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Research Article

Impact of Inhouse Human Milk Bank on Neonatal Mortality and Morbidities in VLBW Neonates in an Extramural Unit: An Observational Study

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Abstract

Introduction: Human Milk is considered the ideal nutrition for all babies especially in preterm and in low birth-weight babies. When mother's milk is not available, the WHO recommends Pasteurised Donor Human Milk (PDHM) as the next best infant feeding alternative.

Methodology: This observational study was conducted in a tertiary level NICU in India to assess the impact of Human Milk Bank (HMB) on mortality and morbidities in VLBW and ELBW neonates. The primary outcome was to compare the incidence of definite and advanced NEC and secondary outcomes were to assess death, exclusive breastfeeding at discharge, feed interruption and growth in both the groups. Pre-Human Milk bank and Post-human Milk Bank data were collected for a period of 24 months each.

Results: The incidence of Definite and Advanced NEC was significantly lower in Post-HMB group (2;1.76%) than in Pre-HMB (10; 9.4%) (p=0.00). 43.4% of babies in Pre-HMB group and 19.5% babies in post-HMB group had NEC (Any stage); p=0.00. Neonatal deaths were higher in the Pre-HMB group 32 (30.2%) than in post-HMB group 22 (19.5%); (p=0.066). The exclusive breastfeeding rate was significantly higher in the post-HMB group 72.6% as compared to 30.2% in the pre-HMB group (p=0.00). Feed interruptions were significantly lower in the post-HMB group 29 (25.7%) as compared to Pre-HMB group 56 (52.8%) (p=0.00). Time to reach full feeds was significantly lower in the post-HMB group Median (IQR) 13 (7.25 - 25.75) days as compared to 10 (5 - 17) days (p=0.007). Time to regain birth weight was significantly lower in the post-HMB group (14.72 + 5.61) as compared to pre-HMB group (11.00 + 4.19) (p=0.00)

Conclusion: Establishment of Human Milk bank can be a worthwhile quality improvement project that NICUs can launch as part of comprehensive plans to enhance preterm care.

Keywords: Necrotising Enterocolitis; Risk Factors; Human Milk Bank; Very Low Birth Weight Babies; Feeding

Introduction

WHO defines Exclusive Breastfeeding (EBF) as "giving the infant only breast milk for the first 6 months without adding any additional water or food". Breastmilk provides optimal nutrition and immunity for the baby. Mother's own milk has been shown to reduce Neonatal mortality, morbidities such as Necrotising Enterocolitis (NEC), Retinopathy of Prematurity (ROP), re-admission to NICU and long-term neurodevelopmental outcomes [1,2]. Human Milk is considered the ideal nutrition for all babies especially in case of babies who are born preterm and in low birth-weight babies.

However, not all babies have access to breastmilk due to various reasons. Mothers of preterm and low birth weight babies admitted in NICUs could have difficulty in establishing lactation. Preterm babies and sick babies whose mothers have lactation

failure, babies of mothers with postpartum illnesses and babies whose mothers died in the immediate postpartum period could be deprived of the benefits of breastmilk. When mother's milk is not available, the WHO recommends Pasteurised Donor Human Milk (PDHM) as the next best infant feeding alternative. Being a vulnerable population, PDHM can be given to very low birth weight and preterm neonates on priority basis.

Human Milk Bank collects, pasteurizes, stores and distributes donated breastmilk. DHM can act as a bridge until Mother's Own Milk (MOM) is available for high-risk neonates. Providing Donor Human Milk rather than formula to VLBW babies can help in reducing neonatal mortality and morbidities, especially feed intolerance and Necrotising Enterocolitis (NEC) [1,3,4]. However, few studies have shown better weight gain in formula fed babies as compared to babies receiving DHM [3,4]. Literature regarding the benefits and usage of DHM in Very Low Birth Weight (VLBW) neonates is sparse and hence we have taken up this study.

Methodology

This Observational study was conducted at a level III NICU in India. Our Neonatal Intensive Care Unit (NICU) caters to several high-risk preterm and low birth weight neonates. To improve the survival of these high-risk newborns, a milk bank was established in our institute in November 2017 as per guidelines of Indian Academy of Pediatrics (IAP) [5]. Donor Human Milk is being collected from mothers of babies admitted to NICU, infants admitted in our hospital and from mothers willing to donate milk from outside. Breast milk is collected under sterile precautions using breast-pumps from healthy lactating mothers after written consent. Breastmilk collected from donors is pasteurised at 62.5°C for 30 minutes by Holder's pasteurisation technique. Microbiological screening of PDHM (Pasteurised Donor Human Milk) is being done after pasteurisation. PDHM is being prescribed on priority basis for preterm, low birth weight and sick neonates.

The aim of our study was to assess the impact of Human Milk Bank (HMB) on mortality and morbidities in VLBW neonates. All VLBW neonates (<1.5 kg) or babies born at gestational age < 32 weeks admitted to NICU during the study period who had received Donor Human Milk (DHM) as > 50% of feed in 1st week after admission/ after initiation of enteral feeding were included in the study. Babies who baby received > 50% of enteral feeding as Mother's Own Milk (MOM) in 1st week after admission/ after initiation of enteral feeding were excluded from the study. Babies who had Definite NEC at admission were excluded from the study. The data was collected retrospectively from NICU database. The Pre-Human Milk Bank (Pre-HMB) data was collected from November 2015 to October 2017 and Post-Human Milk Bank (Post-HMB) data was collected from November 2017 to October 2019. All VLBW (<1.5 kg) and < 32 weeks babies admitted during the study period meeting the inclusion and exclusion criteria were enrolled in the study.

The significant antenatal, natal and postnatal data were recorded in a pre-designed proforma. The primary outcome was to compare the incidence of definite and advanced NEC pre and post inception of HMB among VLBW babies.

The secondary objectives were to compare the following before and after inception of Human Milk Bank

1. Incidence of mortality before discharge
2. Incidence of any stage NEC
3. Growth of the neonate (i) weight gain velocity (g/kg/week) (ii) Length gain (cm/week) (iii) head circumference gain (cm/week)
4. Time to regain birth weight
5. Time of initiation of feeds
6. Time to reach full feeds
7. Feed interruption for > 48 hours
8. Duration of NICU stay
9. Exclusive breastfeeding rate till discharge
10. Initiation of Fortification
11. TFI at which fortification was done

The definitions used in the study were

1. NEC - primary outcome: Definite NEC (Bell's stage 2) and Advanced NEC (Bell's stage 3); secondary outcome - NEC Stage 1/2/3 (Bell's stage)

2. Incidence of mortality among VLBW neonates-number of neonatal deaths among VLBW babies /Total No. of VLBW admissions
3. Exclusive breastfeeding till discharge - giving Mother's Own Milk (MOM) or Donor Human Milk (DHM) as the only food source, with no other foods or liquids, other than vitamins or medications till discharge
4. Time to reach full feeds - Day of life on which 160 ml/kg/day feeds was reached

Statistical Analysis

Data entry was done in Microsoft Excel and the analysis was carried out in IBM SPSS Statistics Version 27. Descriptive statistics of frequency and percentage (for the categorical variables) and mean, SD and median (for the continuous variable) were presented for the pre-HMB and post-HMB groups. Comparisons of all categorical variables by pre-HMB and post-HMB were done by Chi-square test. Mean comparisons between the pre-HMB and post-HMB were done by Student t-test. A p-value of <0.05 was considered as statistical significance.

Results

The total number of admissions were 1762 during the Pre HMB epoch and 1465 during the post HMB epoch. Number of babies admitted at < 32 weeks gestation were 77 (5.2%) and 63 (4.3%) in Pre and Post HMB group respectively. Babies with birth weight < 1.5 kg were 106 (6%) and 113 (7.7%) respectively in Pre HMB and Post HMB group. Baseline maternal and neonatal characteristics in pre and post HMB group were comparable (Table 1).

		Pre HMB (n=106)		**Post HMB (n=113)**		**P-value**
		n	**%**	**n**	**%**	
Maternal age (in years)	≤ 24 years	20	18.9%	16	14.3%	0.491
	25 - 29 years	38	35.8%	37	33.0%	
	≥30 years	48	45.3%	59	52.7%	
	Mean ± SD	28.92 ± 5.53		30.19 ± 4.72		0.072
Parity	Primi	65	61.3%	62	54.9%	0.334
	Multi	41	38.7%	51	45.1%	
Mode of delivery	NVD	39	36.8%	25	22.1%	0.019
	Instrumental	0	0.0%	3	2.7%	
	Caesarean	67	63.2%	85	75.2%	
Multiple pregnancy	Single	43	40.6%	48	42.5%	0.774
	Twin	63	59.4%	65	57.5%	
Antenatal risk factors	GDM	22	20.7%	18	15.9%	0.072
	GHTN	15	14.1%	13	11.5%	
	Hypothyroidism	19	17.9%	31	27.4%	
	None	40	37.7%	35	30.9%	
	Others	17	16%	24	21.2%	
Gestational age	≥34 weeks	5	4.7%	4	3.5%	0.012
	28 - 34 weeks	62	58.5%	87	77.0%	
	< 28 weeks	39	36.8%	22	19.5%	
Sex	Male	63	59.4%	70	62.5%	0.643
	Female	43	40.6%	42	37.5%	
Birth weight	>1.5 kg	22	20.8%	36	31.9%	0.03
	1 - 1.5 kg	39	36.8%	53	46.9%	
	< 1kg	45	42.5%	24	21.2%	
	Mean ± SD	1.14 ± 0.43		1.34 ± 0.45		0.00

Table 1: Baseline maternal and neonatal characteristics during Pre HMB and Post HMB period.

The primary objective was incidence of Definite NEC and Advanced NEC in both groups. It was 9.4% in Pre HMB group and 1.76% in Post HMB group which was statistically significant. 43.4% of babies in Pre HMB group and 18.6% babies in post HMB group had NEC (Any stage) which was statistically significant (Table 2,3, Fig.1).

	Pre HMB (n=106)		Post HMB (n=113)		OR	95% C. I		P-value
	n	%	n	%		Lower	Upper	
No. of babies with any NEC	46	43.4%	22	18.6%	**3.171**	1.734	5.799	0.00
Stage 1	36	34.0%	20	17.7%	2.730	1.445	5.159	0.002
Stage 2	8	7.5%	2	1.76%	6.067	1.245	29.554	0.026
Stage 3	2	1.9%	0	0.0%	4.52	0.46	44.51	0.196
Babies with definite and advanced NEC (Stage 2 and 3)	10	9.4%	2	1.76%	**7.583**	1.605	35.828	0.011

Table 2: Incidence of NEC during Pre and Post HMB period.

	Pre HMB			Post HMB			P-value
	n=106	%		n=113	%		
No of babies who survived	74	69.8%		91	80.5%		0.066
No. of neonatal deaths	32	30.2%		22	19.5%		
Exclusive breastfeeding rate till discharge	34	32.1%		82	72.6%		0.00 OR=0.179
Feed interruptions > 48 hrs	56	52.8%		29	25.7%		0.00 OR=0.14
No. of times feed interrupted - 1	38	67.9%		23	79.3%		0.263
2	11	19.6%		6	20.7%		
3	5	8.9%		0	0.0%		
4	2	3.6%		0	0.0%		
Fortification	69	65.7%		78	69.6%		0.536
	Median	**IQR**		**Median**	**IQR**		**P-value**
Duration of NICU stay (days)	17.0	8	38	17.0	10	38	0.865
Weight gain (g/kg/day)	7.0 (n=78)	3.75	11.08	10.55 (n=94)	7.65	18.53	**0.00**
Length increase (cm/week)	0.5 (n=35)	0.2	0.5	0.5 (n=71)	0.4	0.52	0.171
HC (cm/week)	0.50 (n=55)	0.3	0.5	0.50 (n=89)	0.35	0.6	0.059
Time of initiation of feeds	2 (n=99)	2	3	2 (n=113)	1	3	**0.033**
Time to reach full feeds	13.0 (n=76)	7.25	25.75	10 (n=106)	5	17	**0.007**
Total number of days feed interrupted	4 (n=56)	2	7	3 (n=29)	2	5	0.115
	Pre HMB (n=106)		**Post HMB (n=113)**		**Mean difference**	**95% CI**		**P-value**
	Mean	**SD**	**Mean**	**SD**		**Lower**	**Upper**	
Time to regain birth weight	14.72	5.61	11.00	4.19	-3.72	-5.22	-2.22	0.00
TFI at which fortification started	105.33 (n=69)	33.20	95.86 (n=78)	18.26				0.035

Table 3: Comparison of various parameters between pre HMB and Post HMB group.

Neonatal deaths were higher in the Pre HMB group 32 (30.2%) than in the post HMB group 22 (19.5%), however the data was not statistically significant (p=0.066). The exclusive breastfeeding rate was significantly higher in the post HMB group (72.6%) as compared to 32.1% in the pre HMB group (p=0.00) (Table 3).

Feed interruptions were significantly lower in the post HMB group 29 (25.7%) as compared to Pre HMB group 56 (52.8%) (p=0.00). Total number of days for which feed was interrupted was lower in the post HMB group as compared to Pre HMB group, however the data was not statistically significant. Time to reach full feeds was significantly lower in the post HMB group Median (IQR) 13 (7.25-25.75) days as compared to 10 (5-17) days (p=0.007) (Fig. 2).

Feeds were fortified in 65.7% in Pre HMB and 69.6% in Post HMB group. Fortification was started at an earlier TFI of 95.86 + 18.26 in post HMB group as compared to a TFI of 105.33 + 33.2 in Pre HMB group (p value = 0.035). In the Post HMB group, the proportion of DHM on reaching full feeds was 42.94 (25.98 - 50)%. Duration of NICU stay was not statistically significant between both the groups.

Weight gain (g/kg/day) and was significantly higher in the post HMB group 10.55 (7.65- 18.53) as compared to pre HMB group 7 (3.75 - 11). Increase in head circumference (cm/week) was not statistically significant between both the groups. Time to regain birth weight was significantly lower in the post HMB group (14.72 + 5.61) as compared to pre HMB group (11.00 + 4.19) (p=0.00) (Fig. 2).

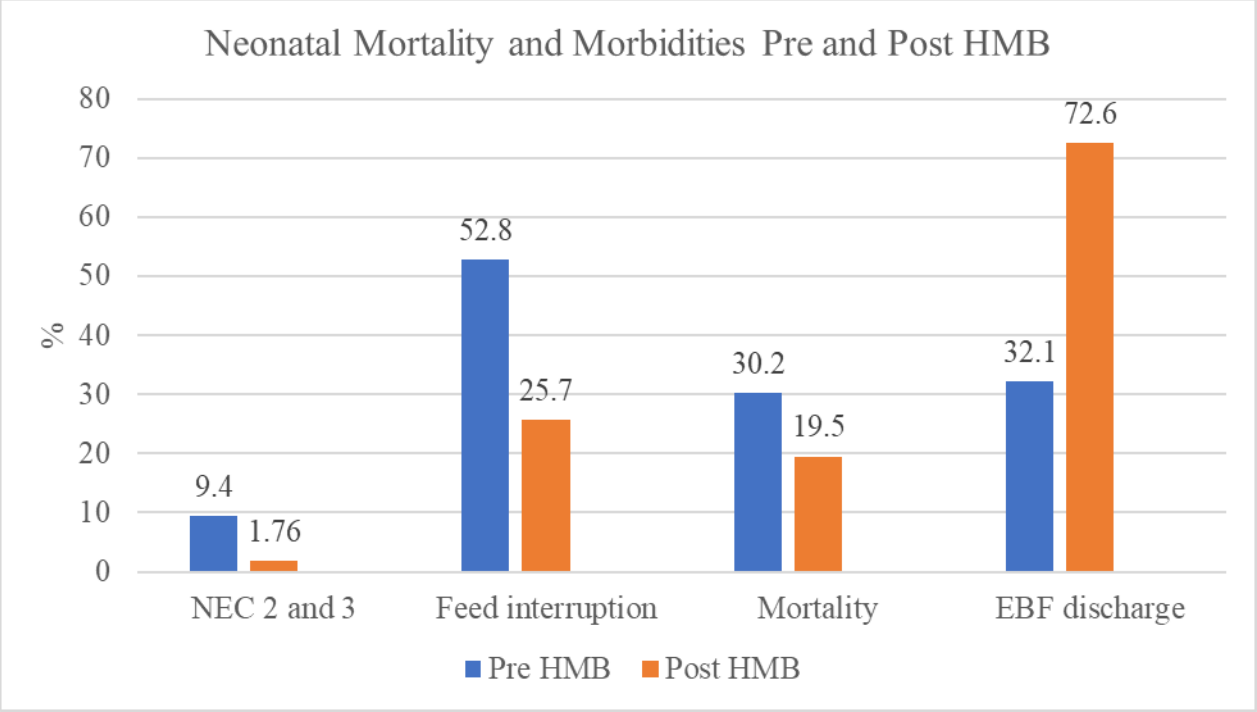

Figure 1: Neonatal mortality and morbidities in pre and post HMB group.

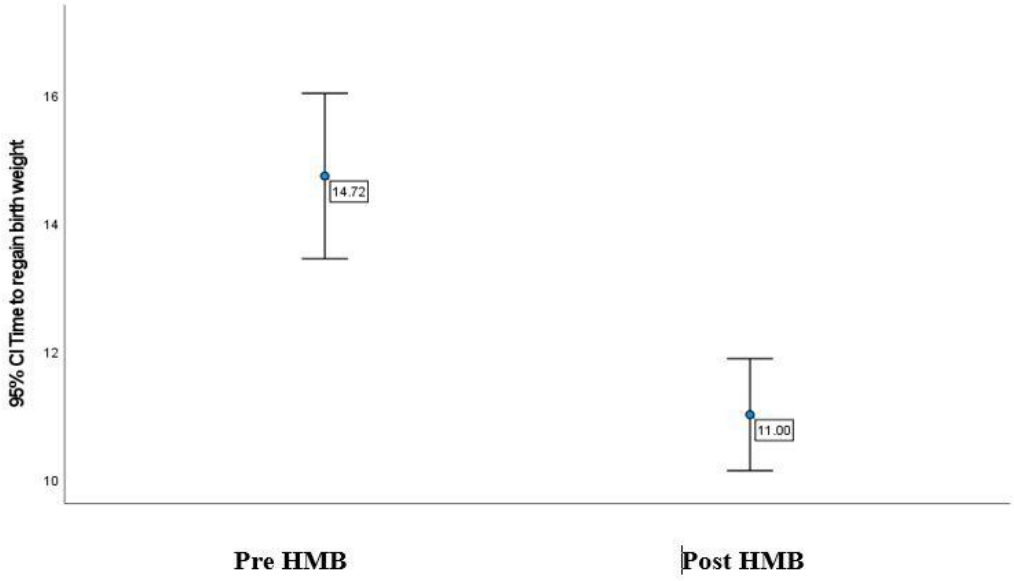

Figure 2: Time to regain birth weight in Pre and Post HMB group.

Discussion

The World Health Organisation (WHO) recommends PDHM as the best alternative in instances in which a mother's milk is unavailable, since it can considerably lower morbidity and mortality rates among neonates at high risk. With more newborns benefiting from PDHM, the number of milk banks has increased in light of the benefits it offers. In our study, the incidence of NEC and feed interruptions had dramatically decreased following the establishment of the milk bank, reiterating the critical role that breastmilk plays in lowering sepsis and feed intolerance. Studies on reducing NEC rates have yielded findings comparable to our study [1,6,7]. The study by Kantorowska, et al., had shown a 2.6% decrease in NEC rates6 on using DHM. Our study showed a decrease in mortality among VLBW and ELBW babies after inception of Milk bank although the data was not statistically significant (30.2% vs 19.5%). Breastmilk reduces sepsis and improves immunity of the baby as compared to formula feeds and helps in reducing mortality. The mortality rate in our study was comparable to the data from other studies done in India [8,9]. The weight gain (g/kg/day) in our study was higher in the post HMB group as compared to pre HMB group. This was in contrast to previous studies by Quigley, et al., Schanler, et al., which had stated better weight gain with preterm formula milk when compared to PDHM [3,4]. The increased weight gain in our study could probably be secondary to the reduced rate of NEC and feed interruption in the post HMB group. Fortification being started earlier in the post HMB group could have also contributed to a better weight gain in the post HMB group. Post HMB inception shows a significantly higher exclusive breastfeeding rate at discharge than the other group. The study by Arasolomgolu, shows that Exclusive breastfeeding rate at discharge was significantly higher in NICUs with a HMB than in NICUs without (29.6% vs. 16.0%) [10]. Early initiation and establishment of exclusive breastfeeding during the initial few days of life has been shown to translate into higher exclusive breastfeeding rates at 6 months. Mothers of VLBW and ELBW babies admitted in NICU may face several challenges during the initial phase to practice exclusive breastfeeding. Supporting them with PDHM and promoting exclusive breastfeeding in NICU can have long term higher EBF rates. Study by Adhisivam, et al., has shown similar results that exclusive breastfeeding rates at 6 months were significantly higher in the post-HMB group compared with the pre-HMB group [11].

Strengths

Our study has shown better weight gain with PDHM as opposed to other studies.

Limitations

- Being a retrospective observational study, few data could not be collected
- Babies who were sick to start with, at admission, could have biased the results

Conclusion

Availability of DHM in a medical facility is associated with improved outcomes for VLBW babies receiving care at that NICU. It can serve as an effective bridge to support VLBW and ELBW babies till lactation is established. Establishment of Human Milk bank can be a worthwhile quality improvement project that NICUs can launch as part of comprehensive plans to enhance preterm care.

Conflict of Interests

The authors have no conflict of interest to declare.

Author's Contribution

Arumugom Archana, Chandra Kumar Natarajan, Vaanathi Hementha Kumar were involved were involved in management of the patients, collected the data, reviewed the literature and drafted the manuscript. Hemalatha R preformed analysis, interpretation of the study results and contributed to the writing of the manuscript. Chandra Kumar Natarajan critically revised the manuscript. All authors approved the final manuscript as submitted. Chandra Kumar Natarajan shall act as guarantor of the paper.

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