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Introduction

This study is based on preterm infants that are born within 37 weeks of gestational age. These infants contain very low iron capacity. During their postnatal period there might be deficiency of iron if it is not expanded from birth. The standard measure is to supply iron in these infants during the time of 6 to 8 weeks of age. (John & Mark, 2012) During this period, supplementation of iron is unnecessary as no active erythropoiesis is present. As this erythropoiesis is build up, the insufficient iron stores might get exhausted. This is normally followed by decline in the tissue iron that could lead to biochemical defects such as collagen and synthesis of DNA. A matured preterm brain is susceptible to effects of iron shortage. The iron shortage might also affect the functioning of organ systems such as Heart and skeletal muscle. (Williams, 1975) The previous studies conducted on early iron supplementation produce differing results. This study is designed on random basis to evaluate whether 14 days of life in VLBW can enhance their iron stores at the age of 60 days.

Study Design

This research was conducted from May 2006 till November 2006 at neonatal unit in India. The preterm infants weighing less than 1500 g and qualified minimum 100 mL/kg/day oral feeds within 14 days were entitled for participation in the study. (Edmond, 2006) Infants

containing anomalies disease were not included. The enrollment process includes written consent made from the parents. The approval of study was made from ethics committee of the institution.

Research Methodology

Randomized Controlled Trials

The enrolled neonates were allocated randomly to control group or early iron on fourteen day life using random computer generated sequence numbers. The laboratory personnel were wearing masks for treatment purpose. The infants were started on oral iron in dosage of 4mg/kg/day for births weighing less than 1000 g or 3 mg/kg/day for births weighing between 1000-1500 g. (Friel & Andrews, 2005)

The daily mixture of iron was maintained using normal preparation of colloidal iron carrying 25 mg of elemental iron/ mL. This preparation contains the mixture of vitamin B12 (5 μg / mL) and folic acid (200 μg / mL). (Gallagher, 1995)The first three doses of iron were monitored and then parents were asked to manage the daily dose requirements. Datasheets were provided to them for marking of daily dose. During the study process, the infants allotted to control groups did not receive iron supplements. Infants of both Groups were feed with EBM (expressed breast milk) until the formula feeds start. An infant that feeds EBM with greater than fifty percent daily uptake were supplemented with human milk that contains minerals & vitamins excluding iron. For Infants feed on specified formula, the iron dose was corrected to cope with required daily dose. The preterm formula contains 13.6 mg/l of iron and provides nearly 2 mg/ kg of elemental iron at daily intake of 150 ml/kg. Those infants feed on specified formula but in

the control group, the expected iron was identified and recorded separately. The guideline over restricted red cell transfusion was adopted in both groups.

Outcome variables

Primary variable include serum ferritin, while secondary variables include anthropometric and haematologic parameters set at sixty days. The outcomes demanded for neonatal morbidities include CLD, PVL, NEC and ROP. CLD requires oxygen till 28 days during postnatal age. ROP was managed and diagnosed according to standard guidelines of (9, 10).

Re Hospitalization was considered to be the time period of more than 1 day after first discharge from hospital. All the basic characteristics of registered infants such as age, sex and iron supplementation were recorded in a format. During the initial hospitalization, other details such as blood loss, blood transfusion including the mode of feeding was recorded.

All the infants were daily monitored until the study period. Weight, length, requirement for blood transfusion and chances of significant morbidities were recorded during visits. Haemoglobin, haematocrit and Ferritin were identified during enrolment and at sixty days of age. (Miles, 1974) Serum Ferritin was projected by enzyme with the help of kit with high variations. (Minimum concentration was 1 μg/l) and low assay variations were 5.4% and 5.7%. It was probable that ferritin level will get affected by inflammation/ infection, so blood samples in infants were delayed with active infection. The samples of two infants were taken when the C reactive protein become negative, which results in the delay of two or three days after enrolment. Haemoglobin and Haematocrit were predicted using Coulter LH Analyzer.

Results

Out of 50 infants, 46 were enrolled and 4 were rejected from the study period. Out of 46 infants 24 were randomized to control group and 22 to early iron. Results were available for 42 infants, 2 samples got Haemolyzed and 2 were lost. Basic characteristics were similar between both the groups. Most infants in both the groups were initially breast milk fed. Among 22 infants in the iron group, nearly 91% received iron everyday till the end of study. The remaining did not receive the iron between 7 till 10 days. The formula of milk in iron group and the mean of iron intake from iron drops was 23.7 ± 16.4 and 114.1 ± 17.4 mg/kg (mean $\pm$ standard deviation). (Hall, Wheeler & Benson, 1993) After adjusting the variables, Serum ferritin at sixty days was similar between the two groups. The men for haemoglobin or haematocrit at sixty days were rarely different between two groups. Other secondary outcome variables such as re-hospitalization rates were (21.7% vs. 19%), need for transfusion (21.7% vs. 19%).

Discussions

Elemental iron is mandatory for biochemical functions such as growth of cells and differentiation. Supplementation of iron at initial stage will avoid its depletion and avoid the chances of iron shortage in preterm infants which have low iron stores during birth. (Seip, 1956) In the existing study we did not find any difference between control groups and iron supplementation of serum ferritin at age of 2 months. Although the scale of fall in serum ferritin starting to the end of study was lower in Infants in early iron groups. The change in mean was also not different between both groups after incorporating variables like mode of feeding and transfusion.

References

Ryan John Mills & Mark W Davies, 2012, *Enteral iron supplementation in preterm and low birth weight infants*, Published by John Wiley & Sons

Hall RT, Wheeler RE, Benson J, Harris G, Rippetoe L. Feeding, 1993, *iron-fortified premature formula during initial hospitalization*, 92: 409–14

Williams ML & Shott RJ, 1975, *Role of daetary iron and fat on vitamin E deficiency anemia of infancy,* published by N Engl J Med

Edmond K, Bahl R, 2006, *Optimal feeding of low-birth-weight infants – Technical Review. Geneva: World Health Organization*,

2005, International *Committee for the Classification of Retinopathy of Prematurity. The International Classification of Retinopathy of Prematurity revisited. Arch Ophthalmol*; 123: 991–9.

Gallagher PG, Ehrenkranz RA, 1995, *Nutritional anemias in infancy. Clin Perinatol* 22: 671–92.

Friel JK, Aziz K, Andrews WL & Serfass RE, 2005, *Iron absorption and oxidant stress during erythropoietin therapy in very low birth weight premature infants: a cohort study BMC Pediatr* 5: 29.

Mackler B, Grace R, Finch CA, 1984, *Iron deficiency in the rat: effects on oxidative metabolism in distinct types of skeletal muscle. Pediatr Res*

Seip M & Halvorsen S, 1956, *Erythrocyte production and iron stores in premature infants during the first months of life,* published by Acta Paediatr

Miles LEM & Lipschitz DA, 1974, *Measurement of serum ferritin by a 2-site immnnoradiometric assay*, published by Anal Biochem

Siimes MA & Addiego JE, 1974, *Ferritin in serum: Diagnosis of iron deficiency and overload in infants and children*,