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**Original Research Article** 

# Impact of Human Milk Bank on Morbidity, Mortality, Duration of Stay, and Feeding Characteristics of Neonates in a Tertiary Care **Centre NICU**

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**Conflict of interest: Nil** 

#### Abstract

**Objective:** To study the impact of Human Milk Bank on morbidity, mortality, duration of stay, and feeding characteristics of neonates in a tertiary care Centre NICU.

Material and Methods: An observational prospective case control single Centre study. All details of the newborns under study were recorded on a structured proforma designed for this study. PDHM was issued from mother milk bank on the request of doctor working in the NICU. All collected data was analyzed with standard software. Statistical analysis of the data was done with Chi-square test, Student t-test with assistance of qualified statistician. P value <0.05 was considered statistically significant.

Results: A total of 140 neonates were included in the study was divided into study group (71) and control group (69). There was no statistical significant difference between study and control groups in terms of gender and weight. Most common indication of PDHM supplementation was insufficient milk production (73.2%). Majority of neonates on PDHM feeding (67.8%) tolerated the feed well, 20% had abdominal distention and 11.2% had vomiting. In study group 12% babies develop NEC, whereas 5.7% babies in control group developed NEC. In the study group 19.7% babies developed clinical features of septicemia whereas in control group only 10.1%. The difference was statistically significant (P-0.047). 67 babies (94.3%) in study group were discharged

Conclusion: Babies fed on PDHM had no significant risk for developing apnea, hypoglycemia and overall complications in comparison to those fed on mothers own milk. Also there was no significant difference in terms of weight recovery time, duration of stay in the hospital and final outcome amongst babies who were fed on PDHM and who were fed on mothers own milk. Hence it is concluded that PDHM can be a safer alternative when mothers own milk is insufficient or unavailable. Also it provides the benefits of mother's milk along with eliminating the demerits of formula feed in a resource limited setting like ours. "Breastfeeding is nature's health plan." **Keywords:** Human Milk Bank, Pasteurized Donor Human Milk, PDHM

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# Background

Bottles fill his stomach, but breastfeeding fills his soul." Breast feeding is the best method of infant feeding because human milk continues to be the only milk which is tailor-made and uniquely suited to the human infant. All mothers should be encouraged to breast feed their infants. India faces its own unique challenges, having the highest number of low birth weight babies with significant morbidity and mortality. Because of inadequate feeding due to any cause mothers start feeding their babies overdiluted and unhygienic top milk resulting into malnutrition and infections. The benefits of human breast milk include optimum infant growth immune functions and development at minimum cost to the family [1].

It has been shown that human breast milk fed infants in the NICU have better feed tolerance, have fewer severe infections lesser chance of NEC and a reduction in chance of colonization by pathological organism. There is a decrease length of hospital stay of babies fed on human milk. Breast fed babies have better neurodevelopmental outcomes in comparison to formula fed one [2,3].

In spite of mother's will many a times she is not able to provide adequate milk to her baby due to various maternal and neonatal conditions like maternal chronic illness, perinatal complications, LSCS delivery, multiples births, preterm birth, separation of baby from mother due to admission in NICU, maternal stress, drug intake by mother like anti thyroid and anti-metabolites [4,5].

In these conditions to provide benefits of mother milk to these babies concept of mother milk bank, developed over time with aiming to provide mother milk to these babies especially the VLBW and ELBW neonates [7].

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#### **Mother Milk Bank**

Historical perspective: It had already been demonstrated in the early twentieth century that infants who did not receive their mother milk had increased risk of dying in the first year of life. Pediatricians concerned to improve the prognosis of infants deprived of their own mother's milk for medical and social reasons developed a means of storing human milk for use in sick infants, and thus first milk bank was opened in Vienna in 1900. First milk bank in America was established in 1910 in Massachusetts. The first international congress on Human Milk Banking "A vision of future" was held in Brazil in 2000 [8,9].

Mother milk bank in India: Modern human milk banking is in its infancy in India. The first milk bank in Asia under the name of SNEHA was founded by DrArmeda Fernandez, in Dharavi, Mumbai on Nov 27, 1989. A national consultative meet for framing guidelines was summoned by the IYCF Chapter and the ministry of Health and Family Welfare, GOV of India on 30<sup>th</sup> June 2013, with representations from various stakeholders [9].

**Aims and Objectives:** The aims and objective of the study is to study the impact of Human Milk Bank on morbidity, mortality, duration of stay, and feeding

characteristics of neonates in tertiary care Centre NICU.

## Material and Method

**Study type**: An observational prospective case control single Centre study.

**Study population**: Newborns admitted in NICU at Department of Pediatrics.

Study group: Low birth weight and very low birth weight newborns (weight ≥1000g - <2500g) who were supplemented or completely on PDHM due to insufficient mother's milk. After counseling consent was taken preferably from mother or other family member if mother was unavailable to give consent. When mother milk became adequately available PDHM feeding was stopped.

**Control group:** Newborns who had similar weight and gestational age and were fed on mother's own milk.

## **Inclusion Criteria**

- 1. Study group- Low birth weight and very low birth weight (weight ≥1000g <2500g) newborns who were supplemented or completely on PDHM.
- 2. Control group- Low birth weight and very low birth weight (weight ≥1000g <2500g) newborns who were fed on their own mother's milk.

## **Exclusion Criteria**

- 1. Babies who had any illness
- 2. Parents who did not give consent
- 3. Those babies who had any risk factor for sepsis

All details of the newborns were recorded on a structured proforma. Indication of admission, hour of life when enteral feeding was started, the indication of feeding the baby on PDHM ,hours of life when PDHM was started, amount of feed required per day, amount of PDHM given per day, percentage of daily feed requirement fulfilled by PDHM, percentage of PDHM issued out of PDHM demanded, duration of PDHM feeding, total

volume of PDHM fed by the baby, tolerance of feed, weight changes on each day of stay, day of life on which daily feed requirement was fulfilled by enteral feed, motivation of mother to breastfed their baby, day of life on which transition from PDHM to own mother's milk occur, complication during stay in terms of NEC, probable sepsis, iaundice requiring phototherapy, hypoglycemia, apnea, length of stay in the hospital and final outcome was recorded on Performa. A nutritional support protocol was used to ensure that milk advancement and use of parenteral nutrition was consistent for all study infants. Infants who weighed <1500g or gestational age <34 weeks were initially fed by tube feeding. The recommended volume goal for feedings was 140-160 ml/kg/day. Babies who weighed >1500g or >34 weeks were mostly fed on breast. PDHM was issued from mother milk bank on the request of doctor working in the NICU during the working hour in sealed glass bottles of 30ml each. Most of the feedings were given by patient mothers or care giver. Weight of the newborn was measured at the same time each day. All the collected data was analysed with standard software of Biostatics. Statistical analysis of the data was done with Chi-square test (for quantitative analysis), Student t-test (for continuous data) with assistance of qualified statistician. P value < 0.05 was considered statistically significant.

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# Result

Majority of newborns in the study group 41(57.7%) were in 1.5-2 kg weight group followed by 23(32.3%) were in 1-1.5 kg group. Similar percentage of babies according to weight group was there in control group also. The difference was statistically non-significant (p - 0.476). There was no significant difference (p-0.49) in the number of male and female babies in study and control group. Out of 71 neonates in study group 26(36.6%) were delivered by lower segment Caesarean section as

compared to 16(23.1%) in control group. This shows that significantly more number of

babies (p-0.01) in PDHM group as compared to study group were born± by LSCS.

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**Table 1: Indication of PDHM feeding** 

Indication	No of cases(n=71)
Insufficient mother milk	52(73.2%)
Mother critically ill	7(9.8%)
Mother not available	7(9.8%)
abandoned neonate	5(7%)

Out of 71 neonates in the study group 73.2% were supplemented with PDHM due to insufficient milk of own mother, 9.8% due to mother being critically ill, in 9.8% cases mother was not available. Mean day of life on which total daily feed requirement was fulfilled by enteral mean was attained in study group was 5.41 days with Standard deviation of  $\pm 3.16$ . Mean of day of life on which total daily feed requirement was fulfilled by enteral mean was attained in control group was 6.17 days with Standard deviation of  $\pm 2.85$ . The deference was statistically non-significant (p-0.343).

**Table 2: Timing of starting of PDHM** 

Hour of life	No of cases(n=71)
0-6 hrs	16(22.5%)
6-12 hrs	15(21.1%)
12-18 hrs	15(21.1%)
18-24 hrs	8(11.2%)
>24 hrs	17(23.8%)

Mean value for hour of life when PDHM was started was 19.23 hours. Median value was 16 hour and mode was 18 hours. Standard deviation was±16.62 hour. Majority of the neonates on PDHM feeding 48(67.8%) tolerated the feed well. 15(21%) had abdominal distention and 8(11.2%) had vomiting. While in control group 57(82.8%) neonates tolerated the feed well, 8(11.5%) had abdominal distention and 4(5.7%) had vomiting. These feeding problems are not significantly more as compared to control group (p-0.121).

**Table 3: Prevalence of neonatal complications** 

Complication	Study group(n=71)	Control group(n=69)
Necrotising Enterocolitis	9(12%)	4(5.7%)
Clinical sepsis	16(19.7%)	7(10.1%)
Hypoglycaemia	15(21.1%)	12(17.3%)
Apnea	2(2.8%)	0(0%)
Jaundice requiring phototherapy	28(39.4%)	21(30.43%)

Nine babies developed NEC in study group whereas 4(5.7%) babies developed NEC in control group. The difference between two groups is statistically non-significant (p-0.160). Sixteen (19.7%) babies in study group and 7(10.1%) in control group developed clinical features of septicemia along with supportive evidence. The difference was statistically significant (p-0.047)

Fifteen (21.1%) babies in study group had episodes of hypoglycemia as compared to 12(17.3%) in control group. The difference was statistically non-significant (p-0.575).

Table 4: Neonates developed septicemia and PDHM

Number of	Neonates developing	Total number of
days of PDHM	septicemia	neonates(n=71)
0-3	6(14.63%)	41
4-6	5(27.7%)	18
7-9	2(50%)	4
10-12	1(33%)	3
>12	2(40%)	5

Out of 41 neonates who were fed on PDHM up to three days 6(14.63%) developed septicemia. 50% neonates who were fed on PDHM for 7-9 days developed septicemia. Out of 71 neonates in study group, complications 23(32.39%) developed whereas 15(21.7%) neonates in control group developed complications during their stay in the NICU. The difference was statistically non-significant (p-0.156). Mean duration of period of PDHM feeding was 4.61 days. Mean volume of PDHM fed to each neonate was 358 ml, with standard deviation+ 208.6. Minimum volume of PDHM fed to a neonate is 24 ml and maximum volume of PDHM fed to neonate was 2260 ml. Mean day of life on which weight gain started in study group and control group was 5.97 and 5.14.day respectively. Mean day of life on which neonates attained their birth weight in study group was 10.39 day with standard deviation of +3.25. Mean of day of life on which neonates attained their birth weight in control group was 9.22 day. Mean duration of stay in study group was 10.89 days with Mean of duration of stay in control group was 8.72 days. The difference was statistically nonsignificant (p 0.073).

## **Discussion**

Present study was conducted in NICU. It was observational prospective case control single Centre study on "Impact of human milk bank on the outcome of neonates admitted in tertiary care Centre NICU". Low birth weight

and very low birth weight neonates admitted in NICU were included in the study with exclusion of neonates who had any illness at the time of recruitment for the study. A total of 140 neonates were included in the study. These 140 neonates were divided into study group (71) and control group (69). Distribution of neonates according to weight is similar in both the groups with 57.5% neonates had weight between 1.5-<2 kgs in study group and 60.6% neonates in control group had weight between 1.5-<2 kgs. The difference was statistically non-significant (P 0.47). Out of 71 neonates in study group 34(47.8%) were male and 37(52.1%) were female neonates whereas in the control group 37(53.6%) were male and 32(46.3%) were female neonates. There was no statistically significant difference (p-0.49) in the number of male and female babies in study and control group. Chapman D J et al in their study found that delayed onset of lactation occurred in women undergoing cesarean section (relative risk-1.35, 95%; CI: 1.20 -1.53). This explains more number of LSCS born babies requiring PDHM feeding [10-12]. In earlier studies it was observed that Primary parity is associated with delayed onset of lactation. In other studies comparison of parity in PDHM and control group was not done. More number of primi mothers demanding PDHM for their babies could be because of delayed establishment of adequate lactation in them possibly due to higher level of stress hormone cortisol

released in primary para woman. Although it's inhibitory action on lactogenesis II is not established [13,14]. Out of the 71 neonates in the study group 73.2% were supplemented with PDHM because their mother had insufficient milk, 9.8% due to mother being critically ill, in 9.8% cases mother was not available as the baby was referred from periphery without mother accompanying, and 7% neonates in the PDHM group were abandoned, hence this was the preferred feed for them. [Table no 1]. In a similar study Coutsoudis et al observed that most common indication of PDHM use was insufficient breast milk production (67.5%), where as in 10% cases it was due to maternal sickness. Our observation was similar to them [15]. In majority of the babies enteral feeding was started within 1st hour of life in both study and control group (56.33% and 72.4% respectively). In most of the remaining babies in study and control group enteral feeding was started in 2<sup>nd</sup> hour of life. These findings show that policy of early enteral feeding to stable babies was strictly followed in our NICU. Early enteral feeding is associated with less feeding intolerance, earlier progression to full enteral feeding, improved weight gain, fewer days on parenteral nutrition and improved calcium phosphorus retention [16].

Babies in PDHM group were switched to total daily feed (fluid) requirement fulfilled enterally earlier than control group perhaps due to availability of desired amount of milk from human milk bank but the difference was statistically non-significant (p-0.343). In our study and study of Aprile M D M the criteria for achieving full enteral feeding was when the daily requirement of baby was fulfilled by enteral mean [17,18]. Mean value for hour of life when PDHM was started was 19.23 hour with SD±16.62 hour. On the earliest PDHM was started on first hour of life and the maximum time from birth on which PDHM was started was 80 hour [Table no 2].

Majority of the neonates on PDHM feeding 48(67.8%) tolerated the feed well. 15(21%) had abdominal distention and 8(11.2%) had vomiting. The immunological biologically active substance present in human milk modify the GI flora and imparts better feed tolerance feature in comparison with formula milk [19]. Out of 71 neonates fed on PDHM only 9(12%) babies developed NEC in study group whereas 4(5.7%) babies developed NEC in control group. The difference between two groups statistically non-significant (p-0.160) [Table no 3]. Several other studies also confirmed that neonates fed on formula milk had relatively higher chances of developing NEC in comparison to those fed on donor human milk [20]. Higher proportion of neonates who were fed on PDHM for more number of days developed septicemia in comparison to those fed on PDHM for lesser number of days. This is probably due to more dependency on PDHM which is immunologically and biologically poorer than mothers own milk [21,22]. No other study has been done regarding the duration of PDHM feeding and its relation with development of septicemia. [Table no 4]. In our study we found that availability of PDHM negatively affects the motivation of mothers to breast feed their babies probably due to providing an acceptable alternative source of mother milk. The positive impact of human milk bank on attitude of mother has been documented. A national survey in Italy showed that neonatal unit associated with human milk bank has higher rate of maternal breast feeding on discharge [23]. Mean duration of stay in study group was 10.89 days+4.98 which is higher than mean duration of stay in control group 8.72 days +3.6. Mean of day on which the transition of feeding occurred from PDHM to exclusive breast feeding was 4.27 days with SD + 1.62 in the study group. Sixty seven (94.3%) babies in study group were discharged. Mean of day on which the transition of feeding occurred from PDHM to

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exclusive breast feeding was 4.27 days with SD  $\pm 1.62$  in the study group. Mean percentage of PDHM issued out of PDHM demanded was 91% with SD  $\pm 7.2\%$ . There was relative shortage of PDHM in comparison to demand.

#### Conclusion

Babies fed on PDHM had no significant risk for developing NEC, apnea, hypoglycemia, jaundice and overall complications in comparison to those fed on mothers own milk. Also there was no significant difference in terms of weight recovery time, duration of stay in the hospital and final outcome amongst babies who were fed on PDHM and who were fed on mothers own milk. But babies fed on PDHM had significantly higher risk of developing clinical features of septicemia and PDHM feeding also had significant negative impact on motivation of mother to breast feed. Hence it is concluded that PDHM can be a safer alternative when mothers own milk is insufficient or unavailable. Also it provides the benefits of mother's milk along with eliminating the demerits of formula feed in a resource limited setting like ours.

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