
**“To study the feeding patterns and growth
parameters of babies fed on Pasteurised Donor
Human Milk- A ONE YEAR OBSERVATIONAL
LONGITUDINAL STUDY AT KLE DR. PRABHAKAR KORE
HOSPITAL AND MRC, BELAGAVI.”**

**BY
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ACCEPTANCE LETTER

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LIST OF ABBREVIATIONS

PDHM	-	Pasteurised Donor human milk
MOM	-	Mothers Own Milk
EBF	-	Exclusive breast feeding
Kg	-	Kilograms
g	-	Grams
GA	-	Gestational age
gm	-	Grams
HM	-	Human milk
HMB	-	Human milk bank
HMO	-	Human milk oligosaccharides
I-FABP	-	Intestinal fatty acid-binding protein
IgA	-	Immunoglobulin A
IL	-	Interleukin
IQR	-	Interquartile range
KMC	-	Kangaroo mother care
LBW	-	Low birth weight
LOS	-	Late onset sepsis
LSCS	-	Lower segment caesarean section
MAS	-	Meconium aspiration syndrome
MDP	-	Muramyl dipeptide
min	-	Minutes
mL	-	Milliliter
L	-	Liter
n	-	Total number

NEC	-	Necrotizing enterocolitis
NMR	-	Neonatal Mortality Rate
NG	-	Nasogastric tube
RT	-	Ryle's tube
NICU	-	Neonatal intensive care unit
NVD	-	Normal vaginal delivery
PTVD	-	Preterm vaginal delivery
OG	-	Orogastric
p	-	Probability
PIH	-	Pregnancy induced hypertension
PPROM	-	Preterm premature rupture of the membranes
RCTs	-	Randomized controlled trial
SD	-	Standard deviation
TLR4	-	Toll - like receptor 4
UK	-	United Kingdom
MP	-	Madhya Pradesh
VLBW	-	Very low birth weight
vs	-	Versus
WHO	-	World Health Organization
wk	-	Week
d	-	Days

ABSTRACT

Background and objectives

Pasteurised Donor Human Milk (PDHM) is recommended when mother's own milk is not available to newborns specially LBW babies. There is lack of evidence regarding feeding patterns and growth of these neonates fed on PDHM. Therefore, this study was conducted with the following goals in mind - To study the feeding patterns and growth parameters of the babies receiving Pasteurised Donor Human Milk following discharge from hospital up to 6 months of age.

Methodology

Study design: Longitudinal observational study.

Study duration and period: January 2020 to December 2020.

Place:

The study was conducted in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, a tertiary care teaching hospital attached to KAHER Jawaharlal Nehru Medical College, Belagavi.

Source of data:

Neonates admitted in the NICU and KMC of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Results

A total of 1554 newborns admitted to the NICU were screened during the study period. Of these 150 neonates were eligible, 102 accepted PDHM. Of these 32 were drop outs, data pertaining to 70 was available for analysis.

Majority of the babies at enrolment were on PDHM feeding. The acceptability rate of PDHM in the study was 68% and the most common reason to opt for PDHM was lack of secretion.

The total amount of PDHM given was 354.72 ± 114.49 ml; the duration of exclusive PDHM was 2.59 ± 1.78 days; The time to switch from PDHM to MOM was 4.05 ± 2.61 days. By the end of six months, 94% babies were on DBF, with 5.7% on DBF +SFs. Significant increase in mean weight, length, head circumference and mid upper arm circumference was observed at 6 months from discharge (p value =0.0001).

Conclusion

This observational longitudinal study conducted to know feeding pattern and growth after discharge from the hospital among neonates receiving PDHM demonstrated a substantial increase in exclusive breastfeeding rate and adequate growth at 6 months of age.

Keywords: Pasteurized donor human milk; mother`s own milk

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INTRODUCTION

Human milk is considered the optimal form of nutrition for all infants, but it is especially important for infants born prematurely. South-east Asia including India faces its own unique challenges, having the highest number of low-birth-weight babies, and significant mortality and morbidity in very low birthweight (VLBW) population⁹. World health organization (WHO) recommends Exclusive Breastfeeding for the first 6 months of life followed by continued breastfeeding upto 2 years of age⁸³. Breastmilk has both nutritional and anti-infective properties which are especially important for preterm neonates¹⁹. A series on child and newborn survival concluded that achieving 90 % coverage with exclusive breastfeeding alone might avoid 13 – 15% of under-five fatalities in resource-poor countries². However, some neonates do not have access to their mother's own milk (MOM) and hence are vulnerable. WHO and UNICEF recommends Pasteurised Donor Human Milk (PDHM) as the next best infant feeding option when mothers milk is not available^{2,8,9}.

Human milk banks play an important role by providing human milk to infants^{5,57,81}. The largest group of recipients are premature infants. Human milk bank systematically collects, pasteurizes, stores and distribute the milk^{5,57,81}. Donor women are carefully selected and screened for HIV-1, HIV-2, Hepatitis b, Hepatitis c and Syphilis. There are circumstances where milk from the infant's own mother milk is not available and the Donor milk fills the gap especially in low-birth-weight babies^{8,9}. There are numerous advantages of PDHM in both term as well as preterm babies¹⁹. It increases feeding tolerance, stimulates infant's growth, improves neurodevelopment, and reduces the risk of Late Onset Sepsis (LOS), Necrotising Enterocolitis (NEC), Bronchopulmonary Dysplasia (BPD) and Retinopathy of Prematurity (ROP)^{19,85}.

It has both nutritional and anti-infective properties. It consists of lysozyme, secretory Immunoglobulin A (IgA), lactoferrin, bile salt-stimulating lipase, growth factors, cytokines, vitamin E, glutathione and epidermal growth factor which stimulate intestinal maturity¹⁹. The Short term and long-term benefits of PDHM on the feeding pattern and growth has not been reported especially from a low resource setting. The scientific evidence to study the impact of human milk banking on feeding practices is unclear. A systematic review and meta-analysis showed no difference in exclusive breastfeeding rate at hospital discharge in very preterm infants after the introduction of donor human milk⁸⁰. Another study found a decrease in exclusive breastfeeding rate in babies ≤ 1500 g birth-weight after introduction of donor human milk in 22 Californian neonatal units⁷⁴.

However, a retrospective study from Spain demonstrated a 9% increase in breastfeeding rates^{74,80} after the opening of a milk bank. A south Indian study has also demonstrated an improving trend in BF rate at 6 months but has attributed this to the indirect effects of decrease use of formula and not completely on opening of Human milk bank⁸³. Therefore, there is lack of evidence to demonstrate the impact of Pasteurised Donor Human Milk (PDHM) on rate of exclusive breast feeding (EBF) after discharge from the hospital, especially in the Indian context. An Indian study on pre and post opening of milk bank demonstrated increase in rate of exclusive breastfeeding at 6 months⁸⁴.

Studies have reported that donor milk is associated with decreased rates of short term in hospital growth, compared to formula milk⁸. However, recent studies and systematic reviews have reported that donor milk has better or no negative short-term impact on the growth at discharge^{74,75,76}. A retrospective study demonstrated better short-term weight gain and head circumference (HC) growth with MOM

supplemented with fortified DM rather than MOM plus formula⁷⁵. Majority of studies have observed feeding types and growth only at discharge. Therefore, there is no clear evidence to demonstrate the effect of PDHM on feeding and short- and long-term growth especially in the Indian setting. So, we conducted the study to know the effect of PDHM on the feeding patterns and growth parameters of the babies following discharge from hospital up to 6 months of age.

OBJECTIVES

Primary

To study the feeding patterns of the babies receiving Pasteurized Donor Human Milk following discharge from hospital up to 6 months of age.

Secondary

To study the growth parameters of babies (weight, length, head circumference and mid upper arm circumference) receiving Pasteurized Donor Human Milk (PDHM) following discharge from hospital up to 6 months of age.

REVIEW OF LITERATURE

Breastfeeding has been the “sine qua non” of survival throughout human history. Breastfeeding was the only technique of child feeding recommended in ancient medical encyclopaedias such as Papyrus Ebers (Egypt 1550 B.C.) and Sushruta Samhita (India 1550 B.C.)¹⁸. The mechanical feeding of neonates has a long history of failure. Using human milk donor substitutes for babies who don't have enough milk has been practised since ancient times, and is described in Ayurveda as the concept of "Dhaatri," or wet nursing, in which lactating women act as donors for babies whose mothers are unable to produce enough milk due to a variety of factors¹⁸. Newborns require adequate nutrition for their optimal growth and development. Breastmilk provides it to all babies, especially preterm and LBW babies.¹ It benefits the infant nutritionally, economically, psychologically and acts as an anti-inflammatory, anti-infectious, anti-allergen source¹.

Table 1: Composition of Human Milk

Macronutrients (per 100ml)	Colostrum	Mature milk
Energy	58 Kcal	68-72Kcal
Total Protein	2.3 g	0.9g
IgA	364 mg	143 mg
Casein	149 mg	187 mg
Lactoferrin	334 mg	337 mg
Lactalbumin	208 mg	361 mg
Total Fat	2.9 g	4.2 g
Lactose	5.3 g	7.6 g
Cholesterol	23 mg	16 mg

When MOM is not available, WHO and UNICEF recommends PDHM as the next best alternative. It is distributed through Human milk bank which systematically collects, pasteurizes, stores and distribute the milk². There are numerous advantages of PDHM in both term as well as preterm babies- It increases feeding tolerance, stimulates baby growth, improves neurodevelopment, and reduces the risk of Late onset sepsis (LOS), Necrotising enterocolitis (NEC), Bronchopulmonary dysplasia (BPD) and Retinopathy of Prematurity (ROP). It has both nutritional and anti-infective properties. It consists of lysozyme, secretory Immunoglobulin A (IgA), lactoferrin, bile salt-stimulating lipase, growth factors, cytokines, vitamin E, glutathione and epidermal growth factor which stimulate intestinal maturity¹⁹. Pasteurized Donor Human Milk is milk that has been expressed and willingly donated by breastfeeding women who is not recipient's biological mother⁵. Human milk banks play an important role in giving human milk to neonates. It systematically collects, pasteurizes, stores and distribute the milk⁵. It is recommended that a Comprehensive Lactation Management Centre (CLMC) must have approximately 350 square metres of space. If this is not possible, the bare minimum is to have a separate milk processing and storage area from the rest of the CLMC. A milk bank setup must have a reception/administration area, counselling area, milk expression area, cleaning/autoclave room, milk processing/storage space, microbiological laboratory, and milk storage area⁵.

At room temperature, the maximum hang time for continuous feedings is 4 hours. Fresh milk can be kept in the milk storage area of a refrigerator (4°C or 39°F) for up to 48 hours. Storage durations and temperatures all have an impact on nutritional quality, physiologically active components in human milk and the incidence of microbial contamination so oldest milk be used first¹. This donor human

milk is pasteurised using the Holder Pasteurization Method, which involves heating the milk in a sealed container to 62.5°C and holding it there for 30 minutes, then rapidly chilling it in a specified device before dispensing it for use by the receiver⁵.

The most common recipients are premature infants and low birth weight neonates followed by sick preterm newborns recovering from illness. Children with severe IUGR, neonates who do not have access to Mother’s Own Milk (MOM), and mothers who are unable to nurse or express breastmilk are among those who benefit¹¹. There are over 500 human milk banks operating in over 37 countries around the world. There are 210 active human milk banks in Europe, with the most banks in France, Italy, and Sweden; the number of human milk banks is steadily increasing. The Italian Association of Human Milk Banks coordinates the activities of 36 human milk banks in Italy as of the end of 2017. Sneha, the first in Asia, was founded by Armada Fernandez in Mumbai in 1989 at the Sion Hospital. There are currently 89 milk banks in operation, the most of which are located in western Maharashtra and Gujarat¹⁰.

Table 2: Impact of Pasteurised Donor Human milk⁴

Survival	Lower breast milk volumes and the risk of TACO in LBW infants by 14% in the first 39 days.
WBC	Lower breast milk volume (BMD) by 20%
APACHE II	It is associated to a lower risk of severe APACHE II
Feeding tolerance	Between 36 hours of a neonate on fortified breast fed milk showed better feeding tolerance.
Reduced length of stay in NICU	<ul style="list-style-type: none"> In the case of giving donor breast milk to premature babies is often by a lot of problems, a drastic step to the NICU and less diseases at times of babies up. In the percentage of neonates who are discharged is increased
Economic	After discharge was used 1.56 higher in NICU of milk. Increase milk feed.
Neutrophil/lymphocyte ratio and long-term benefits	Lower than the milk fed infants. There is a trend of metabolic problems, significantly lower and neutral, neonatal laboratory values four weeks in life.

Torres et al conducted small retrospective studies in Spain looking at feeding practices in a neonatal unit before and after the opening of a milk bank⁸⁰. Feeding with donor human milk, used as a milk substitute for mother's own milk when it is not available or as an additional supply when mother's own milk is not enough, has not led to a decrease in the proportion of children exclusively fed with breast milk upon discharge from hospital. The use of donor milk has dropped the age of commencing enteral feeding by 16 hours. A study of 83 NICUs in Italy found that breastfeeding at discharge tends to be higher in NICUs that had DHM available to them (60.4% vs 52.8%)⁷⁴. Tshmlala D et al in her study observed the proportion of preterm or VLBW babies receiving exclusive breast feeding (EBF) at the time of discharge is the same after the introduction of a milk bank. They were also more likely to be exclusively breastfed if their mothers were older, if these neonates did not have any congenital abnormality and if they had a shorter duration of hospital stay⁷⁹.

A study by Smith H et al in Irish settings found that maternity care practices (mode of childbirth, admission to the NICU and duration of stay in the maternity hospital following childbirth) were all significantly associated with exclusive breast feeding at discharge and at two months of age ($p = <0.001$). Among other factors, they found that NICU admission had the strongest association with decreased rates of exclusive breast feeding. Lower breast-feeding rates in the NICU compared to the postnatal wards in maternity hospitals has also been previously reported. Therefore, management of feeding in NICU should be an area of focus for maternity services to protect and promote breast feeding⁸². Another systematic review and meta-analysis by Williams et al. found no difference in exclusive breastfeeding at hospital discharge in very preterm infants after the introduction of donor human milk⁷². However, Kantorowska et al. found a decrease in exclusive breastfeeding rate

in babies ≤ 1500 g birth-weight after availability of donor human milk in 22 Californian neonatal units. The majority of studies show that PDHM has a negative impact on the rate and frequency of exclusive breastfeeding^{12,13}.

According to a study conducted at the Department of Paediatric Gastroenterology and Nutrition, human milk banks do not compete with breastfeeding but it does reduce the need of formula feeds in the NICU and boosts exclusive breastfeeding rates at discharge. DHM helped these babies enjoy the benefits of early initiation and exclusive breastfeeding¹¹.

A study conducted by Quigley M et al was significantly in favour of donor milk over formula in terms of growth⁷⁶. It was supported by retrospective studies conducted by Connor et al and Morley et al which demonstrated better short-term weight gain and head circumference (HC) growth with MOM supplemented with fortified DM rather than formula⁷⁵. However, Hobban et al demonstrated that PDHM has been associated with no negative impact on short-term growth⁷⁵. Early postnatal weight gain was reported in 6 studies to be better in formula feeds than PDHM^{5,80}. The fact that growth failure is linked to neurodevelopment morbidity is particularly troubling^{3,5}. Some studies comparing donor milk to formula-feeds reported no difference in head circumference velocity⁶. They also reported that slow neonatal growth in neonates with PDHM may not always entail long-term problems, but it may be linked to a leaner body composition⁶. Lucas et al reported that the median time to regain birth weight was considerably less in formula-fed newborns than in PDHM-fed infants (10 versus 16 days)⁸.

Thus, the effect of PDHM on the feeding and growth of infants is studied and the results are variable. Majority of studies have observed feeding types and growth only at discharge.

So, we had planned this study with the following goals in mind - To study the feeding patterns and growth parameters of the babies receiving Pasteurised Donor Human Milk following discharge from hospital up to 6 months of age.

MATERIALS & METHODS

The study was conducted from January 2020 to December 2020 in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Study design

Longitudinal observational study.

Study duration and period

January 2020 to December 2020.

Place

The study was conducted in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, a tertiary care teaching hospital attached to KAHER Jawaharlal Nehru Medical College, Belagavi.

Source of data:

Neonates admitted in the NICU of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Sample Size and calculation:

The minimum sample size formula based on prevalence rate of Exclusive Breast Feeding till 6 months of age is

$$N = Z\alpha^2P(1-p) / d^2$$

Where P is the percentage of prevalence and d is the percentage likely difference in the prevalence.

Z alpha is linked with the level of significance. For 5% level of significance Z alpha =1, With P = 60%^{85,86} and d = 25% of P =15%, the sample size is 41.

By assuming 20% loss to follow up, 49 samples need to be collected. The loss to follow up patient is excluded for data analysis.

Calculated sample size was 49 and actual sample size was 70, neonates admitted to NICU including KMC fulfilling the selection criteria were enrolled.

SELECTION CRITERIA:

INCLUSION CRITERIA:

- 1)Preterm/ LBW babies on Pasteurised Donor Human Milk
- 2)Term babies fed on Pasteurised Donor Human Milk
- 3)Patients staying within 50 km radius of Belgaum

EXCLUSION CRITERIA:

- 1) Major congenital anomalies
- 2) GIT anomalies
- 3) Birth asphyxia
- 4) Sepsis.
- 5) Patients not giving consent

Method of collection of data

The study was conducted after the approval from the ethical committee of the institution, the parents of neonates fulfilling selection criteria were briefed about the nature of the study and a written informed consent was obtained from parents/caregivers to participate in the study prior to the enrollment (Annexure I). Parents/caregivers of the neonates who fulfilled the selection criteria were interviewed and demographic data including age, gender and educational status of the parents, family members, family income and socio-economic status according to the Modified B. G. Prasad's Classification⁸⁵ were noted in a pretested questionnaire.

At admission baseline parameters were recorded which were maternal history, maternal age, gravida, antenatal care, antenatal risk factors, birth history of the neonates like, mode of delivery, gestational age, modified Ballard score, APGAR score and indication for NICU admission. The neonates were subjected to general physical examination followed by systemic examination and all these findings were recorded on a pre-designed and pre-tested proforma. The neonates were followed up for feeding type, method, volume of feeds, mode of feeding and supplements (Vitamin D, Calcium, Iron), growth parameters (weight, length, head circumference, mid upper arm circumference) at discharge, 15 days, 6 weeks, 10 weeks, 14 weeks and 6 months follow up visit. PDHM was given from human milk bank of KAHER Dr. Prabhakar Kore Charitable Hospital, Belagavi to the neonates.

OUTCOMES ASSESSED:

(1) Primary outcomes:

Feeding patterns: at enrolment, discharge and 5 follow up visits 15 days, 6 weeks, 10 weeks, 14 weeks and 6 months

Type of feeding: Mothers Own Milk/ Exclusive breastfeeding, PDHM, Formula feeds.

Exclusive Breastfeeding: WHO definition of exclusive breastfeeding specifically states that this feeding practice requires that the infant receive breast milk (including milk expressed or from a wet nurse).

Pasteurized donor human milk (PDHM): Breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient that is not the mother's own baby⁵³.

Formula feeds: An artificial substitute for breast milk intended for feeding infants, using cow's milk as a base, supplemented with vitamins and minerals²⁴.

Method of feeding: Direct breastfeeding, Spoon / Paladai feeding, Ryle's tube feeding.

Direct Breastfeeding: WHO defines 'direct breastfeeding' as the provision of human breastmilk to the infant by direct feeding at the breast.

Spoon / Paladai feeding: The paladai is a cup-like utensil with a narrow tip has been used traditionally to feed neonates³⁴.

Ryle's tube feeding: A feeding tube is a small, soft, plastic tube placed through the nose (NG) or mouth (OG) into stomach to provide feeds and medicines to the babies after measuring the distance from either the nostril or the mouth (depending on insertion site) to the tragus (lobe of the ear) to the half way point between the xiphisternum and the umbilicus⁴¹.

Frequency of feeds: number of feeds per day.

Supplements: Vitamin D, Calcium, Iron

Secondary Outcomes:

Anthropometric measurements:⁷¹

Weight: The neonate's weight was measured at admission on Seca 334 weighing scale with precision of 0.001 kg, neonate was weighed naked with no clothing or diaper after making sure that scale was placed on flat, hard, even surface. Three readings were noted and mean was taken.

Length: The neonate's length was measured at admission on Seca 417 baby length board after placing it on a horizontal and level surface. Three measurements for each baby were taken and mean was taken after measuring it to nearest 0.1cm.

Head circumference: Neonate's head circumference was measured with Schorr tape with precision of 1 mm by placing it over the occipital protuberance at the back and just over the supraorbital ridge and the glabella in front, once being positioned correctly it was pull tight to compress the hair and the skin, but not too tight causing injury to the baby. Three measurements were taken for each baby and mean was taken of it.

Mid Upper Arm Circumference: Neonate's mid upper arm circumference was measured with Schorr tape at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromion).

Statistical analysis

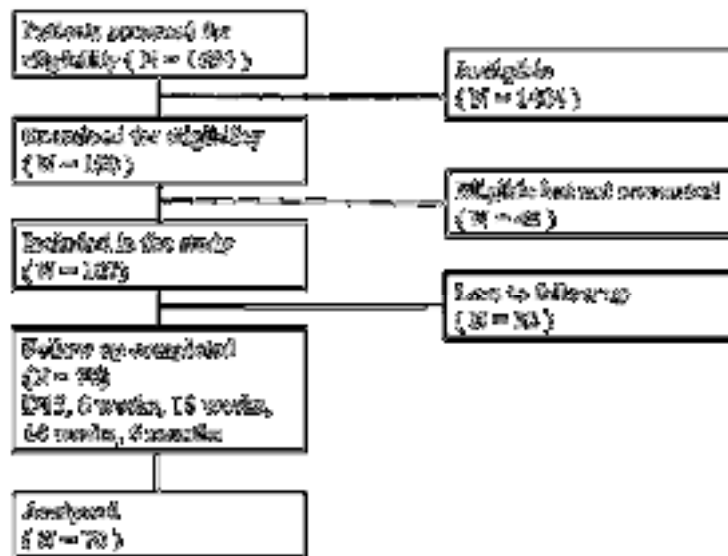
The data obtained was coded and entered into Microsoft Excel spreadsheet. Data was analysed using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, US). The categorical data was expressed in terms of rates, ratios and percentages and the comparison was done by chi square test. For all the continuous variables, the results were either given in Mean \pm SD. The comparison of continuous variables was tested using paired t test. The means of two or more independent groups were compared with one-way ANOVA test. A probability value (p value) of less than or equal to 0.050 at 95% confidence interval was considered as statistically significant.

RESULTS

The longitudinal observational study was conducted from January 2020 to December 2020 in the department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

During the study period, 1554 neonates were admitted to the NICU. There were 150 neonates who were eligible. Out of which, 102 accepted PDHM. Out of these 102 babies; 82, 75, 67, 56 and 55 completed 1st (at 15 days), 2nd (6 weeks), 3rd (10 weeks), 4th (14 weeks) and 5th (6 months) visits respectively. Data from 70 patients who completed follow up visit at 6 months irrespective of number of missed visits were analysed. The drop outs were more than anticipated because of the COVID 19 pandemic Out of 150, 102 accepted PDHM (68%).

Graph1: Diagram for screening and enrolment of newborns



I. Maternal Sociodemographic Profile

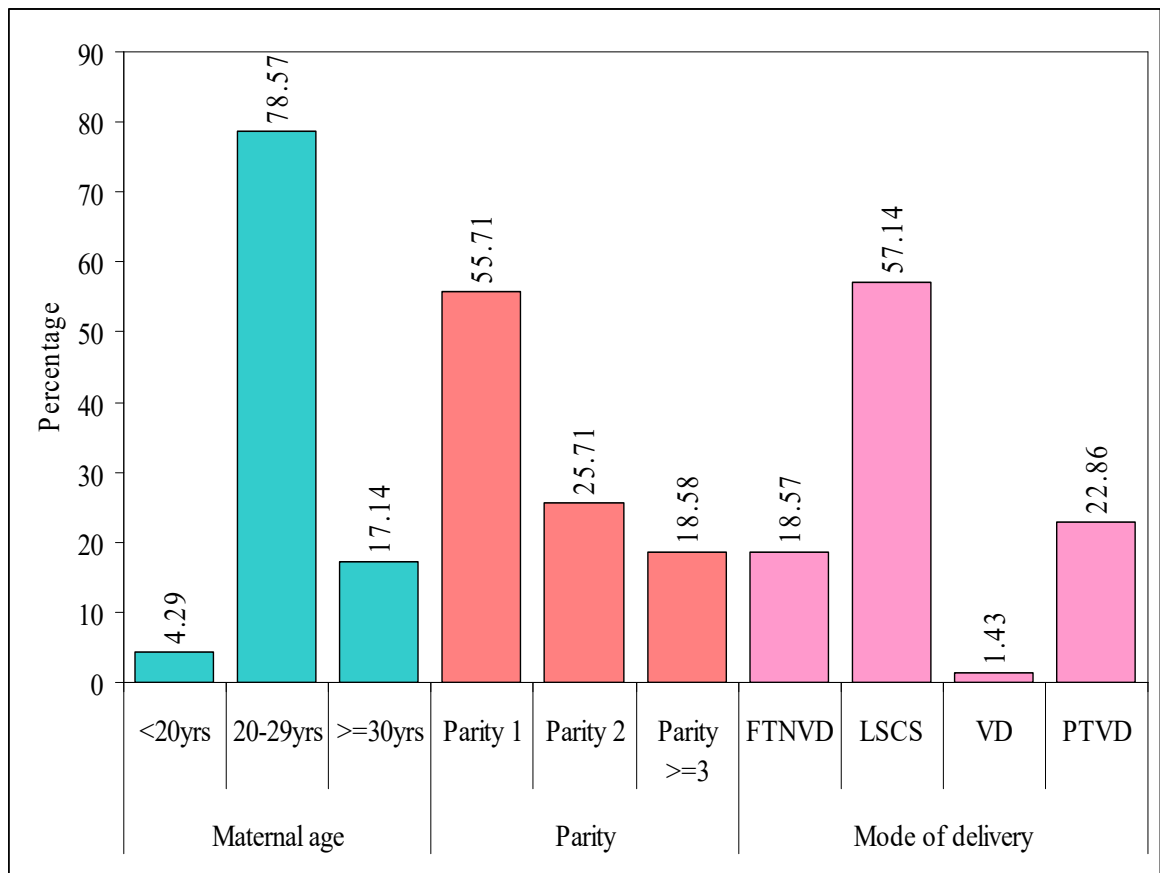
Table 3: Distribution Of Neonates According To The Maternal Sociodemographic profile

Maternal history	No of mothers	% of mothers
Mother`s education		
Illiterates	9	12.86
Primary	48	68.57
Secondary	9	12.86
Graduates	4	5.71
Father`s education		
Illiterates	1	1.43
Primary	32	45.71
Secondary	34	48.57
Graduates	3	4.29
Mother`s occupation		
Homemaker	67	95.71
Others	3	4.29
Father`s occupation		
Farmer	40	57.14
Trader	30	42.86
Religion		
Hindu	66	94.29
Muslim	4	5.71
Socio-economic status		
Class V	7	10.00
Class IV	30	42.86
Class III	16	22.86
Class II	15	21.43
Class I	2	2.86
Total	70	100.00

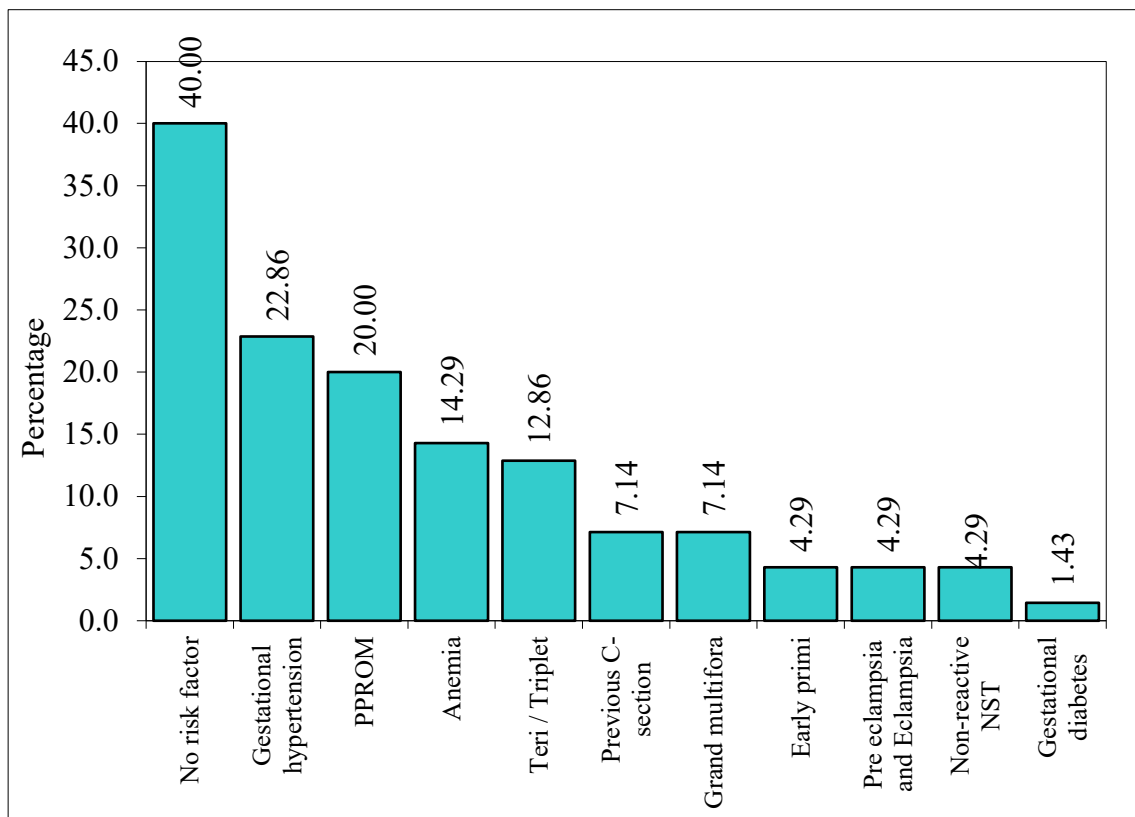
In the present study, 68.5% of the mothers had primary education, majority (94.29%) belonged to Hindu religion and 42.86% belonged to Class IV socioeconomic strata according to the Modified BG Prasad's classification.

II. Maternal Pregnancy Profile

Graph 2: Distribution of Neonates According to the Maternal Pregnancy Profile



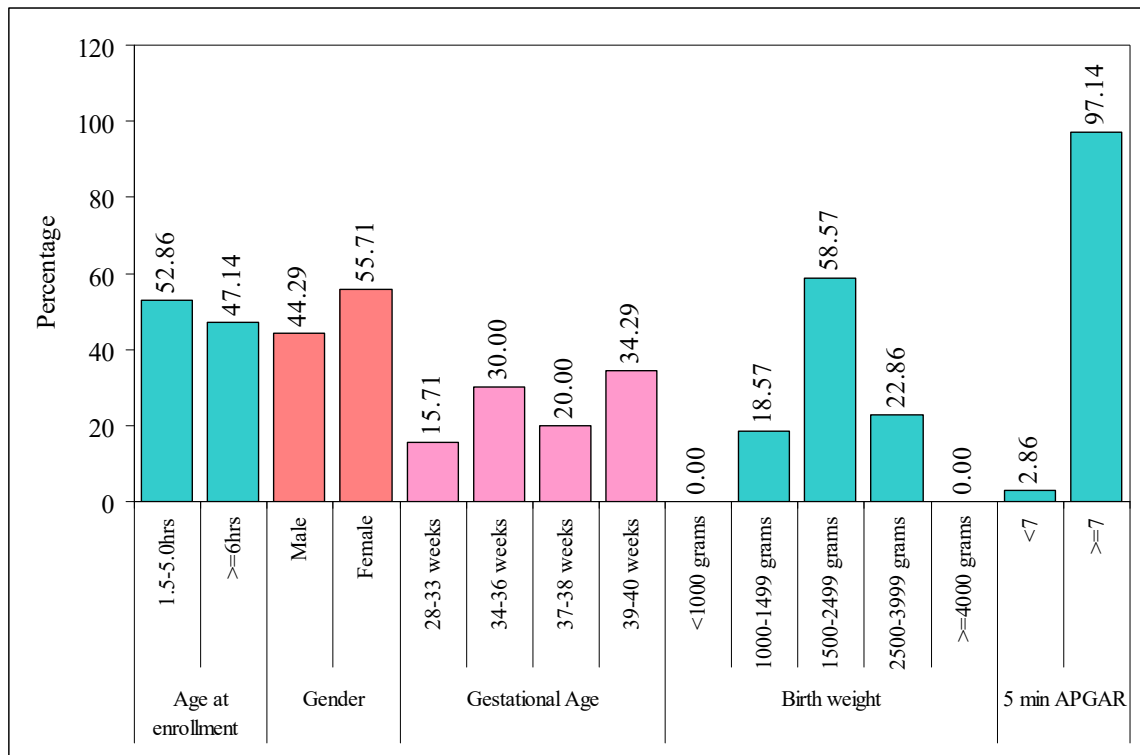
In the present study, 42.86% of the women were aged between 20 to 29 years, 55.71% of the women were primigravida and 57.14% of the mothers had delivered by LSCS.

Graph 3: Antenatal Risk factors

In the study, 40% of the mothers had no risk factors. In the remaining mothers, gestational hypertension (22.86 %) and PPRM (20 %) were the most common antenatal risk factors followed by anemia (14.29%).

III. Birth History

Graph 4: Distribution of Neonates According To Their Clinical Profile



In the study, majority of the newborns were within 1.5-5 hours of age at enrolment (52.86%). 55.71% were females and 44.29% were boys with male to female ratio of 0.79:1. Majority of neonates were term SGA babies with gestational age of 39-40 weeks (34.29%) and with a birth weight of 1500-2499g (58.57%). APGAR score of ≥ 7 at 5 minutes was seen in 97.14%.

IV. Indications For NICU Admission

Table 4: Distribution of Neonates According to the Cause For NICU Admission

Indication for NICU admission	No of neonates	% Of neonates
LBW	50	71.43
Preterm	39	55.71
Respiratory distress	13	18.57
RDS	4	5.71
MAS	2	2.86
NNH	12	17.14
Feeding difficulties	45	64.29
Hypoglycemia	4	5.71
Observation	8	11.43

In the study, Low birth weight (LBW) (71.43%) was the most common reason for admission to the NICU and KMC followed by feeding difficulties (64.29%) and prematurity (55.71%).

V. Primary Outcome- Feeding Patterns of Neonates

68% (102/150) of babies accepted PDHM. The indications of starting PDHM in them- In 57/70 cases (81.4%), it was lack of secretions, in 9/70 cases (12.8%) it was inverted nipples in mother and in 4/70 (5.7%) cases due to maternal illness (Eclampsia)

Table 5: Distribution of Neonates According To Type of Feeding At Different Time Points

Visits	Type of Feeding	N	%
At Enrolment	MOM +PDHM	12	17.1
	PDHM	58	82.9
At Discharge	MOM	69	98.6
	MOM+ PDHM	1	1.4
1 st visit	MOM	69	98.6
	MOM +Formula	1	1.4
2 nd visit	Missed	13	1.4
	MOM	57	81.4
3 rd visit	Missed	14	20
	MOM	55	78.6
	MOM +Formula	1	1.4
4 th visit	Missed	4	1.4
	MOM	63	90
	MOM +Formula	3	4.2
5 th visit	MOM	65	94.5
	MOM +Formula	5	5.5

In the study, at enrolment, 82.61% of the neonates were exclusively on PDHM, whereas 17.39% were on MOM+PDHM. At the time of discharge, 98.55% of newborns were on MOM whereas 1.45% were on MOM+PDHM. By 6 months of age, 94.5% were on MOM and 5.5% were on mixed feeding (MOM + Formula).

Table 6: Amount & Duration of PDHM

	Mean	SD
PDHM at Enrolment	102.03	31.74
Total Amount of PDHM (ml)	354.72	114.49
Duration of exclusive PDHM (days)	2.59	1.78
Duration of mixed feeding (PDHM +MOM) (days)	1.46	1.00
Duration of MOM (days)	1.27	0.81
Days to switch to MOM	5.34	2.61

In the study, at enrolment, the mean of total amount of PDHM given to the neonates was 102 ± 31.74 ml. The mean duration of PDHM feeding was 4.05 ± 2.61 days. Out of which mean duration of exclusive PDHM feeding was 2.59 ± 1.78 days and the mean duration of mixed feeding (PDHM +MOM) was 1.46 ± 1.00 days; the duration of MOM was 1.27 ± 0.81 days; and the time to switch from PDHM to MOM feeding was 4.05 ± 2.61 days. The mean of total amount of PDHM given for the total duration was 354.72 ± 114.49 ml.

Table 7: Distribution of Neonates According To Method of Feeding At Different Time Points.

Visits	Method of feeding	n	%
At Enrolment	DBF +SFs	21	30
	RT Feeds	17	24.3
	RT+SFs	1	1.4
	SFs	31	44.3
At Discharge	DBF	48	68.6
	DBF + SF	22	31.4
1st Visit	Missed	1	1.4
	DBF	49	70
	DBF + SF	19	27.1
	SF	1	1.4
2nd Visit	DBF	62	88.6
	DBF+ SF	5	7.1
	Missed	3	4.3
3rd Visit	DBF	54	77.1
	DBF +SFs	2	2.9
	Missed	14	20
4th Visit	DBF	63	90
	DBF + SF	3	4.3
	Missed	4	5.7
5th Visit	DBF	66	94.3
	DBF +SFs	4	5.7

In the study, at enrolment, 43.48% neonates were on SFs and 18.84% neonates were on RT Feeds. At discharge, 68.12% were on DBF and 31.88% were on DBF +SFs. By six months, 94.3% were on DBF and 5.7% were on DBF + SFs.

It was observed that 44.3% neonates were on SFs at enrolment which had reduced to 27.1%, 7.1% and 2.9 % respectively at 1st, 2nd and 3rd follow up visits but had again increased to 4.3% and 5.7% respectively at 4th and 5th follow up visits.

Table 8: Comparison of Method of Feeding with Type of Feeding at different time points

	Type of feeding								
			At Enrolment	At Discharge	1 st visit	2 nd visit	3 rd visit	4 th visit	5 th visit
Method of feeding	At Enrolment	Chi-square	19.68	1.27	1.27	4.63	6.30	3.36	1.86
		Df	3	3	3	3	6	6	3
		Sig.	0	.73	.73	.20	.39	.76	.60
	At Discharge	Chi-square	0.27	2.21	2.21	0.003	0.58	2.01	0.32
		Df	1	1	1	1	2	2	1
		Sig.	0.59	.13	.13	.95	.74	.36	.56
	1 st visit	Chi-square	5.67	0.43	0.43	8.03	9.73	1.35	0.55
		Df	3	3	3	3	6	6	3
		Sig.	0.12	.93	.93	.04	.13	.96	.90
	2 nd visit	Chi-square	0.62	0.13	0.13	14.53	13.57	54.89	1.52
		Df	2	2	2	2	4	4	2
		Sig.	.73	.937	.93	.001*	.009*	.000*	.46
	3 rd visit	Chi-square	1.60	0.30	0.30	63.86	104.36	27.52	5.74
		Df	2	2	2	2	4	4	2
		Sig.	.44	.86	.86	.000*	.000*	.000*	.05
	4 th visit	Chi-square	3.95	0.11	0.11	9.41	39.71	99.64	19.44
		Df	2	2	2	2	4	4	2
		Sig.	.13	0.94	0.94	0.009*	.000*	.000*	.000*
	5 th visit	Chi-square	3.22	0.06	0.06	0.96	16.99	56.08	55.15
		Df	1	1	1	1	2	2	1
		Sig.	.07	.80	.80	.32	.000*	.000*	.000*

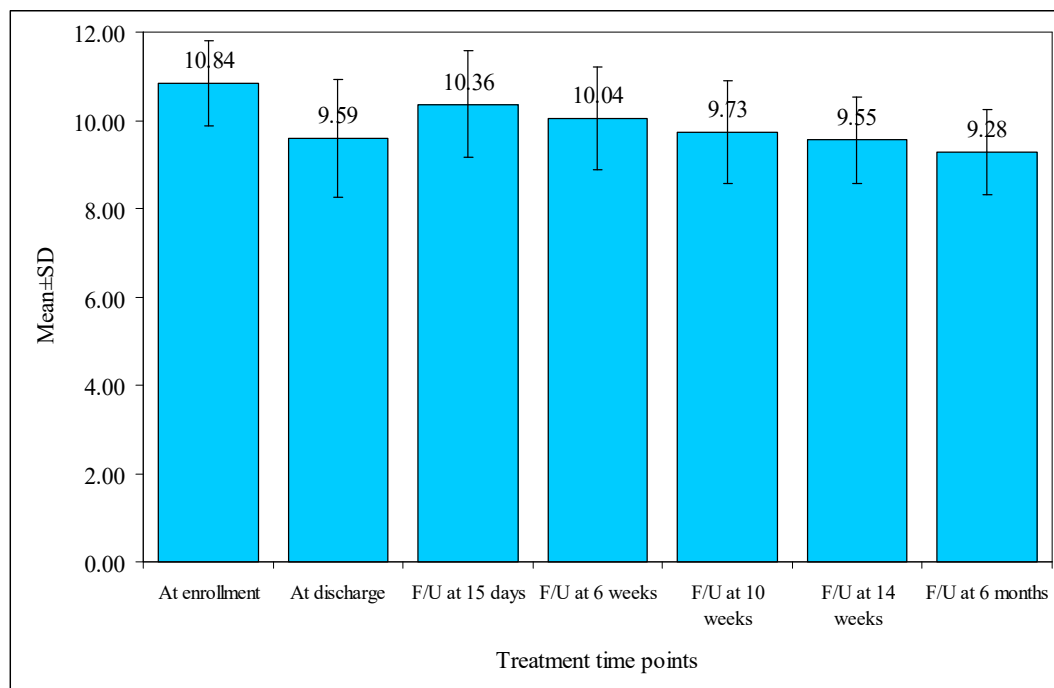
Df- difference, Sig. -Significance

It was observed that type of feeding at 2nd, 3rd, 4th and 5th visit respectively had a significant correlation with method of feeding at each of these visits.

Table 9: Mean Frequency of Feeds At Different Time Points

	Mean	Std. Deviation	T test	p-value
At Enrolment	10.84	0.97	9.24	0.000
At Discharge	9.58	1.33		
1 st visit	10.36	1.21	3.98	0.000
Discharge	9.59	1.34		
2 nd visit	10.03	1.16	1.63	0.108
Discharge	9.70	1.36		
3 rd visit	9.73	1.15	0.08	0.930
Discharge	9.71	1.37		
4 th visit	9.40	1.52	-0.97	0.335
Discharge	9.62	1.35		
5 th visit	9.28	0.96	-1.61	0.111
Discharge	9.62	1.35		

*p<0.05

Graph 5: Distribution of Neonates According To Frequency of Feeds At Different Time Points

In the study, mean frequency of feeds decreased from 10.84 ± 0.97 feeds/day at enrolment to 9.58 ± 1.33 feeds/day at discharge and to 9.28 ± 0.97 feeds/day at 6 months. Mean frequency of feeds at discharge when compared to each of the follow up visits is variable because of the different sample size at each visit.

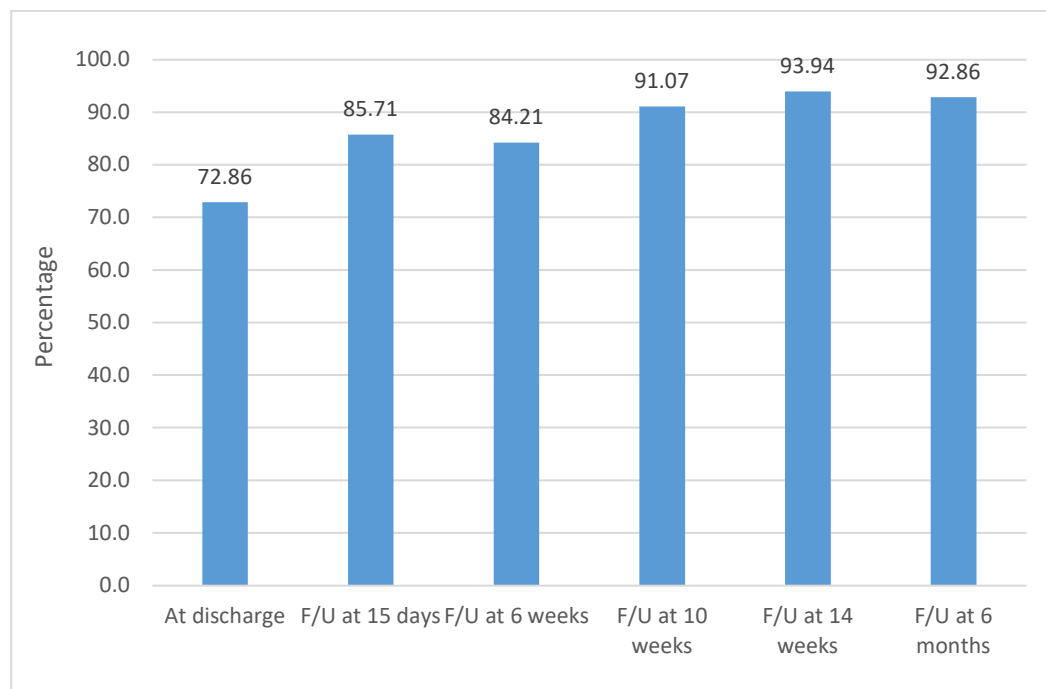
VI. Supplements

Table 10: Vitamin D Supplements Status At Different Time Points

Vitamin D	Yes	%	No	%	Changes from discharge to	p-value
At Discharge	51	72.86	19	27.14	-	-
1 st visit	60	85.71	10	14.29	Discharge to 1 st visit	0.0004*
2 nd visit	48	84.21	9	15.79	Discharge to 2 nd visit	0.0310*
3 rd visit	51	91.07	5	8.93	Discharge to 3 rd visit	0.0020*
4 th visit	62	93.94	4	6.06	Discharge to 4 th visit	0.0001*
5 th visit	65	92.86	5	7.14	Discharge to 5 th visit	0.0001*

*p<0.05

Graph 6: Vitamin D Supplements Status At Different Time Points

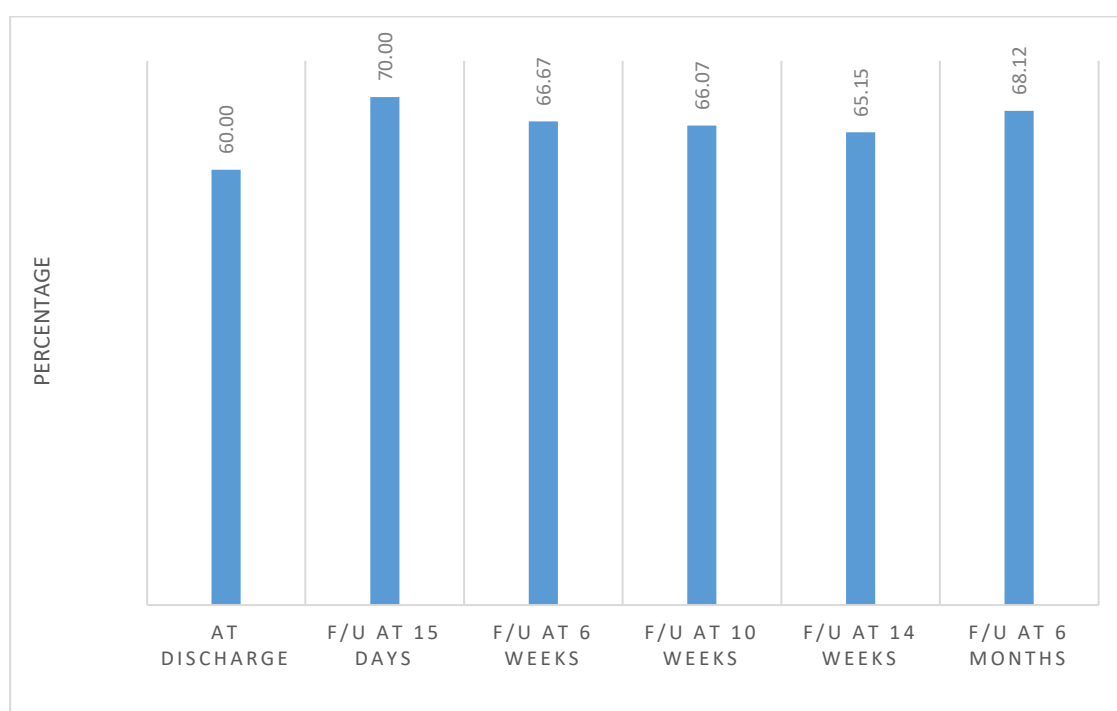


In the study, Vitamin D supplementation increased significantly from 72.86 % at discharge to 92.86% (**p =0.0001***) at the end of six months.

Table 11: Calcium Supplements Status At Different Time Points

Calcium	Yes	%	No	%	Changes from discharge to	p-value
At Discharge	42	60.00	28	40.00	-	-
1 st visit	49	70.00	21	30.00	Discharge to 1 st visit	0.0390*
2 nd visit	38	66.67	19	33.33	Discharge to 2 nd visit	0.2190
3 rd visit	37	66.07	19	33.93	Discharge to 3 rd visit	0.2190
4 th visit	43	65.15	23	34.85	Discharge to 4 th visit	0.3890
5 th visit	47	68.12	22	31.88	Discharge to 5 th visit	0.1460

*p<0.05

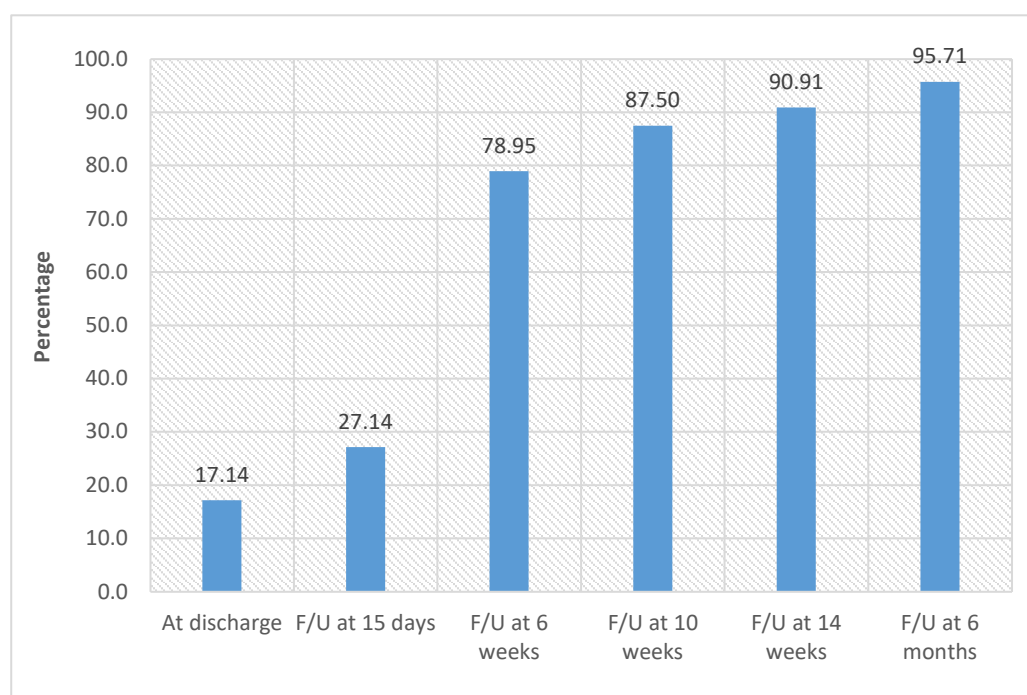
Graph 7: Calcium Supplements Status At Different Time Points.

In the study, Calcium supplementation had increased from 60% at discharge to 68.12% at 6 months ($p = 0.14$) but was not statistically significant.

Table 12: Iron Supplements Status At Different Time Points

Iron	Yes	%	No	%	Changes from discharge to	p-value
At Discharge	12	17.14	58	82.86	-	-
1 st visit	19	27.14	51	72.86	Discharge to 1 st visit	0.0650
2 nd visit	45	78.95	12	21.05	Discharge to 2 nd visit	0.0001 *
3 rd visit	49	87.50	7	12.50	Discharge to 3 rd visit	0.0001 *
4 th visit	60	90.91	6	9.09	Discharge to 4 th visit	0.0001 *
5 th visit	67	95.71	3	4.29	Discharge to 5 th visit	0.0001 *

*p<0.05

Graph 8: Iron Supplements Status At Different Time Points

In the study, Iron supplementation had increased significantly from 17.14% at discharge to 95.71% at 6 months (0.0001*).

Secondary Outcomes

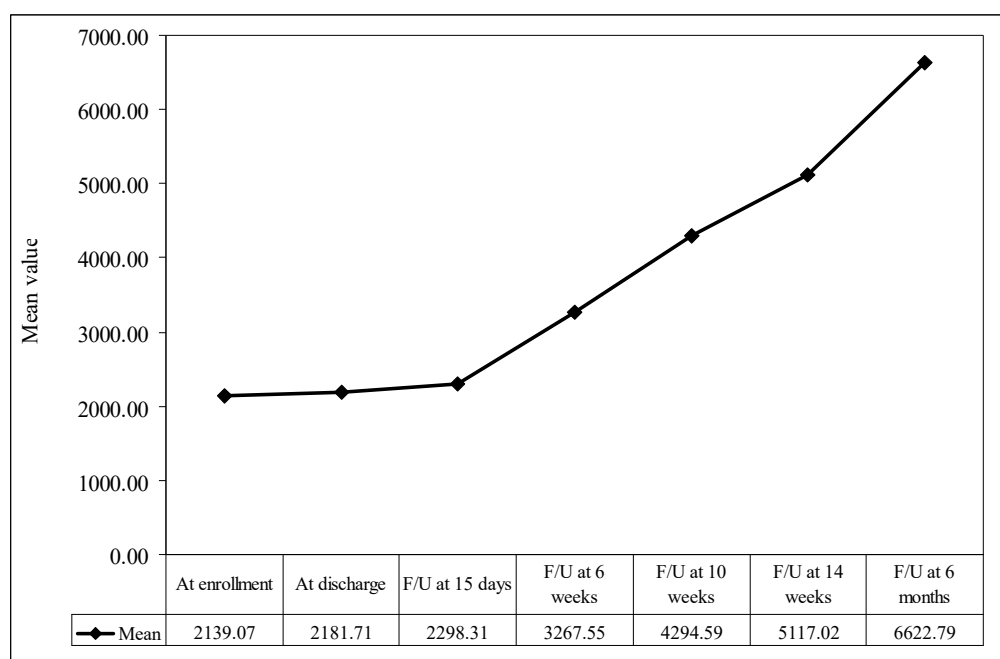
VII. ANTHROPOMETRIC PROFILE OF NEONATES

Table 13: Mean Weight (In G) At Different Time Points

Weight	Mean	Std. Deviation	T test	p-value
At Enrolment	2139.1	574.1	-4.456	0.000
At Discharge	2181.7	550.6		
1 st visit	2298.3	639.9	6.284	0.000
Discharge	2179.1	558.5		
2 nd visit	3267.5	694.7	25.96	0.000
Discharge	2252.5	550.8		
3 rd visit	4294.6	731.5	39.329	0.000
Discharge	2261.6	559.8		
4 th visit	5117.0	674.0	41.876	0.000
Discharge	2262.2	537.3		
5 th visit	6622.8	592.6	76.289	0.000
Discharge	2181.7	550.6		

*p<0.05

Graph 9: Mean Weight (In G) Of Neonates At Different Time Points

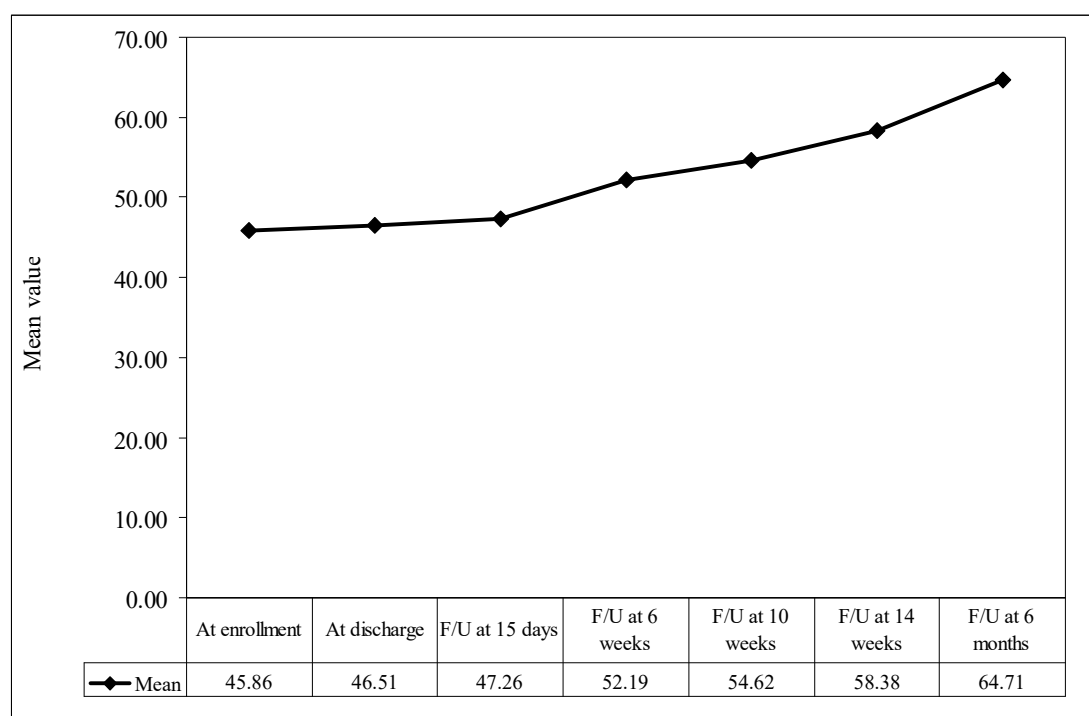


In the study, significant increase in mean weight of babies was observed which had increased from 2.139 ± 0.574 kg at enrolment to 2.181 ± 0.55 kg at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 6.622 ± 0.592 kg by 6 months ($p = 0.000$).

Table 14: Mean Length (In Cm) At Different Time Points

Length	Mean	Std. Deviation	T test	p-value
At Enrolment	45.85	3.21	-8.441	0.000
At Discharge	46.51	2.95		
1 st visit	47.26	3.60	6.213	0.000
Discharge	46.48	2.99		
2 nd visit	50.23	7.92	3.554	0.001
Discharge	46.79	2.79		
3 rd visit	54.62	3.44	28.494	0.000
Discharge	46.75	2.80		
4 th visit	58.32	2.87	36.372	0.000
Discharge	46.89	2.69		
5 th visit	64.71	2.30	64.265	0.000
Discharge	46.51	2.95		

*p<0.05

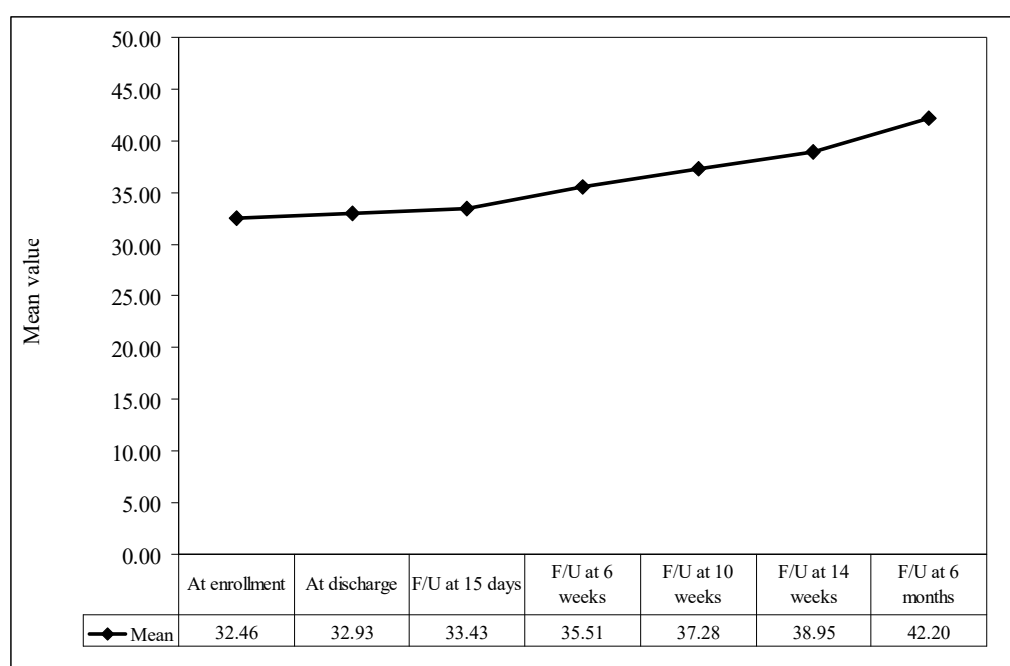
Graph 10: Mean Length (In Cm) Of Neonates At Different Time Points

In the study, significant increase in mean length of babies was observed which had increased from 45.86 ± 3.22 cm at enrolment to 46.51 ± 2.95 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 64.71 ± 2.30 cm by 6 months ($p = 0.000$).

Table 15: Mean Head Circumference (In Cm) At Different Time Points

Head Circumference	Mean	Std. Deviation	T test	p-value
At Enrolment	32.46	1.66	-6.39	0.000
At Discharge	32.92	1.46		
1 st visit	33.43	1.71	7.16	0.000
Discharge	32.91	1.47		
2 nd visit	35.52	1.42	25.02	0.000
Discharge	33.15	1.33		
3 rd visit	37.28	1.25	41.82	0.000
Discharge	33.13	1.33		
4 th visit	38.95	1.08	47.93	0.000
Discharge	33.16	1.29		
5 th visit	42.21	0.98	64.22	0.000
Discharge	32.93	1.45		

*p<0.05

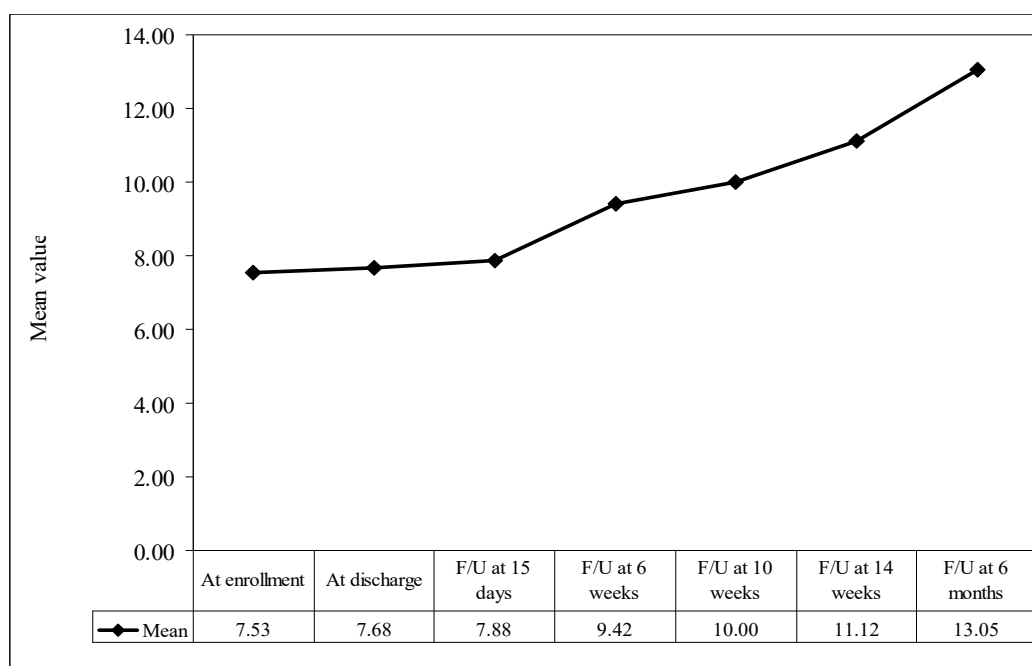
Graph 11: Mean Head Circumference (in cm) Of Neonates At Different Time Points

In the study, significant increase in mean head circumference of babies was observed which had increased from 32.46 ± 1.74 cm, at enrolment to 32.93 ± 1.46 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 42.20 ± 0.99 cm by 6 months ($p = 0.000$).

Table 16: Mean Mid Upper Arm Circumference (In Cm) At Different Time Points

Mid Upper Arm Circumference	Mean	Std. Deviation	T test	p-value
At Enrolment	7.52	0.70	-5	0.000
At Discharge	7.68	0.61		
1 st visit	7.77	1.21	0.72	0.474
MUAC At discharge	7.68	0.62	15.613	0.000
2 nd visit	9.40	0.98		
MUAC At discharge	7.74	0.57	22.921	0.000
3 rd visit	10	0.85		
MUAC At discharge	7.75	0.57	26.11	0.000
4 th visit	11.11	1.02		
MUAC At discharge	7.75	0.55	48.969	0.000
5 th visit	13.05	0.92		
MUAC At discharge	7.68	0.61		

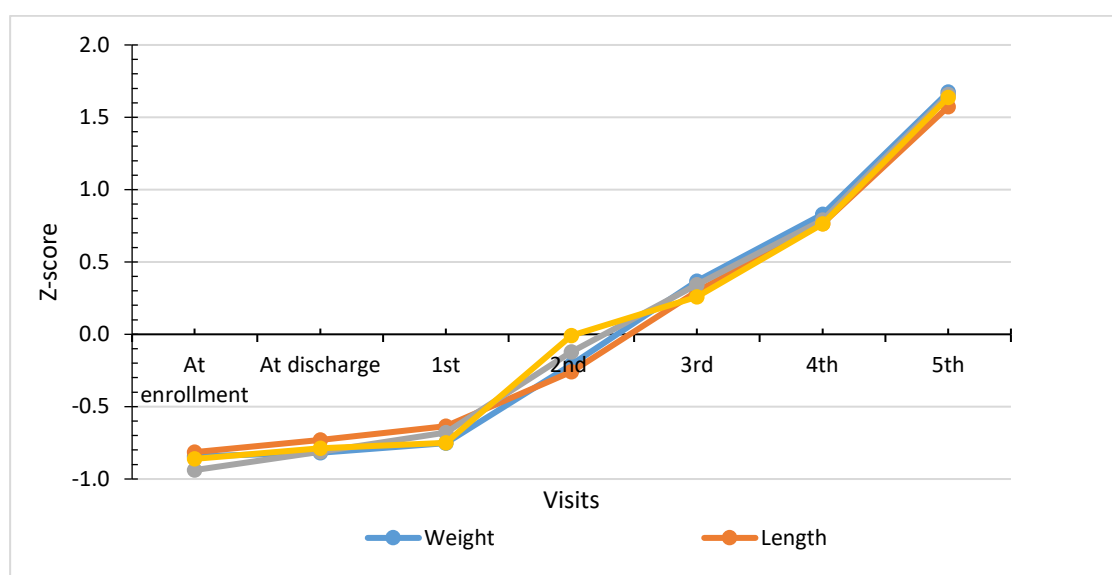
*p<0.05

Graph 12: Mean Mid Upper Arm Circumference (in cm) At Different Time Points

In the study, significant increase in mean mid upper arm circumference of babies was observed which had increased from 7.53 ± 0.70 cm at enrolment to 7.68 ± 0.62 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 13.05 ± 0.92 cm by 6 months ($p = 0.00$).

Table 17: Z- Scores For Growth Velocity At Different Time Points

Visits	Z-score			
	Weight	Length	Head Circumference	Mid Upper Arm Circumference
At Enrolment	-0.84	-0.81	-0.94	-0.86
At Discharge	-0.82	-0.73	-0.81	-0.79
1 st visit	-0.75	-0.64	-0.68	-0.75
2 nd visit	-0.21	-0.26	-0.12	-0.01
3 rd visit	0.37	0.30	0.34	0.26
4 th visit	0.83	0.76	0.79	0.76
5 th visit	1.67	1.57	1.66	1.64

Graph 13: Z-Scores For Growth Velocity At Different Time Points

The mean Z-scores of the growth velocity in the neonates significantly increased after the 1st visit (i.e., 15 days) in all the neonates.

VIII. Comparison of Co-variables With Growth

Table 18: Comparison Of Mother's Age With Growth Of Neonate

Parameters	Time	Summary	<20yrs	20-29yrs	>30yrs	Total	F-value	P-value
Weight (in gram)	At Enrolment	Mean	2206.67	2129.82	2164.58	2139.07	0.0387	0.9621
		SD	390.04	593.05	557.23	574.06		
	At Discharge	Mean	2300.00	2167.00	2219.58	2181.71	0.1142	0.8922
		SD	467.20	568.89	516.47	550.60		
	At 15 days	Mean	2391.67	2296.60	2282.50	2298.31	0.0347	0.9659
		SD	510.55	674.59	541.30	639.93		
	At 6 weeks	Mean	3135.00	3287.56	3225.00	3267.55	0.0845	0.9191
		SD	715.00	721.05	639.08	694.71		
	At 10 weeks	Mean	4322.50	4282.11	4341.11	4294.59	0.0242	0.9761
		SD	604.58	734.45	816.59	731.51		
	At 14 weeks	Mean	4541.67	5151.50	5155.56	5117.02	1.1678	0.3196
		SD	1159.49	628.57	708.46	673.99		
	At 6 months	Mean	6268.33	6629.00	6682.92	6622.79	0.5944	0.5548
		SD	586.54	578.25	678.37	592.57		
Length (in cm)	At Enrolment	Mean	46.00	45.97	45.29	45.86	0.2188	0.8041
		SD	3.12	3.23	3.38	3.22		
	At Discharge	Mean	46.17	46.65	46.00	46.51	0.2518	0.7782
		SD	2.84	2.99	2.98	2.95		
	At 15 days	Mean	46.83	47.46	46.50	47.26	0.3644	0.6960
		SD	3.40	3.72	3.25	3.60		
	At 6 weeks	Mean	50.17	52.80	50.22	52.19	0.5231	0.5960
		SD	5.13	8.35	4.01	7.61		
	At 10 weeks	Mean	52.83	55.04	53.44	54.62	1.2184	0.3049
		SD	5.20	3.07	4.33	3.45		
	At 14 weeks	Mean	56.50	58.53	58.33	58.38	0.6516	0.5257
		SD	3.97	2.83	3.32	2.95		
	At 6 months	Mean	64.40	64.86	64.13	64.71	0.5237	0.5947
		SD	1.15	2.17	3.08	2.30		
HC (in cm)	At Enrolment	Mean	32.50	32.47	32.42	32.46	0.0060	0.9940
		SD	1.00	1.74	1.55	1.67		
	At Discharge	Mean	32.67	32.96	32.88	32.94	0.0702	0.9323
		SD	0.76	1.51	1.37	1.45		
	At 15 days	Mean	33.33	33.47	33.29	33.43	0.0578	0.9439
		SD	1.26	1.79	1.53	1.71		

	At 6 weeks	Mean	35.33	35.65	35.00	35.52	0.7907	0.4593
		SD	1.26	1.37	1.73	1.42		
	At 10 weeks	Mean	37.00	37.38	36.94	37.28	0.5111	0.6031
		SD	1.00	1.27	1.31	1.25		
	At 14 weeks	Mean	38.67	39.08	38.50	38.95	1.1465	0.3261
		SD	0.76	1.05	1.27	1.09		
	At 6 months	Mean	42.00	42.25	42.04	42.21	0.2919	0.7478
		SD	1.32	1.01	0.86	0.99		
MUAC (in cm)	At Enrolment	Mean	7.33	7.53	7.58	7.53	0.1491	0.8617
		SD	0.58	0.71	0.73	0.70		
	At Discharge	Mean	7.33	7.67	7.79	7.68	0.6608	0.5198
		SD	0.58	0.61	0.69	0.62		
	At 15 days	Mean	7.67	7.89	7.88	7.88	0.1191	0.8879
		SD	0.76	0.78	0.64	0.75		
	At 6 weeks	Mean	8.83	9.54	9.11	9.42	1.2484	0.2965
		SD	1.26	0.97	0.99	0.99		
	At 10 weeks	Mean	10.00	9.99	10.06	10.00	0.0224	0.9779
		SD	1.32	0.82	0.98	0.86		
	At 14 weeks	Mean	11.17	11.11	11.11	11.12	0.0038	0.9962
		SD	1.26	0.87	1.62	1.03		
	At 6 months	Mean	13.33	13.05	12.96	13.05	0.1972	0.8215
		SD	1.04	0.89	1.12	0.92		

In the study, the age of the mother had no statistically significant association with the infant's anthropometric parameters at different time points.

Table 19: Comparison of Gender of Neonate with Growth

Parameters	Time	Summary	Male	Female	Total	t-value	P-value	
Weight (in gram)	At Enrolment	Mean	2110.16	2162.05	2139.07	-0.3733	0.7101	
		SD	597.24	561.74	574.06			
	At Discharge	Mean	2132.74	2220.64	2181.71	-0.6607	0.5110	
		SD	553.19	552.61	550.60			
	At 15 days	Mean	2267.10	2324.46	2298.31	-0.3658	0.7157	
		SD	603.88	675.80	639.93			
	At 6 weeks	Mean	3266.14	3268.62	3267.55	-0.0125	0.9901	
		SD	642.06	743.40	694.71			
	At 10 weeks	Mean	4270.71	4312.50	4294.59	-0.1959	0.8455	
		SD	679.60	780.01	731.51			
	At 14 weeks	Mean	5098.41	5130.67	5117.02	-0.1689	0.8666	
		SD	605.54	729.99	673.99			
	At 6 months	Mean	6538.23	6690.00	6622.79	-1.0655	0.2904	
		SD	599.56	585.94	592.57			
	Length (in cm)	At Enrolment	Mean	46.21	45.58	45.86	0.8154	0.4177
			SD	3.24	3.21	3.22		
		At Discharge	Mean	46.82	46.27	46.51	0.7770	0.4399
			SD	2.87	3.03	2.95		
At 15 days		Mean	47.65	46.95	47.26	0.7949	0.4295	
		SD	3.26	3.88	3.60			
At 6 weeks		Mean	51.31	52.86	52.19	-0.7183	0.4760	
		SD	2.90	9.80	7.61			
At 10 weeks		Mean	54.60	54.64	54.62	-0.0428	0.9661	
		SD	2.62	3.99	3.45			
At 14 weeks		Mean	57.93	58.70	58.38	-0.9279	0.3579	
		SD	2.50	3.24	2.95			
At 6 months		Mean	64.56	64.84	64.71	-0.5033	0.6164	
		SD	2.15	2.44	2.30			
HC (in cm)		At Enrolment	Mean	32.65	32.32	32.46	0.8139	0.4186
			SD	1.75	1.61	1.67		
		At Discharge	Mean	32.98	32.90	32.94	0.2457	0.8066
			SD	1.53	1.41	1.45		
	At 15 days	Mean	33.52	33.36	33.43	0.3604	0.7197	
		SD	1.69	1.75	1.71			
	At 6 weeks	Mean	35.68	35.40	35.52	0.7046	0.4844	
		SD	1.27	1.54	1.42			

	At 10 weeks	Mean	37.33	37.24	37.28	0.2534	0.8010
		SD	1.14	1.35	1.25		
	At 14 weeks	Mean	38.95	38.95	38.95	0.0148	0.9883
		SD	1.06	1.12	1.09		
	At 6 months	Mean	42.10	42.29	42.21	-0.8321	0.4083
		SD	1.06	0.93	0.99		
MUAC (in cm)	At Enrolment	Mean	7.53	7.53	7.53	0.0389	0.9691
		SD	0.82	0.61	0.70		
	At Discharge	Mean	7.63	7.72	7.68	-0.5933	0.5550
		SD	0.68	0.57	0.62		
	At 15 days	Mean	7.92	7.84	7.88	0.4437	0.6587
		SD	0.85	0.67	0.75		
	At 6 weeks	Mean	9.67	9.23	9.42	1.5399	0.1303
		SD	1.10	0.88	0.99		
	At 10 weeks	Mean	10.02	9.98	10.00	0.1661	0.8688
		SD	0.81	0.91	0.86		
	At 14 weeks	Mean	10.91	11.27	11.12	-1.2470	0.2182
		SD	1.13	0.94	1.03		
	At 6 months	Mean	13.06	13.04	13.05	0.1167	0.9075
		SD	0.73	1.06	0.92		

In the study, the gender of the neonate did not have statistically significant correlation with the infant's growth.

Table 20: Comparison Of SES Of Family With Growth

Parameters	Time	Summary	Class V	Class IV	Class III	Class II	Class I	F-value	P-value
Weight (in gram)	At Enrolment	Mean	2414.3	2312.3	2142.2	1699.3	1850.0	4.0078	0.0057*
		SD	380.5	551.5	535.2	550.9	70.7		
	At Discharge	Mean	2435.0	2329.2	2186.3	1793.3	1960.0	3.2234	0.0178*
		SD	368.5	535.3	526.6	543.0	212.1		
	At 15 days	Mean	2585.0	2488.6	2295.3	1847.3	2037.5	3.3193	0.0157*
		SD	413.8	692.2	533.6	561.6	102.5		
	At 6 weeks	Mean	3414.0	3557.3	3273.1	2665.5	2110.0	4.6227	0.0032*
		SD	319.0	642.0	639.3	600.5	0.0		
	At 10 weeks	Mean	4341.3	4539.8	4366.3	3754.5	3255.0	2.9217	0.0315*
		SD	513.4	640.1	684.5	798.9	0.0		
	At 14 weeks	Mean	5095.0	5278.3	5041.2	4797.8	5155.0	0.8842	0.4807
		SD	511.6	575.8	767.5	747.0	1265.7		
	At 6 months	Mean	6475.0	6811.7	6523.1	6415.0	6662.5	1.4883	0.2160
		SD	502.9	644.4	529.4	489.9	1035.9		
Length (in cm)	At Enrolment	Mean	48.4	46.7	45.3	43.8	45.0	3.6955	0.0090*
		SD	1.4	3.2	2.8	3.2	4.2		
	At Discharge	Mean	48.6	47.2	45.9	44.9	46.0	2.7573	0.0351*
		SD	1.4	3.1	2.7	2.8	3.5		
	At 15 days	Mean	49.9	48.3	46.3	45.3	46.3	3.3287	0.0155*
		SD	1.4	4.0	2.8	3.2	3.9		
	At 6 weeks	Mean	52.3	52.8	53.8	49.5	44.5	0.7264	0.5785
		SD	1.4	3.1	14.2	3.3	0.0		
	At 10 weeks	Mean	54.4	56.3	53.4	53.6	46.0	4.3825	0.0045*
		SD	2.3	2.9	3.1	3.5	0.0		
	At 14 weeks	Mean	58.1	59.3	57.1	57.9	58.0	1.2647	0.2972
		SD	1.2	3.1	2.7	3.0	4.2		
	At 6 months	Mean	66.0	64.6	64.5	64.5	64.5	0.6024	0.6623
		SD	2.1	2.7	1.6	2.1	3.5		
HC (in cm)	At Enrolment	Mean	33.5	32.7	32.4	31.6	32.0	1.9323	0.1158
		SD	0.8	1.8	1.4	1.7	1.4		
	At Discharge	Mean	33.7	33.2	32.8	32.3	32.5	1.5314	0.2035
		SD	0.9	1.5	1.4	1.6	0.7		
	At 15 days	Mean	34.5	33.8	33.2	32.6	32.8	2.2044	0.0786
		SD	0.6	2.0	1.2	1.7	1.1		

	At 6 weeks	Mean	36.3	36.0	35.0	35.0	32.0	4.1083	0.0063*
		SD	0.8	1.4	1.2	1.3	0.0		
	At 10 weeks	Mean	37.6	37.7	36.9	36.9	35.5	2.0594	0.1020
		SD	0.8	1.3	1.2	1.2	0.0		
	At 14 weeks	Mean	38.8	39.2	38.6	39.0	38.8	0.7098	0.5893
		SD	0.3	1.1	1.0	1.3	1.8		
	At 6 months	Mean	42.2	42.5	42.1	41.7	43.3	2.0850	0.0929
		SD	0.8	1.1	0.8	0.8	1.1		
MUAC (in cm)	At Enrolment	Mean	7.8	7.7	7.7	7.1	7.3	2.4974	0.0512
		SD	0.6	0.7	0.5	0.9	0.4		
	At Discharge	Mean	7.8	7.8	7.8	7.3	7.3	1.9541	0.1120
		SD	0.6	0.6	0.5	0.8	0.4		
	At 15 days	Mean	8.1	8.1	7.8	7.4	7.5	3.2370	0.0177*
		SD	0.6	0.8	0.5	0.8	0.0		
	At 6 weeks	Mean	9.6	10.0	9.3	8.3	7.5	9.1946	0.0001*
		SD	0.6	0.6	0.9	1.0	0.0		
	At 10 weeks	Mean	9.8	10.3	9.7	9.8	9.0	1.6661	0.1749
		SD	0.6	0.8	0.7	1.2	0.0		
	At 14 weeks	Mean	10.8	11.3	11.1	10.7	11.8	0.7703	0.5500
		SD	0.6	0.7	0.8	1.8	1.8		
	At 6 months	Mean	13.1	13.3	12.9	12.8	12.5	0.9256	0.4546
		SD	0.9	0.8	0.7	1.2	2.1		

In the study, family's SES was found to have a statistically significant correlation with the infant's early neonatal growth i.e., families with better SES had better growth of the neonate.

Table 21: Comparison of Birth Weight with Growth

Parameters	Time	Summary	1000-1499 grams	1500-2499 grams	2500-3999 grams	Total	F-value	P-value	
Weight (in gram)	At Enrolment	Mean	1323.08	2111.83	2871.88	2139.07	106.0094	0.0001*	
		SD	107.81	321.75	280.46	574.06			
	At Discharge	Mean	1428.08	2143.90	2890.94	2181.71	95.6014	0.0001*	
		SD	123.69	315.91	288.95	550.60			
	At 15 days	Mean	1439.62	2284.49	3029.69	2298.31	63.5335	0.0001*	
		SD	141.65	454.33	282.92	639.93			
	At 6 weeks	Mean	2231.67	3170.32	3926.79	3267.55	27.1817	0.0001*	
		SD	75.67	569.05	347.80	694.71			
	At 10 weeks	Mean	3265.00	4199.48	4932.86	4294.59	21.2209	0.0001*	
		SD	159.12	623.33	425.49	731.51			
	At 14 weeks	Mean	4496.00	4996.82	5622.14	5117.02	8.5190	0.0007*	
		SD	457.17	649.40	468.96	673.99			
	At 6 months	Mean	6093.08	6603.17	7103.44	6622.79	14.6161	0.0001*	
		SD	490.59	518.56	463.63	592.57			
	Length (in cm)	At Enrolment	Mean	41.38	46.06	48.97	45.86	46.9327	0.0001*
			SD	2.06	2.36	1.24	3.22		
At Discharge		Mean	42.85	46.59	49.31	46.51	33.4803	0.0001*	
		SD	2.01	2.37	1.33	2.95			
At 15 days		Mean	42.81	47.59	50.09	47.26	26.4725	0.0001*	
		SD	2.48	3.13	1.51	3.60			
At 6 weeks		Mean	56.17	50.95	53.25	52.19	1.3913	0.2586	
		SD	21.65	3.52	1.25	7.61			
At 10 weeks		Mean	50.83	54.40	56.71	54.62	8.0733	0.0010*	
		SD	1.97	3.59	1.75	3.45			
At 14 weeks		Mean	56.10	58.08	59.89	58.38	3.9246	0.0262*	
		SD	2.16	3.14	1.92	2.95			
At 6 months		Mean	62.73	64.78	66.16	64.71	10.0753	0.0001*	
		SD	2.29	1.91	2.20	2.30			

HC (in cm)	At Enrolment	Mean	30.42	32.51	34.00	32.46	31.2427	0.0001*
		SD	1.58	1.25	0.66	1.67		
	At Discharge	Mean	31.35	32.93	34.25	32.94	23.8470	0.0001*
		SD	1.36	1.18	0.71	1.45		
	At 15 days	Mean	31.50	33.51	34.81	33.43	21.9857	0.0001*
		SD	1.74	1.37	0.77	1.71		
	At 6 weeks	Mean	34.25	35.31	36.54	35.52	8.0693	0.0010*
		SD	1.29	1.44	0.66	1.42		
	At 10 weeks	Mean	36.17	37.10	38.14	37.28	7.5979	0.0014*
		SD	1.33	1.24	0.60	1.25		
	At 14 weeks	Mean	38.60	38.83	39.36	38.95	1.4602	0.2421
		SD	1.85	1.04	0.79	1.09		
	At 6 months	Mean	41.27	42.18	43.03	42.21	16.6503	0.0001*
		SD	0.75	0.82	0.87	0.99		
MUAC (in cm)	At Enrolment	Mean	6.62	7.55	8.22	7.53	40.0324	0.0001*
		SD	0.55	0.48	0.41	0.70		
	At Discharge	Mean	6.96	7.68	8.25	7.68	27.3090	0.0001*
		SD	0.43	0.50	0.41	0.62		
	At 15 days	Mean	6.92	7.90	8.59	7.88	37.0057	0.0001*
		SD	0.45	0.55	0.49	0.75		
	At 6 weeks	Mean	7.90	9.33	10.14	9.42	15.6379	0.0001*
		SD	0.55	0.90	0.50	0.99		
	At 10 weeks	Mean	8.90	9.92	10.57	10.00	10.0966	0.0002*
		SD	0.42	0.83	0.55	0.86		
	At 14 weeks	Mean	9.30	11.20	11.57	11.12	14.0484	0.0001*
		SD	1.15	0.84	0.70	1.03		
	At 6 months	Mean	12.38	13.05	13.59	13.05	7.3050	0.0013*
		SD	0.68	0.91	0.78	0.92		

*p<0.05

In the study, the infant's birth weight was found to have a statistically significant correlation with the infant's early and late neonatal growth (upto 6 months).

Table 22: Impact of Birth Weight (LBW & VLBW) On Growth Of Neonate

Parameters	Time	Summary	1000-1499 g	p-value	1500-2499 g	p-value			
Weight (in gram)	At enrolment	Mean	1323.08	0.000	2111.83	0.000			
		SD	107.81		321.75				
	At discharge	Mean	1428.08		2143.9				
		SD	123.69		315.91				
	1 st visit	Mean	1439.62		2284.49				
		SD	141.65		454.33				
	2 nd visit	Mean	2231.67		3170.32				
		SD	75.67		569.05				
	3 rd visit	Mean	3265		4199.48				
		SD	159.12		623.33				
	4 th visit	Mean	4496		4996.82				
		SD	457.17		649.4				
	5 th visit	Mean	6093.08		6603.17				
		SD	490.59		518.56				
	Length (in cm)	At enrolment	Mean		41.38		0.000	46.06	0.000
			SD		2.06			2.36	
At discharge		Mean	42.85	46.59					
		SD	2.01	2.37					
1 st visit		Mean	42.81	47.59					
		SD	2.48	3.13					
2 nd visit		Mean	56.17	50.95					
		SD	21.65	3.52					
3 rd visit		Mean	50.83	54.4					
		SD	1.97	3.59					
4 th visit		Mean	56.1	58.08					
		SD	2.16	3.14					
5 th visit		Mean	62.73	64.78					
		SD	2.29	1.91					
HC (in cm)		At enrolment	Mean	30.42	0.000	32.51		0.000	
			SD	1.58		1.25			
	At discharge	Mean	31.35	32.93					
		SD	1.36	1.18					

	1 st visit	Mean	31.5		33.51	
		SD	1.74		1.37	
	2 nd visit	Mean	34.25		35.31	
		SD	1.29		1.44	
	3 rd visit	Mean	36.17		37.1	
		SD	1.33		1.24	
	4 th visit	Mean	38.6		38.83	
		SD	1.85		1.04	
	5 th visit	Mean	41.27		42.18	
		SD	0.75		0.82	
MUAC (in cm)	At enrolment	Mean	6.62	0.000	7.55	0.000
		SD	0.55		0.48	
	At discharge	Mean	6.96		7.68	
		SD	0.43		0.5	
	1 st visit	Mean	6.92		7.9	
		SD	0.45		0.55	
	2 nd visit	Mean	7.9		9.33	
		SD	0.55		0.9	
	3 rd visit	Mean	8.9		9.92	
		SD	0.42		0.83	
	4 th visit	Mean	9.3		11.2	
		SD	1.15		0.84	
	5 th visit	Mean	12.38		13.05	
		SD	0.68		0.91	

Since majority of neonates were Term SGA babies, subset analysis of LBW and VLBW babies was done which showed that all the growth parameters (mean weight, mean length, mean H.C, mean MUAC) had a significant association with birthweight at enrolment, discharge and each of the follow up visits.

Table 23: Post HOC Test to See the Effect of Birthweight on Growth of VLBW Babies from 1000-1499 G

(I) Visits	(J) Visits	1000-1499 grams		
		Mean Difference (I-J)	Std. Error	p-value
Weight				
At enrolment	At discharge	-105.00	105.00	0.321
	1 st visit	-116.54	105.00	0.271
	2 nd visit	-908.59	132.12	0.000
	3 rd visit	-1941.92	132.12	0.000
	4 th visit	-3172.92	140.87	0.000
	5 th visit	-4770.00	105.00	0.000
Length				
At enrolment	At discharge	-1.46	2.33	0.533
	1 st visit	-1.42	2.33	0.543
	2 nd visit	1.88	2.93	0.522
	3 rd visit	-9.45	2.93	0.002
	4 th visit	-14.72	3.12	0.000
	5 th visit	-21.35	2.33	0.000
Head Circumference				
At enrolment	At discharge	-0.92	4.83	0.849
	1 st visit	-1.08	4.83	0.824
	2 nd visit	14.62	4.83	0.003
	3 rd visit	13.73	4.83	0.006
	4 th visit	15.58	4.83	0.002
	5 th visit	-10.85	4.83	0.027
Mid Upper Arm circumference				
At enrolment	At discharge	-0.35	0.23	0.141
	1 st visit	-0.31	0.23	0.190
	2 nd visit	-1.28	0.31	0.000
	3 rd visit	-2.28	0.31	0.000
	4 th visit	-2.68	0.31	0.000
	5 th visit	-5.77	0.23	0.000

The post hoc sensitivity analysis of **V LBW (1000-1499g)** revealed that birth weight had statistically significant association with weight, head circumference and MUAC from 2nd visit. While its association with length was observed from the 3rd visit in the VLBW babies.

Table 24: Post HOC Test to See the Effect of Birthweight on Growth of LBW Babies FROM 1500-2499 G

(I) Visits	(J) Visits	1500-2499 grams		
		Mean Difference (I-J)	Std. Error	p-value
Weight				
At enrolment	At discharge	-32.07	109.38	0.770
	1 st visit	-172.66	110.77	0.120
	2 nd visit	-1058.49	117.87	0.000
	3 rd visit	-2087.65	120.16	0.000
	4 th visit	-2884.99	115.82	0.000
	5 th visit	-4491.34	109.38	0.000
Length				
At enrolment	At discharge	-0.52	0.63	0.404
	1 st visit	-1.53	0.63	0.017
	2 nd visit	-4.88	0.68	0.000
	3 rd visit	-8.34	0.68	0.000
	4 th visit	-11.94	0.66	0.000
	5 th visit	-18.72	0.63	0.000
Head Circumference				
At enrolment	At discharge	-1.21	2.42	0.619
	1 st visit	-0.16	2.42	0.948
	2 nd visit	5.02	2.42	0.039
	3 rd visit	4.57	2.42	0.060
	4 th visit	0.46	2.42	0.849
	5 th visit	-10.48	2.42	0.000
Mid Upper Arm circumference				
At enrolment	At discharge	-0.15	0.19	0.451
	1 st visit	-0.17	0.20	0.389
	2 nd visit	-1.78	0.21	0.000
	3 rd visit	-2.37	0.21	0.000
	4 th visit	-3.65	0.21	0.000
	5 th visit	-5.50	0.19	0.000

The post hoc sensitivity analysis of LBW babies between 1500-2499 revealed that birth weight had statistically significant association with weight, head circumference and MUAC from 2nd visit. While its association with length was observed from the 1st visit in the LBW group.

Table 25: Comparison of Type of Feeding At enrolment With Growth

Type of feeding at enrolment		MOM + PDHM		PDHM		Total		p-value
		Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation	
Weight	At Enrolment	2483.33	533.57	2067.84	560.24	2139.07	574.06	0.021
	At Discharge	2541.67	515.56	2107.24	531.76	2181.71	550.60	0.012
	1 st visit	2777.73	772.19	2205.79	574.12	2298.31	639.93	0.006
	2 nd visit	3601.11	829.05	3196.07	651.76	3267.55	694.71	0.113
	3 rd visit	4642.50	889.55	4226.71	689.01	4294.59	731.51	0.143
	4 th visit	5378.33	802.63	5062.33	641.25	5117.02	673.99	0.204
	5 th visit	6915.83	483.70	6562.16	598.41	6622.79	592.57	0.059
Length	At Enrolment	48.33	2.79	45.34	3.08	45.86	3.22	0.003
	At Discharge	48.75	2.71	46.05	2.80	46.51	2.95	0.003
	1 st visit	50.23	4.12	46.69	3.23	47.26	3.60	0.002
	2 nd visit	53.78	3.35	49.47	8.43	50.23	7.92	0.140
	3 rd visit	57.25	3.77	54.12	3.19	54.62	3.45	0.017
	4 th visit	60.00	3.27	57.98	2.70	58.33	2.88	0.054
	5 th visit	66.50	2.06	64.34	2.19	64.71	2.30	0.003
HC	At Enrolment	33.58	1.06	32.23	1.68	32.46	1.67	0.009
	At Discharge	33.96	0.94	32.72	1.45	32.94	1.45	0.006
	1 st visit	34.64	1.50	33.20	1.66	33.43	1.71	0.010
	2 nd visit	36.44	1.04	35.33	1.43	35.53	1.43	0.033
	3 rd visit	38.25	0.96	37.10	1.23	37.28	1.25	0.015
	4 th visit	39.61	0.99	38.81	1.06	38.95	1.09	0.044
	5 th visit	42.92	0.87	42.07	0.95	42.21	0.99	0.006
MUAC	At Enrolment	7.92	0.47	7.45	0.72	7.53	0.70	0.034
	At Discharge	8.00	0.48	7.62	0.62	7.69	0.61	0.051
	1 st visit	8.36	0.81	7.66	1.25	7.77	1.21	0.077
	2 nd visit	9.56	0.85	9.38	1.02	9.41	0.98	0.623
	3 rd visit	10.44	0.98	9.91	0.82	10.00	0.86	0.117
	4 th visit	11.56	0.81	11.02	1.05	11.12	1.03	0.159
	5 th visit	13.58	0.85	12.94	0.90	13.05	0.92	0.027

In the study, type of feeding at enrolment had a significant association with weight at enrolment, discharge and 5th visit (6 months). Significant association with length was

at enrolment, discharge, 3rd visit and 6months visit. Significant association with head circumference at enrolment, discharge and all the follow up visits. Significant association with mid upper arm circumference at enrolment, discharge and 5th visit.

Table 26: Comparison of Type of Feeding At Discharge With Growth

Type of feeding at discharge		MOM		MOM+PDHM		Total		Sig.
		Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation	
Weight	At enrolment	2125.14	566.23	3100.00	.	2139.07	574.06	0.092
	At discharge	2168.77	543.80	3075.00	.	2181.71	550.60	0.103
	1 st visit	2284.70	634.77	3210.00	.	2298.31	639.93	0.153
	2 nd visit	3250.50	690.90	4120.00	.	3267.55	694.71	0.219
	3 rd visit	4280.94	732.92	4950.00	.	4294.59	731.51	0.371
	4 th visit	5105.39	675.41	5710.00	.	5117.02	673.99	0.38
	5 th visit	6618.62	595.88	6910.00	.	6622.79	592.57	0.629
Length	At enrolment	45.82	3.22	48.50	.	45.86	3.22	0.412
	At discharge	46.49	2.97	48.00	.	46.51	2.95	0.616
	1 st visit	47.23	3.62	49.50	.	47.26	3.60	0.536
	2 nd visit	50.19	8.00	52.50	.	50.23	7.92	0.776
	3 rd visit	54.58	3.47	56.50	.	54.62	3.45	0.587
	4 th visit	58.32	2.91	58.50	.	58.33	2.88	0.952
	5 th visit	64.72	2.32	64.00	.	64.71	2.30	0.757
HC	At enrolment	32.46	1.68	33.00	.	32.46	1.67	0.749
	At discharge	32.93	1.46	33.00	.	32.94	1.45	0.965
	1 st visit	33.43	1.73	33.50	.	33.43	1.71	0.969
	2 nd visit	35.53	1.44	35.50	.	35.53	1.43	0.984
	3 rd visit	37.28	1.27	37.50	.	37.28	1.25	0.861
	4 th visit	38.95	1.10	39.00	.	38.95	1.09	0.965
	5 th visit	42.19	0.97	44.00	.	42.21	0.99	0.068
MUAC	At enrolment	7.51	0.70	8.50	.	7.53	0.70	0.165
	At discharge	7.67	0.61	8.50	.	7.69	0.61	0.184
	1 st visit	7.75	1.21	9.00	.	7.77	1.21	0.312
	2 nd visit	9.39	0.98	10.50	.	9.41	0.98	0.266
	3 rd visit	9.99	0.87	10.50	.	10.00	0.86	0.562
	4 th visit	11.11	1.04	11.50	.	11.12	1.03	0.709
	5 th visit	13.04	0.92	14.00	.	13.05	0.92	0.302

In the study, type of feeding at discharge had no statistically significant association with growth.

Table 27: Comparison Of Mode Of Feeding With Growth

Parameters	Time	Summary	DBF+SFs	RTF	SFs	Total	F-value	P-value	
Weight (in gram)	At enrolment	Mean	2533.33	1655.00	2155.17	2139.78	16.2116	0.0001*	
		SD	376.94	541.35	505.92	578.23			
	At discharge	Mean	2546.90	1736.11	2193.17	2181.59	14.4777	0.0001*	
		SD	390.72	518.41	488.40	554.63			
	At 15 days	Mean	2758.00	1774.44	2304.83	2297.61	16.0588	0.0001*	
		SD	544.73	558.38	511.62	644.73			
	At 6 weeks	Mean	3630.29	2788.00	3211.30	3269.10	5.5502	0.0069*	
		SD	557.31	658.64	695.51	701.68			
	At 10 weeks	Mean	4615.00	3869.50	4245.00	4297.81	3.6757	0.0332*	
		SD	582.12	857.23	707.89	738.90			
	At 14 weeks	Mean	5295.56	4957.78	5045.21	5118.14	0.9990	0.3758	
		SD	579.53	761.50	718.99	680.65			
	At 6 months	Mean	6806.19	6395.28	6627.50	6621.30	2.3948	0.0991	
		SD	592.32	616.74	560.07	596.78			
	Length (in cm)	At enrolment	Mean	48.33	42.22	46.27	45.84	35.9463	0.0001*
			SD	1.59	2.73	2.38	3.24		
At discharge		Mean	48.62	43.36	46.85	46.48	28.4396	0.0001*	
		SD	1.75	2.50	2.29	2.96			
At 15 days		Mean	49.80	43.44	47.81	47.23	27.5228	0.0001*	
		SD	2.66	2.81	2.65	3.62			
At 6 weeks		Mean	53.03	53.70	50.88	52.18	0.6172	0.5438	
		SD	2.57	16.59	3.30	7.69			
At 10 weeks		Mean	56.24	52.45	54.27	54.58	4.4622	0.0169*	

		SD	2.88	3.30	3.48	3.47			
	At 14 weeks	Mean	59.25	57.33	58.08	58.36	1.4742	0.2391	
		SD	2.49	2.83	3.28	2.97			
	At 6 months	Mean	65.21	63.69	64.93	64.70	2.4727	0.0921	
		SD	2.24	2.80	1.90	2.31			
HC (in cm)	At enrolment	Mean	33.64	30.53	32.80	32.46	37.0531	0.0001*	
		SD	0.65	1.46	1.24	1.67			
	At discharge	Mean	33.86	31.47	33.15	32.93	21.8112	0.0001*	
		SD	0.76	1.44	1.18	1.46			
	At 15 days	Mean	34.45	31.69	33.79	33.43	21.5144	0.0001*	
		SD	1.06	1.61	1.36	1.72			
	At 6 weeks	Mean	36.15	34.40	35.52	35.51	5.5077	0.0071*	
		SD	0.90	1.29	1.57	1.44			
	At 10 weeks	Mean	37.85	36.30	37.27	37.28	5.6470	0.0064*	
		SD	0.84	1.25	1.32	1.27			
	At 14 weeks	Mean	39.17	38.28	39.04	38.95	2.2308	0.1185	
		SD	0.91	1.37	1.06	1.10			
	At 6 months	Mean	42.48	41.64	42.35	42.20	4.4268	0.015*	
		SD	0.98	1.01	0.88	0.99			
	MUAC (in cm)	At enrolment	Mean	7.98	6.78	7.68	7.54	26.7476	0.0001*
			SD	0.46	0.57	0.55	0.70		
		At discharge	Mean	8.02	7.14	7.77	7.68	14.2252	0.0001*
			SD	0.46	0.56	0.55	0.62		
At 15 days		Mean	8.33	7.17	8.02	7.88	18.3136	0.0001*	
		SD	0.61	0.62	0.60	0.75			
At 6 weeks		Mean	9.91	8.67	9.34	9.42	5.5674	0.0069*	
		SD	0.57	0.94	1.11	1.00			
At 10 weeks		Mean	10.24	9.39	10.09	10.01	3.2755	0.0470*	

		SD	0.81	0.86	0.83	0.87		
	At 14 weeks	Mean	11.17	10.50	11.31	11.12	2.1315	0.1298
		SD	0.79	1.32	1.04	1.04		
	At 6 months	Mean	13.33	12.67	13.10	13.06	2.6964	0.0749
		SD	0.73	1.00	0.95	0.93		

*p<0.05

In the study, mode of feeding had a statistically significant impact on the infant's growth with increased growth observed in those receiving DBF especially in the early neonatal period.

Table 28: Comparison of Gestational Age with Growth

Parameters	Time	Summary	28-33	34-36	37-38	39-40	F-value	P-value	
Weight (in gram)	At enrolment	Mean	1433.64	1932.38	2210.00	2601.88	22.8392	0.0001*	
		SD	315.89	418.13	390.51	451.07			
	At discharge	Mean	1547.27	1998.10	2216.79	2612.71	18.7001	0.0001*	
		SD	304.37	424.40	380.42	461.42			
	At 15 days	Mean	1534.09	2082.62	2358.57	2847.95	22.5490	0.0001*	
		SD	311.62	420.27	377.90	576.45			
	At 6 weeks	Mean	2261.25	2907.50	3280.42	3774.47	13.1441	0.0001*	
		SD	122.91	530.40	426.17	617.30			
	At 10 weeks	Mean	3276.67	3929.38	4263.18	4781.05	9.1773	0.0001*	
		SD	170.10	689.54	433.33	617.71			
	At 14 weeks	Mean	4373.33	4857.06	5094.55	5445.48	4.4928	0.0074*	
		SD	948.87	699.47	373.96	594.17			
	At 6 months	Mean	6137.73	6518.33	6640.36	6926.25	5.7664	0.0015*	
		SD	565.57	553.86	472.80	549.98			
	Length (in cm)	At enrolment	Mean	40.91	44.43	47.29	48.54	56.4038	0.0001*
			SD	1.58	2.23	1.50	1.42		
At discharge		Mean	42.27	45.19	47.64	48.96	42.4669	0.0001*	
		SD	1.54	2.18	1.49	1.58			
At 15 days		Mean	42.09	45.79	48.68	50.36	42.6275	0.0001*	
		SD	1.84	2.46	1.19	2.36			
At 6 weeks		Mean	45.38	52.30	52.17	53.55	1.2962	0.2868	
		SD	2.32	12.96	1.61	2.45			
At 10 weeks		Mean	49.25	52.69	55.27	57.00	14.9455	0.0001*	
		SD	2.22	2.94	2.03	2.47			
At 14 weeks		Mean	55.33	57.09	59.05	59.50	3.9402	0.0136*	
		SD	3.82	3.04	2.20	2.54			
		At 6 months	Mean	62.97	64.61	63.96	66.04	6.5315	0.0006*
			SD	2.67	1.94	1.89	1.97		
HC (in cm)		At enrolment	Mean	29.82	31.83	33.36	33.76	54.2980	0.0001*
			SD	1.08	1.06	0.84	0.69		
	At discharge	Mean	31.00	32.36	33.57	33.96	26.1525	0.0001*	

		SD	1.16	1.23	0.85	0.76			
	At 15 days	Mean	31.05	32.88	34.11	34.73	28.4807	0.0001*	
		SD	1.47	1.24	0.76	1.07			
	At 6 weeks	Mean	33.63	34.56	35.92	36.47	14.1739	0.0001*	
		SD	1.11	1.29	0.76	1.01			
	At 10 weeks	Mean	35.63	36.41	37.59	38.18	16.3433	0.0001*	
		SD	1.11	1.02	0.58	0.90			
	At 14 weeks	Mean	38.00	38.41	39.00	39.50	4.8614	0.0049*	
		SD	2.00	1.08	0.59	0.89			
	At 6 months	Mean	41.32	42.07	42.07	42.81	8.1222	0.0001*	
		SD	1.03	0.83	0.78	0.86			
	MUAC (in cm)	At enrolment	Mean	6.45	7.36	7.71	8.06	34.0951	0.0001*
			SD	0.42	0.45	0.47	0.45		
		At discharge	Mean	6.91	7.50	7.82	8.10	17.6805	0.0001*
			SD	0.49	0.50	0.50	0.42		
At 15 days		Mean	6.86	7.71	8.04	8.43	21.6360	0.0001*	
		SD	0.50	0.54	0.57	0.54			
At 6 weeks		Mean	7.50	8.84	9.54	10.17	19.3687	0.0001*	
		SD	0.00	0.87	0.54	0.59			
At 10 weeks		Mean	9.17	9.63	10.14	10.37	3.7611	0.0171*	
		SD	0.29	0.96	0.81	0.66			
At 14 weeks		Mean	10.00	11.09	11.00	11.36	1.6821	0.1833	
		SD	1.73	1.31	0.97	0.53			
At 6 months		Mean	12.50	12.83	13.21	13.40	3.2610	0.0269*	
		SD	0.92	1.14	0.73	0.64			

*p<0.05

In the study, gestational age of the newborn was found to have a statistically significant correlation with the infant's growth.

Thus, to conclude association of co-variables with growth; gestational age, birthweight and type of feeding at enrolment had a significant correlation with growth of the baby (p <0.05*). While SES and mode of feeding had significant association only with early neonatal growth (p <0.05*). However, mother's age, gender of neonate and type of feeding at discharge did not have any statistically significant association with growth of infant.

DISCUSSION

Donor Human milk banks are much more than simple centres for collection, storage, processing and distribution of PDHM, as they cover other aspects and represent a real opportunity to promote and support breastfeeding^{83,84,85}. When mother's own milk (MOM) is unavailable, WHO and UNICEF suggest that PDHM be used to bridge the gap⁸. The ingredients of human breast milk include immunoglobulins and other active constituents that can reduce infection, necrotising enterocolitis, cardiovascular risk and metabolic diseases⁸⁵. The short term and long-term benefits of PDHM on feeding patterns and growth have not been reported specially from a low resource setting. Majority of studies reported have observed feeding types and growth only at discharge. There is no clear evidence to demonstrate the impact of Pasteurised Donor Human Milk (PDHM) on rate of exclusive breast feeding (EBF) and growth after discharge from the hospital, especially in the Indian setting. Present study was an attempt to find out the impact of PDHM on feeding patterns and growth parameters following discharge from hospital up to 6 months of age.

General characteristics:

The majority of the mothers of the neonates who received PDHM in the study were between 20 to 29 years (78.57%). Similar observations of the age of the mothers, of the neonates receiving PDHM was reported by other Indian authors namely Melwani V²³ et al (55.7%), Trivedi P. et al.²⁴ (48.2%), Rashmi A. et al.²⁵ (59.14%), and Rajgopal VM et al.²⁶ (71.4%). Contrary to our observation, a recent Indian study in Western Uttar Pradesh (UP)²⁷ found that 39.8% of preterms delivered to mothers under the age of 35.

In our study, 68.57% of the women had completed primary education. An Indian study²⁸ investigating socio-economic factors impacting parental desire and willingness to donate breast milk found contradictory findings on mother's educational status (38.3%). However, according to another survey from Karnataka, 56.80% of the mothers had completed secondary education²⁵.

The majority of the families of newborns who received PDHM in the study (94.29 %) belonged to Hindu religion, which is consistent with the regional sociodemographic profile (84.49% Hindu)²⁹.

According to the 'Modified B G Prasad's classification', majority of the mothers (42.86%) in our study belonged to the Class IV socioeconomic strata, which is similar to other Indian studies looking into risk factors for preterm birth and the maternal sociodemographic profile^{24,28}.

Most of the mothers whose neonates received PDHM were primigravida. In the study, 40% of the mothers had no risk factors. In the remaining mothers, gestational hypertension (22.86 %) and PPRM (20 %) were the most common antenatal risk factors followed by anemia (14.29%). Gestational hypertension causes placental dysfunction, which leads to preterm delivery, according to several studies.^{27,30,31,32,33} It also causes placental malfunction, which leads to preterm birth.³⁴ PPRM and anemia were two other prominent maternal risk factors identified in the study followed by Anemia (14.29%).

In the study, 57.14% of babies were delivered by LSCS which is similar to other Indian studies^{27,38}. This high rate of LSCS in the study is because of the referral of high-risk antenatal cases with complications to our hospital since it is a tertiary care facility.

In the study, we observed that 52.86% neonates were aged 1.5-5 hours at the time of enrollment with mean age of 26.65 hours. 55.71% of the neonates were females and 44.29% were males. The female to male ratio was 1:0.79. In contrast, Hassan N. et al. (2019) in his study revealed that 74.5% of neonates admitted in NICU of a tertiary care institution in Western Uttar Pradesh (UP) were males. Several other studies have found a similar trend of gender distribution with male predominance^{27,28,29}.

Majority of neonates in the study were Term SGA babies with gestational age of 39-40weeks (34.29%) with a mean gestational age of 35.72 ± 2.68 weeks. The reason for this observation may be because of inclusion of stable babies with a birth weight of 1500-2499g (58.57%) for KMC care. This is contrary to findings of Adhisivam et al.³⁹ (31.82 weeks) and Debora et al.⁴⁰ (29.5 ± 2.3 weeks). APGAR score at 5 minutes was ≥ 7 in 97.14%. In contrast, a study from Norway by D Moster et al reported 75% of the neonates with APGAR scores of 7-10⁹⁸.

In the study, Low birth weight (LBW) (71.43%) was the most common reason for admission to the NICU and KMC followed by feeding difficulties (64.29%) and prematurity (55.71%). This is similar to findings of Khasawneh W et al and Bramer et al who observed similar indications of NICU admission^{87,89}.

Primary outcomes

Feeding Patterns of babies fed on PDHM:

Type of feeding

Majority of the babies at enrollment were on PDHM feeding. The acceptability rate of PDHM in the study was 68% and the most common reason to opt for PDHM was lack of secretion. This is similar to the observations of the other which is similar to that reported from a western study done by Ward et al (77%).⁹¹ However

a higher rate of acceptability (85.4%) was reported by an Indian study done by Melwani et al.²³ On the contrary studies from Ethiopia⁹² and Nigeria⁹³ have reported lower rates (15.2% and 13.1%) acceptability of PDHM by the mothers. The commonest reason for non-acceptability of the PDHM in our study was parental refusal, However, reason stated in other studies for non-acceptability of PDHM were fear of transmission to disease to the baby,¹¹¹⁻¹¹³ cultural fear relating to caste and creed.^{82,112}

In the study, the mean duration of PDHM feeding was 4.05 ± 2.61 days and the total amount given 354.72 ± 114.49 ml. The total duration of PDHM and the amount given in our study is less than the other studies reported from India and other countries. A south Indian study by Adhisivam et al reported the mean duration of PDHM of 8.5 ± 5.1 days³⁹. Other European studies also have reported a duration of 8.5 -10.5 days^{53,54}. The shorter duration of PDHM feeding of the neonates in our study when compared to other studies is probably due to inclusion of stable, term SGA babies and also early switching over to mother's milk (4.05 ± 2.61 days). According to an Italian study,⁵⁷ VLBW infants involved in the study consumed 34.9 ± 12.5 ml of donor human milk on average. In a study conducted in Rajasthan, newborns consumed an average of 95 mL of donor milk⁵⁵. Since majority of our babies in the study were stable term SGA babies the consumption of PDHM was more compared to other studies which have included more of preterm babies.

At the time of discharge, 98.55% of newborns were on mother's milk and 68.12% were on direct breast feeding. At each follow up visit, rate of direct breastfeeding had increased and by 6 months of age, 94.5% were on mother's milk and 94 % were on direct breast feeding. It was observed that 5.7% were still on SFs probably because of mixed feeding (MOM+ infant formula).

This is comparable to other studies by Underwood A and Bramer S et al who found that presence of a human milk bank (HMB) and the usage of PDHM in NICU are linked to a higher rate of breast feeding upon discharge^{72,86,87}. According to data from 83 NICUs collected by Italian Association of Human Milk Banks, exclusive breast feeding (EBF) rates were much higher in NICUs using HMB than in NICUs not using HMB.⁷³ In a study evaluating the impact of donor milk supply on preterm outcome in Californian NICUs, breast feeding rates were found to be higher (61.7%) at discharge. This may be probably due to postnatal counselling and lactation support provided by lactation counsellors in milk bank. An Indian study by Adhisivam et al reported an improvement in breastfeeding rates after opening of milk bank at 6months from 34% to 74%⁹⁴. Another south Indian study has also demonstrated an improving trend in BF rate at 6 months but has attributed this to the indirect effects of decrease use of formula and not completely on opening of Human milk bank.⁸³ PDHM availability promotes a breastfeeding-friendly environment which boost breastfeeding rates⁷⁴. Contrary to this observation, studies by Torre et al and Williams T et al found that opening a milk bank reduced EBF from 40% to 13%^{73,80}. A systematic review and meta-analysis showed no difference in exclusive breastfeeding rate at hospital discharge in very preterm infants after the introduction of donor human milk.⁸⁰

Method of feeding:

In the study, at enrolment- 43.48% neonates were on spoon feeds and 18.84% neonates were on Ryles Tube Feeds. 44.3% of these neonates were started on PDHM with spoon feeds while 24.3% on RT feeds as per WHO recommendations on infant feeding because it helps in reaching full enteral feeds and early hospital discharge (26%)^{51,52} when compared to RT feeding.

It was observed that 44.3% neonates were on SFs at enrolment and 31.88% were on DBF +SFs at discharge. The SF rates had reduced to 27.1%, 7.1% and 2.9 % respectively at 1st, 2nd and 3rd follow up visits but had again increased to 4.3% and 5.7% respectively at 4th and 5th follow up visits. It was observed that type of feeding at 3rd, 4th and 5th visits respectively had a statistically significant correlation ($p < 0.05$) with method of feeding at each of these visits. Contrary to this observation, a study on the use of donor human milk in non-hospitalised infant by Bramer S et al revealed no statistically significant association between method and type of feeding⁸⁷.

In the study, mean frequency of feeds decreased from 10.84 ± 0.97 feeds/day at enrolment to 9.59 feeds/day at discharge ($p < 0.05$) and to 9.28 ± 0.97 feeds/ day at 6 months which was statistically insignificant. Similarly, another retrospective study by Hussain A et al reported decrease in frequency of feeds after discharge from hospital which was statistically insignificant⁹⁷.

Supplements

From discharge to 6 months, the administration of supplements grew dramatically, with statistically significant increase in Vitamin D (p value= 0.0001) and iron supplementation (p value = 0.0001) with insignificant increases in calcium supplementation (p value =0.1460). The supplementation with all these vitamins probably had a positive impact on growth of these children. A south Indian study by Adhisivam et al also reported Supplementation and fortification of PDHM with specific nutrients, such as vitamin D, proteins, and calcium, increased weight accretion in premature infants⁹⁵.

Secondary Outcomes**Growth Parameters of babies****Weight**

In the study, significant increase in mean weight of babies was observed which had increased from 2.139 ± 0.574 kg at enrolment to 2.181 ± 0.55 kg at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 6.622 ± 0.592 kg by 6 months ($p = 0.000$). Significant increase in mean length of babies was observed which had increased from 45.86 ± 3.22 cm at enrolment to 46.51 ± 2.95 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 64.71 ± 2.30 cm by 6 months ($p = 0.000$). Significant increase in mean head circumference of babies was observed which had increased from 32.46 ± 1.74 cm, at enrolment to 32.93 ± 1.46 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 42.20 ± 0.99 cm by 6 months ($p = 0.000$). In the study, significant increase in mean mid upper arm circumference of babies was observed which had increased from 7.53 ± 0.70 cm at enrolment to 7.68 ± 0.62 cm at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 13.05 ± 0.92 cm by 6 months ($p = 0.000$).

A retrospective study demonstrated better short-term weight gain and head circumference (HC) growth with MOM supplemented with fortified donor milk compared to MOM plus formula ⁷⁵. Another study by Adhisivam et al reported no significant difference in growth parameters like weight gain and increase in head circumference among neonates in the fortified versus the unfortified group⁹⁵. A study by Quigley M et al reported that donor milk is associated with decreased rates of short term in hospital growth, compared to formula milk⁸. However, recent studies and systematic reviews have reported that donor milk has better or no negative short-term

impact on the growth at discharge.^{74,75,76} Majority of these studies have observed feeding types and growth only at discharge.

A study conducted by L. Lloyd M et al to evaluate the difference in growth of neonates on PDHM when compared to MOM observed transient slow growth in PDHM group but the catch-up growth was evident by discharge. By 3 months of age no difference was observed in 2 groups⁸⁸. Deborah et al.⁴⁰ and Sisk et al.⁷¹ found similar no significant impact on growth with PDHM in their studies.

The mean Z-scores of the growth velocity in the neonates significantly increased after the 1st visit (i.e., 15 days) in all the neonates. Similar observations were made by Hoban et al in a study where he found Z-scores for weight and length decreased during hospitalization but increased for all parameters including head circumference post-discharge⁷⁵. In the study; the multivariate regression analysis suggested that age, gender of the newborn, and frequency of feeding had no statistically significant association with the infant's growth. This is similar to finding of Bramer S et al who studied the effect of donor milk in non-hospitalised infant and found that there is no significant correlation between age and growth of neonate⁸⁷.

Socio economic status and mode of feeding of the family was found to have a significant relationship with the infant's early neonatal growth ($p < 0.05$). The study found that the infant's birth weight and gestational age had a statistically significant association with his or her growth (p value < 0.05). Similar findings were observed by Hoban R et al in a study on Impact of Donor Milk on Short- and Long- Term Growth of VLBW infants where gestational age was associated with growth⁷⁵. This was contrary to findings of a study evaluating the impact of donor milk on the infant's growth where mode of feeding did not have any association with infant's growth⁸⁷.

In the study, type of feeding at enrolment had a significant association with weight at enrolment, discharge and 5th visit (6 months). Significant association with length at enrolment, discharge, 3rd visit and 6 months visit. Significant association with head circumference at enrolment, discharge and all the follow up visit. Significant association with mid upper arm circumference at enrolment, discharge and 5th visit. In the study, type of feeding at discharge had no statistically significant association with growth. Contrary to this, a study by Sisk et al. had shown that maternal milk and PDHM feeding given until 34 weeks postmenstrual age was not associated with any impact on growth of very low birth weight infants⁹⁶. In contrast, a study Hoban et al in Canada reported no impact of type of feeding on short term or long-term growth⁷⁵. Since majority of neonates were Term SGA babies, subset analysis of LBW and VLBW babies was done which showed that all the growth parameters (mean weight, mean length, mean H.C, mean MUAC) had a significant increase at 6 months of age. The post hoc sensitivity analysis of 2 subgroups- LBW (1500-2499) and VLBW (1000-1499g) revealed that birth weight had statistically significant correlation with length as it was observed to have better increment in the 1st visit in the LBW group than in 3rd visit in the VLBW group. While the effect of birth weight had statistically significant correlation with weight, head circumference and mid upper arm circumference from 2nd visit in both the groups.

Overall, the current study found that using PDHM improved both breastfeeding and growth rates (early and late neonatal).

Strengths:

It's the first study to evaluate the impact of PDHM beyond discharge upto 6 months of age with a adequate sample size.

LIMITATIONS

Due to COVID-19 situation, drop-out rate was high. The results of the study were based on the data from a single centre and its study design being longitudinal observational. Ideal would have been RCT study. The study also did not evaluate the knowledge about the PDHM among mothers which is likely to help in promoting the PDHM.

Recommendations

Multicentric randomised controlled studies are required to evaluate the effect of PDHM on feeding patterns and growth parameters. Also, assessment of knowledge of the mothers towards PDHM and long-term outcomes on neurodevelopment may provide the feasibility of PDHM.

CONCLUSION

This observational longitudinal study conducted to know feeding pattern and growth after discharge from the hospital among neonates receiving PDHM demonstrated a substantial increase in exclusive breastfeeding rate and adequate growth at 6 months of age. All growth parameters including weight, length, H.C and MUAC improved considerably in neonates receiving PDHM by time of discharge upto 6 months of age, implying that PDHM had a positive impact on breastfeeding, early and late post neonatal growth. Multicentric, larger sample size Randomised Controlled Trials are recommended to investigate effect of PDHM on feeding patterns and growth parameters.

SUMMARY

- The ingredients of human breast milk include immunoglobulins and other active constituents that can reduce infection, necrotising enterocolitis, cardiovascular risk and metabolic diseases⁸⁵. Under some circumstances, when MOM is not available, PDHM fills the gap. Present study was an attempt to find out the impact of PDHM on feeding patterns and growth parameters of neonates (weight, length, H.C and MUAC), time of initiation of breastfeeding and to assess its acceptability in the recipients.
- The observational longitudinal study was conducted from January 2020 to December 2020 in the Department of Pediatrics, KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. During the study period a total of 1554 neonates admitted in NICU were screened for eligibility. Out of these, 150 neonates were eligible, 102 accepted PDHM which were enrolled in study of which 32 were drop outs and data pertaining to 70 neonates were analysed. The data was analysed and the important findings of the study are summarized as below.
- Out of babies who accepted PDHM (68%)- 102/150. The Indications of starting PDHM- In 57/70 cases (81.4%), it was lack of secretions, in 9/70 cases (12.8%) it was inverted nipples in mother and in 4/70 cases due to maternal illness (Eclampsia)
- Among the infants who received PDHM, most of the mothers (42.86%) were aged between 21 to 29 years, had primary education (68.5%), majority of them (94.29%) belonged to Hindu religion and most of the mother's (42.86%) belonged to Class IV socio economic strata according to the Modified B G Prasad's classification.

- Most of the mothers whose neonates received PDHM were primigravida. In the study, 40% of the mothers had no risk factors. In the remaining mothers, gestational hypertension (22.86 %) and PPRM (20 %) were the most common antenatal risk factors followed by anemia (14.29%).
- 52.86% neonates were aged 1.5-5 hours at the time of enrollment with mean age of 26.65 hours.
- 55.71% of the neonates were females and 44.29% were males. The female to male ratio was 1:0.79.
- Majority of neonates were Term SGA babies with gestational age of 39-40weeks (34.29%) and with a birth weight of 1500-2499g (58.57%). APGAR score at 5 minutes was ≥ 7 in 97.14%.
- In the study, Low birth weight (LBW) (71.43%) was the most common reason for admission to the NICU and KMC followed by feeding difficulties (64.29%) and prematurity (55.71%).
- In the study, at enrolment, 82.61% of the neonates were exclusively on PDHM, whereas 17.39% were on MOM+PDHM. At the time of discharge, 98.55% of newborns were on MOM whereas 1.45% were on MOM+PDHM. By 6 months of age, 94.5% were on MOM and 5.5% were on mixed feeding (MOM + Formula).
- In the study, at enrolment, the mean of total amount of PDHM given to the neonates was 102 ± 31.74 ml. The mean duration of PDHM feeding was 4.05 ± 2.61 days. Out of which mean duration of exclusive PDHM feeding was 2.59 ± 1.78 days and the mean duration of mixed feeding (PDHM +MOM) was 1.46 ± 1.00 days; the

duration of MOM was 1.27 ± 0.81 days; and the time to switch from PDHM to MOM feeding was 4.05 ± 2.61 days. The mean of total amount of PDHM given for the total duration was 354.72 ± 114.49 ml.

- It was observed that 44.3% neonates were on SFs at enrolment which had reduced to 27.1%, 7.1% and 2.9 % respectively at 1st, 2nd and 3rd follow up visits but had again increased to 4.3% and 5.7% respectively at 4th and 5th follow up visits. It was observed that type of feeding at 2nd, 3rd, 4th and 5th visit respectively had a significant correlation with method of feeding at each of these visits.
- In the study, mean frequency of feeds decreased from 10.84 ± 0.97 feeds/day at enrolment to 9.59 feeds/day at discharge and to 9.28 ± 0.97 feeds/ day at 6 months.
- Vitamin D supplementation had increased from 72.86% at the time of discharge to 92.86% at the end of 6 months ($p < 0.05$).
- In the study, calcium supplementation had increased from 60% at discharge to 68.12% at 6 months which was statistically insignificant.
- Iron supplementation increased from 17.14% at discharge to 95.71% at 6 months ($p < 0.05$).
- In the study, significant increase in mean weight of babies was observed which had increased from 2.139 ± 0.574 kg at enrolment to 2.181 ± 0.55 kg at discharge ($p = 0.000^*$), during each follow up visits ($p = 0.000$) and to 6.622 ± 0.592 kg by 6 months ($p = 0.000$).
- In the study, significant increase in mean length of babies was observed which had increased from 45.86 ± 3.22 cm at enrolment to 46.51 ± 2.95 cm at discharge (p

- =0.000*), during each follow up visits (p= 0.000) and to 64.71 ± 2.30 cm by 6 months (p = 0.000).
- In the study, significant increase in mean head circumference of babies was observed which had increased from 32.46 ± 1.74 cm, at enrolment to 32.93 ± 1.46 cm at discharge (p =0.000*), during each follow up visits (p= 0.000) and to 42.20 ± 0.99 cm by 6 months (p = 0.000).
 - In the study, significant increase in mean mid upper arm circumference of babies was observed which had increased from 7.53 ± 0.70 cm at enrolment to 7.68 ± 0.62 cm at discharge (p =0.000*), during each follow up visits (p= 0.000) and to 13.05 ± 0.92 cm by 6 months (p = 0.000).
 - The mean Z-scores of the growth velocity in the neonates significantly increased after the 1st visit (i.e., 15 days) in all the neonates.
 - In the study; gestational age and birthweight had a significant correlation with growth of the baby (p <0.05*). Since majority of neonates were Term SGA babies, subset analysis of LBW and VLBW babies was done which showed that all the growth parameters (mean weight, mean length, mean H.C, mean MUAC) had a significant association with birthweight at enrolment, discharge and each of the follow up visits.
 - The post hoc sensitivity analysis of 2 subgroups of birthweight- LBW (1500-2499) and VLBW (1000-1499g) revealed that birth weight had statistically significant association with length from the 1st visit in the LBW group and from 3rd visit in the VLBW group.

- The post hoc sensitivity analysis of the 2 subgroups- LBW and VLBW revealed that birth weight had statistically significant association with weight, head circumference and mid upper arm circumference from 2nd visit in both the groups.
- In the study, type of feeding at enrolment had a significant association with weight at enrolment, discharge and 5th visit (6 months). Significant association with length at enrolment, discharge, 3rd visit and 6 months visit. Significant association with head circumference at enrolment, discharge and all the follow up visits. Significant association with mid upper arm circumference at enrolment, discharge and 5th visit. In the study, type of feeding at discharge had no statistically significant association with growth.
- In the study, mother's age and gender of neonate did not have any statistically significant association with growth of infant.
- While SES and mode of feeding had significant association only with early neonatal growth ($p < 0.05^*$).

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ANNEXURE I- ETHICAL CLEARANCE LETTER

From,

REG NO. BM0119010

Post Graduate,

Department of Paediatrics,

J. N. Medical College, Belagavi.

To,

The Registrar,

KAHER

Belagavi-10.

Through Proper Channel

Sub: Institutional ethical clearance for the study.

Respected Sir,

With reference to the above, I wish to inform that my study "To study the feeding and growth patterns of babies fed on Pasteurised Donor Human Milk after discharge from the hospital upto 6 months of age- A observational longitudinal study". is cleared by department of ethical clearance committee and college dissertation and research committee.

Thanking you,

Yours faithfully,


DR.ROOPA M. BELLAD, M.D

PROF. OF PEADIATRICS & CHAIRMAN,

JNMC INSTITUTIONAL ETHICS COMMITTEE

ON HUMAN SUBJECTS RESEARCH

J.N.MEDICAL COLLEGE,BELAGAVI-10,

ANNEXURE II – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH

“To study the feeding patterns and growth parameters of babies fed on Pasteurised Donor Human Milk after discharge from the hospital upto 6 months of age- A observational longitudinal study”

Principal Investigator: REG NO. BM0119010

Guide- Dr. _____

You have been asked to involve your child in the above said research to be conducted at NICU of KAHER, JN medical college hospital, Belagavi by Dr. Rohan Sapra, PG student in the Department of Paediatrics at Jawaharlal Nehru Medical College, Belagavi.

Introduction

PURPOSE OF THE STUDY:

Participation of your child will help us to evaluate feeding patterns of infants who have received Pasteurised Donor Human Milk and other observational outcome following discharge. You are free to discontinue the participation in the study at any time for any reasons and you will not be paid any reimbursement for participation in the research. Hence involving your child in the study is your voluntary decision.

Voluntary participation

Your child’s participation in this study is your voluntary decision, whether or not to participate will not affect your current or future relationship with KLEs Dr. Prabhakar Kore Charitable Hospital & MRC, Belagavi.

Risk and benefits

There are no risks involved.

Reduction in morbidity and mortality.

Privacy and Confidentiality

The only people who will know that you are a research participant are member of the research team. No information about you or provided by you, during research will be disclosed to others without your written consent. When the results of the research are published or discussed in the conferences, no information will be disclosed that would reveal your identity. Any information obtained in connections with this study and that can be identified with you remain confidential and will be disclosed only with your permission.

Queries

If you have any queries you may contact

REG NO. BM0119010,

Post Graduate Student
Department of Paediatrics
JNMC, Belagavi-590010

DR. _____

Professor
Department of Paediatrics,
JNMC, Belagavi-590010

If you have any questions about your rights or research participation you may contact
Chairman ethical committee:

DR. ROOPA. M.BELLAD MD DCH

Professor
Department of Paediatrics,
Jawaharlal Nehru Medical College,
Belagavi-590010

You will be given a copy of this form for your information and to keep for your records.

STATEMENT OF CONSENT

I hereby voluntarily agree for my participation in this study. I understand that even if I have the liberty to withdraw at any time. My signature below indicates that I have read or have been told in the language I understand , about this entire consent form including the risks and benefits and have had all my questions answered. I will be given a copy of this consent form.

Signature of the authorized representative/ parent: _____

Date: _____

Name: _____

Relation to the Subject: _____

Signature of the witness: _____

Date: _____

Name: _____

Signature of investigator: _____

Date: _____

Name: _____

ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ

"ಆಸ್ಪತ್ರೆಯಿಂದ ಡಿಸ್ಚಾರ್ಜ್ ಮಾಡಿದ ನಂತರ 6 ತಿಂಗಳ ವಯಸ್ಸಿನವರೆಗೆ ಪಾಶ್ಚರಿಕರಿಸಿದ ದಾನಿ ಮಾನವ ಹಾಲಿಗೆ ಆಹಾರ ನೀಡುವ ಶಿಶುಗಳ ಫೀಡಿಂಗ್ ಪ್ಯಾಟರ್ನ್ಸ್ ಮಾದರಿಗಳು ಮತ್ತು ಬೆಳವಣಿಗೆಯ ನಿಯತಾಂಕಗಳನ್ನು ಅಧ್ಯಯನ ಮಾಡಲು- ಒಂದು ವೀಕ್ಷಣಾ ರೇಖಾಂಶದ ಅಧ್ಯಯನ"

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ: REG NO. BM0119010

ಮಾರ್ಗದರ್ಶಿ: ಡಾ. _____

ಬೆಲಗವಿಯ ಕೆಎಲ್‌ಇ ವಿಶ್ವವಿದ್ಯಾಲಯದ ಜೆಎನ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ಆಸ್ಪತ್ರೆಯ ಎನ್‌ಐಸಿಯು, ಬೆಲಗವಿಯ ಜವಾಹರಲಾಲ್ ನೆಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನಲ್ಲಿ ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ವಿಭಾಗದ ಪಿಜಿ ವಿದ್ಯಾರ್ಥಿ ಡಾ.ರೋಹನ್ ಸಪ್ರಾ ಅವರಿಂದ ನಡೆಸಬೇಕಾದ ಸಂಶೋಧನೆಯಲ್ಲಿ ನಿಮ್ಮ ಮಗುವನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳಲು ನಿಮ್ಮನ್ನು ಕೇಳಲಾಗಿದೆ .

ಪರಿಚಯ

ಅಧ್ಯಯನದ ಉದ್ದೇಶ :

ಪಾಶ್ಚರಿಕರಿಸಿದ ಡೋನರ್ ಮಾನವ ಹಾಲು ಮತ್ತು ವಿಸರ್ಜನೆಯ ನಂತರದ ಇತರ ವೀಕ್ಷಣಾ ಫಲಿತಾಂಶಗಳನ್ನು ಪಡೆದ ಶಿಶುಗಳ ಆಹಾರ ಮಾದರಿಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲು ನಿಮ್ಮ ಮಗುವಿನ ಭಾಗವಹಿಸುವಿಕೆಯು ನಮಗೆ ಸಹಾಯ ಮಾಡುತ್ತದೆ. ಯಾವುದೇ ಕಾರಣಗಳಿಗಾಗಿ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದನ್ನು ನಿಲ್ಲಿಸಲು ನೀವು ಮುಕ್ತರಾಗಿದ್ದೀರಿ ಮತ್ತು ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮಗೆ ಯಾವುದೇ ಮರುಪಾವತಿ ನೀಡಲಾಗುವುದಿಲ್ಲ. ಆದ್ದರಿಂದ ನಿಮ್ಮ ಮಗುವನ್ನು ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಿಕೊಳ್ಳುವುದು ನಿಮ್ಮ ಸ್ವಯಂಪ್ರೇರಿತ ನಿರ್ಧಾರ.

ಸ್ವಯಂಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಮಗುವಿನ ಭಾಗವಹಿಸುವಿಕೆಯು ನಿಮ್ಮ ಸ್ವಯಂಪ್ರೇರಿತ ನಿರ್ಧಾರವಾಗಿದೆ, ಭಾಗವಹಿಸಬೇಕೇ ಅಥವಾ ಬೇಡವೇ ಎಂಬುದು ಕೆಎಲ್‌ಇಗಳೊಂದಿಗಿನ ನಿಮ್ಮ ಪ್ರಸ್ತುತ ಅಥವಾ ಭವಿಷ್ಯದ ಸಂಬಂಧದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ಡಾ. ಪ್ರಭಾಕರ್ ಕೋರೆ ಚಾರಿಟೇಬಲ್ ಹಾಸ್ಪಿಟಲ್ ಮತ್ತು ಎಂಆರ್‌ಸಿ, ಬೆಳಗಾವಿ .

ಅಪಾಯ ಮತ್ತು ಪ್ರಯೋಜನಗಳು

ಯಾವುದೇ ಅಪಾಯಗಳಿಲ್ಲ.

ಕಾಯಿಲೆ ಮತ್ತು ಮರಣ ಪ್ರಮಾಣದಲ್ಲಿನ ಕಡಿತ.

ಗೌಪ್ಯತೆ ಮತ್ತು ಗೌಪ್ಯತೆ

ನೀವು ಸಂಶೋಧನಾ ಭಾಗವಹಿಸುವವರು ಎಂದು ತಿಳಿಯುವ ಜನರು ಮಾತ್ರ ಸಂಶೋಧನಾ ತಂಡದ ಸದಸ್ಯರಾಗಿದ್ದಾರೆ. ನಿಮ್ಮ ಬಗ್ಗೆ ಯಾವುದೇ ಮಾಹಿತಿ ಅಥವಾ ನೀವು ಒದಗಿಸಿಲ್ಲ, ಸಂಶೋಧನೆಯ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಲಿಖಿತ ಒಪ್ಪಿಗೆಯಿಲ್ಲದೆ ಇತರರಿಗೆ ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ. ಸಂಶೋಧನೆಯ ಫಲಿತಾಂಶಗಳನ್ನು ಸಮ್ಮೇಳನಗಳಲ್ಲಿ ಪ್ರಕಟಿಸಿದಾಗ ಅಥವಾ ಚರ್ಚಿಸಿದಾಗ, ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದೊಂದಿಗಿನ ಸಂಪರ್ಕಗಳಲ್ಲಿ ಪಡೆದ ಯಾವುದೇ ಮಾಹಿತಿಯು ಮತ್ತು ಅದನ್ನು ನಿಮ್ಮೊಂದಿಗೆ ಗುರುತಿಸಬಹುದು ಅದು ಗೌಪ್ಯವಾಗಿ ಉಳಿಯುತ್ತದೆ ಮತ್ತು ನಿಮ್ಮ ಅನುಮತಿಯೊಂದಿಗೆ ಮಾತ್ರ ಬಹಿರಂಗಗೊಳ್ಳುತ್ತದೆ.

ಪ್ರಶ್ನೆಗಳು

ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ ನೀವು ಸಂಪರ್ಕಿಸಬಹುದು

ಡಾ. REG NO. BM0119010

ಸ್ನಾತಕೋತ್ತರ ವಿದ್ಯಾರ್ಥಿ

ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ಇಲಾಖೆ

ಜೆಎನ್‌ಎಂಸಿ, ಬೆಳಗಾವಿ -591010

ಡಾ. _____

ಪ್ರೊಫೆಸರ್

ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ಇಲಾಖೆ,

ಕಾಹೇರ್ ಜವಾಹರಲಾಲ್ ನೆಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು,

ಬೆಳಗಾವಿ -590010.

ನಿಮ್ಮ ಹಕ್ಕುಗಳು ಅಥವಾ ಸಂಶೋಧನಾ ಭಾಗವಹಿಸುವಿಕೆಯ ಬಗ್ಗೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ ನೀವು ಸಂಪರ್ಕಿಸಬಹುದು

ಡಾ. ರೂಪಾ ಎಂ. ಬೆಲ್ಲದ, ಎಂಡಿ, ಡಿ ಸಿಎಚ್

ಪ್ರೊಫೆಸರ್

ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ಇಲಾಖೆ,

ಕಾಹೇರ್ ಜವಾಹರಲಾಲ್ ನೆಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು,

ಬೆಳಗಾವಿ -590010.

ನಿಮ್ಮ ಮಾಹಿತಿಗಾಗಿ ಮತ್ತು ನಿಮ್ಮ ದಾಖಲೆಗಳಿಗಾಗಿ ಇರಿಸಿಕೊಳ್ಳಲು ಈ ಫಾರ್ಮ್‌ನ ನಕಲನ್ನು ನಿಮಗೆ ನೀಡಲಾಗುವುದು.

ಒಪ್ಪಿಗೆಯ ಹೇಳಿಕೆ

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಮತ್ತು ನನ್ನ ಮಗುವಿನ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ. ನನ್ನ ಮಗುವಿಗೆ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಅನುಮತಿಸಿದರೂ ಸಹ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಸ್ವಾತಂತ್ರ್ಯವಿದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ. ಕೆಳಗಿನ ನನ್ನ ಸಹಿ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳನ್ನು

Annexure II – Consent Form

ಒಳಗೊಂಡಂತೆ ಈ ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯ ಫಾರ್ಮ್ ಅನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಅಥವಾ ಹೇಳಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿದ್ದೇನೆ ಎಂದು ಸೂಚಿಸುತ್ತದೆ. ಈ ಒಪ್ಪಿಗೆ ಪತ್ರದ ನಕಲನ್ನು ನನಗೆ ನೀಡಲಾಗುವುದು.

ಅಧಿಕೃತ ಪ್ರತಿನಿಧಿ / ವೋಷಕರ ಸಹಿ: _____

ದಿನಾಂಕ: _____

ಹೆಸರು: _____

ವಿಷಯಕ್ಕೆ ಸಂಬಂಧ: _____

ಸಾಕ್ಷಿಯ ಸಹಿ: _____

ದಿನಾಂಕ: _____

ಹೆಸರು: _____

ತನಿಖಾಧಿಕಾರಿಯ ಸಹಿ: _____

ದಿನಾಂಕ: _____

ಹೆಸರು: _____

संशोधनात सहभागी होण्यासाठी संमती

"6 महिन्यांपर्यंत रुग्णालयातून डिस्चार्ज नंतर पाश्चराइज डोनर मानवी दुधावर दिले जाणा-

या मुलांच्या फीडिंग पॅटर्न नमुन्यांचा आणि वाढीच्या मापदंडांचा अभ्यास करण्यासाठी - एक वेधात्मक रेखांशाचा अभ्यास"

प्रधान अन्वेषक: REG NO. BM0119010

मार्गदर्शक: डॉ. _____

तुम्हाला केएलई विद्यापीठाच्या जेएन वैद्यकीय महाविद्यालय रुग्णालयाच्या एनआयसीयू, बेलगावी, जवाहरलाल नेहरू मेडिकल कॉलेज, बेलगावी येथील बाल रोगशास्त्र विभागातील पीजी विद्यार्थी डॉ. रोहन सप्रा यांनी केले असलेल्या उपरोक्त संशोधनात आपल्या मुलास सामील करण्यास सांगितले गेले आहे .

परिचय

अभ्यासाचा हेतू:

आपल्या मुलाचा सहभाग आम्हाला शिशुंच्या आहार पद्धतींचे मूल्यांकन करण्यास मदत करेल ज्याने पाश्चर्युटर डोनेर ह्यूमन मिल्क प्राप्त केला असेल आणि इतर स्त्राव परीक्षणंतर निकाल मिळाला असेल. आपण कोणत्याही कारणास्तव अभ्यासामधील सहभाग कोणत्याही वेळी थांबवू शकता आणि आपल्याला संशोधनात भाग घेण्यासाठी कोणतेही मोबदला दिला जाणार नाही. म्हणूनच आपल्या मुलास अभ्यासामध्ये सामील करणे हा आपला ऐच्छिक निर्णय आहे .

ऐच्छिक सहभाग

या अभ्यासामध्ये आपल्या मुलाचा सहभाग हा आपला ऐच्छिक निर्णय आहे, भाग घ्यावा की नाही या बद्दल केएलईएस, प्रभाकरकोरे चॅरिटेबल हॉस्पिटल आणि एमआरसी, बेलगावी यांच्याशी आपल्या सध्याच्या किंवा भविष्यातील संबंधांवर परिणाम होणार नाही .

जोखीम आणि फायदे

यात कोणतेही धोका नाही.

विकृती आणि मृत्यू कमी.

गोपनीयता

आपण संशोधन सहभागी आहात हे केवळ लोकांनाच कळेल की ते संशोधन पथकाचे सदस्य आहेत. संशोधनाच्या वेळी आपल्याबद्दल किंवा आपल्याद्वारे प्रदान केलेली कोणतीही माहिती आपल्या लेखी संमतीशिवाय इतरांना उघड केली जाणार नाही. जेव्हा संमेलनात संशोधनाचे निकाल प्रकाशित केले जातात किंवा त्यावर चर्चा केली जाते तेव्हा आपली ओळख उघडकीस आणणारी कोणतीही माहिती उघड केली जाणार नाही. या अभ्यासाच्या संबंधात प्राप्त केलेली कोणतीही माहिती आणि ती आपल्याबरोबर ओळखली जाऊ शकते आणि ती केवळ आपल्या परवानगीनेच उघड केली जाईल .

प्रश्नों

आपल्याकडे काही शंका असल्यास आपण संपर्क साधू शकता

REG NO. BM0119010

बालरोग विभाग

जेएनएमसी, बेलगावी -590010

डॉ. _____

प्रोफेसर,

बाल रोग विभाग।

काहेर के एल ई विश्वविद्यालय

जवाहरलाल नेहरू मेडिकल कॉलेज, बेलगाम -590010

आपल्याकडे आपल्या हक्कांबद्दल किंवा संशोधन सहभागाबद्दल काही प्रश्न असल्यास आपण संपर्क साधू शकता

डॉ. रूपा एम बेलाड, एमडी, डी सी एच

प्रोफेसर,

बाल रोग विभाग।

काहेर के एल ई विश्वविद्यालय

जवाहरलाल नेहरू मेडिकल कॉलेज, बेलगाम -590010

आपल्याला आपल्या माहितीसाठी आणि आपल्या नोंदी ठेवण्यासाठी या फॉर्मची एक प्रत दिली जाईल .

संमती विधान

या अभ्यासात माझ्या आणि माझ्या मुलाच्या सहभागासाठी मी स्वेच्छेने सहमत आहे. मला हे समजले आहे की जरी मी माझ्या अभ्यासाला या अभ्यासामध्ये भाग घेण्याची अनुमती दिली तर मला कधीही सोडण्याची स्वातंत्र्य आहे. खाली माझी स्वाक्षरी सूचित करते की मी जोखीम आणि फायदे या संपूर्ण संमती फॉर्मबद्दल वाचले आहे

किंवा मला सांगितले गेले आहे आणि माझ्या सर्व प्रश्नांची उत्तरे दिली आहेत. मला या संमती फॉर्मची एक प्रत दिली जाईल.

अधिकृत प्रतिनिधी / पालकांची स्वाक्षरी: _____

तारीख: _____

नाव: _____

विषयाशी संबंधित: _____

साक्षीदाराची सही: _____

तारीख: _____

नाव: _____

अन्वेषकांची स्वाक्षरी: _____

तारीख: _____

नाव: _____

अनुसंधान में भागीदारी के लिए सहमति

"6 महीने की उम्र तक अस्पताल से छुट्टी के बाद पाश्चराइज्ड डोनर ह्यूमन मिल्क पर खिलाए गए शिशुओं के फीडिंगपार्ट्स पैटर्न और विकास मापदंडों का अध्ययन करने के लिए- एक अवलोकन संबंधी अनुदैर्घ्य अध्ययन"

प्रधान अन्वेषक: **REG NO. BM0119010**

मार्गदर्शक: डॉ. _____

आपको जवाहरलाल नेहरू मेडिकल कॉलेज, बेलागवी में बाल रोग विभाग में पीजी छात्र डॉ। रोहन सपरा द्वारा केएलई विश्वविद्यालय के जेएन मेडिकल कॉलेज अस्पताल, बेलागवी के एनआईसीयू के लिए किए गए उपरोक्त शोध में अपने बच्चे को शामिल करने के लिए कहा गया है।

परिचय

अध्ययन का उद्देश्य :

आपके बच्चे की भागीदारी से हमें उन शिशुओं के दूध पिलाने के पैटर्न का मूल्यांकन करने में मदद मिलेगी, जिन्हें पाश्चुरीज्ड डोनर ह्यूमन मिल्क और डिस्चार्ज के बाद अन्य वेधशाला परिणाम प्राप्त हुए हैं। आप किन्हीं कारणों से किसी भी समय अध्ययन में भागीदारी को रोकने के लिए स्वतंत्र हैं और आपको शोध में भाग लेने के लिए किसी भी प्रतिपूर्ति का भुगतान नहीं किया जाएगा। इसलिए अपने बच्चे को अध्ययन में शामिल करना आपका स्वैच्छिक निर्णय है।

स्वैच्छिक भागीदारी

इस अध्ययन में आपके बच्चे की भागीदारी आपका स्वैच्छिक निर्णय है, चाहे या ना भाग लें, के एल ई एस डॉ। प्रभाकरकोर चैरिटेबलहॉट्स एंड एमआरसी, बेलागवी के साथ आपके वर्तमान या भविष्य के संबंधों को प्रभावित नहीं करेगा।

जोखिम और लाभ

इसमें कोई जोखिम शामिल नहीं हैं।

रुग्णता और मृत्यु दर में कमी।

गोपनीयता और गोपनीयता

केवल वे लोग जो जानते हैं कि आप एक शोध प्रतिभागी हैं, शोध टीम के सदस्य हैं। आपके बारे में या आपके द्वारा प्रदान की गई कोई भी जानकारी, अनुसंधान के दौरान आपकी लिखित सहमति के बिना दूसरों को नहीं बताई जाएगी। जब शोध के परिणाम प्रकाशित होते हैं या सम्मेलनों में चर्चा की जाती है, तो कोई भी जानकारी का खुलासा नहीं किया जाएगा जो आपकी पहचान को उजागर करेगा। इस अध्ययन के संबंध में प्राप्त की गई कोई भी जानकारी और जिसे आपके साथ पहचाना जा सकता है, वह गोपनीय रहेगी और आपकी अनुमति से ही प्रकट की जाएगी।

प्रश्नों

यदि आपके कोई प्रश्न हैं, तो आप संपर्क कर सकते हैं

REG NO. BM0119010

स्नातकोत्तर छात्र

बालरोग विभाग

जेएनएमसी, बेलगावी -590010

फोन नंबर 8839047641/8746040927

डॉ. _____

प्रोफेसर,

बालरोग विभाग,

के.एल.ई. विश्वविद्यालय

जवाहरलाल नेहरू मेडिकल कॉलेज,

बेलगाम -590010।

यदि आपके पास अपने अधिकारों या अनुसंधान भागीदारी के बारे में कोई प्रश्न हैं, तो आप संपर्क कर सकते हैं

डॉ. रूपा एम. बेल्लद, एमडी, डी सी एच

प्रोफेसर,

बाल रोग विभाग।

काहेर के एल ई विश्वविद्यालय

जवाहरलाल नेहरू मेडिकल कॉलेज, बेलगाम -590010।

आपको अपनी जानकारी के लिए और अपने रिकॉर्ड के लिए रखने के लिए इस फॉर्म की एक प्रति दी जाएगी।

सहमति का कथन

मैं इस अध्ययन में अपने और अपने बच्चे की भागीदारी के लिए स्वेच्छा से सहमत हूँ। मैं समझता हूँ कि भले ही मैं अपने बच्चे को इस अध्ययन में भाग लेने की अनुमति देने का चयन करूँ लेकिन मुझे किसी भी समय वापस लेने की स्वतंत्रता है। नीचे दिए गए मेरे हस्ताक्षर इंगित करते हैं कि मैंने इस पूरी सहमति के बारे में पढ़ा है या बताया गया है जिसमें जोखिम और लाभ शामिल हैं और मेरे सभी सवालों के जवाब दिए गए हैं। मुझे इस सहमति फॉर्म की एक प्रति दी जाएगी।

अधिकृत प्रतिनिधि / माता-पिता का हस्ताक्षर: _____

दिनांक: _____

नाम: _____

विषय से संबंधित: _____

गवाह का हस्ताक्षर: _____

दिनांक: _____

नाम: _____

अन्वेषक का हस्ताक्षर: _____

दिनांक: _____

नाम: _____

ANNEXRURE - III

PROFORMA / DATA COLLECTION INSTRUMENT

“To study the feeding and growth patterns of babies fed on Pasteurised Donor Human Milk after discharge from the hospital upto 6 months of age- A observational longitudinal study”

Subject No-

IP No-

Date-

I. SOCIO-DEMOGRAPHIC DATA

1. Identification Number

2. In patient Number

3. Date of Birth

3.1 Date of admission

4. Name

5. Religion: Hindu Muslim Sikh Others

6. Address:

7. Age:

8. Gender: Male Female Ambiguous

9. Mother's Name:

10. Mother's education: Illiterate Primary Secondary Graduate
Post Graduate

11. Mother's Occupation: Home maker Employed Self employed

12. Father's Name:

13. Father's education: Illiterate Primary Secondary Graduate
Post Graduate

14. Number of member's at home:

15. Income:

16. Per capita:

17. Socio economic status according to the Modified B.G. Prasad's Classification

- j. Non reactive NST Yes/ No
- k. Twins/ Triplets Yes/No

III. Birth history

1. Mode of Delivery: FTNVD LSCS Instrumental delivery PTVD
2. Gestational age in weeks: <28 28-34 >34
3. Gestational age by modified ballard score: weeks
4. APGAR score at five minutes <7 ≥ 7
5. Birth Weight
6. AGA /SGA/ LGA
7. Early Preterm/ Late Preterm/ Term/ Post term

IV. Indication of NICU Admission

1. Indication
- a. Low birth weight Yes/No
- b. Preterm Yes/No
- c. Respiratory distress. Yes/ No
- d. Respiratory distress syndrome Yes/ No
- e. MAS Yes/No
- f. Hyperbilirubinemia Yes/No
- g. Feeding difficulties Yes/No
- h. Observation Yes/No
- i. Hypoglycemia Yes/No
- j. Any other Yes/No

2. Examination

a. General physical examination

i. Heart rate:

ii. Respiratory rate:

iii. CFT:

iv. Temperature:

3. Anthropometry

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

Head to toe examination:

- a. Face
- b. Eyes
- c. Ears
- d. Oral cavity
- e. Neck
- f. Chest
- g. Abdomen
- h. Extremities
- j. Congenital markers
- k. Skin

5. Other systems

- a. Cardiovascular system
- b. Respiratory system
- c. Per abdomen
- d. Central nervous system

6. Feeding history

Type	Days of life																												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
MOM																													
PDHM																													
Formula feeds																													
Amount (ml/day)																													
Method RTF																													
SF/Palad ay																													
Direct																													

7. Date of starting PDHM:

Total duration of PDHM given:

8. Hospital stay

- a. NICU: days
- b. NICU +KMC: days
- c. KMC: days
- d. Post natal: days

9. Anthropometry at discharge

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

10. Types of feeds at discharge

	Yes No	If yes: estimate no of time baby is fed	c. If yes: who decided that your baby should be fed this? Myself Doctor Family member			d. If yes, how was this fed to your baby? Cup/ Spoon/ Palladi Bottle with nipple N G tube		
B1	Breastmilk (if yes, ask B2-B5)		a					
B2	Breastmilk directly from your breast	a		b	c	d		
B3	Breastmilk expressed from your breast	a		b	c	d	g	h i
B4	Breastmilk from another mother (Donor Human Milk)	a		b	c	d	g	h i
B5	Infant Formula	a		b	c	d	g	h i
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a		b	c	d	g	h i

X7	Vitamin A Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X8	Iron Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

X9	Calcium Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X10	Vitamin D Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Zinc Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Multivitamin Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

		a. Since the last visit	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
	Babies < 60 days old	No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice	a	b	c	d	e	f	g
Y7	Convulsions	a	b	c	d	e	f	g
Y8	Low body temperature	a	b	c	d	e	f	g
Y9	Umbilical redness extending to skin	a	b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a	b	c	d	e	f	g
	Babies >60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfeed	a	b	c	d	e	f	g
Y12	Fever and vomiting	a	b	c	d	e	f	g
Y13	Fever and convulsions	a	b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a	b	c	d	e	f	g

Baby`s follow up at 15 days

Feeding patterns:

X8	Vitamin A Yes (ask A-C) No		A. Was this given directly via dropper or mixed with something else for the baby to drink? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
----	-------------------------------------	--	--	--	---

	Yes No	If yes: estimate no of time baby is fed	c. If yes: who decided that your baby should be fed this? Myself Doctor Family member	d. If yes, how was this fed to your baby? Cup/ Spoon/ Palladi Bottle with tube nipple N G
B1	Breastmilk (if yes, ask B2-B5)	a		
B2	Breastmilk directly from your breast	a	b c d	
B3	Breastmilk expressed from your breast	a	b c d	g h i
B4	Breastmilk from another mother (Donor Human Milk)	a	b c d	g h i
B5	Infant Formula	a	b c d	g h i
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a	b c d	g h i
B7	Traditional foods (gutti, rice water, ganji etc)	a	b c d	g h i

Annexure III - Proforma

X9	Iron Yes (ask A-C) No		A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X10	Calcium Yes (ask A-C) No		A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Vitamin D Yes (ask A-C) No		A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Zinc Yes (ask A-C) No		A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

		give it to baby?							
Babies < 60 days old		a. Since the last visit?		b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No	Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice	a		b	c	d	e	f	g
Y7	Convulsions	a		b	c	d	e	f	g
Y8	Low body temperature	a		b	c	d	e	f	g

X13	Multivitamin Yes (ask A-C) No		<p>A. Was this given directly via dropper or mixed with something else for the baby to drink ?</p> <p>B. What was it mixed with?</p> <p>C. Who decided to give it to baby?</p>	<p>Directly via dropper Mixed with something else Don't know</p> <p>a Breastmilk b Water</p> <p>a Myself b Doctor</p>	<p>Skip to C Continue to B Skip to C</p>
-----	--	--	--	---	--

		a. Since the last visit?		b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
All babies		No	Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y1	Diarrhoea (frequent watery stools or blood in Stools)	a		b	c	d	e	f	g
Y2	Cough + difficult breathing, fast breathing and/or chest indrawing	a		b	c	d	e	f	g
Y3	Fever	a		b	c	d	e	f	g
Y4	Vomiting	a		b	c	d	e	f	g
Y5	Other infection	a		b	c	d	e	f	g

Annexure III - Proforma

Y9	Umbilical redness extending to skin	a	b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a	b	c	d	e	f	g
	Babies >60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfed	a	b	c	d	e	f	g
Y12	Fever and vomiting	a	b	c	d	e	f	g
Y13	Fever and convulsions	a	b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a	b	c	d	e	f	g

ANTHROPOMETRY:

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

Follow up at 6 weeks

Feeding patterns:

Annexure III - Proforma

	Yes No	If yes: estimate no of times baby is fed	c. If yes: who decided that your baby should be fed this? Myself Doctor Family member	d. If yes, how was this fed to your baby? Cup/ NG Spoon/ tube Palladi nipple
B1	Breastmilk (if yes, ask B2-B5)	a		
B2	Breastmilk directly from your breast	a	b c d	
B3	Breastmilk expressed from your breast	a	b c d	g i h
B4	Breastmilk from another mother (Donor Human Milk)	a	b c d	g i h
B5	Infant Formula	a	b c d	g i h
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a	b c d	g i h
B7	Traditonal foods (gutti, ripe water, ganji etc)	a	b c d	g h i

X8	Vitamin A Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X9	Iron Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

X10	Calcium Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Vitamin D Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Zinc Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X13	Multivitamin Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

		a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
	All babies	No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y1	Diarrhoea (frequent watery stools or blood in Stools)	a	b	c	d	e	f	g
Y2	Cough + difficult breathing, fast breathing and/or chest indrawing	a	b	c	d	e	f	g
Y3	Fever	a	b	c	d	e	f	g
Y4	Vomiting	a	b	c	d	e	f	g
Y5	Other infection	a	b	c	d	e	f	g

	Babies < 60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice	a	b	c	d	e	f	g
Y7	Convulsions	a	b	c	d	e	f	g
Y8	Low body temperature	a	b	c	d	e	f	g
Y9	Umbilical redness extending to skin	a	b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a	b	c	d	e	f	g
	Babies >60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfeed	a	b	c	d	e	f	g
Y12	Fever and vomiting	a	b	c	d	e	f	g
Y13	Fever and convulsions	a	b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a	b	c	d	e	f	g

ANTHROPOMETRY:

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

Follow up at 10 weeks

Feeding patterns:

	No	Yes	a.If yes: estimate no of times baby is fed	c. If yes: who decided that your baby should be fed this? Myself Doctor Family member			d. If yes, how was this fed to your baby? Cup/ NG Bottle Spoon/ tube with Palladi nipple		
B1	Breastmilk		a						
	(if yes, ask B2-B5)								
B2	Breastmilk directly from your breast	a		b	c	d			
B3	Breastmilk expressed from your breast	a		b	c	d	g	i	h
B4	Breastmilk from another mother (Donor Human Milk)	a		b	c	d	g	i	h
B5	Infant Formula	a		b	c	d	g	i	h
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a		b	c	d	g	i	h
B7	Traditonal foods (gutti, ripe water, ganji etc)	a		b	c	d	g	i	h

X8	Vitamin A Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
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Annexure III - Proforma

X9	Iron Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X10	Calcium Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Vitamin D Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Zinc Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X13	Multivitamin Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

		a. Since the last visit?		b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
	All babies	No	Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y1	Diarrhoea (frequent watery stools or blood in Stools)	a		b	c	d	e	f	g
Y2	Cough + difficult breathing, fast breathing and/or chest indrawing	a		b	c	d	e	f	g
Y3	Fever	a		b	c	d	e	f	g
Y4	Vomiting	a		b	c	d	e	f	g
Y5	Other infection	a		b	c	d	e	f	g

Babies < 60 days old		a. Since the last visit?		b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No	Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice	a		b	c	d	e	f	g
Y7	Convulsions	a		b	c	d	e	f	g
Y8	Low body temperature	a		b	c	d	e	f	g
Y9	Umbilical redness extending to skin	a		b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a		b	c	d	e	f	g
Babies >60 days old		a. Since the last visit?		b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No	Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfeed	a		b	c	d	e	f	g
Y12	Fever and vomiting everything	a		b	c	d	e	f	g
Y13	Fever and convulsions	a		b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a		b	c	d	e	f	g

ANTHROPOMETRY

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

Follow up at 14 weeks

Feeding patterns:

		If yes: estimate no of times baby is fed	c. If yes: who decided that your baby should be fed this? Myself Doctor Family			d. If yes, how was this fed to your baby? Cup/ Bottle NG with Spoon/ with tube nipple Palladi		
	No	Yes						
B1	Breastmilk (if yes, ask B2-B5)	a						
B2	Breastmilk directly from your breast	a		b	c	d		
B3	Breastmilk expressed from your breast	a		b	c	d	g i	h
B4	Breastmilk from another mother (Donor Human Milk)	a		b	c	d	g i	h
B5	Infant Formula	a		b	c	d	g i	h
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a		b	c	d	g i	h
B7	Traditonal foods (gutti, ripe water, ganji etc)	a		b	c	d	g	h i

X8	Vitamin A Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
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Annexure III - Proforma

X9	Iron Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X10	Calcium Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Vitamin D Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Zinc Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X13	Multivitamin Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

		a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
	All babies	No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y1	Diarrhoea (frequent watery stools or blood in Stools)	a	b	c	d	e	f	g
Y2	Cough + difficult breathing, fast breathing and/or chest indrawing	a	b	c	d	e	f	g
Y3	Fever	a	b	c	d	e	f	g
Y4	Vomiting	a	b	c	d	e	f	g
Y5	Other infection	a	b	c	d	e	f	g

	Babies < 60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice	a	b	c	d	e	f	g
Y7	Convulsions	a	b	c	d	e	f	g
Y8	Low body temperature	a	b	c	d	e	f	g
Y9	Umbilical redness extending to skin	a	b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a	b	c	d	e	f	g
	Babies >60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfeed	a	b	c	d	e	f	g
Y12	Fever and vomiting everything	a	b	c	d	e	f	g
Y13	Fever and convulsions	a	b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a	b	c	d	e	f	g

ANTHROPOMETRY:

	Measured	Expected
Weight (kg) Reading 1 Reading 2 Reading 3 Mean		
Length (cm) Reading 1 Reading 2 Reading 3 Mean		
Head circumference (cm) Reading 1 Reading 2 Reading 3 Mean		
Mid Upper Arm Circumference (cm) Reading 1 Reading 2 Reading 3 Mean		

Follow up at 6 months

Feeding patterns:

		If yes: estimate no of times baby is fed	c. If yes: who decided that your baby should be fed this?			d. If yes, how was this fed to your baby?		
			Myself Family member	Doctor		Cup/ NG Spoon/ tube Palladi	Bottle with nipple	
	No	Yes						
B1	Breastmilk (if yes, ask B2-B5)	a						
B2	Breastmilk directly from your breast	a		b	c	d		
B3	Breastmilk expressed from your breast	a		b	c	d	g i	h
B4	Breastmilk from another mother (Donor Human Milk)	a		b	c	d	g i	h
B5	Infant Formula	a		b	c	d	g i	h
B6	Tinned, powdered or fresh animal milk (cow, goat, etc.)	a		b	c	d	g i	h
B7	Traditonal foods (gutti, ripe water, ganji etc)	a		b	c	d	g	h i

X8	Vitamin A Yes (ask A-C) No	<p>A. Was this given directly via dropper or mixed with something else for the baby to drink?</p> <p>B. What was it mixed with?</p> <p>C. Who decided to give it to baby?</p>	<p>Directly via dropper Mixed with something else Don't know</p> <p>a Breastmilk b Water</p> <p>a Myself b Doctor</p>	<p>Skip to C Continue to B Skip to C</p>
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Annexure III - Proforma

X9	Iron Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X10	Calcium Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X11	Vitamin D Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X12	Zinc Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C
X13	Multivitamin Yes (ask A-C) No	A. Was this given directly via dropper or mixed with something else for the baby to drink ? B. What was it mixed with? C. Who decided to give it to baby?	Directly via dropper Mixed with something else Don't know a Breastmilk b Water a Myself b Doctor	Skip to C Continue to B Skip to C

Annexure III - Proforma

		a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
	All babies	No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y1	Diarrhoea (frequent watery stools or blood in Stools)	a	b	c	d	e	f	g
Y2	Cough + difficult breathing, fast breathing and/or chest indrawing	a	b	c	d	e	f	g
Y3	Fever	a	b	c	d	e	f	g
Y4	Vomiting	a	b	c	d	e	f	g
Y5	Other infection	a	b	c	d	e	f	g

	Babies < 60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y6	Jaundice		b	c	d	e	f	g
Y7	Convulsions	a	b	c	d	e	f	g
Y8	Low body temperature	a	b	c	d	e	f	g
Y9	Umbilical redness extending to skin	a	b	c	d	e	f	g
Y10	Abdominal distension (belly large and firm)	a	b	c	d	e	f	g
	Babies >60 days old	a. Since the last visit?	b. If yes: How did you feed your baby differently while she/he was ill in the past 7 days?					
		No Yes	Did not feed differently	Feed more frequently	Feed less frequently	Fed water	Fed formula	Fed supplements
Y11	Fever and inability to drink or breastfeed	a	b	c	d	e	f	g
Y12	Fever and vomiting	a	b	c	d	e	f	g
Y13	Fever and convulsions	a	b	c	d	e	f	g
Y14	Fever and baby very sleepy, and difficult to wake up	a	b	c	d	e	f	g

ANTHROPOMETRY:

	Measured	Expected
Weight (kg)		
Reading 1		
Reading 2		
Reading 3		
Mean		
Length (cm)		
Reading 1		
Reading 2		
Reading 3		
Mean		
Head circumference (cm)		
Reading 1		
Reading 2		
Reading 3		
Mean		
Mid Upper Arm Circumference (cm)		
Reading 1		
Reading 2		
Reading 3		
Mean		

ANNEXURE-IV

KEY TO MASTER CHART

Sex

- 1 - Females
- 2 - Males

Religion

- 1 - Hindu
- 2 - Muslim
- 3 - Others

Mother`s & Fathers` education

- 1 - Illiterate
- 2 - Primary
- 3 - Secondary
- 4 - Graduate
- 5 - Post graduate

Occupation

- 1 - Homemaker
- 2 - Employed
- 3 - Self employed

Socio economic status according to modified BG Prasad`s classification

- 1 - Upper class
- 2 - Upper middle class
- 3 - Middle class
- 4 - Lower middle class
- 5 - Lower class

Antenatal risk factors

- 1 - None
- 2 - Elderly primi > 35 years
- 3 - Short statured < 145 cm

Annexure IV - Key To Master Chart

- 4 - Gestational HTN
- 5 - Preeclampsia and eclampsia
- 6 - Anemia
- 7 - Gestational diabetes mellitus
- 8 - Previous still birth, intra uterine death
- 9 - Previous caesarean section
- 10 - Grand multipara
- 11 - Preterm premature rupture of membranes
- 12 - Non-reactive Nonstress test
- 13 - Twins/ Triplets

Mode of delivery

- 1 - Normal vaginal delivery
- 2 - Lower segment caesarean section
- 3 - Instrumental delivery
- 4 - Preterm vaginal delivery

Gestational age in weeks

- 1 - < 28
- 2 - 28 to 34
- 3 - > 34

Indication of NICU admission

- 1 - Low birth weight
- 2 - Preterm
- 3 - Respiratory distress
- 4 - Respiratory Distress syndrome
- 5 - Meconium Aspiration Syndrome
- 6 - NNH
- 7 - Feeding difficulty
- 8 - Observation
- 9 - Hypoglycemia
- 10 - Any other / Kangaroo mother care

Feeding history

MOM	-	Mother's own milk
PDHM	-	Pasteurized donor human milk
RTF	-	Ryles tube feeding
SF/Paladai	-	Spoon feed

Anthropometric Parameters

Wt.	-	Weight
Lt.	-	Length
H.C	-	Head circumference
MUAC	-	Mid Upper Arm Circumference

