

**“EFFECT OF OROMOTOR STIMULATION FREQUENCY ON TIME
OF TRANSITION TO FULL ORAL FEEDS IN PRETERM NEONATES:
ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL”**

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DISSERTATION

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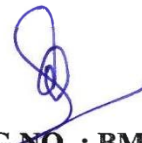
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ABSTRACT

Background and aims

More than one out of ten babies born in the world are preterm which is the second leading cause of death. Prematurity related morbidities and physiological immaturity lead to feeding problems like regurgitation, inadequate nutritional intake among 30%-40% of preterms. Non-nutritive sucking, abdominal massage and Oromotor Stimulation (OMS) are some methods that help to deal with the feeding issues. This study aims to evaluate the effect of oromotor stimulation frequency on time of transition from tube feeding to full spoon or paladai feeds.

Materials and methods

This randomized clinical trial was conducted in a tertiary care centre and 93 preterms between 30-34 weeks were evaluated focussing on the objectives of the study. Eligible neonates were allocated into three groups of 31 each and oromotor stimulation was provided once, twice and thrice daily respectively for 7 consecutive days, 20 minutes before feeding, for 5 minutes. Maternal and neonatal data was collected using a structured proforma. All the infants in the three groups were monitored from admission till discharge for transition time to full oral feeds, Weekly weight gain and Length of hospital stay. The data was analysed using statistical software R version 4.2.0 and Microsoft Excel.

Results

In the study, 87% of the participants were born between 32 and 33+6 weeks, 19% between 30 and 31+6 weeks, and 19% at 34 weeks with females accounting for 52.7%, and males 47.3%. The mean days for achieving full spoon feeds was 8.48 (\pm 4.114) for Group A, 5.84 (\pm 2.505)

for Group B and 5.55 (\pm 3.118) for Group C with a statistically significant difference ($p=0.013$). There was no statistically significant difference ($p=0.064$) for mean duration of hospital stay which was 17.03 days (\pm 7.017) for Group A, 14.35 days (\pm 5.010) for Group B, and 13.61 days (\pm 5.637) for Group C. Weekly weight gain in the first ($p=0.551$), second ($p=0.656$), third ($p=0.428$), fourth ($p=0.713$), fifth ($p=0.185$), and sixth weeks did not show a statistically significant difference amongst the study groups.

Conclusion

Feeding difficulty is one of the major problems faced by preterm neonates. Oromotor stimulation is a major assistance that promotes earlier transition to oral feeding. In this study, providing oromotor stimulation three times a day shortened the transition time from gavage to full oral feeds and duration of hospital stay significantly which led to faster progress. This demonstrates efficacy of increased frequency of intervention to address feeding related issues in preterm babies.

This simple cost effective method should be incorporated into regular neonatal care and can also be given at home by mothers for better outcome.

Keywords

Oromotor stimulation, Prematurity, Feeding issues, Transition time, Weight gain

LIST OF ABBREVIATIONS

BOMI	-	Beckman Oral Motor Intervention
BPD	-	Bronchopulmonary dysplasia
EFS	-	Early Feeding Skills Assessment Tool
EGD	-	Esophagogastroduodenoscopy
EoE	-	Eosinophilic esophagitis
FEES	-	Fiberoptic endoscopic evaluation of swallowing
GER	-	Gastroesophageal reflux
HIE	-	Hypoxic ischemic encephalopathy
H2RA	-	H2-receptor antagonists
IDFS	-	Infant Driven Feeding Scales
IUGR	-	Intrauterine growth restriction
IVH	-	Intraventricular hemorrhage
LBW	-	Low birth weight
MRI	-	Magnetic resonance imaging
NEC	-	Necrotizing enterocolitis
NFAS	-	Neonatal Feeding Assessment Scale
NICU	-	Neonatal intensive care unit
NNS	-	Non-nutritive sucking
NOMAS	-	Neonatal Oral Motor Assessment Scale
NS	-	Nutritive suck
OFS	-	Oral Feeding Skills Scale
OMS	-	Oromotor stimulation
pH-MII	-	pH monitoring multichannel impedance
PIOMI	-	Premature Infant Oral Motor Intervention

PMA	-	Postmenstrual age
POFRAS	-	Preterm Oral Feeding Readiness Assessment Scale
PPIs	-	Proton pump inhibitors
PVL	-	Periventricular leukomalacia
RDS	-	Respiratory distress syndrome
UGI	-	Upper gastrointestinal fluoroscopy
VFSS	-	Videofluoroscopic swallow study
WHO	-	World health organization

CONTENTS

Sr. No.	Topic	Page No.
1.	INTRODUCTION	1-2
2.	OBJECTIVES	3
3.	REVIEW OF LITERATURE	4-21
4.	MATERIALS AND METHODS	22-26
5.	RESULTS	27-38
6.	DISCUSSION	39-42
7.	CONCLUSION	43
8.	SUMMARY	44-45
9.	BIBLIOGRAPHY	46-52
10.	ANNEXURES	
	ANNEXURE I – CONSENT FORM	53-56
	ANNEXURE II – PROFORMA	57-61
	ANNEXURE III – KEY TO MASTER CHART	62
	ANNEXURE IV – MASTER CHART	63

LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	Complications of Prematurity	4
2	Clinical assessment of feeding problems	11
3	Maternal Age distribution across the Study groups	28
4	Gender distribution Across Study Groups	29
5	CPAP Duration Across Study Groups	30
6	Gestational Age Across Study Groups	31
7	Birth weight Across Study Groups	32
8	Age of starting tube feeding	33
9	Age of Starting Spoon feed	34
10	Time Taken to Achieve Full Spoon Feed	35
11	Weekly Weight Gain Across Study Groups	36
12	Duration of Hospital Stay Across Study Groups	37
13	Mean parameters Across Study Groups	38

LIST OF FIGURES

FIGURE NO.	DESCRIPTION	PAGE NO.
1	Risk factors for feeding problems in preterm neonates	6
2	Etiopathophysiology of dysphagia in preterm neonates	8
3	Approach to a preterm infant with feeding problems	10
4	Premature Infant Oromotor Intervention (PIOMI)	17
5	Consort diagram	27
6	Maternal age	28
7	Gender distribution	29
8	CPAP duration	30
9	Gestational age	31
10	Birth weight	32
11	Age of starting tube feeding	33
12	Age of starting spoon feed	34
13	Time taken to achieve full spoon feeds	35
14	Weekly weight gain	36
15	Duration of hospital stay	37

INTRODUCTION

According to WHO, across 184 countries, preterm birth rate ranges from 5% to 18%. More than one out of ten babies born in the world are preterm making it the second leading cause of death. Throughout their stay in the neonatal intensive care unit (NICU), preterm babies must overcome a number of obstacles, such as infections, neurological disorders, and cardiorespiratory issues, all as they grow and meet the neurodevelopmental milestones necessary for NICU discharge.¹

Insults inflicted against a growing fetus or preterm child during tissue differentiation and organ formation can have both immediate and long-term effects. Prenatal factors like stress, environmental exposures, malnourishment, and lifestyle can disrupt the fetus's developmental programming and result in placental anomalies, restriction of fetal growth, and compensatory postnatal growth via altering the maternal–fetal endocrine axis.²

Prematurity related morbidities and physiological immaturity lead to feeding problems like regurgitation, inadequate nutritional intake among 30%-40% of preterms. These issues stem from hypotonia, underdeveloped oro-motor control, and impaired coordination during breathing, sucking, and swallowing.³ Difficulty with oral feedings leads to higher costs and longer hospital stay.

Preterm infant's readiness for oral feeding is a problem that frequently arises near the end of hospitalization. This only becomes apparent once more serious medical issues have been addressed or are under control. Proper feeding during the neonatal period is important for the brain growth and development, especially during the first 2 years of life. Proper neonatal feeding also ensures reduced infections and thus reduced morbidity and mortality.

Oromotor Stimulation (OMS), abdominal massage and non-nutritive sucking are a few techniques that assist in addressing feeding difficulties. Already existing literature demonstrates that oromotor stimulation (OMS) improves the frequency of sucking in preterm neonates, improves feeding performance in terms of overall intake and milk transfer rate, shortens the transition to complete oral feeding, improves daily weight gain and shortens hospital stays. However, the frequency of OMS administration varies amongst studies.⁴

There is paucity of studies comparing the effect of different frequencies of OMS administration on feeding that will help in deciding the frequency of intervention. Hence, the need for the study.

OBJECTIVES

PRIMARY:

To study the effect of oromotor stimulation frequency on transition time from tube feeding to full spoon or paladai feeds.

SECONDARY:

To study the effect of oromotor stimulation frequency on:

1. Weekly weight gain
2. Length of hospital stay

REVIEW OF LITERATURE

1. Prematurity- Magnitude of the problem and it's issues

Prematurity, which affects more than 10% of live births worldwide each year, is regarded as a serious global health issue^{5,6}. Patients, families, and the healthcare system are heavily burdened by the pulmonary morbidities and neurological impairments associated with preterm.⁷

1.1. Complications of Prematurity:

Preterm delivery complications result from premature organ systems that are not yet prepared to support life in the extrauterine environment. Preterm babies are more likely to experience respiratory distress syndrome, chronic lung disease, intestinal damage, weakened immune systems, cardiovascular issues, visual and hearing impairments and neurological insult.

(Table 1).

Table 1: Complications of prematurity

Immediate complications	Short term complications	Long term complications
Respiratory distress syndrome	Feeding and growth difficulties	Cerebral palsy
Intraventricular hemorrhage	Retinopathy of prematurity	Sensorineural deficits
Necrotising enterocolitis	Infections	Behavioural abnormalities
Patent ductus arteriosus		Chronic lung disease
Apnoea of prematurity		Incomplete catch up growth
Metabolic complications like hypoglycemia, hypocalcemia		
Feeding issues		

1.2. Feeding Problems in the Neonatal Period

The phrase “feeding problems” is often used to describe a diverse group of conditions resulting in inadequate nutritional intake orally and could range from oral feeding difficulties, gastroesophageal reflux (GER), dysmotility, and even systemic illnesses, unfortunately contributing to the lack of a uniform definition for feeding problems.

Preterm neonates might face certain problems while oral feeding is attempted such as, weak, irregular rooting reflexes and sucking, inverted lower lips drew inward during breastfeeding.^{7,8} In later life, preterms may show signs of swallowing disorders requiring special attention such as incoordination between sucking and swallowing, weak feeding, alterations in breathing or apnea during the feed, excessive gagging or frequent coughing during the feed, dysphagia, marked irritability, nasal regurgitation, lethargy during the feed, undernutrition and failure to thrive.⁹⁻¹¹

Preterm infants, especially those born <32 weeks, are exposed to multiple life-saving interventions during their NICU stay that contribute to noxious orofacial sensory stimulation during a time of physiologic maturation.

Additionally, during such a vital period of brain development, prolonged oxygen supplementation due to respiratory illnesses like respiratory distress syndrome (RDS) and bronchopulmonary dysplasia (BPD), brain injury (intraventricular hemorrhage, periventricular leukomalacia, also known as hypoxic damage, surgeries, underlying craniofacial deformities, and complicated medical conditions like necrotizing enterocolitis (NEC) can all modify oral sensory and motor experiences that affect normal sucking. and swallowing development. Feeding, Prematurity, pulmonary and neurological issues all have intricate interactions that are separately associated with impairments in neurodevelopment (Figure 1).

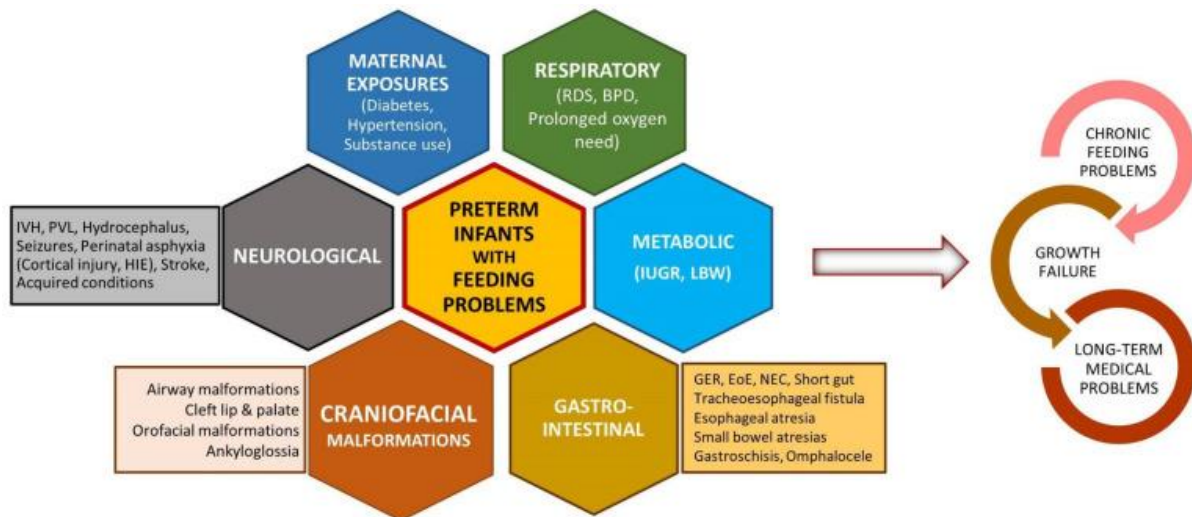


Figure 1: Risk factors: Common clinical conditions associated with feeding problems in preterm infants. (BPD: bronchopulmonary dysplasia, EoE: eosinophilic esophagitis, GER: gastroesophageal reflux, HIE: hypoxic ischemic encephalopathy, IUGR: intrauterine growth restriction, IVH: intraventricular hemorrhage, LBW: low birth weight, NEC: necrotizing enterocolitis, PVL: periventricular leukomalacia, RDS: respiratory distress syndrome).

1.3. Physiology behind feeding problems:

The oral, pharyngeal and esophageal phases are the three stages of mature swallowing.

Infancy's oral phase is characterized by sucking that leaves a vacuum. During the pharyngeal phase, an instinctive swallowing response is activated as the bolus is pushed towards back of the oral cavity. The pharyngeal swallowing reflex then triggers a series of events. The swallow is completed when the bolus enters the esophageal phase, which sets off a sequence of events that send the bolus into the stomach.

- **Disruptions to the Oral phase:**

Premature neonates' oral phase is altered by sustained outside stimulus, non-invasive respiratory support interfaces, oral or nasal endotracheal tubes, orogastric or nasogastric tubes, adhesives, and fastening devices.

Ineffective formation and propulsion of bolus, dribbling during feeding, weak and disorganized sucking, and other subtle to overt signs from an aberrant oral phase are caused by immature or absent oral reflexes^{12,13} (Figure 2). Concerns about breastfeeding failure are also common.

- **Disruptions to the pharyngeal phase:**

The swallowing mechanism and respiratory efficiency are closely related. Since the only shared conduit between the digestive tract and the airway during swallowing is the pharynx, feeding requires a coordinated response between breathing and swallowing.¹⁴

A delayed swallow initiation or aberrant swallow reflex can cause immature sucking, swallowing, and breathing coordination during feeding, which can jeopardize airway safety and lead to aspiration. Sucking–swallowing–breathing incoordination can present with choking, gagging, apneas, bradycardia, or desaturations during feeding¹⁵ (Figure 2).

- **Disruptions of Esophageal phase:**

Jadcherla and colleagues have previously demonstrated that preterm infants' pharyngeal reflexive swallow and pharyngo-lower esophageal sphincter reflex are less developed and immature than those of term infants¹⁵. Non-peristaltic esophageal motility and retrograde esophageal peristalsis both have an impact on abnormal esophageal clearance in preterm children¹⁶.

Food boluses can reflux upward in the esophagus and reach the airway due to immaturity or compromised esophageal swallow reflexes. The stomach acid refluxes and can irritate the esophageal mucosa leading toodynophagia. Dysphagia is

frequently a sign of feeding aversion. To some extent, the esophageal mucosal bicarbonate secretion provides defense against gastric reflux disease (GER); nonetheless, it might be compromised by the intensity and volume of GER (Figure 2).

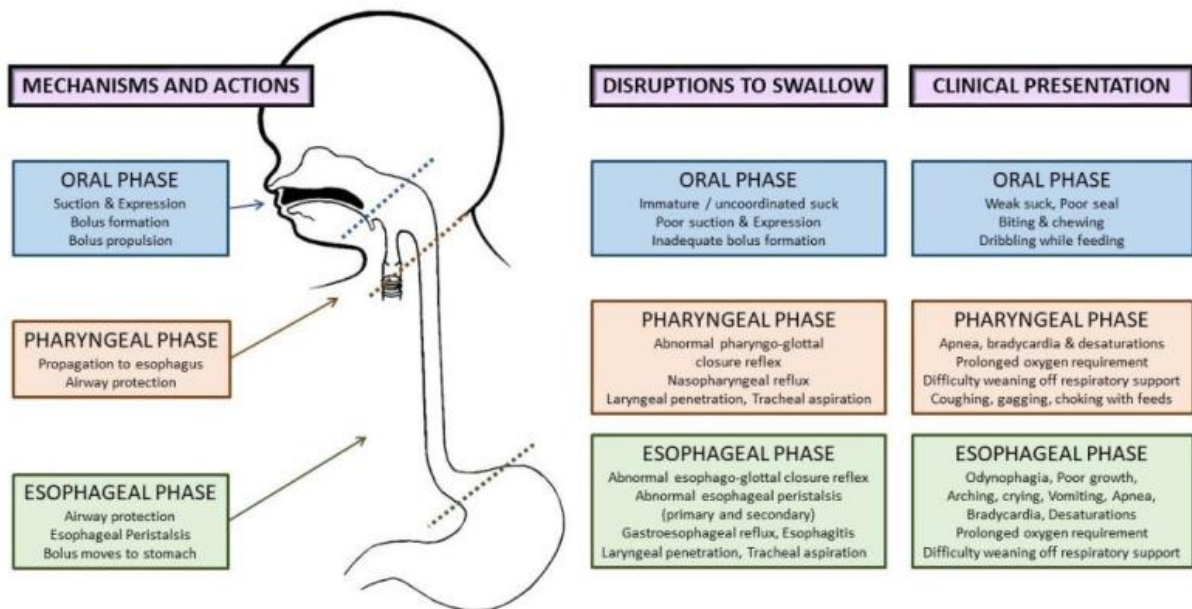


Figure 2: The etiopathophysiology of dysphagia in preterm infants: normal swallowing phases, swallowing disturbances, and neonatal clinical presentation.

1.4. Impact of feeding problems:

- **Immediate impact:**

Feeding issues in neonatal period can appear in a variety of clinical ways like weak suck, regurgitation, apnoea, gagging, prolonged respiratory support (Figure 2) leading to:

- Inadequate nutritional intake which in turn leads to poor growth and neurodevelopment.
- Increased length of hospitalization causing a financial burden and also increased risk of hospital acquired infections.
- Compromised airway safety leading to increased risk of aspiration and sudden death¹⁶.

- **Late impact:**

Growing preterm infants with residual feeding issues can exhibit a wide range of phenotypes, such as feeding tube dependency, non-specific feeding difficulties, feeding aversion, oral aversion, poor progression to solid foods and mild swallowing difficulties¹⁷.

Since the brain pathways for speech and feeding are intricately related, speech and language deficits are frequently seen in these newborns, who also have feeding difficulties. Infants with a feeding issue are more likely to experience linguistic difficulties in early infancy, according to research by Adams-Chapman et al. ¹⁸. For these infants, an early referral to speech therapy is recommended.

2. Approach to Oral Feeding Issues

In order to optimize treatment, feeding issues must be continuously assessed, intervened with, and reevaluated as the infant grows. In order to reduce potential long-term effects, early identification and treatment of feeding issues is essential (Figure 3) ¹⁹.

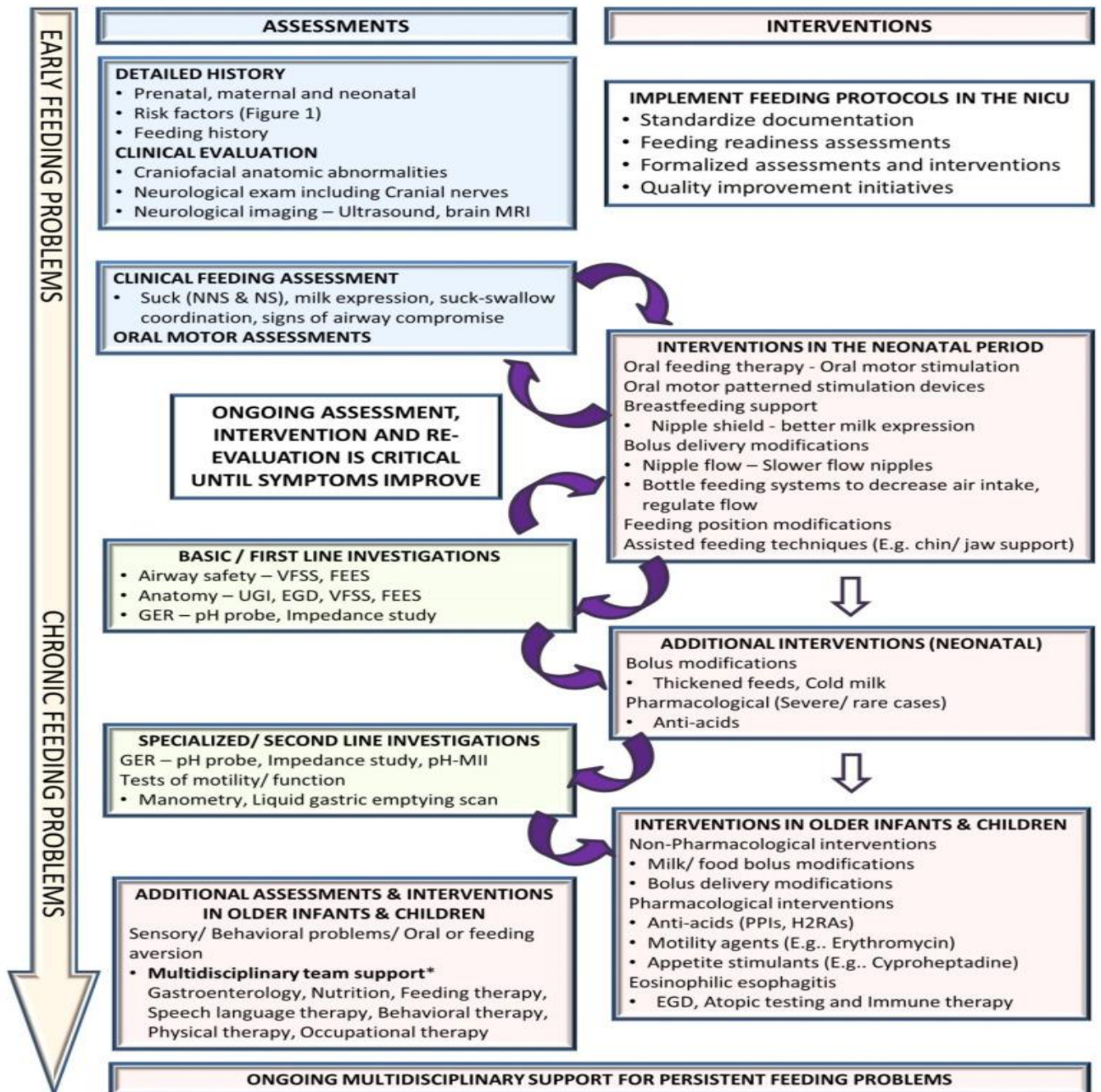


Figure3: Approach to a preterm infant with feeding problems. (EGD: esophagogastroduodenoscopy, FEES: fiberoptic endoscopic evaluation of swallowing, GER: gastroesophageal reflux, H2RA: H2-receptor antagonists, MRI: magnetic resonance imaging, NICU: neonatal intensive care unit, NNS: non-nutritive suck, NS: nutritive suck, pH-MII: pH monitoring multichannel impedance, PPIs: proton pump inhibitors, UGI: upper gastrointestinal fluoroscopy, VFSS: videofluoroscopic swallow study).

2.1. Clinical Assessment:

Table 2: Clinical assessment of feeding problems

History	Examination	Assessment
Antenatal history	Head to toe examination	Neurological imaging
Birth history	Neurological with cranial nerve assessment	Infant driven feeding scales (IDFS) ²⁰
Postnatal history	Other systemic examination	Oral feeding skills scale (OFS) ²¹
Feeding history	Focus on suck swallow coordination	Neonatal feeding assessment scale (NFAS) ²²
		Neonatal oral motor assessment scale (NOMAS) ²³

2.2. Non-Pharmacological Interventions:

In order to fully comprehend the complexities of feeding problems associated with prematurity and the intricate interactions between various comorbidities, having multidisciplinary feeding teams that comprise physical therapy, speech pathology, neonatology and occupational therapy is imperative. Oral motor therapy is an essential element for the improvement of readiness to start feeding ²⁰.

Other interventions include:

- **Non-nutritive sucking:**

Non-nutritive sucking (NNS) occurs in the absence of nutrient flow, serving to fulfil an infant's innate sucking instinct or as a means of state regulation. Pacifiers are instrumental in non-nutritive sucking, serving as a substitute for thumb sucking, a behaviour documented to start as early as 12 weeks into gestation. Other methods of non-nutritive sucking include using a gloved finger or an empty breast. ²⁴

The reasoning behind this intervention lies in the fact that non-nutritive sucking aids in the advancement of sucking patterns and enhances the digestion of enteral feeds. Several enzymes and hormones are thought to contribute to improved digestion during non-nutritive sucking, including lingual lipase, gastrin, insulin, and motilin. It is believed that these hormones and enzymes are released by vagal stimulation when non-nutritive sucking occurs. ²⁴

- **Abdominal massage:**

Studies have demonstrated that abdominal massage offers therapeutic benefits, serving as safe, non-invasive and non-pharmacological nursing care. It holds promise in decreasing gastric residual volume by stimulating parasympathetic activity, thereby

enhancing intestinal peristalsis, reducing abdominal distension, mitigating vomiting frequency and improving gastric motility.²⁵

- **Tactile stimulation:**

A gentle stroking massage is administered for a specific duration, sequentially targeting upper and lower body parts while the individual is in a supine position.

Tactile stimulation is employed to activate muscles and organ systems, thereby stimulating the vagus nerve. This stimulation enhances the efficiency of intestinal peristalsis, leading to quicker gastric emptying and increased satiety in infants.

Additionally, massage therapy enhances blood circulation and metabolic rate.²⁵

- **Olfactory-gustatory interventions:**

Familiarizing the neonate with breastmilk odor by placing mother's breast pad nearby or putting a small drop of breast milk on the tongue tip or lips.

2.3. Pharmacological Interventions:

In the newborn period, pharmacological interventions are usually reserved for the treatment of GER symptoms and are usually the final choice. Anti-acids have a restricted role and should only be used to treat GER after non-pharmacological methods have failed.

Dysmotility associated with severe feeding intolerance has been treated with motility drugs like erythromycin.²⁶

3. Oromotor stimulation

Oromotor stimulation is one of the non-pharmacological ways to deal with feeding issues and is the intervention that has been used in the study. It helps neonates develop sucking and oromotor co-ordination thus promoting earlier oral feeding.

3.1. What is Oromotor stimulation?

It is a scientific, sequential measure in which patterned stimulation is provided to perioral and intraoral muscular structures for strengthening them, thus facilitating normal physiologic feeding patterns.

3.2. History of oromotor stimulation:

- In the 1970s, speech-language pathologists began collaborating with physiotherapists, occupational therapists and other medical specialists. Through the sharing of ideas, the clinical concept of using oral motor therapy in clinics, hospitals and schools was initiated.
- Oral-motor therapy may have started with a three-day seminar on "Oral-motor function and dysfunction in children" in 1977.
- 1993 onwards research articles by the speech language pathologists and occupational therapists came in the area of oral motor therapy in preterm neonates.
- Dr. Brenda Knoll Lessen, a nurse, attempted the first application of oromotor therapy in the treatment of premature newborns in 2008.

3.3. Impact of oromotor stimulation:

Impact of Oromotor stimulation when given to preterm at least 5-15 minutes before feeding include:

- Stretches, improves the tone and length of facial muscles.
- Improves flexion of the lips for mouth closure and puckering.
- Stimulation to the tongue changes the movement of the tongue.
- Reduces pauses in sucking thus improves the frequency of sucking.
- Increases rate and volume of intake during feeds.
- Reduces transition time to exclusive breastfeeding.

3.4. Indications of oromotor stimulation in neonates:

The literature shows that oromotor stimulation can be provided to:

- Preterm neonates born at the gestational age of <29 weeks and it can be until effective oral feeding is achieved.
- Regardless of gestational age, newborns exhibiting abnormal breathing, swallowing, and sucking coordination.
- Neonates with existing brain damage due to birth asphyxia, intraventricular hemorrhage, or other clinical causes.
- Neonates at risk of being deprived of oral feeding due to various clinical co-morbidities (e.g. congenital heart disease at early neonatal life, severe congenital anomalies).

3.5. Prerequisites for oromotor stimulation:

There isn't a single accepted method for giving newborns oromotor stimulation. There are several schools of thought that follow different techniques. However, the newborn must be positioned in a supine or side-lying position at least 10 to 20 minutes before feeding in order to prevent aspiration owing to a gag reflex. This should be done before providing intervention. ²⁷⁻³¹

The pre-requisites for prefeeding oromotor stimulation for preterms are as follows:

- The parents must be given sufficient information about the use of oromotor therapy, its advantages and any potential side effects.
- Throughout the treatment, vital signs should be continuously monitored to identify apnoeic episodes.
- Even when giving nonnutritive sucking to a baby, gloves should be worn to prevent the transmission of infection. If the baby doesn't tolerate the therapy then immediately discontinue.

3.6. Procedure for providing Oromotor stimulation:

In neonatal intensive care units, oromotor stimulation is currently administered manually. The protocol is currently in its early stages of development and does not have a set application frequency.

The Premature Infant Oral Motor Intervention (PIOMI) was adapted by Dr. Brenda Leessen from the Beckman Oral Motor Intervention (BOMI). A 15-minute oral motor intervention called the BOMI is used with newborns and children who had developmental delays and

feeding issues. In order to better serve premature infants, BOMI was created with their physiological needs, safety, and tolerance in mind.

A five-minute assisted movement known as Premature Infant Oral Motor Intervention (PIOMI) is used to stimulate muscular contraction and increase oral cavity strength by moving against resistance. (Figure 4)

The mouth's cheeks, lips, gums, tongue, and palate are among the target regions. It can be administered by any direct care provider of neonates to preterm newborns who are at least 29 weeks postmenstrual age (PMA) using a gloved finger in their mouths.

PIOMI PREMATURE INFANT
ORAL MOTOR INTERVENTION

8 Steps	Technique	
Cheek C - Stretch (30 Sec.)	One finger in the cheek and one outside cheek. Slide and stretch tissue front to back toward the ear, & back to front. Move slowly. Do both cheeks twice.	
Lip Roll (30 Sec.)	Gently roll the lip between your thumb and finger (like rolling a pea). Roll both sides of upper lip once. Roll both sides of lower lip once.	
Lip Curl or Lip Stretch (30 Sec.)	Compress lip between thumb and finger, and curl downward. Curl both sides of upper lip once, and both sides of lower lip once. If lip is too small to grip for the curl, do the Lip Stretch: Lay finger across upper lip, gently compress and stretch side to side. Repeat on lower lip.	
Gum Massage (30 Sec.)	Use finger to put gentle pressure on outside of upper gum. Move finger slowly around upper gum to other side of mouth. (Be sure to touch outer gum surface, not biting surface.) Repeat on lower gum.	
Lateral Borders of Tongue/ Cheek (15 Sec.)	Put finger beside tongue and push to the middle. Then move finger back into cheek, stretching it. Repeat on the other side of tongue/cheek.	
Midblade of Tongue/ Palate (30 Sec.)	Use finger to put pressure on roof of mouth for 3 seconds. Move finger down to tongue and gently press tongue down. Move finger back up to hard palate. Repeat these movements twice.	
Elicit a Suck (15 Sec.)	Put finger or pacifier on tongue and gently stroke to allow sucking.	
Support for Non-Nutritive Sucking (2 Min.)	Allow sucking on finger or pacifier for 2 minutes.	

Figure 4: Premature Infant Oral Motor Intervention (PIOMI)

4. Effect of oromotor stimulation among preterm neonates:

Long-term oral feeding issues increase medical costs, lead to aversion to feeding, and stress the mother, all of which complicate the reunion of the mother and child.

There is currently no direct tool to measure the oral feeding readiness among preterms, hence research is needed to establish an evidence base for the therapeutic efficacy of intervention and to adopt their usage to assess feeding readiness in the preterm infant population.^{32, 33}

Published research indicates that when oromotor stimulation is given to preterm neonates, they begin oral feeding earlier, have better sucking frequency, feed better overall in terms of intake and milk transfer rate, transition to independent oral feeding more quickly, gain weight more quickly each day, switch from spoon feeding to breastfeeding earlier, spend less time in the hospital, and perform better on the Infant Neurological International Battery (INFANIB) score-an assessment tool for early motor development.³⁴⁻³⁶

4.1. Effect on transition time:

In a study by Senay arasdoğan et al., enrolled 77 preterm infants into experimental group (n = 39) who received oral motor stimulation and control group (n = 38) who received routine care. The findings indicated that the experimental group had a shorter transition period to full oral feeding (P=0.010) and higher LATCH scores (P=0.001) than control group. They concluded that preterm babies that received oral motor stimulation were able to start full oral feeding earlier and had greater sucking success.³⁷

Chun-Chi Huang et al., randomly assigned 46 preterm infants to the oral stimulation and routine care group in order to assess the impact of PIOMI on feeding readiness. The Preterm

Oral feeding Readiness Assessment Scale (POFRAS) was used to assess feeding readiness on Day 1 (baseline), Day 3, and Day 7. While the baseline POFRAS scores showed no significant differences between the 2 groups, the oral stimulation group had better score on Days 3 and 7, thus demonstrating the impact of OMS on feeding readiness.³⁸

Nilay Comuk Balci et al., conducted a where the intervention group (20) underwent a 1 month oral-motor therapy program, while the control group (20) did not. The Early Feeding Skills Assessment Tool (EFS) and the Preterm Oral Eating Readiness Scales (POFRAS) were used to evaluate the feeding abilities. The EFS and POFRAS scores and transition to breast feeding after discharge were significantly different ($p < 0.05$) between the groups. Though the time required to transition to full enteral feedings did not differ significantly ($p > 0.05$), there were notable differences in the type and style of feeding at discharge for the intervention group.³⁹

4.2. Effect on weight gain:

A study was conducted by Pari Singh et al., where 84 neonates were included and randomised into 2 groups of 42 each into Premature Infant Oral Motor Intervention (PIOMI) and Oromotor Stimulation (OMS) groups. The PIOMI group experienced an average weight increase of 4.9 g/kg/day ($p < 0.05$) and had greater exclusive breastfeeding rates at one month and three months post-discharge, by 24.7% ($p = 0.01$) and 24.5% ($p = 0.02$) respectively than OMS group. The duration of hospital stay was reduced by 8 days, and the transition time to full oral feeding was lowered by 2 days for PIOMI group. Authors concluded that PIOMI is a more effective oromotor stimulation method that encourages earlier and better oral feeding in preterm infants.⁴⁰

The impact of oromotor stimulation on feeding performance and weight gain was evaluated in selected hospitals in Kolkata through a randomized control trial of 60 preterm babies (30 into intervention and 30 into control). The results showed a significant difference in pre and post intervention weight and breastfeeding performance of preterm babies between day 1 and day 7 in the intervention group ($P < 0.05$), thus concluding that oromotor stimulation is effective in improving feeding performance and weight gain of preterm babies.⁴¹

In a trial at the KAHER Institute of Physiotherapy, Belagavi, 42 low birthweight preterm infants were randomised equally into intervention and control group. The intervention group received oromotor stimulation for 21 days, while the control group received standard care. The findings showed that, in comparison to the control group, oromotor stimulation significantly increased LATCH scores and hastened the transition from spoon-feeding to breastfeeding in the intervention group ($P < 0.05$). There was no statistically significant difference in weight gain between the two groups.⁴²

4.3. Effect on duration of hospital stay:

A randomized control trial was carried out on 40 premature infants admitted to the NICU of Hospital in Iran where the subjects were equally allocated to intervention and control groups. In the intervention group, 5-minute oral stimulations were performed based on premature infant oral motor stimulation on a daily basis and control group received routine care. Results showed that the intervention group achieved independent feeding significantly earlier than the control group ($P=0.034$). In addition, the duration of hospitalization was shorter in the intervention group, compared to that of the control group ($P=0.027$).⁴³

Sherihan Fathey et al., conducted a case control study to evaluate the impact of oromotor sensory stimulation on the clinical outcomes of 100 premature infants where study group of 50 preterms received oromotor stimulation whereas control group of 50 preterms received routine care. It was observed that weight gain ($P < 0.000$), length of hospital stay ($P < 0.000$), and transition time from gavage to full oral feeding ($P < 0.000$), were all improved by applying oral sensory motor stimulation.⁴⁴

Suvashri Sasmal et al. conducted a study in which 120 preterms were randomly assigned to intervention (OMS) and control group of 60 each. Study finding showed the intervention group was able to achieve independent oral feeding faster ($p < 0.001$) and spent less time in the hospital ($p < 0.05$) than the control group. However there was no significant difference in weight gain during their hospital stay. Thus the study findings demonstrated positive impact of oromotor stimulation.⁴⁵

MATERIALS AND METHODS

The study was conducted in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi affiliated to JN Medical College, Belagavi from January 2023 to December 2023.

Study design

A Randomised Clinical Trial

Study period

One year (January 2023 to December 2023)

Place

KLES Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi, a teaching hospital affiliated to Jawaharlal Nehru Medical College, Belagavi.

Source of data

Preterm neonates (30-34 weeks) admitted to the NICU of KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, affiliated to Jawaharlal Nehru Medical College, Belagavi.

Sample size

The formula used for sample size calculation is,

$$n = \frac{2 \left(Z_{1-\frac{\alpha}{2*k}} + Z_{1-\beta} \right)^2}{f^2}$$

$$\text{where, } f = \left(\frac{\min(|\mu_i - \mu_j|)}{\sigma} \right)$$

where, μ_i is mean of i th group, μ_j is mean of j th group, σ^2 is the common error variance, $Z_{1-\frac{\alpha}{2*k}}$ is Z score adjusted for α level of significance (Bonferroni Correction), k is the number of pairwise comparisons and $Z_{1-\beta}$ value is Z score for $(1-\beta)$ % power.

Assuming between group effect size to be 0.5, at 5% level of significance, and 80% power, the sample size is obtained to be 28 subjects for each group. Hence, total sample size required is $28 \times 3 = 84$ subjects.

Considering 10% follow-up loss, the sample size will be 31 subjects for each group. Total sample size required is $31 \times 3 = \mathbf{93}$ subjects.

Ethical clearance

Prior to the commencement, study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi.

Eligibility

Inclusion criteria

- 1) Inborn babies between 30-34 weeks of gestation
- 2) Babies on minimal respiratory support (CPAP with FiO_2 of less than 40%, PEEP ≤ 5 and duration less than 48 hours)
- 3) Willing to participate in the study

Exclusion criteria

- 1) Newborns clinically unstable (on ventilatory support, CPAP with Fio2 of more than 40% or duration more than 48 hours and requiring inotropes)
- 2) Major congenital anomalies (craniofacial malformation, hypoplastic left heart, neural tube defect, congenital diaphragmatic hernia, intestinal obstruction etc.)
- 3) Necrotizing enterocolitis stage 2 and 3
- 4) Perinatal asphyxia with HIE stage 2 and 3
- 5) Any other conditions where oral feeding is contraindicated
- 6) If the intervention could not be provided for 7 days due to any reason

Methodology

Data collection procedure: Neonates who met the eligibility criteria were enrolled into the study after obtaining written informed consent from parents. Maternal and neonatal data was collected in a structured proforma.

Maternal data

Name, Age, Inpatient number, Last menstrual period (LMP), Expected date of delivery (EDD) and Gestation period.

Neonatal data

Demographic details included inpatient number, Sex, Date and Time of birth, Admission and Discharge date.

Gestational age (week), Birth weight (gm), Weight at admission (gm), weekly weight gain(gm), weight at discharge(gm) were also recorded.

Intervention assignment

Eligible neonates were allocated to three study groups by sequential sampling according to date and time of birth (1 to A,2 to B,3 to C,4 to A,5 to B,6 to C.....)

Group A: OMS was provided once a day

Group B: OMS was provided two times a day

Group C: OMS was provided three times a day

All the groups received care as per NICU protocol.

All the infants in the three groups were monitored from admission till discharge to capture the following study outcomes: Transition time to full oral feeds (150-180ml/kg/day); Weekly weight gain and length of hospital stay.

Length of hospital stay, defined as duration from date of admission to date of discharge

Weight was recorded using digital weight scale

Intervention

Premature Infant Oral Motor Intervention (PIOMI) is a 5-minute procedure that consists of following steps: cheek-C stretch, Lip roll, Lip curl or Lip stretch, Gum massage, lateral borders of tongue, mid blade of tongue. Elicit a suck.

Infants received oromotor stimulation by investigator or mother or nursing staff who were trained to deliver intervention through a video and handouts of the procedure. Frequency of intervention provided was as follows: **Group 'A' once a day (10 am), Group 'B' twice a day (10 am, 1pm) and Group 'C' three times a day (10 am ,1 pm, 4 pm)** for seven successive days using gloved fingers under all sterile precautions. Intervention was performed during day time 20 minutes before feeding, for 5 minutes. A monitoring chart was used to record intervention provided as per schedule.

OMS was discontinued if the infants became unstable (had desaturation or apnea or bradycardia during the intervention) and was restarted when the baby became stable to complete remaining days of intervention.

Statistical analysis

The data was coded and tabulated on excel spreadsheet and master chart was prepared. The data was analysed using statistical software R version 4.2.0 and Microsoft Excel. Frequency tables were used to represent categorical variables. The Mean \pm SD was used to represent continuous variables. Chi-Square test was employed to check the association between attributes. The means/distributions between the groups were compared using the one-way ANOVA test. P-value less than or equal to 0.05 indicates statistical significance.

RESULTS

This study was conducted on preterms with gestational age of 30-34 weeks. A total of 102 subjects were screened out of which 93 eligible participants were enrolled and randomized into three groups of 31 each. All 93 were followed up till discharge with no loss to follow up (Figure 5).

Figure 5: Consort diagram

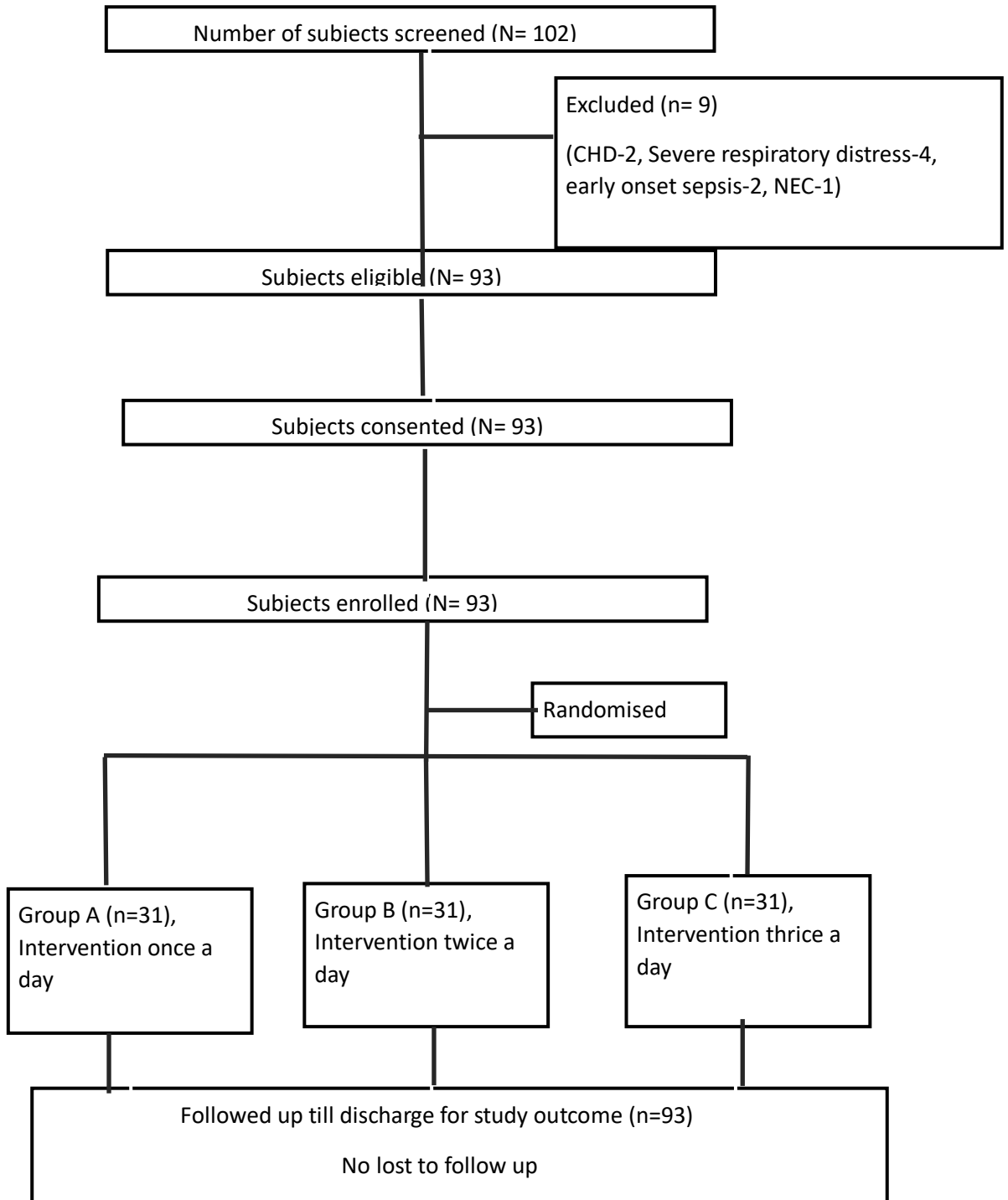


Table 3: Maternal age distribution across the study groups

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Maternal Age (years)	18 to 25	18 (58.10)	18 (58.10)	20 (64.50)	56 (60.20)
	26 to 30	10 (32.30)	10(32.30)	8(25.80)	28(30.10)
	>30	3 (9.70)	3 (9.70)	3 (9.70)	9 (9.70)
Total		31	31	31	93(100)

P =0.980

In our study, 60.2% participants were in 18 to 25 years range, 30.1% in 26 to 30 years range and 9.7% more than 30 years. No statistically significant difference is noted in age distribution across the study groups. (P=0.980)

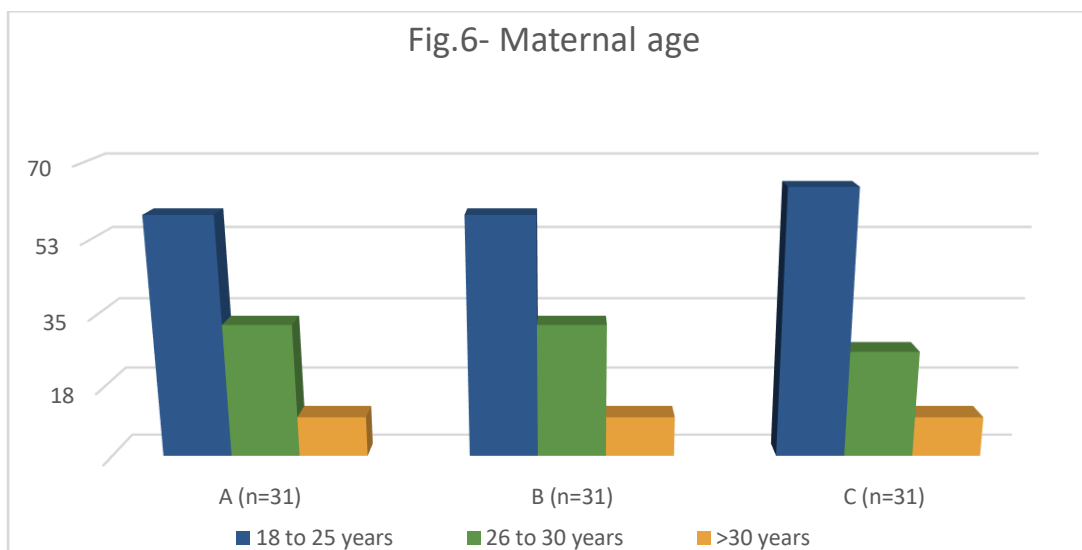


Table 4: Gender distribution across study groups

	Study Groups (N=93)			Total (%)
	A n (%)	B n (%)	C n (%)	
Female	14 (45.2)	15 (48.4)	20 (64.5)	49 (52.7)
Male	17 (54.8)	16 (51.6)	11 (35.5)	44 (47.3)
Total	31	31	31	93 (100)

P=0.263

In our study, females accounted for 52.7%, and males 47.3%, showing a relatively balanced distribution. Gender distribution shows no significant statistical difference across the groups. (P=0.263)

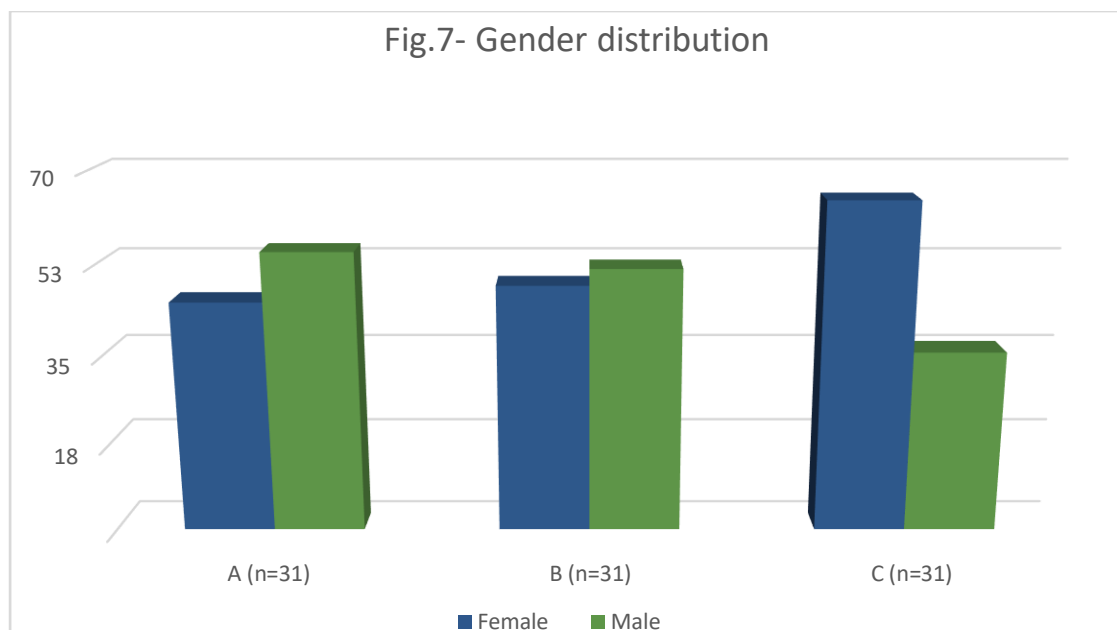


Table 5: CPAP duration across study groups

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
CPAP Duration (hours)	≤ 36	10 (32.3)	5 (16.1)	10 (32.3)	25 (26.9)
	37-48	2 (6.5)	3 (9.7)	2 (6.5)	7 (7.5)
	No CPAP	19 (61.3)	23 (74.2)	19 (61.3)	61 (65.6)
Total		31	31	31	93 (100)

P=0.590

There were 26.9% preterms who received CPAP for ≤ 36 hours, 7.5% for 37 to 48 hours, 65.6% did not receive CPAP and there is no significant difference among the groups. (P=0.590)

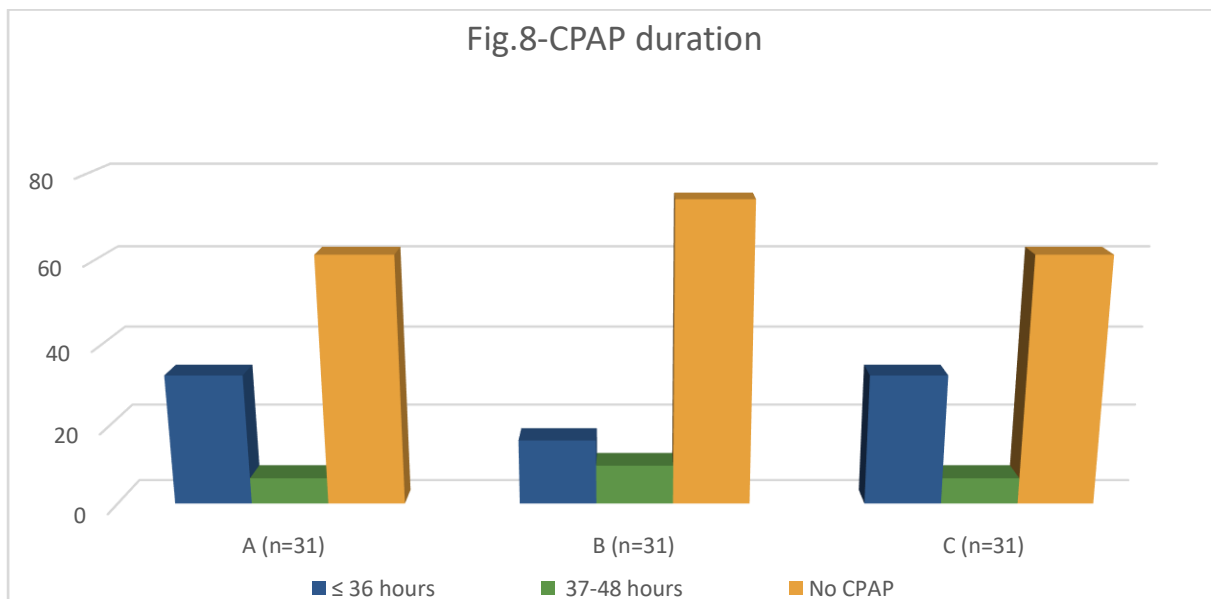


Table 6: Gestational age of study groups

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Gestational Age (weeks)	30-31 ⁺⁶	4 (13)	2 (6.4)	3 (9.7)	9 (9.7)
	32-33 ⁺⁶	25 (80.6)	24 (77.4)	26 (83.9)	75 (80.7)
	34	2 (6.5)	5 (16.1)	2 (6.5)	9 (9.7)
Total		31	31	31	93 (100)

P=0.856

In this study, 80.7% participants were born between 32 and 33⁺⁶ weeks, 9.7% between 30-31⁺⁶ weeks and 9.7% at 34 weeks. There is no statistically significant difference (P=0.856)

Fig.9-Gestational age

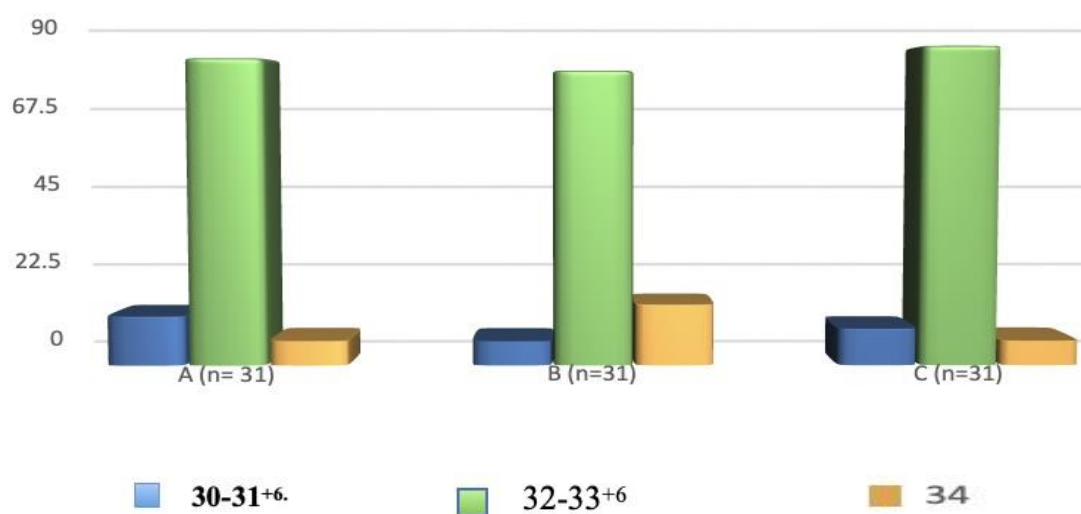


Table 7: Birth weight across study groups

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Birth Weight (grams)	≤1500	5 (16.1)	3 (9.7)	11(35.5)	19 (20.4)
	1501 to 2000	24 (77.4)	27 (87.1)	16 (51.6)	67 (72)
	>2000	2 (6.5)	1(3.2)	4(12.9)	7 (7.5)
Total		31	31	31	93 (100)

P =0.750

There is no significant variation in birth weight among the study subjects with 20.4% weighing less than 1500 grams, 72% between 1501 and 2000 grams, and 7.5% more than 2000 grams in our study. (P=0.750)

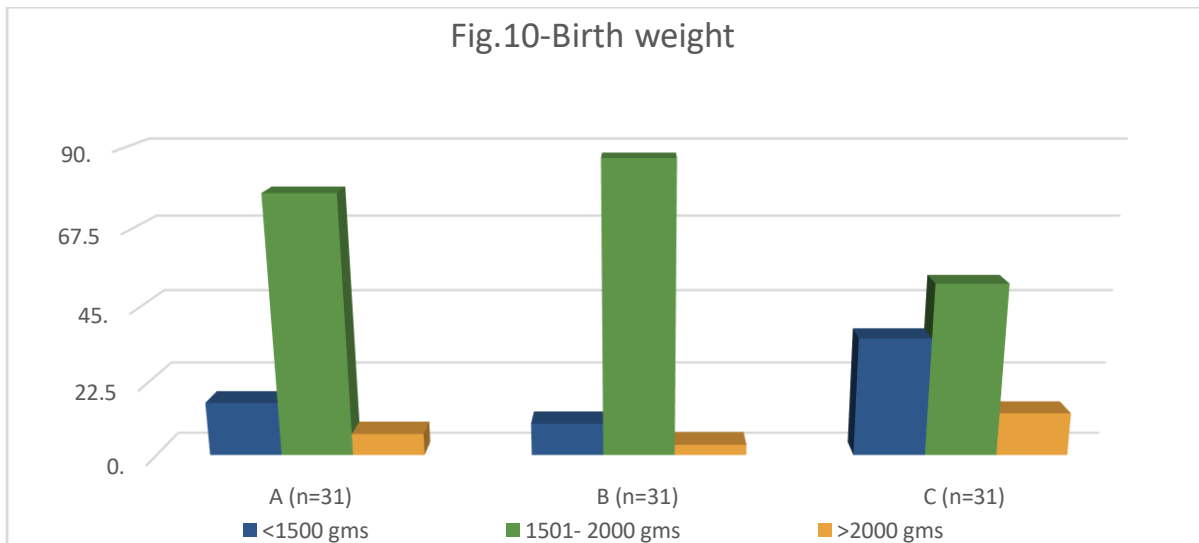


Table 8: Age of starting tube feeding

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Age (day)	1	20 (64.5)	23 (74.2)	19 (61.3)	62 (66.7)
	2	6 (19.4)	2 (6.5)	7 (22.6)	15 (16.1)
	3	4 (12.9)	6 (19.4)	5 (16.1)	15 (16.1)
	4	1 (3.2)	0 (0)	0 (0)	1 (1)
Total		31	31	31	93 (100)

P=0.467

On day one 66.7% subjects were started tube feeding, 16.1% each on day two and day three.

No significant difference is noted with respect to day of initiation of tube feed in our study.

(P=0.467)

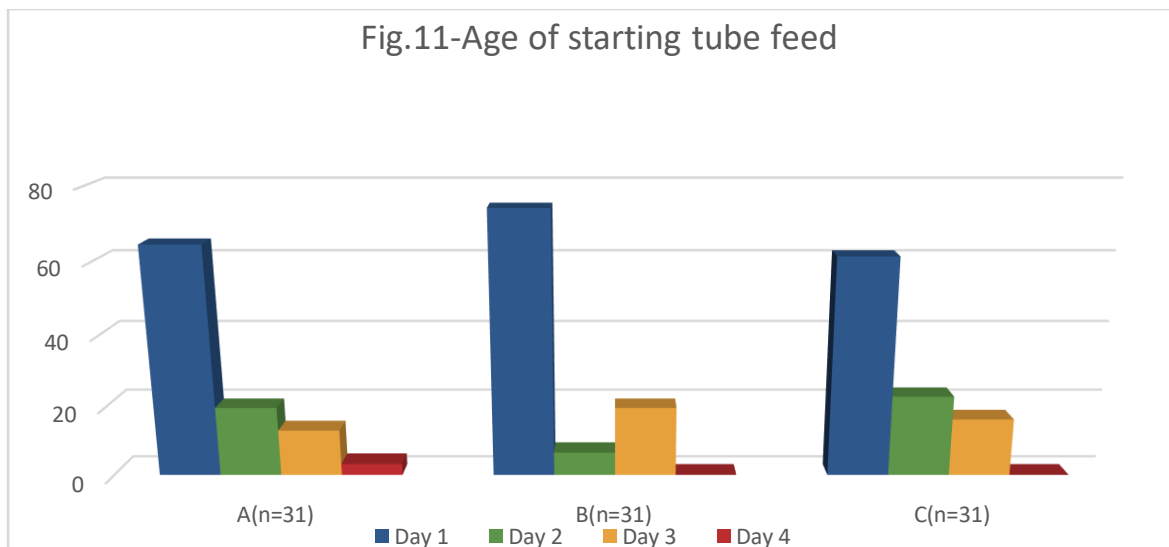


Table 9: Age of starting spoon feed

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Age (Day)	1- 3	6 (19.4)	15 (48.4)	18 (58.1)	39 (41.9)
	4-6	18 (58.1)	13 (41.9)	7 (22.6)	38 (40.9)
	7- 9	4 (12.9)	2 (6.5)	3 (9.7)	9 (9.7)
	> 9	3 (9.7)	1 (3.2)	3 (9.7)	7 (7.5)
Total		31	31	31	93 (100)

P=0.050

There is a significant difference in the time of spoon-feeding initiation across groups with 41.9% preterms on spoon feeding between 1-3 days, 40.9% between 4-6 days, 9.7% between 7-9 days and 7.5% taking more than 9 days. (P=0.050)

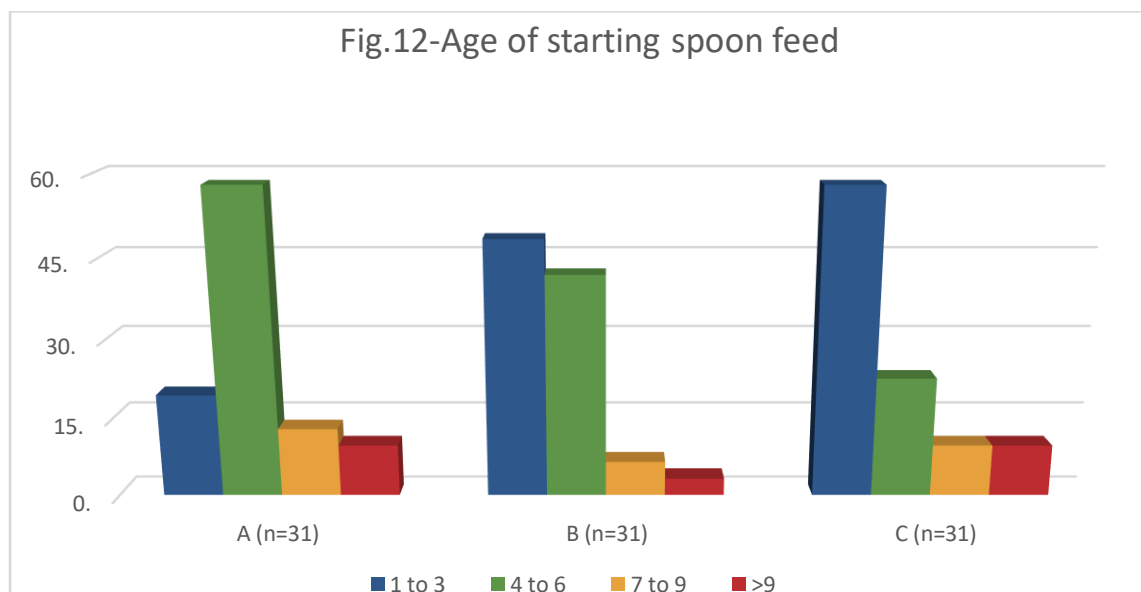


Table 10: Time taken to achieve full spoon feed

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Time (days)	≤6	13 (41.9)	25 (80.6)	24 (77.4)	62 (66.7)
	7-10	11 (35.5)	4 (12.9)	3 (9.7)	18 (19.4)
	11-15	4 (12.9)	1 (3.2)	4 (12.9)	9 (9.7)
	> 15	3 (9.7)	1 (3.2)	0	4 (4.3)
Total		31	31	31	93 (100)

P=0.013

Significant difference in the time taken to achieve full spoon feeding across groups is noted with 66.7% achieving in ≤6 days, 19.4% in 7-10 days, 9.7% in 11-15 days and 4.3% in more than 15 days. (P=0.013)

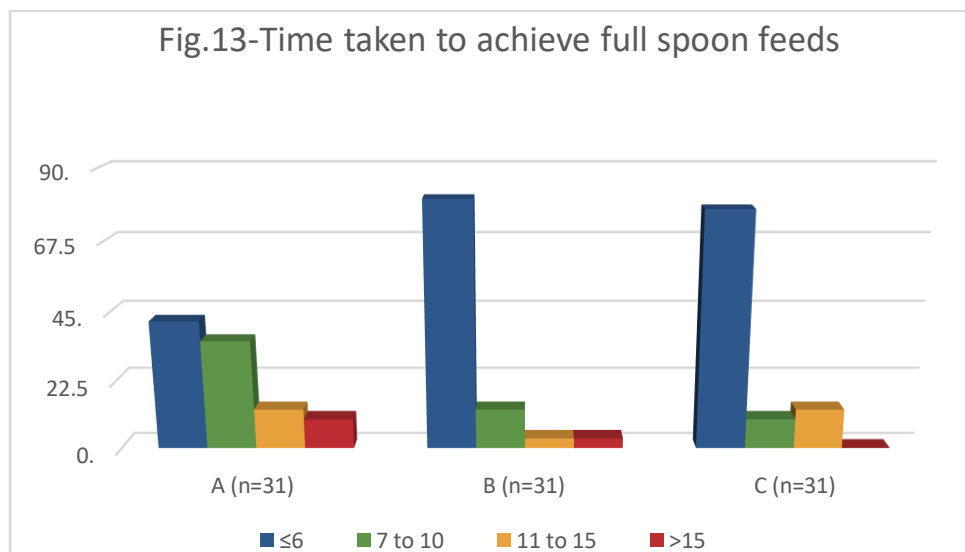


Table 11: Weekly Weight Gain Across Study Groups

Week	Study groups						P value
	Group A		Group B		Group C		
	Mean (n) (grams)	SD	Mean (n) (grams)	SD	Mean (n) (grams)	SD	
First	0 (31)	0	0.32 (31)	1.796	0.16 (31)	0.898	0.551
Second	77.42 (31)	28.921	80.65 (31)	24.757	74.19 (31)	28.957	0.656
Third	66.25 (16)	32.787	50.45 (11)	22.853	61.25 (8)	35.33	0.428
Fourth	86.25 (4)	37.97	107.50 (2)	7.50	78.75 (4)	46.82	0.713
Fifth	90.00 (3)	21.794	52.50 (2)	10.607	50.00 (1)	-	0.185
Sixth	30.00 (2)	10.0	0	0	0	0	-

Among the study groups, no significant statistical difference is noted in weekly weight gain in first ($p=0.551$), second ($p=0.656$), third ($p=0.428$), fourth ($p=0.713$), fifth ($p=0.185$) and sixth week.

Fig.14-weekly weight gain

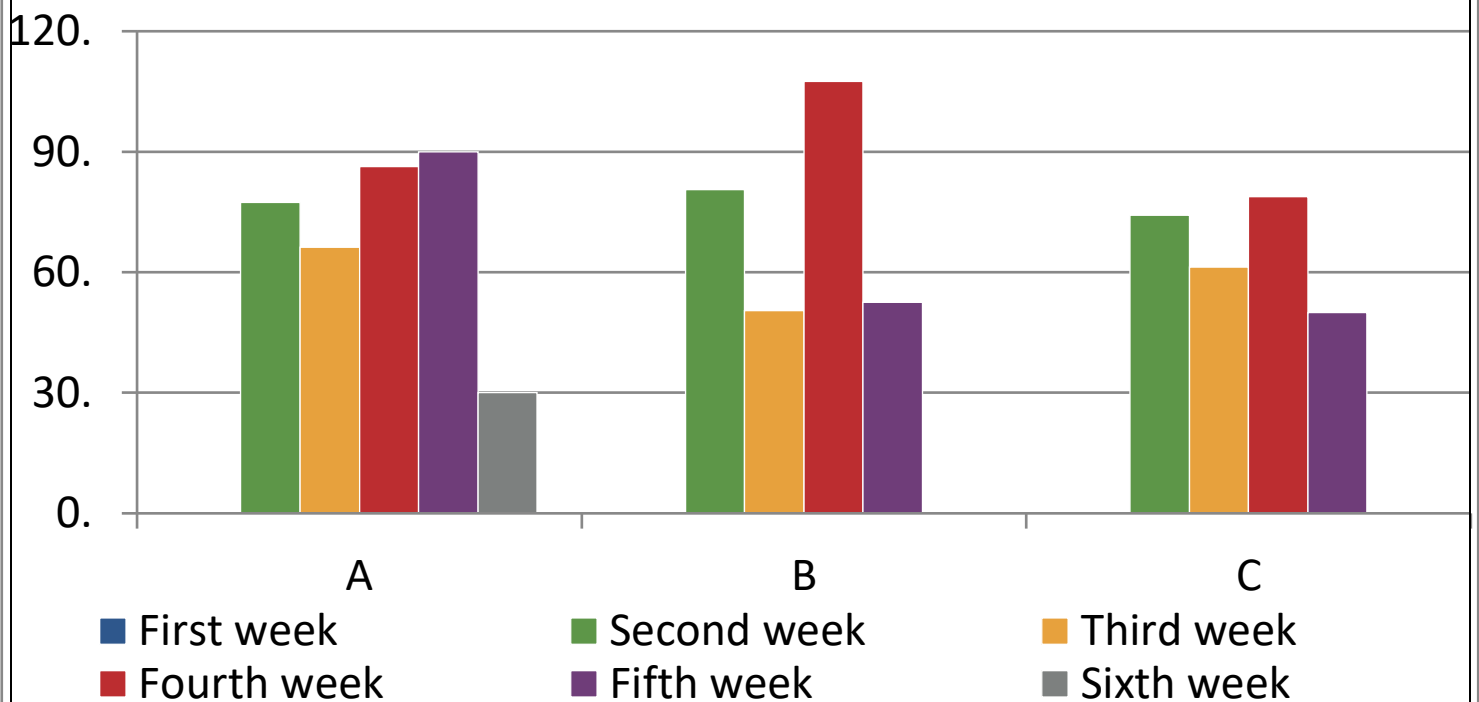


Table 12: Duration of hospital stay across study groups

		Study Groups (N=93)			Total (%)
		A n (%)	B n (%)	C n (%)	
Duration of hospital stay (days)	≤10	1 (3.2)	3 (9.7)	11 (35.5)	15 (16.1)
	11-20	26 (83.9)	26 (83.9)	16 (51.6)	68 (73.1)
	21-30	1 (3.2)	0	3 (9.7)	4 (4.3)
	31-40	3 (9.7)	2 (6.5)	1 (3.2)	6 (6.5)
Total		31	31	31	93 (100)

P=0.005

Significant difference in the duration of hospital stay across groups is noted with 16.1% stayed ≤10 days, 73.1% between 11-20 days, 4.3% between 21-30 days and 6.5% between 31-40 days.

(P=0.005)

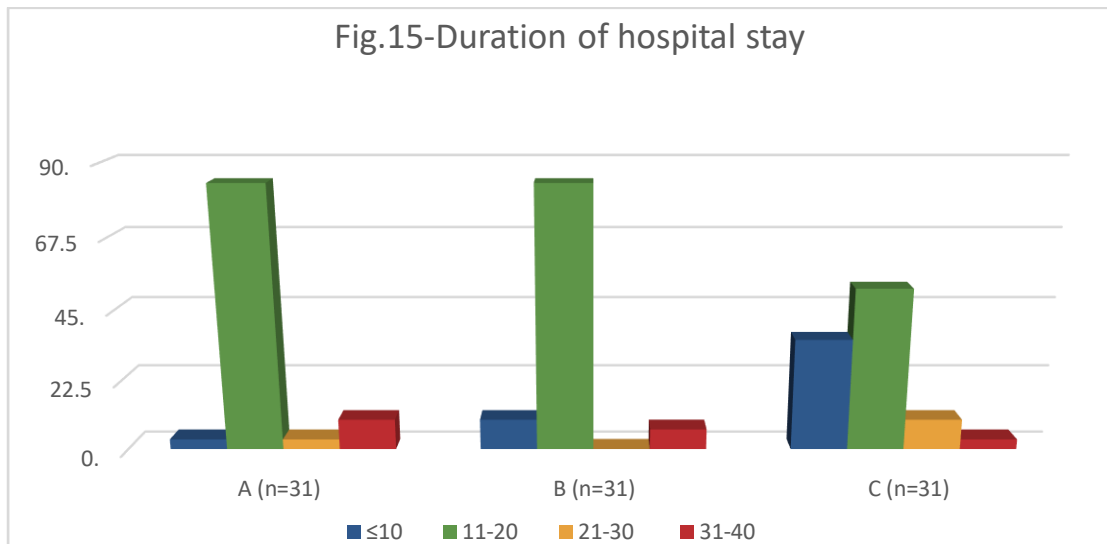


Table 13: Mean parameters across study groups

Parameters	Group A		Group B		Group C		P value
	Mean	SD	Mean	SD	Mean	SD	
Birth Weight (gram)	1690.5	227.5	1708.4	218.1	1660.0	301.9	0.747
Day of life spoon feed started	6.2	3.6	4.3	2.5	4.3	2.7	0.018
Time to achieve full spoon feeds (days)	8.48	4.114	5.84	2.505	5.55	3.118	0.001
Duration of hospital stay (days)	17.03	7.017	14.35	5.010	13.61	5.637	0.064

In our study, the study groups differed significantly with regard to starting spoon feed with Group A starting later when compared to Groups B and C (P-0.018) and thus Group A took longer time to reach full spoon feeding compared to Groups B and C. (P-0.001)

DISCUSSION

More than one out of ten babies born in the world are preterm which is the second leading cause of death. Throughout their stay in the neonatal intensive care unit (NICU), preterm babies must overcome a number of obstacles, such as infections, neurological disorders, and cardiorespiratory issues, all as they grow and meet the neurodevelopmental milestones necessary for NICU discharge.¹

In preterm neonates, optimal feeding is limited due to several reasons like illnesses, gut immaturity and inadequate suck, swallow and breathing in-coordination due to poor oromotor skills⁴⁶. Non-nutritive sucking, abdominal massage and Oromotor Stimulation (OMS) are some methods that help to deal with the feeding issues.

According to recent studies⁴⁷⁻⁴⁹, oromotor stimulation can help preterm neonates improve their sucking abilities and shorten the time taken them to achieve full oral (spoon/paladai) feeds^{50, 51}. The likelihood that more preterm newborns will be breastfed at discharge is likewise increased by OMS and nonnutritive sucking (NNS)⁵².

This study aims to evaluate the effect of oromotor stimulation frequency on transition time from tube feeding to full spoon or paladai feeds.

In the present study, gestational age, birth weight, sex distribution, maternal age and CPAP duration across study groups showed no statistically significant differences indicating that subjects participating in the study were comparable (Table 3,4,5,6,7). This ensures that study results are due to intervention and not related to difference in study participants.

This is consistent with the results of the study conducted by **Pari Singh et al.**, where gestational age and birth weight across the intervention and control group were similar.⁴⁰

The mean duration for achieving full spoon feeds was statistically significant in our study (Table 10). This shows that three times a day stimulation produces better results than once a day stimulation indicating decrease in transition time with increased frequency of intervention.

Although there are few studies that test the impact of frequency of oromotor stimulation on transition time, similar observations were made by **Poonam Bala et al.**, where the intervention group attained transition earlier than control group indicating that the intervention led to faster progress in achieving full feeds.⁵³

Findings of the studies by **Karine da Rosa Pereira et al. and Jaywant and Kale** support our study and also aligns with previous research reported in the literature, indicating that control group have a longer transition time from gavage to oral feeding compared to intervention group (OMS).^{54,55}

In the current study, there was no statistically significant difference in weekly weight gain among the three study groups (Table 11) which is consistent with findings of a study by **Lyu TC et al.**⁵⁶

Though the number of studies done to evaluate effect of oromotor stimulation frequency on weekly weight gain are limited, our finding is in contrast to the studies by **Rocha et al.**, **Topkar et al.**, and **Thakkar PA et al.**, where there was a significant weight gain in intervention group than the control group.⁵⁷⁻⁵⁹

In our study, though difference in length of hospital stay was observed individually among the groups with group C having more subjects getting discharged within 10 days ($p=0.005$), no significant statistical difference was observed with respect to mean hospital stay duration amongst the groups. ($p=0.064$). (Table 12,13)

Reports by **Abed Elrhman S et al., Mahmoodi N et al.**, showed that preterm in the intervention group were discharged earlier than those in the control group which is contrary to findings in our study.^{60,61}

STRENGTHS AND LIMITATIONS

- In our study the intervention was given by mothers and significant improvement in feeding related issues like transition time to full spoon feed and duration of hospital stay was noted indicating that intervention can be delivered by mother and also impact is dependent on the frequency of intervention.
- As the study included limited population from single centre, results cannot be extrapolated to the whole population. Therefore, a study with large sample size from different geographical areas should be conducted.
- There is limited data in the literature on the effect of oromotor stimulation frequency on transition time to full feeds so results could not be compared with other studies.
- There is scope for testing the impact of oromotor stimulation frequency on time taken to achieve breastfeeding.
- Our study like most of the previous studies was done on stable preterms. Effect of oromotor stimulation on preterms with medical complications is still not known, so further research is required in this area.

CONCLUSION

Feeding difficulty is one of the major problems faced by preterm neonates. Oromotor stimulation promotes earlier transition to oral feeding. In this study, providing oromotor stimulation three times a day shortened the transition time from gavage to full oral feeds and duration of hospital stay significantly which led to faster progress .This demonstrates efficacy of increased frequency of intervention to address feeding related issues in preterm babies.

This simple cost effective method should be incorporated into routine neonatal care and can also be given at home by mothers for better outcome.

SUMMARY

A randomized clinical trial was conducted from January 2023 to December 2023 in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi affiliated to JN Medical College, Belagavi. A total of 93 preterms with gestational age between 30-34 weeks were enrolled.

Following is the summary of study findings:

- Parameters like maternal age ($P=0.980$) and CPAP duration ($P=0.590$) among the groups had no statistical significance.
- There was no statistically significant difference in gender distribution among the groups with females constituting 52.7% of the total population, while males constituted 47.3%.
- In this study, 80.7% participants were born between 32 and 33⁺⁶ weeks, 9.7% between 30-31⁺⁶ weeks and 9.7% at 34 weeks with no statistically significant difference.
- No significant variation in birth weight among the study subjects with 20.4% weighing less than 1500 grams, 72% between 1501 and 2000 grams, and 7.5% more than 2000 grams was noted in our study.
- The mean duration (days) for achieving full spoon feeds in this study were 8.48(± 4.114) for Group A, 5.84 (± 2.505) for Group B, and 5.55 (± 3.118) for Group C which signifies that Group C had earlier transition to full feeds.

- The weekly weight gain in first ($p=0.551$), second ($p=0.656$), third ($p=0.428$), fourth ($p=0.713$), fifth ($p=0.185$) and sixth week among the three study groups shows no statistically significant difference.
- No difference in the mean length of hospital stay among the study groups was observed in our study but difference was seen only with group C having more subjects getting discharged before 10 days.
- This research shows that three times stimulation produces better results than one time stimulation and as the frequency of intervention increases, the time taken to achieve full feeds shortens.
- Further research is needed to study the impact of oromotor stimulation frequency on breastfeeding and also on unstable preterms.

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ANNEXURE I – CONSENT FORM

INFORMED CONSENT FORM

“EFFECT OF OROMOTOR STIMULATION FREQUENCY ON TIME OF TRANSITION TO FULL ORAL FEEDS IN PRETERM NEONATES: ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL”.

Principle Investigator: REG NO.BM0121003

Guide: _____

Co- Guide: _____

Objective:

Primary:

To study the effect of oromotor stimulation frequency on transition from tube feeding to spoon or paladai feeds.

Secondary:

To study the effect of oromotor stimulation frequency on:

- Weekly weight gain
- Length of hospital stay

Introduction: Prematurity related morbidities and physiological immaturity lead to feeding problems among 30%-40% of preterms. These difficulties are due to hypotonia, immature oro-motor control and lack of coordination in sucking- swallowing and breathing.² **Premature infant oral motor stimulation** is a new intervention that is based on Beckman oral motor intervention that provides assisted movement to activate muscle contraction and improve neonate’s oral feeding skills. Studies show that Oromotor Stimulation (OMS) when administered to the preterm neonates results in shorter time to independent oral feeding, better weight gain and shorter duration of hospital stay² but the frequency of OMS administration varied widely between them. There is paucity of studies comparing the different frequencies of

OMS administration which will help in deciding the ideal frequency of administration. Hence, the need for this study.

Explanation of procedure:

Neonates will be allocated to three groups. All groups will receive care as per NICU protocol and the intervention at different frequencies.

Oromotor stimulation programme is a 5 minute intervention that consists of following steps: cheek-C stretch, Lip roll, Lip curl or Lip stretch, Gum massage, lateral borders of tongue, mid blade of tongue. Elicit a suck. All the infants in the three groups will be monitored from admission till discharge for the following study outcomes: Transition time to full oral feeds; Weekly weight gain and Length of hospital stay defined as duration from date of admission to date of discharge.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: “REG NO. BM0121003, DEPARTRMENT OF PEDIATRICS, KAHER University’s J.N Medical College” If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **“EFFECT OF OROMOTOR STIMULATION FREQUENCY ON TIME OF TRANSITION TO FULL ORAL FEEDS IN PRETERM NEONATES: ONE YEAR HOSPITAL BASED RANDOMISED CLINICAL TRIAL”**. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE II–PROFORMA

**“EFFECT OF OROMOTOR STIMULATION FREQUENCY ON TIME OF
TRANSITION TO FULL ORAL FEEDS IN PRETERM NEONATES: ONE YEAR
HOSPITAL BASED RANDOMISED CLINICAL TRIAL”**

Principal Investigator: REG NO. BM0121003

Guide-

Co-guide-

SUBJECT NO.:- _____

IP No :- _____

MATERNAL INFORMATION:

1) Name:

2) Age:

3) IP No. :

4) Permanent address:

5) Telephone No.:

6) LMP: EDD: Gestational age(weeks):

NEONATAL INFORMATION:

1) Date of birth: __/ __ / __

3) Study group : A

2) Time of birth:

B

C

4) Gestational age (weeks): _____ weeks

5) Age at enrollment: -

6) Sex: Male / Female

7) Birth weight: - _____ gm

8) Weight at enrollment: - _____ gm

9) Diagnosis at Admission: -

10) Duration of CPAP given: -

11).	FEEDING	Tube feeding	Tube + spoon feed (Partial)	Full spoon feed
	DAY OF LIFE			
	TIME TAKEN TO ACHIEVE IN DAYS			

12).	Day 7 of life	Day 14 of life	Day 21 of life	Day 28 of life
Weight (grams)				
Weight gain				

13) Weight at discharge:-

14) Duration of hospital stay :- _____ days.

Date of discharge:

GROUP A:

	10:00 AM	Remarks
Day 1		
Day 2		
Day 3		
Day 4		
Day 5		
Day 6		
Day 7		

GROUP B:

	10:00 AM	1:00 PM	Remarks
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

GROUP C:

	10:00 AM	1:00 PM	4:00 PM	Remarks
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

ANNEXURE III

KEY TO MASTERCHART

Neonatal information

Gest. Age (W+ days)- Gestational age in weeks + days

B. Weight (GMS)- Birth weight in grams

SUBJECT NO.	NAME	IP NO.	RANDOMISATION ID	MATERNAL AGE (IN YEARS)	DATE OF BIRTH	GEST. AGE	DAY OF ENROLLMENT	SEX	B. WEIGHT(GMS)	CPAP Duration(hours)	Day of life tube feeding started	Day of life spoon feed started	Day of life full spoon feed started	Days taken to achieve partial feeding	Days taken to achieve full spoon feeds	weight gain(1st week)	weight gain(2nd week)	weight gain(3rd week)	weight gain(4th week)	weight gain(5th week)	weight gain(6th week)	Discharge weight	Duration of hospital stay
1	B/O SHAMSHAD KHATIB	1176995	A1	25	3/16/2023	33 W	DAY 1 OF LIFE	FEMALE	1500	NIL	15T	5TH	8TH	5 DAYS	8 DAYS	NIL	160 GMS	90 GMS				1650 GMS	20 DAYS
2	B/O SHITAL KAGANKAR	1177696	B1	27	3/20/2023	33 W	DAY 3 OF LIFE	FEMALE	2000	38	3RD	6TH	8TH	5 DAYS	5 DAYS	NIL	100 GMS	20 GMS				2000 GMS	15 DAYS
3	B/O PRADYUMN MOLAKE	1179084	C1	24	3/27/2023	32 W	DAY 2 OF LIFE	FEMALE	1300	24	2ND	4TH	6TH	5 DAYS	8 DAYS	NIL	90 GMS	60GMS				1410 GMS	18 DAYS
4	B/O VARSHA CHITRAGAR (TRIPLET 1)	1179279	A2	28	3/28/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	MALE	1600	NIL	15T	4TH	6TH	5 DAYS	6 DAYS	NIL	50 GMS					1620 GMS	11 DAYS
5	B/O VARSHA CHITRAGAR (TRIPLET 2)	1179282	B2	28	3/28/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	MALE	1780	NIL	15T	3RD	5TH	3 DAYS	5 DAYS	NIL	50 GMS					1800 GMS	11 DAYS
6	B/O VARSHA CHITRAGAR (TRIPLET 3)	1179287	C2	28	3/28/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	FEMALE	1390	NIL	15T	3RD	6TH	3 DAYS	6 DAYS	NIL	50 GMS					1420 GMS	11 DAYS
7	B/O LAXMI PATIL (TWIN 1)	1179656	A3	26	3/30/2023	33 W+ 1 DAY	DAY 1 OF LIFE	MALE	1680	NIL	15T	5TH	7TH	5 DAYS	7 DAYS	NIL	10 GMS					1690 GMS	9 DAYS
8	B/O LAXMI PATIL (TWIN 2)	1179657	B3	26	3/30/2023	33 W+ 1 DAY	DAY 1 OF LIFE	MALE	1920	NIL	15T	3RD	5TH	3 DAYS	5 DAYS	NIL	40 GMS					1920 GMS	9 DAYS
9	B/O SHILPA MADAR (TWIN 1)	1181828	C3	25	4/10/2023	32 W+ 1 DAY	DAY 1 OF LIFE	FEMALE	1500	NIL	15T	6TH	11TH	6 DAYS	11 DAYS	NIL	120 GMS					1610 GMS	14 DAYS
10	B/O SHILPA MADAR (TWIN 2)	1181829	A4	25	4/10/2023	32 W+ 1 DAY	DAY 1 OF LIFE	MALE	1500	NIL	15T	8TH	12TH	8 DAYS	12 DAYS	NIL	90 GMS					1520 GMS	14 DAYS
11	B/O ANKITA HIREKODI	1182127	B4	28	4/11/2023	33 W+ 4 DAYS	DAY 3 OF LIFE	MALE	1500	46	3RD	5TH	7TH	2 DAYS	4 DAYS	10 GMS	30 GMS					1790 GMS	10 DAYS
12	B/O PREMA PATIL	1183188	C4	22	4/15/2023	32 W+ 1 DAY	DAY 3 OF LIFE	FEMALE	1050	32	2ND	10TH	12TH	7 DAYS	12 DAYS	NIL	15 GMS	35 GMS	10 GMS			1010 GMS	22 DAYS
13	B/O RENJUKA KARVE (TWIN 1)	1183318	A5	21	4/16/2023	33 W+ 1 DAY	DAY 2 OF LIFE	MALE	1750	24	2ND	5TH	8TH	3 DAYS	6 DAYS	NIL	30 GMS					1760 GMS	11 DAYS
14	B/O RENJUKA KARVE (TWIN 2)	1183320	B5	21	4/16/2023	33 W+ 1 DAY	DAY 3 OF LIFE	MALE	1040	41	3RD	7TH	9TH	4 DAYS	6 DAYS	NIL	45 GMS					1040 GMS	11 DAYS
15	B/O NEHARANI PASWAN	1185293	C5	29	4/26/2023	33 W+ 1 DAY	DAY 3 OF LIFE	MALE	2450	30	3RD	5TH	7TH	2 DAYS	4 DAYS	NIL	40 GMS					2400 GMS	10 DAYS
16	B/O VASHALI KUTALE	1206553	A6	23	8/1/2023	30 W+ 4 DAYS	DAY 1 OF LIFE	FEMALE	1400	24	3RD	15TH	20TH	12 DAYS	17 DAYS	NIL	75 GMS	85 GMS	110 GMS	100 GMS	40 GMS	1720 GMS	38 DAYS
17	B/O HEENA NANDGADI	1206838	B6	22	8/2/2023	33 W+ 2 DAYS	DAY 1 OF LIFE	FEMALE	1600	NIL	15T	4TH	6TH	4 DAYS	6 DAYS	NIL	95 GMS	45 GMS				1680 GMS	16 DAYS
18	B/O JYOTHI JADHAV	1207148	C6	24	8/3/2023	32 W+ 6 DAYS	DAY 1 OF LIFE	FEMALE	1500	NIL	15T	3RD	5TH	3 DAYS	5 DAYS	NIL	85 GMS					1760 GMS	12 DAYS
19	B/O BHAGYASHREE HAVAL	1207128	A7	32	8/3/2023	33 W + 4 DAYS	DAY 1 OF LIFE	FEMALE	2100	NIL	15T	4TH	7TH	4 DAYS	7 DAYS	NIL	55 GMS					2135 GMS	14 DAYS
20	B/O MANJULA PATIL	1207428	B7	25	8/4/2023	33 W+ 5 DAYS	DAY 1 OF LIFE	MALE	1800	NIL	15T	3RD	6TH	3 DAYS	6 DAYS	NIL	110 GMS					1810 GMS	15 DAYS
21	B/O SAVITA HULAMANI	1207962	C7	26	8/6/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	FEMALE	1420	NIL	15T	3RD	4TH	3 DAYS	4 DAYS	NIL	65 GMS	30 GMS				1475 GMS	9 DAYS
22	B/O JYOTI MEDARI (TWIN 1)	1209193	A8	24	8/11/2023	33 W	DAY 1 OF LIFE	MALE	1700	NIL	15T	5TH	8TH	5 DAYS	8 DAYS	NIL	105 GMS	50 GMS				1815 GMS	17 DAYS
23	B/O JYOTI MEDARI (TWIN 2)	1209194	B8	24	8/11/2023	33 W	DAY 1 OF LIFE	MALE	1600	NIL	15T	5TH	7TH	5 DAYS	7 DAYS	NIL	120 GMS	45 GMS				1745 GMS	17 DAYS
24	B/O PRATIKSHA PRAMOD	10001774	C8	25	8/21/2023	33 W+ 5 DAYS	DAY 1 OF LIFE	FEMALE	1950	30	2ND	4TH	6TH	2 DAYS	4 DAYS	NIL	55 GMS					1955 GMS	10 DAYS
25	B/O ABEDA TASHILDAR	10002311	A9	23	8/23/2023	32 W+ 2 DAYS	DAY 1 OF LIFE	MALE	1635	15T	9TH	13TH	9 DAYS	13 DAYS	NIL	85 GMS	100 GMS				1765 GMS	20 DAYS	
26	B/O MANGAL JADHAV	10002634	B9	39	8/25/2023	33 W+ 4 DAYS	DAY 1 OF LIFE	FEMALE	1560	36	2ND	6TH	8TH	4 DAYS	6 DAYS	NIL	115 GMS					1630 GMS	13 DAYS
27	B/O SHRUTI SURESH	10003023	C9	23	8/26/2023	33 W+ 1 DAY	DAY 1 OF LIFE	MALE	1400	6TH	15T	6TH	8TH	4 DAYS	6 DAYS	NIL	120 GMS	20 GMS				1550 GMS	15 DAYS
28	B/O MANJULA AJABADI	10004679	A10	24	9/3/2023	33 W+ 2 DAYS	DAY 1 OF LIFE	FEMALE	1560	15T	5TH	8TH	8TH	5 DAYS	8 DAYS	NIL	105 GMS					1645 GMS	13 DAYS
29	B/O SUVARNA KUNDERKAR	10004761	B10	29	9/3/2023	33 W + 5 DAYS	DAY 1 OF LIFE	MALE	1750	NIL	15T	3RD	6TH	3 DAYS	6 DAYS	NIL	125 GMS					1815 GMS	14 DAYS
30	B/O VASUDHA GHEVADE	10006282	C10	22	9/9/2023	33 W+ 3 DAYS	DAY 1 OF LIFE	MALE	2100	24	2ND	4TH	5TH	2 DAYS	3 DAYS	NIL	80 GMS					2130 GMS	10 DAYS
31	B/O MITRA TURKULAKI	10006732	A11	27	9/11/2023	33 W	DAY 1 OF LIFE	FEMALE	1220	40	3RD	15TH	22ND	12 DAYS	19 DAYS	NIL	65 GMS	125 GMS	120 GMS	65 GMS		1525 GMS	31 DAYS
32	B/O KAVITA LALAGE (TWIN 1)	10006940	B11	25	9/12/2023	33 W+ 2 DAYS	DAY 1 OF LIFE	FEMALE	1760	NIL	15T	4TH	6TH	4 DAYS	6 DAYS	NIL	70 GMS					1800 GMS	11 DAYS
33	B/O KAVITA LALAGE (TWIN 2)	10006941	C11	25	9/12/2023	33 W+ 2 DAYS	DAY 1 OF LIFE	FEMALE	1820	24	3RD	5TH	7TH	1 DAY	3 DAYS	NIL	65 GMS					1870 GMS	11 DAYS
34	B/O SUMITRA PAMMAR	10007713	A12	34	9/16/2023	31 W+ 1 DAY	DAY 1 OF LIFE	MALE	1940	24	2ND	11TH	16TH	9 DAYS	14 DAYS	NIL	120 GMS	105 GMS	20 GMS			2125 GMS	22 DAYS
35	B/O YAMUNA PATIL	10007901	B12	32	9/16/2023	32 W+ 1 DAY	DAY 1 OF LIFE	MALE	1300	NIL	15T	5TH	8TH	5 DAYS	8 DAYS	NIL	105 GMS	25 GMS				1395 GMS	15 DAYS
36	B/O PRACHI BAMBARGEKAR	10007946	C12	20	9/17/2023	32 W	DAY 1 OF LIFE	FEMALE	1280	24	2ND	8TH	12TH	6 DAYS	10 DAYS	NIL	125 GMS	55 GMS				1410 GMS	18 DAYS
37	B/O PRIYANKA TORDAL	10007953	A13	25	9/17/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	MALE	1600	NIL	15T	3RD	6TH	3 DAYS	6 DAYS	NIL	85 GMS					1660 GMS	12 DAYS
38	B/O ANISABI KULAGOD	10007832	B13	23	9/17/2023	33 W+ 5 DAYS	DAY 1 OF LIFE	FEMALE	1900	NIL	15T	3RD	5TH	3 DAYS	5 DAYS	NIL	75 GMS					1925 GMS	11 DAYS
39	B/O RASHMI LAKASHE	10008851	C13	35	9/22/2023	32 W+ 1 DAY	DAY 1 OF LIFE	MALE	1500	30	2ND	6TH	8TH	4 DAYS	6 DAYS	NIL	115 GMS					1605 GMS	13 DAYS
40	B/O LAXMI KOTAGI (TWIN 1)	10010093	A14	24	9/27/2023	32 W+ 5 DAYS	DAY 1 OF LIFE	FEMALE	1520	30	2ND	7TH	8TH	5 DAYS	9 DAYS	NIL	150 GMS	40 GMS				1590 GMS	16 DAYS
41	B/O LAXMI KOTAGI (TWIN 2)	10010094	B14	24	9/27/2023	32 W+ 5 DAYS	DAY 1 OF LIFE	MALE	1830	NIL	15T	4TH	7TH	4 DAYS	7 DAYS	NIL	90 GMS	45 GMS				1920 GMS	16 DAYS
42	B/O ANJALI GAVADE	10010614	C14	21	9/27/2023	30 W+ 6 DAYS	DAY 1 OF LIFE	FEMALE	1560	40	3RD	10TH	15TH	7 DAYS	12 DAYS	NIL	80 GMS	115 GMS	65 GMS			1720 GMS	24 DAYS
43	B/O RIYA PATIL	10010162	A15	24	9/27/2023	33 W+ 4 DAYS	DAY 1 OF LIFE	MALE	1900	NIL	15T	4TH	6TH	4 DAYS	8 DAYS	NIL	110 GMS					1905 GMS	14 DAYS
44	B/O DEEPASHARI DESAI	10010198	B15	28	9/28/2023	34 W	DAY 1 OF LIFE	FEMALE	2100	NIL	15T	2ND	4TH	2 DAYS	4 DAYS	NIL	50 GMS					2150 GMS	9 DAYS
45	B/O RASIKA CHOUGALA	10010537	C15	22	9/30/2023	33 W+ 5 DAYS	DAY 1 OF LIFE	FEMALE	1940	NIL	15T	3RD	4TH	3 DAYS	4 DAYS	NIL	55 GMS					1980 GMS	9 DAYS
46	B/O POOJA BADIGER	10011660	A16	28	10/5/2023	33 W	DAY 1 OF LIFE	MALE	1920	NIL	15T	6TH	9TH	6 DAYS	9 DAYS	NIL	85 GMS	60 GMS				2000 GMS	18 DAYS
47	B/O LAXMI HURAKANNANAVAR	10012349	B16	18	10/8/2023	30 W+ 3 DAYS	DAY 1 OF LIFE	FEMALE	1530	36	3RD	15TH	19TH	12 DAYS	16 DAYS	NIL	80 GMS	85 GMS	115 GMS	45 GMS		1765 GMS	31 DAYS
48	B/O KAVITA GURUVANNANAVAR	10012464	C16	24	10/9/2023	33 W+ 6 DAYS	DAY 1 OF LIFE	MALE	2020	NIL	15T	2ND	3RD	2 DAYS	3 DAYS	5 GMS	40 GMS					2065 GMS	9 DAYS
49	B/O MEENAZ MALDAR (TWIN 1)	10012743	A17	27	10/11/2023	34 W	DAY 1 OF LIFE	FEMALE	1660	NIL	15T	3RD	5TH	3 DAYS	5 DAYS	NIL	90 GMS	25 GMS				1715 GMS	16 DAYS
50	B/O MEENAZ MALDAR (TWIN 2)	10012745	B17	27	10/11/2023	34 W	DAY 1 OF LIFE	FEMALE	1560	24	2ND	4TH	5TH	2 DAYS	3 DAYS	NIL	105 GMS	40 GMS				1630 GMS	16 DAYS
51	B/O MANISHA CHOUGALE (TWIN 1)	10013113	C17	26	10/12/2023	33 W+ 4 DAYS	DAY 1 OF LIFE	MALE	1560	NIL	15T	3RD	4TH	3 DAYS	4 DAYS	NIL	115 GMS	25 GMS				1610 GMS	15 DAYS
52	B/O MANISHA CHOUGALE (TWIN 2)	10013114	A18	26	10/12/2023	33 W+ 4 DAYS	DAY 1 OF LIFE	MALE	1700	36	3RD	6TH	8TH	3 DAYS	5 DAYS	NIL	100 GMS	20 GMS				1730 GMS	15 DAYS
53	B/O LAXMI SAVADATTI	10014353	B18	25	10/16/2023	33 W+ 2 DAYS	DAY 1 OF LIFE	MALE	1650	NIL	15T	4TH	6TH	4 DAYS	6 DAYS	NIL	110 GMS					1700 GMS	14 DAYS
54	B/O AYESHA SANDI	10015634	C18	28	10/21/2023	33 W+ 1 DAY	DAY 1 OF LIFE	FEMALE	1730	NIL	15T	3RD	4TH	3 DAYS	4 DAYS	N							