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Comparison of the short-term neonatal outcomes of preterm neonates before and after the launch of human milk bank in Iran: a retrospective descriptive study

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Abstract

Background Preterm delivery continues to be a major concern in the global health system. Where accessible, mother's milk is the optimal option for neonate nutrition. In recent years, donor milk as the best substitute for mother's milk where this is not available has become a popular option. The safest method to obtain this milk is from human milk banks. Thus, this study aims to compare the short-term outcomes of preterm neonates pre- and post-launch of human milk bank in Iran.

Methods This is a retrospective descriptive study conducted over two time periods pre- and post-launch of the human milk bank at Shahid Akbar Abadi Hospital in Tehran. 580 neonates were included in the study during the pre-launch period from November 2018 to June 2019. In the post-launch period, 580 neonates were also included in the study from April 2021 to November 2021. Individual data were gathered using a maternal and neonatal form. Data on outcomes were collected in a neonatal outcomes form, including necrotizing enterocolitis, late onset sepsis, mortality, feeding intolerance, time of initiating supplementary nutrition, and discharge date. In all statistical tests, $P < 0.05$ was considered statistically significant.

Results The results showed that the NEC frequency in neonates pre- and post-launch period was not statistically significant (12 vs. 6, $P = 0.11$). Sepsis occurred in 90 cases of neonates pre-launch and the figure was diminished to 80 neonates post-launch. Sepsis (90 vs. 80, $P = 0.02$) and feeding intolerance (420 vs. 402, $P = 0.01$) were significantly different in post-launch period. The mortality rate was significantly reduced after the launch of human milk bank ($P = 0.002$, 44 vs. 18). The number of neonates who received supplementary nutrition earlier than 30 days was significantly higher post-launch period (420 vs. 460, $P = 0.003$). In addition, the number of neonates discharged from the hospital post-launch increased significantly (407 vs. 460, $P = 0.001$).

Conclusions Comparing neonatal outcomes showed that sepsis, feeding intolerance, mortality, and the neonates achieving supplementary nutrition earlier than 30 days and being discharged were reduced in post-launch period.

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Considering the significant outcomes of launching a human milk bank, it is recommended to have milk banks in hospitals with neonatal intensive care units (NICU).

Keywords Preterm neonates, Human milk banks, Donor milk, Short-term neonatal outcomes

Introduction

Breastfeeding is considered the best start in life for a newborn and can significantly affect the health and emotional state of the mother and baby [1]. MM[1] protects the baby and strengthens the immune system against sepsis due to its bioactive compounds (BACs[2]) with antimicrobial activity [2]. In September 2015, the UN[3] announced that it aimed to end preventable infant and child deaths by 2030 as one of its sustainable development goals (SDG[4]) by promoting breastfeeding as an effective intervention.

Annually, an estimated 15 million premature neonates (gestation age ˂ 37 weeks) and over 20 million infants of low birth weight (LBW[5]) are born worldwide and these numbers are on the rise [3, 4]. In Iran, the incidence of preterm deliveries has been estimated to be 10%, and the birth of LBW infants at 7.95% [5, 6]. Preterm neonates also have an immature gastrointestinal (GI[6]) tract and a weak immune system that exposes them to several risks such as NEC[7] and bronchopulmonary dysplasia (BPD[8]) [7]. Preterm neonates have lower gastric digestion capacity because of an immature GI tract, leading to growth restriction and neonatal complications [8].

Because of hospitalization, prematurity, or problems related to prematurity, most infants are unable to breastfeed [9]. In these cases, formula (F[9]) is used as a substitute. However, formula feeding is associated with a higher risk of neonatal mortality and morbidity, particularly in preterm neonates [10]. The increased risk of NEC by using formula compared with MM is one such morbidity in high-risk neonates, especially those of very LBW [11, 12]. WHO[10] also recommends donor human milk as a second choice for mothers who are unable to breastfeed their baby, especially for preterm neonates with low birth weights and other high-risk infants [13].

Compared with formula, DM[11] strengthens the immune system of preterm or LBW neonates, lowers the risk of disease, and protects the infants against NEC [12, 14, 15]. It also significantly reduces hospitalization time and related costs in neonates with LBW. Donor human milk is a logical alternative for neonatal nursing [16]. In 1980, WHO and UNICEF[12] issued a joint statement on human donor milk being the first and best choice when the biological mother's milk is not available to the neonate and the safest way to access this is at donor milk banks [17].

A retrospective study by M. Hosseini et al. [18] examined the short-term neonatal outcomes post-launch of human milk banks, and reported that NEC and LOS[13] were significantly reduced post-launch but this did not significantly affect mortality. Another study reported that the enteral nutrition (EN[14]) of preterm neonates post-launch was initiated 31 h earlier on average and initiating supplementary nutrition of 100 ml/kg/day and 150 ml/kg/day began much earlier. However, the incidence of NEC and LOS was not statistically significant. In the literature review of similar studies, different results were reported in terms of NEC frequency, instances of sepsis, mortality rates, and neonatal outcomes pre- and post-launch of human milk banks. Some studies showed no difference in NEC frequency following feeding with donor human milk [19–21], but this was observed in several other studies [12, 18, 22, 23]. In terms of neonatal infections, Hosseini et al. [18] reported that LOS was reduced post-launch, but two other studies showed no difference in LOS and infections in neonates following feeding with DM [20, 21]. In studies by Vázquez-Román et al. [21] and Yu-Li et al. [22], nutrition of 100 and 150 ml/kg/day was achieved much faster [21, 22]. However, the study by Corpeleijn et al. showed no difference in the time of initiating nutrition of 120 ml/kg/day [20]. Despite the existence of numerous human milk banks, few studies have been conducted on the neonatal outcomes of preterm neonates pre- and post-launch in Iran and globally. The only study in Iran was conducted in the city of Tabriz over a short period of six months with a small sample size, increasing the risk of data bias due to the small sample size. The effect size reported in this study was also small. The study compared NEC frequency as a primary outcome and LOS, mortality, FI[15], and the time to initiate feeding of 100 and 150 ml/kg/

[1] MM: Mother's milk.

[2] BACs: Bioactive compounds.

[3] UN: United nations.

[4] SDG: Sustainable development goals.

[5] LBW: Low birth weight.

[6] GI: Gastrointestinal.

[7] NEC: Necrotizing enterocolitis.

[8] BPD: Bronchopulmonary disease.

[9] F: Formula.

[10] WHO: World health organization.

[11] DM: Donor milk.

[12] UNICEF: United nations international children's emergency fund.

[13] LOS: Late onset of sepsis.

[14] EN: Enteral nutrition.

[15] FI: Feeding intolerance.

day as secondary outcomes, pre- and post-launch of the human milk bank.

Methods

Study design

This was a retrospective descriptive-comparative study. Data were obtained from patient files of preterm neonates hospitalized at the NICU[16] of Shahid AkbarAbadi Hospital (Tehran, Iran) over the two time periods of November 2018 to June 2019 and April 2021 to November 2021. Participants were assured of the confidentiality of their information.

Study sample

We used R statistical software to determine the required sample size. Hosseini et al. considered a Type I error with a significance level of 0.05 and 80% power, calculating the sample size at 492 participants (246 in each group) to compare the level of NEC pre- and post-launch of a human milk bank. To compare the rate of LOS frequency pre- and post-launch of a human milk bank, a sample size of 330 participants (165 in each group) was calculated, and to compare the mortality rate pre- and post-launch of a human milk bank, a sample size of 1150 participants (580 in each group) was calculated. Finally, by considering the mortality rate as the extreme outcome, the sample size of 580 participants for each group was calculated [18].

The inclusion criteria consisted of preterm neonates with LBW ˂ 2000 g and/or gestational age ˂ 32 weeks. The exclusion criteria consisted of neonates with major congenital anomalies such as congenital heart diseases (CHDs[17]), chromosome abnormalities, genetic disorders, hypoxic-ischemic encephalopathy, and neonate deaths before 72 h. To select neonates meeting these criteria, the researcher referred to the hospital archives and used availability sampling to extract data from the files.

Outcome measures and measurements

Data collection tools included mother and neonate characteristics (independent variables) and neonatal outcomes (dependent variables).

Maternal demographics included age, place of residence (urban/rural), delivery method (vaginal/C-section), substance abuse, family marriage, history of hypertension, preeclampsia, thyroid disorder, diabetes (gestational diabetes, diabetes mellitus), other diseases, use of assisted reproductive technologies (ART[18]), history of infertility, and IUFD[19]. Neonate characteristics included gender (girl/boy), gestational age (28weeks until 31w + 6d, 24weeks until 27w + 6d, 20weeks until 23w + 6d), birth weight in grams (1500–2000, 1000–1500, ˂1000 g), Apgar score 1 min after birth and 5 min after birth, premature rupture of fetal membranes (PROM[20]) (No, > 18 h, ˂ 18 h), antenatal corticosteroid therapy (nonuse, complete use, incomplete use), meconium contamination, feeding practices during the initial 28 days of life (MM, DM, F), and CPR[21] (With ventilator, without ventilator). The data were extracted and recorded by the researcher.

Data on neonatal outcomes, including Stage 2 NEC or higher, LOS, mortality, FI (number of interruption of feeds), number of infants achieving full feeding (150 ml/kg/day) before 30 days, and number of infants discharged within a month, were extracted by the researcher from every neonate file. The diagnosis of necrotizing enterocolitis (NEC) and neonatal sepsis was based on ICD-10 codes P77 and P36.0–P36.9, respectively. To ensure accuracy, a clinician validated the diagnoses of the conditions studied.

Analysis

The data were analyzed using SPSS V.21 (SPSS). Quantitative data are presented as mean and SD[22] and qualitative data were described using frequency and percentage. To compare the mothers' and neonates' variables pre and post-launch of the human milk bank in quantitative variables, an independent sample t-test and Mann-Whitney U Test were used. For categorical variables, the chi-square test and Fisher's exact test were used. A multivariate logistic regression was used to evaluate the relationship between the independent variables with neonatal outcomes. Variables that confirmed significance in the univariate analysis ($P < 0.05$) were entered into the logistic regression model. The level of statistical significance was set at $P < 0.05$.

Results

According to the calculated sample volume for the study prelaunch of the human milk bank, a total of 622 records were examined from November 2018 to June 2020. Fifteen cases were excluded from the study based on the inclusion criteria due to major congenital anomalies, 10 cases were excluded due to incomplete records, and 17 cases were excluded due to neonate deaths within 72 h. Finally, 580 cases were included in the study for the prelaunch period of the human milk bank. After the launch of the human milk bank, a total of 630 cases from April 2021 to November 2021 were examined. Of these, 21

[16] NICU: Neonatal intensive care unit.

[17] CHD: Congenital heart disease.

[18] ART: Assisted reproductive technologies.

[19] IUFD: Intra uterine fetal death.

[20] PROM: Premature rupture of membrane.

[21] CPR: Cardiopulmonary resuscitation.

[22] SD: Standard deviation.

cases were excluded due to major congenital anomalies of neonates, 14 cases were excluded due to incomplete records, and 15 cases were excluded because of neonate deaths within 72 h. Finally, 580 cases were also included in the study for the post-launch period of the human milk bank.

Table 1 shows that the mean age of mothers was 26.4 years with a standard deviation (SD) of 5.27 years in the pre-launch group, and 25.7 years with a standard deviation of 4.54 years in the post-launch group. The demographics showed that 90% of the mothers in the pre-launch group live in rural areas. This figure is 91.2% in the post-launch group. The Frequency of vaginal deliveries is 19.5% in the pre-launch group and 16.7% in the post-launch group.

Table 2 shows that 61% of the neonates were boys in the pre-launch group. This figure was reduced to 57% in the post-launch group. The frequency of neonates with a gestational age of 28–32 weeks increased in the post-launch group. The frequency of neonates with a birth- weight of 1500–2000 g increased in the post-launch group. The frequency of neonates whose mothers had used antenatal corticosteroid therapy was significantly different between the two groups.

In Table 3, the frequency of NEC stage 2 or higher was reported as lower in the post-launch group (1%) compared to the pre-launch group (2%), but the decrease was insignificant ($P = 0.11$). The proportion of neonates with LOS in the post-launch group (13.7%) was diminished compared with that in the pre-launch group (15.5%), but this decrease was also insignificant ($P = 0.22$). The mortality rate in the post-launch group (3.1%) was lower than that in the pre-launch group (7.5%). This decrease was significant ($P = 0.002$). The frequency of neonates with FI was reported as lower in the post-launch group (69.3%) compared to the pre-launch group (72.4%), but this decrease was also insignificant ($P = 0.14$).

There was a small variation in the frequency of neonates who took longer than one month to achieve supplementary nutrition in both groups (17% in the post-launch group and 15% in the pre-launch group). The frequency of neonates who took less than 1 month to achieve supplementary nutrition in both groups is statistically significant (79% in the post-launch group and 72% in the pre-launch group) ($P = 0.003$). Also, the frequency of neonates who were hospitalized for less than one month was significantly different in the pre-launch group (70.1%) and post-launch group (79.3%) ($P = 0.001$).

The results of the logistic regression model show that even by considering the effect of confounding variables, no significant difference was observed in NEC frequency in preterm neonates pre- and post-launch of the human milk banks (Table 4).

By considering Table 6, the effect of confounding variables on FI in preterm neonates was adjusted pre- and post-launch of the human milk bank in the logistic regression model. The results of the logistic regression model showed that the model became significant after the adjustment of confounding variables and the likelihood of feeding interruptions for 6–12 h decreased by 74% in preterm neonates post-launch of the human milk bank. Thus, FI in preterm neonates before and after launch of the human milk bank was significantly different ($P = 0.01$).

Table 1 Maternal characteristics across both groups before and after launch of the human milk bank

Variables		**Human milk bank pre-launch group (*n* = 580) (%)**	**Human milk bank post-launch group (*n* = 580) (%)**	***P*-value**
Mother's age (mean ± SD)		26.4 ± 5.27	25.7 ± 4.54	*0.07
Residence	Urban	(90) 522	(91.2) 529	**0.27
	Rural	(10) 58	(8.8) 51	
Delivery method	Vaginal	(19.4) 113	(16.7) 97	**0.13
	C-section	(80.6) 467	(83.3) 483	
Substance abuse (Yes)		(0.1) 10	(0.6) 4	**0.19
Family marriages (Yes)		(11.5) 67	(10.1) 59	**0.26
Maternal hypertension (Yes)		(13.4) 78	(11.3) 66	**0.16
Preeclampsia (Yes)		(22) 128	(24.3) 141	**0.20
Thyroid disorder (Yes)		(7.2) 42	(11) 64	****0.02**
Maternal diabetes	Diabetes mellitus	(1.5) 9	(1.5) 9	**0.64
	Gestational diabetes	(12.5) 73	(14.4) 84	
Other diseases (Yes)		(1.7) 10	(1.8) 11	**0.50
ART (Yes)		(12.7) 74	(15.3) 89	**0.12
History of infertility (Yes)		(14.6) 85	(17) 99	**0.15
History of IUFD (Yes)		(2.5) 15	(1.8) 11	**0.28

* Independent t-test

** Chi-square test

Table 2 Neonate characteristics across both groups before and after launch of the human milk bank

Variables		Human milk bank pre-launch group (n = 580) N (%)	Human milk bank post-launch group (n = 580) N (%)	P-value
Gender	Boy	354 (61)	332 (57.2)	**0.11
	Girl	226 (39)	248 (42.7)	
Gestational age	28–32 weeks (28w-31w + 6d)	453 (78.1)	438 (75.5)	***0.46
	24–28 weeks)24w-27w + 6d)	125 (21.5)	138 (23.7)	
	20–24 weeks (20w-23w + 6d)	(0.3) 2	(0.4) 4	
Birth weight	1500–2000 g	328 (56.5)	305 (52.5)	**0.40
	1000–1500 g	212 (36.5)	232 (40)	
	˂ 1000 g	(6.8) 40	(7.4) 43	
Apgar, Mean (SD)	Minute 1	5.37 (1.4)	5.13 (1.3)	***0.008**
	Minute 5	7.24 (1.01)	7.03 (1.04)	***0.001**
PROM	Healthy	481 (82.9)	485 (83.6)	***0.43
	˂ 18 h	85 (14.6)	75 (12.9)	
	> 18 h	(2.4) 14	(3.4) 20	
Antenatal corticosteroid therapy	nonuse	(5.1) 30	(3.2) 19	*****0.0001**
	Incomplete use	357 (61.5)	175 (30.1)	
	Complete use	193 (33.2)	386 (66.5)	
Meconium contamination		(4.4) 26	(4.4) 26	**0.55
Feeding method	MM	(5.1) 30	(4.6) 27	*****0.0001**
	F	48 (8.27)	(0.1) 1	
	DM	0	62 (10.6)	
	MM + F	494 (85.1)	(1) 6	
	MM + donor	0	479 (82.5)	
	Fasting	(1.3) 8	(0.8) 5	
CPR	Without ventilator	496 (85.3)	519 (89.4)	*****0.03**
	With ventilator	85 (14.6)	61 (10.5)	

*Mann-Whitney U test

**Chi-square tests

***Fisher's exact test

Discussion

This study aimed to compare the short-term neonatal outcomes of preterm neonates pre-launch and post-launch of human milk banks in Iran. The results showed that the NEC frequency in neonates pre-launch of human milk banks was twice the NEC frequency post-launch of human milk banks, but the comparison of NEC frequency showed no significant difference. Another study in Iran showed that the frequency of NEC Stage 2 or higher decreased significantly following adjustment of the effect of confounding variables post-launch of human milk banks ($P = 0.01$) [18]. The sample size in this study

Table 3 Univariate analysis of frequency distribution and percentages of neonatal outcomes in both groups before and after launch of the human milk bank

Variables		Human milk bank pre-launch group ($n=580$) *N* (%)	Human milk bank post-launch group ($n=580$) *N* (%)	*P*-Value*
NEC stage 2 or higher		(2) 12	(1) 6	0.11
LOS (Yes)		90 (15.5)	(13.7) 80	0.22
Mortality (Yes)		(7.5) 44	(3.1) 18	**0.002**
Feeding intolerance	0 or 1 interruption in feeding	160 (27.5)	178 (30.6)	0.14
	two or more interruptions in feeding	420 (72.4)	(69.3) 402	
Supplementary nutritional achievement	Mortality	(7.5) 44	(3.1) 18	**0.003**
	Dispatch	(2.4) 14	(1.7) 10	
	Over one month	102 (17.5)	(15.8) 92	
	Under one month	420 (72.4)	460 (79.3)	
Hospital discharge time	Unknown	(7.9) 58	(4.8) 28	**0.001**
	Over one month	115 (19.8)	(15.8) 92	
	Under one month	407 (70.1)	460 (79.3)	

* Fisher's exact test

Table 4 Results of the logistic regression model investigating the relationship between establishment of a human milk bank and NEC after adjustment of confounding variables

Variables		*P*-value	Adjusted odd ratio	95% CI	
				Lower bound	Upper bound
Groups	Prelaunch of human milk banks				
	Post-launch of human milk banks	0.998	1.00	0.13	7.65
Apgar 1		0.413	1.23	0.75	2.04
Apgar 5		0.497	0.78	0.39	1.58
Antenatal corticosteroid therapy	nonuse				
	Incomplete use	0.235	0.22	0.02	2.69
	Complete use	0.374	0.57	0.16	1.98
Feeding practices	MM				
	F	0.001	64.33	5.99	191.15
	DM	0.008	9.68	1.82	51.33
	MM + F	0.002	72.79	4.54	167.64
	MM + DM	0.000	683.95	57.62	118.08
	Fasting	0.000	267.48	24.27	2947.72
CPR	Without ventilator				
	With ventilator	0.408	1.78	0.46	6.90
Thyroid disorder	Yes				
	No	0.499	0.55	0.12	2.57

was three times larger than that in the Hosseini et al. study. In addition, this study examined neonatal outcomes for eight months which is a longer time period than six months compared to the study by Hosseini et al. [18].

In a clinical trial, Corpeleijn et al. [20] examined the effect of DM in the prime of 10 days of life in preterm neonates compared with formula in reducing serious infections, NEC, and mortality rates. The results showed that primary outcomes such as NEC were not significantly different between the two groups ($P=0.95$). One hypothesis for the lack of significance is the loss of bioactive components during DM pasteurization. Another hypothesis is the uniqueness of immune system factors such as immunoglobulin A in every mother and baby. NEC is the most serious gastrointestinal problem in neonates with LBW. In new evidence-based studies, an incidence of NEC of up to 20.7% has even been reported

Table 5 Results of the logistic regression model investigating the relationship between starting a human milk bank and LOS in preterm neonates after adjustment for confounding variables

Variables	Category	*P*-value	Adjusted odd ratio	95% CI	
				Lower bound	Upper bound
Groups	Prelaunch of the human milk bank group		1		
	Post-launch of human milk bank group	0.03	0.20	0.04	0.87
Apgar 1		0.25	0.92	0.79	1.06
Apgar 5		0.026	1.12	0.92	1.37
Antenatal corticosteroid therapy	Nonuse		1		
	Incomplete use	0.10	0.53	0.25	1.13
	Complete use	0.09	0.73	0.51	1.05
Feeding practices	MM	0.76	1.27	0.27	5.98
	F	0.72	1.33	0.29	6.12
	DM	0.41	0.43	0.06	3.24
	MM + F	0.16	2.77	0.68	11.32
	MM + DM	0.39	0.43	0.06	2.89
	Fasting		1		
CPR	Without ventilator		1		
	With ventilator	0.63	0.88	0.53	1.47
Thyroid disorder	Yes	0.16	0.69	0.41	1.16
	No		1		

Table 6 Results of the logistic regression model investigating the relationship between the launch of the human milk bank and FI in preterm neonates and adjustment for confounding variables

Variables		*P*-value	Adjusted odd ratio	95% CI	
				Lower bound	Upper bound
Groups	Prelaunch of the human milk bank group		1		
	Post-launch of human milk bank group	0.01	0.26	0.10	0.72
Apgar 1		0.17	0.92	0.82	1.04
Apgar 5		0.15	1.12	0.96	1.32
Antenatal corticosteroid therapy	nonuse		1		
	Incomplete use	0.82	0.92	0.47	1.81
	Complete use	0.00	0.65	0.49	0.86
Feeding practices	MM	0.00	55.52	5.95	17.518
	F	0.07	7.51	0.86	34.65
	DM	0.00	68.28	6.671	12.695
	MM + F	0.00	21.25	2.61	26.173
	MM + DM	0.00	80.12	8.34	11.770
	Fasting		1		
CPR	Without ventilator		1		
	With ventilator	0.73	1.07	0.73	58.1
Thyroid disorder	Yes	0.10	1.51	0.92	47.2
	No		1		

[24, 25]. In this study, NEC frequency was 2% pre-launch and 1% post-launch. Various factors can help prevent its occurrence. Of these, feeding practices for neonates are one of the most important ones. Feeding on a mix of MM + F enhanced the risk of developing NEC in neonates compared with neonates who were fed on MM only [24].

Comparing the frequency of LOS in preterm neonates pre- and post-launch of the human milk bank, the results showed that the blood and body fluid cultures of 90 babies were positive, while the figure dropped to 80 post-launch. The launch of the human milk bank reduced LOS in the postlaunch group.

LOS usually occurs within 72 h after birth and originates outside the body. In this type of sepsis, pathogens are transmitted from the environment to the neonate through intravenous catheters or invasive feeding practices. Preterm neonates are more exposed to sepsis because of a variety of reasons such as weak immune systems or exposure to invasive therapy. Many believe that MM protects babies against sepsis because it contains bioactive components with bactericidal and immunogenic properties. DM is a suitable option for mothers who are unable to breastfeed their babies. Notably, DM is pasteurized to prevent the transmission of pathogens from the donor to the neonate [24, 25].

A similar study by M. Hosseini et al. [18] reported a significant difference in the onset of sepsis in neonates ($P=0.003$) with a reduced risk of LOS by 70.3% after the launch of human milk banks. Another study reported no effect of DM in preventing serious infections in preterm neonates in the first 10 days of life. The lack of significance was explained by the possible destruction of bioactive and immunogenic components in DM during pasteurization [20].

One of the most significant objectives of this study was to investigate the mortality rate in preterm neonates pre- and post-launch of the human milk bank. The mortality rate decreased significantly 72 h after birth post-launch ($P=0.002$). Human milk provides infants with nutrients and immunity, which can lead to protective effects against diseases. Although the most neonates who are hospitalized are unable to breastfeed due to prematurity or complications associated with it [9], breastfeeding also reduces the sudden infant death syndrome (SIDS[23]) by 73% [26]. Fortunately, in this study, using DM as the best substitute for MM significantly reduced neonatal mortality rates.

No significant difference was reported by Hosseini et al. [18] in neonatal mortality 72 h after birth pre- and post-launch of the human milk bank, although the mortality rate dropped from 15 cases in the first group to 8 in the second group. A meta-analysis study by Li et al. [22] of five papers on the role of DM in reducing neonatal mortality rates showed that, overall, DM does not play a significant role in reducing neonatal mortality [22]. Nevertheless, since neonates were mainly fed with MM and DM post-launch, the change in feeding practices may be a good justification for reduced mortality rates post-launch of the human milk bank.

The frequency of FI was examined pre- and post-launch because it is a significant neonatal outcome in preterm neonates. The volume remaining in the stomach is the most significant sign of FI and is generally manifested in preterm neonates by vomiting and abdominal distention. The best management is to interrupt oral nutrition [27]. FI in neonates was examined in this study by interrupting feeding twice or more during hospitalization. In the pre-launch period, feeding was interrupted twice in 420 neonates, whereas this was carried out in 402 neonates post-launch. After adjustment for the effect of confounding variables, the results showed that the launch of the human milk bank reduced FI by 74% in the post-launch group ($P=0.01$).

[23] SIDS: Sudden infant death syndrome.

Fang et al. reported that feeding was interrupted significantly less in the DM group ($P=0.0001$). The results of the study are consistent with those of the present study [28].

A comparison of the time neonates achieved full supplementary nutrition (150 ml/kg/day) pre- and post-launch showed that of the 580 examined neonates 420 achieved supplementary nutrition in the pre-launch group before one month. This figure increased to 460 neonates in the post-launch group ($P=0.003$), showing a significant rise in the number of neonates achieving supplementary nutrition earlier in the post-launch group. In a similar study by S. Vazquez-Roman et al., it was reported that the median for enteral feeding in preterm neonates post-launch was 31 h earlier, and supplementary nutrition of 100 ml/kg/day and 150 ml/kg/day was achieved much more rapidly. Another study reported that the median time to achieve nutrition of 120 cc/kg/day was 11 days in the F group and 10 days in the DM group. The results of both studies were consistent with those of the present study [20, 21].

Hospitalization times of less than 1 month in the NICU for neonates pre- and post-launch of the human milk bank were also compared. In the pre-launch period, 407 neonates remained in the NICU for less than one month, whereas the figure rose to 460 neonates post-launch, showing a significant difference ($P=0.0001$). In a prospective study, Fang et al. [28] concluded that neonates fed on DM spent less time in the NICU ($P<0.05$) [28]. It cannot be disregarded that a range of factors affect the duration of hospitalization in NICU. It is possible that a number of neonates in this study were discharged from the hospital with parental consent. However, using DM from the human milk bank can be considered a factor in improving neonatal outcomes and, consequently, the earlier discharge of neonates in this study.

Limitations and suggestions for future research

A limitation of this study was that there may have been influential factors affecting NEC and FI that were not examined and interpreted in the results. In addition, it must be noted that certain neonates were discharged with parental consent and this may not have been due to reduced outcomes and recovery. It is recommended to compare the long-term neonatal outcomes in preterm neonates before and after the launch of the human milk bank.

Conclusion

The results demonstrated that the most significant variable in examining neonate characteristics was feeding practice, including the three methods of feeding with MM, F, and a combination of MM + F. During the post-launch period of the human milk bank, the use of formula was extensively limited in this hospital and substituted with DM from the human milk bank. Thus, neonates were fed mainly MM, DM, and mixed MM + DM. Assessing the results of the short-term neonatal outcomes as the main research objective also demonstrated that there were 12 cases of NEC pre-launch of the human milk bank at Shahid AkbarAbadi Hospital, while this figure dropped to 6 cases post-launch, but this was not statistically significant. LOS decreased by 80% post-launch and neonatal mortality dropped significantly. FI decreased by 74% and the number of neonates who achieved full supplementary nutrition under one month rose significantly from 72 to 79%. In addition, the number of neonates who were discharged before one month rose from 407 to 460, showing a significant increase. Using the results of this study, it is recommended to raise awareness, promote, and educate more lactating mothers to donate milk. National policy-making must also focus more on launching human milk banks.

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Author contributions
N.H. and S.M. designed the study. L.A.F., S.M., N.H. and A.K. analyzed and interpreted the data. N.H, S.M, M.S and L.A.F. made interpretations, and wrote and revised the paper.

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Data availability
All the information obtained from this study is not available to the public due to the confidentiality of the information, but it can be made available upon reasonable request through the Corresponding author.

Declarations

Ethics approval and consent to participate
The research project was confirmed by the Ethics Committee of the Iran University of Medical Sciences, Tehran, Iran, with the ethics code of (IR.IUMS.REC.1401.175) and blanket consent was obtained from the university and hospital for accessing and utilizing patient data for this study. also This research adhered to the principles set forth in the Declaration of Helsinki.

Competing interests
The authors declare no competing interests.

Consent for publication
Not applicable.

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