



Effect of expressed breast milk, formula feeding and mixed feeding on occurrence of NEC rate among preterm babies admitted in NICU in selected hospitals of Indore (M.P.) in the year 2017-2018

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Abstract

Necrotizing Enterocolitis (NEC) is a syndrome of intestinal injury comprises nonspecific aspects of the history, such as vomiting, diarrhea, feeding intolerance and high gastric residuals following feeding. Breast milk decreases the risk of late-onset sepsis and necrotizing enterocolitis in preterm neonates and is therefore preferred over formula milk. The present study was a prospective cohort study design to compare the effect of breast milk formula/top feed and mix feeding on the incidence of NEC among preterm babies admitted in NICU in view to find out of effect of breast milk formula feed and mix feed on the incidence of necrotizing enterocolitis among preterm babies. The study was conducted among 60 preterm babies who were divided into 3 cohort, in cohort1; 20 preterm were selected who were on breast milk feeding, in cohort 2; 20 preterm were selected who were on formula/top feeding and in cohort3; 20 preterm were selected who were on mix feed. Preterm babies were selected with Authoritive sampling technique. All preterm were selected who were admitted on first, second and third day of life in NICU at selected hospitals. Each preterm was observed from the day of admission till 15-20 days for sign and symptoms of NEC which was checked using the tool i.e. Bell's Stage of NEC. The results revealed that among all three groups in cohort1; none of the preterm developed NEC, in cohort2; majority 10(50%) preterm developed NEC whereas in cohort3; most 16(80%) of preterm developed NEC. Repeated measure ANOVA-F test revealed that there was statistical difference found between the rates of NEC among cohort 1, cohort 2 and cohort 3 at $p \leq 0.05$ proving that breast feeding have significant impact on reducing risk of NEC among preterm babies. Another statistical interpretation was done using chi square test which showed that mothers who had received at least one dose of corticosteroid during their antenatal period had reduced rates of NEC among their preterm babies at the level $p \leq 0.05$. The regression showed that sepsis and reduced birth weight

had positive impact on incidence of NEC at the significant level $p \leq 0.05$. Thus, as per the analysis it can be concluded that breast feed and antenatal steroid can reduce the risk of NEC among preterm. Along with that sepsis and reduced birth weight can increase the risk of development NEC among preterm babies.

Key words: NEC, Bell's stage of NEC, antenatal corticosteroid, preterm babies.

BACKGROUND

Prematurity is related with immaturity of the gastrointestinal tract, including decreased integrity of the intestinal mucosal barrier, depressed mucosal enzymes, suppressed gastrointestinal hormones, suppressed intestinal host defense system, decreased co-ordination of peristaltic movements and differences in blood flow, which play a significant role in the pathogenesis of NEC. Feeding with breast milk has shown a significant role in decreasing the incidence of NEC. **(J Marcdante 2015)**

The incidence of NEC varies from center to center and from year to year. An estimated 0.3 to 2.4 cases occur in every 1000 live births. In most centers, NEC occurs in 2% to 5% of all NICU admission and 5% to 10 % of very low birth weight (VLBW) infants. If VLBW infants who die early are excluded and only infants who have been fed included, the incidence is approximately 15%. **(Cloherty 2015)**

Several studies have analyzed that administration of steroids during antenatal period is associated with maturation of intestinal mucosa resulting in low risk of developing NEC among preterm babies **(P. Alexander 2009)**

A quantitative approach using prospective cohort study group design was adopted to see the effect of expressed breast milk, formula feeding and mixed feeding on occurrence of NEC rate among preterm babies admitted in NICU (Total $N=60$, cohort 1 $n_1=20$, cohort 2 $n_2=20$, cohort 3 $n_3=20$ samples were selected according to the inclusion criteria).

NEED OF THE STUDY

Necrotizing enterocolitis (NEC) is a worldwide problem that has emerged in the past 25 years as the most common gastrointestinal emergency in neonatal intensive care units (NICU). According to an Indian report from a single center the incidence of NEC in babies less than 32 weeks gestation was 5.2 %. In the United States the incidence ranges from 1 percent to 7.7% of NICU admissions. Ninety percent of the patients were premature infants. Three major pathogenic factors i.e. mucosal injury, bacterial colonization and formula feeding that have been documented in most infants who have developed NEC. Although, NEC may develop only if a threshold of injury, imposed by the coincidence of at least two of three events (intestinal ischemia, pathogenic bacteria, and excess of protein substrate) is exceeded. Immunological immaturity of the gut in premature babies may represent the vital risk factor. **(Shah J, 2012)**

The investigator during her clinical posting in NICU experience that the infants who receives formula feed acquire NEC while who are taking expressed breast milk does not develop NEC. It is essential to develop an evidence-based protocol to reduce consequences of NEC in preterm. By judicious selection of feeding regimen, improving the nursing care to prevent the occurrence of NEC in preterm. So, the researcher was highly interested to verify the effect of breastfeeding, formula/top feed and mix feed on the incidence of NEC among preterm babies.

LITERATURE REVIEW

Meaghan Sullivan conducted a study in 2016 on Breast milk exposure and the incidence of Necrotizing Enterocolitis in Very Low Birth Weight Preterm infants. All the infants born between 1997-2009 and admitted in NICU. Secondary data analysis of 56 VLBW preterm infants diagnosed with NEC and 56 age-matched VLBW infant who served as controls, reveals that breast milk feeding was protective against NEC at a threshold of 50%. When over 50% of the total feeding volume consisted of breast milk versus infant formula, infants were nearly half as likely to develop NEC. This finding was clinically significant and underscores the importance of breast milk in NEC protection.

Reese H Clark conducted a prospective cohort study on exposure to any antenatal corticosteroids and outcomes in preterm infants by gestational age in year 2017. The setting was selected 300 neonatal intensive care units of the pediatrics Medical group in United States. The sample size of 117 941 infants who were between 23 to 34 weeks gestational age and born between 1 January 2009 and 31 December 2013 were taken. Infants exposed to antenatal corticosteroids. The finding of the study revealed that infants who exposed to antenatal corticosteroid had lowest rates of necrotizing enterocolitis stage 2 or above or death, severe intracranial hemorrhage or death and severe retinopathy of prematurity or death compared with infants without exposure at all gestations less than 30 weeks and most gestations for infants born at 30 weeks gestation or later.

Brigit M. Carter, conducted a longitudinal study on the topic risk factors for Necrotizing Enterocolitis (NEC) in preterm infants: how race, gender and health status contribute in year 2008. For this study, 134 preterm newborn had risk of necrotizing enterocolitis because of low birth weight and mechanical ventilator. Weekly review of infant's medical record until discharge was done. Demographic queries were asked to the mothers of preterm during time of admission. Data analysis done with logistic regression, Fischer's exact tests and correlations. Results of the study shows that mechanical ventilation is directly related to incidence of necrotizing enterocolitis i.e. as the no. of days of the mechanical ventilator increase the rate of Necrotizing Enterocolitis (NEC) also increase. It is also found in the results of study that necrotizing enterocolitis is not related to gender anyhow. Birth weight was not significantly associated with necrotizing enterocolitis, probably due to its correlation with mechanical ventilation and number of infections.

Problem statement

A prospective cohort study to compare the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies at selected NICUs of Indore in 2017 and 2018.

Objectives

- To compare the incidence of NEC among cohort1, cohort2 and cohort3
- To find out the association between incidence of NEC on administration of antenatal steroid.
- To identify the other associated factor developing NEC
- Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

Hypotheses

All hypotheses will be tested at level of $p \leq 0.05$

H₀₁: There is no significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3

H₁: There is significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.

H₀₂: There is no significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.

H₂: There is significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.

RESEARCH METHODOLOGY

Research Approach: A quantitative approach was used in the present study

Research Design: the study followed a prospective non-randomized cohort study design

Setting: Selected tertiary NICUs of Indore i.e. Choithram Hospital and Research Center and Seva and Samarpan Hospital, Indore.

Population: Preterm babies less than 37 weeks and admitted in NICU of Choithram Hospital and Research Center and Seva and Samarpan hospital, Indore.

Sample size: In this study the sample size comprises 60 preterm and divided in three cohort in cohort 1; 20 preterm were taken who were on breast feed, in cohort 2; 20 preterm who received formula/top feed were taken and in cohort 3; 20 preterm who were on mix feed were taken [N=60 (cohort 1 $n_1=20$, cohort 2 $n_2=20$, cohort 3 $n_3=20$)]

Sampling technique: The samples were selected through authoritative sampling technique.

Description of tool: The following tool after content validity from experts was used to collect data.

Section A

(Part I): Maternal baseline data: Consist of six items of close ended questions to collect data regarding maternal condition.

(Part II): Neonatal baseline data: This part consists of six items of close ended questions to collect data regarding newborn admitted in NICUs.

Section B: Co-morbid condition of NEC:

(Part I): Feeding assessment: This part of section contains assessment of each feed till 20 days of hospitalization.

(Part II): Associated risk factor of NEC: In this part of the section 8 items were included which were associated with developing risk of NEC.

(Part III): Clinical feature of NEC: It comprises of 9 items showing sign and symptoms of NEC.

(Part IV): Bell's stage of NEC: It is a standardized tool comprising six items describing stages of NEC.

Validity: The content validity of the tool was established by 7 experts from the field of pediatrics in which one Neonatologist, two Pediatric Consultant, four pediatric Nursing professors, one statistician. Minor suggestions were incorporated with the concurrence of all experts and the tool was finalized after discussion with the guide.

Reliability: Modified Bell's stage of NEC is a tool to assess the stage of NEC in newborn infants which was calculated using Split half method and computed by Spearman-Brown formula and it was found to be $r=0.96$.

Pilot study: The pilot study was conducted in the month of May and June in NICU of Medicare Hospital and research center, Indore. Permission was taken from ethical committee of CH&RC and administrative authority of Medicare Hospital and research center, Indore. Data were collected from 6 the mothers regarding their preterm [N=6(cohort1 $n_1=2$, cohort2 $n_2=2$ and cohort3 $n_3=2$)] who fulfilled the inclusion criteria and informed consent was obtained from the consultant and mothers of the preterm prior to the data collection. The purpose of the study was explained to the mothers of the participants and confidentiality was assured. The average time taken for data collection was 15 to 20 days. The findings of the study revealed that the preterm babies who received breast milk i.e. cohort 1 didn't develop NEC. In cohort2 and cohort 3: 50% (1) preterm developed NEC. Preterm who received antenatal corticosteroid didn't develop NEC. The tool was tested, and researcher moved on for data collection of main study.

DATA COLLECTION PROCEDURE

Written permission was obtained from ethical committee and administrative authority, of Choithram Hospital and Research Centre and Seva and Samarpan Hospital, Indore. The main study was conducted from 5th July to 30 August. Total sample size was 60(N=60 cohort1 n₁=20, cohort2 n₂=20 and cohort3 n₃ =20). Consent was taken from mother of the samples. Training was provided to the staff member about the observation of feeding and NEC and how to document the Bell's chart. The assessment of the staff's observation was done by researcher every day. Sample were observed for feeding from admission till discharge, only those sample were observed who are admitted in NICU on 1st 2nd or 3rd day of life. Confidentiality was maintained by assigning code to each subject. After the data collection all mothers were advised to provide breast milk, advantages of breast milk were taught and explained about lactating diet.

Findings

The data were analyzed according to the objectives of the study using descriptive and inferential statistics

Socio demographic variables

SECTION A: Frequency and percentage distribution of neonatal baseline data.

Section A (I): Maternal baseline data

Outcome of the 20 sample in cohort1, majority 7(35%) of mother in the group of 28-31 years. In cohort 2, majority 7(35%) of the mother were in the group of 24-27 years, and in group of 28-31 years. In cohort 3, most 8(40%) in the group of 24-27 years and also in the group of 28-31 years.

Regarding gravida of mother in cohort 1 majority 14(70%) mother were in the group of G1-G2, in cohort 2, most 16(80%) of the mothers were in the group of G1-G2. Also, in cohort3, majority 16(80%) were in the group of G1-G2.

Regarding corticosteroid in antenatal phase in cohort 1 majority 19(95%) mother didn't received antenatal steroid, whereas in cohort 2 half i.e. 10(50%) of mother received antenatal steroid, and in cohort 3 majority 16(80%) mother didn't received antenatal steroid.

In terms of mode of delivery in cohort 1 majority 17(85%) mother had LSCS and in cohort 2 most 16(80%) of mother had LSCS whereas in cohort 3 majority 13(65%) mothers had LSCS delivery.

In terms of diagnosis in cohort1, majority 5(25%) of mother had diagnosed with per vaginal leaking. In cohort 2, most 7(35%) of mother had diagnosed with per vaginal leaking. In cohort 3, 4(20%) of mothers were diagnosed with pre-eclampsia.

Section A (II): Neonatal baseline data

Table 1: Frequency and Percentage of Neonatal Variables

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
(1) GENDER						
MALE	17	85%	11	55%	9	45%
FEMALE	3	15%	9	45%	11	55%
(2) AGE AT THE TIME OF ADMISSION						
DAY 1	17	85%	17	85%	19	95%
DAY 2	3	15%	2	10%	0	0%
DAY 3	0	0%	1	5%	1	5%

Regarding gender in table no 1 preterm of cohort1, majority 17(85%) of preterm were male and 3(15%) preterm were female. In cohort2 most 11(55%) of preterm were male and in cohort3 majority 11(55%) were female and 9(45%) were male.

In respect of age at the time of admission in cohort1 majority 17(85%) preterm were admitted in NICU on day of life 1st, whereas in cohort2 most 17(85%) preterm were admitted on 1st day of life and in cohort 3 majority 19(95%) of preterm were admitted on 1st day of life.

Table 2: Frequency and Percentage of Neonatal Variables

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
(3) BIRTH WEIGHT (IN GRAMS)						
600-1000	2	10%	5	25%	6	95%
1000-1400	3	15%	6	30%	4	0%
1400-1800	8	40%	5	25%	10	5%
1800-2200	4	20%	2	10%	0	0%
2200-2600	3	15%	2	10%	0	%
(4) REASONE FOR ADMISSION IN NICU						

Preterm LBW And Respiratory Distress	9	45%	11	55%	9	45%
Preterm VLBW And Respiratory Distress	3	15%	1	5%	4	20%
Preterm, ELBW, Respiratory Distress	3	15%	4	20%	5	25%
Preterm, ELBW, Respiratory Distress and Congenital Heart Disease	0	0%	0	0%	1	5%
Preterm, Respiratory Distress and Sepsis	1	5%	1	5%	0	0%

Data in table no2 shows that in terms of birth weight of the preterm in cohort 1 majority 8(40%) of preterm's birth weight between 1400gms- 1800gms, whereas in cohort2 majority 6(30%) of preterm's birth weight between 1000gms-1400gms and in cohort3 most 10(50%) of preterm's birth weight between 1400gms- 1800gms.

In regards with preterm babies diagnosis on admission of NICU in cohort1 preterm, majority 9(45%) preterm were admitted for LBW care and Respiratory distress whereas in cohort2 preterm, most 11(55%) of the preterm were admitted with complaint of LBW and Respiratory distress. In cohort3, majority 9(45%) preterm was admitted with complaint of LBW and Respiratory distress.

SECTION B: CLINICAL ASSESMENT

Table 3: Frequency and percentage of clinical features of NEC

VARIABLE	COHORT n1=20		COHORT n2=20		COHORT n3=20	
	F	%	F	%	F	%
CLINICAL FEATURE OF NEC						
Abdominal Distention	4	20%	3	0%	3	15%
Vomiting, Feeding Intolerance and Abdominal Distention	1	5%	4	5%	3	15%
Vomiting, Abdominal Distention	0	0%	0	0%	1	5%
Vomiting, Abdominal Distention and Occult Blood in Stool	1	5%	3	30%	3	15%
Vomiting Increased Gastric Residual and Abdominal Distention and Occult Blood in Stool	1	5%	1	5%	3	15%

Vomiting, Palpable Bowel Loops and Occult Blood in Stool	0	0%	1	0%	1	5%
Increased Gastric Residual and Abdominal Distention and Palpable Bowel Loops.	0	0%	2	0%	2	10%
Didn't develop any clinical feature of NEC	13	65%	6	30%	4	20%

From table 3 it is evident that in cohort1 majority 13(65%) didn't develop any clinical feature of NEC, where as in cohort2 majority 6(30%) didn't develop any clinical feature of NEC and in cohort3, most 4(20%) of the preterm didn't develop any clinical feature of NEC.

Table 4: Frequency and Percentage of associated risk factor of NEC

VARIABLE	COHORTA1 n1=20		COHORTA2 n2=20		COHORTA3 n3=20	
	F	%	F	%	F	%
ASSOCIATED RISK FACTOR OF NEC						
Preterms received blood Transfusion only	1	5%	0	0%	0	0%
Preterm only with Sepsis	1	5%	0	0%	1	5%
Preterm on only Mechanical Ventilation	5	25%	5	25%	5	25%
Preterm only had Umbilical Vein Catheter	2	10%	3	15%	2	10%
Sepsis, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	1	5%	2	10%	0	0%
Mechanical Ventilation, Umbilical Vein Catheter, Congenital Heart Disease and reduced birth weight	0	0%	0	0%	1	5%
Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	3	15%	1	5%	0	0%
Mechanical Ventilation and Sepsis and reduced birth weight	0	0%	2	10%	2	10%
Blood Transfusion, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	1	5%	0	0%	1	5%
Blood Transfusion, And Umbilical Vein Catheter	0	0%	0	0%	0	0%
Umbilical Vein Catheter and Sepsis	0	0%	1	5%	0	0%
Asphyxia, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	0	0%	0	0%	0	0%
Didn't develop any risk factor of NEC	6	30%	6	30%	6	30%

Data in table no. 4 shows that in cohort1 majority 6(30%) preterm didn't develop any risk factor whereas in cohort2 most 6(30%) preterm didn't develop any risk factor of NEC, also in cohort 3 most 6(30%) preterm didn't develop any risk factor of NEC

Table 5: Frequency and percentage of development of Bell's stage of NEC

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
BELL'S STAGE OF NEC						
STAGE I A	0	0%	3	15%	8	40%
STAGE II A	0	0%	3	15%	3	15%
STAGE I B	0	0%	2	10%	5	25%
STAGE II B	0	0%	2	10%	0	0%
DIDN'T DEVELOP NEC	20	100%	10	50%	4	20%

The table no. 5 shows that in cohort 1 none of the preterm develops NEC. While in cohort 2; half of the preterm i.e. 10(50%) of preterm develops NEC among which 3(15%) of the preterm develops stage IA and stage IIA however 2(10%) preterms develops stage IB and stage IIB, whereas in cohort 3 majority 8(40%)of the preterm develops stage IA of NEC, 5(25%) of the preterm develops stage IB of NEC, 4 (20%) preterm didn't develop NEC and 3(15%) preterm develops stage IIA of NEC.

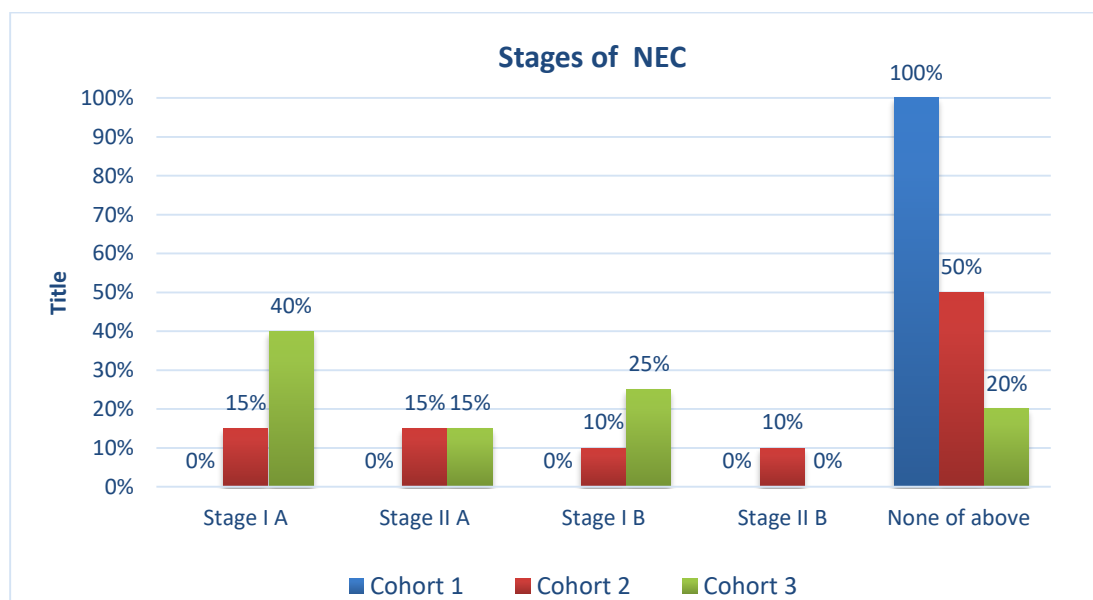


Figure shows stage of NEC developed in preterm

Section B (I): Difference Between incidences of NEC among cohort 1 cohort 2 and cohort 3

Table 6: ANOVA showing difference between incidences of NEC among cohort 1 cohort 2 and cohort 3

S.NO	COHORT	Mean	Df	SS	Mean of sum of square	F' ration	TABLE VALUE
1	COHORT 1	0	In Rows (19)	4.1	0.21579	4.17073	2.15
2	COHORT 2	0.5					
3	COHORT 3	0.8	In column(1)159	0.9	0.9		

The table no. 6 shows that there was 0% of NEC among cohort 1, in cohort 2 rate of NEC was increased and in cohort 3 highest rates of NEC seen due to decreased use of corticosteroid in antenatal phase. **Hence hypothesis H1 is accepted.**

Section B (II): Association between incidences of NEC on administration of antenatal steroid.

Table 7: Assessment of association between incidences of NEC on administration of antenatal steroid.

S.NO	COHORT	GIVEN	NOT GIVEN	DEVELOPMENT OF NEC	df	X ²	TABLE VALUE
1	COHORT 1	1	19	0	4	18.126 S	9.49
2	COHORT 2	9	11	11			
3	COHORT 3	5	15	15			

The table no. 7 reveals that there was 0% of NEC among cohort 1, in cohort 2 rate of NEC is increased and in cohort 3 highest rates of NEC seen. It also reveals that preterm who received at least one of corticosteroid didn't develop NEC. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at $p < 0.05$ i.e. statically significant.

SECTIN B (III): Association between incidences of NEC on administration of antenatal steroid.

Table 8: Assessment of association between incidences of NEC on administration of antenatal steroid.

$N=60(n_1=20, n_2=20 \text{ and } n_3=20)$

S.NO	COHORT	GIVEN	NOT GIVEN	DEVELOPMENT OF NEC	df	X ²	TABLE VALUE
1	COHORT 1	1	19	0	4	18.126 S	9.49
2	COHORT 2	9	11	11			

3	COHORT 3	5	15	15
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The table no 8 reveals that there was 0% of NEC among cohort 1, in cohort 2 rate of NEC was increased and in cohort 3 highest rates of NEC seen. It also reveals that preterm who received at least one of corticosteroid didn't develop NEC. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at $p < 0.05$ i.e. statically significant. **Hence hypothesis H₂ is accepted.**

Section B (IV): Association of risk factor of NEC and incidence of NEC among cohort 1 cohort 2 and cohort 3

Table 9: Association of risk factor of NEC and incidence of NEC among cohort 1 cohort 2 and cohort 3

S.NO	RISK FACTOR OF NEC	Co-efficient	df	SS	Mean of sum of square	F' ratio	Significance F
1	Mechanical ventilator	-0.55					
2	Umbilical vein catheter	-1.08	2	31.8	2.76	2.79	0.05
3	Sepsis	0.03	5	4			
4	Birth weight	0.85					

Table no. 9 shows statistically risk factor of NEC i.e. mechanical ventilator didn't have any impact on incidence of NEC whereas it is clinically significant that mechanical ventilator and umbilical vein catheter have positive relation with incidence of NEC. Data also depict that sepsis and decreased birth weight of preterm is directly proportional to incidence of NEC among preterm and it is significant at the level of $p < 0.001$ level.

Discussion

Comparison of incidence of NEC among cohort1, cohort2 and cohort3

All preterm who were admitted in NICU in month between June to august were observed for 15-20 days those preterm who got discharged before 15 days were excluded from research sample. All samples were observed from admission till discharge. In cohort 1 those preterm were included who mostly received breast milk through Ryles tube or from katori spoon feed or from direct breast. In cohort 2 those preterm were included who majorly received top/formula feed thorough katori spoon or from ryles tube. And in cohort 3 those preterm were included who received both formula/top milk and breast milk in approximately equal amount.

Data depicts that none of the preterm of cohort 1 develop NEC. In cohort 2, 3(15%) developed Stage I A, 3(15%) preterm developed Stage II A, 2(10%) preterm developed Stage I B, 2(10%) preterm developed Stage II B, majority 10(50%) preterm didn't develop NEC. In cohort3, 8(40%) developed Stage I A, 3(15%) preterm developed Stage II A, 5(25%) preterm developed Stage I B, 0(0%) preterm developed Stage II B, 4(20%) preterm didn't develop NEC.

With respect to development of NEC data reveals that the preterm who receive breast milk i.e. in cohort 1 none of the preterm develop NEC, whereas in cohort2 mean of development of NEC is 0.5 and in cohort 3 mean of development of NEC is 0.8. There is significant difference in the rates of NEC among cohort1 cohort2 and cohort3 at $p \leq 0.05$ i.e., statically significant

Findings revealed that there was increased incidence of NEC among cohort 2 and cohort3 in comparison of cohort 1, cohort 1 preterm didn't develop any stage of NEC. This shows that breast milk can prevent NEC and formula/top feed and mix feed might lead to NEC. Thus, breast milk should be provided to all preterm to reduce the rate of NEC and avoid top/formula or mix feed. **Hence hypothesis H1 is accepted.**

The findings were supported by a study was conducted by Xiao-Ming Ben, Rui Chen, Zong-Tai Feng, et. al; in year 2011 on "The Benefits of Expressed Maternal Milk and Donor Breast Milk for Preventing Necrotizing Enterocolitis in Preterm Infants: Systematic Review and Meta- Analysis". The data were searched from our library's electronic databases including PUBMED/MEDLINE, SCIENCEDIRECT (1997-2008), EBSCOHOST (1965-2008), EMBASE (1974-2008), (1993-2008) and Cochrane Library. Meta-analysis found that preterm infants feeding with donor breast milk was associated with a significantly reduced relative risk of necrotizing enterocolitis. Suspected necrotizing enterocolitis was three times less likely (relative risk 0.31; 95% confidence interval 0.12-0.81; $p=0.02 < 0.05$) and confirmed necrotizing enterocolitis was four times less likely in premature infants feeding with donor breast milk compared with formula milk given as a sole diet. No data to date was available to be combined in our meta-analysis to compare expressed maternal milk with formula milk given as a sole diet.

Associated risk factor of NEC among cohort 1 cohort 2 and cohort 3

Finding of the study reveals that the preterm babies in most of the preterm of cohort 1 didn't have any risk factor of NEC, in cohort 2 most of the sample were on mechanical ventilator and also in cohort3 most of the sample were on mechanical ventilator. Whereas it is already proven in some researches that low birth weight is directly proportional to increased incidence of NEC.

With respect of sepsis and birth weight data reveals that beside all the risk factor sepsis and reduction of birth weight is directly proportional to incidence of NEC. Whereas statically mechanical ventilator and umbilical vein

catheter didn't have any strong impact on incidence of NEC although it is clinically significant that mechanical ventilator and umbilical vein catheter have strong impact on incidence of NEC

Findings revealed that there are increased in incidence of NEC among preterm who had sepsis and decreased birth weight. Other risk factor of NEC did not have any strong impact on incidence NEC among preterm.

The findings were supported by a study, conducted by Tian Qian Rong Zhanget. al; in 2011 on "Risk Factors for Necrotizing Enterocolitis in Neonates: A Retrospective Case-Control Study" There were 1167 cases of necrotizing enterocolitis identified from the 95 participating neonatal intensive care units in mainland China. In VLBW infants, the major risk factors for mortality were small for gestation age and stage 3 NEC. In moderate LBW infants (birth weight 1500–2499 g), the risk factors identified for mortality were sepsis during hospitalization and stage 3 NEC. Necrotizing enterocolitis remains an important cause of morbidity and mortality in prematurely born neonates in Chinese neonatal units. Awareness of the associated risk factors and appropriate interventions may improve the outcome of necrotizing enterocolitis in different birth weight subgroup.

Discussion on association between incidences of NEC on administration of antenatal steroid.

Data depicts that there was 0% of NEC among cohort 1, in cohort rate of NEC is increased and in cohort 3 highest rates of NEC seen. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at $p < 0.05$ i.e. statically significant.

With respect of development of NEC among corticosteroid received preterm in antenatal phase chi square was 18.126 at the level of $p < 0.05$.

Finding revealed that in cohort 1 only one antenatal mother received corticosteroid but all the preterm of cohort 1 received breast milk so they didn't develop NEC. In cohort 2, 10(50%) of mother received antenatal steroid so the incidence of NEC among preterm of cohort 2 was 10(50%) and in cohort 3 only 4 mother received antenatal steroid and the rates of NEC were high among that group. The mother who received at least single dose of steroid there preterm didn't develop any stage of NEC. This shows that administration of at least on dose of antenatal steroid during antenatal phase can prevent NEC among preterm. So antenatal should be administered to the mother during antenatal phase to reduce the incidence of NEC. **Hence hypothesis H2 is accepted.**

Finding was supported by a study conducted by Clarissa Bonanno and Ronald J. Wapner in year 2012 on Antenatal Corticosteroids in the Management of Preterm Birth. As preterm birth can result in serious long-term medical and developmental problems, with tremendous individual, family and societal cost, this represents a most welcome trend. Results of the study shows this antenatal corticosteroid therapy significantly reduced RDS and other neonatal morbidities such as intraventricular hemorrhage (IVH) and necrotizing enterocolitis (NEC) as well as overall neonatal mortality.

CONCLUSION

In preterm infants, due to the immaturity of the gastrointestinal system developed NEC on enteral feeding of formula/top feed and mix feed. Due to presence of probiotics in breast milk it can prevent NEC among preterm. Sepsis and reduced birth weight are also the risk factor to develop NEC. Corticosteroid helps to provide gut and lung maturity in preterm mother with at least one dose of antenatal steroid reduced the chances of occurring NEC among their preterm.

Researcher suggest that each preterm should provide breast milk for feeding to reduce the incidence of NEC with that for gut maturity of preterm, antenatal mothers should be administer at least one dose of steroid as soon as preterm delivery is suspected with that preterm were observed with sepsis and low birth weight and strictly breast feed should be provided to them, and if NEC is developed due to sepsis than withhold the feeding and provide antibiotic against the bacteria found in the report of culture. Staff should be skilled enough to identify the clinical features of NEC in its primary stage to avoid the complication like surgery.

It was a great experience of doing this research study. All the mothers Doctors and staff was cooperative there was no interference to the hospital routine throughout the study and got constant encouragement from guide. I experienced immeasurable excitement and zeal along with exploring new areas, improving the knowledge while concluding the main study, along with that to help mothers in express milk and helping them to provide proper breast feed to their baby provide me inner satisfaction. The study was fruitfully and successfully completed by the grace of almighty.

CHAPTER-I

INTRODUCTION

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Necrotizing enterocolitis is an acute inflammatory disease of the bowel with increased incidence in preterm infants. The precise cause of NEC is still uncertain, but it appears to occur in infant whose gastrointestinal tracts have experienced vascular compromise. Intestinal ischemia of unknown etiology, immature gastrointestinal host defenses, bacterial proliferation, and feeding substrate are now believed to have a multi-factorial role in the etiology of NEC. Prematurity remains the most prominent risk factor in the development of NEC. (Schurr and Perkins 2011)

Necrotizing enterocolitis is a syndrome of intestinal injury and is the most common intestinal emergency occurring in preterm infants admitted to the neonatal intensive care unit. NEC occurs in 1-3 per 1000 live births and 1-8% of admissions to the neonatal intensive care unit. Prematurity is the most consistent and significant factor associated with neonatal NEC. The disease occurs in 4-13% of infants who weigh less than 1500gm at birth. NEC is infrequent in term infants (< 10% of affected infants). (Sudha Rao Chandrashekhar 2015)

Factors that place the premature infant at the risk for necrotizing enterocolitis include perinatal asphyxia, low Apgar score, idiopathic respiratory distress syndrome, sepsis and congenital heart disease. Relative ischemia or hypovolemia of the intestinal tract that is associated with hypotension, the use of umbilical catheters, exchange transfusions, and hypertonic foods, medications, of fluids may also play a role in the development of this condition. Changes in the intestinal flora associated with early and aggressive formula feeding may predispose the infant to necrotizing enterocolitis. This disease generally appears during the first week of life, but au occurs from 2 to 4 weeks after birth. (Dorothy R. Marlow and Barbara A. Redding 2009)

Prematurity is related with immaturity of the gastrointestinal tract, including decreased integrity of the intestinal mucosal barrier, depressed mucosal enzymes, suppressed gastrointestinal hormones, suppressed intestinal host defense system, decreased co-ordination of intestinal mortality and differences in blood flow auto regulation, which play a significant role in the pathogenesis of NEC. More than 90% of infants diagnosed with NEC have been fed enterally, but NEC has been reported in infants who have never been fed. Feeding with human milk has shown a significant role in decreasing the incidence of NEC. In addition, probiotics may offer potential benefits for the preterm infant by increasing mucosal barrier function, improving nutrition, up regulating the immune system and reducing mucosal colonization by potential pathogens. It also is theorized that compromised intestinal blood flow contributes to NEC. (Karen j. Marcdante 2015)

Enteral feeding is perhaps the next greatest risk factor. More than 90% of infants have been fed before the onset of this disease. In the extremely premature infants, the risk is least with infants who are exclusively breast-fed, and any kind of exposure to bovine milk-based products may increase the risk of NEC. Factors that have been considered included osmolality of formula, the lack of immunoprotected factors in formula and the timing, volume, and rate of feeding. Breast milk has been shown to have protective factors. Although breast milk alone does not prevent development of NEC in extremely premature infants, exclusive human milk diet in contrast to a combination of mother's milk and bovine-based products has shown to reduce the rates of NEC and surgical NEC. However, the rate of daily feeding increment that may protect infants from developing NEC has not been identified, and the mechanism by which larger volumes may predispose to the development of NEC is not known. It has been shown that adoption of standardized feeding regimen, dictating the advance of feedings in the VLBW population and strict adherence to it reduce the risk of NEC by up to 86% despite heterogeneity of the feeding regimens used. (Cloherty 2015)

Similar to the effect on the lungs, antenatal steroids have been shown to improve the maturity of the GI tract. Use of antenatal steroids have shown reduced incidence of NEC among the infants treated with antenatal steroids. (Muralidhar H. Premkumar)

More than 90% of infants have been fed before the onset of this disease. In the extremely premature infants, the risk is least with infants who are exclusively breast-fed, and any kind the exposure to bovine milk-based products may increase the risk of NEC. (Meharban Singh 2015).

Most of the cases of NEC occur in premature infants born before 34 week's gestation who have been fed enterally. Prematurity is associated with immaturity of the gastrointestinal tract, including decreased integrity of the intestinal mucosal barrier, depressed mucosal enzymes, suppressed gastrointestinal hormones, suppressed intestinal host defense system, decreased coordination of intestinal mortality and differences in blood flow auto regulation, which is thought to play a significant role in the pathogenesis of NEC. More than 90% of infants diagnosed with NEC have been fed enterally. Feeding with human milk has shown a beneficial role in reducing the incidence of NEC (Marcdante 2015)

An epidemiological study was conducted by Jadwiga Wójkowska-Mach (2014), on necrotizing enterocolitis (NEC) in Preterm Infants in Neonatal Intensive Care Units in the year 2009. Prospective surveillance method was used and performed by local infection control teams. The study aimed to define the epidemiology of necrotizing enterocolitis (NEC) Total 910 infants were included in the study and admitted in 6 NICUs of Poland. The result shows that incidence of NEC was 8.7 percent and fatality rate was 19 percent. It was also found that Low birth weight and decreased gestational age are the 2 risk factor for NEC. Infants who are diagnosed with NEC were used mechanical ventilator considerably for long time in comparison to remaining neonates who were not diagnosed with NEC. Hence it is conclude that risk of NEC is directly proportional to VLBW and with inflammation of the amnion during labor.

Meinzen-Derr J et.al;(2009) carried out a study on Role of human milk in extremely low birth weight infants to determine the risk of necrotizing enterocolitis or death in year 2008. The aim of the study was to find out the relation between human milk intake and risk of necrotizing enterocolitis (NEC) or death among infants. The sample included in the study had birth weight between 401 to 1000 gm. Analysis of 1272 infants was performed in the National Institute of Child Health and Human Development Neonatal Network. Glutamine Trial was performed to determine the risk of NEC or death. 14 Days observation of milk intake was done. Several NEC risk factors were included. The finding of the study shows that 13.6% died or developed NEC after 14 days. The occurrence of NEC or death after 14 days was decreased by a factor of 0.83 for each 10% increase in the proportion of total intake as human milk. Each 100 ml per kg (-1) increase in human milk intake during the first 14 days was associated with decreased risk of NEC or death. The study concluded that there is a trend towards a decreased risk of NEC or death among infants who received 100% human milk as a proportion to total enteral

intake. These data suggest a dose-related association of human milk feeding with a reduction of risk of NEC or death after the first 2 weeks of life among extremely low birth weight infants.

1.2 NEED OF THE STUDY:

Necrotizing enterocolitis (NEC) is a worldwide problem that has emerged in the past 25 years as the most common gastrointestinal emergency in neonatal intensive care units (NICU). According to an Indian report from a single center the incidence of NEC in babies less than 32 weeks gestation was 5.2 %. In the United States the incidence ranges from 1 percent to 7.7% of NICU admissions. Ninety percent of the patients were premature infants. Three major pathogenic factors i.e. mucosal injury, bacterial colonization and formula feeding that have been documented in most infants who have developed NEC. Although, NEC may develop only if a threshold of injury, imposed by the coincidence of at least two of three events (intestinal ischemia, pathogenic bacteria, and excess of protein substrate) is exceeded. Immunological immaturity of the gut in premature babies may represent the vital risk factor. (Shah J, 2012)

According to World Health Organization (WHO), preterm birth rates have been reported from 5% to 7% of live births in some developed countries, but premature birth rate in developing countries is higher. Per year, an estimated 15 million babies born preterm and this number is increasing day by day. Preterm birth complications are the leading causes of death among children below 5 year of age, responsible for nearly 1 million deaths in 2013. Among several developing countries India ranks first with the greatest number of preterm(2014)

Preterm infants usually show increase in physical signs of prematurity with the decreased gestational age. As a result, these infants are at risk for numerous medical problems like Neurological problems, cardiovascular complications, Respiratory problems, Gastrointestinal and metabolic issues Hematologic complications. Among these problem Gastrointestinal and metabolic issues can arise from neonatal hypoglycemia, feeding difficulties, necrotizing enterocolitis (NEC), rickets of prematurity, hypocalcaemia and inguinal hernia.

Maria M. Talavera et al (2016) conducted a study on Quality Improvement Initiative to Reduce the Necrotizing Enterocolitis Rate in Premature Infants in year 2016 in Ohio (USA). The objective of the study was to reduce the incidence of necrotizing enterocolitis (NEC) among very low birth weight (VLBW) infants admitted to 8 intensive care nurseries from 2010 baseline of 8.0% to <4.0% by 2012 and sustain for 6 months using quality improvement (QI) methodology. A multidisciplinary NEC QI team used the Vermont Oxford Network definition of NEC and the Institute for Healthcare Improvement model. The specific aims were evidenced based that includes (1) standardized early human milk feedings, (2) conservative feeding guidelines during blood transfusions and indomethacin treatment, and (3) restriction of ranitidine use in VLBW infants. Inclusion criteria comprised VLBW infants admitted within the study period without NEC. Exclusion criteriacomprised established NEC or spontaneous intestinal perforation unrelated to NEC. The incidence of NEC and NEC-related surgery were traced using statistical process control methodology. The outcomes of the study show that the baseline NEC rate in 2010 was 8% (27 NEC cases in 335 VLBW infants). After initiation of early human-milk feeding and

conservative feeds during blood transfusions guidelines in November 2011, only 3.1% had developed NEC through December 2013. Special cause variation was noted in June 2012. Hence it is concluded that implementation of QI initiatives decreased the NEC rate from 8.0% to <4.0%. Early human milk feedings and conservative feeding during blood transfusion policies appear to have significant impact on NEC reduction.

Necrotizing enterocolitis (NEC) is a frequently faced condition in the premature neonate, which can have devastating effects. The sign and symptoms of NEC and sepsis are approximately similar and can confuse. An abdominal radiograph is often obtained for diagnosis, and findings that indicate NEC include pneumatosis and portal venous gas. The treatment of NEC includes gastrointestinal rest, gastric decompression, broad-spectrum intravenous antibiotics, and systemic support. A finding of pneumoperitoneum signifies intestinal perforation, which requires surgical intervention. Long-term sequel of NEC includes short-gut syndrome, intestinal stricture, and neurodevelopmental delays. The demonstration of intestinal stricture can be puzzling. It can appear at presentation as a bowel obstruction or, conversely, as increased stool output or diarrhea. The clinician should have a high level of suspicion for intestinal stricture in a patient with a history of NEC. (American Academy of Pediatrics, 2017)

Interaction of several factors like gut immaturity, mucosal injury due to hypoxia-ischemia, milk feeding and infection results in NEC. Antenatal steroids and breastfeeding are the two factors which can protect against NEC. Delaying enteral feeding does not prevent NEC while feeding only with Human Milk can prevent. (Vinod K Paul 2013)

The NEC is in most cases constrained to preterm because of immaturity of the gastrointestinal tract. Preterm infants are prone to expand NEC because of high prevalence of perinatal distress factor, stasis of gut due to autonomic immaturity, lack of feeding with human milk and higher occurrence of nosocomial infections. (Meharban Singh 2015)

Abhik das et al (2017) regulated a prospective cohort study on exposure to any antenatal corticosteroids and outcomes in preterm infants by gestational age in year 2013. The objective of the study was to determine whether exposure to any antenatal corticosteroids is associated with a lower rate of motility and morbidity at each gestational age at which administration is currently recommended. In this study 300 preterm were selected who were admitted in NICU of pediatrix Medical group in the United States. Those preterm were exposed through corticosteroid in there antenatal phase. It was found that those infants who exposed to antenatal corticosteroids had a significantly lower rate of death and NEC before discharge at each gestation 29 weeks or less, 31 weeks and 33-34 weeks compared with infants without exposure. The rate of survival without major hospital morbidity was higher among infants exposed to antenatal corticosteroids at the lowest gestations. Infants exposed to antenatal corticosteroids had lower rates of necrotizing enterocolitis. Among all infants born between 23 to 34 weeks of gestation antenatal exposure to corticosteroids compared with no exposure was associated with lower mortality

and morbidity at most gestations. The effect of exposure to antenatal corticosteroids on mortality seems to be larger in infants born at the lowest gestations.

Preterm babies are vulnerable to develop NEC due to high incidence of prenatal distress factor, stasis of gut due to autonomic immaturity, lack of feeding with human milk and higher incidence of nosocomial infections. Investigator during clinical posting found that there was increased rate of NEC among preterm babies. Top feeding just after birth is provided to the newborn infant in NICUs. NEC is not diagnosed in its initial stage when the NEC majorly affect the health status of newborn than the newborn is diagnosed with NEC only pediatricians prescribed only breast milk to the newborn for feed which cure the NEC. Some of the pediatricians prescribed expressed breast milk to the preterm babies which prevent development of NEC in that preterm. Those preterm who received formula/top feed are prone to develop NEC. Investigator felt that preterm who received breast milk has reduced incidence of NEC than preterm who received other type of feedings like formula/top or mix feed. Thus the investigator decided of doing a study to compare the effect of breast milk formula/top feed and mix feed on the incidence of NEC among preterm babies admitted in NICU. The finding of the study will help to prepare protocol on feeding regimen to prevent NEC among preterm admitted in NICU. There is a great need to implement feeding regimen to prevent NEC among preterm admitted in NICU.

1.3 STATEMENT OF THE PROBLEM

A prospective cohort study to compare the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies at selected NICUs of Indore in 2017 and 2018.

1.4 OBJECTIVES

- To compare the incidence of NEC among cohort1, cohort2 and cohort3
- To find out the association between incidence of NEC on administration of antenatal steroid.
- To identify the other associated factor developing NEC
- Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

1.5 ASSUMPTION

- Breastfeeding reduces the risk of NEC among all preterm babies and due to formula/top feed and mix feed risk of developing NEC among preterm babies is increased.

1.6 HYPOTHESIS

- H_{01} : There is no significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3
- H_1 : There is significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.
- H_{02} : There is no significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.
- H_2 : There is significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.

1.7 OPERATIONAL DEFINITION

- **Effect:** In this study effect refers to the change that occurs in NEC rate due to breastfeeding, formula/top feed and mixed feed among preterm infant
- **Cohort 1:** In this study cohort1 refers to the preterm babies who are receiving the breast milk either by the katori spoon or ryles tube or from direct breast.
- **Cohort 2:** In this study cohort2 refers to the preterm babies who are receiving top feed (formula feed or bovine milk) either by katori spoon or ryles tube.
- **Cohort 3:** In this study cohort3 refers to the preterm babies who are receiving both mother milk and top feed by the katori spoon, ryles tube or from direct breast.
- **Preterm babies:** In this study preterm refers to babies who have gestational age less than 37 weeks and are admitted in NICU.
- **NEC:** Necrotizing Enterocolitis (NEC) is a syndrome of intestinal injury comprises nonspecific aspects of the history, such as vomiting, diarrhea, feeding intolerance and high gastric residuals following feeding. In my study Necrotizing enterocolitis is categories under Bell's 3 stages

Modified Bell's Staging Criteria for Necrotizing Enterocolitis (NEC)

Stage	Systemic signs	Abdominal signs
IA Suspected	Temperature instability, apnea, bradycardia, lethargy	Gastric retention, abdominal distention, emesis, heme-positive stool
IB Suspected	Same as above	Grossly bloody stool
IIA Definite, mildly ill	Same as above	Same as above, plus absent bowel sounds with or without abdominal tenderness
IIB Definite, moderately ill	Same as above, plus mild metabolic	Same as above, plus absent bowel

	acidosis and thrombocytopenia	sounds, definite tenderness, with or without abdominal cellulitis or right lower quadrant mass
IIIA Advanced, severely ill, intact bowel	Same as IIB, plus hypotension, bradycardia, severe apnea, combined respiratory and metabolic acidosis, <u>DIC</u> , and neutropenia	Same as above, plus signs of peritonitis, marked tenderness, and abdominal distention
IIIB Advanced, severely ill, perforated bowel	Same as IIIA	Same as IIIA

- **Antenatal steroid:** In this study antenatal steroid refers to medication i.e. betamethasone and dexamethasone, received at least one time by mother of preterm baby before 24 hrs of delivery. Steroid is administered to the antenatal mother when the fetus is expected to be delivered within 24 hours to 48 hours. Treatment consist of 2 doses of 12 mg of betamethasone given intramuscularly 12 hours apart or 4 doses of 6mg of dexamethasone given 12 hours apart.
- **Breast milk:** In the study breast milk refers to milk which is produced by mother from her breast and given to baby either by expressing breast or direct from the breast.
- **Formula feed:** In this study formula feed refers to infant formula or top feed (bovine milk i.e. other than mother's milk) usually prepared for feeding neonate who is admitted in NICU through katori spoon or ryles tube.
- **Mixed feeding:** In this study mixed feeding includes both breast milk and formula/top feed through katori spoon, nasogastric and orogastric tube or from direct breast.

1.8 DELIMITATION

The study will be delimited to preterm babies admitted in NICU at selected hospital of Indore.

1.9 ETHICAL AND LEGAL ASPECTS

- A written permission will be obtained to conduct the study from the administrative authority of the institution.
- Confidentiality will be maintained by assigning code to each subject.
- The study will be beneficial to newborns.

CONCEPTUAL FRAMEWORK

A conceptual framework deals with the concepts assembled together by virtue of their relevance to the research problem which provides a certain framework of reference for clinical practice research and education.

The present study is aimed at exploring the effect of breast milk, formula/top feed and mix feed on the incidence of NEC among preterm admitted in NICU. The conceptual framework adopted for the study is based on modified theory given by King Imogene and Ida Jean Orlando.

Orlando (1972) nursing process discipline is based on the “process by which any individual acts”. The purpose of the process discipline, when it is used between a patient and a nurse is to meet the patient immediate need for help. Improvement in the patient behavior that indicates resolution of the need is the desired result.

King Imogene presents several assumptions that are basic to her conceptual system. These include the assumptions that human beings are open systems in constant interaction with their environment that nursing’s goal is to help individuals and groups maintain health.

NEED FOR HELP

Nursing is concerned with “individuals who suffer or anticipate a sense of helplessness”. Orlando defines need as “a requirement of the patient which, if supplied, relieves or diminished his immediate distress or improves his immediate sense of adequacy or well-being”

The present study includes: -

- Preterm newborn and decreased frequency of breast milk.

GOAL

King Imogene defines goal as “to help individuals to maintain their health so they can function in their roles”

In the study goal includes: -

- To compare the incidence of NEC among all cohorts
- To find out the associate risk factor of NEC

IMPLIMENTAION

According to King’s theory Implementation occurs in the activities that seek to meet the goals. She states that the concept involved in the making of transactions.

In the present study

- All preterm were divided into three cohorts: -
 - In cohort 1 those preterm were selected who received breast milk.
 - In cohort 2 those preterm were selected who received formula/top feed.
 - In cohort 3 those preterm were selected who received mix feed.
- Associated risk factors were identified and observed among preterm of all cohorts.

ENVIRONMENT

Environment and society are indicated as major concepts in King's conceptual system. She has stated that "environment is a function of balance between internal and external interactions"

In the present study environment provided to the preterm was NICU.

ACTION

King Imogene defines action as a sequence of behaviors involving mental and physical action.

In the study action refers to: -

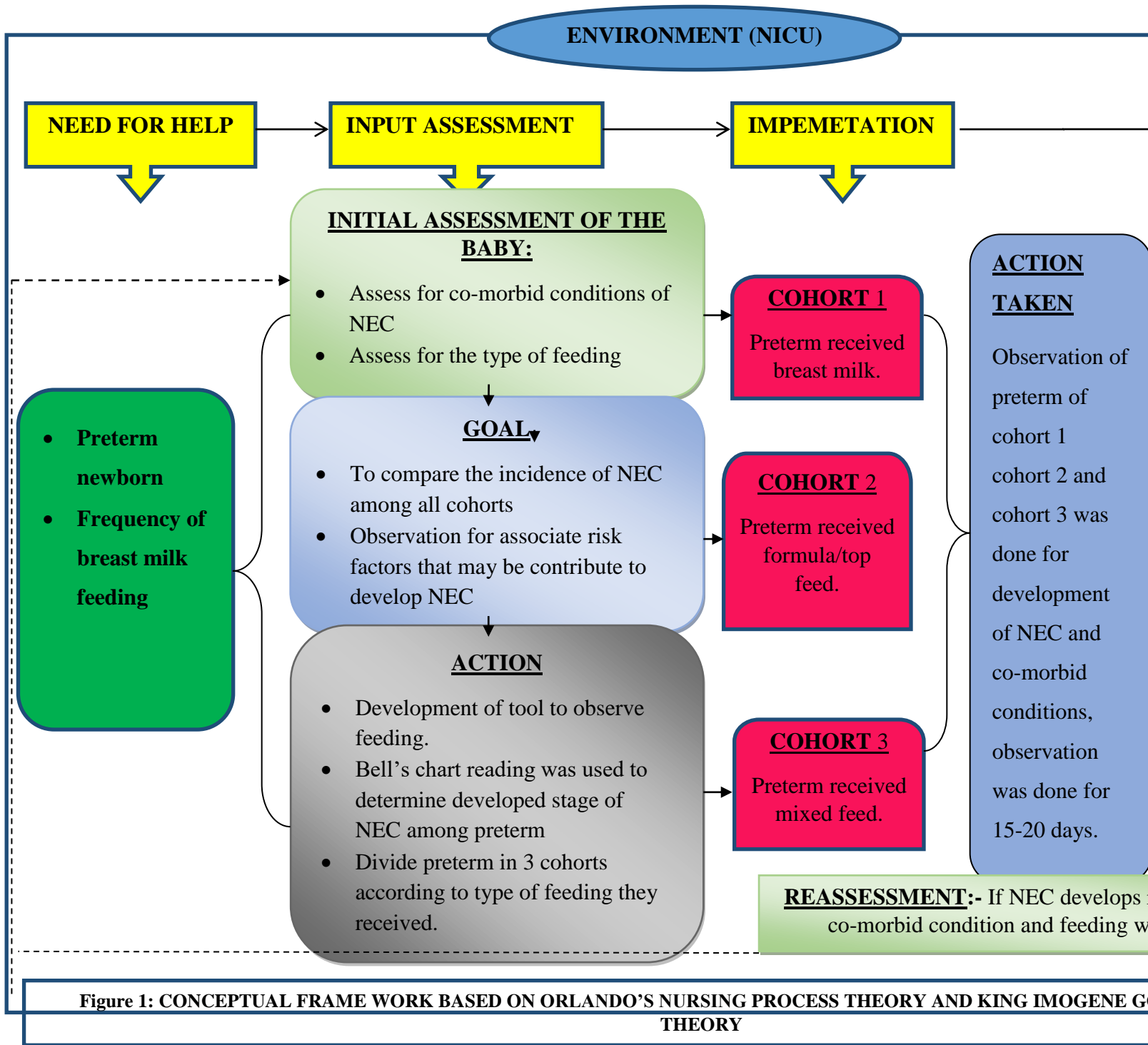
- Observation of the preterm receiving breast milk for 15-20 days
- Observation of the preterm receiving formula/top feed for 15-20 days
- Observation of the preterm receiving mix feed for 15-20 days.

EVALUATION

King Imogene defines evaluation as finding out whether goals are achieved or not, or attainment of goal and effectiveness of nursing care.

In this study evaluation includes:

15-20 days of observations are, there is no NEC developed in the breast-feeding group i.e. cohort 1 and in cohort of 2 and cohort 3 preterm developed NEC.



1.10 PLAN OF WRITING THE REPORT

The chapters inside the dissertation are:

- Chapter I: Dealt with introduction in which background of the study, need of the study, research question, statement of the problem, objectives, purpose, operational definition, delimitation and ethical consideration of the study have been included.
- Chapter II: Discussed review of literature.
- Chapter III: Explained the research methodology.

- Chapter IV: Discussed data analysis and interpretations
- Chapter V: Discussed major finding, discussion, conclusion, implications, limitations and recommendations.

1.11 SUMMARY

This chapter has been dealt with the background of the problem, need of the study, statement of the problem, objective of the study, hypothesis, operational definition, delimitation and conceptual framework of the study.

CHAPTER-II

REVIEW OF LITERATURE

Literature review is an account of what has been already established or published on a particular research topic by accredited scholar and researchers, it helps the researcher to carry out the research successfully. It is further intended to serve as a means of exchanging information with the hope that it could prevent further duplication, of respondents determine what is already known from similar research. (S K Sharma 2016)

The review of literature helps the researcher in developing a deeper understanding and insight into the problem under the study. It also provides information and the trends and developments in this area. The review of literature also helps to collect determined and appropriate information for building up the study in a scientific manner to achieve the desired result.

The literature review for the existing study is prepared under following headings:

- 2.1 Review of literature related to incidence of NEC among preterm.
- 2.2 Studies associated with effect of expressed breast milk, formula feeding and mix feeding on prevalence of NEC among preterm infants.
- 2.3 Review of literature associated with prevalence of risk factor in developing NEC among preterm.
- 2.4 Studies related to effect of antenatal steroids on incidence of NEC among preterm.

2.1 Review related to incidence of NEC among preterm.

Buch NA, Ahmad SM, Ali SW and Hassan HM conducted an epidemiological study of neonatal necrotizing enterocolitis in year 2014. It was a retrospective hospital-based study, total 3235 neonates admitted in NICU of Sheri Kashmir Institute, were evaluated. Among these, 42 were diagnosed as cases of necrotizing enterocolitis based on various clinical features and radiological parameters and grouped in 3 stage as per modified Bell's classification. The case records of these 42 babies and 303 of the control group were reviewed for the alleged risk factors and logged on previously tested proforma and at last statistically analyzed. For almost 10 years, they documented necrotizing enterocolitis in 42 neonates, with an incidence of 1% of all NICU admissions and 1% of

all live births. 81% were less than 2000 gms and 76% were less than 36 weeks of gestation. On further categorization based on stages, 24 % had stage I disease, 33% had stage II, and 43% babies had stage III disease. Several risk factors were present in these babies, with significant differences between Necrotizing Enterocolitis and the control group of patients, mainly hypothermia respiratory distress polycythemia acidosis sepsis enteral feeding and asphyxia. From the 59 babies (<2000 gms) with hypothermia (< 35 degrees C), 39% developed Necrotizing Enterocolitis, compared to 4% babies (11/28), who did not have hypothermia, statistically significant result. Average birth weight less than 1000 gms and gestational age were lower in control group. Severity of Necrotizing Enterocolitis as per modified Bell's classification and mortality was inversely proportional to birth weight and gestational age. 100 % mortality was noted in the babies, with birth weight less than 1000 gms and gestational age less than 28 weeks. Stage-wise the overall mortality was 45% for stage I, 20%, for stage II, 36% and 67% for stage III. Necrotizing enterocolitis cases accounted for maximum mortality in NICU than in control group. From this result it can be concluded that "Recognition of factors such as prematurity, low birth weight, hypothermia, asphyxia and their timely prevention would help in reducing morbidity and mortality due to necrotizing enterocolitis".

CWS Battersby, S Mandalia, N Fitz-Simon, K Costeloe and N Modi conducted a prospective population study of the incidence of severe necrotizing enterocolitis in England in the year 2012-2013. They conducted a 2-year, national population surveillance study of severe Necrotizing enterocolitis. The information was taken from the National Neonatal Research Database. These data were verified with local research leads. They used multivariable logistic regression calculation to determine patient characteristics associated with severe stage of Necrotizing Enterocolitis. They calculated all the unadjusted and adjusted incidence and the ratio of observed to predicted no. of cases, for all the operational delivery network and represented this graphically with funnel charts. Considering that the survival of preterm infants can inflate the occurrence of necrotizing enterocolitis, they performed a sensitivity analysis with survival free of necrotizing enterocolitis as the result. The results of the study were operational delivery networks (n=13) consist 63 neonatal units in England participated. During year 2012-13, total 118,073 infants of all gestational ages were born and admitted to NICUs; 529 of them died or received surgery for necrotizing enterocolitis. 33.0% of them died who received surgery. The incidence of severe necrotizing enterocolitis/1000 admissions was highest for infants born before 26 weeks. Lower gestational age and growth restriction were significantly independent predictors of several diseases. The average incidence per 1000 preterm admission ranged from 20.0 to 41.1 among all the operational delivery networks. The operational delivery network has an incidence of severe necrotizing enterocolitis which falls outside the 95 % control limits; whereas several adjustments for gestational age, birth weight and antenatal steroids, all operational delivery networks fall within 95% control limits. As per the analysis there was no evidence of variation in survival-free of necrotizing enterocolitis surgery at operational delivery network level.

Hull MA, Fisher JG, et al conducted a prospective cohort study on mortality and management of surgical necrotizing enterocolitis in very low birth weight neonates. There were 655 US centers that prospectively evaluated 188703 very low birth weight infants between the year 2006-2010. The outcome of the study was 17159 (9%) preterm developed NEC with mortality of 28 %; 8224 preterm didn't had any surgery regarding NEC and 8935 were operated (mortality) of around 30% persisted in spite of birth weight > 750 g; medical. Necrotizing Enterocolitis Mortality fell consistency with increasing birth weight. For an example, if neonates weighing 1251 to 1500 g, mortality was 27% in surgical vs 6% in medical NEC. Those who are treated surgically, 6131 (69%) underwent laparotomy only (mortality 34%), and 1,521 had peritoneal drainage and a laparotomy (mortality 34%), and 1521 had peritoneal drainage alone (mortality 50%).

All over the world, the incidence of Necrotizing Enterocolitis varies between 6% and 14% of babies born weighing less than 1500 g i.e. low birth weight. There is substantial geographic variability: a huge tertiary care center in Hong Kong reported 28% in this birth weight group, nurseries in Argentina experienced a 14% rate, Australia observed an incidence rates of under 3% in neonate born weighing less than 1500gm, but with individual NICUs varying between 2% and 22%. (Michaels Caplan 2014)

2.2 Review of literature associated with prevalence of risk factor in developing NEC among preterm.

Jadwiga Wojkowska-Mach and Anna Rozanka in 2009 conducted a study on the topic necrotizing enterocolitis in preterm infants: Epidemiology and antibiotic consumption in the polish neonatology network neonatal intensive care units. In this study 910 infants were counted-in who were admitted in NICUs. Basically 2 different types of indicators were used to determine antibiotic usage: the duration of treatment (days of treatment, DOTs) and the defined daily dose (DDD). In outcome of study necrotizing enterocolitis incidence was 8.7 % and casualty rate was 19 % chorioamnionitis, decreased gestational age and low birth weight were recognized risk factors for necrotizing enterocolitis. Umbilical vein catheter, mechanical ventilation and other chosen actions were used significantly longer in newborns with necrotizing enterocolitis than in the remaining preterm newborns. Usage of antibiotics reached 2.9 defined daily doses or 1.437 days of treatment. The level of antibiotic usage was studied with correlation to microbiological tests performed and it was non-significantly higher in the group of neonates with necrotizing enterocolitis in whom the test was performed.

Bertino E, et al conducted a case control study on the topic necrotizing enterocolitis: risk factor analysis and role of gastric residuals in very less birth weight infants. Necrotizing enterocolitis cases were compared with control subjects by gestational age and birth weight. Feeding tolerance was measured by maximum gastric residual volume, maximum residual as percentage of earlier feeding residual appearance. Mortality and necrotizing enterocolitis risk factors were estimated. The outcome of the study was that 844 infants of very low birth weight were admitted to the neonatal intensive care unit during research period with an overall mortality prior to discharge of 14.6%. Necrotizing enterocolitis frequency was 2 %. Patent ducts arteriosus was significantly linked with necrotizing enterocolitis, it means maximum residual from birth to necrotizing enterocolitis onset and

maximum residual as percentage of the corresponding feed volume was significantly increased in cases than in controls, as well as percentage of infants with hemorrhagic residuals.

Ling-ping Zhang et al conducted a case control study was conducted on “risk factor for necrotizing enterocolitis in very preterm infants in southwest china.” This study included all preterm babies with gestational age less than 32 weeks appearing their institution from 2013 to 2016. The necrotizing enterocolitis group contain patients with necrotizing enterocolitis registered as per the criteria of the study. Controls were selected from the record and were compared for gender, gestational age, and birth weight enumeration data were stated as percentage and were compare using chi-square test. Quantitative data were stated as mean and were compared using student’s t-test. To identify the factors significantly associated with necrotizing enterocolitis, Conditional logistic regression analysis was performed. During the study phase, 945 very preterm babies were admitted in NICU of whom 46 (4.87%) developed necrotizing enterocolitis. The sum of 33 cases was enrolled in the necrotizing enterocolitis group, and 33 controls were selected from the record. Analyses revealed important differences among groups in the incidence of maternal placenta previa neonatal infection symptoms, septicemia, and intravenous aminophylline administration. Conditional logistic regression analysis demonstrated statistically significant relations of neonatal septicemia and intravenous aminophylline with necrotizing enterocolitis.

Brigit M. Carter, conducted a longitudinal study on risk factors for Necrotizing Enterocolitis (NEC) in preterm infants: how race, gender and health status contribute. For this study, 134 preterm newborn had risk of necrotizing enterocolitis because of low birth weight and mechanical ventilator. Weekly review of infant’s medical record until discharge was done. Demographic queries were asked to the mothers of preterm during time of admission. Data analysis done with logistic regression, Fischer’s exact tests and correlations. Results of the study shows that mechanical ventilation is directly related to incidence of necrotizing enterocolitis i.e. as the no. of days of the mechanical ventilator increase the rate of Necrotizing Enterocolitis (NEC) also increase. It is also found in the results of study that necrotizing enterocolitis is not related to gender anyhow. Birth weight was not significantly associated with necrotizing enterocolitis, probably due to its correlation with mechanical ventilation and number of infections.

2.3 Review of literature associated with effect of expressed breast milk, formula feeding and mix feeding on prevalence of NEC among preterm infants.

World Health Organization recommends that low birth weight (LBW) infants should be fed mother’s own breast milk. In case if mother’s own breast milk is not available, then other possibilities - either expressed breast milk form donor mother or formula milk. Available evidence shows that on comparing with formula milk, donor milk is associated with the lower incidence of the severe gut disorder, Necrotizing Enterocolitis (NEC), and other infections during the initial hospital stay after birth.

William McGuire et al conducted a study on formula milk v/s donor breast milk for feeding preterm or low birth weight infants in year 2017. The object of this study is to determine the effect of feeding with formula milk compared to donor breast milk, on growth and development in preterm or low birth weight (LBW) infants. Cochrane neonatal search strategy, comprise electronic searches of the Cochrane central register of controlled trials, Ovid MEDLINE and the cumulative index to nursing and allied health literature as well as conference proceedings and previous reviews. 11 trials were performed, in which total 1809 infants were included, fulfilled the inclusion criteria. 4 trials compared standard term formula milk v/s donor breast milk and 7 compared nutrients-enriched preterm formula milk v/s donor milk. Only the four most recent trials used nutrient-fortified donor breast milk. The trials contain various weakness in methodological quality, specifically concerns about allocation concealment in four trials and lack of blinding in most of the trials. Infants who were fed by formula milk had long hospital stay and had increased risk of necrotizing enterocolitis.

Meaghan Sullian (2016) carried out a study on breast milk exposure and the occurrence of necrotizing enterocolitis in very low birth weight (VLBW) pre-term babies. The secondary information calculation of 56 very low birth weight (VLBW) infants who served as controls. All babies have been born among 1997 and 2009 and cared for inside the new child intensive care unit. Infants have been born at or earlier than 29 weeks gestation and with a initial weight less than 1500grams. Statistics involved the extent fed each day and kind of feeding alongside demographic start information. The result of the research was breast milk feeding changed into protection towards NEC at a threshold of 50 %. When over 50 % of the overall feeding extent consisted of breast milk as opposed to infant formulation, babies were almost half of as likely to develop NEC. This finding turned into clinically large and underscores the significance of breast milk in NEC protection.

B Jasanin and S Patole conducted a systemic review study on standardized feeding regimen for reducing necrotizing enterocolitis in preterm infants: the data were collected from PubMed, EMBASE, CINAHL and E-abstract from the pediatric academic society meetings and other pediatric and neonatal conference proceedings were examined in May 2016. Observational studies reporting incidence of Necrotizing Enterocolitis (NEC), before and after implementing a Standard feeding regimen were included. Relevant data were extracted independently by two assessors. Meta-analysis was led using random effects model (REM) and outcomes rechecked with fixed effects model. Findings from 15 observational studies using random effects model, showed that standard feeding regimen significantly reduced the incidence of NEC. The results persisted significant after comparing studies in two epochs (1978 to 2003 vs 2004 to 2016). Standard feeding regimen endures to be an important tool in prevention of NEC in preterm infants.

Li YW, Maria Luisa Ventura, Marco Colombo and Davide Bernasconi conducted a study on effect of breastfeeding as opposed to system milk feeding on preterm infants in the neonatal extensive care unit. A set of 639 preterm infants with a gestational age of less than 36 weeks had been enrolled, and consistent with the feeding sample, they had been divided into unique breastfeeding institution (n=237) and components milk feeding organization (fed with liquid milk for preterm babies; n=402). In comparison with the method milk feeding group,

the breastfeeding group had a drastically faster boom in frame weight, a extensively lower occurrence rate of NEC and shortening the length of hospital stay in preterm babies with a gestational age of 28-33 weeks.

Maffei D, Schanler RJ (Nov 2016) performed a study at on the subject human milk is the feeding approach to prevent from necrotizing enterocolitis (NEC). Human milk is the desired weight loss program for preterm infants as it protects against many NICU demanding situations, specifically necrotizing enterocolitis. Babies who receive more than 50% of mother's own milk within the 2 weeks after start have a very less chance of NEC. An additional element within the latest decreasing charges of NEC is extended utilization of donor milk (DHM.)

Muller MJ, Paul T, Seelinger S conducted a study on necrotizing enterocolitis in premature newborns in year 2016. Necrotizing enterocolitis (NEC) is the maximum common place obtained sickness of the gastrointestinal tract in premature babies and newborns. It is well-defined as an ulcerative inflammation of the intestinal wall. The scientific indications to comprehensive signs of sepsis. NEC is categorized depend on its severity into disorder states according to the modified bell's class. Treatment of NEC stages relying on its severity from an old-fashioned healing technique to surgical treatment with resection of the affected elements of the gut. Mortality is considerably high in extremely small preterm toddlers reaching as much as 42% of the affected youngest. Measures which embrace breastfeeding or rather vitamins with pasteurized human donor milk from a milk bank, administration of probiotics. Avoidance of histamine type II receptor antagonist, and restrictive antibiotic remedy need to be taken into consideration early on for prevention of NEC.

Colaizy TT, Bartick MC, Jegier BJ, Green BD, Reinhold AG, Schaefer AJ et al conducted a study to see the impact of optimized breastfeeding at the costs of necrotizing enterocolitis in extremely low birth weight babies in the year 2016. NEC occurrence among all the infants receiving $\geq 98\%$ human milk became 1.3%; while 11.1% among the infants who fed simplest pf; and 8.2% among babies fed a blended weight reduction plan ($p = .002$). In adjusted models, in comparison with preterm mostly human milk, we observed an enhanced hazard of NEC linked with distinctive pf or a mixed food plan. In Monte Carlo simulation, current feeding of ELBW toddlers was related to 928 excess NEC instances and 12.1 additional deaths yearly, in comparison with a version in which 90% of babies acquired $\geq 98\%$ human milk. Amongst ELBW babies, not being fed chiefly human milk is related to an enhanced risk of NEC. Efforts to guide milk production through motherof ELBW babies may save a little one's death and reduce casualties.

Hair ab, Peluso AM, Hawthorne KM, Perez J, Smith DP, Khan JY et al conducted a study in March 2016 the study was multicentered retrospective cohort study past necrotizing enterocolitis prevention: enhancing effects with an exclusive human milk primarily based weight-reduction plan. Total 1,587 toddlers have been covered from four facilities in Texas, Illinois, Florida, and California. Extremely premature infant who obtained a unique hum weight loss program had a notably lower incidence of NEC and mortality. The human organization also had a reduction in past due-onset sepsis, retinopathy of prematurity (ROP), and bronchopulmonary dysplasia (BPD).

This multicenter study in addition highlights the numerous blessing of a distinctive human weight-reduction plan and demonstrates a couple of unconventional consequences after implementation of such a feeding protocol.

Alshaikh b, Emma Tonkin, Raechel A. Damarell and Andrew J. McPhee (November 2009) performed a study on the impact of an excellent development mission to use special mother's own milk on cost of necrotizing enterocolitis in preterm babies. The topics have been divided into 3 categories; baseline (12 month 2009; n=189), intervention segment (year 2010;n=202) and preserve section (January 2011-march2012; n=245). Clinical effects of the baseline and preserve stages have been taken in comparison. Qi tasks have been effective in growing use of distinct mother at time of first feed and of any mother at time of discharge and in lowering NEC incidence in the neonatal extensive care unit.

Xiao-Ming Ben, Rui Chen, Zong-Tai Feng, Tao-ying Chen and Jin-Han Zhan conducted a systemic review and meta-analysis of the benefits of expressed maternal milk and donor breast milk for preventing necrotizing enterocolitis in preterm infants in March 2012 in China. Data was searched from library's electronic records including PUBMED/MEDLINE, DCIENCEDIRECT, EBSCOHOST, EMBASE, OVID and Cochrane Library. This study has systemic review and meta-analysis of randomized controlled trials or quasi-randomized controlled trials. In this study only 5 trials fulfilled the inclusion criteria. Except for one study, all the rest included studies which were initiated nearly three decades ago. None of the individual trials found any statistically significant difference in the incidence of necrotizing enterocolitis. However, meta-analysis found that preterm infants feeding with donor milk was associated with a significantly less relative risk of necrotizing enterocolitis. Suspected necrotizing enterocolitis was three times less likely and confirmed necrotizing enterocolitis was four times less likely (relative risk 0.24;95%) in premature infants feeding with donor breast milk compared with formula milk given as a sole diet. No data to date was available to be combined in this meta-analysis to compare expressed maternal milk with formula milk given as a sole diet. This study conclude that donor milk reduces risk of necrotizing enterocolitis in preterm infants, but its advantages are described as of borderline effect and the quality of the evidence is limited.

Mother's own milk (MOM) is typically the first choice of nutrition for infants in NICU, including those at risk of NEC, because of its many associated benefits. Among the numerous valuable components of MOM, it contains protein, growth factors, immunological agents and pro and prebiotics to promote appropriate growth, enhance immune protection and develop a healthy microbiota. In inadequacy of MOM. Pasteurized milk donor human milk purchased from registered milk bank is an alternative source of human milk prioritized for preterm because it consists many of the immunological and digestive benefits as MOM (**JocelyShulhan 2017**)

Christofalo et al conducted a systemic review in the year 2014 to compare bovine milk-based formula with DHM for feeding preterm or LBW infants. It involves 1070 infants were analyzed. In this study DHM compared with formula in preterm or LBW infants in regard to short and long term growth and neurodevelopmental outcomes. Secondary outcomes were all cause mortality, NEC, days to full enteral feeds, feeding intolerance, and invasive

infections. Most studies analyzed included patients who were stable, aged < 2 weeks and weighed < 1800 g at birth. Four trials compared term formula with DHM, and 5 trial compared preterm formula with (donor human milk) DHM.

2.4 Review of literature related to effect of antenatal steroids on incidence of NEC among preterm.

Clarissa Bonanno, MD and Ronald J. Wapner carried out a study on the topic antenatal corticosteroids in the management of preterm birth: are we back where we started? The most recent Cochrane review on antenatal corticosteroids for women at risk for preterm birth included 21 studies of 3885 patients and 4269 infants. the authors included all randomized comparisons of antenatal corticosteroid (betamethasone, dexamethasone or hydrocortisone) administration to placebo or no treatment for women expected to deliver preterm. Treatment with administration to placebo or no treatment for women expected to deliver preterm. Treatment with a single course of antenatal corticosteroid decreased the risk of neonatal death by 31%. The risk of RDS was reduced by 34%, IVH by 46%, NEC by 54% and infection in the first 48 hours by 44%. need for respiratory support and admission to the neonatal intensive care unit were also reduced by therapy.

Another prospective cohort study was conducted by **Colm PTravers** in 2013 on the topic Exposure to any antenatal corticosteroids and outcomes in preterm infants by gestational age: prospective cohort study. 300 participating neonatal intensive care units of the pediatric medical group in the United States. Findings of the study was, infants exposed to antenatal corticosteroids (n=81 832) had a significantly lower rate of death before discharge at each gestation 29 weeks or less, 31 weeks, and 33-34 weeks compared with infants without exposure. The number needed to treat with antenatal corticosteroids to prevent one death before discharge increased from six at 23 -24 weeks gestation to 798 at 34 weeks gestation to 798 at 34 weeks' gestation. The rate of survival without major hospital morbidity was higher among infants exposed to antenatal corticosteroids had lower rates of severe intracranial hemorrhage or death, necrotizing enterocolitis stage 2 or above or death, and severe intracranial hemorrhage or death, necrotizing enterocolitis stage 2 or above or death, and severe retinopathy of prematurity or death compared with infants without exposure at all gestations less than 30 weeks and most gestations for infants born at 30 weeks gestation or later.

2.5 Summary

The chapter dealt with the review of literature in four areas namely, Review of literature related to incidence of NEC among preterm. Review of literature associated with effect of expressed breast milk, components feeding and mix feeding on prevalence of NEC among preterm infants. Review of literature associated with prevalence of risk factor in developing NEC among preterm. Review of literature related to effect of antenatal steroids on incidence of NEC among preterm.

CHAPTER-III

RESEARCH

METHODOLOGY

RESEARCH METHODOLOGY

Research methodology is concerned with problem solving, problem statement, historical research and evaluation of research. It includes the collection, assembling and examination of available data, making assumption about data, testing the assumptions and developing practical applications from the laws or principles that have been derived from the verifications of the assumptions. (Sharma S.K, 2011)

The present study aimed to compare the incidence of NEC among cohort1, cohort2 and cohort3, and find out the association between incidences of NEC on administration of antenatal steroid, identify the other associated factor developing NEC using modified Bells stage of NEC and Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

The chapter deals with research approach, research design, variables under study, setting of the study, population, sample, sampling technique and sampling criteria, data collection instrument etc.

3.1 RESEARCH APPROACH

A research approach tells the researcher as to what data to collect and how to analyze them. It is the overall plan or blue print chosen to carry out the study. It also suggests the possible conclusion to be drawn from the data.

In the view of objective of the present study, quantitative research approach was considered to be suitable.

A prospective cohort study is a cohort study that follows over time a group of comparable people (cohorts) who dissent with relevancy bound factors below study, to see however these factors have an effect on rates of a certain outcome. This study adopted prospective cohort technique to spot the impact of expressed breast milk, formula feeding/top feeding and mix feeding on incidence of NEC among preterm babies.

3.2 RESEARCH DESIGN

The research design is the master plan specifying the methods and procedures for collecting and analysing the needed information in research study.

In this study, the prospective randomized cohort study design which was intended to measure the change in the incidence of NEC among breast feeding preterm. formula/top feeding preterm and mix fed preterm.

So, the design can be presented as-

Cohort 1 \longrightarrow X1 \longrightarrow Outcome

Expressed breast milk**Observation for 15-20 days**

Cohort 2 \longrightarrow X2 \longrightarrow Outcome

Formula/Top feeding**Observation for 15-20 days**

Cohort 3 \longrightarrow X3 \longrightarrow Outcome

Mixed feeding**Observation for 15-20 days****3.3 VARIABLES UNDER STUDY****RESEARCH VARIABLE**

“A concept which can be taken on different quantitative values is called variable.”

Two types of variable were identified in this study.

- Independent variables
- Dependent variables

Independent variable

Independent variable is the variable that stands alone and is not dependent on any other.

In this study independent variables are breast milk, formula/top feed, and mix feed.

Dependent variable

It is the outcome variable of interest, the variable that is hypothesized to depend on or caused by another variable.

In this study dependent variable is incidence of NEC.

3.4 THE RESEARCH SETTING

Setting is the physical location and condition in which the data collection takes in a study.

The present study was conducted in Choithram Hospital and Research Center, Indore and Seva And Samarpan Hospital, Indore. Both have tertiary level NICU. Choithram Hospital and Research center Indore is a well-equipped, multi-specialty 350 bedded hospital, having 20 bedded NICU which is sub divided in 3-unit i.e. IN-BORN 8 bedded and SICK BORN 4 bedded where as Seva and Samarpan hospital there are 18 beds in NICU. Both the NICUs are of tertiary level. In Seva and Samarpan Hospital the average monthly admission in NICU is 20-30 and in Choithram Hospital it is 30-35 admission per month.

TARGET POPULATION

The target population was newborn babies with gestational age less than 37 weeks and who are receiving breast milk, formula feed/top feed and mix feed admitted and in NICU.

ACCESSIBLE POPULATION

The accessible population included preterm babies less than 37 weeks and who are receiving breast milk, formula feed/top feed and mix feed admitted and in NICU at Choithram hospital and research centre and Seva and samarpan Hospital Indore.

SAMPLING TECHNIQUE

Authoritive sampling technique

SAMPLE SIZE

Total N=60, cohort 1 $n_1=20$, cohort 2 $n_2=20$, cohort 3 $n_3 =20$ samples were selected according to the inclusion criteria.

TOOL AND DATA COLLECTION

Observation table for feeding and Bell's stage of NEC tool assessment of stages of NEC

Cohort 1

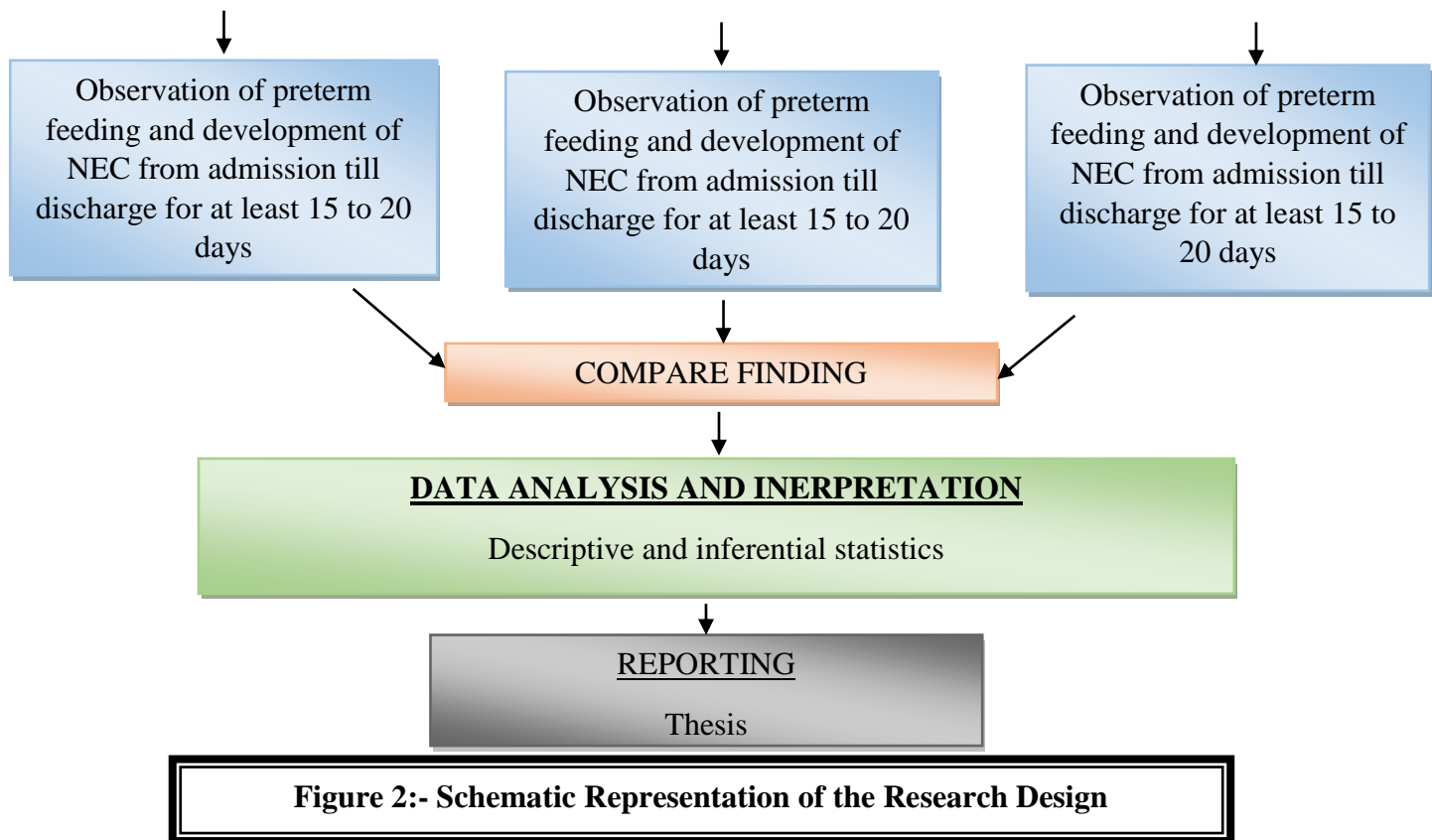
20 babies who receives expressed breast milk

Cohort 2

20 babies who receives formula/top feeding

Cohort 3

20 babies who receives mixed feeding



3.5 THE POPULATION

Population is the entire aggregation of the cases that met a designed set of criteria. The researcher specifies the broad population (target population) as well as the actual population that is available for the study (accessible population)

TARGET POPULATION

In the present study target population was newborn babies with gestational age less than 37 weeks and who are receiving breast milk, formula feed/top feed and mix feed admitted in NICU on 1st to 3rd day of life.

ACCESSIBLE POPULATION

The accessible population included preterm babies less than 37 weeks and who are receiving breast milk, formula feed/top feed and mix feed admitted in NICU at Choithram hospital and research centre and Seva and Samarpan Hospital, Indore.

3.6 THE SAMPLE SIZE AND SAMPLING

A sample is a subset of a population selected for the observation and analysis.

In the present study the sample size comprised of total 60 preterm babies ($n_1=20$), 20 in cohort 2 ($n_2=20$) and in cohort 3 ($n_3=20$).

3.7 SAMPLING TECHNIQUE

The samples were selected through Authoritive sampling technique was used for selection of preterm babies. Authoritive sampling is based in the belief that a researcher's knowledge about the population can be used to hand pick the cases to be included in the sample.

Authoritive sampling technique was used to separate samples in cohort's i.e. cohort 1, cohort 2 and cohort 3.

RECRUITMENT CHART

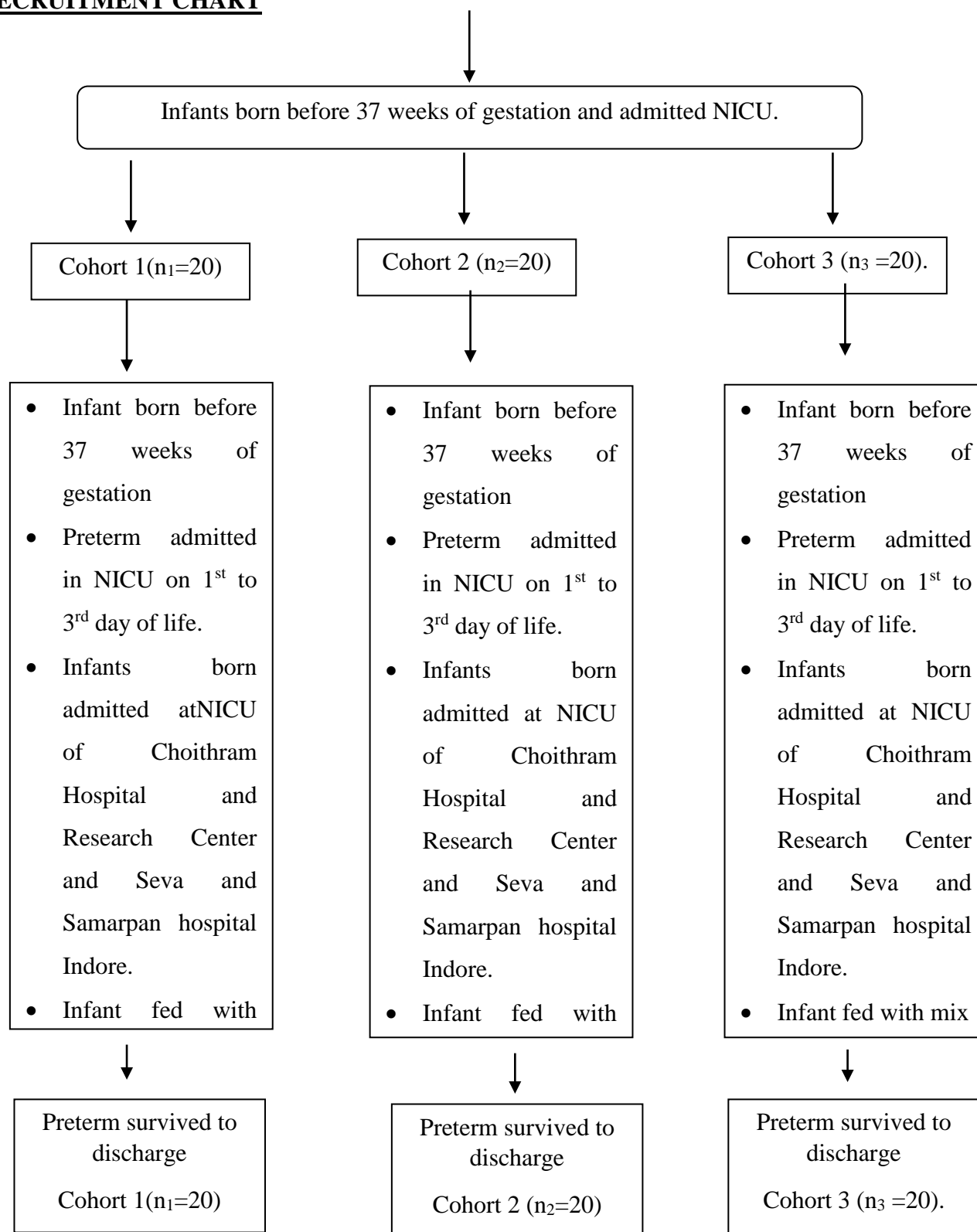


Figure 3: Recruitment chart**3.8 SAMPLE SELECTION CRITERIA**

The sampling frame structured by the investigator included the following criteria:

Inclusion criteria

- The babies born with the gestational age less than 37 weeks
- The babies admitted in NICU between 1st and 3rd day of life at selected hospital.

Exclusion criteria

- The babies admitted with congenital anomalies, chromosomal anomalies.

3.9 DEVELOPMENT AND DESCRIPTION OF TOOL

Data collection is the procedure and instruments used by the researcher to observe or measure the key variable in the research problem.

- Tool consist of 2 sections: -
 1. Section A: Socio demographic variables
 2. Section B: Clinical assessment

The following steps were adopted prior to the development of the tools:

1. Prior to the development of the tool the researcher consulted the guide, co-guide and the experts in this field.
2. Personal experience of the investigator was an added benefit for the tool construction
3. Extensive review of literature to provide adequate content for tool preparation
4. The investigator consulted the experts in the field of pediatrics and child health Nursing for refinement of the tool.

The tool used in the study consists of:

SECTION A: SOCIO DEMOGRAPHIC VARIABLES

1. First section consisted of 6 socio demographic variables of mother and newborn to collect baseline data, consist of

- (i) **MATERNAL BASLINE DATA:** It consist of six items for obtaining information about selected factors like, Age of mother, Diagnosis, gravida, mode of delivery, Antenatal Corticosteroid (received or not) if received then no. of doses received.
- (ii) **NEONATAL BASELINE DATA:** It consist of 5 items for obtaining information about selected factors like gender, age of preterm on admission in NICU, gestational age in week and days, birth weight in grams, reason of admission in NICU.

SECTION B: CLINICAL ASSESMENT

This section consists 9 of associated risk factors of NEC i.e. Blood transfusion, Meconium aspiration syndrome, Asphyxia, Sepsis, Congenital heart disease, Nosocomial infection, Mechanical ventilation, Umbilical vein catheter, Umbilical artery catheter. It also consist of 9 clinical feature of NEC i.e. Vomiting, Diarrhea, Feeding intolerance, increased gastric residuals, Abdominal distention, Occult blood in stool, Abdominal tenderness, Abdominal wall edema, Palpable bowel loops; assessment of type of feed provided to the neonate in every day and each time and also consist of Bells stage of NEC (standardized tool)

Modified Bell's Staging Criteria for Necrotizing Enterocolitis (NEC)

Stage	Systemic signs	Abdominal signs
IA Suspected	Temperature instability, apnea, bradycardia, lethargy	Gastric retention, abdominal distention, emesis, heme-positive stool
IB Suspected	Same as above	Grossly bloody stool
IIA Definite, mildly ill	Same as above	Same as above, plus absent bowel sounds with or without abdominal tenderness
IIB Definite, moderately ill	Same as above, plus mild metabolic acidosis and thrombocytopenia	Same as above, plus absent bowel sounds, definite tenderness, with or without abdominal cellulitis or right lower quadrant mass
IIIA Advanced, severely ill, intact bowel	Same as IIB, plus hypotension, bradycardia, severe apnea, combined respiratory and metabolic acidosis, DIC, and neutropenia	Same as above, plus signs of peritonitis, marked tenderness, and abdominal distention
IIIB Advanced, severely ill, perforated bowel	Same as IIIA	Same as IIIA

3.10 VALIDATION OF TOOL

Validity is a criterion for evaluating the quality of measure of an instrument. Content validity refers to the degree to which an instrument measurement what it is supposed to measure.

The prepared tool along with the statement, objectives, hypothesis, operational definition and criteria checklist were given to 7 experts from the field of pediatrics, one (Neonatologist), two (Pediatric Consultant), four (Pediatric nursing Professors) one (statistician). For establishing content criteria checklist was prepared. Criteria Checklist consisted of two criteria- 'agree' and 'disagree'. A remark column was prepared for each item, where experts could give their suggestions and remarks.

The changes were discussed with guide and minor changes were re-established.

3.11 RELIABILITY OF THE TOOL

Reliability of research instrument is defined as the degree of consistency and accuracy with which an instrument measures the attribute for which it is designed to measure.

Modified Bell's stage of NEC is a tool to assess the stage of NEC in newborn infants which was calculated using Split half method and computed by Spearman-Brown formula and it was found to be $r=0.96$

3.12 PILOT STUDY

The predominant objective of the pilot study was to help investigator to become familiar with the use of the tool and to find out any difficulties to conduct the main study. It also aimed to assess the feasibility of the study, to refine semi structured questionnaire, clarity of language and makes plans for analysis thus helping in finalizing the tool.

The pilot study conducted from 1 April to 20 April in Medicare Hospital, Indore. Written permission was taken from ethical committee of CH&RC and administrative authority of Medicare Hospital and research center, Indore. Data were collected from 6 the mothers regarding their preterm [$N=6$ (cohort1 $n_1=2$, cohort2 $n_2=2$ and cohort3 $n_3=2$)] who fulfilled the inclusion criteria and informed consent was obtained from the consultant and mothers of the preterm prior to the data collection. The purpose of the study was explained to the mothers of the participants and confidentiality was assured. Only those preterm who are admitted to NICU on their first to third day of life were included in the study. The average time taken for data collection was 15 to 20 days. Assessment of every preterm baby's feeding for each time was done. With the assessment of type of feeding preterm babies were also observed for the clinical features of NEC. A feeding assessment and assessment of clinical features were taught to staff nurses and also taught about how to fill the feeding chart according to assessment. Those

preterm babies were also observed for type of feeding and clinical features/development of NEC whose mother received corticosteroids in their antenatal phase.

The analysis of the study revealed that the objectives of the study would be fulfilled; preterm babies who received majority of breast milk i.e. cohort 1 didn't develop NEC. In cohort2 and cohort 3: 50% (1) preterm developed NEC. Preterm who received antenatal corticosteroid didn't develop NEC.

Based on this information the investigator proceeds with the actual data collection for the main study.

After the pilot study changes were made in the feeding of preterm i.e. preterm who received majority of breast milk in whole feeding assessment were included in cohort 1, preterm who received formula/top feed in majority feedings were included in cohort 2 and in cohort 3 those preterm were included who received both formula/top feed and breast milk in approximately equal amount.

3.13PROCEDURE FOR DATA COLLECTION

Written permission was obtained from ethical committee and administrative authority, of Choithram Hospital and Research Centre and Seva and Samarpan Hospital, Indore. The main study was conducted from 5th July to 30 August and it was carried out in the same way as that of the pilot study.

Total sample size was 60(N=60 cohort1 $n_1=20$, cohort2 $n_2=20$ and cohort3 $n_3 =20$) samples was selected through authoritative sampling technique to meet the inclusion criteria for the study. The purpose of the study was explained to the mother of the preterm and written consent was taken from mother and confidentiality was assured to the entire mothers. the sample were selected as per the inclusion criteria of the study. Researcher visited NICUs and training was provided to the staff member about the observation of feeding and NEC and how to document the Bell's chart. The assessment of the staff's observation was done by researcher every day. Sample were observed for feeding from admission till discharge, only those sample were observed who are admitted in NICU on 1st 2nd or 3rd day of life. After the data collection all mothers were advised to provide breast milk, advantages of breast milk were taught and also explained about lactating diet.

3.14PLANS FOR DATA ANALYSIS

Data analysis was the systemic organization of research data and the testing of research hypothesis using the data. The present study was analyzed the data based on the objectives. The data obtained from 60 samples was analyzed by using descriptive and inferential statistics as follows

Analysis of data was planned on the basis of objectives of the study.

Section 1: Frequency and percentage distribution of socio demographic variables of mother and association between incidence of NEC and antenatal steroid was planned to analyze using chi square

Section 2: Regression was planned to analyze effect of risk factors on incidence of NEC with that comparison in the incidence of NEC among cohort1, cohort2 and cohort3 was planned to analyze using ANOVA

3.15 SUMMARY

The research methodology reveals the overall plan of the research problem in a systematic and scientific manner. This chapter dealt with the description of the research design, sample and sampling technique, research setting and study instruments, reliability of instrument, pilot study and data analysis plan. This chapter gives direction for the analysis and interpretation of the data.

CHAPTER-IV

DATA ANALYSIS AND INTERPRETATION

Method of organizing, sorting and scrutinizing data in such a way that research question can be answered, or meaningful inference can be drawn (S.K. Sharma 2014)

This chapter deals with the analysis and interpretation of data collected to assess the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies at selected hospital of Indore. Data collected from 60 selected preterm according to objective and hypothesis of the study.

Analysis and interpretation of data were collected through observation table, using differential and inferential statistics.

OBJECTIVES:

The objectives of the study were

- To compare the incidence of NEC among cohort1, cohort2 and cohort3
- To find out the association between incidence of NEC on administration of antenatal steroid.
- To identify the associated risk factor developing NEC
- Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

HYPOTHESIS

All the hypotheses are tested at level of $p \leq 0.05$

- H_0 : There is no significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3
- H_1 : There is significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.
- H_{02} : There is no significance difference in the rate of NEC among preterm after giving antenatal corticosteroid.

- H₂: There is significance difference in the rate of NEC among preterm after giving antenatal corticosteroid.

ORGANIZATION AND PRESENTATION OF DATA

The raw data was collected and entered in a master sheet for the statistical analysis. It was interpreted using descriptive and inferential statistics. The data findings have been organized and presented under the following sections:

SECTION A (I): Frequency and percentage distribution of maternal baseline data and

SECTION A (II): Frequency and percentage distribution of neonatal baseline data

SECTION B (I): Assessment of associated risk factors of NEC

SECTION B (II): Assessment of association between incidences of NEC on administration of antenatal steroid.

SECTION B (III): Assessment of clinical feature of NEC

SECTION B (IV): Assessment of difference between including of NEC among cohort 1, cohort 2 and cohort 3.

4.1 SECTION A (I): Frequency and percentage distribution of maternal baseline data

Table No. 1 (a): Frequency and percentage distribution of socio demographic variable of maternal baseline data

N=60(n₁=20, n₂=20 and n₃=20)

Variable	Cohort 1 N ₁ =20		Cohort 2 N ₂ =20		Cohort 3 N ₃ =20	
	F	%	F	%	F	%
(1) Age of mother in years						
20-23	4	20%	5	25%	1	5%
24-27	6	30%	7	35%	8	40%
28-31	7	35%	7	35%	8	40%
32-35	3	15%	1	5%	3	15%
(2) GRAVIDA						
G1	8	40%	7	35%	6	30%
G2	6	30%	9	45%	9	45%
G3	3	15%	1	5%	2	10%
G4	2	10%	1	5%	1	5%

G5	0	0%	2	10%	0	0%
G6	1	5%	0	0%	2	10%

(3) MODE OF DELIVERY

NVD	3	15%	4	20%	7	35%
LSCS	17	85%	16	80%	13	65%

*G1-Gravida 1 *G2-Gravida 1 *G3-Gravida 3 *G4-Gravida 4 *G5-Gravida 5 *G6-Gravida 6 NVD- Normal vaginal delivery LSCS-Lower segment caesarian section.

Data presented in this table no. 1 (a) depicts the frequency and percentage distribution of maternal age, which reveals that in cohort 1 majority of mother 7(35%) were in the group of 28-31 years of age, 6(30%) in the group of 24-27 years, 4(20%) of mother were in the age group of 20-23 years, and 3(15%) in the group of 32-35 years. In cohort 2, most of the mother 7(35%) were in the group of 24-27 years and 28-31 years, 5(25%) of mother were in the age group of 20-23 years, and 1(5%) in the group of 32-35 years. In cohort 3 most of the mothers 8(40%) were in the group of 24-27 years, 8(40%) and 28-31 years, 3(15%) in the group of 32-35 years and 1(5%) of mother were in the age group of 20-23 years.

In this study in cohort 1 most 8(40%) had gravida one, 6(30%) of the mother had gravida two, 3(15%) mother had gravid three, 2(10%) mother had gravida four and 1 mother had gravida six. Whereas in cohort2; majority of the mothers 9(45%) were in group of gravid two, 7(35%) of the mother had gravid one, 2(10%) mother had gravida five, 1(5%) of the mother had gravida three, 1(5%) of the mother had gravida four. In cohort 3 most 9(45%) of the mothers had gravida two, 6(30%) of the mother had gravida one, 2(10%) of the mothers had gravida three, 2(10%) of the mothers had gravida six and 1(5%) of the mother had gravida four.

Table no. 1 also included that in cohort 1 majority 17(85%) mother had LSCS, 3(15%) of the mothers had NVD and in cohort 2 most 16(80%) of mother had LSCS and 4(20%) mother had NVD whereas in cohort 3 majority 13(65%) mothers had LSCS delivery and 7(35%) mothers had NVD.

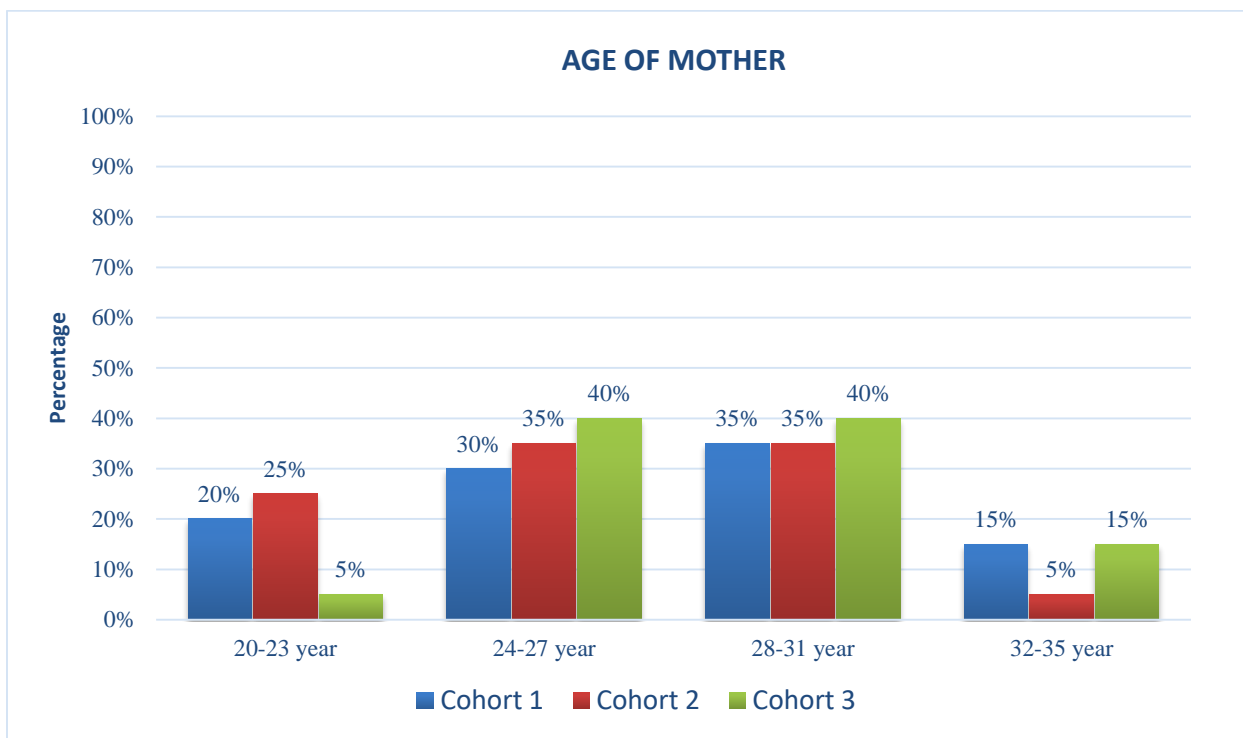


Figure 4: Bar diagram showing distribution of maternal age in year.

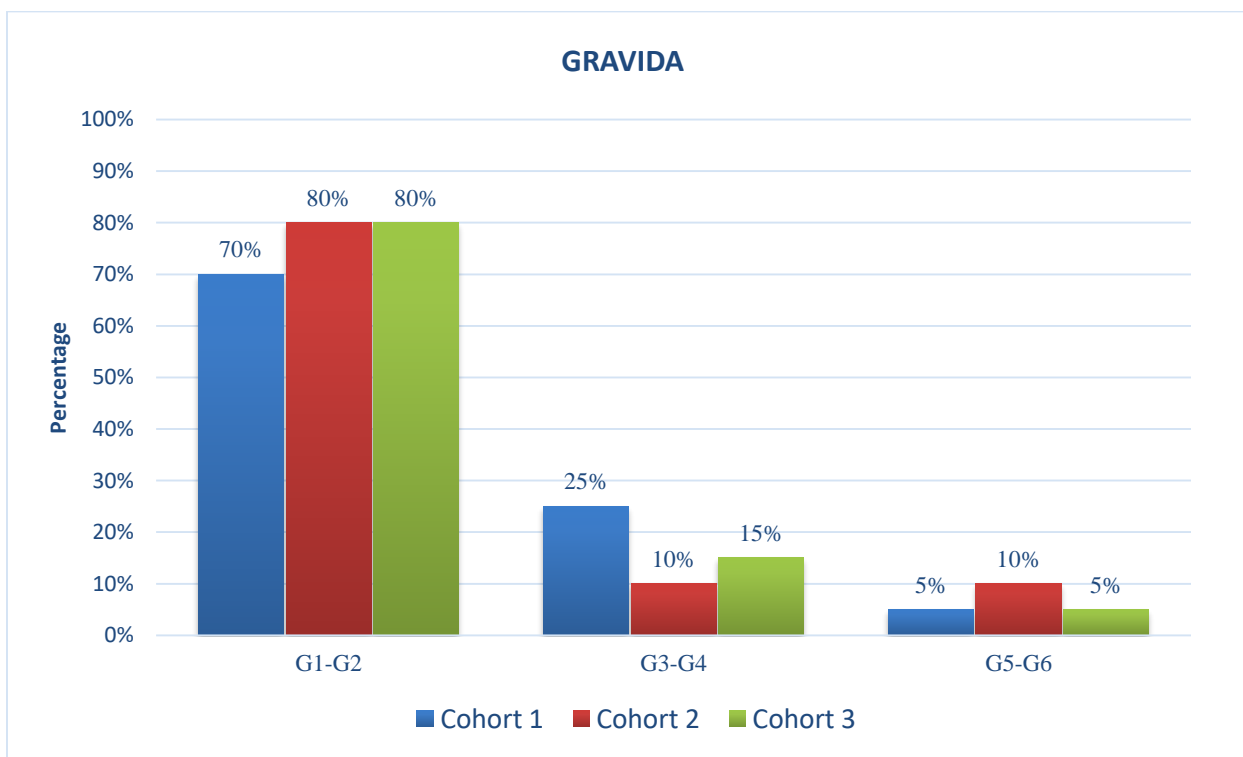


Figure 5: Bar diagram showing percentage of maternal gravida.

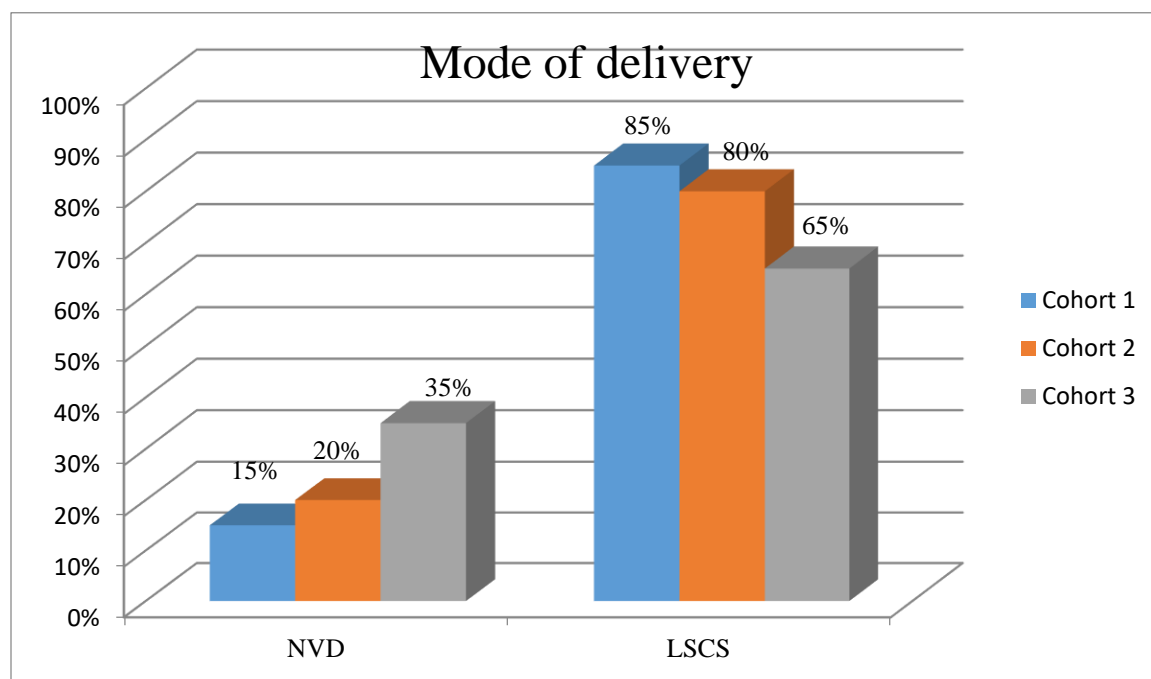


Figure 6: Bar graph shows Mode of delivery.

TABLE 1(b): Frequency and percentage distribution of maternal baseline data

N=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
(4) DIAGNOSIS						
Per Vaginal Leaking	5	25%	7	35%	3	15%
PROM	4	20%	2	10%	3	15%
PreEclampsia	2	20%	3	35%	4	40%
Oligohydromonos	2	15%	3	15%	1	5%
FetalDistress	1	5%	2	10%	2	10%
EarlyContraction	3	15%	1	5%	3	40%
PlacentaPrevia	2	10%	1	5%	2	40%
GDM	1	5%	1	5%	2	15%

*GDM-Gestational diabetes mellitus *PROM-Pre rupture of membrane

Data in this table no. 1 (b) shows that in cohort1 majority 5(25%) mother had diagnosed with per vaginal leaking, 4(20%) mother were diagnosed with PROM, 3(15%) mother had early contraction, 2(10%)mother had placenta

previa, 2(10%) mothers were diagnosed with pre-eclampsia, 2(10%) mothers were diagnosed oligohydramnios, 1(5%) mother diagnosed with fetal distress. and 1(5%) mothers had Gestational diabetes mellitus. In cohort 2 most of 7(35%) mother had diagnosed with per vaginal leaking, 3(15%) mothers were diagnosed with pre-eclampsia, 3(15%) mothers were diagnosed oligohydramnios, 2(10%) mother are diagnosed with PROM, 2(10%) mother diagnosed with fetal distress. 1(5%) mother had early contraction, 1(5%) mother had placenta previa, and 1(5%) mothers had Gestational diabetes mellitus. In cohort3, majority 4(20%) mothers were diagnosed with pre-eclampsia, 3(15%) mother had diagnosed with per vaginal leaking, 3(15%) mother are diagnosed with PROM, 3(15%) mother had early contraction, 2(10%) mother had placenta previa, 2(10%) mother diagnosed with fetal distress. 1(5%) mothers were diagnosed oligohydramnios, and 1(5%) mothers had Gestational diabetes mellitus.

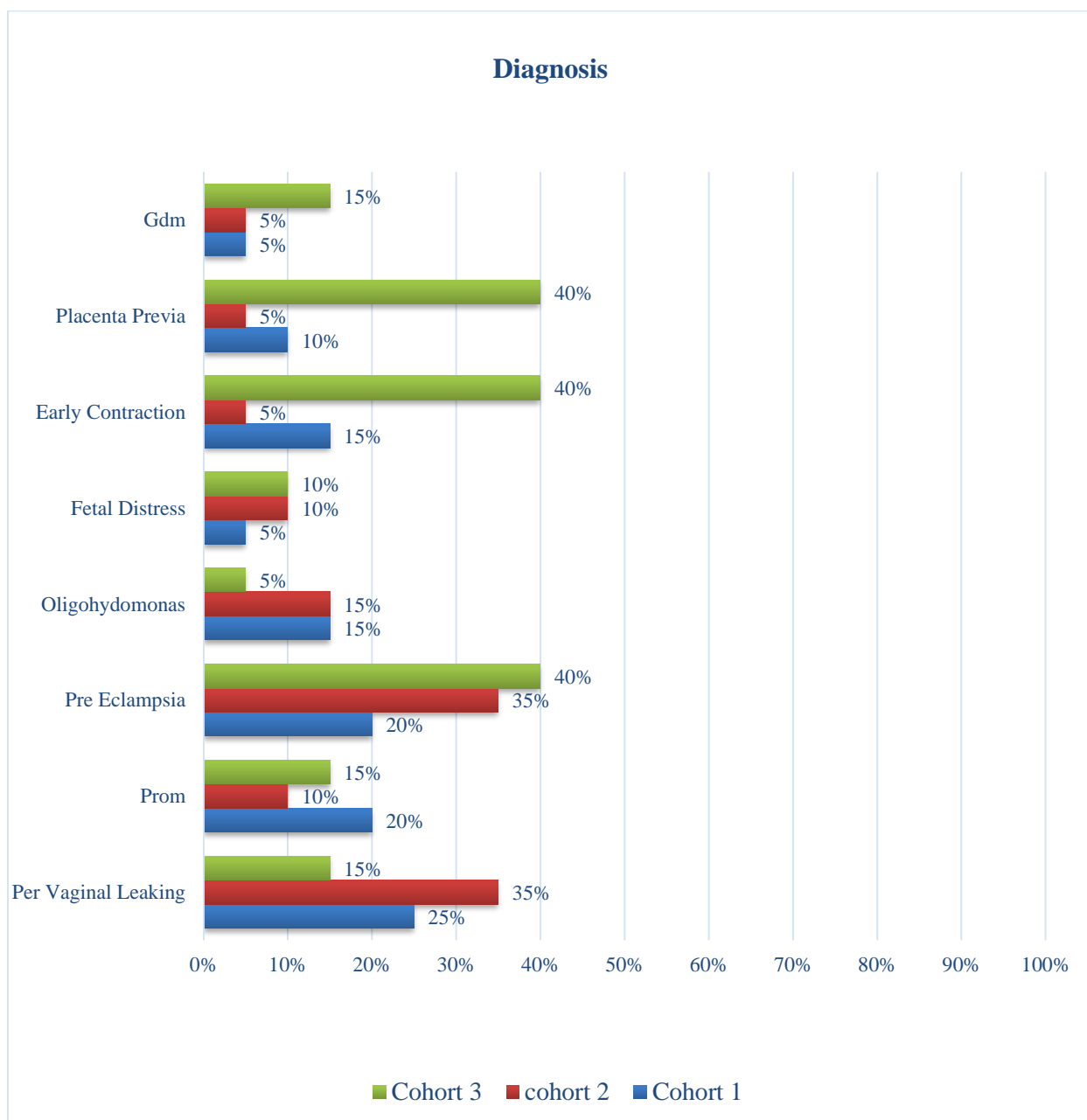


Figure 7: Bar diagram showing diagnosis of mother for preterm deliver

4.2 SECTION A (II): Frequency and percentage distribution of neonatal baseline data

Table 1(c): Frequency and percentage distribution of neonatal baseline data

N=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
(5) GENDER						
MALE	17	85%	11	55%	9	45%
FEMALE	3	15%	9	45%	11	55%
(6) AGE AT THE TIME OF ADMISSION						
DAY1	17	85%	17	85%	19	95%
DAY 2	3	15%	2	10%	0	0%
DAY 3	0	0%	1	5%	1	5%

Data presented in this table no. 1(c) shows that in cohort1, majority 17(85%) of preterm were male and 3(15%) preterm were female. In cohort2 most 11(55%) of preterm were male and 9(45%) and in cohort3 majority 11(55%) were female and 9(45%) were male.

In respect of age at the time of admission in cohort1 majority 17(85%) preterm were admitted in NICU on day of life 1st, 3(15%) preterm were admitted on 2nd day of life, none of the preterm were admitted on 3rd day of life whereas in cohort2 most 17(85%) preterm were admitted on 1st day of life, 2(10%) preterm were admitted on 2nd day of life, 1(5%) preterm were admitted on 3rd day of life. In cohort 3 majority 19(95%) of preterm were admitted on 1st day of life, 1(5%) preterm were admitted on 3rd day of life and none of the preterm preterm were admitted on 2nd day of life.

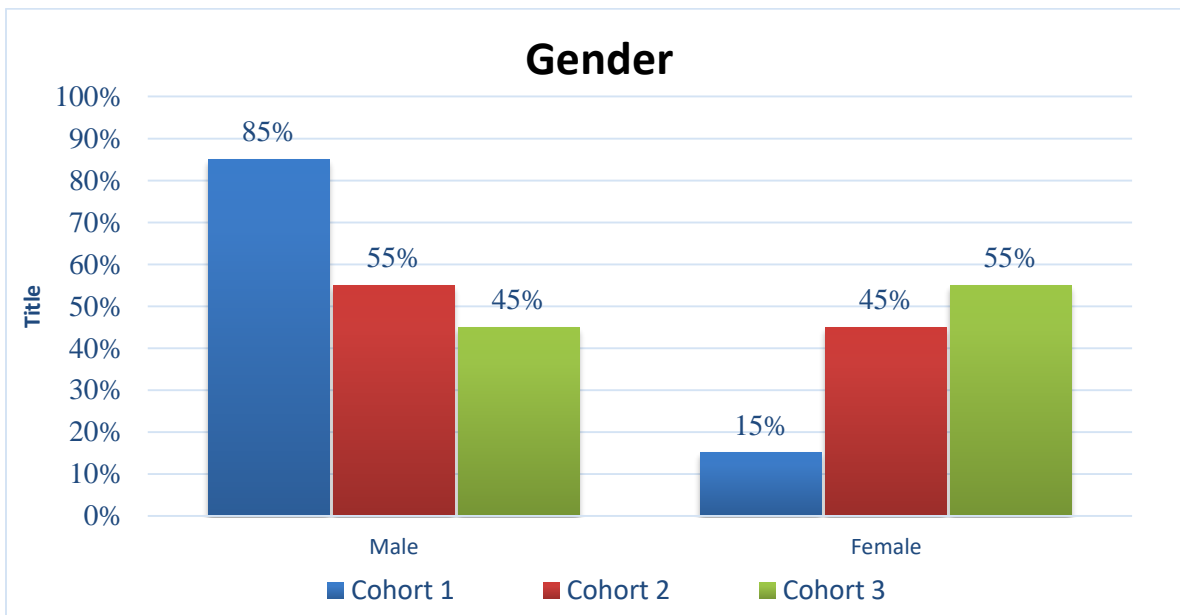


Figure 8: Bar showing gender of the preterm babies

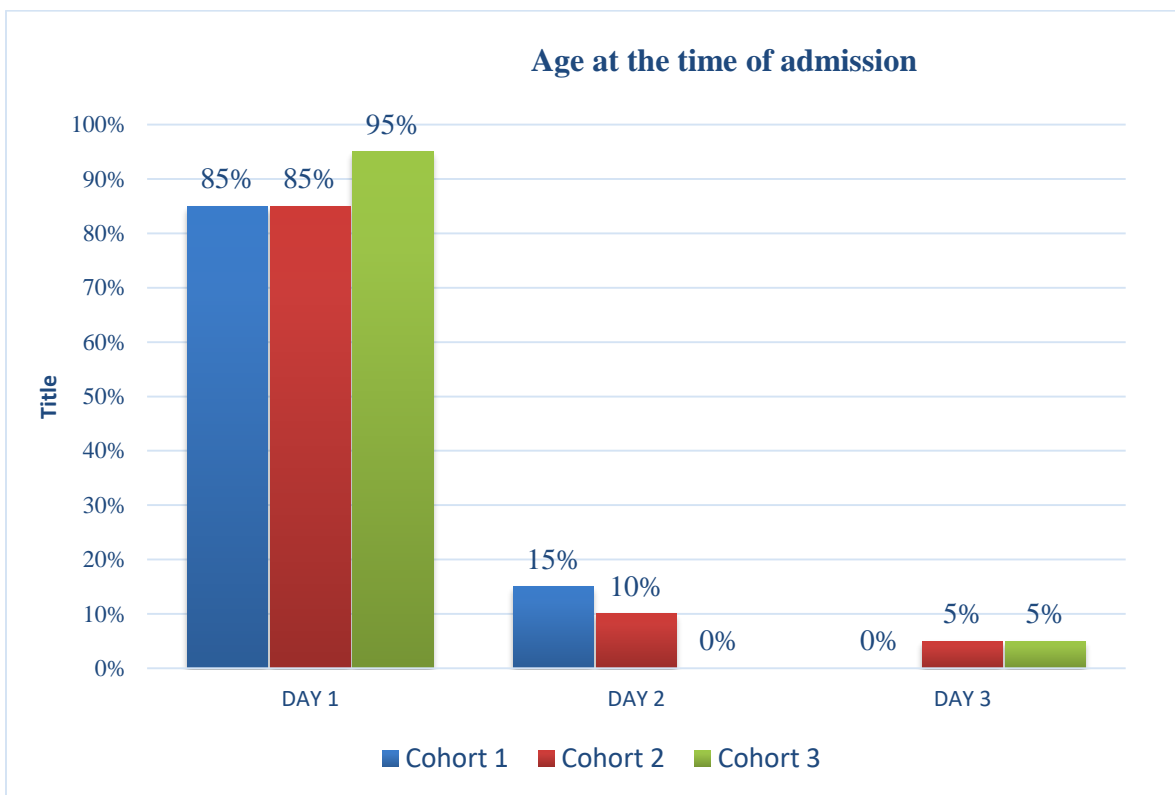


Figure 9: Bar graph showing age of the preterm at the time of admission in NICU.

TABLE 1 (d) Frequency and percentage distribution of neonatal baseline dataN=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
(7) BIRTH WEIGHT (IN GRAMS)						
600-1000	2	10%	5	25%	6	95%
1000-1400	3	15%	6	30%	4	0%
1400-1800	8	40%	5	25%	10	5%
1800-2200	4	20%	2	10%	0	0%
2200-2600	3	15%	2	10%	0	%
(8) REASONE FOR ADMISSION IN NICU						
Preterm LBW And Respiratory Distress	9	45%	11	55%	9	45%
Preterm VLBW And Respiratory Distress	3	15%	1	5%	4	20%
Preterm, ELBW, Respiratory Distress	3	15%	4	20%	5	25%
Preterm, ELBW, Respiratory Distress and Congenital Heart Disease	0	0%	0	0%	1	5%
Preterm, Respiratory Distress and Sepsis	1	5%	1	5%	0	0%

Data table presented in the table no. 1(d) shows that in cohort 1 majority 8(40%) of preterm's birth weight between 1400gms- 1800gms, 4(20%) of preterm's weigh between 1800-2200gms, 3(15%) of preterm's birth weight between 1000-1400, and 2200gms-2600gms 2(10%) preterm had birth weight between 600gms-1000gms. In cohort2 majority 6(30%) of preterm's birth weight between 1000gms-1400gms, 5(15%) preterm had birth weight between 600gms-1000gms, 2(10%) of preterm's in each category weight between 1800-2200gms and 2200gms-2600gms. In cohort3 most 10(50%) of preterm's birth weight between 1400gms- 1800gms, 6(30%) preterm had birth weight between 600gms-1000gms, 4(20%) of preterm's birth weight between 1000gms-1400gms.

In regards with preterm babies diagnosis on admission of NICU in cohort1 preterm, majority 9(45%) preterm were admitted for LBW care and Respiratory distress, 3(15%) were admitted in NICU with complaint of Preterm VLBW and Respiratory distress, 3(15%) Preterm, ELBW and Respiratory distress, 1(5%) preterm were admitted in NICU with the complaint of preterm, 1(5%) preterm were admitted in NICU with the complaint of respiratory distress and sepsis, 1(5%) Preterm and Respiratory distress, 1(5%) Preterm VLBW and meconium aspiration,

1(5%) Preterm, Respiratory distress and birth asphyxia, 1(5%) Preterm LBW and sepsis, In cohort2 preterm, most 11(55%) of the preterm were admitted with complaint of LBW and Respiratory distress, 2(10%) Preterm, Respiratory distress and birth asphyxia, 1(5%) were admitted in NICU with complaint of Preterm VLBW and Respiratory distress, ELBW, respiratory distress and congenital heart disease, 1(5%) preterm were admitted in NICU with the complaint of preterm, 1(5%) preterm was admitted in NICU with the complaint of respiratory distress and sepsis, 1(5%) Preterm and Respiratory distress, 1(5%) Preterm, Respiratory distress and congenital pneumonia in cohort1 preterm. In cohort3, majority 9(45%) preterm were admitted with complaint of LBW and Respiratory distress, 5(25%) Preterm had ELBW and Respiratory distress, 4(20%) were admitted in NICU with complaint of Preterm VLBW and Respiratory distress, 1(5%) preterm was admitted in NICU with the complaint of preterm, ELBW, respiratory distress and congenital heart disease, 1(5%) preterm was admitted in NICU with the complaint of respiratory distress and sepsis, (5%) Preterm, Respiratory distress and congenital pneumonia.

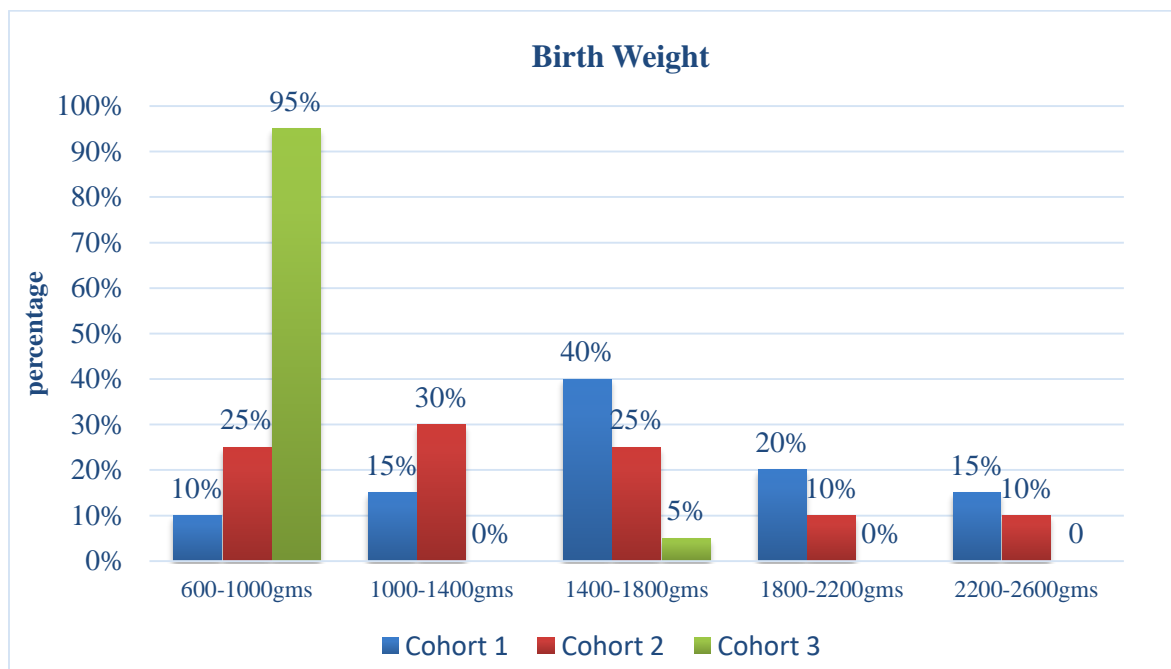


Figure 10: Bar diagram shows birth weight of the preterm.

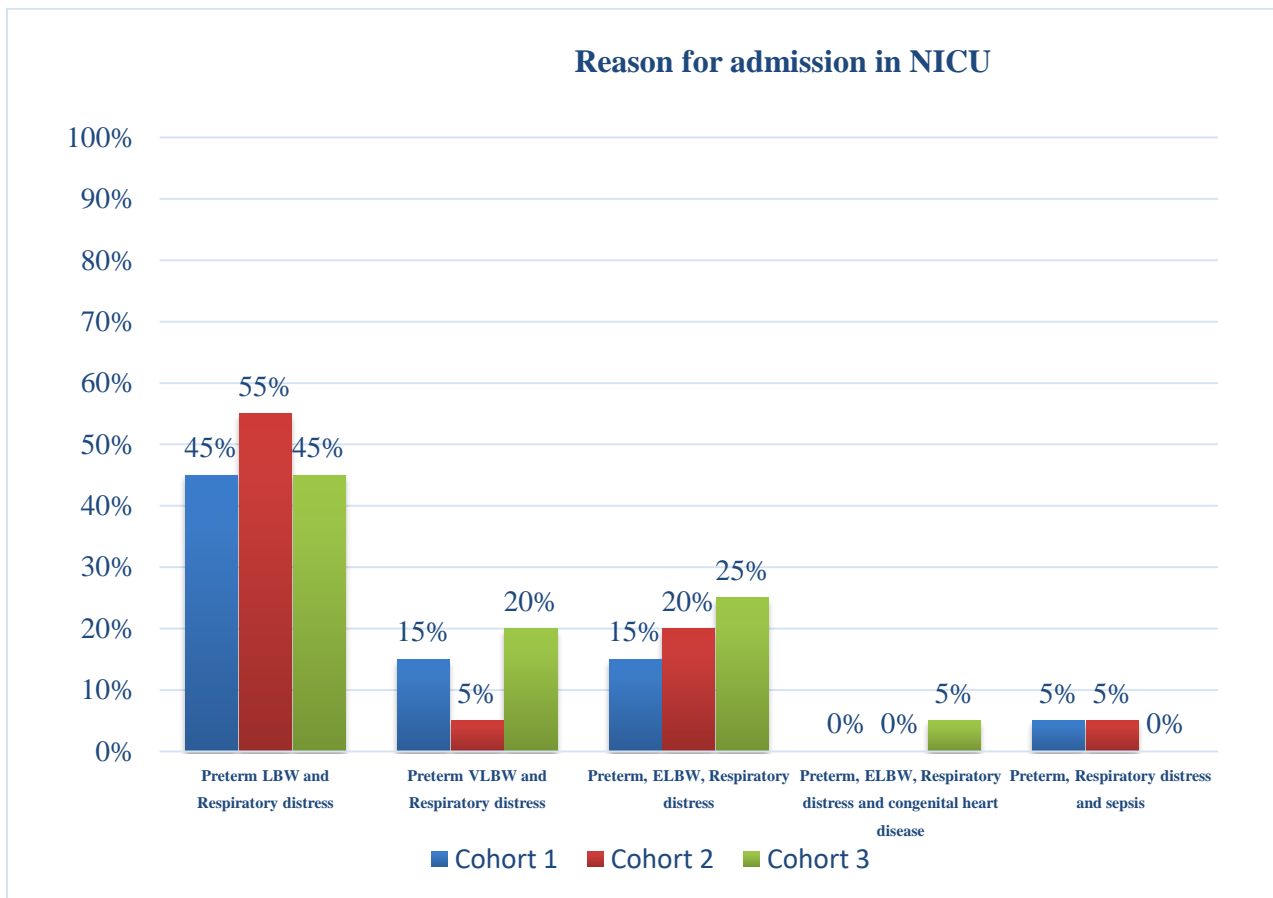


Figure 11: Bar graph shows reason for admission in NICU

4.3 SECTION B (III): ASSESSMENT OF CLINICAL FEATURE OF NEC

Table 2 (a) Frequency and percentage of clinical features of NEC

N=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORT n ₁ =20		COHORT n ₂ =20		COHORT n ₃ =20	
	F	%	F	%	F	%
CLINICAL FEATURE OF NEC						
Abdominal Distention	4	20%	3	0%	3	15%
Vomiting, Feeding Intolerance and Abdominal Distention	1	5%	4	5%	3	15%
Vomiting, Abdominal Distention	0	0%	0	0%	1	5%
Vomiting, Abdominal Distention and Occult Blood in Stool	1	5%	3	30%	3	15%
Vomiting Increased Gastric Residual and Abdominal Distention and Occult Blood in Stool	1	5%	1	5%	3	15%

Vomiting, Palpable Bowel Loops and Occult Blood in Stool	0	0%	1	0%	1	5%
Increased Gastric Residual and Abdominal Distention and Palpable Bowel Loops.	0	0%	2	0%	2	10%
Didn't develop any clinical feature of NEC	13	65%	6	30%	4	20%

The data in table no. 2 (a) shows that in cohort1 majority 13(65%) didn't develop any clinical feature of NEC, 4(20%) preterm developed Abdominal distention, 1(5%) preterm had Vomiting, feeding intolerance and abdominal distention, 1(5%) had vomiting, abdominal distention and occult blood in stool, 1(5%) had vomiting, increased gastric residual and abdominal distention and occult blood in stool.

In cohort2 majority 6(30%) didn't develop any clinical feature of NEC, 4(20%) preterm had Vomiting, feeding intolerance and abdominal distention, 3(15%) preterm developed Abdominal distention, 3(15%) had vomiting, abdominal distention and occult blood in stool, 2(10%) had Increased gastric residual and abdominal distention and Palpable bowel loops, 1(5%) had vomiting, increased gastric residual and abdominal distention and occult blood in stool, 1(5%) Vomiting, palpable bowel loops and occult blood in stool,

In cohort3, most 4(20%) of the preterm didn't develop any clinical feature of NEC, 3(15%) preterm developed Abdominal distention, 3(15%) preterm had Vomiting, feeding intolerance and abdominal distention, 1(5%) had Vomiting, abdominal distention 3(15%) had vomiting, abdominal distention and occult blood in stool, 3(15%) had vomiting, increased gastric residual and abdominal distention and occult blood in stool, 1(5%) Vomiting, palpable bowel loops and occult blood in stool, 2(10%) had Increased gastric residual and abdominal distention and Palpable bowel loops. 4(20%) didn't develop any clinical feature of NEC.

Objective I: To compare the incidence of NEC among cohort1, cohort2 and cohort3

Table 2 (b) Frequency and percentage of development of Bell's stage of NEC

N=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORT 1 n ₁ =20		COHORT 2 n ₂ =20		COHORT 3 n ₃ =20	
	F	%	F	%	F	%
BELL'S STAGE OF NEC						
STAGE I A	0	0%	3	15%	8	40%
STAGE II A	0	0%	3	15%	3	15%
STAGE I B	0	0%	2	10%	5	25%
STAGE II B	0	0%	2	10%	0	0%
DIDN'T DEVELOP NEC	20	100%	10	50%	4	20%

In cohort 1 none of the preterm develops NEC. While in cohort 2; half of the preterm i.e. 10(50%) of preterm develops NEC among which 3(15%) of the preterm develops stage IA and stage IIA however 2(10%) preterm develops stage IB and stage IIB, whereas in cohort 3 majority 8(40%)of the preterm develops stage IA of NEC, 5(25%) of the preterm develops stage IB of NEC, 4 (20%) preterm didn't develop NEC and 3(15%) preterm develops stage IIA of NEC.

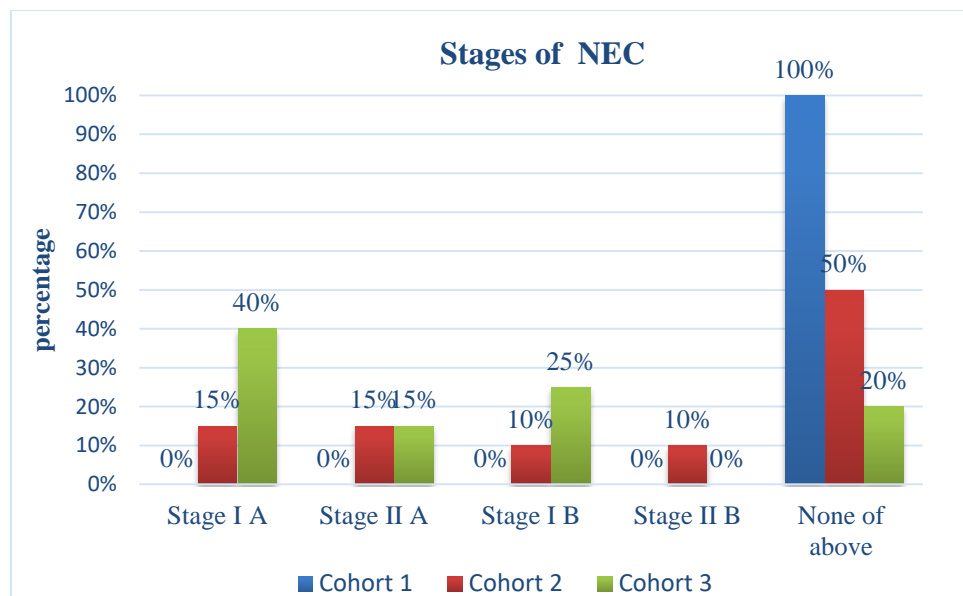


Figure12: Bar diagram showing Developed stages of NEC

4.4 SECTION B (IV): ANOVA SHOWING DIFFERENCE BETWEEN INCIDENCE OF NEC AMONG COHORT1 COHORT2 AND COHORT3

Table 2 (c) ANOVA showing difference between incidences of NEC among cohort 1 cohort 2 and cohort 3

S.NO	COHORT	Mean	df	SS	Mean of sum of square	F' ration	TABLE VALUE
1	COHORT 1	0	In Rows (19)	4.1	0.21579	4.17073	2.15
2	COHORT 2	0.5					
3	COHORT 3	0.8	In columns(1)15 9	0.9	0.9		

The table no. 2(c) shows that there is 0% of NEC among cohort 1, in cohort 2 rate of NEC was increased and in cohort 3 highest rates of NEC seen due to decreased use of corticosteroid in antenatal phase.

Hence the hypothesis 1 (H₁) is accepted here i.e. there is significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.

Objective II: To find out the association between incidence of NEC on administration of antenatal steroid.

Table 3(a): Frequency and percentage of doses of antenatal steroid given to the mothers

DOSES OF STEROID						
	f	%	F	%	f	%
1 dose	0	0%	2	10%	2	10%
2 dose	1	5%	8	40%	2	10%
No steroid	19	95%	10	50%	16	80%

The table no.1 (a) also shows that in cohort 1 majority 19(95%) mother didn't received antenatal steroid, 1(5%) of mother received 2 dose of antenatal steroid, whereas in cohort 2 half i.e. 10(50%) of mother received antenatal steroid, 8(40%) of mother received 2 dose of antenatal steroid, 2(10%) mother received 1dose of antenatal steroid and in cohort 3 majority 16(80%) mother didn't received antenatal steroid, 2 (10%) of the mother received 1 dose and 2 dose of antenatal steroid.

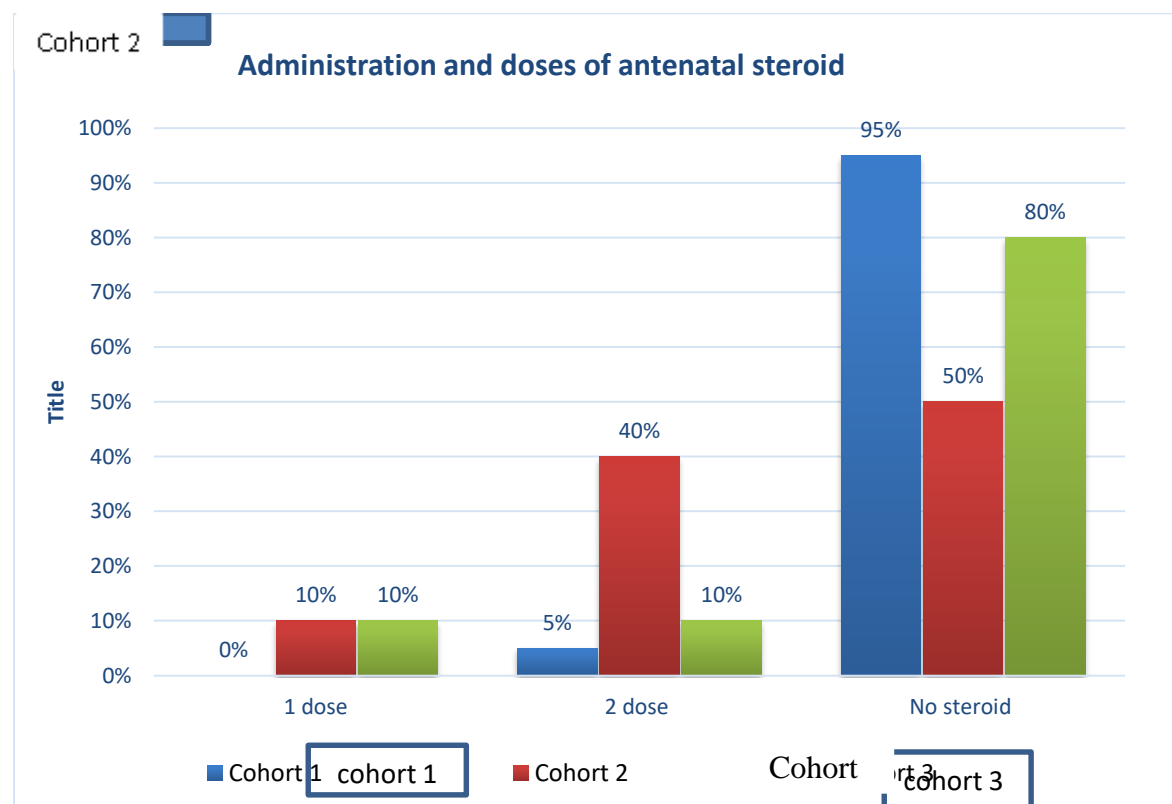


Figure 13 shows administration and doses of antenatal steroid

Table 3 (b) Association between administrations of antenatal steroid and incidence of NEC among preterm who received antenatal steroid

COHORT 1

N=60(n ₁ =20, n ₂ =20 and n ₃ =20)			N=60(n ₁ =0, n ₂ =1 and n ₃ =19)		
Steroid	F	%	NEC	F	%
1dose	0	0%	Developed NEC(n ₁)	0	0%
2dose	1	5%	Developed NEC(n ₂)	0	0%
No steroid	19	95%	Developed of NEC(n ₃)	0	0%

COHORT 2

N=60(n ₁ =20, n ₂ =20 and n ₃ =20)			N=60(n ₁ =2, n ₂ =8 and n ₃ =10)		
Steroid	F	%	NEC	F	%
1dose	2	10%	Developed NEC(n ₁)	0	0%
2dose	8	40%	Developed NEC(n ₂)	0	0%
No steroid	10	50%	Developed of NEC(n ₃)	10	100%

COHORT 3

N=60(n ₁ =20, n ₂ =20 and n ₃ =20)			N=60(n ₁ =2, n ₂ =2 and n ₃ =16)		
Steroid	F	%	NEC	F	%
1dose	2	10%	Developed NEC(n ₁)	0	0%
2dose	2	10%	Developed NEC(n ₂)	0	0%
No steroid	16	80%	Developed of NEC(n ₃)	16	100%

Table no. 3(b) Shows that in cohort 1; 1 (5%) preterm received 1 dose of corticosteroid and didn't develop NEC and 1 preterm received 2 dose of corticosteroid and didn't develop NEC whereas in cohort 2; half of the preterm i.e. 10(50%) didn't received steroid and they all develop NEC, 2(10%) preterm received 1 dose of corticosteroid and didn't develop any stage of NEC, 2(10%) of the preterm received 2 dose of steroid and didn't develop NEC,. In cohort 3; majority 16(80%) of the preterm received no dose of corticosteroid and they all develops NEC, 2(10%) of the preterm received 1 dose of corticosteroid and didn't develop NEC and 2 (10%) of the preterm received 2 dose of corticosteroid and they didn't develop NEC.

4.5 Section B (II): Assessment of association between incidences of NEC on administration of antenatal steroid.

Table 3 (c) Association between incidences of NEC on administration of antenatal Steroid

N=60(n₁=20, n₂=20 and n₃=20)

S.NO	COHORT	GIVEN	NOT GIVEN	DEVELOPMENT OF NEC	df	X ²	TABLE VALUE
1	COHORT 1	1	19	0			
2	COHORT 2	9	11	11	4	18.126 S	9.49
3	COHORT 3	5	15	15			

The table no. 3 (c) reveals that there was 0% of NEC among cohort 1, in cohort 2 rate of NEC is increased and in cohort 3 highest rates of NEC seen. It also reveals that preterm who received at least one of corticosteroid didn't develop NEC. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at p< 0.05 i.e. statically significant.

Hence hypothesis H₂ is accepted here i.e. there is significance difference in the rate of NEC among preterm after giving antenatal corticosteroid

Objective III: To identify the associated risk factor developing NEC

4.6 SECTION B (I): Assessment of associated risk factors of NEC

TABLE 4 (a) Frequency and percentage of associated risk factor of NEC

N=60(n₁=20, n₂=20 and n₃=20)

VARIABLE	COHORTA1 n ₁ =20		COHORTA2 n ₂ =20		COHORTA3 n ₃ =20	
	F	%	F	%	F	%
ASSOCIATED RISK FACTOR OF NEC						
Preterm received blood Transfusion only	1	5%	0	0%	0	0%
Preterm only with Sepsis	1	5%	0	0%	1	5%
Preterm on only Mechanical Ventilation	5	25%	5	25%	5	25%
Preterm only had Umbilical Vein Catheter	2	10%	3	15%	2	10%
Sepsis, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	1	5%	2	10%	0	0%
Mechanical Ventilation, Umbilical Vein Catheter, Congenital Heart Disease and reduced birth weight	0	0%	0	0%	1	5%

Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	3	15%	1	5%	0	0%
Mechanical Ventilation and Sepsis and reduced birth weight	0	0%	2	10%	2	10%
Blood Transfusion, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	1	5%	0	0%	1	5%
Blood Transfusion, And Umbilical Vein Catheter	0	0%	0	0%	0	0%
Umbilical Vein Catheter and Sepsis	0	0%	1	5%	0	0%
Asphyxia, Mechanical Ventilation, Umbilical Vein Catheter and reduced birth weight	0	0%	0	0%	0	0%
Didn't develop any risk factor of NEC	6	30%	6	30%	6	30%

Data in table no. 2(a) shows that in cohort1 majority 6(30%) preterm didn't develop any risk factor, 5(25%) preterm were only on Mechanical ventilation during NICU stay, 3(15%) preterm had were on Mechanical ventilator with umbilical vein catheter reduced birth weight, 2(10%) preterm had only Umbilical vein catheter,1(5%) preterm had only Blood transfusion during , 1(5%) preterm developed Sepsis during admission in NICU, 1(5%) preterm had Sepsis, mechanical ventilation, Umbilical vein catheter and reduced birth weight, 1(5%) preterm had Blood transfusion with Mechanical ventilation and Umbilical vein catheter and reduced birth weight.

In cohort 1 none of the preterm develops NEC during NICU stay.

In cohort2 most 6(30%) preterm didn't develop any risk factor of NEC, 5 (25%) of the preterm were only on mechanical ventilator, 3(15%) preterm only had Umbilical vein catheter during NICU stay, 2(10%) preterm had Sepsis with mechanical ventilation and Umbilical vein catheter and reduced birth weight, 2(10%) preterm were on Mechanical ventilation with sepsis and reduced birth weight, 1(5%) preterm were on Mechanical ventilation along with umbilical vein catheter and reduced birth weight, and 1(5%) preterm had Umbilical vein catheter with sepsis.

In cohort 2; 6 (30%) preterm develops stage I A of NEC among which 2(10%) preterm had associated risk factor of sepsis with mechanical ventilator, umbilical vein catheter and reduced birth weight, 2(10%) preterm had only umbilical vein catheter 1(5%) preterm had only on mechanical ventilator, 1(5%) preterm was on mechanical ventilator and also had sepsis and reduced birth weight. 2(10%) preterm develops stage I B of NEC among which 1 preterm was on mechanical ventilator and another preterm was on umbilical vein catheter along sepsis. Only 1 preterm develops stage IIA of NEC and 1 preterm develops stage IIB in cohort 2

Whereas in cohort 3 majority 6(30%) preterm didn't develop any risk factor, 1(5%) preterm developed Sepsis during admission in NICU, 5(25%) preterm were on Mechanical ventilation during NICU stay, 2(10%) preterm had Umbilical vein catheter during admission in NICU, 2(10%) preterm had Mechanical ventilation, sepsis and

reduced birth weight, 1(5%) preterm had Blood transfusion, Mechanical ventilation, Umbilical vein catheter and reduced birth weight.

Among preterm of cohort 3; 16(80%) preterm develops NEC among them 5(25%) preterm develops stage IB of NEC in which 1(5%) preterm didn't have any risk factor of NEC, 4(20%) preterm were only on mechanical ventilator. 4(20%) preterm develops stage IA among which 1(5%) preterm had blood transfusion with mechanical ventilator, umbilical vein catheter and reduced birth weight, 1(5%) preterm had blood transfusion with umbilical vein catheter, 1(5%) preterm was on mechanical ventilator with umbilical vein catheter and reduced birth weight and 1(5%) preterm was only on mechanical ventilator. 4(20%) preterm develops stage IIA among which 1 preterm had only umbilical vein catheter, 1(5%) preterm was on mechanical ventilator with sepsis and reduced birth weight, 2(10%) preterm didn't had any risk factor of NEC. 3(15%) preterm develops stage IIB of NEC in which 1(5%) preterm had only sepsis, 2(10%) preterm didn't had any risk factor of NEC.

4.4 ASSOCIATION OF RISK FACTOR OF NEC AND INCIDENCE OF NEC AMONG COHORT 1 COHORT 2 AND COHORT 3

TABLE 4 (b) Association of risk factor of NEC and incidence of NEC among cohort 1 cohort 2 and cohort 3

S.NO	RISK FACTOR OF NEC	Co-efficient	df	SS	Mean of sum of square	F' ration	Significance F
1	Mechanical ventilator	-0.55					
2	Umbilical vein catheter	-1.08	25	31.84	2.76	2.79	0.05
3	Sepsis	0.03					
4	Birth weight	0.85					

The data in the table no. 4(b) shows statistically risk factor of NEC i.e. mechanical ventilator didn't have any impact on incidence of NEC whereas it is clinically significant that mechanical ventilator and umbilical vein catheter have positive relation with incidence of NEC. Data also depict that sepsis and decreased birth weight of preterm is directly proportional to incidence of NEC among preterm and it is significant at the level of $p < 0.001$ level.

Objective IV: Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

On the basis of the findings of the study following recommendations have been made.

- At least one dose should be administered as soon as preterm delivery is suspected.
- Provide only breast milk to the preterm to reduce the rates of NEC among preterm.

- Instead of mix feed or formula feed newborn should be fed with breast milk either by expressed breast milk or direct breast feeding.
- Keep an eye on preterm babies for development of sign and symptom of NEC.
- When sign and symptoms of NEC is seen in preterm keep the child NBM and then feed with only breastmilk.
- Counsel the of mother about importance of breast-milk for both mother and preterm baby along with that it is also important to teach skill to provide breast milk when mother and baby were separated.
- There is a need of extensive nursing research in the area of NEC in preterm admitted in NICUs.
- The nurses should collaborate with other staff and mothers for providing only breast milk to the preterm, it can be introduced as hospital protocol and policy regarding breast milk/feed for low birth weight and specially very low and extreme low birth weight baby with that antenatal steroid for mothers expecting preterm delivery.

SUMMARY

This chapter has dealt with analysis and interpretation of the data collected from 60 newborn preterm admitted in neonatal intensive care unit. The data gather were summarized and use descriptive and inferential statistics. The analysis had been organized and presented under various sections. From the above study inferential is that there is significant difference in the rate of NEC among preterm of breastfeeding group, formula/top feeding group and mix feeding group.

CHAPTER-V

MAJOR FINDINGS, DISCUSSION, CONCLUSION, IMPLICATIONS, LIMITATIONS AND RECOMMENDATION

MAJOR FINDINGS DISCUSSION, CONCLUSION, IMPLICATION, LIMITATION, RECOMMENDATION AND SUMMARY

This chapter deals with major findings, discussion, and conclusion, nursing implication, limitation, recommendation and summary. The chapter ends with suggestions and recommendations for future research in the field.

PROBLEM STATEMENT

“A prospective cohort study to compare the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies at selected hospitals of Indore in year 2017-2018”.

OBJECTIVES

- To compare the incidence of NEC among cohort1, cohort2 and cohort3
- To find out the association between incidence of NEC on administration of antenatal steroid.
- To identify the other associated factor developing NEC
- Based on finding prepare recommendation for feeding guidelines and nursing care to prevent possible risk of NEC.

Hypotheses

All hypotheses is tested at the level of $p \leq 0.05$

H₀₁: There is no significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3

H₁: There is significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.

H₀₂: There is no significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.

H₂: There is significance difference in the rate of NEC among preterm after receiving maternal antenatal corticosteroid.

5.1 MAJOR FINDINGS

SOCIO DEMOGRAPHIC VARIABLES

Maternal baseline data

- 1) The data gathered from the socio-demographic variable of the mother revealed that in cohort1, most of the mothers 7(35%) were in the group of 28-31 years, in cohort 2, majority of the mothers 7(35%) were in the group of 24-27 years and 28-31 years and in cohort 3, most of the mothers 8(40%) were in the group of 28-31 years.
- 2) In this study in cohort 1 most 8(40%) of the mothers were gravida 1, 6(30%) of the mother were gravida 2, 3(15%) mother had gravid 3, 2(10%) mother were gravida 4 and 1 mother had gravida 6. Whereas in cohort2; majority of the mothers 9(45%) were in group of gravid 2, 7(35%) of the mother were gravid 1, 2(10%) mother were gravida 5, 1(5%) each of the mother was gravida 3 and gravida 4. In cohort 3 most 9(45%) of the

mothers had gravida 2, 6(30%) of the mother had gravida 1, 2(10%) of the mothers had gravida 3, 2(10%) of the mothers were gravida 6 and 1(5%) of the mother was in gravida 4.

- 3) In terms of administration of corticosteroid in cohort 1; majority 19(95%) mother didn't received antenatal steroid, in cohort2; most 10(50%) of mother received antenatal steroid, and in cohort3; majority 16(80%) mother didn't received antenatal steroid.

Neonatal baseline data

- 1) In viewing the gender in cohort1 most 17(85%) of the preterm were male. In cohort 2 majority 11(55%) of preterm were male and in cohort3 11 (55%) preterm were female.
- 2) In terms day of life on admission cohort1 majority 17(85%) of the preterm were admitted in NICU on 1st day of life. In cohort 2, most 17(85%) of the preterm were admitted on 1st day of life and in cohort 3, most 19(95%) of the preterm were admitted on first day of life.
- 3) In terms of birth weight cohort1 majority 8(40%) of the preterm's birth weight between 1400gms-1800gms, in cohort2, most 6(30%) of the preterm's weight between 1000gms-1400gms and in cohort3 10(50%) preterm weight between 1400gms-1800gms.
- 4) With respect of reason for admission in cohort1, majority 9(45%) of the preterm were admitted with Low birth weight and complaint of Respiratory distress, in cohort2, most 11(55%) of the preterm were admitted with Low birth weight and complaint of Respiratory distress, and in cohort3, most 9(45%) of preterm were admitted with Low birth weight and complaint of Respiratory distress.

Assessment of risk factors of NEC

Regarding risk factor of NEC in all cohorts majority 6(30%) of the preterm didn't had any risk factor of NEC. As we see the impact of sepsis and birth weight data reveals that beside all the risk factor sepsis and reduced birth weight is directly proportional to incidence of NEC. Whereas statically mechanical ventilator and umbilical vein catheter didn't have any strong impact on incidence of NEC although it is clinically significant that mechanical ventilator and umbilical vein catheter have strong impact on incidence of NEC. Data also depict that sepsis and decreased birth weight of preterm is directly proportional to incidence of NEC among preterm and it is significant at the level of $p < 0.001$ level. It also reveals that preterm who received at least one of corticosteroid didn't develop NEC. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at $p < 0.05$ i.e. statically significant.

Association of incidence of NEC among preterm who received antenatal steroid

The table no. 3 (c) reveals that there was 0% of NEC among cohort 1, in cohort 2 rate of NEC is increased and in cohort 3 highest rates of NEC seen. It also reveals that preterm who received at least one of corticosteroid didn't develop NEC. There is significant difference in the rates of NEC among cohort 1 cohort 2 and cohort 3 at $p < 0.05$ i.e. statically significant.

Assessment of clinical features of NEC

With respect of development of clinical feature of NEC among preterm babies in cohort1; in majority 13(65%) of the preterm do not develop any clinical feature of NEC and had no NEC. In cohort2, most 6(30%) didn't develop any clinical feature of NEC and 10(50%) of preterm develop NEC. In cohort3, majority 6(30%) didn't develop any clinical feature of NEC and 10(50%) of preterm develop NEC.

Assessment of incidence of NEC among cohort 1, cohort 2 and cohort 3

In terms of development of NEC in cohort1 preterm (who were on only expressed breast milk) none of the preterm developed NEC, in cohort2 (preterm who were on top/formula feed); half of the preterm 10(50%) didn't develop NEC. In cohort3 (preterm who were on mix feed), 8(40%) developed NEC. The computed f-value was 4.17073 at degree of freedom 159. The researcher found that there was a statistically significance difference in rate of NEC among preterm of cohort1, cohort2 and cohort3.

5.2 DISCUSSION

Discussion on comparison of incidence of NEC among cohort1, cohort2 and cohort3

All preterm who were admitted in NICU in month between June to August were observed for 15-20 days those preterm who got discharged before 15 days were excluded from research sample. All samples were observed from admission till discharge. In cohort 1 those preterm were included who mostly received breast milk through Ryles tube or from katori spoon feed or from direct breast. In cohort 2 those preterm were included who majorly received top/formula feed thorough katori spoon or from ryles tube. And in cohort 3 those preterm were included who received both formula/top milk and breast milk in approximately equal amount.

Data depicts that the in cohort 1 none of the preterm developed NEC i.e. 20(100%). In cohort 2, 3(15%) developed Stage I A, 3(15%) preterm developed Stage II A, 2(10%) preterm developed Stage I B, 2(10%) preterm developed Stage II B, 10(50%) preterm didn't develop NEC. In cohort3, 8(40%) developed Stage I A, 3(15%) preterm developed Stage II A, 5(25%) preterm developed Stage I B, 0(0%) preterm developed Stage II B, 4(20%) preterm didn't develop NEC.

In terms of development of NEC among cohort 1(breast milk feeding group), cohort 2(formula/top feed group) and cohort 3(mix feed group), ANOVA is used and the F ration was 4.17073 and found significant at the level of $p < 0.05$.

Findings revealed NEC among preterm the data depicts that there was 0% of NEC among preterm who were on breast milk, in preterm who were on formula/top feed rate of NEC was increased and preterm who were on mix feed had highest rates of NEC. There is significant difference in the rates of NEC among cohort 1(breast milk group) cohort 2(formula or top feed group) and cohort 3(mix feed group) at $p < 0.05$ i.e, statically significant.

Finding was supported by a study conducted by Colaizy TT, Bartick MC, Jegier BJ, Green BD, Reinhold AG, Schaefer AJ et al on Impact of Optimized Breastfeeding on the Costs of Necrotizing Enterocolitis in Extremely Low Birth-weight Infants in the year 2016. The study aimed to estimate risk of necrotizing enterocolitis (NEC) for extremely low birth weight (ELBW) infants as a function of preterm formula (PF) and maternal milk intake and calculate the impact of suboptimal feeding on the incidence and costs of NEC. They used current suboptimal feeding practices, compared with a theoretical cohort in which 90% of infants received at least 98% human milk. The result of the study was, NEC incidence among infants receiving $\geq 98\%$ human milk was 1.3%; 11.1% among infants fed only PF; and 8.2% among infants fed a mixed diet. In adjusted models, compared with infants fed predominantly human milk, we found an increased risk of NEC associated with exclusive PF or a mixed diet. It can be concluded that among ELBW infants, not being fed predominantly human milk is associated with an increased risk of NEC. Efforts to support milk production by mothers of ELBW infants may prevent infant deaths and reduce costs.

Hence hypothesis H₁ is accepted here

Discussion on association between incidences of NEC on administration of antenatal steroid.

With respect of development of NEC among preterm who received corticosteroid during antenatal phase chi square was 18.126 and found significant at the level of $p < 0.05$.

Finding revealed that in cohort 1 only one antenatal mother received corticosteroid but all the preterm of cohort 1 received breast milk so they didn't develop NEC. In cohort 2 10(50%) of mother received antenatal steroid so the incidence of NEC among preterm of cohort 2 was 10(50%) and in cohort 3 only 4 mother received antenatal steroid and the rates of NEC were high among that group. The mother who received at least single dose of steroid there preterm didn't develop any stage of NEC. This shows that administration of at least one dose of antenatal steroid during antenatal phase can prevent NEC among preterm. So corticosteroid should be administered to the mother during antenatal phase to reduce the incidence of NEC. . **Hence hypothesis H₂ is accepted.**

Finding was supported by the study conducted by Alexander Roberto Precioso and Renata Suman et.al; in year 2010 on the topic necrotizing enterocolitis, pathogenesis and the protector effect of prenatal corticosteroids. Study includes 542 samples. The findings reveal that the administration of prenatal corticosteroids is associated with maturation of intestinal mucosal so; to prevent necrotizing enterocolitis among preterm babies antenatal corticosteroid is used.

Discussion on risk factors associated with NEC

Data depicts that the preterm babies in most of the preterm of cohort 1 didn't have any risk factor of NEC, in cohort 2 & cohort 3 most of the sample were on mechanical ventilator.

With respect of sepsis and birth weight data reveals that beside all the risk factor sepsis and reduction of birth weight was directly proportional to incidence of NEC. Whereas statically mechanical ventilator and umbilical vein catheter didn't have any strong impact on incidence of NEC although it is clinically significant that mechanical ventilator and umbilical vein catheter have strong impact on incidence of NEC.

Findings revealed that there are increased in incidence of NEC among preterm who had sepsis and decreased birth weight. Other risk factor of NEC did not have any strong impact on incidence of NEC among preterm.

The findings were supported by a retrospective case-control study, conducted by TianQian Rong Zhanget. al; on "Risk Factors for Necrotizing Enterocolitis in Neonates" in year 2011. There were 1167 cases of necrotizing enterocolitis identified from the 95 participating neonatal intensive care units in mainland China. Data pertaining to antenatal period, labor and birth, and the postnatal course of illness were collected. Multivariate analysis and logistic regression were used to analyze the risk factors. The findings of this study reveals that VLBW infants had the major risk factors for mortality were small for gestation age and stage 3 NEC. In moderate LBW infants (birth weight 1500–2499 g), the risk factors identified for mortality were sepsis during hospitalization and stage 3 NEC. Necrotizing enterocolitis remains an important cause of morbidity and mortality in prematurely born neonates in Chinese neonatal units. Awareness of the associated risk factors and appropriate interventions may improve the outcome of necrotizing enterocolitis in different birth weight subgroup.

5.3 CONCLUSION

In preterm infants, due to the immaturity of the gastrointestinal system developed NEC on enteral feeding of formula/top feed and mix feed. Due to presence of probiotics in breast milk it can prevent NEC among preterm. Sepsis and reduced birth weight are also the risk factor to develop NEC. Corticosteroid helps to provide gut and lung maturity in preterm mother with at least one dose of antenatal steroid reduced the chances of occurring NEC among their preterm.

Researcher suggest that each preterm should provide breast milk for feeding to reduce the incidence of NEC with that for gut maturity of preterm, antenatal mothers should be administer at least 1 dose of steroid as soon as preterm delivery is suspected with that preterm were observed with sepsis and low birth weight and strictly breast feed should be provided to them, and if NEC is developed due to sepsis than withhold the feeding and provide antibiotic against the bacteria found in the report of culture. Staff should be skilled enough to identify the clinical features of NEC in its primary stage to avoid the complication like surgery.

It was a great experience of doing this research study. All the mothers Doctors and staff was cooperative, there was no interference to the hospital routine throughout the study and got constant encouragement from guide and co-guide Ms Saranya Pillai. I experienced immeasurable excitement and zeal along with exploring new areas, improving the knowledge while concluding the main study, along with that to help mothers in express milk and

helping them to provide proper breast feed to their baby provided me immense inner satisfaction. The study was fruitfully and successfully completed by the grace of almighty.

5.4 IMPLICATION OF THE STUDY

The findings of the present study have several implications in the field of nursing practice, nursing education, nursing administration and nursing research.

Nursing practice

The nurses are the key person in the health care team, who play a vital role in the disease prevention health promotion and maintenance. The nurses should collaborate with other staff and mothers for providing only breast milk to the preterm it can be introducing as hospital protocol and policy regarding breast milk/feed for low birth weight and specially very low and extreme low birth weight baby with that antenatal steroid for mothers expecting preterm delivery.

Nursing education

Breast milk has an effect of probiotic which is beneficial for preterm babies who have immature gut thus it plays a major role in preventing NEC. The present study emphasizes on the importance of mother education to for availability of breast milk and reduction in complication for both mother and preterm baby along with that it is also important to educate staff nurse to identify risk factors and clinical feature of NEC to manage it in its initial stage and reduce the complication like surgery.

Nursing administration

Nurse administrator can prepare hospital protocols and policy regarding proper feeding of newborn especially for those who are preterm. The nurse administrator can plan in-service education for the nurses so that they can help the mothers assess the mother in providing breast milk to their infant. She can also take an initiative in providing opportunities for further research and taking steps in changing new born nursing care practices.

Nursing research

The essence of researcher is to build a body of knowledge in nursing as it is an evolving profession. There is a need of extensive nursing research in the area of NEC in preterm admitted in NICUS. As NEC's incidences are increasing, so many cases are even didn't enrolled. The prevention of NEC is no cost effort i.e. providing breast milk and prevention of NEC reduce the rates of morbidity and mortality of NEC

5.5 LIMITATIONS OF THE STUDY

A few limitations of the study are listed below;

- All the risk factors and their impact were not found as the availability of sample was less.
- Study was limited to the selected NICU setting.
- Study didn't differentiate the effect of mix feeding of different types i.e.
 - Mixing of bovine milk and formula feed
 - Mixing of formula feed and breast milk
 - Mixing of bovine milk to breast milk.

5.6 RECOMMENDATIONS

On the basis of study findings the following recommendations have been made for further study.

- The study can be done to see the effect of human milk and top feed on incidence of NEC
- A comparative study can be done on the risk factors of NEC among preterm infant.

5.7 SUMMARY

This chapter dealt with the major findings of the study, discussion and implication to the nursing education, nursing administration and nursing research, limitations recommendations for the future research and concluded with the researcher's experience throughout the study.

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ANNEXURES

Annexure – i

LETTER SEEKING PERMISSION TO CONDUCT STUDY

	Institutional Ethics Committee
	Choithram Hospital & Research Centre, Indore (M.P.)
	E-mail: ethics.chrc@gmail.com
	Registration No: ECR/204/Inst/M.P./2013.
Dr. B. K. Sharma Chairperson	Dr. S. P. Jaiswal Member Secretary
	Date: July 11, 2018
<u>Membership List</u>	EC/Jul/2018/5
Dr. C.S. Chamania Ex Officio member	<u>Permission Letter</u>
Hon'ble Justice SC Vyas M.A., LL.B. Legal Expert	The enclosed list of M.Sc. Nursing Research Protocols submitted by Choithram College of Nursing is hereby permitted to be undertaken as per the protocol. The protocol was reviewed & approved by the members of Ethics Committee in meeting held on 11/07/2018 at Conference Room of Choithram Hospital & Research centre, Indore.
Dr. Sunil Chandiwai M.B.B.S. D.A. M.H.A. Director Medical Services	The ethics committee of Choithram Hospital & Research Centre, Indore should be informed:
Dr. Norman Sharma M.D. Director Academics	<ol style="list-style-type: none"> 1. Any serious adverse event occurring the course of the treatment within 24 Hours days of the occurrence. 2. Any changes in the protocol and patient information/ informed consent documents, prior to their implementation 3. And provide a copy of final report.
Dr. D.S. Chitnis M.Sc., Ph.D. Basic Scientist	
Dr. Deepak Mansharamani M.D. Clinician	Dr. S. P. Jaiswal Member Secretary Institutional Ethics Committee Choithram Hospital & Research Centre Indore(M.P.)
Dr. Usha Ukande M.Sc (N), Ph.D. Principal, College of Nursing	
Mrs. Sangeeta Uppal M.Sc., MA, B.ed Principal	
Sister Arokia Mary BA, MSW	

E.C.T.W/2023

6.	An exploratory study to assess the psychiatric morbidity among patients attending selected outpatient departments of tertiary care hospitals of Indore in the year 2017-2018.	Mr. Shyam Gurjar	Mrs. Blessy Antony Professor	Mr. M.k. Acharya Clinical Psychologist Dr. Ashish Goyal Consultant Psychiatrist
7.	An exploratory study to assess the various mental health problems and its association with aggressiveness of security guards in selected organization of Indore in the year 2017-2018.	Mr. Pankaj Singh Shekhawat	Prof. Blessy Antony	Dr. Ashish Goyal Consultant Psychiatrist Mr. M.k. Acharya Clinical Psychologist
CHILD HEALTH NURSING				
8.	A quasi experimental study to assess the effectiveness of developmentally supportive care (positioning along with nesting) on stress behavior, physiological stability and level of pain among preterm babies admitted in NICU at selected hospital of Indore in the year 2017-2018.	Ms. Vandana Dewar	Prof. Shreeja Vijayan	Dr. Kamna jain HOD Pediatric Department Choithram Hospital and Research Center Asso.Prof. Rakhi Phandse
9.	A prospective cohort study to compare the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies admitted in NICU at selected hospital of Indore in the year 2017-2018.	Ms. Shraddha kochale	Prof. Shreeja Vijayan	Dr. Kamna jain HOD, Pediatric Department CH&RC Asst. Lecturer. Saranya .S
10.	A cross sectional study to identify the prevalence and causative factors of stunting among under five children at selected villages of district Jhabua Madhya Pradesh in the year 2017- 2018.	Ms. Nisha Patil	Asso. Prof. Rakhi Phandse	Prof. Shreeja vijayan Asst. Lecturer. Saranya.S
11.	A quality improvement study to assess the effectiveness of "aseptic intravenous line insertion and maintenance bundle" on reduction of incidence of phlebitis and infiltration among children at selected hospitals of Indore in 2017-18.	Mr. Sudheer Verma	Mrs. Rakhi Phandse Associate professor	Dr. Kamna Jain HOD, Pediatric Department CH&RC Prof. Shreeja Vijayan



Annexure – ii

LETTER SEEKING PERMISSION FOR CONDUCTING PILOT STUDY

मेडिकेअर हॉस्पिटल एण्ड रिसर्च सेन्टर

4/5, रवीन्द्र नगर, ओल्ड पलासिया,
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& Research Centre4/5, Ravindra Nagar, Old Palasia,
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MHRC/150/2018

13/07/2018

To,

...*Administrators*........*Medicare Hospital and Research Center*...*Indore*.....

Through: Proper channel

Subject: Permission letter for Pilot study.

We hereby give permission to Ms. Shraddha Kochale, M.Sc. Nursing final year postgraduate student of Choithram College of Nursing to conduct her pilot research study on below mention topic.

Topic: "A prospective cohort study to compare the effect of expressed breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies admitted in selected NICU's of Indore in the year 2017-2018".


We don't have any objection regarding her study.

Thanking You,


Mr. Anil Verulkar

C.E.O

Lahoti Medicare Pvt. Ltd.
MEDICARE
4/5, Ravindra Nagar, INDORE-1

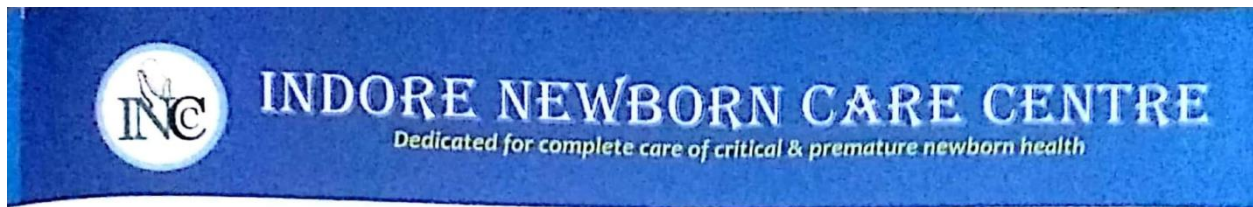

Ms. Shraddha Kochale
Applicant

(A unit of Lahoti Medicare Pvt. Ltd.)



Annexure – iii

LETTER SEEKING PERMISSION FOR MAIN STUDY



To,
NICU.....Indore.....
 ..Seva and Sushrutha hospital
Indore.....

13/07/2018

Through: Proper channel


Subject: Permission letter for research study.


We hereby give permission to Ms. Shraddha Kochale, M.Sc. Nursing final year postgraduate student of Choithram College of Nursing to conduct her pilot research study on below mention topic.

Topic: **“A prospective cohort study to compare the effect of expressed breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies admitted in selected NICU’s of Indore in the year 2017-2018”.**

We don’t have any objection regarding her study.

Thanking You,


 Dr Jafar Khan
 Consultant and NICU In charge
 SNS Hospital and Indore Newborn Care centre
 , Indore


 Ms.Shraddha Kochale
 Applicant

Dr. Jafar Khan
 Consultant Neonatologist
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Annexure – iv

SAMPLE LETTER FOR VALIDATION REQUEST



CHOITHRAM COLLEGE OF NURSING

(Affiliated to Devi Ahilya Vishwa Vidyalaya, Indore)
CHOITHRAM HOSPITAL & RESEARCH CENTRE
 Manik Bagh Road, INDORE-452 014 (M.P.)

Our Ref. No. CCON/1343Date 13-6-18

To,
 Dr. Gauri Rao Passi
 Consultant Pediatrician
 Choithram Hospital and Research Center
 Indore, Madhya Pradesh.

Subject: Requesting letter to gather opinion and suggestion of experts for establishing content validity of research data collection tool.

Respected Sir/Madam,

I am "Ms. Shraddha Kochale" postgraduate student of Choithram College of Nursing, Indore, have selected the below mentioned topic for the research project to be submitted to Madhya Pradesh Medical Science University Jabalpur, as a partial fulfilment of Masters of Nursing Degree.

TOPIC: "A prospective cohort study to compare the effect of expressed breast milk formula feeding and mix feeding on incidence of NEC among preterm babies admitted in selected NICU's of Indore in the year 2017-2018".

For your kind consideration and scrutiny, I am enclosing the following for reference.

- Statement of the Problem
- Objectives
- Operational definitions
- Tool
- Criteria check list

I request you to kindly validate the tool against the criteria checklist and render your valuable remarks on the matter.

Thanking you in anticipation.

Yours Sincerely,

Ms. Shraddha Kochale
 Applicant,

Prof. Shreeja Vijayan
 Guide of the Research
 HOD Child Health Nursing,

Dr. Usha Ukande
 Principal

Dr. G. R. Passi

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Annexure – v**ACCEPTANCE LETTER FOR TOOL VALIDATION**

Name :

Designation :

Name of the college :

STATEMENT OF THE ACCEPTANCE/NON-ACCEPTANCE

I give my any acceptance/non-acceptance to validate the tool

Topic: “A prospective cohort study to compare the effect of expressed breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies admitted in selected NICU’s of Indore.”

Annexure – vi**CERTIFICATE FOR CONTENT VALIDITY**

This is to certify that the tool used by Ms. Shraddha Kochale M.Sc. (Nursing) Final year student of Choithram College of Nursing, Indore (M.P) affiliated to Madhya Pradesh Medical Science University Jabalpur, is validated by the under signed and can proceed with this tool and content for the main study of the dissertation entitled.

Topic: “A prospective cohort study to compare the effect of expressed breast milk formula feeding and mix feeding on incidence of NEC among preterm babies admitted in selected NICU’s of Indore in the year 2017-2018”

Annexure – vii**LIST OF EXPERTS WHO VALIDATED THE TOOL**

1. Dr. Nancy Fernandes,
Principal
SNDT University, Mumbai

2. Alpanamayi Bera
Deputy Nursing Superintendent
NRS Medical College Hospital, Kolkata

3. Prof. Daisy Abraham
HOD, Pediatric Nursing
P.G College of Nursing, Bhilai, Chhattisgarh

4. Associate Professor Meno. S. Deep
Associate Professor, Pediatric Department
Pragyan College of Nursing, Bhopal

5. Dr. G.R. Passi
Senior Consultant Pediatric
Choithram Hospital & Research Center, Indore

6. Dr. Vivek Pathak
Consultant Neonatology
Medicare Hospital and Research Center, Indore

7. Dr. S.P Jaiswal
Immunologist, PhD Statistics
Choithram Hospital & Research Center, Indore

Annexure – viii

TOOL

SECTION A: QUESTIONNAIRE ON BASELINE DATA

A. (i) MATERNAL BASELINE DATA

1. Age of mother:
2. Diagnosis
3. LMP.....
4. EDD
5. Gravida
6. Mode of delivery
7. Antenatal Corticosteroid (yes/no)
No of doses received

1. (ii) NEONATAL BASELINE DATA
1. Gender.....
2. Age
3. Gestational ageweek.....days
4. Birth weight.....grams
5. Date of admission.....
6. Reason of admission in NICU.....

SECTION B: CLINICAL ASSESSMENT

SCREENING FOR CO-MORBID CONDITION

ASSOCIATED RISK FACTOR OF NEC	Yes	No	Remark
Blood transfusion			
Meconium aspiration syndrome			
Asphyxia			
Sepsis (Positive blood culture sent date)			
Congenital heart disease			
Nosocomial infection			
Mechanical ventilation start / end			
Umbilical vein catheter in /out			
Umbilical artery catheter in/out			

CLINICAL FEATURE OF NEC	DEVELOPMENT IN DAY OF LIFE
Vomiting	
Diarrhea	
Feeding intolerance	
Increased gastric residuals	
Abdominal distention	

Occult blood in stool	
Abdominal tenderness	
Abdominal wall edema	
Palpable bowel loops	

Bell's stage of NEC	Day of development of Stage of NEC

No. of feedings																			
No. of Days	1.																		
	2.																		
	3																		
	4																		
	5																		
	6																		
	7																		
	8																		
	9																		
	10																		
	11																		
	12																		
	13																		
	14																		
	15																		
	16																		

17																			
18																			
19																			
20																			
21																			

SECTION C: MANAGEMENT OF NEC

DAYS	FEEDING	AMOUNT OF FEEDING	MEDICATION FOR NEC
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			
Day 13			
Day 14			
Day 15			
Day 16			
Day 17			
Day 18			
Day 19			
Day 20			

Annexure – ix

BELL'S STAGE OF NEC

Stage	Systemic signs	Abdominal signs	Radiographic Signs	Treatment
IA Suspected	Temperature instability, apnea, bradycardia, lethargy	Gastric retention, abdominal distention, emesis, heme-positive stool	Normal or intestinal dilation, mild ileus	NPO, antibiotics x 3 days
IB Suspected	Same as above	Grossly bloody stool	Same as above	Same as IA
IIA Definite, mildly ill	Same as above	Same as above, plus absent bowel sounds with or without abdominal tenderness	Intestinal dilation, ileus, pneumatosis intestinalis	NPO, antibiotics x 7 to 10 days
IIB Definite, moderately ill	Same as above, plus mild metabolic acidosis and thrombocytopenia	Same as above, plus absent bowel sounds, definite tenderness, with or without abdominal cellulitis or right lower quadrant mass	Same as IIA, plus ascites	NPO, antibiotics x 14 days
IIIA Advanced, severely ill, intact bowel	Same as IIB, plus hypotension, bradycardia, severe apnea, combined respiratory and metabolic acidosis, DIC, and neutropenia	Same as above, plus signs of peritonitis, marked tenderness, and abdominal distention	Same as IIA, plus ascites	NPO, antibiotics x 14 days, fluid resuscitation, inotropic support, ventilator therapy, paracentesis
IIIB Advanced, severely ill, perforated bowel	Same as IIIA	Same as IIIA	Same as above, plus pneumoperitoneum	Same as IIA, plus surgery

*DIC: disseminated intravascular coagulation

*NPO: “nil per os” or nothing by mouth

Annexure -x

CRITERIA CHECKLIST FOR VALIDATION OF TOOL

Kindly go through the items of the tool and give your valuable suggestions regarding accuracy, relevancy and appropriateness of the content. There are two response columns in the checklist name **Agree and Disagree**. Please mark (√) against specific column. If there are any suggestions or comments, please mention in the remark column.

SECTION A**A (i) MATERNAL BASELINE DATA**

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			
6.			
7.			

A (ii) NEONATAL BASELINE DATA

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			
6.			

SECTION-B**CLINICAL ASSESSMENT****SCREENING FOR CO-MORBID CONDITION**

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			

CLINIAL FEATURE OF NEC

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			

6.			
7.			
8.			

BELL'S STAGE OF NEC

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			

FEEDING OF PRETERM

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
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14.			
15.			
16.			
17.			
18.			
19.			
20.			

SECTION-C

MANGMENT OF NEC

ITEMS	AGREE	DISAGREE	REMARK
1.			
2.			
3.			
4.			
5.			
6.			

7.			
8.			
9.			
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Annexure – xi

LETTER SEEKING CONSENT FOR PARTICIPATION IN THE STUDY INFORMED CONSENT

Study title: Effect of breast milk formula feed and mix feed on the incidence of NEC among preterm admitted in NICU.

I have received the information about type of feeding provided to the preterm from Ms. Shraddha Kochale of Child Health Nursing Department, Choithram College of Nursing, Indore.

The information that will be provided by me shall be kept confidential and shall not be shared by any other person. The information provided by me will only be used for analysis and interpretation purpose for the study done by Ms. Shraddha Kochale, but my personal information will always be kept confidential.

I have been informed that I can withdraw my consent at any stage of the study and regarding my consent withdrawal no questions/pressure shall be given to me.

After understanding the complete information regarding the study being conducted, voluntarily give my written consent for participation in this study.

Thanks

.....

Signature/thumb impression of subject

Signature of the person getting questionnaire filled

Annexure – xii

LETTER SEEKING CONSENT FROM THE PARTICIPANT (HINDI)

सहमति पत्र

शोध का शीर्षक :

मैंने उक्त शोधकार्य की पूर्ण जानकारी शोधकर्ता मिस श्रद्धा कोचले , जो शिशु स्वास्थ्य रोग नर्सिंग विभाग , चोइथराम नर्सिंग कॉलेज , इंदौर की छात्रा है से प्राप्त की है।

मेरे द्वारा दी गई जानकारी को पूर्ण रूप से गोपनीयता रखा जाएगा एवम् इस जानकारी का इस्तेमाल सिर्फ शोधकार्य के लिए ही किया जाएगा, परन्तु वे जानकारिया जो मुझे से जुडी है, उन्हे हमेशा गोपनीयता ही रखा जायेगा।

मुझे यह भी बताया गया है की अपनी स्वेच्छा से इस शोध के किसी चरण में अपनी भागीदारी हटा सकती हूँ , और इसके लिए कोई दबाव मुझ पर नहीं बनाया जायेगा ।

पूर्ण रूप से इस शोध की जानकारी प्राप्त करने के पश्चात् मै स्वेच्छा से इस शोध मे भाग लेने के लिए अपनी भागीदारी की सहमती प्रदान करती हूँ ।

धन्यवाद ।

.....
भागीदारी के हस्ताक्षर/ अंगूठे का निशान

.....
दिनांक

.....
प्रश्नावली भरवाने वाले का हस्ताक्षर

.....
दिनांक

Annexure – xiii

EDITING CERTIFICATION OF DISSERTATION/THESIS

EDITING CERTIFICATE

EDITING CERTIFICATE OF DISSERTATION/THESIS

EDITOR'S CERTIFICATE

This is to certify that I Mr. Virendra Joshi have read the English version of dissertation/thesis of Ms. Shraddha Kochale, a post graduate student of Choithram College of Nursing, Indore, on the below mentioned topic to the best of the satisfaction.

Topic "A prospective cohort study to compare the effect of breast milk, formula feeding and mix feeding on incidence of NEC among preterm babies at selected NICUs of Indore in 2017 and 2018." which is being submitted in fulfillment of the requirement for the award degree in Master of Science in Nursing.

DATE: 08/10/2018



SIGNATURE

PLACE: Khargone

Annexure- xiv

STATICAL FORMULA USED IN THE STUDY

- Mean:

$$\bar{x} = \frac{\sum x}{n}$$

- Chi Square:

$$\chi^2 = \frac{\sum(O - E)^2}{E}$$

$$\text{d.f.} = (c-1)(r-1)$$

- Multiple liner regression

$$y' = a + b_1x_1 + b_2x_2 + b_3x_3$$

- Karl Pearson Coefficient of correlation

$$r = \frac{\sum XY - \frac{\sum X \sum Y}{N}}{\sqrt{(\sum X^2 - \frac{(\sum X)^2}{N})(\sum Y^2 - \frac{(\sum Y)^2}{N})}}$$

- ANOVA

$$\frac{(\sum \bar{x}_1)^2}{n_1} + \frac{(\sum \bar{x}_2)^2}{n_2} + \frac{(\sum \bar{x}_3)^2}{n_3}$$

r = Correlation coefficient

n = sample size

\bar{x} = Mean

SD = Standard Deviation

Y = Predicted value for variable Y

a = Intercept constant

K = Number of predictor variable

b₁ b₂ b₃ = regression coefficient for the variable

x₁ x₂ x₃ = values on the independent variables