Original Research Article

Need of the hour? does breast milk bank reduces perinatal morbidity and mortality: a retrospective observational study

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ABSTRACT

Background: Human milk bank plays an essential role by providing human milk to infants who would otherwise not be able to receive human milk. The aims and Objectives is to study the morbidity and mortality outcome profile of babies fed with PDHM (pasteurized donor human milk) comparing data between Pre Human Milk Breast bank (2015) and Post Human Milk Breast bank (2016, 2017 and 2018).
Methods: Milk bank collect, screen, store, process, and distribute human milk. Retrospective observational study was done in Department of Neonatology, Institute of Obstetrics and Gynaecology and Women and Children Hospital, Chennai. Data obtained retrospectively comparing data Pre HMB (2015) and Post HMB (2016, 2017 and 2018).
Results: In this study authors collected the data comparing Pre human milk bank (Pre HMB) and Post human milk bank (Post HMB). After starting human milk bank, around 1799 babies were benefitted and 14.45 lakh ml milk was collected from 16000 donor mothers in last 3 years. Bacterial contamination rate of PDHM has reduced to 4.39% (2018) compared to 7.73% (2016) with P Value 0.0042 (statistically significant). CONS and *Staphylococcus aureus* were the most common Organisms isolated. There was reduction in morbidity profile like sepsis rate, NEC/ Feed intolerance and ROP profile. Mortality profile also reduced to (7.73-9.31%). Duration of hospital and Duration to attain full feeds were improved all GA group babies.
Conclusions: In this study, after starting human milk bank there was reduction in mortality, morbidity outcome, sepsis. Duration to attain full feeds and duration of hospital stay reduced. We concluded that establishment of breast milk bank will be more useful and beneficial for all GA group babies for better outcome.

Keywords: Duration of hospital stay and duration to attain full feeds, *Necrotizing enterocolitis*, Retinopathy of prematurity, Sepsis

INTRODUCTION

Breastfeeding 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. When a mother, for some reason, is unable to feed her infant directly, her breastmilk should be expressed and fed to the infant. If mother's own milk is unavailable or insufficient, the next best option is to use pasteurized donor human milk (PDHM).

India faces its own unique challenges, having the highest number of low birth weight babies, and significant mortality and morbidity in very low birth weight (VLBW) population. In this country, the burden of low birth weight babies in various hospitals is about 20% with significant mortality and morbidities.[1,2]

Human milk banking started informally almost a hundred years ago, however the first human milk bank was set up in the United States in mid 1980s. First human milk bank of Asia 'Sneha' was founded in 1989 in Mumbai, but there is still insufficient number of milk banks in India (around 22; most in private hospitals).[3] This tertiary care's milk bank was established in oct 2015.

METHODS

Study period of donor and recipients data were collected from the records maintained in human milk bank at department of Neonatology, Institute of Obstetrics and Gynaecology, Chennai. Data was collected retrospectively from 2015 (pre HMB) compared with post HMB (2016-2018). It is a retrospective observational Study and ethical clearance was taken and accepted.

Study population of all newborns who are admitted and observed (term and preterm) fed with early donor human milk followed by mothers own milk were included in the study .In this study, we reviewed the basic characteristics of donors, (age, residence, gravida, type of delivery and education status) and recipients (age), the number of donors and recipients, amount of human milk for collection and processing, bacterial contamination rate of donor milk after pasteurization. Data was collected from 2015 (Pre HMB) compared with post HMB (2016-2018). After proper counselling, checking suitability for donation, getting written informed consent, history taking, physical examination and sampling for laboratory tests, the donor is sent to designated breastmilk collection area in the milk bank or in the milk collection center. Breastmilk is collected by trained staff with hygienic precautions, after method of breastmilk expression is chosen by the donor. Home collection of breastmilk is better avoided at present in this country due of the risk of contamination. Washing the breast with water before expression is as good as washing with disinfectant. Once pasteurized, milk is placed in small (30ml) containers and is stored frozen for up to 6 months. After processing, pasteurized milk undergoes bacteriological testing to ensure the absence of detectable bacterial growth. In the hospital approved microbiology laboratory, each milk sample was inoculated onto blood agar plate and incubated aerobically at 36°C for 48 hours. All contaminated milk was discarded.

Statistical analysis was done using chi-square test and p value <0.5 is considered significant

RESULTS

In our study, after starting human milk bank, around 1799 babies were benefitted and 14.45 lakh ml milk was collected from 16 thousand donor mothers in last three years. Bacterial contamination rate of PDHM has reduced to 4.39% (2018) compared to 7.73% in 2016.CONS and Staphylococcus aureus were the most common Organisms isolated form PDHM. There was reduction in

morbidity profile like sepsis rate, NEC/ Feed intolerance and ROP profile in 2018 compare to last 2 years compared to Pre HMB .Mortality profile also reduced to (7.73-9.31%) POST HMB compared to PRE HMB (12.9%). Duration of hospital and Duration to attain full feeds were improved all GA group babies. No babies were noticed with Bronchopulmonary dysplasia in last 1 year among babies fed with PDHM during initial phase.

Table no 1 showed characteristics of donor mother .Most of the mothers were in the age group of 20-25 yrs (60.3%), from urban area (79.9%), primi mothers were more (76.9%), more deliveries were through LSCS(59.9%).most mothers were literate (84.9%).

Table 1: Donor mother characteristics-(2018)-N-5739.

Age	20-25 yrs	3464 (60.3%)
	26-30yrs	1685 (29.3%)
	>30yrs	589 (10.2 %)
Residence	Urban	4591(79.9%)
	Rural	1148 (20.0%)
Gravida	Primi	4419 (76.9%)
	Multi	1262 (21.9%)
Type of delivery	Labour natural	2294 (39.9%)
	LSCS	3443 (59.9%)
Education status	Literate	4878 (84.9%)
	Illiterate	861 (15.0%)

Table 2 shows number of donors were 16029 ,amount of milk collected was 14,45,100 ml and number of recipients benefitted were 8350 in last three years of human milk bank. In each there were exponentially increase in donors around 4158 in 2016, 6132(2017) and 5739(2018). Amount of milk collected in 2016 was around 4.27 lakh ml and in 2018 amount of milk collected increased to 5.11 lakh. Number of recipients also increased in each year comparing 2019 benefitted in 2016 and in 2018, recipients benefitted were 3275. This increased numbers was due to counselling given to donor mothers regarding human milk and benefits to babies.

Table 2: Human milk bank.

Year	No of donors	Amount of milk collected	No of recipients
2016	4158	4,27,480ml	2019
2017	6132	5,05,760ml	3056
2018	5739	5,11,860ml	3275
Total	16029	14,45,100	8350

Table 3 shows, regarding babies benefitted from human milk bank according to gestational age compared data of three years. Most babies benefitted from Human milk bank were in the gestational age group of 30wk -37 wks. Total number of babies benefitted were almost the same in three years. Admissions were 5087 and babies benefitted were 633 in 2016, 5772 admissions and 594

babies were benefitted in 2017 and in 2018, admissions were 5112, 572 babies were benefitted

Table 3: Babies benefitted with HMB.

	2016	2017	2018
Gestational age	Adm(5087)	Adm(5772)	Adm(5112)
<28 WKS	42	53	24
28+1/7-30wks	88	64	48
30+1/7-32wks	114	128	119
32+1/7-34wks	158	139	151
34+1/7-37 wks	128	154	141
>37 WKS	103	56	89
Total	633	594	572
Percentage	12.4%	10.29%	11.18%

In this study, Table 4, Bacterial contamination rate of pasteurized donor human milk of three years data were compared. Contamination rate was decreased from 7.78%(2016) to 4.39%(2018). With Statistical analysis P value was compared and obtained value of (<0.0042) which is considered to be statistically significant. Contamination rate of PDHM was reduced could be due to proper hand hygiene technique, proper collection of milk from donors, awareness regarding asepsis and good storage facility at human milk bank.

Table 4: Bacterial contamination rate pasteurized human milk.

Year	Culture sent(n)	Culture negative	Culture positive	Percentage
2016	3071	2832	239	7.78%
2017	3379	3130	249	7.36%
2018	3457	3305	152	4.39%
Total	9907	9207	640	6.46%

Table 5 shows; most common organisms isolated from PDHM were coagulase neg *Staphylococcus aureus* (24.5%), *Micrococci* (23.6%) and *Staphylococcus aureus* (21.9%). *Proteus mirabilis* (4.38%) was the least common organism isolated from pasteurized donor human milk.

The comparison of data regarding the blood culture positivity from overall admissions and babied fed with Pasteurized donor human milk (PDHM) followed by mothers own milk (MOM). Blood culture positivity was decreased to 9.4% in babies fed with PDHM compared with blood culture among overall admissions (36.38%). p value is (0.0035) considered as statistically significant (Table 6).

Comparision of data regarding morbidity profilr of NEC between Pre human milk bank year (2015) with Post Human milk bank (2018). Morbidity profile of NEC in Post HMB were less in GA <28 wks and 28-30wks (20.8%) compared with Pre HMB <28wks (22.6%) and 28-30 wks (23.4%). No babies with NEC were detected in GA group between 32 wks to 37 wks in 2018 compared with 2015 data around 1.4% (32-34 wks) and 1.2 % (34-37 wks) (Table 7).

Table 5: Organism isolated from Donor Milk.

Organism	Number	Percentage
Coagulase negative staphylococcus	28	24.5%
Micrococci	27	23.6%
Staphylococcus	25	21.9%
Klebsiella pneumonia	18	15.7%
Ecoli	8	7.01%
Proteus mirabilis	5	4.38%

Table 6: Morbidity profile-sepsis rate.

	Blood culture sent	Blood culture positive	Percentage
Overall admissions	2732	994	36.38%
Babies fed with PDHM followed by MOM	572	54	9.4%

Table 7: Morbidity profile-NEC.

Gestational age	2015(N0-633)		2018(N0-572)	
	ADM	NEC/FI	ADM	NEC/FI
<28 wks	53	12(22.6%	24	5(20.8
28+1/7-30wks	64	15(23.4%)	48	5(20.8%)
30+1/7-32wks	128	6(4.4%)	119	3(2.52%
32+1/7-34wks	1391	2(1.4%)	151	0
34+1/7-37wks	154	2(1.2%)	141	0
>37 wks	56	0	89	0

Comparison of data regarding morbidity profile of ROP between Pre human milk bank years (2015) with Post Human milk bank (2018). Morbidity profile of ROP in Post Human Milk Bank were less in GA <28 wks (16.6%) and 28-30wks (12.5%) compared with Pre HMB <28wks (30.76%) and 28-30 wks (18.7%) (Table 8).

Mortality profile compared between Pre human milk bank(Pre HMB) (2015) and Post human milk bank (Post HMB) (2018). Mortality rate were less in Post HMB (7.73-9.31%) compared with Pre HMB (12,9%). p Value is 0.0042 considered as statistically significant (Table 9). Comparing the data regarding duration of hospital stay between Pre HMB (2015) and Post HMB (2018) Duration of hospital

stay were less in Post HMB babies in all GA compared with

Pre HMB babies (Table 10).

Table 8: Morbidity profile-ROP.

GA	2014-15			2018		
	ROP screened (314)	Without laser	With laser	ROP screened (489)	No laser	Laser
<28wks	26	12	30.76%	24	20	16.6%
28 +1/7-30	64	48	18.7%	48	30	12.5%
30+1/7-32	102	39	7.8%	119	54	3.36%
32+1/7-34	78	32	5.12%	157	48	0.63%
34+1/7-36	48	12	4.1%	141	42	0%

Table 9: Mortality profile.

	Pre HMB	Post HMB		
	2015	2016	2017	2018
Admissions	4263	5087	5772	5112
Mortality	454	471	450	479
Percentage	12.9%	7.73%	7.79%	9.31%

Table 10: Duration Of hospital stay.

Gestational age	2015	2018 (MEAN±SD) (Days)
<28 WKS	74.4±15.1	(56.1±10.7)
28+1/7–30 WKS	56.2±10.2	(35.6±13.4)
30+1/7–32 WKS	39.5±7.2	(26.2±10.7)
32+1/7–34 WKS	25.4±9.4	(17.4±7.8)
34+1/7–37 WKS	20.3±5.2	(14.7±7.4)
>37 WKS	13.2±6.4	(10.4±6)

Table 11 showed comparisons of data regarding duration to attain full feeds between Pre HMB (2015) and Post HMB (2018). Duration to attain full feeds was less among Post HMB babies compared with Pre HMB in all GA group babies.

Table 11: Duration to attain full feeds.

Gestational age	2015 (Pre HMB)	2018(Mean±SD) (Post HMB)
<28 WKS	28.5±9.2	21.8±6.5
28+1/7–30 WKS	19.5±4.3	16.1±5.7
30+1/7–32 WKS	16.5±6.3	15.9±3.3
32+1/7–34 WKS	10.3±3.2	9.6±2.6
34+1/7–37 WKS	10.5±3.6	8.0±2.4
>37 WKS	8.4±2.5	6.8±1.8

DISCUSSION

The Pasteurised Human Donor Milk (PDHM) is recommended because of its acknowledged benefits with respect to infant nutrition, gastrointestinal function, host defence, and psychological wellbeing.[4] Donor breast milk is defined as milk which is donated by another mother and processed by milk bank to be used by a receiver mother who cannot nurse her baby.[5,6] A human milk bank is a service established for collecting, screening, processing, storing and distributing pasteurised donated human milk. Lucas and Cole found that NEC was 610 times more likely to develop in exclusively formula fed infants than in those fed only breast milk, and that NEC was 3 times more likely when formula-only fed infants were compared to those receiving both breast milk and formula.[7,8] Other studies have demonstrated that formula fed infants had lower IQ scores than infants fed breast milk. Therefore, Pasteurized donor human milk (PDHM) is regarded as "the next best" after the biological mother's breast milk.[9,10] Unfortunately, there are circumstances where mothers are not able to breastfeed their babies for a number of reasons despite the various benefits. Commercial infant formula is a common replacement for breast milk in these instances. However, donor breast milk can be an excellent alternative to formula feed.

During this study, we collected the 3 years data from the human milk bank register which will be maintained in the department of Neonatology, IOG, and Chennai. We collected the data regarding donor mother basic characteristics (age, residency, education status, gravida and type of delivery. Most mothers were in the age group of 20-25 yrs (60.3%) which compared with Korean study by Jang et al, where most mothers in the age group of 30-39 yrs.[11] This can be explained by earlier age at marriage, early conception and childbirth in Indian subcontinent compared to western countries. Most were from urban residency (79.9%) and primi gravida (76.9%) with literacy rate around (84.5%). No of Donor mothers were increased from 4158 to 5739, No of recipients were also increased from (2019 to 3275) and amount of milk collection were also in increased trend from 4.27 lakh ml to 5.[11] lakh ml since last three years. This is due to increase in awareness of human milk bank and benefits of human milk among donor mothers. Bacterial contamination rate of pasteurized donor human milk was reduced from (7.78% to 4.39%) with p Value is 0.0042 considered as statistically significant, compared with Poonam Singh study on bacterial contamination rate between pre pasteurized (9.1%) and post pasteurized

(2.34%) donor human milk. Most common organisms isolated from the pasteurized donor milk were *staph aureus* (24.5%) followed by micrococci (23.6%) and CONS (21.9%) compared with Poonam Singh study where common organisms were gram positive bacilli (88.23%) and CONS(11.76%).[12] Morbidity profile of sepsis rate among babies who fed with donor human milk was (9.4%) compared with overall admissions (36.38%) p value is (0.0035) considered as statistically significant. Morbidity profile for NEC compared between Pre Human milk Bank (2015) and Post Human milk bank (2018) were less in GA of 28-30wks (23.4% vs 10.4%) compared with Eun Jeon Kim study NEC was lower in the DHM group (0% vs 9.3%) vs Preterm formula group.[13] Morbidity profile for ROP compared between Pre HMB and Post HMB were less in GA of 28-30 wks in Post HMB group (18.7% vs 12.5%).Duration of hospital stay were less in post HMB among GA less than 28 wks (mean±SD - 56.1±10.1) than pre HMB (mean±SD - 74.4±15.1). Duration of attaining full needs less in post HMB babies among GA less than 28 weeks (mean±SD - 21.8±6.5) compared with pre HMB (mean±SD - 28.5± 9.2) compared with Eun jeon kim study preterm infants in the DHM group were more likely to achieve full feeding (130mL/kg/d) within a shorter period (29.6±12.0 vs 52.2±17.6 days). So, in this study there was reduction in morbidity and mortality rate, duration of hospital stay and duration to attain full feeds among babies who fed with initial Donor human milk and followed by mother own milk (MoM). The most common reason for receiving donated breast milk was a premature baby, which appears to be growing in proportion in recent years. Although the majority of the recipients were preterm infants, donor milk was also being ordered for babies and children for a variety of other reasons, including adoption, baby's refusal of formula, milk allergy, decreased amount of mother's breast milk, and mother receiving chemotherapy for cancer or underlying diseases.

Greatest beneficiaries to human milk banking will be preterm babies who are at risk of necrotizing enterocolitis and neonatal sepsis - diseases well known to be associated with high mortality and morbidity. It also helps them to reach full enteral feeds earlier than without human milk by strong trophic effects on gut.[14]

A meta-analysis of trials comparing formula feeds versus donor milk has shown significant protective effect of donor milk compared to formula in preventing necrotizing enterocolitis.[15-17]

Hylander MA in 'Human milk feedings and retinopathy of prematurity among very low birth weight infants' concluded that incidence and severity of retinopathy of prematurity are significantly low in those who were exclusively breast fed or whose diet consist of 80% of human milk.[18] They found a 47% combined infection incidence in the formula group compared to 29% in the human milk group. In addition, in a randomized trial by Narayanan et al, human milk consumption (both milk from the mother and pasteurized donor milk) reduced the incidence of infection.

CONCLUSION

Human milk banks serve a vital function by providing human milk for premature infants, sick or hospitalized infants and others who, for a variety of reasons, would otherwise not have access to mothers' milk. In conclusion, exclusive DHM feeding in the early postnatal period can provide protective benefits from several morbidities such as LOS/NEC and ROP and decrease duration of hospital and decrease duration to attain full feeds. Therefore, in situations where mother's own breast milk is unavailable, DHM can be the first choice of an alternative source of nutrition in both Term and preterm infants.

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