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PROSPECTIVE OBSERVATIONAL STUDY ON PREVALENCE OF IRON-DEFICIENCY (ID) / IRON DEFICIENCY ANEMIA (IDA) IN EXCLUSIVELY BREAST-FED TERM INFANTS UNDER 14 WEEKS OF AGE

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Abstract

Background & Objectives: There is paucity of data in IDA in infants less than 4 months of age. Therefore, it is a felt need to investigate Iron Deficiency/Iron Deficiency Anemia in Indian infants under 14 weeks of age and explore the feasibility of early iron supplements in term breastfed babies.

Method: 300 pregnant mothers enrolled (at the time of term delivery), after written and informed consent, 234 infants were investigated at 6 weeks, 209 at 10 weeks, 163 at 14 weeks of age. Samples were taken at baseline (cord blood), 6 weeks, 10 weeks, and 14 weeks i.e. at the time of vaccination and screened for Hb, MCV, Serum ferritin, Serum Iron, TIBC. A single blood sample (around 3 ml) taken for CBC, Serum Ferritin, Serum Iron, and TIBC from pregnant mothers.

Results: In this study although the hematological parameters do change from their cord blood i.e. baseline level to 14th week but they are found to be within normal limits. Serum ferritin levels dropped from 282.01 µg/L at baseline to 156.99 µg/L at 14 weeks. Serum iron levels initially reduced from cord blood level of 163.04 µg/dl to 101.29 µg/dl at 6 weeks but then increased slightly to 112.99 µg/dl by the end of 14 weeks. TIBC levels showed consistent rise from 271.21 µg/dl at baseline to 404.53 µg/dl at 14 weeks.

Conclusion: Results shows that exclusively breast-fed infants born to mothers who got iron supplementation in ante-natal period do not become anemic or iron deficient by 14 weeks of age. It would be wise to supplement iron from 4th month of infancy onwards.

Key words: Iron-deficiency anemia, Neonate, Infant, Iron supplement

INTRODUCTION

Iron deficiency is the most prevalent micronutrient deficiency around the globe according to World Health Organization[1]. Iron deficiency leads to decreased level of hemoglobin which finally leads to anemia. Iron deficiency during infancy or childhood may is not just related to development of anemia but is responsible for a long list of other manifestations especially in infancy and early childhood.

In 2021, global anemia prevalence was[1] –

- 29.9% in women of reproductive age, equivalent to over half a billion women aged 15-49 years.

- 39.8% in children aged 6-59 months, equivalent to 269 million children with anemia.

As per National Family Health Survey-4 (NFHS-4) prevalence of anemia is 58 % among pregnant women and much higher reaching almost 70 per cent among children under 3 years of age [2]. The most common reason for anemia across all ages is iron deficiency. Iron deficiency (ID) in infancy has long term effects that lead to poorer cognitive, motor, and social-emotional function, as well as persisting neurophysiologic differences. Children with iron deficiency may manifest low intelligent quotient scores, even before the development of anemia.[3]

Iron requirements are at their highest during the first 1000 days of life. They increase almost 10-fold during pregnancy, increasing from 0.8 mg/d in the first trimester to about 7.5 mg/d in the third trimester.[4] The newborn's iron status may depend on the pregnant woman's iron status. At delivery, there is a correlation between the mother's and the newborn's serum ferritin.[5]

Milman et al 1999 [5] while studying iron supplementation found that between iron-treated pregnant women and placebo treated pregnant women, the former shows higher Hb levels, higher iron stores and a lower prevalence of iron deficiency anemia during pregnancy as well as postpartum period. Similarly, children born to iron-treated mothers have shown higher serum ferritin levels compared to those born to placebo-treated mothers.[5] Another important determinant of the newborn's iron status is the amount of blood transfused from the placenta before the clamping of the umbilical cord. [6]

There is evidence in favor of screening for iron deficiency and using iron supplementation for pediatric neurodevelopmental disorders (primarily from ADHD studies). [7]

Organization of The United Nations (FAO) states that: 'Iron requirements in the second and third trimesters cannot be satisfied by dietary iron alone, even if it is of high bioavailability and, unless stores of about 500 mg are believed to exist before pregnancy, administration of iron supplements may be indicated if impairment of the expected increase in hemoglobin mass in the mother is to be avoided' [8] Neonates who are exclusively breast fed are more at risk of iron deficiency in view of low iron content of breast milk. [9]

The Government of India (GOI) intensified national iron plus initiative (I-NIPI) recommends routine iron supplementation starting at 6 months and beyond. [10]

American academy of Pediatrics (AAP) recommends iron supplementation from 4 months age assuming maternally transmitted iron stores will be sufficient in the first 4 months, however in the population with high prevalence of iron deficiency this may not hold true and the infant may be iron deficient even before 4 months. [11]

There has been controversy about the adequacy of breast milk in maintaining optimum iron status of exclusively breastfed babies. Studies have shown that infants having low iron stores at birth (less than 75 µg/dl) may develop cognitive and neuro-developmental disorders which persist even after correction of iron deficiency.[3] WHO in the 54th World Health Assembly, had expressed concern that some infants exclusively breastfed for 6 months may become iron deficient. [12]

The concept of fetus as "perfect parasite" wherein fetus would be able to acquire sufficient iron even in the face of mild-to-moderate maternal anemia has been challenged and there is enough evidence that fetal iron needs will be compromised when maternal iron stores are suboptimal. Suboptimal iron stores at birth are associated with long-term, irreversible cognitive deficits in the offspring. A cord ferritin concentration <76 mg/L have been associated with impaired language ability, tractability, and fine motor skills in children subsequently studied at 5 years of age. [13]

The iron endowment at birth is also critical in insuring that the neonate maintains iron stores over early infancy because the neonatal gut is developmentally immature and may not regulate iron absorption in response to iron stores until 6–9 months of age. Even in developed countries, full-term infants with low cord ferritin concentrations have low serum ferritin concentration at 9 months of age. [14]

The adequacy of breast milk for iron levels fall as lactation progresses over time.[15] Greater attention on relationships between maternal iron status and neonatal iron stores is needed, particularly since new data indicate that infants whose mothers were anemic during pregnancy have been found to be more than twice as likely to have an abnormal laboratory indicator of iron status at 9 months of age in comparison with infants born to non-anemic women. Assessment of iron status in neonates is challenging; there are few normative data because universal screening for anemia is considered unwarranted, and venipuncture is not routinely undertaken among healthy newborns.

There is paucity of data in IDA in infants less than 4 months of age. Therefore, it is a felt need to investigate Iron Deficiency/Iron Deficiency Anemia in Indian infants under 14 weeks of age and explore the feasibility of early iron supplements in term breastfed babies.

MATERIAL & METHODS

STUDY POPULATION AND STUDY DESIGN: This prospective observational study was conducted in the department of Pediatrics Command Hospital (Central Command), Lucknow, a tertiary care, referral and teaching hospital for a period of one year from April 2021 to March 2022. All the mother and infants who fulfilling the eligibility criteria in the Command Hospital during this period were recruited in the study after written informed consent. Permission for the study was granted from the Institutional Ethics Committee.

- **Inclusion criteria**:
  1. POG (Period of gestation) >/=37 weeks
  2. Birth weight >/=2500gm
  3. Exclusively breastfed neonates (Exclusive breastfeeding was defined as per WHO guidelines as, 'no other food or drink, not even water, except breast milk (including milk expressed or from a wet nurse), for 6 months of life, the exceptions being oral rehydration solution, drops and syrups vitamins, minerals and medicines)'
  4. Written and informed consent.
- **Exclusion criteria:**
  1. Unwilling for consent
  2. Multiple gestation
  3. Contraindication of breast feeding
  4. Medical /Surgical condition precluding breast feeding
  5. Sick infants, infants with other cell line involvement

METHODOLOGY:

- A written and detailed consent was obtained from parents. Socio-demographic factors such as name of the parents, age of mother etc. were noted.
- All the eligible mothers at their third trimester were enrolled for the studies. Age, LMP (Last Menstrual Period), EDD (Expected Date of Delivery), POG (Period of Gestation), Parity, Spontaneous/ assisted, ANC (Ante natal check-up) details regarding co morbidities, H/O Iron supplementation during antenatal period were recorded.

SAMPLE COLLECTION:

- The pregnant mothers at the time of term delivery were enrolled for the study.
- A written informed consent was taken.
- A single blood sample (around 3 ml) taken for CBC, Serum Ferritin, Serum Iron, and TIBC
- Cord blood samples for above parameters at the time of delivery was taken.
- Their infants born at ≥37 weeks gestation and birth weight≥2500gm were included in the study.
- Infants sampled for above parameters at 6 weeks, 10 weeks, and 14 weeks i.e. at the time point of immunization.1.5 ml of blood drawn at each time point.

SAMPLE SIZE CALCULATION: To estimate the prevalence of IDA in infants with 95% confidence, a prevalence of 15% with a precision error of 5% was assumed. The estimated sample size was 196. A greater number of pregnant females (n=300) and infants (n=300) will be enrolled to account for elimination due to exclusion criteria, loss to follow up and sample storage issues.

The sample will be calculated on the basis of prevalence using the formula

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Z is the statistic corresponding to level of confidence,
P is expected prevalence
d is precision (corresponding to effect size).

Sample size calculation:

Assumptions:
Precision = 5.0% (0.05)
Prevalence = 15.0% (0.15)
Population size = Infinite (0)
Z=1.96
Estimated sample size:
n = 196

STATISTICAL TOOLS USED:

Analysis was done using Statistical Package for Social Sciences (SPSS) version -23. Categorical variables were presented in number and percentage and continuous variables were presented as mean and SD (Standard Deviation). Quantitative variables were presented using one way ANOVA among more than two groups. To measure the strength of relationship between 2 scale parameter using Pierson co-relation co-efficient. Quantitative variables were compared using chi-square test/ fisher exact test as appropriate. P value of <0.05 was considered statistically significant.

RESULTS:

This was an observational prospective study, conducted at command hospital, Lucknow, a tertiary care hospital located at central India. A written and informed consent was taken from expectant mothers. Demographic details were entered. Blood samples collected from mothers. Cord blood samples taken at the time of delivery of the babies for various laboratory parameters.

As vaccination is available at nearby PHCs, the no. of infants reporting for vaccination and so the no. of samples collected decreased over time. Some mothers couldn't breastfeed exclusively and shifted to formula feeds or other feeding practices. (300 mothers enrolled, after written and informed consent, 234 infants were investigated at 6 weeks, 209 at 10 weeks, 163 at 14 weeks of age.)

Samples were taken at baseline (cord blood), 6 weeks, 10 weeks, and 14 weeks i.e. at the time of vaccination. Results of blood tests and subsequent statistical analysis has been written below.

Table 1: Period of Gestation of Mothers

Mothers at the time of admission were enrolled for the study after written and informed consent**.** Mothers enrolled for the study had period of gestation >/=37 weeks.

	Mean	SD	Median	Percentile 25	Percentile 75	Valid N
POG	38.17	1.18	38.00	37.20	39.00	300

Table 1 shows that mean of Period of Gestation among mothers was 38.17±1.18 and median was 38.

Table 2: Laboratory Parameters of Mothers

Below table shows laboratory parameters of mothers enrolled for study. Almost all the mothers were booked cases, and had iron supplementation received during antenatal period.

	Mean	Standard Deviation	Valid N
Hb of Mother	11.38	.87	300
MCV	86.16	6.16	300
Serum Ferritin	95.48	109.61	300
Total Iron	85.28	44.18	300
TIBC	490.35	132.25	300

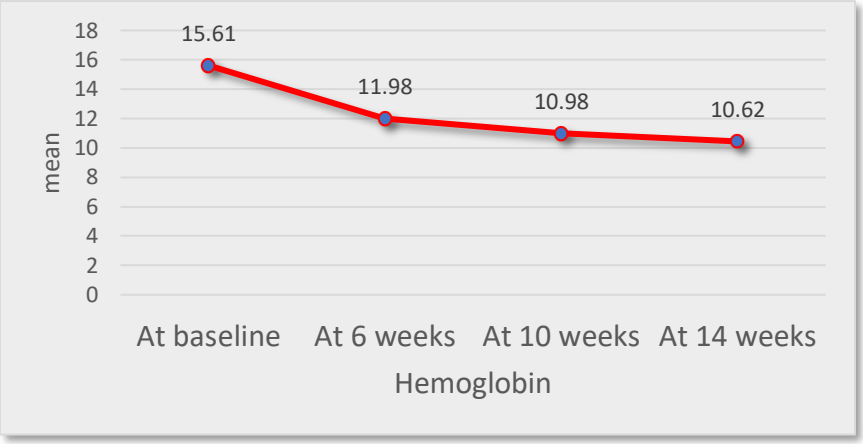
Table 2 shows the mean ± standard deviation of clinical parameters of mother. Hemoglobin of mother was 11.38±0.87 g/dl, MCV was 86.16±6.16 fL,

Serum Ferritin was 95.48±109.61 µg/L, total iron was 85.28±44.18 µg/dl, TIBC was 490.35±132.25 µg/dl.

Table 3: Haemoglobin of Baby

Cord blood sample was taken at the time of delivery, followed by the time of vaccination at 6th week, 10th week and 14th week. Following table shows the trend of hemoglobin level right from baseline to 6, 10, and 14 weeks**.**

Hb	Mean	Standard Deviation	Valid N
At baseline	15.61	1.97	300
At 6 weeks	11.98	1.15	234
At 10 weeks	10.98	1.15	209
At 14 weeks	10.62	1.19	163



The above table shows the haemoglobin of study population on bounded intervals of baseline, six weeks, ten weeks and fourteen weeks. On baseline, the mean haemoglobin of patients was 15.61±1.97 g/dl. Followed by six weeks, mean was 11.98±1.15 g/dl and at 10 weeks, mean was 10.98±1.15 g/dl. In the end, mean on week 14, mean was 10.62±1.19 g/dl.

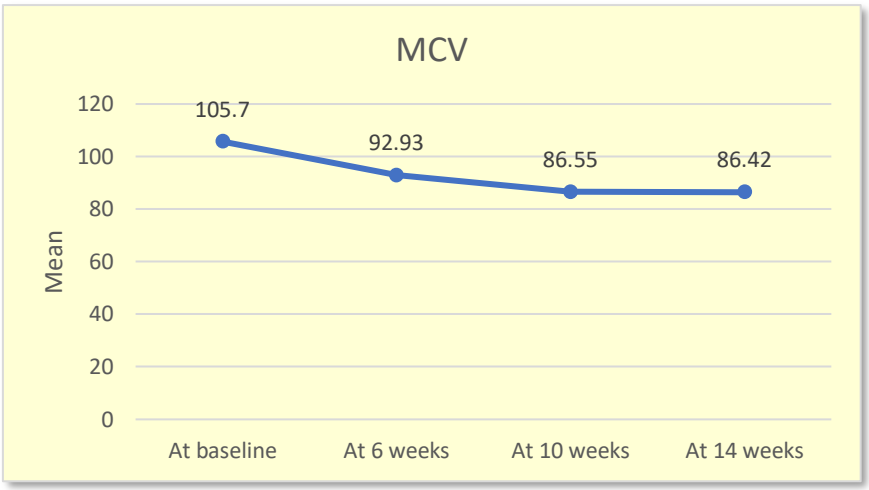
	Mean	N	Std. Deviation	% mean change	p-value
At baseline	15.66	234	1.97	23.51%	**<0.001**
At 6 weeks	11.98	234	1.15		
At baseline	15.58	209	2.02	29.53%	**<0.001**
At 10 weeks	10.98	209	1.15		
At baseline	15.51	163	2.06	32.70%	**<0.001**
At 14 weeks	10.44	163	1.19		

This table shows the pair wise analysis of haemoglobin of study population. The decrease of haemoglobin was subsequent in all the three pairs. When haemoglobin at baseline and 6 weeks were analyzed, a significant mean difference was found (p value= <0.001) and % mean change was 23.51%. Haemoglobin at baseline and 10 weeks also shows a significant change (p value= <0.001%) of 29.53%. The prime change was observed when baseline versus 14 weeks was followed; the % mean change was 32.70% with a significant difference (p value=<0.001).

Table 4: Mean Corpuscular Volume (MCV) of Baby

MCV of the samples at baseline, 6 weeks, 10 weeks and 14 weeks. The decrease in MCV value was noted in all 4 samples.

MCV	Mean	Standard Deviation	Valid N
At baseline	105.70	11.69	300
At 6 weeks	92.93	5.14	234
At 10 weeks	86.55	6.31	209
At 14 weeks	86.42	6.53	163



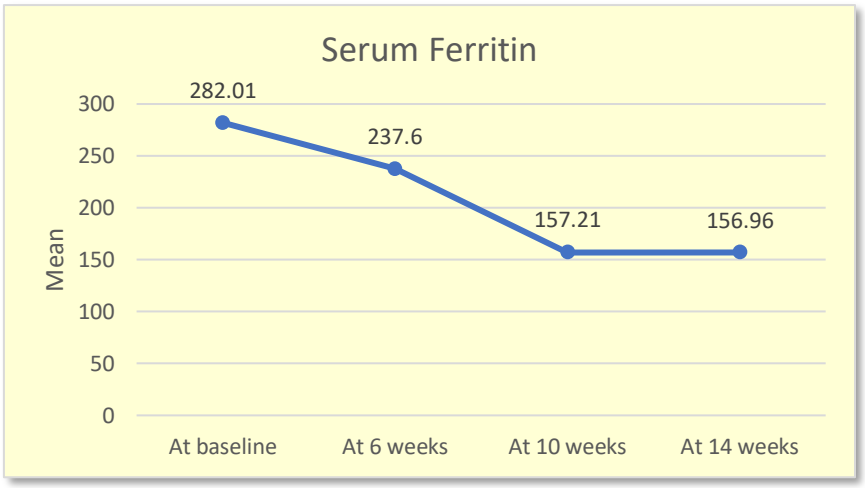
The above table shows the MCV of study population on bounded intervals of baseline, six weeks, ten weeks and fourteen weeks. On baseline, the mean MCV of patients was 105.70±11.69 fL. Followed by six weeks, mean was 92.93±5.14 fL and at 10 weeks, mean was 86.55±6.31 fL. In the end, mean on week 14, mean was 86.42±6.53 fL

MCV	Mean	N	Std. Deviation	% mean change	p-value
At baseline	105.94	234	11.27	12.28%	**<0.001**
At 6 weeks	92.93	234	5.14		
At baseline	105.48	209	11.69	17.94%	**<0.001**
At 10 weeks	86.55	209	6.31		
At baseline	105.99	163	10.70	18.47%	**<0.001**
At 14 weeks	86.42	163	6.53		

Table shows the pair wise analysis of MCV of study population. The decrease of MCV was uninterrupted in all the three pairs. When MCV at baseline and 6 weeks were analyzed, a significant mean difference was found (p value= <0.001) and % mean change was 12.28%.
MCV at baseline and 10 weeks; also shows a significant change (p value= <0.001) of 17.94%. The prime change was observed when baseline versus 14 weeks was followed; the % mean change was 18.47% with a significant difference (p value=<0.001).

Table 5: Serum Ferritin of Baby
Serum ferritin level of the baby at the time of birth (cord blood) ie baseline and at 6th, 10th, and 14th week at the time of vaccination. All the values further compared to the baseline. A decline in serum ferritin level is noted in all 4 samples, but iron deficiency was not present**.**

Serum Ferritin	Mean	Standard Deviation	Valid N
At baseline	282.01	341.11	300
At 6 weeks	237.60	120.21	234
At 10 weeks	157.21	65.98	209
At 14 weeks	156.96	67.27	163



The above table shows the Serum Ferritin of study population on bounded intervals of baseline, six weeks, ten weeks and fourteen weeks. On baseline, the mean Serum Ferritin of patients was 282.01±341.11 µg/L. Followed by six weeks, mean was 237.60±120.21 µg/L and at 10 weeks, mean was 157.21±65.98 µg/L. In the end, mean on week 14, mean was 156.96±67.27 µg/L.

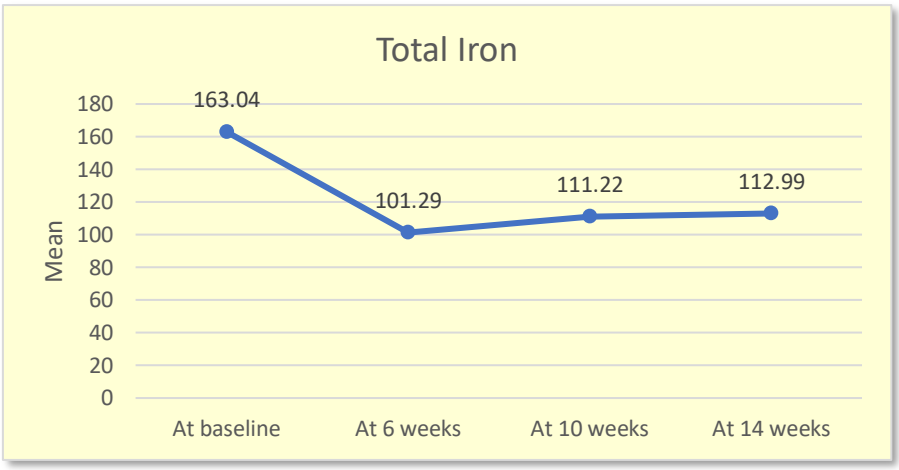
Serum Ferritin	Mean	N	Std. Deviation	% mean change	p-value
At baseline	269.00	234	322.51	11.67%	0.163
At 6 weeks	237.60	234	120.21		
At baseline	266.45	209	319.64	41.00%	**<0.001**
At 10 weeks	157.21	209	65.98		
At baseline	255.39	163	303.85	38.54%	**<0.001**
At 14 weeks	156.96	163	67.27		

Table shows the pair wise analysis of Serum Ferritin of study population. The decrease of Serum Ferritin was consequent in all the three pairs. When Serum Ferritin at baseline and 6 weeks were analyzed, there was no significant mean difference found (p value= 0.163) and % mean change was 11.67%. Serum Ferritin at baseline and 14 weeks; also shows a significant change (p value= <0.001) of 38.54%. The prime change was observed when baseline versus 10 weeks was followed; the % mean change was 41% with a significant difference (p value=<0.001).

Table 6: Total Iron of Baby

Total iron concentration was measured in cord blood ie baseline, 6, 10, and 14 weeks samples and further compared to the baseline. A decrease in total iron concentration was noted in all 3 pairs.

Total Iron	Mean	Standard Deviation	Valid N
At baseline	163.04	92.45	300
At 6 weeks	101.29	30.34	234
At 10 weeks	111.22	31.76	209
At 14 weeks	112.99	31.35	163



The above table shows the total iron of study population on bounded intervals of baseline, six weeks, ten weeks and fourteen weeks. On baseline, the mean total iron of patients was 163.04±92.45 µg/dl Followed by six weeks, mean was 101.29±30.34 µg/dl and at 10 weeks, mean was 111.22±31.76 µg/dl. In the end, mean on week 14, mean was 112.99±31.35 µg/dl.

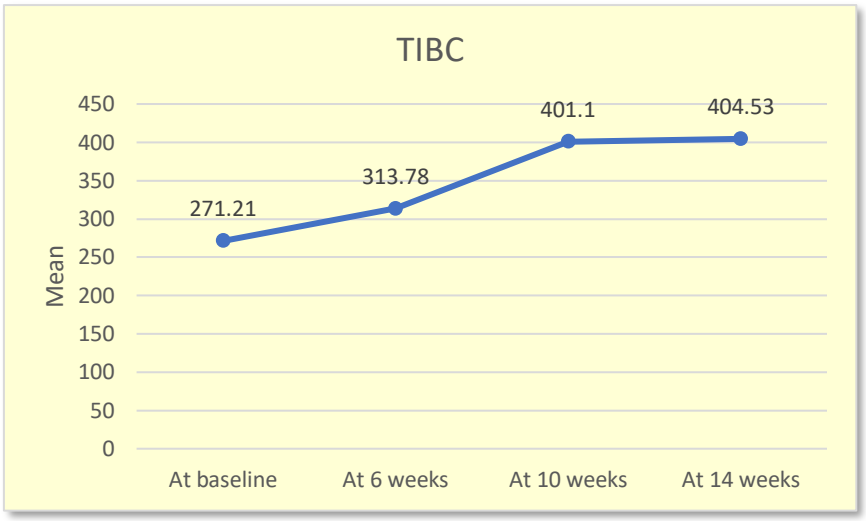
Total Iron	Mean	N	Std. Deviation	% mean change	p-value
At baseline	164.38	234	100.08	38.38%	**<0.001**
At 6 weeks	101.29	234	30.34		
At baseline	165.00	209	104.50	32.59%	**<0.001**
At 10 weeks	111.22	209	31.76		
At baseline	168.20	163	112.55	32.82%	**<0.001**
At 14 weeks	112.99	163	31.35		

Table shows the pair wise analysis of total iron of study population. The decrease of total iron was following in all the three pairs. A huge change was observed when mean total iron at baseline and 6 weeks were analyzed, there was a significant mean difference found (p value= <0.001) and % mean change was 38.38%. Total iron at baseline and 10 weeks; also shows a significant change (p value= <0.001) of 32.59%. When baseline versus 14 weeks was followed; the % mean change was 32.82% with a significant difference (p value=<0.001).

Table 7: TIBC of Baby

Total Iron Binding Capacity was measured at baseline 6, 10, and 14 weeks and was further compared to the baseline in paired samples.

TIBC	Mean	Standard Deviation	Valid N
At baseline	271.21	93.68	300
At 6 weeks	313.78	86.41	234
At 10 weeks	401.10	92.13	209
At 14 weeks	404.53	95.08	163



The above table shows the TIBC of study population on bounded intervals of baseline, six weeks, ten weeks and fourteen weeks. On baseline, the mean TIBC of patients was 271.21±93.68 µg/dl. Followed by six weeks, mean was 313.78±86.41 µg/dl and at 10 weeks, mean was 401.10±92.13 µg/dl. In the end, mean on week 14, mean was 404.53±95.08 µg/dl.

TIBC	Mean	N	Std. Deviation	% mean change	p-value
At baseline	269.16	234	92.65	-16.58%	**<0.001**
At 6 weeks	313.78	234	86.41		
At baseline	271.26	209	96.27	-47.86%	**<0.001**
At 10 weeks	401.10	209	92.13		
At baseline	272.60	163	90.36	-48.40%	**<0.001**
At 14 weeks	404.53	163	95.08		

Table shows the pair wise analysis of TIBC of study population. The increase of TIBC was subsequent in all the three pairs. A change was observed when mean TIBC at baseline and 6 weeks were analyzed, there was a significant mean difference found (p value=< 0.001) and % mean change was -16.58%. There was a change observed when TIBC was analyzed with baseline and follow-ups of 10 and 14 weeks; the % mean change was -47.86% (p value =<0.001) and -48.40% (p value =<0.001) respectively.

Table 8: Correlation of hemoglobin, serum ferritin and total iron of baby at baseline with Mother

Correlations			
		Hb Mother	HB baby
Hb Mother	Pearson Correlation	1	.104
	Sig. (2-tailed)		.073
	N	300	300
		Serum Ferritin of mother	Serum Ferritin of baby
Serum Ferritin of mother	Pearson Correlation	1	.069
	Sig. (2-tailed)		.232
	N	300	300
		Total Iron of mother	Total Iron of baby
Total Iron	Pearson Correlation	1	-.061
	Sig. (2-tailed)		.292

	N	300	300

Table above shows the Correlation of hemoglobin, serum ferritin and total iron of mother with the baby at baseline. There was no significant difference found when the above stated parameters were associated. Hemoglobin (Pearson Correlation = 0.104) and serum ferritin (Pearson Correlation = 0.069) was positively corelated with the mother's but total iron shows a negative correlation when co-related (Pearson Correlation = -0.061).

DISCUSSION

ID is one of the most prevalent nutrient deficiencies in the world.[1] It is intriguing to note that iron supplementation is recommended at 4 months of age in the USA, while the same is not followed in India, despite a greater prevalence of IDA in the population. One major reason is the limitation of Indian studies that have evaluated the prevalence of ID in breastfed infants prior to 6 months of age.

There has been controversy about the adequacy of breast milk in maintaining optimum iron status of exclusively breastfed babies. WHO in the 54th World Health Assembly, had expressed concern that some infants exclusively breastfed for 6 months may become iron deficient. [12]

The have been studies in the past which addressed the issue of whether iron supplementation before 6 months of age is reasonable or not. Earliest studies have supported the theory that breast milk is sufficient for all iron demand in the infant up to 6 months like Owen et al. 1981[16] who found that infants breastfed until 20 weeks of life, had sufficient iron stores at 6 months of age, or even up to an year like McMillan et al 1976 [17] who reported that reported that term breastfed infants did not need supplemental iron until the birth weight tripled, which occurred at about 12 months of age.

But recent studies have shown different scenario where many studies have advocated for possibilities of iron deficiency with or without anemia developing in three- to four-month-old breast-fed infants without iron supplementation. Most studies were related to four-month-old infants like in Turkey, Arvas A et al 2000 [18] found out that significant iron deficiency and iron deficiency anemia have been found in four-month-old exclusively breast-fed full-term infants. In this study 116 term infants were followed up with formation of two groups A and B in which group A was given supplementary food beside breast milk and group B gets ferrous sulfate (1mg/kg/d). After 6 months 45% infants from group A became iron deficient while only 7% infants from group B became iron deficient. It was observed that complementary food alone is insufficient; there is need for iron supplementation.

Mohamed Cherif Rahimy et al 2007 [19] while studying the efficacy of oral ferrous fumarate for prevention of iron deficiency in infants of Benin Africa found similar results. Two groups of infants, group 1 (n = 252) of 4-month-old healthy infants and group 2 (n = 360) comprising 6–10-month-old infants were studied during their vaccination visits at primary health care (PHC) centers. Ninety-six pregnant women (PW) over 36 weeks gestational age attending the same PHC during the study period were also studied. Infants were offered 2 months supplementation with oral powdered generic ferrous fumarate (GFF), that is, 5 mg/kg/day of elemental iron, given twice and were reevaluated 2 months later for hematological indices. The prevalence of anemia was 42.0%, 61.9%, and 37.5% in groups 1, 2, and PW, respectively. All anemic pregnant women were found to be iron deficient.

In India Kashyap et al 2020 [20] reported that infants after 3 months, should be evaluated for anemia and iron deficiency and should be supplemented with oral iron in addition to exclusive breast feeding for 6 months. For this study 110 infants (65 males and 45 females) were enrolled with mean age 4.5 month (35, 47 and 28 babies belonging to 3-4, 4-5 and 5-6 months respectively). Mean Hb was 9.9 mg/dl. Median Hb was 9.6 mg/dl. A total of 92 children had anemia as per WHO criteria of <11 gm% of Hb, giving a prevalence of anemia of 83.64%. However, if we take 10.5 mg% as cut off value 85 (77.27%) had anemia. Out of 92, 31 (88.57%) babies with age of 3-4 months, 40 (85.11%) aged 4-5 months and 21 (75%) aged 5-6 months had anemia. Out of 92, 62 males and 30 females were anemic.

Krishnaswamy et al 2017 [9] also suggested iron supplementation from 4th month of age instead of the usual 6th months onward national plan. Their study evaluated 215 predominantly breastfed infants aged 3 to 6 months for Iron deficiency. The prevalence of ID at 3rd, 4th and 5th months of age was 5.4%, 21.4% and 36.4%, while that of IDA was 4.6%, 16.7% and 11.4%, respectively. The mean Hb was 10.8 (±1.2) g/dl. The median serum ferritin was 44 µg/L (18-120).

There is a need to establish strong reason in favor of or against screening for iron deficiency or iron supplementation from 3- to 4-month-old breast-fed infants.

In this study although the hematological parameters do change from their cord blood i.e., baseline level to 14th week but they are found to be within normal limits. Serum ferritin levels dropped from 282.01 µg/L at baseline to 156.99 µg/L at 14 weeks. Serum iron levels initially reduced from cord blood level of 163.04 µg/dl to 101.29 µg/dl at 6 weeks but then increased slightly to 112.99 µg/dl by the end of 14 weeks. TIBC levels showed consistent rise from 271.21 µg/dl at baseline to 404.53 µg/dl at 14 weeks. Thus, it shows that exclusively breast-fed infants born to mothers who got iron supplementation in ante-natal period do not become anemic or iron deficient by 14 weeks of age.

CONCLUSION

This study shows that it would be wise to supplement iron from 4th month of infancy onwards. Although this study has taken into account mostly affluent or well-informed mothers thus a better understanding of actual prevalence of iron deficiency would need a bigger and more evenly distributed group of mothers.
It is crucial to run similar trials with a larger sample size in different regions of India. If similar results are observed, it would be reasonable to recommend iron supplementation at 4 months (as already recommended by AAP in the USA), instead of the current common practice of 6 months, in predominantly breastfed, 'healthy babies.

Limitations of the study: There are a few limitations of our study. It was conducted only on the population residing in the northern part of India. It is a time-bound single-center study conducted on a small sample size. However, additional studies with larger sample sizes and with different ethnic population groups are needed to further validate our study findings.

DECLARATIONS

Conflicts of interest: There is no any conflict of interest associated with this study

Consent to participate: There is consent to participate.

Consent for publication: There is consent for the publication of this paper.

Authors' contributions: Author equally contributed the work.

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