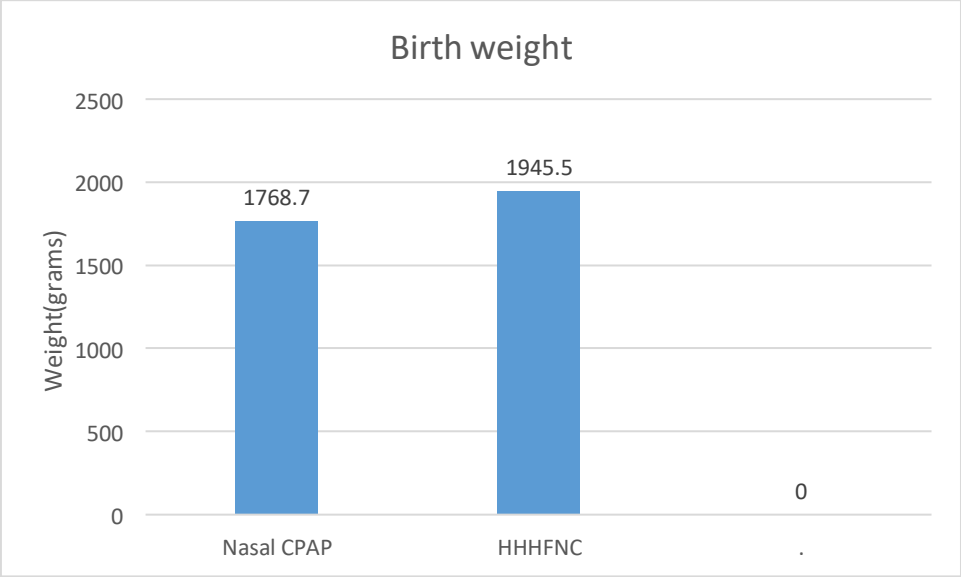


Table 4: Distribution of study population based on primary respiratory support and mean gestational age

Group	Gestational age(Mean ±SD)	p value
Nasal CPAP	33.57±1.8	0.570
HHHFNC	34.21±1.7	

Fig:4: Distribution of study population based on primary respiratory support and mean gestational age

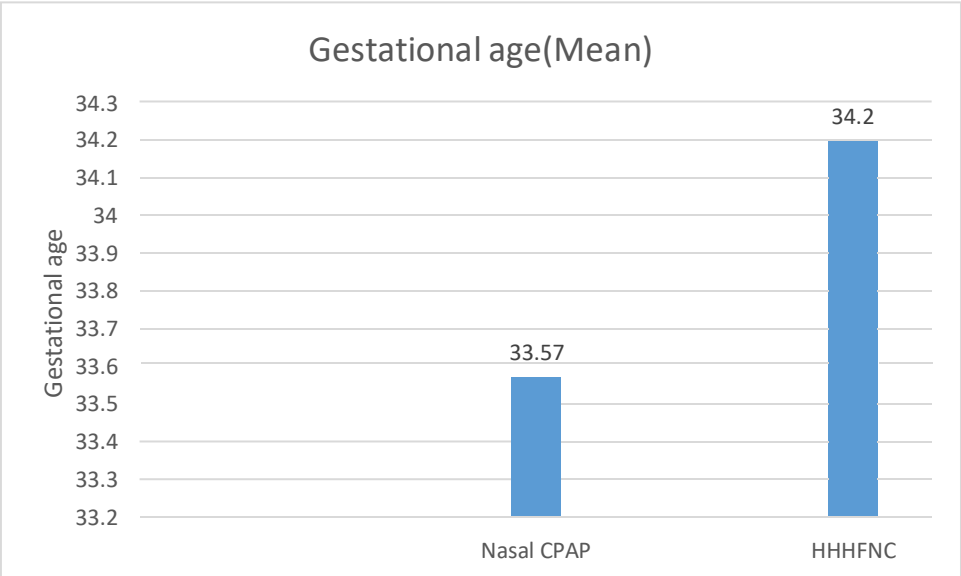


TABLE 5: Distribution of babies as born Inborn Or Outborn.

Delivered at	HHHFNC		Nasal C PAP	
	N	%	N	%
In-born	37	68.6	33	61.1
Out-born	17	31.5	21	38.9
Total	54	100.0	54	100.0

In our study, 37 babies were Inborn and 17 babies were Outborn in HHHFNC Group and 33 babies were In born and 21 babies in Outborn in Nasal CPAP Group.

Fig:5: Distribution of babies as born Inborn Or Outborn.

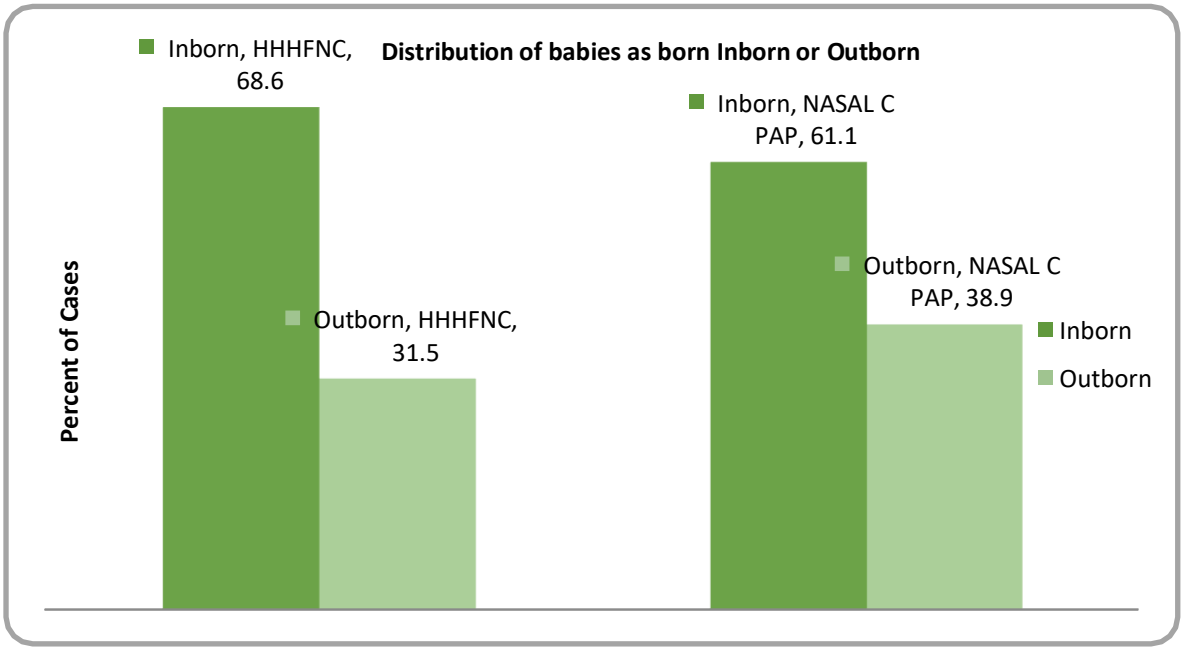


Table 6: Distribution of babies based on Mode of Delivery between study groups.

Mode of Delivery	HHHFNC		Nasal C PAP	
	N	%	N	%
LSCS	40	74.1	35	64.8
VD	14	25.9	19	35.2
Total	54	100.0	54	100.0

In our study, 40 babies born via LSCS and 14 babies born via VD in HHHFNC group.

In Nasal CPAP group 35 babies delivered via LSCS and 19 babies delivered via VD.

Fig:6: Distribution of babies based on Mode of Delivery between study groups.

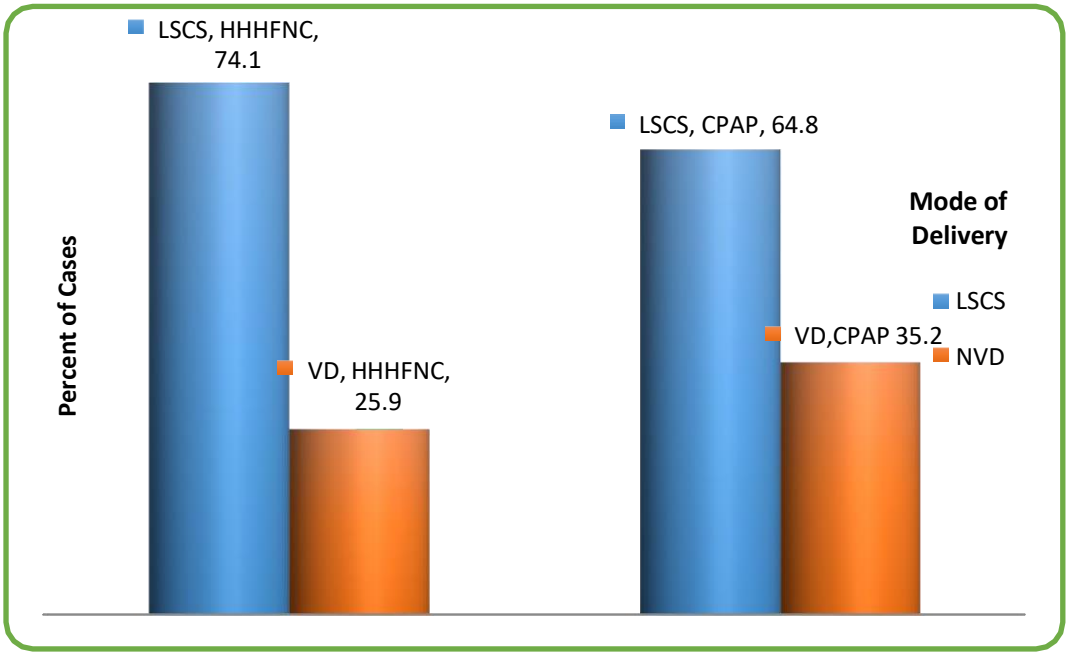


Table 7: Distribution of babies based on Receiving Surfactant.

Received Surfactant?	HHHFNC		Nasal CPAP		Fisher's Exact test	P value
	N	%	N	%		
Yes	0	0	02	3.7	2.038	0.248
No	54	100.0	52	96.3		
Total	54	100.0	54	100.0		

In our study, No babies received surfactant in HHHFNC group and 2 babies received surfactant in Nasal CPAP group which is statistically insignificant.

Fig:7: Distribution of babies based on Receiving Surfactant.

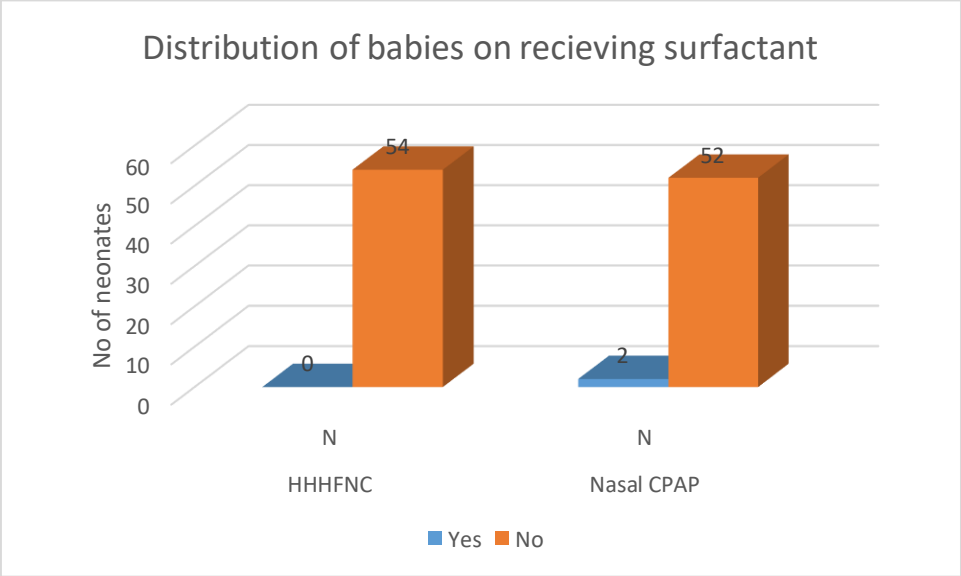
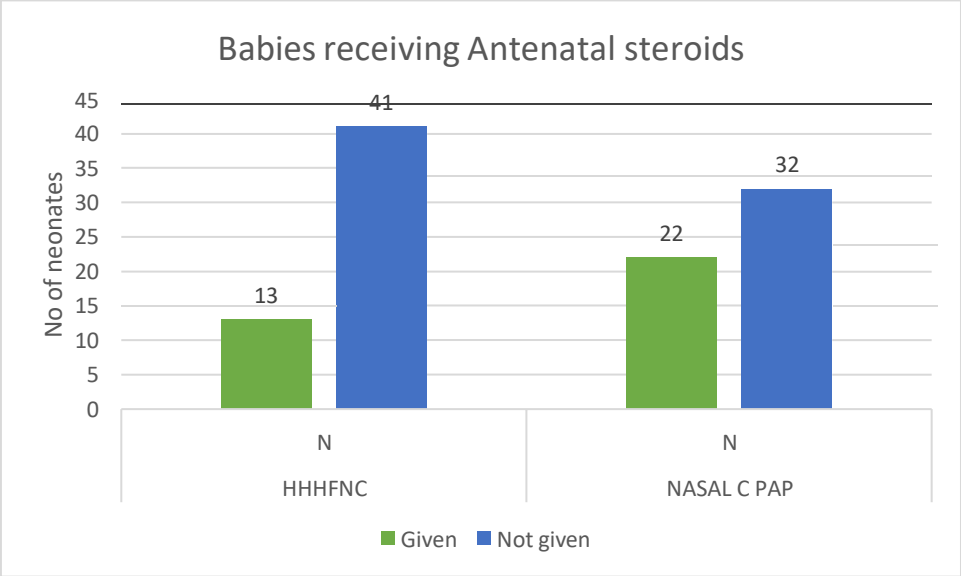


Table 8: Distribution of babies based on receiving Antenatal Steroids

Antenatal Steroids	HHHFNC		Nasal C PAP		Chi square test	P value
	N	%	N	%		
Given	13	24.1	22	40.7	3.424	0.064
Not given	41	75.9	32	59.3		
Total	54	100.0	54	100.0		

In our study 13 babies received Antenatal steroids in HHHFNC Group and 22 babies received in Nasal CPAP Group.

Fig:8: Distribution of babies based on receiving Antenatal Steroids



Primary outcomes

Table 9: Failure of assigned means of respiratory support between study groups

HHHNC	17(31.5)	P value-0.072
Nasal CPAP	09(16.7)	

Failure of assigned mode of respiratory support was seen in 17 babies in HHHFNC Group and 9 in Nasal CPAP Group. This difference was statistically not significant.

Fig:9: Failure of assigned means of respiratory support between study groups

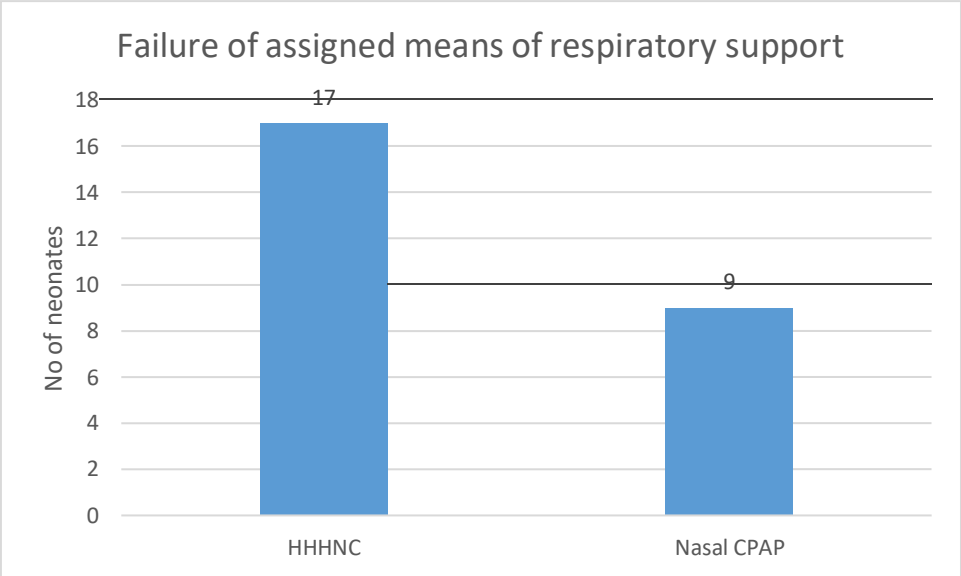


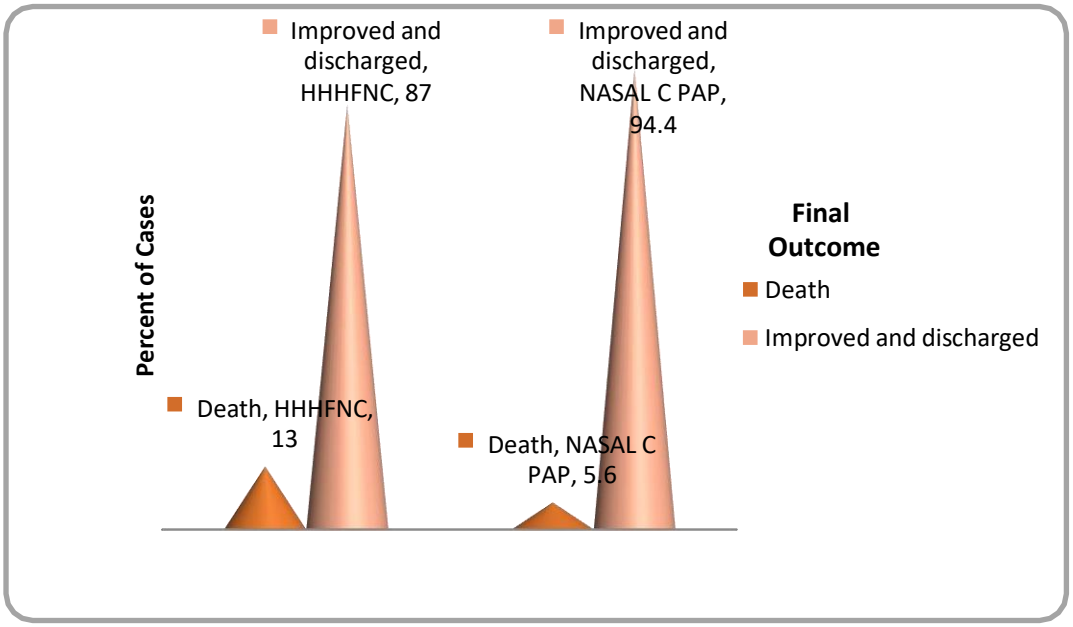
Table 10: Death prior to discharge between study groups

Final Outcome	HHHFNC		Nasal C PAP		Fisher's Exact test	P value
	N	%	N	%		
Death	7	13.0	3	5.6	1.763	0.160
Improved and discharged	47	87.0	51	94.4		
Total	54	100.0	54	100.0		

Death of the baby prior to discharge was seen in seven babies put on HHHFNC and three babies on NCPAP. This difference was statistically not significant.

(Causes of death: Severe RDS, Severe PPHN, HSPDA, HIE 2/3)

Fig:10: Death prior to discharge between study groups



Secondary Outcomes

Table 11: Distribution of babies based on Xray abnormality between study groups

Chest Xray	HHHFNC		Nasal C PAP		Chi square test	P value
	N	%	N	%		
Normal	39	72.3	37	68.5	0.716	0.397
Abnormal*	15	27.7	17	31.5		
Total	54	100.0	54	100.0		

In our study, 15 babies in HHHFNC Group had abnormal Xray findings and 17 babies in Nasal CPAP Group.

*Abnormalities noted: Low volume lungs, Reticulo granular pattern, Ground glass appearance, Sun burst pattern.

Fig:11: Distribution of babies based on Xray abnormality between study groups

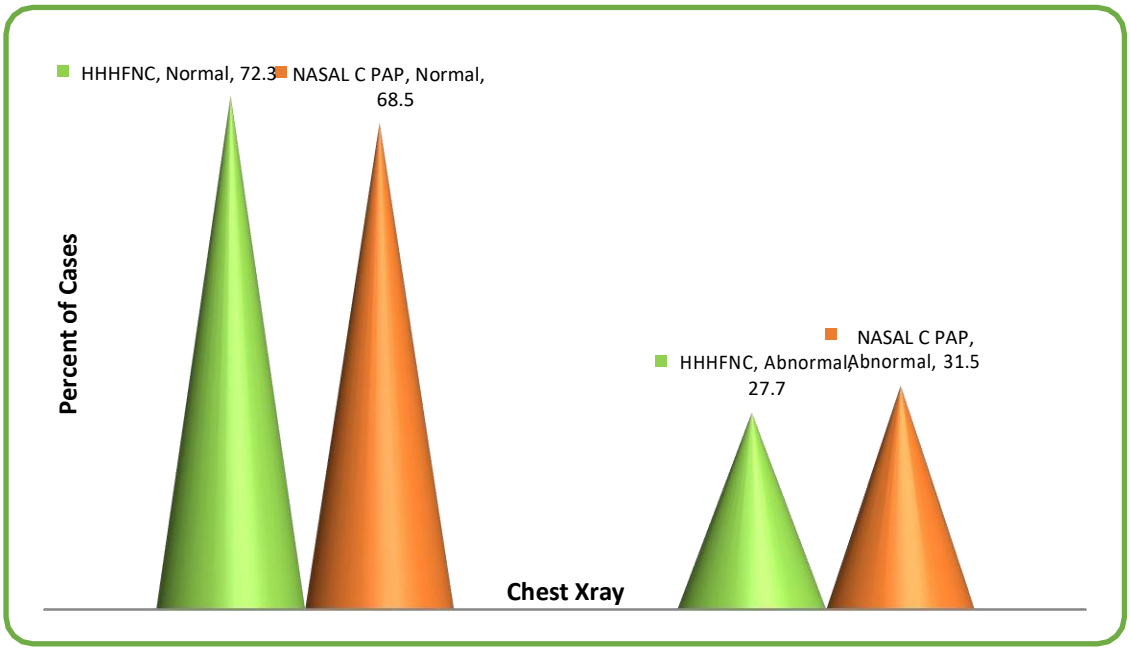


Table 12: Distribution of babies based on Neurosonogram findings between study groups.

NSG	HHHFNC		Nasal C PAP		Chi square test	P value
	N	%	N	%		
IVH	1	1.9	1	1.9	2.041	0.564
Periventricular flair	2	3.8	3	5.7		
Cerebral oedema	1	1.9	1	1.9		
Normal	50	92.6	49	90.5		
Total	54	100.0	54	100.0		

1 baby in each group had Intraventricular hemorrhage, 2 babies had periventricular flair ,and 1 cerebral edema in HHHFNC Group.

50 babies had NSG normal in HHHFNC Group and 49 babies had normal NSG in Nasal CPAP Group.

Fig:12: Distribution of babies based on Neurosonogram findings between studygroups.

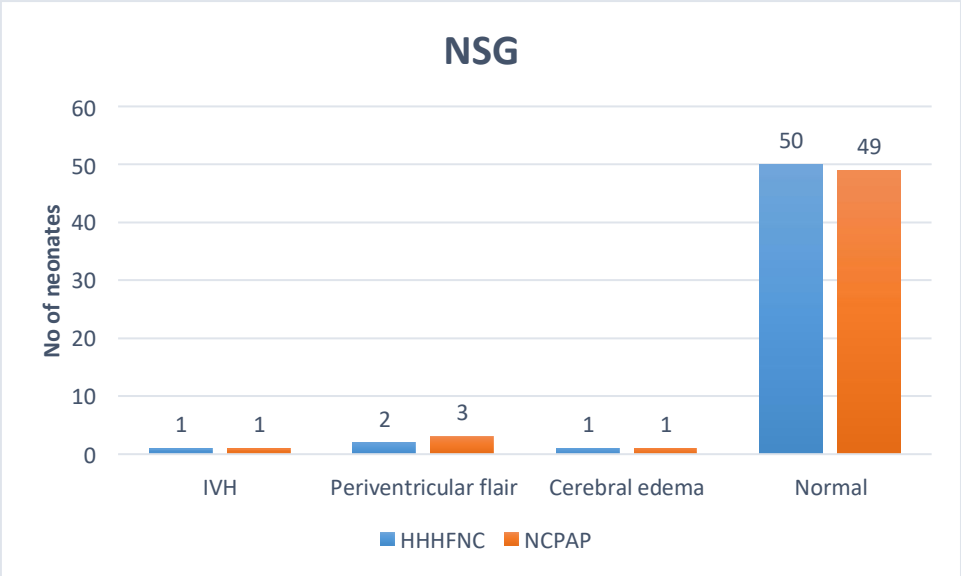


TABLE:13- Distribution of babies based on Blood culture Positivity.

Blood culture	HHHFNC		Nasal CPAP		Fisher's Exact test	P value
	N	%	N	%		
Sterile	48	88.9	52	96.2	3.722	0.062
Positive	06 *	11.1	02*	3.8		
Total	54	100.0	541	100.0		

In our study, 6 babies among HHHFNC group had Culture growth present and 2 babies in Nasal CPAP Group. The difference is statistically insignificant.

02* MRSA, Pseudomonas aeruginosa,

06* CONS, Citrobacter species, Klebsiella pneumonia-2, MRSA-2.

Fig:13: Distribution of babies based on Blood culture growth

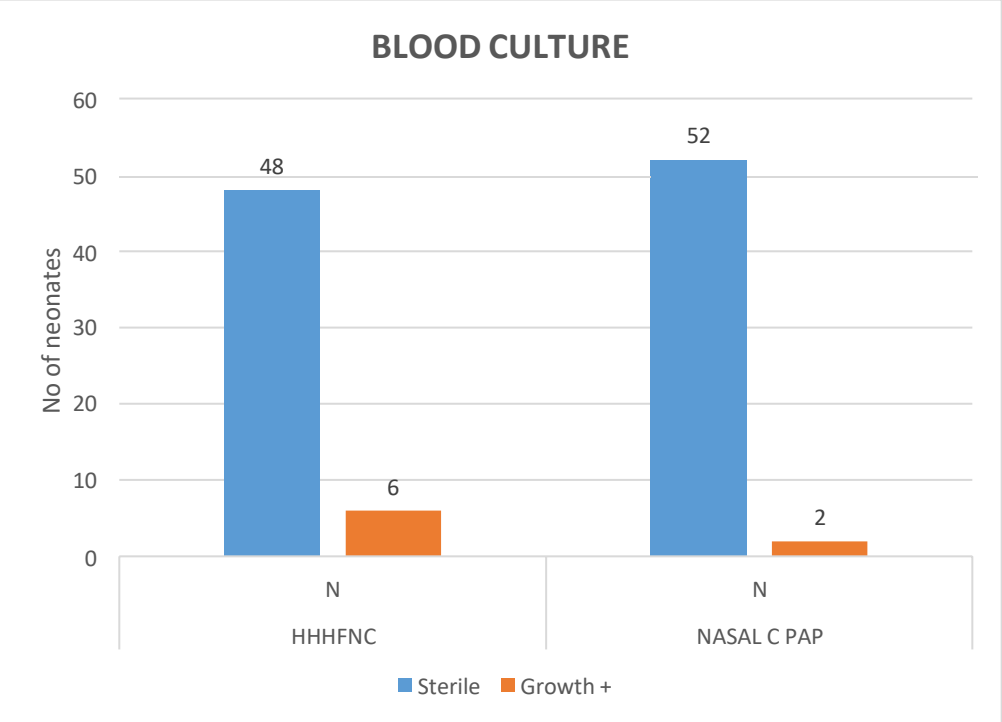


Table 14: Distribution of study population based on primary respiratory support and Duration of stay in NICU(in days)

Duration of stay in NICU(in days)	Nasal CPAP **No. (%)**	HHHFNC	**p value**
2-12 days	37(64.8)	42(31.5)	0.168
13-30 days	17(35.2)	12(68.5)	

*Chi square- not significant

Duration of NICU stay between two study groups is not statistically significant.

Fig:14: Distribution of study population based on primary respiratory support and Duration of stay in NICU(in days)

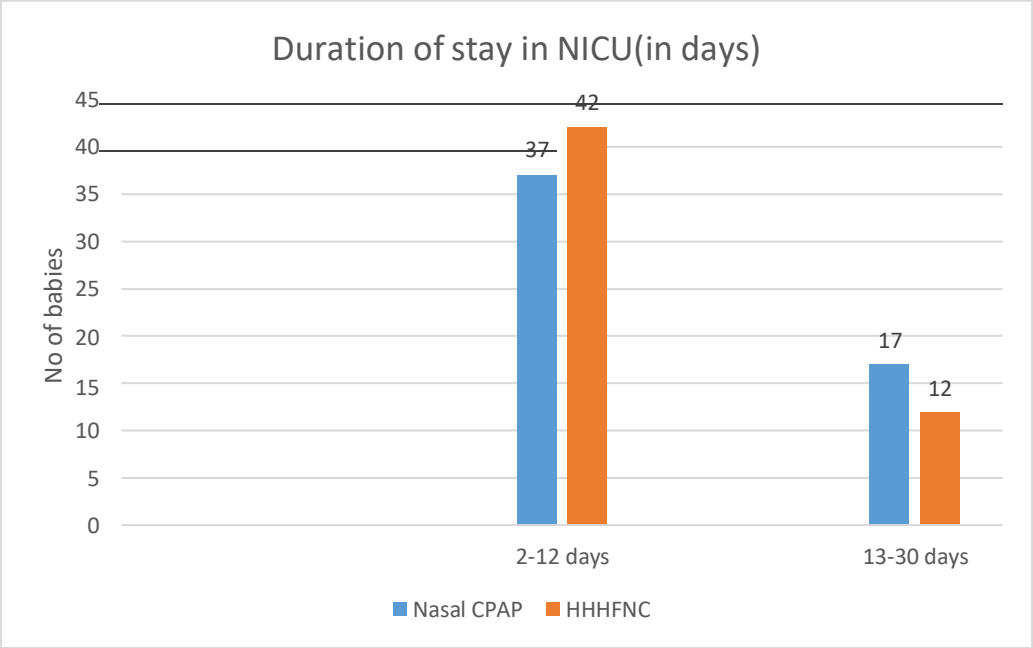


Table 15: Distribution of study population based on primary respiratory support and Mean duration of respiratory support (In days)

Mean Duration of respiratory support (in days)	Nasal CPAP	HHHFNC	**p value**
2-10 days	41(75.9)	45(83.3)	0.082
10-30 days	13(24.1)	9(16.7)	

Chi square- not significant

Duration of respiratory support between two study groups is not statistically significant.

Fig:15: Distribution of study population based on primary respiratory support and Mean duration of respiratory support (in days).

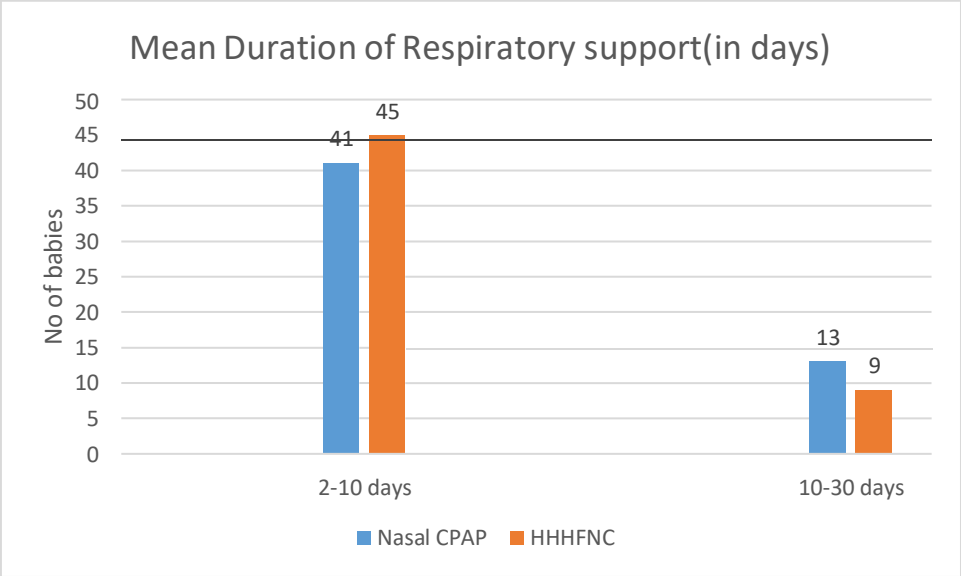
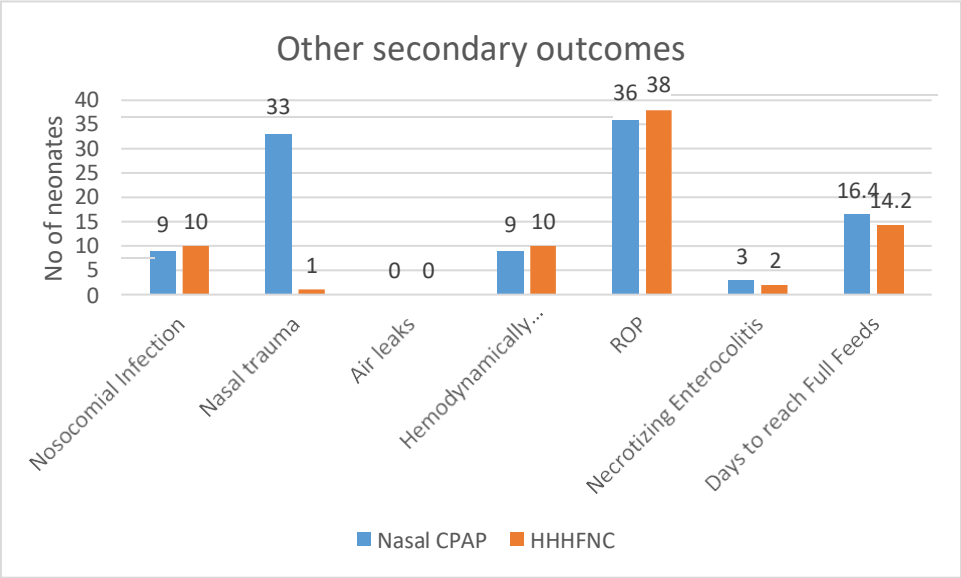


Table:16: Other Secondary Outcomes

	Nasal CPAP	HHHFNC	**p value**
Nosocomial Infection	9(47.4)	10(52.6)	0.536
Nasal trauma	33(97.1)	1(2.9)	0.01*
Air leaks	00	00	-
Hemodynamically significant patent ductus arteriosus	9(47.4)	10(52.6)	0.536
ROP	36(68.1)	38(72.2)	0.92
Necrotizing Enterocolitis	3(60)	2(40)	0.482
Days to reach Full Feeds	16.4	14.2	0.047*

In our study, there was no significant differences in secondary outcomes including Nosocomial infection, Air leaks, Hemodynamically significant PDA, NEC. Outcomes such as Nasal trauma and days to reach full feeds show statistically significant difference between HHHFNC and Nasal CPAP groups.

Fig:16: Other Secondary Outcomes



DISCUSSION

In NICUs all around the world, the usage of HHHFNC has significantly increased in recent years. This is mostly attributable to the simplicity of use and improved patient tolerance. Additionally, compared to NCPAP, it has benefits including minimal nasal trauma and less disruption of feeding or kangaroo mother care. Despite its widespread clinical acceptability, there is scant information about its effectiveness and safety as a primary support in preterm newborns. Some neonatologists believe that the clinical outcomes related to the use of HHHFNC are at least comparable to those of NCPAP use

In comparison to current practice, earlier randomized controlled trials (RCTs) conducted between 2006 and 2010 (comparing NCPAP with HHHFNC or various high-flow devices) had very small study populations and low flow rates.[45,46,47]

In 2013, the publication of three large RCTs added to the evidence for the use of HHHFNC.

The first by Demirel et al[48] included 107 neonates <32 weeks of gestation, who were randomized to either HHHFNC or NCPAP as primary mode of respiratory support. There was no difference in primary outcome i.e treatment failure in between the two groups. Regarding the secondary outcomes, there was no distinction between the groups.

The second RCT by Yoder et al. [49] trial involved 432 newborns with intended nCPAP support as either primary therapy or postextubation, with gestational ages ranging from 28 to 42 weeks. The main result, which was the requirement for intubation after 72

hours of the application of noninvasive treatment, did not differ substantially between the two groups (32/212 [15.1%] in HHHFNC versus 25/220 [11.4%] in NCPAP; P =.252).

There were no changes in the primary outcomes of death between HHHFNC and CPAP when used as primary respiratory support after birth, according to Wilkinson et al. [50] (4 trials, 439 newborns). The mean risk ratio (RR) was 0.36, with a 95% confidence interval (CI) of 0.01 to 8.73. The length of respiratory support was prolonged when HFNC was used, but there were no differences in the other secondary outcomes.

Our study was done at a Level 3A NICU of Shri B.M. Patil Medical College, Hospital & Research Centre, Vijaypura. A total of 108 neonates between 30-37 weeks of gestation were included in the study. Babies were placed on either HHHFNC or NCPAP as a primary mode of respiratory support. Fifty-four babies were placed on HHHFNC, while 54 babies received NCPAP. The primary characteristics were similar in both the study groups. The primary outcomes of the study were failure of assigned mode of respiratory support and death of a neonate prior to discharge.

Failure of the assigned means of respiratory support was seen in seventeen babies in the HHHFNC group and nine babies in the NCPAP group. This difference was statistically not significant. Similar results were obtained in the study by Yoder et al and Demirel et al.

Death of the neonate prior to discharge was seen in seven babies from the HHHFNC group and three babies in the NCPAP group. This difference was statistically not significant.

Secondary outcomes of the study were ROP, NEC, Neurosonogram findings, nasal trauma, nosocomial infection, air leaks, Chest Xray findings, Blood culture report, Hemodynamically significant PDA, Duration of NICU stay, Duration of respiratory support and Days to reach fullfeeds.

Most of the parameters showed no statistically significant difference between the HHHFNC and NCPAP groups except nasal trauma which were more in the NCPAP group.

The duration of respiratory support, duration of NICU stay and Air leaks were comparable between the two groups in our study. These findings were similar to the observations by Demirel et al.

The incidence of nasal trauma was more in the NCPAP group as compared to the HHHFNC group, and this difference was statistically significant in our study. Similar results were obtained in the study by Wilkinson et al.

The number of days on respiratory support and duration of NICU stay were comparable between the NCPAP and HHHFNC groups. These findings were similar to those in the study by Demirel et al. However, in our study, the duration required to reach full feeds was longer in the NCPAP group as compared to the HHHFNC group, with the difference being statistically significant.

At 5% level of significance, HHHFNC was found to be noninferior compared to NCPAP with 14.8% difference in the rates of failure of assigned mode of respiratory support. In fact, it had added advantages such as minimal nasal trauma and lesser

number of days required to reach full feeds.

Although this study is limited by smaller sample size, the data presented here indicate that HHFNC is better tolerated and an effective alternative respiratory support mode to NCPAP in the preterm newborn population.

Out comes of our study.

1) At 5% level of significance, HHHFNC was found to be noninferior compared to NCPAP.

2) 14.8% difference in the rates of failure of assigned mode of respiratory support.

3) There was no statistically significant difference in the primary outcome(Failure of assigned means of respiratory support, Death prior to discharge) and secondary outcomes(X-ray abnormality, Neurosonogram findings, Nosocomial infection, HSPDA, Blood culture positivity, Duration of NICU stay , Duration of Respiratory support, Air leak, ROP,NEC).

4) It was observed that babies on HHHFNC had lesser incidence of nasal trauma and lesser number of days required to reach full feeds.

CONCLUSION

HHHFNC is Not inferior compared to NCPAP as a primary mode of respiratory support. HHHFNC can be considered to be a safe, efficacious, and more easily acceptable mode of respiratory support as compared to NCPAP in preterm neonates as a primary mode of respiratory support.

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IEC/NO-09/2021
Date- 22/01/2021

B.L.D.E. (DEEMED TO BE UNIVERSITY)
(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)
The Constituent College
SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Institutional ethical committee of this college met on 11-01-2021 at 11-00 am to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: Heated humidified high flow nasal cannula versus nasal continuous positive pressure as a primary mode for respiratory support of newborns in gestational age group of 30-37 weeks – Prospective observational study

Name of PG student: Dr G D Harshitha, Department of Paediatrics

Name of Guide/Co-investigator: Dr R H Gobbur, Professor of Paediatrics

DR .S.V.PATIL
CHAIRMAN, IEC
Institutional Ethical Committee
B L D E (Deemed to be University)
Shri B.M. Patil Medical College,
VIJAYAPUR-586103 (Karnataka)

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.

7

RESEARCH INFORMED CONSENT FORM

BLDEA's Shri B.M.PATIL Medical College, Hospital & Research Centre,

Vijayapura, Karnataka -586103.

TITLE OF THE PROJECT : "HEATED HUMIDIFIED HIGH FLOW NASAL CANNULA VERSUS NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE AS A PRIMARY MODE FOR RESPIRATORY SUPPORT OF NEWBORNS IN GESTATIONAL AGE GROUP OF 30-37 WEEKS- A NON INFERIORITY TRIAL"

GUIDE : DR. R. H. GOBBUR, MD

PROFESSOR,

DEPARTMENT OF PEDIATRICS

PG STUDENT : DR G D HARSHITHA

- I HAVE BEEN EXPLAINED ABOUT THE RESEARCH IN LOCAL LANGUAGE.

PURPOSE OF RESEARCH: To assess the efficacy and safety of HFNC as compared to CPAP in providing respiratory support in 30 to 37 weeks period of gestation as primary mode.

PROCEDURE: I understand that after having obtained a detailed clinical history,thorough clinical examination and relevant investigations, a final work up of the procedure and its outcome is planned

RISK AND DISCOMFORTS:

I understand that I may experience some pain and discomforts during the examination or during my treatment. This is mainly the result of my condition and the procedures of this study are not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS:

I understand that my participation in the study will have no direct benefit to me other than the potential benefit of the treatment.

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of hospital records and will be subject to the confidentiality. Information of sensitive personal nature will not be part of the medical record, but will be stored in the investigations research file. If the data are used for publication in the medical literature or for teaching purpose, no name will be used and other identifiers such as photographs will be used only with special written permission. I understand that I may see the photograph before giving the permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time; Dr. G D HARSHITHA, at the department of pediatrics is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice. I also understand that Dr. G D HARSHITHA may terminate my participation in the study after he/she has explained the reasons for doing so.

INJURY STATEMENT:

I understand that in the unlikely event of injury to my child resulting directly from child's participation in this study, if such injury were reported promptly, the appropriate treatment would be available to the child. But, no further compensation would be provided by the

hospital. I understand that by my agreements to participate in this study and not waiving any of my legal rights.

I have explained to_____the purpose of the research, the procedures required and the possible risks to the best of my ability.

DR G D HARSHITHA Date

(Investigator)

PARENTS / GUARDIAN CONSENT STATEMENT:

We confirm that Dr G D HARSHITHA is doing a study on "HEATED HUMIDIFIED HIGH FLOW NASAL CANNULA VERSUS NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE AS A PRIMARY MODE FOR RESPIRATORY SUPPORT OF NEWBORNS IN GESTATIONAL AGE GROUP OF 30-37 WEEKS- PROSPECTIVE OBSERVATIONAL STUDY"

admitted In NICU In Shri B. M. Patil Medical College Hospital, Vijayapura, Karnataka. Dr. G D HARSHITHA has explained to us the purpose of research and the study procedure. We are willing to allow our child to get treated in Shri B.M. Patil Medical College Hospital, Vijayapura. We have been explained about the study, benefits and possible discomforts in detail in our native language and we understand the same. We are aware that child will get best treatment, and no compensation like financial benefits will be given if our child's condition deteriorates and any untoward complication happens, and we will not sue anyone regarding this. Therefore we agree to give our full consent for child's participation as a subject in this research project.

_____

(Parents / Guardian) (Witness to signature)

Date Date

PROFORMA

BABY OF :

SEX : Male/Female

IP NO :

ADDRESS :

DATE OF BIRTH :

DATE OF ADMISSION :

DATE OF DISCHARGE :

DATE OF DEATH :

GESTATIONAL AGE : Preterm-

PARITY:

GRBS AT TIME OF ADMISSION :

SpO_2 AT TIME OF ADMISSION : Preductal- ,Postductal-

MATERNAL HISTORY :

AGE : OBSTETRIC SCORE :

CONSANGUINITY :

LMP : EDD :

MOTHER'S BLOOD GROUP :

H/O ANY RISK FACTORS :
Anemia/PIH/Hyperthroidism/Hypothyroidism/Epilepsy/
Asthama/GDM/Heart disease/Any other

ANTENATAL STEROID:

BIRTH ORDER :

WEIGHT ON NICU ADMISSION:

DELIVERED AT : INBORN / OUTBORN :

IF OUTBORN SPECIFY PLACE :

DATE & TIME OF DELIVERY :

MODE OF DELIVERY :

BIRTH WEIGHT :

APGAR SCORE AT 1 MINUTE:

APGAR SCORE AFTER 5 MINUTES :

ANY RESUSCITATIVE MEASURES TAKEN UP :

DURATION OF NICU STAY :

HOURS OF LIFE AT NICU ADMISSION :

TYPE OF PRIMARY RESPIRATORY SUPPORT USED: HHHFNC / NASAL CPAP

DURATION OF RESPIRATORY SUPPORT:

NEED FOR VENTILATION: 1)Indications:

2)Hours of life:

3)Type of ventilation:

RECEIVED SURFACTANT: Yes/No Indication:

COMPLIACTIONS DUE TO CPAP/HFNC:

Treatment failure-	Yes	No
Death of neonate prior to discharge-	Yes	No
Retinopathy of prematurity-	Yes	No
Intraventricular haemorrhage-	Yes	No
Nosocomial sepsis-	Yes	No
NEC-	Yes	No
Nasal trauma (erythema or erosion of nasal septum)-	Yes	No

Air leak syndromes (pneumothorax, pneumomediastinum)- Yes No

Hemodynamically Significant Patent ductus arteriosus- Yes No

SEQUENCE AND DURATION OF RESPIRATORY SUPPORT-

DURATION OF SUPPLEMENTORY OXYGEN-

DURATION OF HOSPITALISATION-

INVESTIGATIONS-a) Blood-Hb

TC

DC

Platlet count

Immature to total neutrophil ratio(I/T)

b) CRP

c) USG CHEST USG ABDOMEN CRANIAL USG

d) XRAY CHEST PA

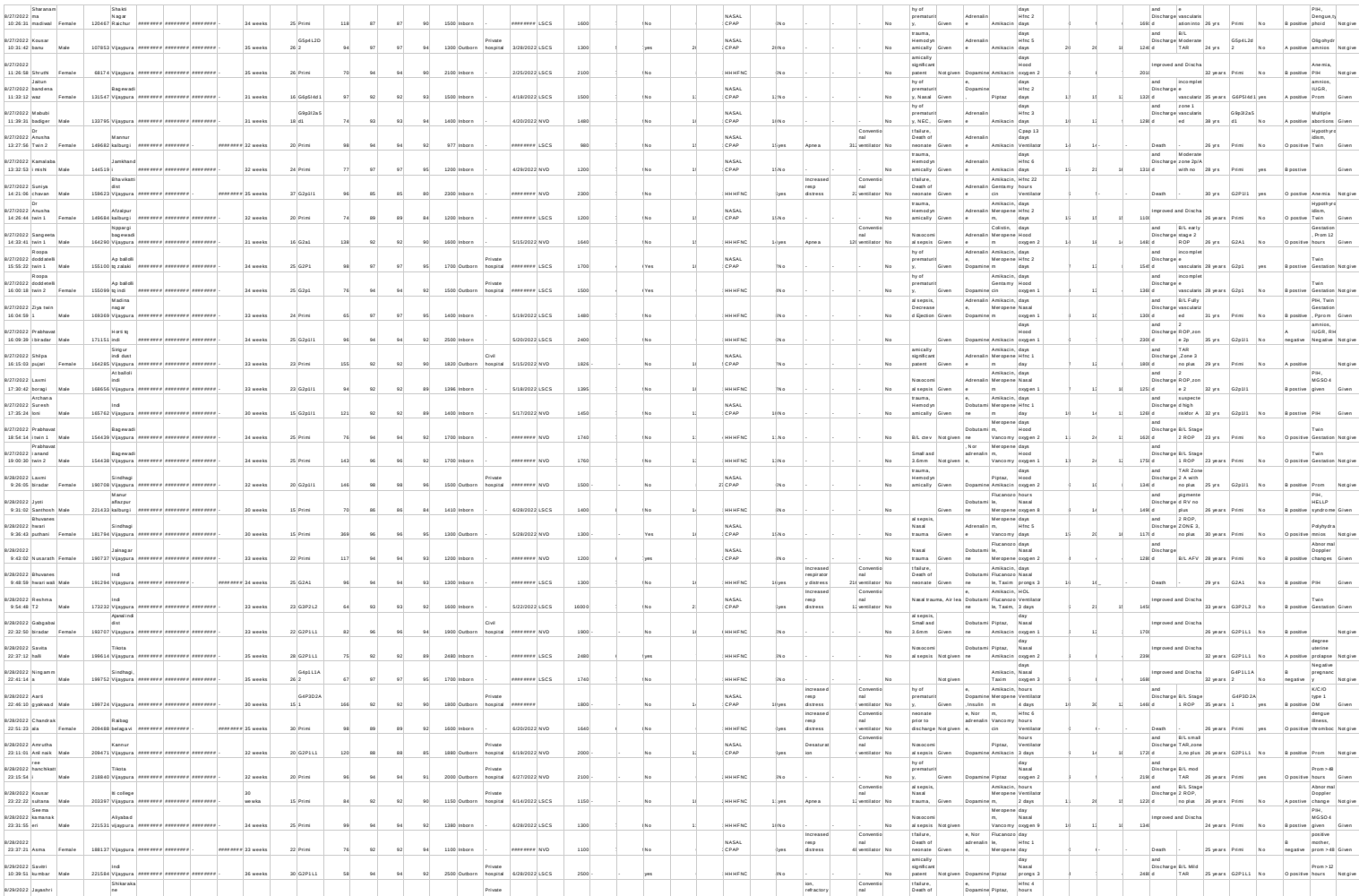
e) BLOOD CULTURE

f) ROP SCREENING

NUMBER OF DAYS TO ATTAIN FULL FEEDS(120ml/kg/day)-

WEIGHT GAIN PRIOR TO DISCHARGE FROM NICU:

FINAL OUTCOME- a)Improved and Discharged b)Referred c)DAMA d)Death



8/30/2022 0:12:50	Vanita naiktwin 1	Female	234381	Baratagi Vijaypura	########	########	########	-	35 weeks	26	Primib	96	98	98	94	1800	Outborn	Private hospital	########	LSCS	1809	-	-	No	4	1	HHHFNC	4	No	-	-	-	No	al sepsis, Hemodyn amically	Not given	Dobutamine	Piptaz, Amikacin	day Nasal oxygen 3	4	4	3	1760	and Discharged	B/L Mild TAR	26 years	Primi	No	B positive	Twi Ge
8/30/2022 0:18:44	Sangita pujari	Male	235673	Sindhagi Vijaypura	########	########	########	-	36 weeks	30	G3p2a1d 1	129	98	98	95	2300	Outborn	Private hospital	########	LSCS	2340	-	-	No	10	1	NASAL CPAP	5	yes	Increased resp distress	5	Conventional ventilator	No	cular haemorrhage,	Not given	e, Dopamine ,	Piptaz, Amikacin	hours Ventilator 2 days	5	13	8	2080	and Discharged	B/L Mild TAR,zone 3,no plus	34 years	G3p2a1d 1	No	A positive	Cer inc enc
8/30/2022 1:02:50	Bhagyalaxmi kallurmath	Male	234386	Indi Vijaypura	########	########	########	-	37 weeks	32	G3P2L2	90	92	92	90	2800	Outborn	Private hospital	########	LSCS	2800	-	-	No	4	3	HHHFNC	2	No	-	-	-	No	amically significant patent	Not given	Dopamine	Piptaz, Amikacin	Hfnc 2 days Room air	2	4	2	1100	and Discharged	Normal fundus	30 years	G3p2l2	No	B positive	
8/30/2022 20:45:12	a devanganamath	Female	235598	Hippargi Vijaypura	########	########	########	-	33 weeks	22	G2P1L1	149	94	94	92	1250	Outborn	Private hospital	########	LSCS	1250	-	-	No	5	2	NASAL CPAP	4	No	-	-	-	No		Given	Dopamine	Piptaz	days Hood oxygen 1	4	5	4	1190	Improved and Discha		28 years	G2P1L1	yes	A positive	PIH
8/30/2022 20:55:00	Mallamma dalwai twin 1	Female	237002	Bagewadi Vijaypura	########	########	########	-	35 weeks	26	G3p2L1D 1	70	92	92	90	2200	Inborn	-	########	LSCS	2200	8	9	No	10	2	HHHFNC	7	No	-	-	-	No	amically significant patent	Not given	Dobutamine	Amikacin, Taxim	days Nasal oxygen 2	7	10	9	2100	Improved and Discha		34 years	G3p2l1d1	yes	A positive	Ge , Ank
8/30/2022 21:00:52	Mallamma Dalwai twin 2	Female	237001	Bagewadi Vijaypura	########	########	########	-	35 weeks	26	G3P2L1D 1	60	96	96	94	2100	Inborn	-	########	LSCS	2100	5	9	yes	10	2	HHHFNC	9	No	-	-	-	No	ssia with cleft palate	Not given	Dobutamine	Amikacin, Taxim	days Nasal oxygen 2	9	10	8	1990	Improved and Discha		34 years	G3p2l1d1	No	A positive	PIH Ge
8/30/2022 21:09:14	Shilpa pawar twin 2	Female	244619	Indi Vijaypura	########	########	########	-	35 weeks	26	Primi	108	96	96	94	1600	Outborn	Private hospital	7/16/2022	LSCS	1600	-	-	No	10	1	HHHFNC	8	No	-	-	-	No	al sepsis, Hemodyn amically	Given	, Nor adrenaline,	Amikacin, Meropenem	days Hood oxygen 3	8	12	10	1590	and Discharged	2 ROP,zone 2A,no	26 years	Primi	No	B positive	Twi Ge ,Pr
8/30/2022 21:13:37	Shilpa pawar twin 1	Female	244613	Indi Vijaypura	########	########	########	-	35 weeks	26	Primi	98	96	96	94	1500	Outborn	Private hospital	7/16/2022	LSCS	1500	-	-	No	10	1	NASAL CPAP	8	No	-	-	-	No	amically significant patent	Given	Dopamine	Piptaz, Amikacin	days Hood oxygen 4	8	12	8	1480	and Discharged	2 ROP,zone 2A,no	26 years	Primi	No	B positive	Twi Ge
8/30/2022 22:56:34	Tasleem agani	Female	245942	Surpur Vijaypura	########	########	########	-	34 weeks	25	G3p3a0l2	66	90	90	88	1700	Outborn	Private hospital	7/16/2022	LSCS	1700	8	9	No	13	1	HHHFNC	4	yes	Increased resp distress	8	Conventional ventilator	No	amically significant patent	Given	Adrenaline, Dopamine	Piptaz	hours Ventilator 2 days	4	16	10	1600	and Discharged	Moderate Zone 2A, no	31 years	G3p3L2	yes	A positive	Pol mni
8/30/2022 23:58:16	Malasbai bhise	Male	249483	Arakeri Vijaypura	########	########	########	-	36 weeks	30	G3p2L2	48	89	89	85	1910	Outborn	Private hospital	7/19/2022	LSCS	1900	-	-	No	5	2	NASAL CPAP	3	No	-	-	-	No		Not given		Piptaz, Amikacin	days Hood oxygen 1	3	5	3	1880	and Discharged	B/L Normal fundus	32 years	G3P2L2	yes	B positive	
8/31/2022 0:05:54	Akshata kamble	Female	244870	Aliyabad Vijaypura	########	########	########	-	33 weeks	22	G2P1L1	83	91	91	89	1400	Outborn	Private hospital	########	NVD	1500	7	9	No	10	144	HHHFNC	8	yes	Apnea	162	Conventional ventilator	No	cular haemorrhage,	Given	, Nor adrenaline	Amikacin, Meropenem	hours Ventilator 3 days	8	12	9	1890	and Discharged	TAR Zone 1 with looping	30 yearsv	G2P1L1	No	A positive	
8/31/2022 1:39:18	Arati sarawad	Female	246650	Bableshwar dist Vijaypura	########	########	########	-	33 weeks	22	Primi	69	90	90	85	1690	Inborn	-	7/17/2022	LSCS	1600	6	6	yes	13	1	HHHFNC	10	yes	Increased resp distress	4	Conventional ventilator	No		Not given	e, Dobutamine	Amikacin, Taxim	hours Ventilator 3 days	10	13	8	1560	and Discharged	B/L Mild TAR	26 yearsv	Primi	yes	O negative	Neg pre y, F
8/31/2022 18:56:07	Savitri kumbar	Male	252264	Nagatan vijaypura	########	########	########	-	36 weeks	30	G2A1	62	98	98	96	2700	Inborn	-	7/21/2022	NVD	2700	7	9	No	4	1	HHHFNC	2	No	No	-	-	No		Not given	Dobutamine	Amikacin, Taxim	day Nasal oxygen 1	2	4	3	2680	and Discharged	Normal fundus	26 years	G2A1	No	Ab negative	idis Neg pre
8/31/2022 19:05:38	Renuka biradar	Male	255578	Tikota Vijaypura	########	########	########	-	36 weeks	30	Primi	87	89	89	85	2400	Outborn	Private hospital	7/23/2022	LSCS	2400	-	-	No	9	20	HHHFNC	7	yes	Increased resp distress	26	Conventional ventilator	No	al sepsis, Severe PAH,	Not given	e, Dopamine , Nor	Piptaz, Amikacin	hours Ventilator 3 days	7	9	7	2360	Improved and Discha		22 years	Primi	No	B positive	Olig am
8/31/2022 19:11:57	Laxmi gadiwaddar	Male	249491	At nagatan Vijaypura	########	########	########	-	34 weeks	25	Primi	69	96	96	94	2300	Inborn	-	7/20/2022	NVD	2300	7	9	No	8	1	HHHFNC	6	No	-	-	-	No	Small asd 3mm L to R	Not given	Dobutamine	Meropenem, Vancomy	days Nasal oxygen 3	6	11	8	2180	Improved and Discha		20 years	Primi	No	B positive	give Imm ecl
8/31/2022 19:19:49	Saniya gunaki	Female	255626	khade majid mandir	########	########	########	-	36 weeks	30	G3P1A1	97	98	98	97	2700	Outborn	Private hospital	7/23/2022	LSCS	2750	-	-	No	5	36	HHHFNC	3	No	-	-	-	No		Not given	Adrenaline	Piptaz, Amikacin, Metrogyl	days Hood oxygen 1	3	6	5	2700	and Discharged	Normal fundus	30 years	G3P1A1	yes	B positive	
8/31/2022 19:32:45	Heena kousar	Male	256936	Asar galli Vijaypura	########	########	########	-	32 weeks	20	Primi	70	93	93	90	1800		Private hospital	7/23/2022	NVD	1780	-	-	No	7	50	HHHFNC	6	No	-	-	-	No	Decreased Ejection fraction	Given	e, Milrinone, Dobutami	Amikacin, Meropenem	days Nasal oxygen 3	6	9	5	1280	and Discharged	-	23 years	Primi	No	A negative	Pv
8/31/2022 19:38:36	Boramma baddar	Female	258355	Kalebag vijaypura	########	########	########	-	35 weeks	27	Primi	79	87	87	85	1680	Inborn	-	7/26/2022	LSCS	1690	7	9	No	6	1	HHHFNC	5	No	-	-	-	No	Nosocomial sepsis	Not given	Dobutamine	Piptaz, Amikacin	days Nasal oxygen 2	5	7	5	1620	and Discharged	ROP 2 AND 3,no plus	28 yearsv	Primi	No	B positive	PIH
8/31/2022 19:44:55	Kavita kolekar	Female	263750	Aliyabad Vijaypura	########	########	-	########	37 weeks	32	Primi	143	90	90	85	3100	Outborn	Private hospital	7/30/2022	NVD	3100	-	-	yes	6	1	HHHFNC	6	yes	Convulsions , resp distress	4	Conventional ventilator	No	t failure, Death of neonate	Not given	e, Midazolam	Piptaz, Amikacin	Hfnc 3 hours Ventilator	6	6	-	-	Death	-	22 yearsv	Primi	No	Ab positive	PIH
8/31/2022 19:51:20	Shilpa kumbar	Female	263878	Ingalgali Vijaypura	########	########	########	-	36 weeks	30	G4p2l2a1	62	91	91	89	1700	Inborn	-	7/30/2022	LSCS	1780	7	9	No	4	2	HHHFNC	2	No	-	-	-	No	amically significant patent	Not given	Dobutamine	Amikacin, Taxim	day Nasal oxygen 1	2	5	3	1680	and Discharged	Normal fundus	26 years	G4P2L2A 1	No	O positive	