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## **Original Research Article**

# A comparative study of intravenous iron sucrose versus oral iron therapy in iron deficiency anemia during postpartum period

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#### **ABSTRACT**

**Background:** Anemia is the commonest major contributing factor in maternal mortality and morbidity in developing countries and according to World Health Organization (WHO) criteria, it contributes to 20% of maternal deaths. Anemia in pregnancy defined as haemoglobin level <11 gm/dl (7.45 mmol/L) and haematocrit less than 33% (WHO). Aim of this study was to compare the efficacy of oral iron ferrous sulphate therapy with intravenous iron sucrose therapy in the treatment of iron deficiency anemia during postpartum period.

**Methods:** This was a prospective randomized comparative clinical trial single center study conducted on 200 postpartum women aged >18 years (after normal delivery or LSCS) within 10 days of delivery with Hb level more or equal to 6 gm/dl but less than 10 gm/dl were included in the study. This was a one-year study conducted during 1<sup>st</sup> December 2018 to 30<sup>th</sup> November 2019.

**Results:** There was a significant increase in the hemoglobin level in both the groups i.e. in IV iron group, from 8.26±1.03 gm/dl on day 1 to 11.62±0.94 gm/dl on day 45 as compared to oral iron group, from 8.24±1.09 gm/dl on day 1 to 11.07±1.14 gm/dl on day 45; and serum ferritin level from 41.69±40.45 ng/ml on day 1 to 77.34±41.60 ng/ml on day 45 in IV iron group as compared to the oral iron group from 22.20±8.82 ng/ml on day 1 to 31.72±9.72 ng/ml on day 45. So, there was a rapid increase in both hemoglobin and serum ferritin levels in IV iron group as compared to the oral iron group.

**Conclusions:** Intravenous iron sucrose administration increases the hemoglobin level and serum ferritin more rapidly in compare to the oral intake of ferrous sulphate in women with iron deficiency anemia in postpartum women in our study.

Keywords: Iron deficiency anemia, Intravenous iron sucrose, Maternal mortality, Serum ferritin

## INTRODUCTION

Anemia is the commonest major contributing factor in maternal mortality and morbidity in developing countries and according to World Health Organization (WHO) criteria, it contributes to 20% of maternal deaths. Anemia in pregnancy defined as haemoglobin level <11 gm/dl (7.45 mmol/L) and haematocrit less than 33% (WHO). Nutritional iron deficiency is the most common deficiency disorder in the world, affecting more than two

billion people worldwide, with pregnant women at particular risk.<sup>2-4</sup> World Health Organization states that iron deficiency anemia in pregnancy is a significant problem throughout the world with a prevalence ranging from an average of 14% of pregnant women in industrialized countries to an average of 56% in developing countries (range 35-75%).<sup>3,4</sup>

Postpartum anemia is observed in up to 27% of women. Postpartum anemia defined as haemoglobin of less than

10 gm/dl and serum ferritin less than 15  $\mu$ g/L in 24-48 hours of post-delivery period which is observed in upto 30% of women.<sup>5</sup>

Nutrition of a woman in the family is always being ignored because of various social and cultural practices and on the top of it, she always remains in the dark about her own health. High prevalence of iron deficiency is attributable to faulty diet habits, faulty absorption mechanism because of high prevalence of intestinal infestation and increased iron loss as consequence of repeated pregnancies at short intervals, excessive blood loss during menstruation, hookworm infestation and chronic malaria.<sup>6</sup>

In typical singleton gestation, the mother requires iron approximately 1000 mg. Out of these, 300 mg is for the growing fetus and placenta, 500 mg for maternal haemoglobin mass expansion and 200 mg is shed normally through gut, urine and skin. The total demand of 1000 mg exceeds the iron store of most women which results in iron deficiency anemia unless iron supplementation is given. At the present time, there is no consensus on the management of postpartum anemia. The standard approach to treatment in the majority of institutions is oral supplementation, with blood transfusion reserved for more severe or symptomatic cases. 8

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 the young mother.<sup>9</sup> These hazards, together with the national shortage of blood products, mean that transfusion should be viewed as a last resort in otherwise young and healthy women.<sup>10</sup>

Parenteral iron administration with ferrous sucrose is now available and can be used for treatment of iron deficiency anemia in postpartum period. Parenteral iron is an alternative for oral therapy provides a quick and certain correction of total iron deficit. The current gold standard for checking for IDA includes looking at both the Hb levels and the serum ferritin values. By the time a patient is anaemic, they have already depleted their iron storage, as evidence by decreased levels of serum ferritin.

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. 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.

## **METHODS**

This study was conducted in the department of obstetrics and gynecology, S. P. Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India.

Postpartum women with iron deficiency anemia (IDA) consenting to participate in the study, 200 women (100 in each group) met within the inclusion criteria were included from 1st December 2018 to 30th November 2019.

#### Inclusion criteria

 Postpartum women aged >18 years (after normal delivery or LSCS) during 24-48 hours post delivery within 10 days of delivery with Hb level more or equal to 6 gm/dl but less than 10 gm/dl were included in the study.

#### Exclusion criteria

- Women with intolerance to iron derivatives
- H/O acute thromboembolism, seizures or drug abuse
- Women with signs of worm infestation
- Evidences of renal or hepatic dysfunction
- Diagnosed cases of anemia other than iron deficiency anemia for e.g. thalassemia
- Chronic anemia.

This was a hospital based, randomized, comparative, prospective, clinical study. The sample size of 200 women was selected from the postpartum women admitted in maternity ward after fulfilling the selection criteria. After careful history taking, clinical examination and minimal investigations other causes of anemia were ruled out. The initial iron status of the woman was assessed by the clinical and laboratory examinations (complete blood count, hemoglobin and serum ferritin levels).

Subjects were randomized and divided into 2 groups, each of 100 women:

- Group 1- Received 400 mg of Intravenous Iron sucrose divided in two doses of 200 mg as an infusion in 300 ml NS on alternate days (day 2 and day 4) + 500 µg folic acid orally daily for 6 weeks.
- Group 2- Received 200 mg oral ferrous sulphate divided into 2 doses, 100 mg of each given BD + 500 µg folic acid daily for 6 weeks.

The post therapy evaluation was done with the estimation of haemoglobin and serum ferritin levels of both the treatment groups on day 14 and day 45.

## Statistical analysis

The statistical analysis was performed using the mean, standard deviation, Chi square test and t-test. Variations of p <0.05 were considered to be statistically significant.

### **RESULTS**

The baseline mean Hb was  $8.26\pm1.03$  gm/dl in IV iron group and  $8.24\pm1.09$  gm/dl in oral iron group (Table 1).

Table 1: Comparison of the mean and the standard deviation in haemoglobin levels in both the groups.

| Day of haemoglobin | IV iron group |      | OFS group |      |
|--------------------|---------------|------|-----------|------|
| estimation         | Mean          | SD   | Mean      | SD   |
| Day 1              | 8.26          | 1.03 | 8.24      | 1.09 |
| Day 14             | 10.25         | 1.06 | 9.64      | 1.04 |
| Day 45             | 11.62         | 0.94 | 11.07     | 1.14 |

Table 2: Comparison of the mean and the standard deviation in serum ferritin levels in both the groups.

| Day of serum        | IV iron group |       | OFS group |      |
|---------------------|---------------|-------|-----------|------|
| ferritin estimation | Mean          | SD    | Mean      | SD   |
| Day 1               | 41.69         | 40.45 | 22.20     | 8.82 |
| Day 14              | 62.26         | 40.54 | 27.12     | 8.94 |
| Day 45              | 77.34         | 41.60 | 31.72     | 9.72 |

There was a significant increase in the haemoglobin level in both the groups i.e. in IV iron group, from  $8.26\pm1.03$  gm/dl on day 1 to  $11.62\pm0.94$  gm/dl on day 45 as compared to oral iron group, from  $8.24\pm1.09$  gm/dl on day 1 to  $11.07\pm1.14$  gm/dl on day 45; but, there was a rapid increase found in IV iron group as compared to the oral iron group (Table 1).

The baseline mean serum ferritin level in IV iron group was 41.69±40.45 ng/ml and in oral iron group was 22.20±8.82 ng/dl i.e. on day 1 (Table 2).

There was a significant rapid increase in the serum ferritin level from 41.69±40.45 ng/ml on day 1 to 77.34±41.60 ng/ml on day 45 in IV iron group as compared to the oral iron group from 22.20±8.82 ng/ml on day 1 to 31.72±9.72 ng/ml on day 45 (Table 2).

## **DISCUSSION**

The mean baseline Hb (day 1) was  $8.26\pm1.03$  gm/dl in IV iron group and  $8.24\pm1.09$  gm/dl in oral iron group. On day 14, there was a rapid increase in mean Hb from  $8.26\pm1.03$  gm/dl to  $10.25\pm1.06$  gm/dl in IV iron group as compared to the oral iron group i.e. from  $8.24\pm1.09$  gm/dl to  $9.64\pm1.04$  gm/dl. On day 45, there was an increase in mean Hb in both the groups i.e. from  $10.25\pm1.06$  gm/dl to  $11.62\pm0.94$  gm/dl in IV iron group and from  $9.64\pm1.04$  gm/dl to  $11.07\pm1.14$  gm/dl in oral iron group (Table 1).

This illustrated that there was a significant increase in the hemoglobin level from day 1 to day 45 in both the study groups; but there was a rapid increase found in IV iron group as compared to the oral iron group.

The results are comparable to the study done by Vijaylakshmi et al, in their study, in IV iron group, there was a significant increase in the mean Hb from  $8.8\pm0.6$  gm/dl on day 1 to  $11.1\pm0.8$  gm/dl on day 28 as compared to oral iron group, from  $8.7\pm0.9$  gm/dl on day 1 to  $10.6\pm0.9$  gm/dl on day 28.9 The study done by Pradhan et

al5 also comparable to this study, as in their study, there was a significant increase in the mean Hb from 7.822±0.542 gm/dl on day 1 to 12.858±0.661 gm/dl at the end of 6th week (i.e. on day 45) as compared to oral iron group, from 8.008±0.543 gm/dl on day 1 to 9.889±0.9467 gm/dl at the end of 6th week (i.e. on day 45). In the study done by Kharde et al, in their study, there was a significant increase in the mean Hb in IV iron group i.e. from 7.47±0.767 gm/dl on day 1 to 11.41±0.790 gm/dl on day 40 as compared to oral iron group, from 7.76±0.713 gm/dl on day 1 to 10.78±0.767 gm/dl on day 40.13 In the study done by Gupta et al, also comparable to this study, as there was also a significant increase in the mean Hb in IV iron group i.e. from 7.23±0.57 gm/dl on day 1 to 11.24±0.53 gm/dl on day 30 as compared to oral iron group, from 7.33±0.41 gm/dl on day 1 to 10.33±0.38 gm/dl on day 30.6

In this study, there was a significant rapid increase in the serum ferritin level from 41.69±40.45 ng/ml on day 1 to 77.34±41.60 ng/ml on day 45 in IV iron group as compared to the oral iron group, from  $22.20 \pm 8.82$  ng/ml on day 1 to 31.72±9.72 ng/ml on day 45 (Table 2). These results are comparable to the study done by Bhandal and Russell, as there was also a significant increase in the serum ferritin level in IV iron group from 13±3 ng/ml on day 1 to 42.2±7 ng/ml on day 40 as compared to the oral iron group, from 11±4 ng/ml on day 1 to 15±3 ng/ml on day 40.14 In the study done by Kharde et al, there was also a significant increase in the serum ferritin level in IV iron group from 11.47±1.655 ng/ml on day 1 to 53.47±5.011 ng/ml on day 40 as compared to the oral iron group, from 11.35±1.55 ng/ml on day 1 to 15.40±1.049 ng/ml on day 40, that is also comparable to this study. 15 In the study done by Pradhan et al also, there was a significant increase in the serum ferritin level in IV iron group from 11.920±0.936 ng/ml on day 1 to 53.885±5.111 ng/ml on day 45 as compared to the oral iron group, from 11.579±0.680 ng/ml on day 1 to 15.063±1.086 ng/ml on day 45, that is also comparable to this study.<sup>16</sup>

On the basis of currently available data, IV iron sucrose emerged out as a more convenient, safe and effective treatment option for women with postpartum iron deficiency anemia with advantages over oral iron, including a short treatment period, ensured compliance, no gastro-intestinal side effects and rapid replenishment of iron stores. It also reduces the need of blood transfusion in women with postpartum iron deficiency anemia as 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 the young mother.

## **CONCLUSION**

This study illustrates that intravenous iron sucrose administration increases the haemoglobin level more rapidly than oral intake of ferrous sulphate in women with iron deficiency anemia. It also replenishes iron stores more rapidly without any serious adverse effect than oral iron and it is safe and well tolerated. Administration of oral iron supplementations is not sufficiently enough in order to reverse anemia promptly, due to the limited absorption, the gastrointestinal symptoms and the poor compliance for long treatment of the patients. Thus, Intravenous iron sucrose is an effective, convenient, and safe route to cure postpartum anemia in comparison to oral iron supplementation.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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