International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Pandit V et al. Int J Reprod Contracept Obstet Gynecol. 2026 Sep;15(9):3476-3481
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20263029

Original Research Article

Comparative efficacy and safety of oral ferrous fumarate versus intravenous iron sucrose in pregnancy with iron deficiency anemia: a prospective comparative study

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Received: 30 June 2026
Accepted: 04 August 2026

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ABSTRACT

Background: Iron deficiency anemia (IDA) during pregnancy remains highly prevalent and is associated with maternal morbidity and adverse perinatal outcomes. Oral iron is widely used but limited by gastrointestinal intolerance and variable absorption, whereas intravenous (i.v.) iron sucrose may produce faster correction and improved iron stores. Objectives were to compare oral ferrous fumarate versus i.v. iron sucrose for improvement of hemoglobin and iron indices in pregnant women with IDA, and to compare adverse effects and pregnancy/neonatal outcomes.
Methods: In this prospective comparative interventional study, 164 pregnant women with biochemical evidence of iron deficiency were allocated to group A (oral ferrous fumarate 300 mg/day ≈100 mg elemental iron + folic acid; n=82) or group B (i.v. iron sucrose 200 mg on alternate days + folic acid; n=82). Hemoglobin and iron profile were assessed at baseline and repeated at 3 and 8 weeks. Adverse effects and obstetric/neonatal outcomes were documented. Between-group comparisons used appropriate parametric/non-parametric tests; $p<0.05$ was significant.
Results: Baseline characteristics and iron indices were comparable. Hemoglobin increased in both groups but was higher in group B at 3 weeks (10.05±0.73 versus 9.59±0.73 gm/dl; $p<0.001$) and 8 weeks (10.69±0.89 versus 10.32±0.77; $p=0.006$). Ferritin rose more in group B at 3 weeks (118.16±54.89 versus 58.87±16.99 ng/ml; $p<0.001$) and remained higher at 8 weeks (64.58±14.19 versus 56.59±14.82 ng/mL; $p=0.001$). Transferrin saturation improved more in group B at both follow-ups ($p<0.001$). Oral iron caused more gastrointestinal adverse effects, whereas i.v. therapy showed more itching, thrombophlebitis and hypotension. Delivery and neonatal outcomes were comparable.
Conclusions: I.v. iron sucrose achieved faster and greater improvement in hemoglobin and iron stores with a route-specific adverse-effect profile, supporting its use in selected pregnant women needing rapid correction or with poor tolerance/adherence to oral iron.

Keywords: Adverse effects, Ferritin, Intravenous iron sucrose, Iron deficiency anemia, Oral iron, Pregnancy, Transferrin saturation

INTRODUCTION

Iron deficiency anemia (IDA) remains one of the most common nutritional disorders during pregnancy and continues to pose a substantial public health burden, particularly in low- and middle-income countries. In India, analysis of the National Family Health Survey-5 showed that anemia continues to affect more than half of pregnant women, reflecting persistent gaps in nutrition and effective antenatal supplementation.[1]

Pregnancy increases iron requirements because of expansion of maternal red cell mass, placental development and fetal growth. Women who begin pregnancy with depleted iron stores are therefore vulnerable to progressive iron deficiency as gestation

advances.[2] IDA is clinically important because it contributes to fatigue and reduced functional capacity and is associated with adverse maternal and perinatal outcomes, including preterm birth and low birth weight.[3]

Oral iron supplementation, usually in the form of a ferrous salt combined with folic acid, remains the standard population-level strategy because it is inexpensive, widely available and suitable for routine antenatal care.[4] Its effectiveness in clinical practice may nevertheless be reduced by gastrointestinal adverse effects, poor adherence, dietary inhibitors and variable absorption influenced by hepcidin-mediated regulation.[5]

Intravenous (i.v.) iron bypasses intestinal absorption and can replenish iron stores more rapidly. Iron sucrose has been widely used in pregnancy, and a large multicentre Indian trial demonstrated its effectiveness as an alternative to standard oral iron in women with moderate-to-severe anemia.[6] A systematic review and meta-analysis similarly found that i.v. iron achieves a faster hematological response and more reliable iron-store restoration than oral iron.[7]

Given the persistent burden of antenatal IDA and the practical limitations of oral therapy, comparative evidence from tertiary-care settings remains clinically relevant. The present study compared oral ferrous fumarate with i.v. iron sucrose over 3- and 8-week follow-up periods, focusing on hemoglobin response, iron-store repletion, adverse effects and obstetric and neonatal outcomes.

METHODS

Study design and setting

A prospective comparative interventional study was conducted in the department of obstetrics and gynecology, Al Ameen Medical College and Hospital, Vijayapura, Karnataka, India. The study was conducted for 18 months, from July 2024 to January 2026. Eligible antenatal women attending outpatient clinics and antenatal wards were screened and enrolled as per the study protocol. The study was approved by institutional ethical committee.

Participants

Pregnant women with singleton pregnancy and laboratory evidence of iron deficiency anemia were eligible. Written informed consent was obtained prior to enrolment.

Eligibility criteria

Inclusion criteria were as follows: serum ferritin <20 ng/mL; serum iron <60 µg/dl; TIBC 250-435 µg/dl; transferrin saturation (TSat) <20%; peripheral smear showing microcytic hypochromic anemia; MCV <78 fl; and MCH <28 pg/cell.

Exclusion criteria included multiple pregnancy, pregnancy with heart disease, history of antepartum haemorrhage, severe anemia (Hb <5 gm/dl), history of allergy to iron/iron-containing preparations, blood transfusion within the prior 120 days, and chronic systemic disorders (e.g., inflammatory bowel disease, liver disease, renal disease, hypersplenism or active infection).

Sample size and group allocation

A total of 164 participants were included, with 82 participants allocated to each group (group A: oral iron; group B: i.v. iron). Allocation was done as per the study protocol in equal numbers. Baseline demographic and obstetric characteristics were recorded using a structured proforma.

Interventions

Group A received ferrous fumarate 300 mg once daily (approximately 100 mg elemental iron/day) along with folic acid. Participants were counselled to take the tablet between meals and avoid tea/coffee around dosing to improve absorption. Group B received intravenous iron sucrose 200 mg administered on alternate days along with folic acid. Infusions were administered under supervision with monitoring during and after infusion for adverse reactions; standard venous access care was used to minimise local complications.

Data collection and laboratory assessment

Baseline evaluation included age, residence, education, parity, gestational age at enrolment and anthropometry (height, weight, BMI). Laboratory assessment included hemoglobin and red cell indices (MCV, MCH), peripheral smear, serum ferritin, serum iron and TIBC; transferrin saturation was calculated as (serum iron/TIBC) × 100. All tests were performed in the central laboratory using standard clinical methods and quality control procedures.

Follow-up and outcome measures

Participants were followed up at 3 weeks and 8 weeks after initiation of therapy. Primary outcomes were change in hemoglobin, ferritin and transferrin saturation from baseline to follow-ups and between-group differences at each time point. Secondary outcomes included adverse effects (gastrointestinal symptoms versus infusion-related events), and obstetric/neonatal outcomes (gestational age at delivery, mode of delivery, birth weight, Apgar scores at 1 and 5 minutes, and NICU admission).

Statistical analysis

Continuous variables were summarised as mean±standard deviation (SD) and categorical variables as number (percentage). Between-group comparisons for continuous variables used independent samples t-test (Welch) when approximately normal or Mann-Whitney U test otherwise.

Categorical variables were compared using Chi-square test; Fisher's exact test was used when expected cell counts were <5 in 2×2 tables. Within-group changes from baseline to follow-ups were assessed using paired t-test. A p value <0.05 was considered statistically significant.

Ethical considerations

Institutional ethics committee approval was obtained prior to study initiation. Confidentiality was maintained, and participants were free to withdraw at any time without affecting routine clinical care.

RESULTS

A total of 164 pregnant women were analysed (group A n=82; group B n=82). Baseline demographic and iron profile parameters were comparable between groups (all p>0.05).

Table 1: Comparison of baseline demographics and enrolment characteristics.

Variables	Group A (n=82)	Group B (n=82)	P value
Age (years)	27.65±5.29	28.16±6.28	0.661^{NS}
Gestational age at enrolment (weeks)	22.45±3.49	22.06±2.98	0.368^{NS}
BMI (kg/m^2)	23.92±3.95	24.93±4.05	0.179^{NS}
Rural residence (%)	46.3	36.6	0.260^{NS}

^{NS}- non significant (student t test).

Table 2: Comparison of baseline hematological indices and iron profile.

Parameters	Group A (n=82)	Group B (n=82)	P value
Hb (gm/dl)	8.91±0.67	8.89±0.67	0.955 ^{NS}
MCV (fl)	70.83±3.23	70.48±3.56	0.562 ^{NS}
MCH (pg)	24.22±1.68	23.99±1.56	0.360 ^{NS}
Ferritin (ng/ml)	14.30±3.98	13.60±3.96	0.226 ^{NS}
Serum iron (µg/dl)	44.96±7.37	43.82±7.72	0.333 ^{NS}
TIBC (µg/dl)	351.36±32.28	350.82±33.89	0.917 ^{NS}
TSat (%)	12.91±2.44	12.59±2.48	0.420 ^{NS}

^{NS}- non significant (student t test).

Table 3: Comparison of Hb, ferritin and transferrin saturation at baseline, 3 weeks and 8 weeks.

Time point	Hb (group A)	Hb (group B)	P value	Ferritin (group A)	Ferritin (group B)	P value	TSat (group A)	TSat (group B)	P value
Baseline	8.91±0.67	8.89±0.67	0.955^{NS}	14.30±3.98	13.60±3.96	0.226^{NS}	12.91±2.44	12.59±2.48	0.420^{NS}
3 weeks	9.59±0.73	10.05±0.73	<0.001*	58.87±16.99	118.16±54.89	<0.001*	10.53±1.72	19.75±3.04	<0.001*
8 weeks	10.32±0.77	10.69±0.89	0.006*	56.59±14.82	64.58±14.19	0.001*	19.04±3.58	26.70±4.27	<0.001*

*Denotes significant (p<0.05); ^{NS}- non significant (Student t test)

Baseline demographic and enrolment characteristics were similar in both groups. Mean age was 27.65±5.29 years in group A and 28.16±6.28 years in group B (p=0.661). Gestational age at enrolment (22.45±3.49 versus 22.06±2.98 weeks; p=0.368) and BMI (23.92±3.95 versus 24.93 ± 4.05 kg/m^2; p=0.179) were comparable; residence distribution also did not differ significantly (p=0.260) (Table 1).

Baseline hemoglobin and iron indices were comparable, confirming similar severity of iron deficiency anemia at enrolment. Baseline Hb was 8.91±0.67 gm/dl in group A and 8.89±0.67 gm/dl in group B (p=0.955). Ferritin (14.30±3.98 versus 13.60±3.96 ng/ml; p=0.226) and TSat (12.91±2.44% versus 12.59±2.48%; p=0.420) did not differ significantly (Table 2).

Both groups showed significant improvement in hemoglobin and iron indices during follow-up; however, the i.v. iron group demonstrated a faster and greater response. At 3 weeks, Hb was significantly higher in group B than group A (10.05±0.73 versus 9.59±0.73 gm/dl; p<0.001) and the difference persisted at 8 weeks (10.69±0.89 versus 10.32±0.77 gm/dl; p=0.006). Ferritin rose markedly in group B at 3 weeks (118.16±54.89 versus 58.87±16.99 ng/ml; p<0.001) and remained higher at 8 weeks (p=0.001). TSat improved more in group B at both follow-ups (p<0.001) (Table 3).

The magnitude of hemoglobin rise was significantly greater in the i.v. group. From baseline to 3 weeks, ΔHb was 0.67±0.27 gm/dl in group A versus 1.16 ± 0.36 gm/dl in group B (p<0.001). From baseline to 8 weeks, ΔHb was

1.41±0.37 gm/dl versus 1.80±0.49 gm/dl, respectively (p<0.001) (Table 4).

Table 4: Comparison of hemoglobin rise (ΔHb) from baseline to follow-up.

Change interval	Group A (gm/dl)	Group B (gm/dl)	P value
ΔHb (0-3 weeks)	0.67±0.27	1.16±0.36	<0.001*
ΔHb (0-8 weeks)	1.41±0.37	1.80±0.49	<0.001*

*Denotes significant (p<0.05) (Student t test).

Adverse effects were route-specific. Gastrointestinal symptoms were more frequent with oral therapy: nausea/vomiting (23.2% versus 1.2%), dyspepsia (28.0% versus 1.2%), constipation (31.7% versus 4.9%) and abdominal cramps (13.4% versus 2.4%), with statistically significant differences for these events. Infusion-related reactions were more common in the i.v. group, notably itching (23.2% versus 1.2%), thrombophlebitis (25.6% versus 2.4%) and hypotension (8.5% versus 0%) (Table 5).

Table 5: Comparison of adverse effects between the groups.

Adverse effect	Group A (%)	Group B (%)	P value
Nausea/vomiting	23.2	1.2	<0.001*
Dyspepsia	28.0	1.2	<0.001*
Constipation	31.7	4.9	<0.001*
Abdominal cramps	13.4	2.4	0.021*
Itching	1.2	23.2	<0.001*
Thrombophlebitis	2.4	25.6	<0.001*
Hypotension	0.0	8.5	0.014*

*Denotes significant (p<0.05) (Chi square test).

Obstetric and neonatal outcomes were comparable between groups. Gestational age at delivery was 38.39±1.25 weeks in group A and 38.29±1.49 weeks in group B (p=0.659). Birth weight and Apgar scores at 1 and 5 minutes were similar (all p>0.05), and overall mode of delivery distribution did not differ significantly (p=0.377) (Table 6).

Table 6: Delivery and neonatal outcomes.

Outcomes	Group A	Group B	P value
Gestational age at delivery (weeks)	38.3±1.25	38.29±1.49	0.659[aNS]
Birth weight (kg)	2.82±0.34	2.78±0.35	0.549[aNS]
Apgar 1 minute	7.39±0.94	7.46±0.89	0.750[aNS]
Apgar 5 minutes	8.76±0.81	8.76±0.79	0.859[aNS]
Mode of delivery (overall)	—	—	0.377[aNS]
NICU admission (%)	7.3	14.6	>0.05[bNS]

NS- non significant (a-Student t test; b- Chi square test).

DISCUSSION

The present study showed that both oral ferrous fumarate and i.v. iron sucrose improved hemoglobin and iron indices, although the i.v. regimen produced a faster and greater response. The mean hemoglobin rise with i.v. iron was 1.16 gm/dl at 3 weeks and 1.80 gm/dl at 8 weeks, compared with 0.67 and 1.41 gm/dl, respectively, with oral therapy. Anjum et al likewise reported a greater early hemoglobin increase with i.v. iron sucrose than with oral ferrous sulphate.[8] Kriplani et al. also documented effective correction of moderate-to-severe antenatal anemia with i.v. iron sucrose, supporting its value when rapid repletion is required.[9]

The superior early response in the i.v. group is consistent with earlier comparative evidence. Neeru et al observed a more rapid rise in hemoglobin and improved iron status with iron sucrose than with oral therapy.[10] Froessler et al similarly reported favourable antenatal and postpartum haematological responses following i.v. iron sucrose compared with oral ferrous sulphate.[11] In another randomized trial, Al et al found that i.v. iron corrected anemia more rapidly and restored iron stores more effectively than oral iron during pregnancy.[12]

Ferritin and transferrin saturation provide information beyond hemoglobin by reflecting storage iron and circulating iron available for erythropoiesis. In our study, ferritin at 3 weeks was 118.16±54.89 ng/ml in the i.v. group compared with 58.87±16.99 ng/ml in the oral group, and transferrin saturation remained significantly higher with i.v. therapy at both follow-ups. The REVAMP trial demonstrated substantial improvement in maternal iron status following i.v. ferric carboxymaltose compared with standard oral treatment.[13] The IVON trial also reported superior haematological correction with i.v. iron in pregnant women with anemia.[14] Hansen et al found that IV ferric derisomaltose was more effective than oral iron in preventing persistent iron deficiency during pregnancy.[15]

Gastrointestinal adverse effects were substantially more frequent with oral ferrous fumarate, particularly nausea or vomiting, dyspepsia and constipation. Such intolerance is clinically important because it can reduce adherence and diminish the effectiveness of an otherwise appropriate regimen. A recent systematic review found that intermittent oral iron may reduce adverse effects while maintaining an acceptable haematological response.[16] A pilot randomized trial of oral iron doses initiated early in

pregnancy further highlighted the need to balance elemental iron exposure with tolerability and adherence.[17]

Infusion-related reactions in the i.v. group included itching, thrombophlebitis and occasional hypotension. Although these events require supervised administration and careful venous access, they were generally manageable. A systematic review and meta-analysis of treatment studies found fewer overall adverse events and maternal complications with i.v. iron than with oral iron.[18] A broader safety meta-analysis concluded that serious reactions to contemporary i.v. iron preparations are uncommon.[19] Long-term obstetric experience with the iron-sucrose complex has likewise supported its use when administered with appropriate monitoring.[20]

Gestational age at delivery, birth weight, Apgar scores and NICU admission were comparable between the groups. This finding is consistent with evidence syntheses showing that the biochemical superiority of i.v. iron is more consistent than its effect on neonatal outcomes, which are influenced by multiple maternal, placental and socioeconomic factors.[21]

The better transferrin-saturation response with i.v. iron is pharmacologically plausible because parenteral administration bypasses intestinal absorption and hepcidin-mediated restriction.[22] Current expert recommendations support individualising therapy according to anemia severity, gestational age, response to oral iron, treatment tolerance and the time available before delivery.[23] The continuing global burden of anemia among pregnant women reinforces the need for effective antenatal detection and treatment pathways.[24] Oral iron and folic acid should remain the foundation of routine prophylaxis, while i.v. iron sucrose can be considered for selected women who require rapid correction or cannot tolerate or respond adequately to oral therapy.[25]

Follow-up was limited to 8 weeks and postpartum hemoglobin/iron status were not assessed. Quality-of-life measures and severity grading of adverse events were not included. The study may be underpowered to detect differences in uncommon maternal or neonatal endpoints.

CONCLUSION

Both oral ferrous fumarate and i.v. iron sucrose improved hemoglobin and iron indices over follow-up. I.v. iron sucrose achieved faster hemoglobin correction and superior replenishment of iron stores with a distinct adverse-effect profile. I.v. iron sucrose may be considered in selected pregnant women requiring rapid correction or with poor tolerance/adherence to oral iron.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Pandit V, Rathod LH. Comparative efficacy and safety of oral ferrous fumarate versus intravenous iron sucrose in pregnancy with iron deficiency anemia: a prospective comparative study. Int J Reprod Contracept Obstet Gynecol 2026;15:3476-81.