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The Efficacy of Intravenous and Oral Iron Therapy in Postpartum Anaemic Mothers in a Tertiary Medical College: A Comparative Study

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Abstract: *Postpartumanaemia is caused primarily due to two causes – ion deficiency anaemia (inadequate iron intake prior to and during pregnancy) and acute peripartum blood loss which can be related to each other. Patients with postpartum anaemia have a longer average length of hospital stay, are more likely to receive blood transfusion and incur higher hospitalization costs. .*
The aim of the study is to compare the efficacy and safety of treatment in between intravenous ferrous sucrose and oral ferrous sulphate therapy in postpartum anaemia. So, the objectives of our study are –To compare the changes (i.e rise or fall) of Hb%, serum ferritin, haematocrit or packed cell volume (PCV) & mean corpuscular haemoglobin concentration (MCHC) at day 15 and day 42 after starting the therapy in between the two groups of postpartum anaemic mothers – one group (Group-A) receivied intravenous ferrous sucrose and another group (Group-B) receivied ferrous sulphate orally.
A hospital based experimental randomized controlled trial is used for these purposes.Patients, who fulfilled the inclusion & exclusion criterias, were randomly selected and divided into two equal groups. Written informed consent from all patients was obtained in this study. In one group i.e ***Group-A*** *was advised with intravenous ferrous sucrose.In another group i.e.* ***Group-B****, mothers were advised to take oral ferrous sulphate (each tablet containing 60 mg of elemental iron) tablet twice daily for 6 weeks from the date of recruitmentt. At the end, each group had 25 subjects who were enrolled for the final analysis. Investigation parameters i.eHb%, serum ferritin, haematocrit or packed cell volume, MCHC which were done as baseline value are repeated on day 15 and day 42. It was found that :a)There was highly significant difference (p=0.000000) of changes of hematological parameters (hemoglobin %, serum ferritin, PCV and MCHC) before and after treatment between the two groups (Group A and Group B) and b)there was significant rise of MCHC after starting of therapy at Day 15 and Day 42 in Group A, but there was no significant rise of MCHC in Group B at Day 15 though there was significant rise of MCHC at Day 42* ***CONCLUSION****: Iron sucrose is effective in pregnancy and in the postpartum period in patients who do not respond to oral iron, who are non-compliant to oral iron or who are treated with recombinant human erythropoietin (rHuEPO).*

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I. Introduction

The term anaemia came from Greek word "anhaima". Haime means blood. So the term anaemia (an+haima) is meant no blood. Anaemia is defied as qualitative and quantitative deficiency of red cell mass or hemoglobin or both. And thereby there is inadequate oxygen supply to peripheral tissues. With reference to Hb level, anaemia might be regarded as follows (Chatterjee J.K. 1964).
Below 5.8 gm% - severe anaemia
5.1 gm% to 7.5 gm% - Moderate anaemia
7.6 gm% to 10 gm% - Mild anaemia
Over 10 gm% no anaemia
According to Indian Council of Medical Research (ICMR) classification, Hb%:
10.9 to 10 gm% - mild anaemia
10 to 7 gm% - moderate anaemia
> 7 gm% - severe anaemia
> 4 gm% - very severe anaemia

The commonly used definition for diagnosis of anaemia in pregnancy is that of WHO where a hemoglobin concentration of less than 11 gm/dl and hematocrit of less than 33% is defined as anaemia. The

centers for Disease Control and Prevention has defined anaemia in pregnancy as a Hb of less than 11 gm/dl in first and third trimesters of pregnancy and Hb of less than 10.5 gm/dl in second trimester of pregnancy. [6]

Exact data on prevalence of anaemia in women is not available but a crude estimate is that 500 million women between 15 and 49 years of age worldwide are anaemic.[12] According to World Health Organization estimates, up to 56% of all women living in developing countries are anaemic.[8]Nearly half of the pregnant women in the world are estimated to be anaemic: 52% in non-industrialized versus 23% in industrialized countries. In industrialized countries, however, most pregnant women are thought to suffer from some degree of iron deficiency.

Postpartum anaemia is caused primarily due to two causes – ion deficiency anaemia (inadequate iron intake prior to and during pregnancy) and acute peripartum blood loss which can be related to each other. Patients with postpartum anaemia have a longer average length of hospital stay, are more likely to receive blood transfusion and incur higher hospitalization costs. During the period of pregnancy the extra needs of iron are about 1000 mg in total and they should be replaced in order to avoid severe anaemia. The usual management is the replacement of iron by oral supplementations. Blood transfusion is the last resort used only in very severe cases of anaemia (Hb< 7.0 gm%) with symptomatic mothers[3,4] (e.g. having lethargy, lactational failure, depression, stress, anxiety, cognitive impairment, poor mother-infant interaction etc.).

Though oral iron therapy is more commonly used, it is time consuming and probably not enough in severe cases of anaemia. Besides that, the utility of oral iron is limited by gastrointestinal complaints and patients' nonadherence. On the other hand, blood transfusion although it can promptly and reliably treat anaemia, entails a lot of danger like cross reactions and viral infections. In order to avoid these side effects parenteral iron therapy can be given. Unlike previous formulations, most notoriously ferrous dextran which was associated with significant risk of anaphylactoid reactions, ferrous sucrose could be a convenient and reliable solution.

The present work consists of those methods which will guide us to diagnose postpartum anaemia earlier and more accurately so that proper treatment can be started earlier and thereby lowering the seriousness of its nature. The aim of the study is to compare the efficacy and safety of treatment in between intravenous ferrous sucrose and oral ferrous sulphate therapy in postpartum anaemia. So, the objectives of our study are –

1) To compare the changes (i.e rise or fall) of Hb%, serum ferritin, haematocrit or packed cell volume (PCV) & mean corpuscular haemoglobin concentration (MCHC) at day 15 and day 42 after starting the therapy in between the two groups of postpartum anaemic mothers – one group (Group-A) receiving intravenous ferrous sucrose and another group (Group-B) receiving ferrous sulphate orally.

II. Materials And Method Of The Study

•**TYPE OF STUDY:** In this study, hospital based experimental randomized controlled trial is used.

•**STUDY DESIGN** : Design is prospective in nature

•**PLACE OF STUDY** : The study was conducted at Malda medical college and hospital, Malda , West Bengal, India

•**TIME OF STUDY** : 6 MONTHS

•**STUDY POPULATION:**Patients attending at antenatal clinic of out-patient department and patients who were admitted in the obstetrics ward of Malda medical college and hospital as booked cases or referred from outside and delivered babies within 48 hours, were taken as study population in this study irrespective of patient's age, mode of delivery, parity & gestational age.

•**SAMPLE SIZE**: In the prospective study the study population are 50 postpartum women with iron deficiency anaemia . Among them 25 postpartum women were in Group A who received intravenous ferrous sucrose & rest 25 postpartum women were in Group B who received oral ferrous sulphate table for their treatment therapy of iron deficiency anaemia.

•**CRITERIA FOR SELECTION :**

Inclusion Criteria

Postpartum mothers who had iron deficiency with Hb% < 11.0 gm/dl and serum ferritin level ≤ 20.0 µg/lit (as iron store depletion and iron deficiency are accompanied by a fall in serum ferritin level below 20.0 µg/lit)[10] were included this study.

Exclusion Criteria

1) Mothers who had a history of anaemia other than iron deficiency due to hepatic, renal or other medical diseases

2) Mother who received peripartum blood transfusion
3) Mothers who had history of asthma, thromboembolism, seizures or signs & symptoms of infecfections or inflammations
4) Mothers who were known cases of haemoglobinopathies, haemolyticanaemia or had current myelosuppressive therapy
5) Mothers who were allergic to iron sucrose
6) Mothers who were intolerant to both iron sucrose & ferrous sulphate.

III. Methods

History and relevant clinical data were collected according to a preset proforma. The clinically diagnosed cases of anaemia were evaluated by appropriate investigations e.gHb%, serum ferritin level, haematocrit or packed cell volume & MCHC (mean corpuscular haemoglobin concentration).

After obtaining approval of Ethics Committee, a prospective randomized comparative study was conducted. Patients, who fulfilled the inclusion & exclusion criterias, were randomly selected and divided into two equal groups. Written informed consent from all patients was obtained in this study. In one group i.e **Group-A** was advised with intravenous ferrous sucrose. It was administered in a dose of 200 mg elemental iron diluted in 200 ml 0.9% Nacl over a period of at least 30 minutes thrice a week until the total calculated dose had been achieved.

Calculated total dose (Ganzoni's Formula): 2.4 × Body Weight × D + 500 mg
D =Target Hb level (i.eHb% -11gm/dl) – current Hb level in gm/dl.
No test dose is given.

In another group i.e. **Group-B**, mothers were advised to take oral ferrous sulphate (each tablet containing 60 mg of elemental iron) tablet twice daily for 6 weeks from the date of recruitment.

In both groups, treatment started within 48hours of delivery irrespective of mother's age, parity, gestational age, mode of delivery & baby's birth weight. At the end, each group had 25 subjects who were enrolled for the final analysis.

Each & every patient of both the groups had been asked to note any symptoms or adverse effects of treatment. Investigation parameters i.eHb%, serum ferritin, haematocrit or packed cell volume, MCHC which were done as baseline value are repeated on day 15 and day 42.

STATISTICAL ANALYSIS PLAN: This was a prospective randomized comparative study. For the efficacy variables i.e. the difference of percentage of Hb, serum ferritin level, PCV, MCHC between baseline and post therapy levels after 15 days and 42 days were calculated and statistically analyzed by student's 't' test and analysis of variance (ANOVA).

ETHICAL CLEARANCE: A proper ethical clearance has been taken for the study from appropriate authority

IV. Results

Table 1: Comparison ofmaternal age, gestational age and baby's birth weight between Group A and Group B

Variables	**Group A** **Mean ± SD**	**Group B** **Mean ± SD**
Maternal Age (years)	26.10 ± 3.66	25.52 ±4.37
Gestational Age (days)	268.76 ± 10.92	267.02 ± 19.89
Baby's Birth Weight (kg)	2.78 ± 0.58	2.54 ± 0.51

SD = Standard Deviation

Table 2: Comparison of hemoglobin parameters on Day 1 (baseline), Day 15, Day 42 between Group A and Group B

Variables	Group A	Group B	p value
	Mean ± SD	Mean ± SD	
Hemoglobin in Day 1 (mg/dl)	7.52 ± 1.12	8.79 ± 0.72	0.00000
Hemoglobin in Day 15 (mg/dl)	10.31 ±0.97	9.39 ± 0.60	0.000000
Hemoglobin in Day 42 (mg/dl)	13.55 ± 0.72	10.25 ± 0.44	0.000000

SD = Standard Deviation

Table 3: Comparison of serum ferritin parameters on Day 1 (baseline), Day 15, Day 42 between Group A and Group B

	Group A	Group B	p value
	Mean ± SD	Mean ± SD	
Ferritin in Day 1 (µg/l)	11.95 ± 4.13	16.55 ± 3.54	0.000000
Ferritin in Day 15 (µg/l)	60.84 ± 8.23	40.79 ± 5.90	0.000000
Ferritin in Day 42 (µg/l)	125.56 ± 11.34	91.04 ± 10.76	0.000000

SD = Standard Deviation

Table 4: Comparison of PCV (hematocrit) parameters on Day 1 (baseline), Day 15, Day 42 between Group A and Group B

	Group A	Group B	p value
	Mean ± SD	Mean ± SD	
PCV in Day 1 (%)	24.60 ± 3.51	26.36 ± 2.21	0.004
PCV in Day 15 (%)	33.86 ± 2.57	30.54 ± 1.15	0.000000
PCV in Day 42 (%)	40.23 ± 2.12	33.56 ± 1.70	0.000000

SD = Standard Deviation

Table 5: Comparison of MCHC parameters on Day 1 (baseline), Day 15, Day 42 between Group A and Group B

	Group A	Group B	p value
	Mean ± SD	Mean ± SD	
MCHC in Day 1 (gm/dl)	30.76 ± 1.50	32.25 ± 0.71	0.0000
MCHC in Day 15 (gm/dl)	32.19 ± 0.50	32.15 ± 0.73	0.0000
MCHC in Day 42 (gm/dl)	33.77 ± 0.31	33.70 ± 0.78	0.0000

SD = Standard Deviation

Table 6A: Assessment of change over time in individual hematological parameters of Group A

Hematological Parameters		Mean difference	p value
Hemoglobin (mg/dl)	Day 1 vs Day 15	3.22	<0.001
	Day 15 vs Day 42	2.29	<0.001
	Day 1 vs Day 42	5.33	<0.001
Ferritin (µg/l)	Day 1 vs Day 15	56.69	<0.001
	Day 15 vs Day 42	51.32	<0.001
	Day 1 vs Day 42	108.31	<0.001
PCV (%)	Day 1 vs Day 15	8.66	<0.001
	Day 15 vs Day 42	6.77	<0.001
	Day 1 vs Day 42	14.73	<0.001
MCHC (gm/dl)	Day 1 vs Day 15	2.33	<0.001
	Day 15 vs Day 42	0.88	>0.05
	Day 1 vs Day 42	2.49	<0.001

Table 6B: Assessment of change over time in individual hematological parameters of Group B

Hematological Parameters		Mean difference	p value
Hemoglobin (mg/dl)	Day 1 vs Day 15	1.99	<0.001
	Day 15 vs Day 42	1.66	<0.001
	Day 1 vs Day 42	2.54	<0.001
Ferritin (µg/l)	Day 1 vs Day 15	21.54	<0.001
	Day 15 vs Day 42	34.36	<0.001
	Day 1 vs Day 42	55.58	<0.001
PCV (%)	Day 1 vs Day 15	3.58	<0.001
	Day 15 vs Day 42	2.92	<0.001
	Day 1 vs Day 42	6.19	<0.001
MCHC (gm/dl)	Day 1 vs Day 15	0.19	>0.05
	Day 15 vs Day 42	0.55	<0.01
	Day 1 vs Day 42	0.75	<0.001

Table 1 showed that there was no significant difference between two groups in regards with maternal age, gestational age and birth weight of babies. The mean maternal age of both groups was around 25 years; the mean gestational age in both groups was approximate 265 days and both the groups had mean baby's birth weight > 2.5 kg.

In **Table 2**, it was seen that mean baseline haemoglobin (Hb) of Group A was 7.52 gm% and that of Group B was 8.79 gm% . After starting therapy, at day 15, it was seen that in Group A the mean Hb% was 10.31gm% and in Group B it was 9.39 gm% (p value 0.000000). So, there was significant difference of rise of Hb at day 15

between the two groups. At day 42 in Group A, mean hemoglobin was 13.55 gm% and in Group B it was 10.25 gm% (p value 0.000000). So there was also significant difference of rise of hemoglobin between the two groups at the end of the study.

Table 3 demonstrated that mean baseline serum ferritin of Group A was 11.95 µg/l and that of Group B was 16.55 µg/l . After starting therapy at day 15, it was seen that in Group A the mean serum ferritin was 60.84 µg/l and in Group B it was 40.79 µg/l (p value 0.000000). So, there was significant difference of rise of serum ferritin at day 15 between the two groups. At day 42 in Group A, mean serum ferritin was 125.56 µg/l and in Group B it was 91.04 µg/l (p value 0.000000). So there was also significant difference of rise of serum ferritin between the two groups at the end of the study.

Table 4 established that mean baseline PCV of Group A was 24.60% and that of Group B was 26.36% . After starting therapy at day 15, it was seen that in Group A the mean PCV was 33.86% and in Group B it was 30.54% (p value 0.000000). So, there was significant difference of rise of PCV at day 15 between the two groups. At day 42 in Group A, mean PCV was 40.23% and in Group B it was 33.56% (p value 0.000000). So there was also significant difference of rise of PCV between the two groups at the end of the study.

Table 5, it can be said that mean baseline MCHC of Group A was 30.76 gm/dl and that of Group B was 32.25 gm/dl . After starting therapy at day 15, it was seen that in Group A the mean MCHC was 32.79 gm/dl and in Group B it was 32.15 gm/dl (p value 0.000040). So, there was significant difference of rise of MCHC at day 15 between the two groups. At day 42 in Group A, mean MCHC was 33.77 gm/dl and in Group B it was 33.70 gm/dl (p value 0.000005). So there was also significant difference of rise of MCHC between the two groups at the end of the study.

Table 6A and 6B revealed that in Group A, mean rise of hemoglobin at Day 15 and at Day 42 from baseline were 3.22 gm/dl ($p<0.001$) and 5.33 gm/dl ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of hemoglobin of 2.29 gm/dl ($p<0.001$). In Group B, mean rise of hemoglobin at Day 15 and at Day 42 from baseline were 1.99 gm/dl ($p<0.001$) and 2.54 gm/dl ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of hemoglobin of 1.66 gm/dl ($p<0.001$). So it can be interpreted that though in both groups there was rise in hemoglobin at different phases of study period after starting of therapy but there was more significant rise of hemoglobin in Group A than Group B

Table 6A and 6B demonstrated that in Group A, mean rise of serum ferritin at Day 15 and at Day 42 from baseline were 56.39 µg/l ($p<0.001$) and 108.31 µg/l ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of serum ferritin of 51.32 µg/l ($p<0.001$). In Group B, mean rise of serum ferritin at Day 15 and at Day 42 from baseline were 21.54 µg/l ($p<0.001$) and 55.58 µg/l ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of serum ferritin of 34.36 µg/l ($p<0.001$). So it can be interpreted that though in both groups there was rise in serum ferritin at different phases of study period after starting of therapy but there was more significant rise of serum ferritin in Group A than Group B .

Table 6A and 6B revealed that in Group A, mean rise of serum PCV at Day 15 and at Day 42 from baseline were 8.66% ($p<0.001$) and 14.73% ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of PCV of 6.77% ($p<0.001$). In Group B, mean rise of PCV at Day 15 and at Day 42 from baseline were 3.58% ($p<0.001$) and 6.19% ($p<0.001$) respectively. From Day 15 to Day 42 there was mean rise of PCV of 2.92% ($p<0.001$). So it can be interpreted that though in both groups there was rise in PCV at different phases of study period after starting of therapy but there was more significant rise of PCV in Group A than Group B .

Table 6A and 6B demonstrated that in Group A, mean rise of serum MCHC at Day 15 and at Day 42 from baseline were 2.33 gm/dl ($p<0.001$) and 2.49 gm/dl ($p<0.001$) respectively. In Group B, mean rise of MCHC at Day 15 and at Day 42 from baseline were 0.19 gm/dl ($p>0.05$) and 0.75 gm/dl ($p<0.001$) respectively. So it can be interpreted that there was significant rise of MCHC after starting of therapy at Day 15 and Day 42 in Group A, but there was no significant rise of MCHC in Group B at Day 15 though there was significant rise of MCHC at Day 42

Since 1996, several studies have been published by Breymann et al on the use of iron sucrose with or without recombinant human erythropoietin (rHuEPO) for postpartum anaemia in various dosages between 100 and 800 mg (total dose). Depending on the selected total dose, Hb increases between 2.1 and 3.5 g/dL were observed after 14 days. [10,11,14, 21, 22]

Gravier*et al* showed a Hb increase of 3.8 g/dL after 14 days (400 to 600 mg total dose) and a time difference of 14 days versus 30 days (with oral iron) until target
Hb was reached.[23]
Giannoulis C *et al* compared the efficacy of oral and intravenous administration of iron supplements for treating postpartum anaemia. At the end of the study, in group A (receiving iv iron) the increase in Hb mean level was 4.6 gm/dl and that of ferritin mean level was 105 µg/l. In proup B(receiving oral iron) increase in Hb mean level was 2.3 gm/dl and that of ferritin mean level was 68 µg/l. There was significant difference in the increase of Hb level ($p = 0.0001$) and also in the increase in ferritin level ($p=0.0004$) between the two groups.[25]

Bhandal N, Russell R conducted a prospective randomized study to compare the effect of treatment with ferrous sulphate and intravenous ferrous sucrose in postpartum iron deficiency anaemic mothers. Women treated with I.V iron had significantly higher Hb level on day 5 & day 14 ($p < 0.01$) than those treated with oral iron; although by day 40, there was no significant diference between the two groups. Throughout the study, ferritin levels rose rapidly in those treated with I.V iron and remained significantly higher than in those treated with oral iron ($p < 0.01$).[18]

V. Summary

Childbirth is the main cause of large blood losses in young women and depending upon the severity of blood loss, postpartum anaemic patients may present with increased morbidities, which prolong hospital stay. In the postpartum period, upto 30% of women are affected by anaemia with a Hb level under 10 gm/dl and upto 10% are affected by severe anaemia of Hb< 8 gm/dl.

Oral supplementation is neither fast enough nor sufficient to treat the postpartum anaemia as a result of its limited resorption and secondary effects that lead to low compliance.

We got the following interpretations after analyzing the result of our study:

- There was highly significant difference ($p=0.000000$) of changes of hematological parameters (hemoglobin %, serum ferritin, PCV and MCHC) before and after treatment between the two groups (Group A and Group B).
- there was significant rise of MCHC after starting of therapy at Day 15 and Day 42 in Group A, but there was no significant rise of MCHC in Group B at Day 15 though there was significant rise of MCHC at Day 42

VI. Conclusion

Iron sucrose is effective in pregnancy and in the postpartum period in patients who do not respond to oral iron, who are non-compliant to oral iron or who are treated with recombinant human erythropoietin (rHuEPO).

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