A COMPARATIVE STUDY OF TWO-HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES

By

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SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH

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DOCTOR OF MEDICINE
IN
PAEDIATRICS

Under The Guidance Of

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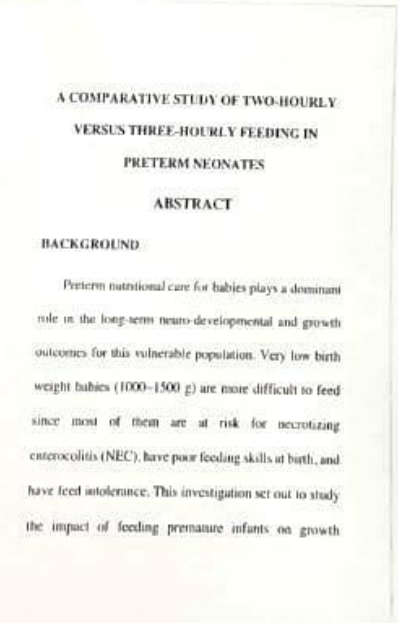

A COMPARATIVE STUDY OF TWO-HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES

ABSTRACT

BACKGROUND

Preterm nutritional care for babies plays a dominant role in the long-term neuro-developmental and growth outcomes for this vulnerable population. Very low birth weight babies (1000–1500 g) are more difficult to feed since most of them are at risk for necrotizing enterocolitis (NEC), have poor feeding skills at birth, and have feed intolerance. This investigation set out to study the impact of feeding premature infants on growth

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A COMPARATIVE STUDY OF TWO-HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES ABSTRACT

BACKGROUND Preterm nutritional care for babies plays a dominant role in the long-term neuro-developmental and growth outcomes for this vulnerable population. Very low birth weight babies (1000–1500 g) are more difficult to feed since most of them are at risk for necrotizing enterocolitis (NEC), have poor feeding skills at birth, and have feed intolerance. This investigation set out to study the impact of feeding premature infants on growth parameters, respiratory endurance, and time required to attain complete enteral feeding. Material and Methods Among stable newborns of preterm admitted to the NICU, a comparative open-label study was carried out. The final sample size consisted of approximately 45 cases in the 2H group and 45 cases in the 3H group. Neonatal data was collected, including gender, neonatal age, birth weight, Apgar score at five minutes, gestational age, weight on admission, hyperbilirubinemia signs and symptoms and complaints at the time of admission. A clinical examination was performed in the NICU for all the babies who were admitted for preterm care. Eneteral feeds were offered every two hours in first group, while the second group received it every three hours. Once the neonate was stable, feeding was initiated with expressed breast milk, and Intravenous fluid was administered in first group until the enteral feed up to 120 mL/kg/day volume. RESULTS In both groups, there were more male newborns than female babies. In 31.1% of the cases in the two-hourly group and in 40.0% of the individuals in the three-hourly group, the gestational age was 35 weeks. Approximately 13.3% of the 2H group and 77.8% of the 3H group were overweight when they were admitted. 13.3% of the 2H group and 77.8% of the 3H group had an APGAR score of greater than 8 after five minutes. In less than an hour, 91.1% of the 3-hour group and 84.4% of the 2-hour group began feeding. The length of stay in hospital was 12.7 days for 3H group and 14.0 days for the 2H group, which was not statistically significant. 4.4% of the neonates in the two-hourly study had NEC, 8.9% experienced hypoglycemia, and 8.9% had feed intolerance. 4.4% of the neonates in the three-hour group showed feed intolerance, while 4.4% had hypoglycemia. There was no statistically significant difference. CONCLUSION This study had shown that, 3rd hourly feeding was found better than the 2nd hourly feeding. INTRODUCTION Premature birth is vulnerable group for nutritional support. For this vulnerable population, long term neurodevelopmental and growth results are significantly influenced by nutritional support. Preterm neonates have high rate of extra-uterine restriction of growth because of immaturity of development of intestine in terms of absorptive surface area, hormone control and motility, which makes it difficult to provide the best nutritional support.1 The chance of an invasive infection may also rise with delayed establishment of full enteral nutrition. In an effort to lower the feeding intolerance risk and other issues, number of strategies has been used to try and decrease the full enteral feeding time.2 Very low birth weight (VLBW) babies (1000–1500 g) are not easy to feed since most of them are at risk for necrotizing enterocolitis (NEC), have poor feeding skills at birth, and have feed intolerance. For premature VLBW neonates receiving their mother's milk, early enteral feeding is recommended to reduce non-essential carbohydrate intake (NEC); improve neurodevelopment outcomes, prevent stomach atrophy, improve gut motility, and facilitate early complete feedings. Compared to continuous feeding; bolus feeding promotes a natural rise in gut hormones and facilitates the early attainment of full enteral feeding.3, 4, 5, 6 VLBW preterm infants are frequently fed continuously by an infusion pump or sporadically every two to three hours, however there isn't enough data to determine the ideal feeding plan. A comparative study with open label was carried out on stable preterm babies who were admitted to the Neonatal Intensive Care Unit. It also may potentially reduce significant feed residue in stomach as gastric emptying time is longer in premature neonates. Whereas second hourly feeding may avoid distension of stomach due to lesser volume and hence low gastroesophageal reflux. Smaller volume feeds could also mean small residual absolute volume, and thus decreased episodes of perceived feed intolerance. Although an additional risk of hypoglycemia may increase in case of third hourly feeds, the total nursing time involved may decrease due to less engagement per neonate. Data comparing the impact of feeding intervals on the occurrence of feed intolerance and the time it takes for VLBW newborns to complete full enteral feedings are inconsistent.7, 8 A two-hour timetable gives little uninterrupted time for Kangaroo mother care (KMC) and is very taxing on the mothers. It is difficult for mothers who are recuperating from pregnancy and childbirth to handle. KMC must be stopped in order to express milk and feed. KMC entails mothers to provide early, extended and continuous contact with skin-to-skin to their LBW neonates. By providing warmth, improving nutrition and breast milk intake, providing neurosensory stimulation, preventing nosocomial infections, and providing warmth, it has been shown to lower mortality in preterm neonates. These interventions are the standard of care for these babies. A two-hour schedule also means that nurses have to spend more time feeding patients, which can pose a challenge in wards with low nurse to patient ratio.9, 10 In addition to helping moms and nurses overcome challenges, a 3H feeding schedule may have the benefit of accelerating feed advancement. Physiological studies suggest that feeding every three hours could improve stomach emptying and reduce the chance of developing a feed intolerance. However, due to worries about feed resistance and hypoglycemia, three-hourly feeding regimens are not frequently used with premature newborns. Randomised controlled trials (RCTs) comparing feeding schedules of two hours to three hours have shown comparable risks of feed intolerance, necrotizing enterocolitis and hypoglycemia.11, 12, 13 Following two or three hourly feeds is not widely agreed upon. Nursing time spent feeding preterm neonates can be decreased if a 3-hour feeding plan can be implemented without endangering the babies. There is no much data on 3 hourly feeding and whether it can lead to adequate weight gain and

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Date: **DR RANA PRATAP RAYALU CHALASANI**

Place: Kolar

LIST OF ABBREVIATIONS

VLBW	:	Very Low Birth Weight
NEC	:	Necrotizing Enterocolitis
KMC	:	Kangaroo Mother Care
RCT	:	Randomized Controlled Trial
HBM	:	Human Breast Milk
HMO	:	Human Milk Oligosaccharide
miRNA	:	Micro Ribonucleic Acid
NICU	:	Neonatal Intensive Care Unit
PCA	:	Post Conceptional Age
MD	:	Mean Difference
CI	:	Confidence Interval
IQR	:	Inter Quartile Range
RR	:	Relative Risk
HIV	:	Human Immunodeficiency Virus

TABLE OF CONTENTS

LIST OF TABLES

LIST OF CHARTS

A COMPARATIVE STUDY OF TWO-HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES

ABSTRACT

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MATERIAL AND METHODS

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RESULTS

In both groups, there were more male newborns than female babies. In 31.1% of the cases in the two-hourly group and in 40.0% of the individuals in the three-hourly group, the gestational age was 35 weeks. Approximately 13.3% of the 2H group and 77.8% of the 3H group were over the weight of 1800 grams when they were admitted. 13.3% of the 2H group and 77.8% of the 3H group had an APGAR score of greater than 8 after five minutes. In less than an hour, 91.1% of the 3-hour group and 84.4% of the 2-hour group began feeding. The length of stay in hospital was 12.7 days for 3H group and 14.0 days for the 2H group, which was not statistically significant. Mean time to attain full feeds was 13.5 days in 2H group and 11 days in 3H group which was statistically significant.

4.4% of the neonates in the two-hourly study had NEC, 8.9% experienced hypoglycemia, and 8.9% had feed intolerance. 4.4% of the neonates in the three-hour group showed feed intolerance, while 4.4% had hypoglycemia. There was no statistically significant difference.

CONCLUSION

This study had shown that, 3rd hourly feeding was found better than the 2nd hourly feeding.

INTRODUCTION

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Premature birth is vulnerable group for nutritional support. For this vulnerable population, long-term neurodevelopmental and growth results are significantly influenced by nutritional support. Preterm neonates have high rate of extra-uterine restriction of growth because of immaturity of development of intestine in terms of absorptive surface area, hormone control and motility, which makes it difficult to provide the best nutritional support.[1]

The chance of an invasive infection may also rise with delayed establishment of full enteral nutrition. In an effort to lower the feeding intolerance risk and other issues, number of strategies has been used to try and decrease the full enteral feeding time.[2]

Very low birth weight (VLBW) babies (1000–1500 g) are not easy to feed since most of them are at risk for necrotizing enterocolitis (NEC), have poor feeding skills at birth, and have feed intolerance. For premature VLBW neonates receiving their mother's milk, early enteral feeding is recommended to reduce necrotising enterocolitis (NEC), improve neurodevelopment outcomes, prevent stomach atrophy, improve gut motility, and facilitate early complete feedings. Compared to continuous feeding, bolus feeding promotes a natural rise in gut hormones and facilitates the early attainment of full enteral feeding.[3, 4, 5, 6]

VLBW preterm neonates are frequently fed continuously by an infusion pump or sporadically every two to three hours, however there isn't enough data to determine the ideal feeding plan. By increasing the interval between feeds to third hourly it reduces feed intolerance. It also may potentially reduce significant feed residue in stomach as gastric emptying time is longer in premature neonates. Whereas second hourly feeding may avoid distension of stomach due to lesser volume and hence low gastroesophageal reflux. Smaller volume feeds could also mean small residual absolute volume, and thus decreased episodes of perceived feed intolerance. Although an additional risk of hypoglycemia may increase in case of third hourly feeds, the total nursing time involved may decrease due to less engagement per neonate. Data comparing the impact of feeding intervals on the occurrence of feed intolerance and the time it takes for VLBW newborns to complete full enteral feedings are inconsistent.[7, 8]

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KMC entails mothers to provide early, extended and continuous contact with skin-to-skin to their LBW neonates. By providing warmth, improving nutrition and breast milk intake, providing neurosensory stimulation, preventing nosocomial infections, and providing warmth, it has been shown to lower

mortality in preterm neonates. These interventions are the standard of care for these babies. A two-hour schedule also means that nurses have to spend more time feeding patients, which can pose a challenge in wards with low nurse to patient ratio.[9, 10]

In addition to helping moms and nurses overcome challenges, a 3H feeding schedule may have the benefit of accelerating feed advancement. Physiological studies suggest that feeding every three hours could improve stomach emptying and reduce the chance of developing a feed intolerance. However, due to worries about feed resistance and hypoglycemia, three-hourly feeding regimens are not frequently used with premature newborns. Randomised controlled trials (RCTs) comparing feeding schedules of two hours to three hours have shown comparable risks of feed intolerance, necrotizing enterocolitis and hypoglycemia.[11, 12, 13]

Following two or three hourly feeds is not widely agreed upon. Nursing time spent feeding preterm neonates can be decreased if a 3-hour feeding plan can be implemented without endangering the babies. There is no much data on 3 hourly feeding and whether it can lead to adequate weight gain and can reduce complications in preterm neonates as compared to 2 hourly feeding. Routinely 2 hourly feed is followed in our country whereas in countries like Australia 3 hourly feed is being followed. Consequently, there is not enough data to determine whether preterm neonates should be fed every two hours or every three hours. The objective of this research is to study effects of feeding babies

who were born before their due date on growth metrics, respiratory tolerance, and time took to achieve full enteral feeding.

AIMS & OBJECTIVES

AIM AND OBJECTIVES

1. To record the attainment of full feeds in 2H and 3H in stable preterm neonates.
2. To record the complication in 2H and 3H feeding in Stable preterm neonates.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Breast Milk

Breast milk of human is most important for a newborn's growth as well as development and is a critical source of nourishment for human early life. Because of this, WHO and UNICEF advocates exclusive breastfeeding for not less than six months after delivery and for a maximum age of two years.[15] Recently, number of infant formulae were made to resemble HBM more closely and are being enhanced with components unique to breast milk, like human milk oligosaccharide (HMO). While many of the components in these formulations are similar to those in HBM, there is no exact replacement for HBM.[16]

HBM is a vital package of nutrition for early human survival and is necessary for the growth and development. While many infant formulae have many components with HBM, there isn't a perfect replacement for HBM. The roles of different components of breast milk have recently been explored in accordance with the advancement of different techniques of analysis. It is known that, the macronutrient composition of HBM is around 84 g/L of solid components (124 gm/Lt of water), 1% (8 to 10 gm/Lt) of protein, 7% (60 to 70 gm/Lt) of carbohydrates and 3.9% (35 to 40 gm/Lt) of fat. The mother's diet is one example of an external event that can alter a component. Colostrum is rich in components that defend the immune system and less in fat. It is more in

proteins. Colostrum has rich factors defending the immune system and less in fat. It is higher in proteins. Vitamins D and K may not be present in sufficient amounts in HBM, and the infant may need to take supplements to guarantee proper growth. Growth factors in HBM also function on the gastrointestinal tract, vascular, neurological system, and endocrine system as different bioactive proteins and peptides. Healthy mother HBM was previously believed to be infertile. On the other hand, a number of further investigations have verified that HBM contains rich and varied microbial communities. Although some research indicates that Streptococcus and Staphylococcus genera may be ubiquitously prominent in Human Breast Milk, the origin of microbiota is still up for debate. Finally, because microRNAs are absorbed by epithelial cells of intestine and given by Human Breast Milk, milk is one of the bodily fluids with the highest concentration of these molecules. MicroRNAs are known in variety of functions, including immunoprotection and developmental programming. In conclusion, HBM, which contains microbiota and mi-RNAs for immunity, growth and development, is the most significant source of nutrition for newborns.[17]

Formula Milk

Infant formulas need to contain the required amounts of water, protein, carbohydrates, fat, minerals and vitamins. Government authorities have developed tight regulations on the infant formula composition and

manufacturers are required to adhere to this requirement.[18] For instance, there is a range of lesser and higher values for the effectiveness of each of the three primary elements (protein, lipids, and carbohydrates) added to the formula.[19] These parts need to have a track record of safe usage. Every nutrient's necessary range needs to be preserved for the duration of life(shelf-life) of product. Only the amino acids with L-forms may be administered; the D forms cannot be added since they may result in D-lactic acidosis.[20] Because of fructose sensitivity, fructose should be avoided. Hydrogenated oils and fats are prohibited as well. The formula product cannot be exposed to ionising radiation since it could deteriorate the product. When prepared and ready for consumption, infant formula should have a minimum calorie content of 60 kcal and a higher energy content of 70 kcal per 100 mL (CAC, 1981).[21] Moreover, medical and nutritional research results must serve as the foundation for product reformulation. "Manufacturers must demonstrate that the formula containing the new ingredient is capable of sustaining physical growth and development over 120 days when formula is likely to be the sole source of infant nutrition," according to the committee's recommendation regarding the "Evaluation of the addition of Ingredients New to Infant Formula."[22]

Types of formula milk

Cow milk-based formula

Majority of baby formula is made with milk of cow. But in comparison to HBM, bovine milk has larger quantities of fat, minerals, and protein. In order to make cow milk more like human breast milk, it must be skimmed and diluted. Most healthy full-term infants can consume additional vitamins, vegetable oils, minerals, and iron from cow-milk-based infant formula.[18, 19]

Cow's milk is leading reason of food allergies, is also one of first things given to a baby. Clinical reactions typically begin relatively early in life, following the breastfeeding cessation and introduction of cow's milk in diet; lactation is rarely the time for symptoms to manifest.[23]

Soy based formula

For babies with congenital lactase deficiency or galactosemia, soy protein formulas are a good alternative. They alleviate colic and milk allergies; nevertheless, in rare occasions, newborns with cow's milk allergies may also have soymilk sensitivities. Infants with food allergies less than six months should not use soy products. Because soy-based formulae contain phytoestrogens, their potential to harm infants is a concern that limits their use, though this is still up for debate.[24, 25, 26]

Hypoallergic formulas

Formulas containing protein hydrolysate are designed for babies and infants who cannot take formulas containing soy or cow's milk. They have protein which can be hydrolyzed, either completely or partially, into smaller sized pieces than what is present in goods made from cow or soy. Formulas that have been substantially hydrolyzed provide a satisfactory substitute for infants with allergy to proteins.

Formulas of Amino Acid

Severe cow milk allergy in infants react to or refuse to eat acceptable quantity of severely hydrolyzed formula, amino acid formulas represent an additional choice. They supply protein as free form amino acids only and not peptide.

Non-Bovine Milk Sources

When products of cow’s milk are completely removed from a baby's or child's diet without using suitable replacements that have been supplemented and adjusted, specific nutrient deficiencies with or without malnutrition may occur. Infant milk formulas made from other animals (goats, ewes, mares, donkeys, or camels) or lamb or chicken formulas are widely promoted as cow milk alternatives in order to cure cow milk allergy in infants and toddlers.

However, a number of formula based on animal milk are not licensed in different locations due to deficiency of robust RCTs.

Probiotics and Prebiotics

Human milk oligosaccharides are distinct from other milk proteins due to their high concentration and structural variety. Infants fed formula typically do not have a Bifidobacterium species dominating their gut microbiota in the absence of probiotic and prebiotic supplements. Research indicates that compared to formula-fed neonates, breastfed newborns have a more consistent and homogenous population of oligaosaccharides. One of the most important tactics for lowering infants' incidence and severity of diarrhoea is to incorporate probiotics into formula.

Kumar et al reported that, average age was 16.56 ± 6.26 days, and their average age of gestation was 8.52 ± 0.97 months. About 1.3:1 was the male to female ratio. The weight gain of the study groups at the 10-, 14-, and 4-month follow-ups was significant. About 52.3 percent of the infants in this study were breastfed. According to findings, breastfed babies gained weight more quickly than formula-fed babies, but it was not statistically significant in the length gains.[29]

Choice of feeding methods[30]

Gestational age	Maturation of feeding skills	Initial feeding method
< 28 weeks	No proper sucking efforts No propulsive motility in the gut	Intravenous fluids
28 – 31 weeks	Sucking bursts develop No coordination between suck/ swallow and breathing	Oro – gastric (or nasogatric) tube feeding with occasion spoon/ paladai feeding
32 – 34 weeks	Slightly mature sucking pattern Coordination beteen breathing and swallowing begins	Feeding by spoon/ paladai/ cup
> 34 weeks	Mature sucking pattern More coordination between breathing and swallowing	Breastfeeding

Paladai feed/ OG feed

Premature infants require correct nutrition and appropriate hydration and energy via venous line, due to their lack of dexterity when sucking and swallowing. For oral feeding, they also require the capacity to swallow with

strength, coordination, the ability to obstruct the nasopharynx and larynx with the uvula and epiglottis, and natural esophageal movements.[30] Any feeding technique that does not involve oral nutrition denies the baby the chance to naturally cycle between being hungry and satisfied; as length of non-oral feeding increases, more challenging will be the nutritional issues.[31] Regretfully, the majority of preterm newborns experience development limitation and malnutrition as a result of not getting enough protein and calories after delivery, which has a noticeable impact on their weight, height and nervous system.[32]

Unhealthy gain in weight increases the risk of sepsis by keeping newborns in the ward for longer periods of time. The likelihood that a newborn would experience nutritional issues, which could lead to low birth weight or its advancement, as well as the processes involved in treatment and care, all serve as obstacles to a newborn's ability to feed themselves orally on their own. For example, in premature infants, tube feeding reduces the sucking function and motor development.[33] Additionally, proper mother-neonate relationship during feeding is hindered by this kind of feeding. Infants can typically obtain all the nutrients they require by breastfeeding prior to discharge; but, in order to expedite their nutritional growth and allow for an earlier hospital departure, intervention is required.[34] Among preterm newborns, there may be a few days or months between the starting feeding orally and complete oral feeding, which can lengthen hospital stays and cause worry among mothers. An extended

hospital stay may also mean a greater financial strain on the family and the healthcare system. In situations where early neonates seek Neonatal Intensive Care Unit (NICU) admissions, including feeding of milk of low-volume, consuming supplements based on milk, or stopping mother milk owing to extended hospital stays, their feeding regimen may need to be adjusted. Nursing should not be used to provide nutrition in these situations; instead, another technique should be used. Cup methods take the place of the feeding method.[35] For newborns who can swallow fine but do not have good sucking, cup feeding is appropriate. For newborns who are not able to be breastfed, strengthening their sucking ability is also advised. For newborns who cannot be breastfed directly, a palady is used; it resembles a teaspoon with a tongue stud. This is very healthy equipment that is used to feed the newborns traditionally in India.[36]

In a study by Dalal et al, Groups I was studied for 47 sessions and group II for 27 sessions. In the two groups, the median PCA at the onset of feeding by paladai was 30 weeks and 32 weeks. In every behavioural condition, the babies accepted paladai feedings. About 25% of the sessions in both groups showed signs of feeding and respiratory coordination issues. With practice, authors saw a sharp increase in feeding performance; in groups I and II, proficiency increased in both the groups. With a median PCA of 30.9 weeks, group I infants' proficiency was high when compared with group II new borns, whose PCA was 31.7 weeks. Paladai can be given to stable preterm newborns starting

at 30 weeks PCA. It is possible that postnatal experiences have a greater influence on oropharyngeal capacity than does birth maturity. [37]

A 2007 study done in England revealed that because there was a greater quantity of lost milk while using the palady method, the newborns received less milk when fed this way than when they were bottle-fed. Additionally, the palady method required longer time to feed the neonate. The newborns are also under higher stress due to pallidy.[38]

In a study by Nidhi et al, with the paladai, the babies stayed silent the longest and consumed the most volume in less time. Results were especially noteworthy for the group of newborns that included every category. The cup caused the most spills, particularly with premature babies.[39]

Continuous feeding versus intermittent feeding

Earlier research had shown the advantages and disadvantages of both intermittent bolus feeding and continuous feeding in premature babies. Constant feeding maintains high levels insulin and gastrin, which improves absorption and reduces expending energy. On the other hand, if milk is offered continuously injected into digestive system, it may result in aberrant gastrointestinal hormones and long-term development inhibition. According to study conducted on animal models, glucagon-like peptide-1 is reduced by continuous eating as opposed to intermittent bolus feeding, which may be a

factor in organ failure. Furthermore, continuous feeding results in a far higher prevalence of long apnea and apnea associated hypoxic illnesses like retinopathy than intermittent feeding.[39, 40, 41] Furthermore, compared to intermittent feeding, occurrence of sustained apnea and apnea associated hypoxic illnesses as retinopathy is substantially higher with continuous feeding. It was thought that feeding babies infrequently via bolus would be more physiological since it would cause periodic increases in insulin, gastrin, and stomach inhibitory peptide, which would help the gastrointestinal system develop. Additionally, feeding intermittently enables greater parental participation in both splanchnic perfusion and feeding. Additionally, sporadic feeding enhances the body's protein balance and encourages the synthesis of new proteins, both of them are important in controlling nutritional issues in young children.[42, 43] But, feeding milk intermittently may result in eating intolerance in premature babies since milk infusion as bolus makes it easy for newborns to absorb more than their gastrointestinal tract can handle. Intermittent feeding has also been connected to impaired pulmonary function and metabolic instability in preterm infants.[45]

Feeding and Associated Problems

Complete enteral feed can be defined as ingesting 150 milliliters per kilogram per day.[30] The definition of hypoglycemia is blood glucose levels less than 45 mg/dL. Distension of Abdomen (girth of abdomen ≥2 cm), aspirates containing

bile or blood, vomiting, or gastric residual volume before feeding exceeding feed volume of 50% last of which was only measured when feeds had reached a volume of 5 mL/kg—were all considered indicators of feed intolerance.

Problems of two-hourly feeding

Due to lower volume, 2 Hourly feeding may result in less stomach distension and, thus, less gastroesophageal reflux. Reduced episodes of perceived feed intolerance could result from smaller feed volumes, which could also translate into smaller absolute volumes of residuals.[45]

Problems of three-hourly feeding

Regarding the various feeding schedules, on the one hand, feeding three times a day reduces the effort for nurses, the amount of time that infants must be handled, and the risk of infection. In the event of 3 Hourly feeds, there may be an increased risk of hypoglycemia; nevertheless, because each newborn requires less attention, the overall amount of nursing time may be reduced. Comparison of Data about impact of interval of feeding in the time it takes for VLBW newborns to complete full enteral feedings and the prevalence of feed intolerance are inconsistent.[46]

Anushree N et al conducted a study in 2018. They included total of 60 neonates weighing less than 1500 grams were divided into two groups with 30 each in 2H and 3H feeding schedules and found that the occurrence of intolerance to feed between the two groups was not different statistically. No difference was

observed in the incidence of hypoglycaemia, Necrotizing Enterocolitis, apnea, and time to reach full feeds between two groups. They came to the conclusion that for VLBW infants, 3H feeding may be just as beneficial as 2H feeding.[47]

- A study by Aradhya et al noted, five newborns were studied in baseline on 2H schedule. About 122 neonates were investigated on a 3H schedule in PDSA cycles. The median maternal fatigue score significantly decreased, going from 13 to 3. Two neonates experienced mild, asymptomatic, transitory hypoglycemia, and only one suffered feed intolerance. For temporary reasons, six (5%) newborns were switched to two-hourly feeding. Mothers might spend more time caring for Kangaroo mothers, according to nursing personnel. The amount of expressed breast milk and formula feed requirements did not vary from the three-hourly plan. Using a quality improvement methodology, it was possible to objectively document the safety and benefits of switching stable preterm newborns from the conventional 2H schedule of feeding to a 3H schedule.[48]
- Chu E et al conducted a Retrospective research in 2019. They included 113 neonates with birth weight ≤1,250 grams in two groups. About 59 in Q3H group and 54 in Q2H group. Although it wasn't statistically significant, they discovered that Q2H neonates needed 10% additional days in order to achieve full enteral feeding. There was a 16% increase in

days of central catheter (P = 0.02) and a 17% increase in days of parenteral nutrition with Q2H feeding. Growth metrics and respiratory outcomes did not differ between the groups. They came to the conclusion that very preterm newborns fed Q3H had fewer days requiring parenteral nutrition and central catheterization than those fed Q2H, but no appreciable growth differences or outcomes of respiration.[1]

- In a study by Kumar et al, occurrence of Second stage or third stage necrotizing enterocolitis (NEC) was main result. Other results included mortality, delay to full enteral feeds, hospital stay, and incidence of any stage NEC. There are six trials, totaling 872 individuals. There was no difference between the 3H feeding group and two-hourly feeding group in the occurrence of stage II/III NEC and any stage NEC. Full feed achievement and other results were the same in both groups. Subgroup analysis revealed that neonates receiving three-hourly feedings and having birth weights under 1000 g attained full feeds more slowly than receiving two-hourly feedings. Three-hourly feeding are safely continued in stable preterm newborns (1000–1500 g). Although a 2-hour period could be desirable, there is not enough information to recommend an ideal feeding interval for newborns under 1000 g. There were 100 newborns in all, with ages ranging from 5 to 13 days. Mean time to reach full feeds in group 2 was significantly longer than that of group 1 In 3H schedules, mean time to acquire a full feed birth weight of 1 to 1.5 kg was

12.86 days; in 2H schedules, it was 14.67 days. The time it took to acquire complete feeding decreased as gestational age grew. In comparison to 2-H schedules, 3H schedules had faster times to reach full feeds. The feed tolerance improved with 3-hourly feeding schedules as well. In comparison to 2-hourly feeding regimens, problems were less common with 3H feeding schedules.[49]

- Yadav A et al conducted an open labelled, Randomized control trial in January 2021. The study revealed that incidence of hypoglycemia, feed intolerance, and necrotizing enterocolitis between the two feeding schedule groups was significantly different. Full enteral time achievement median time was found to be comparable in both groups (P=0.6650). They came to the conclusion that 3H feeding doesn't raise the risk of feed intolerance, necrotizing enterocolitis, or hypoglycemia.[8]
- In a study by Sunil B et al, about 100 newborns in all, divided into two groups with ages ranging from 5 to 13 days and of which there were 50 male and 50 female neonates. In group 2, Mean time to reach full feeds was longer significantly than that of group 1. In 3H schedules, the time to acquire a full feed birth weight of 1 to 1.5 kg was 12.86 days; in 2H schedules, it was 14.67 days. The time it took to acquire complete feeding decreased as gestational age grew. In comparison to 2H feeding schedules, 3H feeding schedules had faster times to reach full feeds. The feed tolerance improved with 3H feeding schedules as well. In

comparison to 2-hourly feeding regimens, problems were less common with 3-hourly feeding schedules.[50]

- In 2021, Ibrahim NR et al. carried out four randomized controlled trials (RCTs) with 417 infants and discovered that number of days required to attain complete enteral feeding differed either little or not between 2H and three-hourly feeding. The mean difference (MD) = 0.62, 95% CI indicated a modest level of significance, nonetheless. The data was insufficient to establish impact of shorter feeding intervals on any secondary outcomes, including the risk of NEC and duration of hospital stay. Additionally, it was uncertain if neonates fed every two hours would take a little longer to regain birth weight than those fed every three hours. They concluded that there might not be any differences between feeding intervals of two and three hours that are clinically meaningful. There is a dearth of information about potential feeding problems, including NEC.[13]

MATERIALS & METHODS

MATERIAL AND METHODS

An open labelled comparative study was undertaken among stable Preterm babies in Neonatal intensive care unit at RLJH, in whom feed could be started immediately, were randomized to 2H or 3H feeding schedule between September 2022 to April 2024. Before the study began, the institution's ethical committee gave its approval. Prior to their inclusion in the study, each parent signed an informed consent form.

SAMPLE SIZE CALCULATION

The difference in the Meantime to full enteral feeding between 3-hourly group and the 2-hourly group from the study by Abraham NR et al. was used to estimate the sample size. In the 3-hourly group, mean time was 11.3 days for complete enteral feeding, while in the 2-hourly group, it was 10.2. Using the formula below and the Med Calc program, sample size of 79 was obtained in each group using these values at the 95% Confidence Limit and 80% Power. A sample size of 79 + 7.9 +/- 90 cases will be included, with a 10% nonresponse rate.

About 45 cases in 2H group and 45 cases in 3H group.

Sample Size Estimation:

$$N = \frac{2\,SD^2(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

- Where Zα/2 is the Normal distribution's critical value at α/2 (for example, if α is 0.05 and the critical value is 1.96 at a 95% confidence level).
- The β value is denoted as Zβ. For example, with a power of 80%, ß is 0.2 and the critical value is 0.84.
- SD is the population standard deviation variation from the prior study and
- D is the difference between two means, and.

INCLUSION CRITERIA

1. All stable preterm babies (less than 37-week gestational age) admitted to NICU/SNICU.
2. Every stable preterm infant weighing under two kilograms at delivery.

EXCLUSION CRITERIA

1. Babies with severe illness leading on to stopping feeds.
2. Neonates with major congenital anomalies like trachea-oesophageal fistula, oesophageal atresia, etc and neonates going against medical advice.

METHODOLOGY

All neonates fulfilling the inclusion criteria was included in the study. 90 neonates will be studied and randomized into two groups by block randomization

About 45 neonates in 2H group and 45 neonates in 3H group

Gender, neonatal age, birth weight, gestational age, 5-minute Apgar score, weight at admission, hyperbilirubinemia symptoms and complaints, blood group and Direct Coombs test, frequency and timing of breastfeeding initiation, passing meconium, length of hospital stay, and other relevant data were among the neonatal data was collected.

Babies were followed at intervals of 24 hours, 48 hours and 72 hours for body weight.

Clinical examination of all the babies who got admitted for preterm care was done in NICU. All those babies who were having evidence of major congenital anomalies at any point of time during the NICU stay was excluded from the study. And only stable babies for feeds were taken up for the study.

Further information that was needed to be gathered included antenatal registration, parity (Primigravida, 2nd/3rd Multigravida), maternal age, history of illness during pregnancy, and high-risk factors like pregnancy-induced hypertension, a poor obstetric history, premature membrane rupture of more than 18 hours, medical diseases during pregnancy (diabetes, heart disease), others (anemia, chronic respiratory diseases), and the mother's status with regard to HIV/HBsAg. Methods of delivery: vacuum/forceps, lower segment cesarean section (LSCS), full-term normal birth. Rh factor blood type, previous

sibling's history of jaundice, and length of stay in the hospital following childbirth.

Neonates' weight was measured as follows: birth weight on day 1, 24 hours after delivery; birth weight on day 2, 48 hours after delivery; and birth weight on day 3, 72 hours after delivery. Calculations of percentages and ratios were made, and data will be placed into Excel sheets.

A complete enteral feed was 150 millilitres per kilogram per day. The definition of hypoglycemia is blood glucose levels less than 45 mg/dL (30). Distension of Abdomen, aspirates containing bile or blood, vomiting, or gastric residual volume before feed exceeding 50% of feed volume the last of which was only measured when feeds had reached a volume of 5 mL/kg—were all considered indicators of feed intolerance .[30]

Enteral feeding was administered to the first group every two hours and the second group every three hours. As soon as the newborn was stable, breastfeeding was initiated. If there was not enough breast milk, preterm formula was utilized. Both groups adhered to the unit's feeding procedure in the same way. For babies weighing 1000–1250 g, feeding was started and increased by 30 mL/kg/day; for babies in the 1251–1500 g weight group, feeding was administered as complete enteral feeds (in accordance with the daily standard fluid requirement).

Intravenous fluid was administered to the former group until reaching enteral feed of 120 mL/kg daily volume.

Newborns were fed through orogastric tube by gravity or with the aid of a cup or paladai, depending on their gestational maturity.

The abdominal girth of newborns receiving oral nutrition is assessed every twelve hours. Gastric residual volume was measured if the baby vomited or if the abdomen circumference increased by more than 2 cm. When feed volume reaches 5 mL/kg, feedstuffs are fed until the aspirate is milky and less than 25% of the feed volume. If the aspirate is between 25 and feed volume of 50%, is then lowered to match the aspirate volume. When aspirate volume of more than feed volume of 50% or 5 mL/kg, one or two feeds were stopped, and feeds were then resumed while keeping an eye on the belly girth.

Feeds were stopped for a minimum of twenty-four hours and resumed once the problem was rectified, if the feed intolerance returned and was accompanied by symptoms and systemic signs or if aspirate was blood or bile stained. Using a laboratory sample, Blood sugar values within the hypoglycemic range will be verified. Every hypoglycemic episode will be managed in accordance with the unit's normal protocol.

Every day, nurse used a standardized, accurately by using digital weighing machine which is calibrated (± 5g) (Seca) to weigh the newborns. When a neonate achieved full enteral feeding and maintained for 48 hours without experiencing intolerance to feeds, the neonate was deemed to have finished the research.

Statistical analysis

After entering the data into a Microsoft Excel data sheet, the data was analyzed using SPSS 22 version software. To represent categorical data, proportions and frequencies were utilized. The significance test used was the chi-square method. Continuous data was presented using the mean and standard deviation.

The independent sample t test was used as a significance test to find the mean difference. P values below 0.05 were considered statistically significant.

RESULTS

RESULTS

Table 1. Gender of study groups

Sex	2 hourly group	3 hourly group
Male	29 (64.4)	35 (77.8)
Female	16 (35.6)	10 (22.2)
Total	45 (100)	45 (100)

Males outnumbered female babies in both the groups which was not significant.

Chart 1. Gender of study groups

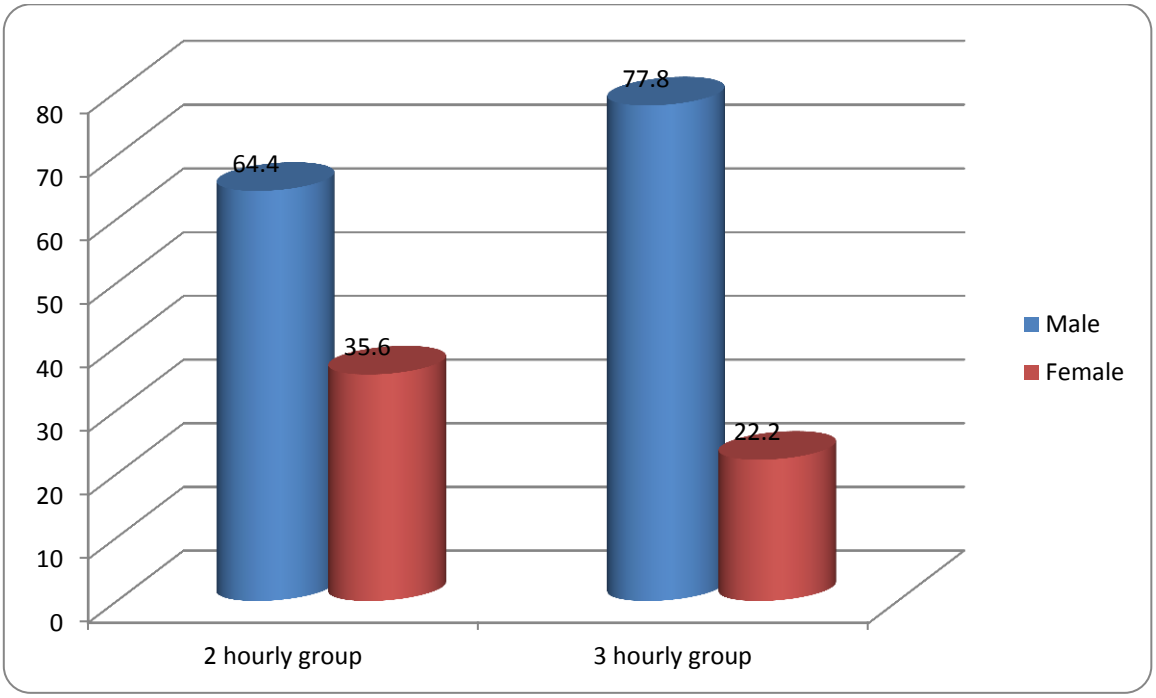


Table 2. Gestational age of study groups

Gestational age	2 hourly group	3 hourly group
30-32 weeks	10 (22.2)	0
33-34 weeks	14 (31.1)	13 (28.9)
35 weeks	7 (15.6)	18 (40.0)
36 weeks	14(31.1)	14 (31.1)

The gestational age was 36 weeks in 31.1% of the cases in 2 hourly group and 35 weeks in 40.0% of the subjects in 3 hourly group.

Chart 2. Gestational age of study groups

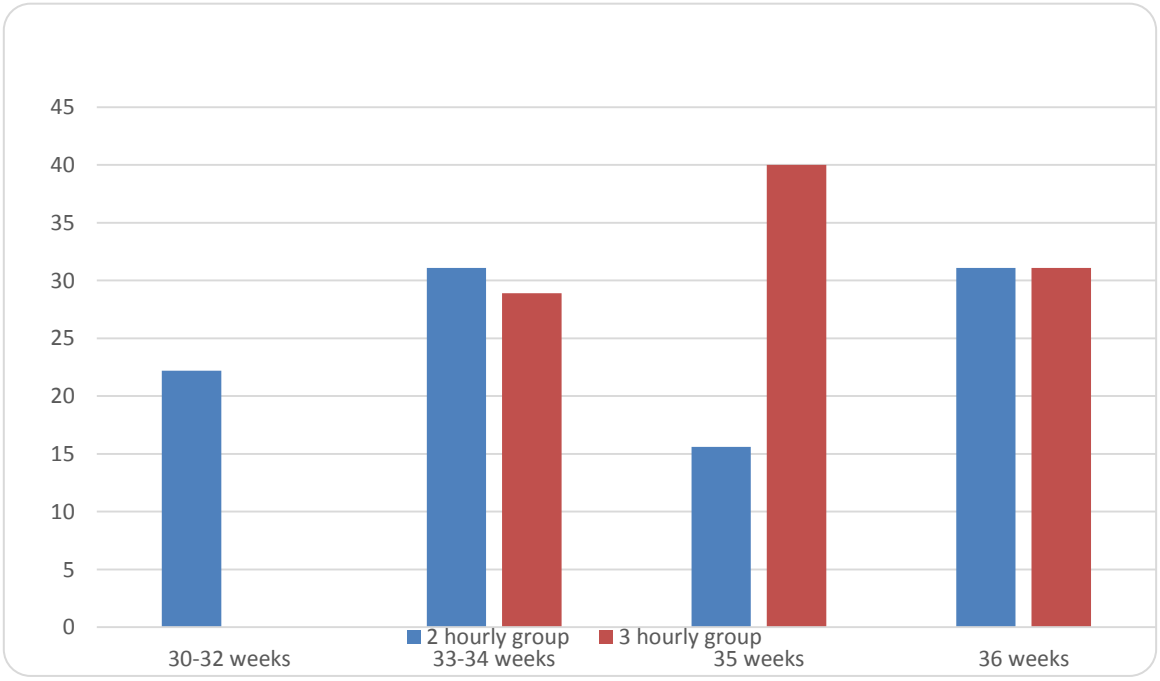


Table 3. Weight on admission

Weight on admission	2 hourly group	3 hourly group
Less than or equal to 1800 grams	39 (86.7)	10 (22.2)
More than 1800 grams	6 (13.3)	35 (77.8)

About 13.3% of the 2H and 77.8% of the 3H group had weight on admission of more than 1800 grams.

Chart 3. Weight on admission

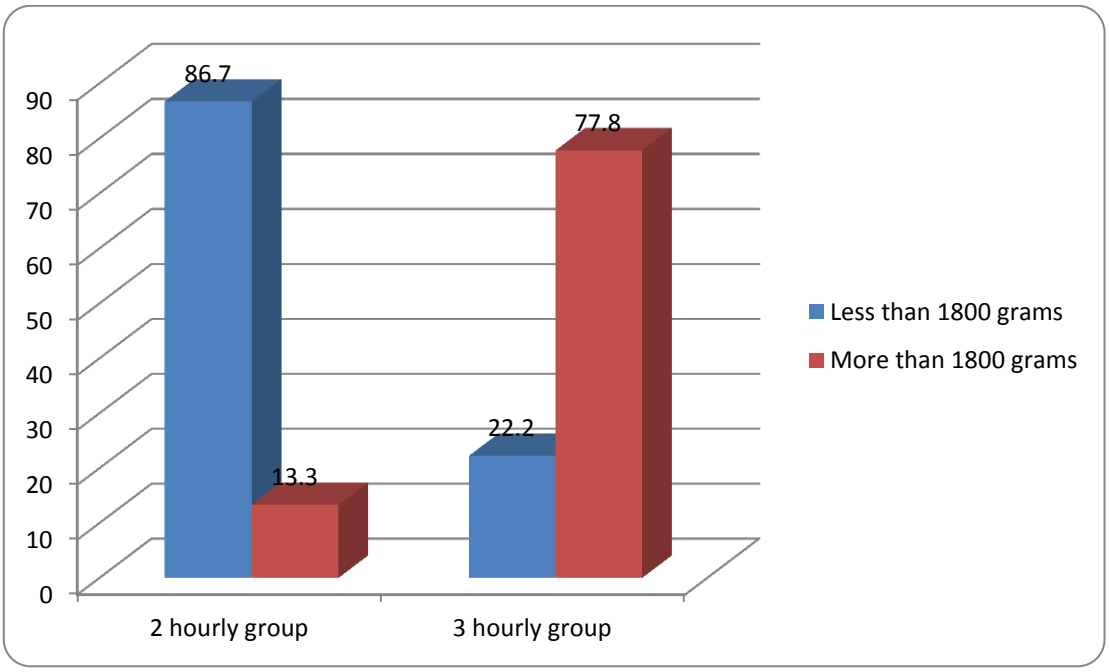


Table 4. Five min APGAR score of study groups

5minute APGAR score	2 hourly group	3 hourly group
Less than or equal to 8	39 (86.7)	10 (22.2)
More than 8	6 (13.3)	35 (77.8)

Five minutes APGAR score was more than 8 in 13.3% of the 2 hourly and 77.8% of the 3 hourly group

Chart 4. Five min APGAR score of study groups

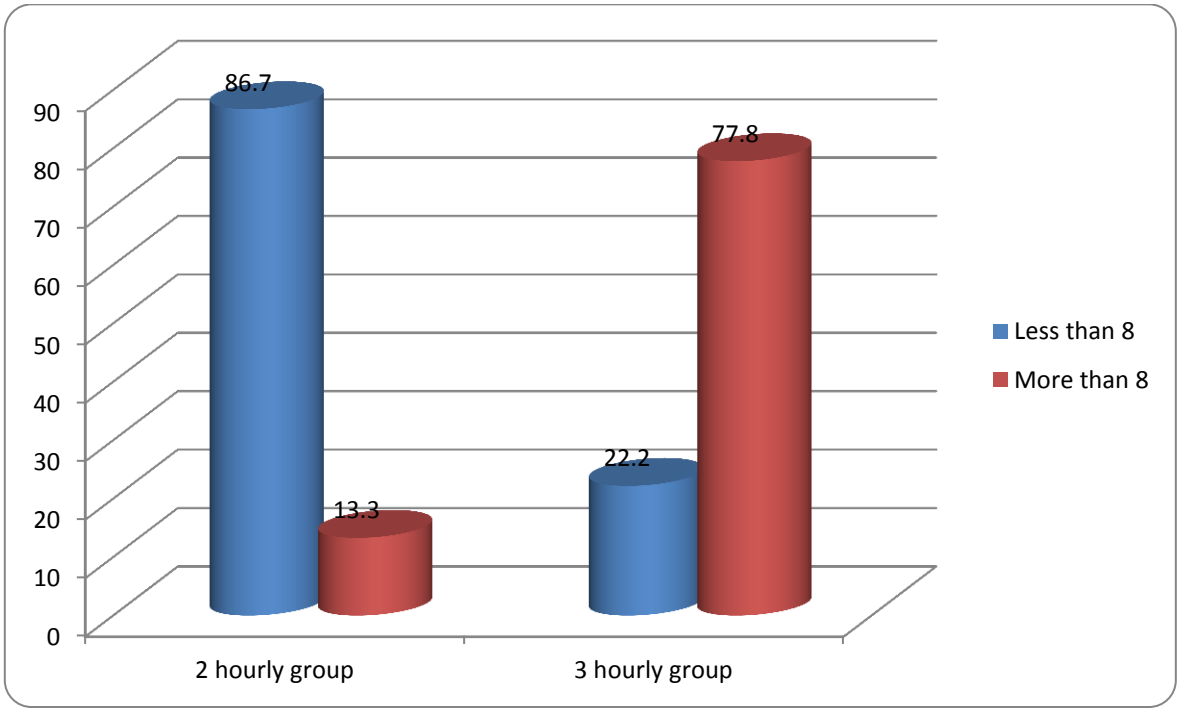


Table 5. Time for initiation of Enteral feeding in the study groups

Time of initiation of feeding in hours	2 hourly group	3 hourly group
Less than 1 hour	38 (84.4)	41 (91.1)
More than 1 hour	7 (15.6)	4 (8.9)

The time for initiation of feeding was less than 1 hour in 91.1% of 3 hourly group and 84.4% of 2 hourly group.

Chart 5. Time for initiation of Enteral feeding in the study groups

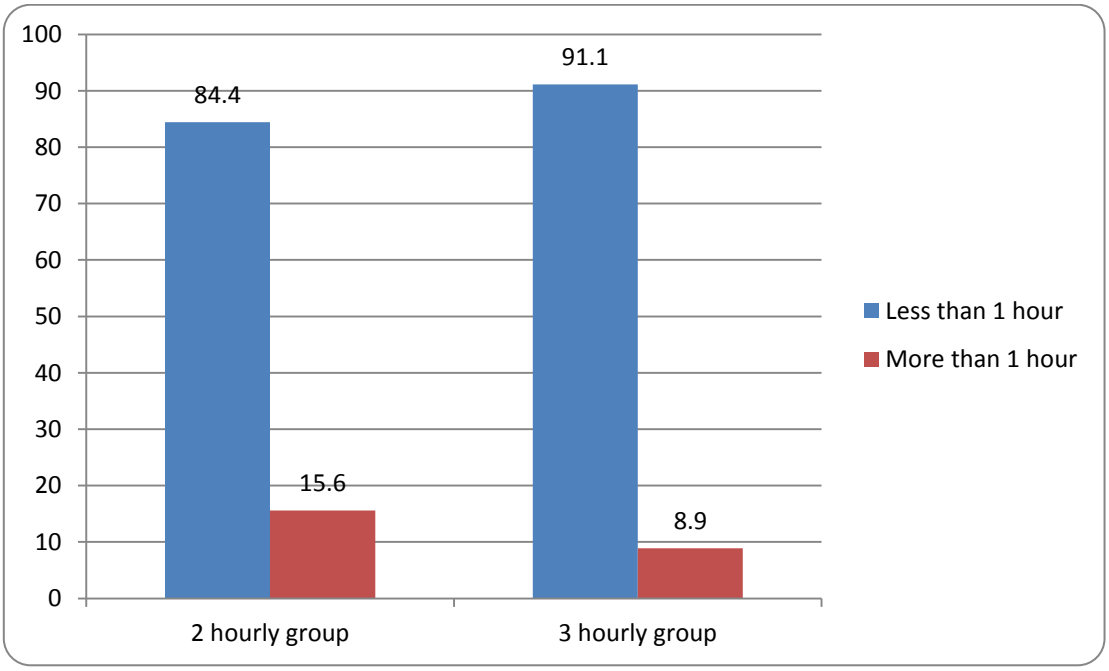


Table 6. Duration of hospital stay of study groups

Duration	2 hourly group	3 hourly group	T value	P value, sig
Mean ± SD	14.0 ± 1.9	12.7 ± 2.0	0.647	0.520, NS

Duration of hospital stay in 2 hourly group was 14.0 days and in 3 hourly group was 12.7 days. This difference was not statistically significant.

Chart 6. Duration of hospital stay of study groups

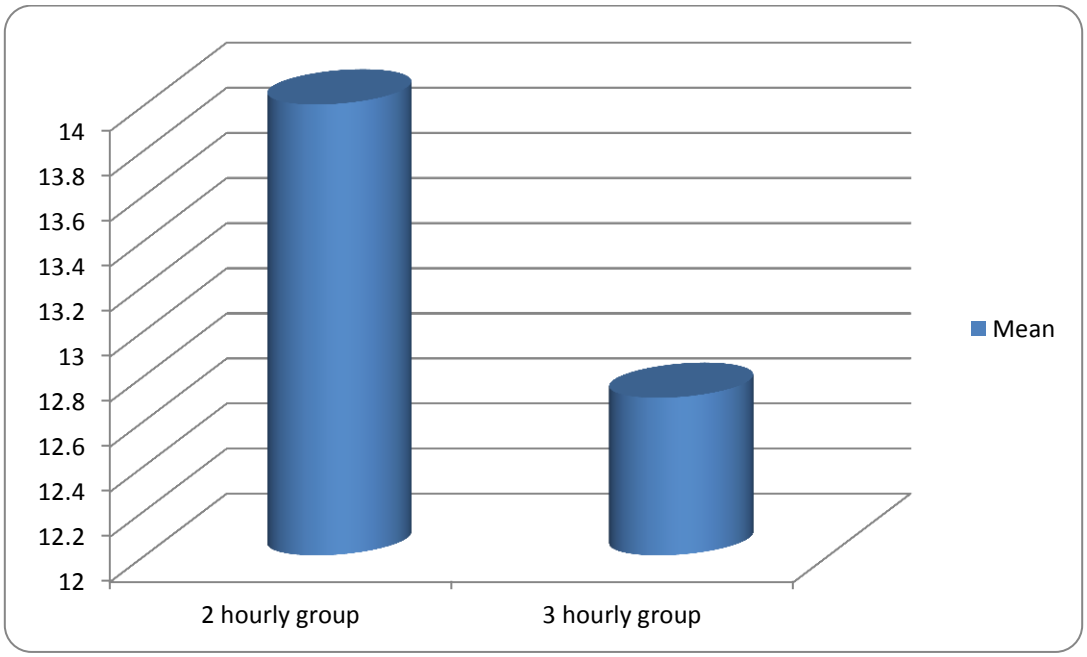


Table 7. Mean time to reach full feeds in the study groups

Duration of hospital stay	2 hourly group	3 hourly group	T value	P value, sig
Mean ± SD	13.5 ± 1.42	11.0 ± 2.1	6.419	0.000, Sig

Mean time to attain full feeds was 13.5 days in 2H group and 11 days in 3H group which was statistically significant.

Chart 7. Mean time to reach full feeds in the study groups

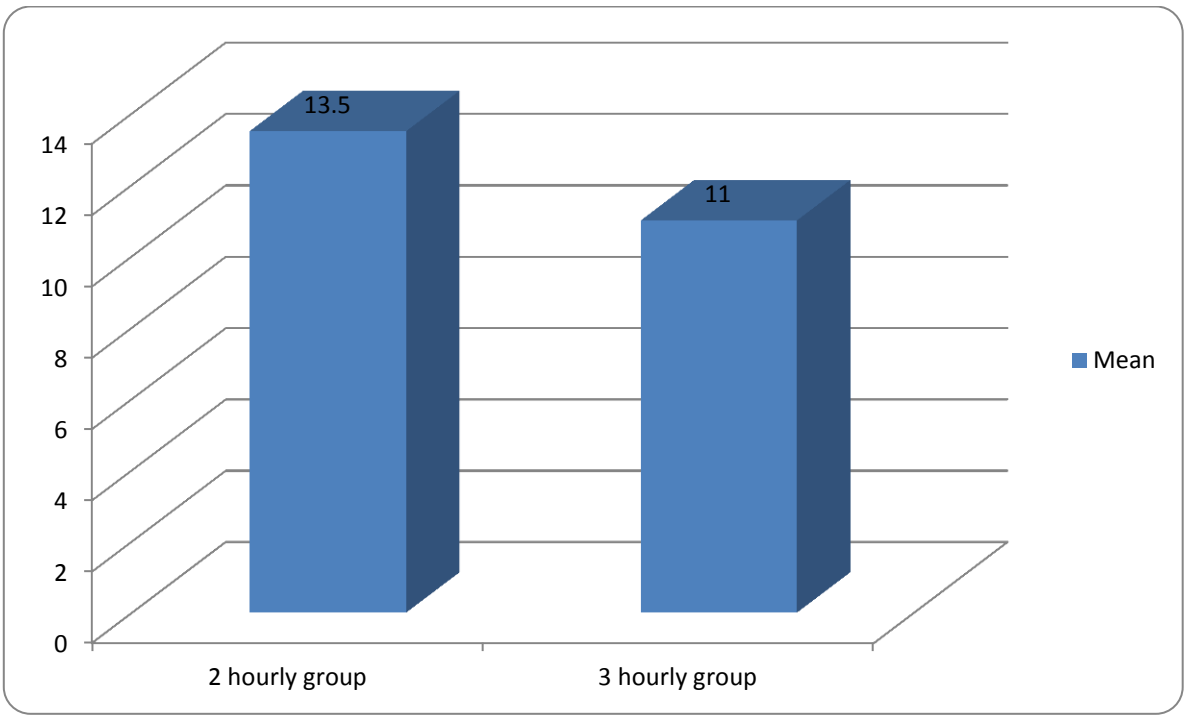


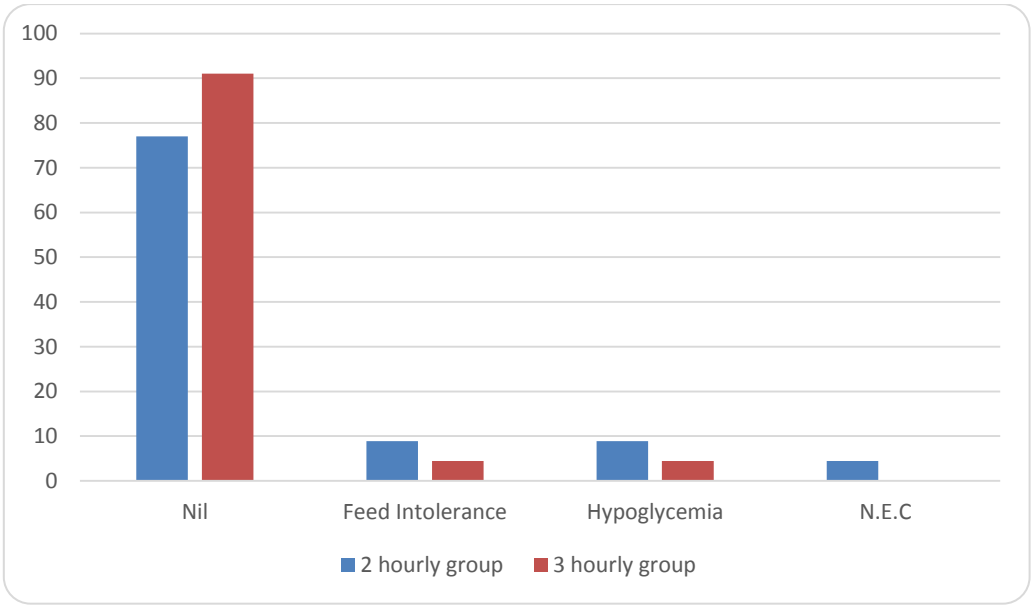
Table 8. Complications in study groups

Complications	2 hourly group n (%)	3 hourly group n (%)
Nil	35 (77.77)	41 (91.1)
Feed intolerance	4 (8.9)	2 (4.4)
Hypoglycemia	4 (8.9)	2 (4.4)
NEC	2 (4.4)	0
Total	45 (100)	45 (100)

χ^2 Value = 7.443 df=3 p value, sig= 0.059, NS

About 8.9% of the neonates in 2 hourly had feed intolerance, 8.9% had hypoglycemia and 4.4% had NEC. Of the 3 hourly group, 4.4% of the neonates had feed intolerance and 4.4% had hypoglycemia. There was no statistically significant difference.

Chart 8. Complications in study groups



DISCUSSION

DISCUSSION

For this vulnerable population, preterm neonates' long-term neurodevelopmental and growth results are significantly influenced by their nutritional care. Preterm neonates have a higher rate of extra-uterine growth restriction due to developmental intestinal immaturity due to absorptive surface area, hormone control and motility, which makes it difficult to provide the best nutritional support.[1]

The chance of an invasive infection may also rise with delayed establishment of full enteral nutrition. In an effort to lower feeding intolerance risk and other issues, a number of strategies have been used to try and decrease time to full enteral feeding.[2]

VLBW premature neonates are frequently fed continuously by an infusion pump or sporadically every two to three hours, however there isn't enough data to determine the ideal feeding plan. By extending the time between feedings from two hours to three hours, it may prevent the chronic hyperemia that occurs in the superior mesenteric artery when feedings are done hourly, which could reduce feed intolerance. Additionally, as premature neonates have prolonged gastric emptying times, it might lessen the amount of feed residue that remains in the stomach. On the other hand, Two-hourly feeding may result in less gastric distension because of its smaller volume and, thus, less gastroesophageal reflux. Reduced episodes of perceived feed intolerance could

result from smaller feed volumes, which could also translate into smaller absolute volumes of residuals. In the event of Third-hourly feeds, there may be an increased risk of hypoglycemia; nevertheless, because each newborn requires less attention, the overall amount of nursing time may be reduced. Data comparing the impact of feeding intervals on the feed intolerance incidence and the time it takes for VLBW newborns to complete full enteral feedings are inconsistent.[3]

Following two or three hourly feeds is not widely agreed upon. Nursing time needed to feed preterm newborns can be decreased if a 3-hour feeding plan can be implemented without endangering the babies. Few studies care carried out on the effects of 3-hour feeding schedules versus 2-hour feeding schedules on appropriate weight growth and problems in preterm newborns. In this country, typically follow a two-hour feed, but in places like Australia, people follow a three-hour feed. Thus, there is not enough data to determine whether preterm newborns should be fed every two hours or every three hours.

Between September 2022 and April 2024, stable preterm neonates of NICU and able to begin feeding within life of 96 hours were randomly assigned to a 2- or 3-hour feeding regimen in an open-label comparative research.

Gender

In both groups, there were more male newborns than female babies. There was no statistically significant difference. In a Yadav et al. study, males

made up roughly 59.4% of the 2H feeding group and 59.4% of the 3H feeding group.[8] About 50% of the 2 hourly group cases and 55.3% of the 3 hourly instances in a research by Anushree et al. involved male sex.[47]

Gestational age

The gestational age was 36 weeks in 31.1% of the cases in 2 hourly group and 35 weeks in 40.0% of the subjects in 3 hourly group. A study by Yadav et al had shown that, the mean gestational age was 32.3 weeks in 2 hourly group and 32.5 weeks in 3 hourly group.[8] A study by Sunil et al, the gestational age of 48.07 of the 2 hourly neonates and 51.92% of the 3 hourly group neonates was 33 – 36 weeks. Mean gestational age was 31.1 weeks in 2 hourly group and 32.51 weeks in 3 hourly group.[50]

Mean weight on admission

About 13.3% of the 2H group and 77.8% of the 3H group had weight on admission of more than 1800 grams. A study by Sunil et al, mean birth weight was 1.39 kgs in 2 hourly group and 1.47 kgs in 3 hourly group.[50]

APGAR score

Five minutes APGAR score was more than 8 in 13.3% of the 2 hourly and 77.8% of the 3 hourly group

Time of initiation of breastfeeding

The time for initiation of feeding was less than 1 hour in 91.1% of 3 hourly group and 84.4% of 2 hourly group.

Duration of hospital stay

The hospital stay duration in 2H group was 14.0 days and in 3H group was 12.7 days which was not statistically significant.

Time to reach full feeds

It took a mean of 13.5 days for the 2H group and 11 days for the 3H group to reach full feeds, a statistically significant difference. Achievement of time to full enteral feed was equivalent in two and three hourly groups in a study by Yadav et al., but it was not statistically significant, therefore it is not comparable with this study.[8]

Weight gain at 24 hours

Weight at 24 hours after admission was more than 1800 grams in 73.3% of 3H group and 8.9% in 2H group.

Weight gain in 48 hours

Weight at 48 hours after admission was more than 1800 grams in 68.8% of 3H group and 2.3% in 2H group.

Weight gain in 72 hours

Weight at 72 hours after admission was more than 1800 grams in 75.5% of 3H group and 2.3% in 2 hourly group. A study by Anushree et al had shown that, the time to attain full feeds was 10 days in 2H group and 10 days in 3H group.[50]

COMPLICATIONS

About 8.9% in 2 hourly had feed intolerance, 8.9% had hypoglycemia and 4.4% had NEC. Of the 3 hourly group, 4.4% of the neonates had feed intolerance and 4.4% had hypoglycemia. This difference was not statistically significant. A study by Yadav et al had shown that, the feed intolerance was higher in 2 hourly group when compared to 3 hourly group. Hypoglycemia and NEC were higher in 3 hourly group.[8] In a study by Sunil et al, the complications in 2 hourly group included abdominal distension, apnea, feeding intolerance sepsis and vomiting. The complications in 3 hourly group was abdominal distension, feeding intolerance and vomiting.[49] In a study by Anushree et al, feed intolerance and apnea were common complications for 2 hourly groups. In neonates with 3 hourly group, feed intolerance, hypoglycemia and apnea were complications noted.[50]

CONCLUSION

CONCLUSION

- This study was undertaken in order to find the weight gain difference between the 2nd hourly and 3rd hourly feeding.
- This study had shown that, 3rd hourly feeding was found better than the 2nd hourly feeding.
- Mean time to attain full feeds was 13.5 days in 2H group and 11 days in 3H group.
- Only two out of 45 babies fed by three hourly feeding had feed intolerance whereas 4/90 babies fed by two hourly feeding had feed intolerance.
- Three-hourly feeding mainly focuses on patient centered outcome in preterm children.
- But this study is not without limitations.
- The sample size is small to generalize the study findings.
- A study with larger sample size can bring out more facts about the usefulness of three hourly breastfeeding.

SUMMARY

SUMMARY

- Very low birthweight (VLBW) babies are more difficult to feed since most of them are at risk for necrotizing enterocolitis (NEC), have poor feeding skills at birth, and have feed intolerance.
- Males outnumbered female babies in both the groups.
- The gestational age was 36 weeks in 31.1% of the cases in 2 hourly group and 35 weeks in 40.0% of the subjects in 3 hourly group.
- About 13.3% of the 2H group and 77.8% of the 3H group had weight on admission of more than 1800 grams.
- Five minutes APGAR score was more than 8 in 13.3% of the 2 hourly and 77.8% of the 3 hourly group
- The time for initiation of feeding was less than 1 hour in 91.1% of 3H group and 84.4% of 2H group.
- Mean time to attain full feeds was 13.5 days in 2H group and 11 days in 3H group.
- Hospital stay duration in 2H group was 14.0 days and in 3H group was 12.7 days.
- Weight at 24 hours after admission was more than 1800 grams in 73.3% of 3 hourly group and 8.9% in 2 hourly group.
- Weight at 48 hours after admission was more than 1800 grams in 68.8% of 3H and 2.3% in 2H group.

- Weight at 72 hours after admission was more than 1800 grams in 75.5% of 3H and 2.3% in 2H group.
- About 8.9% of the neonates in 2 hourly had feed intolerance, 8.9% had hypoglycemia and 4.4% had NEC. Of the 3 hourly group, 4.4% of the neonates had feed intolerance and 4.4% had hypoglycemia.

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ANNEXURE

INFORMED CONSENT FORM

Date:

I, Mr/Mrs have been explained in my own vernacular language that my child will be included in the study, **A COMPARITIVE STUDY OF TWO- HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES**

I hereby give my valid written informed consent without any force or prejudice for recording the observations and investigations to be done for my child. 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 consent voluntarily to participate my child as a participant in this research. I hereby give consent to provide my child's history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc., to the doctor / institute etc. and 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.A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

_____

(Signature & Name of Pt. Attendant)

_____

(Signature/Thumb impression & Name of Patient/Guardian)

(Relation with patient)

Witness: _____

(Signature & Name of Research person /doctor)

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ದಿನಾಂಕ:

ನಾನು, ಶ್ರೀ/ಶ್ರೀಮತಿ ನನ್ನ ಸ್ವಂತ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ನನ್ನ ಮಗುವನ್ನು ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುವುದು ಎಂದು ವಿವರಿಸಲಾಗಿದೆ, ಎರಡು ಗಂಟೆಯ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ಮತ್ತು ಅವಧಿಪೂರ್ವ ನವಜಾತ ಶಿಶುಗಳಿಗೆ ಮೂರು ಗಂಟೆಗಳ ಕಾಲ ಆಹಾರ ನೀಡುವುದು

ನನ್ನ ಮಗುವಿಗೆ ಮಾಡಬೇಕಾದ ವೀಕ್ಷಣೆಗಳು ಮತ್ತು ತನಿಖೆಗಳನ್ನು ದಾಖಲಿಸಲು ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನಾನು ಈ ಮೂಲಕ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡುತ್ತೇನೆ. ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳನ್ನು ನನಗೆ ತೃಪ್ತಿಪಡಿಸಲು ವಿವರಿಸಲಾಗಿದೆ. ನಡೆಸುತ್ತಿರುವ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ.

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ನನ್ನ ಮಗುವನ್ನು ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಮಗುವಿನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ ಮತ್ತು ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಹೊಣೆಗಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ.

ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿಸಲಾಗಿದೆ.

_____

(ಪಂ. ಅಟೆಂಡೆಂಟ್‌ನ ಸಹಿ ಮತ್ತು ಹೆಸರು)

_____

ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತು ಮತ್ತು ರೋಗಿಯ/ರಕ್ಷಕರ ಹೆಸರು)

(ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ)

ಸಾಕ್ಷಿ: _____

(ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ/ವೈದ್ಯರ ಸಹಿ ಮತ್ತು ಹೆಸರು) ಪ್ರಸವಪೂರ್ವ ನವಜಾತ ಶಿಶುಗಳಲ್ಲಿ ಎರಡು ಗಂಟೆಯ ಮತ್ತು ಮೂರು ಗಂಟೆಯ ಆಹಾರದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ

A COMPARITIVE STUDY OF TWO- HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES

PATIENT INFORMATION SHEET

Principal Investigators: Dr. Rana Pratap Rayalu Chalasani/ Dr.K.N.V Prasad

I, **DR. RANA PRATAP RAYALU CHALASANI** , post-graduate student in Department of Pediatrics at Sri Devaraj Urs Medical College, will be conducting a study titled "**A COMPARITIVE STUDY OF TWO- HOURLY VERSUS THREE-HOURLY FEEDING IN PRETERM NEONATES**." for my dissertation under the guidance of Dr. K.N.V Prasad, Professor , Department of Pediatrics. The participants of this study i.e., preterm neonates will be included in observational study wherein the vital parameters of the participants s will be monitored at serial intervals.

You will not be paid any financial compensation for participating 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 participation of your child in the 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

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಗಳು: ಡಾ. ರಾಣಾ ಪ್ರತಾಪ್ ರಾಯಲು ಚಲಸಾನಿ/ ಡಾ.ಕೆ.ಎನ್.ವಿ ಪ್ರಸಾದ್

ನಾನು, ಡಾ.ಡಿ.ಆರ್. ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜಿನ ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ವಿಭಾಗದ ಸ್ನಾತಕೋತ್ತರ ವಿದ್ಯಾರ್ಥಿ ರಾಣಾ ಪ್ರತಾಪ್ ರಾಯಲು ಚಲಸಾನಿ ಅವರು "ಎರಡು ಗಂಟೆಯ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ಮತ್ತು ಮೂರು ಗಂಟೆಗಳ ಕಾಲ ಪೂರ್ವಭಾವಿಯಾಗಿ ಆಹಾರ ನೀಡುವುದು" ಎಂಬ ಅಧ್ಯಯನವನ್ನು ನಡೆಸಲಿದ್ದಾರೆ. ಮಕ್ಕಳ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕರಾದ ಡಾ. ಕೆ.ಎನ್.ವಿ ಪ್ರಸಾದ್ ಅವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ನನ್ನ ಪ್ರಬಂಧಕ್ಕಾಗಿ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವವರು ಅಂದರೆ, ಪ್ರಸವಪೂರ್ವ ನವಜಾತ ಶಿಶುಗಳನ್ನು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ, ಇದರಲ್ಲಿ ಭಾಗವಹಿಸುವವರ ಪ್ರಮುಖ ನಿಯತಾಂಕಗಳನ್ನು ಸರಣಿ ಮಧ್ಯಂತರಗಳಲ್ಲಿ ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲಾಗುತ್ತದೆ.

ಈ ಸಂಶೋಧನಾ ಯೋಜನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಿದ್ದಕ್ಕಾಗಿ ನಿಮಗೆ ಯಾವುದೇ ಹಣಕಾಸಿನ ಪರಿಹಾರವನ್ನು ನೀಡಲಾಗುವುದಿಲ್ಲ. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಈ ಸಂಸ್ಥೆಯಿಂದ ಸಂಶೋಧನಾ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ. 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

PROFORMA

Title: A Comparative study of two- hourly versus three-hourly feeding in preterm neonates.

Date of Enrollment:

UHID no:

PARENT DETAILS:

1. Name of mother:

Age of mother:

Occupation of mother:

2. Name of the father:

Particulars of gestation:

Gestational age at delivery:

Mode of delivery:

Particulars of neonate:

Sex of baby:

Weight of the baby at birth as per Gestational age:

Weight of baby at discharge:

Provisional diagnosis for admission:

APGAR Score:

Resuscitation done: yes/no

Bio chemical abnormalities:

RBS:

Sr calcium:

Sr. Magnesium:

Sr. Phosphorous:

Sr. Bilirubin:

CRP:

Blood C/s

Clinical examination findings:

APGAR score:

Respiratory instability: yes/ no

RS:distress secondary to T.T.N.B: HRS

Surfactant given: yes/no

CVS: Heart rate:

C.F.T

Shock

-Cardiovascular anomalies: yes/no:will specify

CNS: 1) Seizures

2)Activity

GIT: a) Abdominal girth

b) Bowel sounds

c) Stools- frequency:

-colour:

(feed intolerance: yes/no)

(N.E.C developed: yes/no)

Details of feeding:

Time/ Day of starting feeds

Frequency of feeding

Full feed/ Partial feed

Type of feed: EBM/ Formula

Quantity fed:

Time taken for nursing the baby:

Mode of feeding: cup/spoon/paldai/NG:

Outcomes:

Time taken to achieve full enteral feed:

Days taken for feeding transition:

Length of hospital stay:

Time taken to regain birth weight:

No. Of days of parenteral nutrition: DAY

DOSE:

WHICH IVF

Secondary outcomes:

Episodes of hypoglycaemia:

If yes, timing of hypoglycaemic attack:

Apnoea: yes/ no

N.E.C: yes/ no

Sepsis: yes/ no

Mortality: yes/ no

Feeding intolerance: yes/ no

Weight at discharge:

MASTER CHART

Slno	Group	Gender	GA	Birth weight	WOA	5 minute Apgar score	Hour of Initiation of Feeds	Duration of hopsital stay	Weight 24 hours	Weight 48 hours	Weight 72 hours	Complications		Mean time to reach full feeds
1	3 hourly	F	36	1920	1920	9	1	12	1880	1860	1840			11
2	3 hourly	F	34	1980	1980	9	1	14	1940	1920	1900			12
3	3 hourly	M	34	1840	1840	9	1	15	1800	1780	1760	Hypoglycemia	,Feed intolerance	17
4	3 hourly	M	36	1940	1940	9	2	13	1920	1900	1880			15
5	3 hourly	M	35	1900	1900	8	1	12	1880	1860	1840			14
6	3 hourly	F	34	1840	1840	9	2	12	1820	1800	1820			14
7	3 hourly	M	35	1930	1930	8	1	11	1900	1880	1900			10
8	3 hourly	M	34	1780	1780	8	3	14	1760	1740	1720			9
9	3 hourly	M	34	1750	1750	9	2	15	1730	1710	1680			10
10	3 hourly	M	36	1850	1850	9	1	13	1820	1800	1780			11
11	3 hourly	M	35	1980	1980	9	1	14	1940	1920	1940			8
12	3 hourly	M	36	1960	1960	8	1	11	1920	1900	1880			9
13	3 hourly	F	36	1840	1840	8	1	13	1800	1780	1780			10
14	3 hourly	M	35	1960	1960	9	1	11	1940	1920	1900			11
15	3 hourly	M	36	1940	1940	9	1	12	1920	1900	1900			12
16	3 hourly	F	34	1820	1820	9	2	14	1780	1740	1740			13
17	3 hourly	M	36	1950	1950	8	1	14	1930	1900	1920			14
18	3 hourly	M	34	1680	1680	8	3	12	1640	1620	1600			12
19	3 hourly	F	36	1920	1920	9	1	15	1900	1880	1880			10
20	3 hourly	M	36	1980	1980	9	1	13	1940	1920	1900			9
21	3 hourly	M	35	1860	1860	8	1	14	1840	1820	1820			8
22	3 hourly	M	36	1940	1940	9	1	11	1920	1900	1880			10
23	3 hourly	M	36	1870	1870	8	1	14	1850	1820	1820			14
24	3 hourly	F	34	1780	1780	9	2	12	1740	1720	1740			10
25	3 hourly	M	36	1820	1820	9	1	14	1800	1780	1760			9
26	3 hourly	F	36	1920	1920	9	1	9	1900	1880	1900			10
27	3 hourly	M	36	1980	1980	9	1	9	1940	1920	1920			11
28	3 hourly	M	35	1760	1760	8	1	13	1740	1720	1700			8
29	3 hourly	M	35	1940	1940	9	1	9	1920	1900	1880			9
30	3 hourly	M	35	1880	1880	9	1	9	1840	1860	1880			10
31	3 hourly	F	35	1900	1900	9	1	10	1860	1840	1860			11
32	3 hourly	M	34	1500	1500	9	1	14	1460	1420	1420	hypoglycemia	,Feed intolerance	12
33	3 hourly	F	34	1760	1760	9	1	15	1720	1700	1700			13
34	3 hourly	M	35	1850	1850	9	1	13	1830	1810	1780			14
35	3 hourly	M	35	1920	1920	9	1	9	1900	1880	1860			10
36	3 hourly	M	34	1780	1780	9	1	13	1740	1720	1720			9
37	3 hourly	M	34	1860	1860	9	1	11	1840	1800	1820			10
38	3 hourly	M	35	1930	1930	9	1	10	1900	1860	1880			11
39	3 hourly	M	35	1880	1880	9	1	14	1840	1820	1820			8
40	3 hourly	M	35	1980	1980	9	1	10	1940	1920	1900			9
41	3 hourly	M	35	1900	1900	9	1	11	1840	1840	1820			10

Slno	Group	Gender	GA	Birth weight	WOA	5 minute Apgar score	Hour of Initiation of Feeds	Duration of hopsital stay	Weight 24 hours	Weight 48 hours	Weight 72 hours	Complications		Mean time to reach full feeds
42	3 hourly	M	35	1860	1860	9	1	12	1840	1820	1820			11
43	3 hourly	M	35	1920	1920	9	1	10	1900	1880	1840			12
44	3 hourly	M	34	1700	1700	9	1	13	1660	1640	1620			13
45	3 hourly	M	35	1740	1740	9	1	12	1720	1700	1680			14
1	2 hourly	F	35	1920	1920	9	1	14	1880	1840	1820			14
2	2 hourly	F	34	1780	1780	8	1	12	1740	1720	1700	Hypoglycemia		15
3	2 hourly	M	35	1660	1660	8	1	15	1620	1600	1580			13
4	2 hourly	M	33	1680	1680	8	1	14	1640	1620	1620			11
5	2 hourly	F	36	1780	1780	7	1	14	1740	1720	1700			15
6	2 hourly	M	33	1860	1860	8	1	15	1820	1800	1780			14
7	2 hourly	F	34	1800	1800	8	1	13	1760	1740	1720			16
8	2 hourly	F	33	1720	1720	7	1	16	1680	1660	1620	Feed intolerance		15
9	2 hourly	F	36	1700	1700	8	2	12	1660	1640	1620			14
10	2 hourly	M	32	1460	1460	7	4	15	1420	1400	1400			12
11	2 hourly	F	33	1560	1560	8	2	13	1530	1510	1480			13
12	2 hourly	M	34	1680	1680	8	2	11	1640	1620	1600			14
13	2 hourly	M	32	1580	1580	8	1	14	1540	1500	1480			15
14	2 hourly	F	32	1400	1400	7	1	14	1380	1360	1320	Feed intolerance		12
15	2 hourly	M	36	1780	1780	9	1	11	1740	1720	1700			13
16	2 hourly	M	35	1600	1600	7	1	12	1580	1540	1560			14
17	2 hourly	M	32	1520	1520	8	1	10	1500	1480	1440			11
18	2 hourly	M	35	1740	1740	7	1	12	1710	1700	1700			12
19	2 hourly	M	33	1480	1480	8	2	15	1440	1420	1400			14
20	2 hourly	M	34	1640	1640	8	1	14	1620	1600	1580			14
21	2 hourly	M	34	1800	1800	7	1	15	1760	1720	1700			15
22	2 hourly	M	35	1900	1900	8	1	12	1860	1840	1800			12
23	2 hourly	M	33	1780	1780	8	1	14	1740	1720	1700			13
24	2 hourly	M	36	1820	1820	9	1	14	1800	1760	1740			12
25	2 hourly	F	36	1780	1780	8	1	14	1740	1720	1700			13
26	2 hourly	M	36	1700	1700	7	1	14	1660	1640	1620			14
27	2 hourly	M	32	1540	1540	8	1	14	1500	1480	1480	hypoglycemia		15
28	2 hourly	F	32	1780	1780	9	1	11	1760	1740	1720			13
29	2 hourly	M	36	1740	1740	8	1	12	1720	1720	1700			12
30	2 hourly	F	36	1700	1700	8	1	12	1680	1640	1620			15
31	2 hourly	F	36	1680	1680	8	1	13	1660	1620	1600			12
32	2 hourly	M	32	1740	1740	8	1	14	1700	1680	1660			12
33	2 hourly	M	34	1560	1560	8	1	15	1540	1520	1500			14
34	2 hourly	M	34	1640	1640	8	1	14	1620	1600	1580			15
35	2 hourly	F	35	1720	1720	8	1	12	1700	1660	1640			14
36	2 hourly	M	35	1680	1680	8	1	13	1660	1620	1600			12
37	2 hourly	M	34	1660	1660	8	1	15	1640	1620	1600			13

Slno	Group	Gender	GA	Birth weight	WOA	5 minute Apgar score	Hour of Initiation of Feeds	Duration of hopsital stay	Weight 24 hours	Weight 48 hours	Weight 72 hours	Complications		Mean time to reach full feeds
38	2 hourly	F	34	1700	1700	7	1	15	1640	1620	1600			12
39	2 hourly	M	32	1400	1400	8	1	16	1340	1340	1320	hypoglycemia		14
40	2 hourly	M	34	1720	1720	9	1	11	1680	1640	1620			11
41	2 hourly	M	32	1160	1160	7	1	20	1120	1100	1080	Feed intolerance,N.E.C-2	,N.E.C	16
42	2 hourly	F	32	1100	1100	7	1	20	1080	1040	1020	Feed intolerance	,N.E.C	16S
43	2 hourly	F	34	1460	1460	8	1	16	1440	1420	1400	hypoglycemia		13
44	2 hourly	M	34	1560	1560	8	1	15	1540	1520	1500			15
45	2 hourly	M	35	1740	1740	9	1	13	1720	1700	1680			12