

A COMPARATIVE STUDY OF INJECTABLE IRON-SUCROSE VERSUS ORAL IRON IN POSTPARTUM MODERATE ANEMIA PATIENTSR. P. Patange¹, Viral Kashyap Sheth²**HOW TO CITE THIS ARTICLE:**

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ABSTRACT: BACKGROUND: Postpartum anemia can develop after delivery because of unforeseen medical problems during and after delivery which could complicate a mother's ability to properly care for her newborn child. The current treatment for postpartum anemia is oral iron supplementation but this treatment has been associated with gastrointestinal side effects. Alternative treatment includes blood transfusions and intravenous iron therapy. Since blood transfusions are very costly, intravenous iron treatments have become more popular. **OBJECTIVES:** The objective of this study was to evaluate the hematological parameters and to compare the efficacy and safety of postpartum moderate anemic patients while being treated with IV iron sucrose and oral ferrous sulphate. **METHODS:** A randomized comparative prospective clinical study was conducted in our hospital. In this study 100 women with postpartum anemia with hemoglobin (Hb) between 6 to 8 gm. percent after 24 hours postpartum were randomized into two groups. Group A consisted of 50 women who received 100 mg of IV iron sucrose on alternate day for 3 days along with 0.5mg of folic acid. Group B consisted of 50 women who received two tablets of ferrous sulphate 200mg twice daily for 30 days. **RESULTS:** Significant rise in Hb level was seen on day 7.14 and 30 with IV iron as compared to oral iron. Mean rise in Hb level was 4.1 gm. % with IV iron as compared to 3.4 gm. % with oral iron on day 30 of treatment with P value less than 0.0001 which was significant. Mean rise in PCV level was 12.22% with IV iron and 10.46% with oral iron on day 30. Mean rise in MCV was 12.65u3 with IV iron and 7.9u3 with oral iron. Mean rise in MCH was 5.86pg with IV iron and 3.31pg with oral iron. Mean rise in MCHC was 5.52% with IV iron and 4.17% with oral iron. Mean rise in serum iron was 24.09ug/dl with IV iron and 18.95ug/dl with oral iron. TIBC levels drop by 185.14ug/dl with IV iron and 168.94Ug/dl with oral iron on day 30. **CONCLUSION:** These results suggest that IV iron sucrose increases the Hb level more rapidly than oral ferrous sulphate in postpartum anemia without any serious side effects.

KEYWORDS: Postpartum moderate anemia, intravenous iron sucrose, oral iron, ferrous sulphate.

INTRODUCTION: Anemia is one of the major contributing factors in maternal mortality and morbidity in third world countries and according to WHO contributes to 20% of maternal deaths. Postpartum anemia is observed in up to 27% of women.¹ Iron deficiency anemia is very much prevalent in the tropics particularly amongst women of child bearing age especially in under privileged population.²

Puerperal anemia condition is a subclass of iron deficiency that occurs in women who has recently given birth. In the first trimester iron requirement is reduced but in the second and third trimester there is rise between 4 and 6 mg iron. Iron deficiency during pregnancy and postpartum due to insufficient absorption increases needs. During the period of pregnancy extra need on iron are

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1000 mg in total. The absorption of iron from oral supplements is influenced by dose; the patients iron store and time of intake in relation to meal time.

Postpartum anemia is associated with longer hospital stays, depression, anxiety and delayed infant development.³ The standard approach to treatment in majority of institutions is oral supplementation with blood transfusion reserved for more severe or symptomatic cases.⁴ There are number of hazards of blood transfusion including transfusion of wrong blood, anaphylaxis and risk of transmission of infections, any of which would be devastating for young mother.⁵ Oral iron is unreliable in treatment of severe anemia due to its limited absorption and gastrointestinal side effects that affect compliance.

Parental iron administration with ferrous sucrose is now available and can be used for treatment of iron deficiency anemia in postpartum period.⁶

Parental iron is an alternative for oral therapy provides a quick and certain correction of total iron deficit. Moderate anemia is defined as hemoglobin between 6 to 8 gm./dl. Incidence of iron deficiency anemia in our country is 35-70% incidence of postpartum anemia is 4-27%. Postpartum levels of Hb<10 gm./dl is seen 30% of cases.

The World Health Organization (WHO) defines iron deficiency anemia (IDA) as a hemoglobin (Hb) of less than 12 g/dL.⁷ The current gold standard for checking for IDA includes looking at both the Hb levels and the serum ferritin values.⁸ By the time a patient is anemic they have already depleted their iron storage, as evidenced by decreased levels of serum ferritin. However ferritin can be falsely elevated because of a secondary inflammatory response. Although ferritin alone cannot accurately predict IDA, it has been shown to have a possible association with depression and impairment of short-term memory.^{9,10}

According to the National Pregnancy Nutrition Surveillance System, 29.8% of women who were not previously anemic during pregnancy become anemic after delivery.¹¹ Consequences of postpartum IDA have been associated with fatigue, depression, cognitive dysfunction, stress, and anxiety. It can also interrupt mother-child bonding. Studies have shown that infants of anemic mothers were developmentally delayed, possibly due to the fact that anemic mothers were significantly more "negative" towards their baby, engaged less in goal setting, and were less "responsive" than non-anemic mothers.

Fatigue alone can be difficult to manage. The everyday challenges of fatigue are significantly compounded after childbirth. In addition to a new mother's demanding tasks of caring for a child, postpartum fatigue can impact her postpartum maternal role attainment and may place her at greater risk for postpartum depression.¹² Studies have shown that low Hb levels are significantly related to postpartum depression and postpartum fatigue.

Currently, the standard treatment for anemia is oral iron supplementation. However, this is limited by patient noncompliance and gastrointestinal symptoms such as nausea, vomiting, and diarrhea. Absorption of oral iron is influenced by the dosage, the patient's iron storage, and the proximity of taking the medication relative to mealtime. Ideally, the supplement should be taken on an empty stomach as food can impair its absorption. This method of treatment is slow to take effect, often requiring several weeks for results to transpire.

Hematologic changes, like Hb and ferritin, are fairly rapid with IV iron therapy and have a positive effect on the body's iron storage which is measured by the ferritin level.

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Iron sucrose has an excellent safety record, unlike older IV formulations such as ferrous dextran, which has been associated with a significant risk of anaphylactic reactions. Intravenous iron sucrose can be administered as an infusion in small doses (about 200mg) over a 30-minute time period.

METHODOLOGY: Approval of institutional ethics committee was taken before starting treatment. A randomized prospective single center study was performed in 100 postpartum moderate anemic patients.

PARTICIPANTS: The study population consisted of women aged 18years or more with postpartum moderate iron deficiency anemia (Hb 6 to 8 gm. %)

RANDOMIZATION: The women were randomized to one of the two groups using a computer generated randomization schedule. Opaque sealed envelopes containing the treatment allocation were prepared and marked with a sequential numerical code by an independent person. After obtaining consent, the next consecutive envelope was opened by the recruiter and the woman was prescribed the appropriate treatment.

INCLUSION CRITERIA:

- Patients whose haemoglobin level is between 6gms/dl to 8gms/dl at 24 hours after delivery.
- Patients without any K/C/O medical or surgical illness without any H/O asthma, thromboembolism and seizures.
- Patients who are delivered in the Obstetrics and Gynaecology Department of our hospital.

EXCLUSION CRITERIA:

- Patients with H/O hypersensitivity to iron preparations
- Patients with H/O blood transfusion.
- Patients with signs of infection or evidence of renal or hepatic dysfunction
- All patients with placenta previa, abruption, preeclampsia and clotting disorders.
- Patients with hereditary anaemia, chronic haemorrhagic anaemia like hook worm infestations, bleeding piles, bone marrow insufficiency.

TREATMENT: Treatment was started 24 hours after delivery. The initial iron status of the woman was assessed by clinical and laboratory examination (Hb). Women having Hb levels between 6 to 8 gm. percent at 24 hours post-delivery were included in the study. They were randomly divided into two groups. Group a received three doses of IV iron sucrose 100mg on alternate days with 0.5mg of folic acid following recruitment in the study. Group B received oral ferrous sulphate 200mg twice daily for 30days. Iron sucrose was administered as 100mg in 100ml of normal saline over a period of 30 minutes. Patients were monitored for signs of intolerance such as anaphylactic reactions, skin rash, dyspnea, facial flushing, metallic taste, urticarial, hypotension, tachycardia etc. They will not be receiving any further iron supplementation (Group A).

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LABORATORY PROCEDURES: Blood samples were taken at recruitment into study (day 0) and at days 7, 14 and 30 after the start of treatment and Hb was investigated.

On day 1 and 30 – Hb, PCV, red cell indices, serum iron and total iron binding capacity were measured.

STATISTICAL ANALYSIS: Were performed using SPSS software(V18.0, SPSS inc, Chicago IL).Fishers exact test were performed to test for differences between 2 groups. The effect of iron supplementation on maternal iron status was analyzed by student's t-test value <0.005 was considered to be significant.

OBSERVATIONS AND RESULTS:

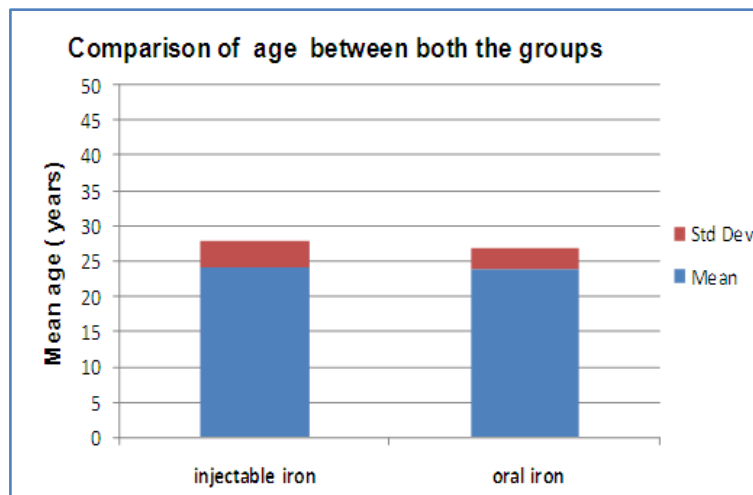


Figure 1

Unpaired t test is applied. P value is significant if < 0.05 .

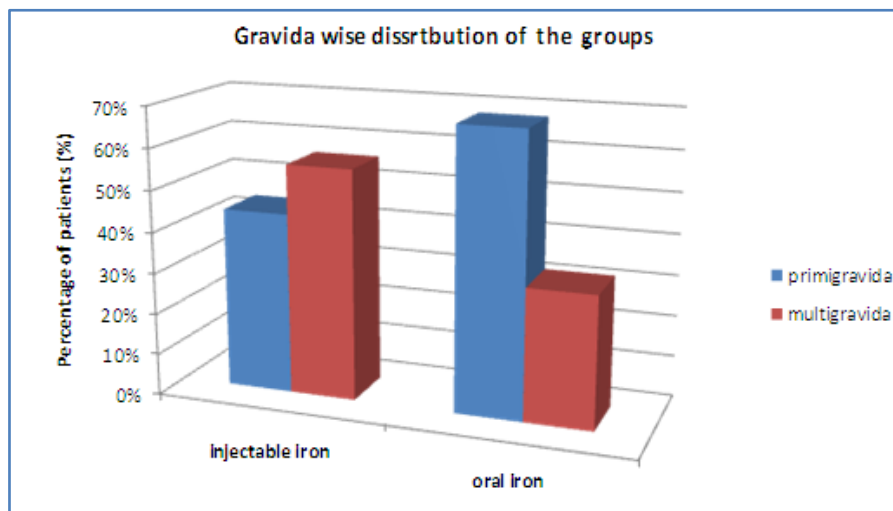


Figure 2

Fisher exact test is applied. P value is significant if < 0.05 .

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HAEMOGLOBIN (gm. %)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	7.09 \pm 0.52	6.97 \pm 0.50	0.2469
Day 7	7.59 \pm 0.54	8.39 \pm 0.66	<0.0001
Day 14	8.67 \pm 0.71	9.20 \pm 0.56	<0.0001
Day 30	10.51 \pm 0.69	11.07 \pm 0.65	<0.0001

Table 3: Comparison of Hemoglobin levels between both the groups

Unpaired t test is applied. P value is significant if < 0.05

PCV (%)	Mean \pm SD		P value
	Oral iron	IV iron	
Day 1	20.88 \pm 1.81	20.66 \pm 1.71	0.5394
Day 30	31.34 \pm 1.95	32.88 \pm 3.39	0.0064

Table 4: Comparison of Packed cell volume (PCV) levels between both the groups

Unpaired t test is applied. P value is significant if < 0.05

MCV (u ³)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	72.75 \pm 5.88	72.39 \pm 6.79	0.7753
Day 30	80.65 \pm 5.39	85.04 \pm 7.81	0.0015

Table 5: Comparison of Mean Corpuscular Volume (MCV) between both the groups

Unpaired t test is applied. P value is significant if < 0.05

MCH (pg)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	23.13 \pm 3.25	22.58 \pm 4.17	0.4629
Day 30	26.44 \pm 2.91	28.44 \pm 3.70	0.0033

Table 6: Comparison of Mean Corpuscular Hemoglobin (MCH) between both the groups

Unpaired t test is applied. P value is significant if <0.05

MCHC (%)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	29.57 \pm 3.44	30.12 \pm 2.90	0.3919
Day 30	33.74 \pm 3.72	35.64 \pm 2.82	0.0051

Table 7: Comparison of Mean Corpuscular Hemoglobin Concentration (MCHC) Between both the groups

Unpaired t test is applied. P value is significant if < 0.05

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Serum iron (μ /dl)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	32.85 \pm 4.47	32.50 \pm 4.51	0.7010
Day 30	51.80 \pm 5.51	56.59 \pm 4.40	<0.0001

Table 8: Comparison of Serum iron levels between both the groups

Unpaired t test is applied. P value is significant if < 0.05

TIBC (μ g/dl)	Mean \pm SD		P value
	Oral iron	IV iron	
Day1	347.28 \pm 19.29	351.34 \pm 18.13	0.2809
Day 30	178.34 \pm 12.08	166.20 \pm 11.02	<0.0001

Table 9: Comparison of Total iron binding capacity (TIBC) between both the groups

Unpaired t test is applied. P value is significant if < 0.05

Mode of Delivery	Oral iron N (%)	Injectable N (%)	P value
Vaginal	37 (74%)	20 (40%)	
LSCS	13 (26%)	30 (60%)	
Grand total	50	50	

Table 10: Comparison of mode of delivery between both the groups

Fisher exact test is applied. P value is significant if < 0.0

Hb	Oral iron				Injectable			
	Day 1	Day 7	Day 14	Day 30	Day 1	Day 7	Day 14	Day 30
<7	30	10	0	0	36	0	0	0
7-8	20	25	10	5	14	15	2	0
8.1-9	0	12	20	4	0	15	5	0
9.1-10	0	3	16	6	0	10	20	8
10.1-11	0	0	4	25	0	8	15	26
>11	0	0	0	10	0	2	8	16
TOTAL PATIENTS	50	50	50	50	50	50	50	50

Table 11: Comparison between two modalities of iron therapy in relation to Improvement in Hb

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ADVERSE REACTIONS	IV GROUP	ORAL GROUP
Nausea/ vomiting	1	2
Epigastric pain	1	2
Constipation	0	1
Staining	0	0
Thrombophlebitis	2	0
Rashes	0	0
Myalgia	0	0
Fever	0	0
Hypotension	0	0
Total	4	5

TABLE 12: Adverse reactions

Table 12 showing distribution of patients according to adverse reactions, there were no serious side effects in the study. However 4(8%) patients out of 50 in IV group and 5(10%) out of 50 in oral group had minimal side effects.

RESULTS: In our prospective study, 100 postpartum women with moderate anaemia were randomized to receive IV iron sucrose (Group A) or oral ferrous sulphate (Group B). All patients reported regular use of iron tablets during pregnancy. Before treatment, iron deficiency anaemia was confirmed with Hb levels. In our study we use serum iron as an indicator of iron storage as ferritin is not carried out. In our significant rise in Hb level on day7, 14 and 30 were seen with IV iron as compared to oral iron.

Mean rise in Hb level was 4.1gm% with IV iron and 3.4gm% with oral iron on day 30 of treatment. Mean rise in PCV level was 12.22% with IV iron and 10.46% with oral iron on day 30. Mean rise in MCV was 12.65u3 with IV iron and 7.9u3 with oral iron. Mean rise in MCH was 5.86pg with IV iron and 3.31pg with oral iron. Mean rise in MCHC was 5.52% with IV iron and 4.17% with oral iron. Mean rise in serum iron was 24.09ug/dl with IV iron and 18.95ug/dl with oral iron.

TIBC levels drop by 185.14ug/dl with IV iron and 168.94Ug/dl with oral iron on day 30. Age is comparable between injectable and oral iron group indicating equal distribution of patients in both the groups. Majority of patients belonged to middle socioeconomic status scale i.e. class 3 and 4 of modified Kuppaswamy classification and booked cases are maximum and both are statistically comparable. Primigravida comprised the maximum number of patients in both the groups. None of the patients in IV iron group has any of the dreaded side effects which are known to occur with IV iron. None of the patients from either group has failure of treatment. None of the patient is excluded from the study. There were no dropouts. The findings of our study are in line with published literature.

DISCUSSION: For many pregnant women, postpartum iron deficiency anaemia (IDA) is inevitable and can be detrimental to the mother and newborn. After childbirth, it is normal for haemoglobin (Hb) levels to drop during the first 24 hours due to the loss of blood during delivery, however the Hb level

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should rise over the next two to five days and return to normal by the seventh day after delivery.¹³ If the Hb level does not rise adequately, postpartum IDA may become a serious problem and may create other problems for the new mother. Therefore, in order to preclude the onset of postpartum depression, it is extremely important to determine a treatment that reduces recovery time for women with postpartum anaemia.

The characteristics of patients in both groups were statistically comparable in relation to age. Majority (80 – 82%) were Hindu and remaining Muslims. In the present study, majority of patients belong to middle socio economic status scale i.e. class 3 and 4 of Modified Kuppaswamy Classification and majority of the patients were booked.

In our study maximum patients were primigravida. The results of the sub-analysis in Westad et al¹⁴ revealed a significant change in Hb of at least 2.0g/dL by week four in the treatment group and there was a significant increase in the mean Hb levels of the treatment group at weeks eight and twelve when compared to the oral group. This is comparable to our study as by week 4 rise in Hb levels is 4.1g/dl with IV iron compared to 3.42g/dl with oral iron.

Each of the studies except Bhandal et al¹⁵ and Breyman et al,¹⁶ reported a higher percentage of patients who achieved a Hb of greater than 12g/dL at some point during the study using either IV ferric carboxymaltose or IV iron sucrose. However only the studies done by Seid et al,¹⁷ Van Wyck et al,¹⁸ and Westad et al¹⁴ were statistically significant. Although the Bhandal et al¹⁵ study participants did not reach Hb of 12g/dL, the mean Hb baseline was 7.4g/dL. Despite the low baseline Hb, the IV group was able to achieve a significant mean Hb increase of 2.5g/dL in the IV group by day five and a statistically significant mean Hb increase of 1.2g/dL in the IV group by day 14. Seid et al¹⁷ also reported the time to achieve anemia correction was significantly less in the IV treatment group, 14 versus 27 days, while improvements in Hb levels continued for the remainder of the study.

Our study differs from Breyman 2008 et al, Seid et al and Van wyck et al as they used ferric carboxymaltose as IV iron.

Al Momen et al¹⁹ in their study group compared 52 women treated with intravenous iron sucrose and 59 women treated with 300 mg oral iron sulphate. Intravenous iron sucrose group achieved significantly higher Hb levels 128.5±6.6 versus 111.4±12.4g/dl with oral iron group (P <0.001) in a shorter period 6.9±1.8 versus 14.9±3.1 weeks in control group (P <=0.001) iron sucrose complex showed no major side effects while 4(6%) of the control group could not tolerate ferrous sulphate, 18 (30%) complained of disturbing gastrointestinal symptoms and 18 (30%) has poor compliance. The authors concluded that iron sucrose was a safe and effective alternative in the treatment of iron deficiency anemia. In our study the compliance was good with oral iron and only 5(10%) patients had minor adverse effects.

In the study done by Bayoumeu²⁰ et al involving 50 women with intravenous iron sucrose was compared with ferrous sulphate. In the intravenous group an increase in Hb was observed rising from 9.6±0.79 to 11.11±1.3g/dl on day 30 and from 9.7±0.5 to 11±1.25g/dl on day 30 in the oral group which was not significant. This study deviates from our study because the sample size is small and also there no significant increase in Hb levels on day 30.

In a study by Al RA et al²¹ compared intravenous iron sucrose with oral iron polymaltose complex (300 mg elemental iron per day).The change in Hb from baseline was significantly higher in the IV group than oral group at each measurement; the changes with respect to subsequent Hb were higher on day 14th (P=0.004) and 28th (P=0.031) which is comparable to our study.

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Bencaivo²² et al assessed and compared the efficacy of and safety of iv iron sucrose to ferrous sulphate. There was a non-significant increase in Hb in the IV group but the depleted iron stores were significantly higher than oral group which deviates from our study as difference in Hb level was not significant.

GIANNOULIS C: study in 2009 included 104 postpartum anemic women. The criteria for the diagnosis was hemoglobin < 8 g/dl. The women were randomized in two groups. Group A consisted of 78 women who received IV total amount of 300 mg iron sucrose in three days. Group B consisted of 26 women who received 800 mg iron protein succinylate daily for four weeks. At the end of the study group A increase in Hb mean level was 4.6 g/dl and group B increase in Hb mean was 2.3 g/dl which is comparable to our study.

CONCLUSION: This study concluded that IV iron therapy is safe and highly efficacious for treating postpartum iron deficiency anemia. It restores iron levels more promptly. IV iron therapy is more effective in achieving the optimal results. IV iron sucrose can be used as safe and effective alternative to blood transfusion and oral iron therapy in the treatment of postpartum iron deficiency anemia.

“It may not be possible to setup the blood bank in every remote corner of the country but it is certainly possible to make a blood bank in the woman’s body by building up her hemoglobin.”

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