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Original Research Article

Comparison of parenteral iron sucrose and oral iron preparations in the treatment of postpartum anemia at tertiary health care centre: randomised controlled trial study

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ABSTRACT

Background: Postpartum anemia is a leading cause of maternal morbidity and delayed recovery after childbirth. Oral iron therapy, though widely used, is often limited by gastrointestinal side effects and poor absorption. This study compared the efficacy and safety of intravenous (i.v.) iron sucrose versus oral iron in treating postpartum anemia.
Methods: A randomized controlled trial was conducted in the department of obstetrics and gynecology, Government Medical College, Akola, Maharashtra. A total of 108 postpartum women with iron deficiency anemia were randomly assigned to two groups. Group A received i.v. iron sucrose (200 mg on alternate days, total 1000 mg) and group B received oral ferrous sulphate (325 mg thrice daily) for six weeks. Hemoglobin (Hb) and serum ferritin were measured at baseline, four, and six weeks. Adverse drug reactions (ADRs) and treatment efficacy (Hb rise >3.5 gm/dl) were analysed statistically.
Results: Both groups were comparable at baseline. Mean Hb rise was significantly higher with i.v. iron (3.8±0.6 gm/dl at 4 weeks; 4.2±0.7 gm/dl at 6 weeks) than with oral iron (2.9±0.7 and 3.3±0.6 gm/dl; p<0.001). Serum ferritin increased more with i.v. iron (95.4 ng/ml versus 71.1 ng/ml; p<0.001). ADRs were fewer in the i.v. group (14.8%) than in the oral group (40.7%; p<0.001).
Conclusions: Intravenous iron sucrose is a safe, well-tolerated, and more effective alternative to oral iron for rapid correction of postpartum anemia.

Keywords: Hemoglobin, Intravenous iron sucrose, Oral iron, Postpartum anemia, Randomized trial

INTRODUCTION

Postpartum anemia is a major global health concern, particularly in low- and middle-income countries where many women begin pregnancy with depleted iron stores.[1] It is defined as haemoglobin <11 gm/dl in the first postpartum week and <12 gm/dl thereafter, and is associated with fatigue, impaired cognition, reduced quality of life, and increased risks in future pregnancies.[2] Most cases arise from intrapartum blood loss combined with pre-existing iron deficiency anemia, highlighting the need for prompt and effective treatment.[3]

Oral iron remains the conventional first-line therapy due to its low cost and ease of use.[4] However, gastrointestinal side effects such as nausea, constipation, and epigastric discomfort frequently reduce adherence.[5] Postpartum inflammatory changes may also limit iron absorption, slowing haemoglobin recovery.[6] Intravenous (i.v.) iron sucrose offers advantages of rapid iron repletion, better bioavailability, and fewer gastrointestinal adverse effects.[7] Several studies have reported superior improvements in haemoglobin and ferritin with i.v. iron compared to oral therapy in pregnancy and postpartum periods.[8] Yet, its wider use is limited by cost, availability, and concerns

about infusion reactions, especially in resource-limited settings.[9,10]

The present randomized controlled trial aimed to compare the efficacy and safety of i.v. iron sucrose versus oral iron in postpartum anemia, focusing on haemoglobin improvement at the 4th and 6th weeks and documenting adverse drug reactions.

METHODS

This randomized controlled trial was conducted in the department of obstetrics and gynecology, Government Medical College, Akola, Maharashtra, between May 2023 and April 2024 after obtaining institutional ethics committee approval. Written informed consent was taken from all participants before inclusion.

Postpartum women aged 20 to 35 years diagnosed with iron deficiency anemia were included. Anemia was defined as Hb below 11 gm/dl within the first week postpartum or below 12 gm/dl up to six weeks after delivery.

Women with known hypersensitivity to iron, those requiring blood transfusion, or those with chronic renal, hepatic, or hypertensive diseases were excluded. Patients with thalassemia, folate deficiency were excluded.

The sample size was calculated using efficacy rates of 81.8% for i.v. iron and 55.5% for oral iron from a previous study, with a confidence level of 95% and power of 90%.[11] The minimum sample size required was 52 per group, which was increased to 54 in each group to account for possible dropouts. Thus, 108 participants were enrolled and randomly allocated into two groups using a simple randomization method.

Group A received intravenous iron sucrose- 200 mg diluted in 100 ml normal saline and infused over 30 minutes on alternate days to a total dose of 1000 mg. A 1 ml test dose was given before the first infusion, and all patients were observed for 15 minutes for allergic reactions. Group B received oral iron therapy- ferrous sulfate 325 mg (containing 100 mg elemental iron) three times daily for six weeks. All participants were given folic acid 500 µg daily and dietary advice on iron-rich foods.

Baseline investigations included haemoglobin, serum ferritin, peripheral smear, and urine and renal function tests. Follow-up was conducted at the fourth and sixth weeks after therapy. Efficacy was defined as a rise in haemoglobin of more than 3.5 gm/dl after six weeks of treatment. Adverse drug reactions (ADRs) were recorded. Data were analyzed using SPSS version 16.0. Quantitative variables were expressed as mean ± standard deviation and compared using the Student's t-test, while categorical variables were analyzed using the Chi-square test. A p value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics

Both groups were comparable in age, parity, and baseline Hb and ferritin levels (Table 1).

Table 1: Baseline characteristics of participants (n=108).

Parameters	I.v. iron (n=54)	Oral iron (n=54)	P value
Mean age (years)	26.8±4.3	27.2±5.1	0.67
Parity (1-2)	38 (70.4%)	36 (66.7%)	0.72
Baseline Hb (gm/dl)	6.5±0.4	6.4±0.5	0.89
Ferritin (ng/ml)	8.2±1.9	8.0±2.1	0.61

Hemoglobin response

At 4 weeks, mean Hb rise was significantly higher in the i.v. group (3.8±0.6 gm/dl) versus the oral group (2.9±0.7 gm/dl; p<0.001). At 6 weeks, the mean Hb increase reached 4.2±0.7 gm/dl and 3.3±0.6 gm/dl respectively (p<0.001) (Table 2).

Table 2: Mean hemoglobin change over time.

Time point	I.v. iron (Mean±SD)	Oral iron (Mean±SD)	P value
Baseline	6.5±0.4	6.4±0.5	0.89
4 weeks	10.3±0.7	9.3±0.8	<0.001
6 weeks	10.7±0.6	9.7±0.9	<0.001

Serum ferritin levels

Ferritin increased significantly more in the i.v. group (mean 95.4±45.8 ng/ml) than the oral group (71.1±27.2 ng/ml; p<0.001).

Table 3: Serum ferritin levels (ng/ml).

Parameters	I.v. iron	Oral iron	P value
Baseline	8.2±1.9	8.0±2.1	0.61
At 6 weeks	95.4±45.8	71.1±27.2	<0.001

Table 4: Adverse drug reactions.

Adverse drug reactions	I.v. iron (%)	Oral iron (%)	P value
Any adverse drug reactions	14.8	40.7	0.002
Nausea	1.9	25.9	<0.001
Abdominal pain	0	18.5	0.001
Constipation	0	14.8	0.006
Discontinuation	0	9.3	0.024

Adverse drug reactions

ADRs were more frequent with oral iron (40.7%) compared to i.v. iron (14.8%, p<0.001). Common complaints with oral iron were nausea (25.9%), abdominal pain (18.5%), and constipation (14.8%). None of the patients on i.v. iron developed hypersensitivity or required discontinuation.

Efficacy rate

At 6 weeks, efficacy (Hb rise ≥3.5 gm/dl) was achieved in 88.9% of the i.v. group and 70.4% of the oral group (p=0.016). Treatment adherence was 100% in the i.v. group versus 90.7% in the oral group.

DISCUSSION

Postpartum anemia remains a pervasive public health challenge in India and other low- and middle-income countries, where nutritional inadequacies, limited antenatal care, and higher obstetric risks converge to generate substantial disease burden. The present randomized controlled trial, conducted at a tertiary care centre in Western Vidarbha, strengthens current evidence by directly comparing intravenous (i.v.) iron sucrose with conventional oral iron therapy for postpartum iron deficiency anemia. The study population- 108 women with moderate-to-severe anemia- closely mirrors national epidemiological patterns, as seen in studies from Mumbai and Uttar Pradesh, thereby supporting external validity. Notably, despite a high rate of reported antenatal iron-folic acid (IFA) compliance (70-76%), most participants still developed significant postpartum anemia, a trend consistent with Deshpande et al, highlighting real-world limitations of oral iron effectiveness in settings with high inflammatory burdens and suboptimal absorption.[12-14]

The findings of this trial reaffirm the superior efficacy of i.v. iron sucrose. The greater haemoglobin rise at both 4 and 6 weeks, compared with oral therapy, aligns with robust evidence reported by Bhandal et al, Kumar et al, and Breymann et al.[15-17] The more rapid correction of anemia is particularly important in the postpartum period, where women must simultaneously recuperate from delivery and meet the demands of lactation and neonatal care. Ferritin repletion was significantly higher in the i.v. group, supporting earlier evidence from Aggarwal et al and Radhika et al.[18,19] Subgroup analyses yielded clinically meaningful insights: younger women (≤25 years), multiparous women, and those with severe baseline anemia responded particularly well to i.v. iron, echoing findings from Okafor et al, Deshpande et al, FOGSI, and Sharma et al.[14,20-22] These stratified results offer valuable guidance for more individualized postpartum anemia management.

The study also demonstrated the clear tolerability advantages of i.v. iron sucrose. Gastrointestinal discomfort was markedly higher in the oral iron group, leading to treatment discontinuation in nearly one in ten participants, consistent with reported tolerability issues in Sultan et al and Kaur et al.[23,24] Improved adherence in the i.v. group has strong implications for low-resource settings, where poor compliance remains a major barrier to effective anemia control. Mechanistically, the superior performance of i.v. iron is supported by the well-established role of hepcidin-mediated suppression of intestinal iron absorption in the postpartum inflammatory state.[25] The ability of i.v. iron to bypass this barrier and provide complete iron repletion, as shown by Breymann et al, offers a physiological explanation for its markedly better clinical outcomes.[26]

Strengths of this study include its randomized controlled design, strong follow-up retention, detailed subgroup analysis, and comprehensive evaluation of both efficacy and adverse effects.

The limitations of this study include it being a single-centre study, generalizability to primary or rural health settings is limited. The follow-up duration of 6 weeks did not permit assessment of long-term iron repletion, recurrent anemia, or subsequent pregnancy outcomes. Extremely severe anemia (Hb<5 gm/dl) and women with comorbidities were excluded, limiting applicability to the highest-risk groups. Cost-effectiveness was not directly assessed, and patient-reported outcomes such as fatigue, quality of life, or breastfeeding success were not measured. Additionally, recruitment from a tertiary care centre may introduce selection bias toward more health-aware participants.

Despite these limitations, the study offers compelling evidence supporting i.v. iron sucrose as a superior modality for postpartum anemia treatment and provides actionable clinical insights for targeted therapeutic decisions.

CONCLUSION

The above study demonstrates that intravenous (i.v.) iron sucrose is significantly more effective and better tolerated than oral iron for postpartum anemia, offering faster haemoglobin improvement, superior iron store repletion, and fewer adverse effects, especially among younger, multiparous, and severely anaemic women. Given these advantages, i.v. iron should be prioritized as first-line therapy for moderate-to-severe postpartum anemia and for patients unable to tolerate or respond to oral iron. Strengthening standardized infusion protocols, improving provider training, and ensuring availability through public health programs and essential medicine lists will support broader implementation.

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