



Intravenous Iron Sucrose Versus Oral Iron Therapy During Pregnancy: A Critical Appraisal of Reported Haematological Outcomes and Treatment Tolerability

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Abstract

Background: Iron-deficiency anaemia during pregnancy requires appropriate treatment to restore haemoglobin concentrations and iron stores while minimising treatment-related complications. Oral iron preparations are widely used, although gastrointestinal intolerance and inconsistent adherence may affect treatment response. Intravenous iron sucrose is an alternative for selected patients who require parenteral iron replacement.

Objective: To critically examine the reported haematological response, treatment adherence, adverse effects and pregnancy outcomes in a published comparison of intravenous iron sucrose and oral ferrous sulfate.

Methods: This manuscript presents a narrative critical appraisal of a previously published randomized comparative study by Kumari and colleagues. The reported study enrolled 100 pregnant women and allocated 50 participants to each treatment group. Its published results were reviewed descriptively, with attention to participant retention, haemoglobin response, other haematological measurements and treatment tolerability. No new participants were recruited, and no independent patient-level statistical analysis was performed.

Results: The source study reported that 48 participants in the intravenous iron sucrose group and 35 in the oral ferrous sulfate group were included in the six-week analysis. Mean haemoglobin concentration reportedly increased from 8.41 ± 0.13 to 11.63 ± 0.14 g/dL in the intravenous group and from 8.43 ± 0.15 to 10.09 ± 0.16 g/dL in the oral group. The corresponding reported increases were 3.22 and 1.66 g/dL. Two participants in the intravenous group were reported to have experienced hypersensitivity reactions, while 15 participants in the oral group were reported to have taken tablets irregularly. The publication also described differences in other haematological parameters and treatment-related adverse effects. However, several entries presented as p-values exceed the permissible statistical range, and detailed numerical pregnancy outcome data were not provided in the supplied material.

Conclusion: The published findings describe a larger reported haemoglobin increase with intravenous iron sucrose than with oral ferrous sulfate over the assessed period. However, unequal numbers of participants in the final analysis, unresolved statistical inconsistencies and incomplete information on pregnancy outcomes limit the strength of the conclusions. These findings should be interpreted as those of the published study and not as results from a new clinical investigation.

Keywords: Pregnancy; iron-deficiency anaemia; intravenous iron sucrose; oral ferrous sulfate; haemoglobin concentration; treatment adherence; critical appraisal.

INTRODUCTION

Iron-deficiency anaemia is an important clinical concern during pregnancy because iron requirements increase as pregnancy progresses. Iron is essential for haemoglobin formation and oxygen transport, and insufficient iron availability can impair maternal haematological adaptation. The clinical consequences depend on the degree of anaemia, the

gestational stage at diagnosis and the presence of additional medical or obstetric complications.

Oral iron is commonly used to correct iron deficiency because it is accessible and can be administered outside a hospital setting. Nevertheless, its practical effectiveness may be reduced when gastrointestinal symptoms interfere with regular intake. Treatment response may also vary according to the severity of iron deficiency, absorption, dosing, adherence and the interval available for correction before delivery.

Intravenous iron sucrose provides an alternative route of iron administration. Clinical studies have compared it with oral iron preparations to evaluate the speed and magnitude of haemoglobin recovery, restoration of iron stores and tolerability. Some trials have reported greater short-term improvements in haemoglobin or ferritin with intravenous treatment, although treatment protocols, populations and outcomes differ across studies [1–4].

The interpretation of comparative treatment studies requires more than a numerical comparison of mean haemoglobin values. Participant retention, allocation procedures, outcome measurement, adverse-event ascertainment and statistical methods should also be evaluated. In particular, results based on participants who completed follow-up may differ from those obtained when all randomized participants are retained in the analysis.

Kumari, Biswas and Dayal published a comparative study of intravenous iron sucrose and oral iron in pregnant women with iron-deficiency anaemia [1]. The present article provides a rewritten, source-attributed appraisal of the findings supplied from that publication. Its purpose is to interpret the reported results cautiously and identify issues that should be considered when evaluating the evidence.

OBJECTIVE

The objective was to appraise the reported differences between intravenous iron sucrose and oral ferrous sulfate in haemoglobin response, additional haematological parameters, treatment adherence, adverse effects and pregnancy outcomes during the treatment of iron-deficiency anaemia in pregnancy.

MATERIALS AND METHODS

Article under review

The principal source was the published comparative study by Kumari and colleagues [1]. Related clinical studies were considered for context when discussing iron replacement during pregnancy [2–4].

This article is a narrative critical appraisal of previously published research. It does not report newly collected patient data or an independently conducted clinical trial.

Population and treatment groups described in the source

The source study reported enrolling 100 pregnant women who met its eligibility criteria. Participants were allocated to two groups:

- **Group A:** Intravenous iron sucrose, initially 50 participants.
- **Group B:** Oral ferrous sulfate, initially 50 participants.

The detailed eligibility criteria, treatment doses, randomization procedure, ethics approval and study setting should be consulted in the original publication before this appraisal is used in a formal submission.

Outcomes considered

The outcomes described in the supplied publication results included baseline and post-treatment haemoglobin concentrations, changes in other haematological parameters, weekly haemoglobin changes, treatment adherence, adverse effects and pregnancy outcomes.

The source reported observations after approximately six weeks of treatment, with additional observations at delivery and one week postpartum.

Approach to interpretation

The numerical findings below are attributed to the published study rather than presented as new observations. The values have not been recalculated from participant-level data.

The appraisal also considers whether the reported statistical results are internally interpretable. Any value that is mathematically incompatible with its stated statistical label is identified as requiring verification rather than being silently corrected.

RESULTS

Participant enrolment and analysis

The source reported that 100 pregnant women were initially allocated equally between the intravenous and oral treatment groups. At the six-week assessment, 48 participants from Group A and 35 from Group B were included in the analysis.

Two participants in the intravenous group were reported to have developed hypersensitivity reactions. In the oral group, 15 participants were reported to have taken the prescribed tablets irregularly.

Table 1. Participant allocation and reported six-week analysis in the published study

Participant disposition	Intravenous iron sucrose	Oral ferrous sulfate
Initial allocation	50	50
Included in reported six-week analysis	48	35
Not included in reported six-week analysis	2	15
Reason described in the supplied results	Hypersensitivity reactions	Irregular tablet intake

Source: Kumari et al. [1]. The table summarises the supplied published results. The original publication and study records should be consulted to establish whether irregular adherence resulted in exclusion, discontinuation or another analytical decision.

The difference in the numbers analysed is important. Only 83 of the 100 initially allocated participants were included in the reported six-week analysis. The available information does not establish how all exclusions were handled or whether the findings were analysed according to the initial randomized allocation.

Age characteristics

Most participants were reported to be between 25 and 29 years of age. The mean age was reported as 27.9 ± 0.95 years in the intravenous group and 29.1 ± 1.0 years in the oral group.

A full age-distribution table cannot be reconstructed because the numbers in individual age categories were not supplied. The meaning of the variability estimates also requires confirmation from the original report.

Haemoglobin response

The published results described an increase in mean haemoglobin concentration in both groups. The intravenous group reportedly increased from 8.41 ± 0.13 g/dL before treatment to 11.63 ± 0.14 g/dL after treatment. In the oral group, the reported values rose from 8.43 ± 0.15 g/dL to 10.09 ± 0.16 g/dL.

Table 2. Reported haemoglobin concentrations before and after treatment

Group	Baseline haemoglobin (g/dL)	Post-treatment haemoglobin (g/dL)	Reported increase (g/dL)
Intravenous iron sucrose	8.41 ± 0.13	11.63 ± 0.14	3.22
Oral ferrous sulfate	8.43 ± 0.15	10.09 ± 0.16	1.66

Source: Kumari et al. [1]. The published report supplied a between-group *p*-value of 0.0012 for the change in haemoglobin. The underlying statistical output should be checked before this value is used in a new analysis.

The reported increase was numerically larger in the intravenous group. However, the comparison requires careful interpretation because the numbers included in the six-week analysis differed between groups. It is also necessary to establish whether the values following the $\pm$ sign represent standard deviations or standard errors.

Other haematological measurements

The supplied results described changes in red blood cell count, packed cell volume, mean corpuscular haemoglobin concentration, reticulocyte count, serum iron, serum ferritin and total iron-binding capacity.

Table 3. Additional haematological changes reported in the source publication

No.	Parameter	Intravenous group change	Oral group change	P-value printed in supplied source
1	Haemoglobin (g/dL)	3.22	1.66	0.0012
2	Red blood cell count (million/mm ³)	0.98	1.02	4.2021
3	Packed cell volume (%)	9.94	11.74	4.9721
4	Mean corpuscular haemoglobin concentration (%)	4.97	4.34	3.5412
5	Reticulocyte count (%)	0.74	0.59	2.1210
6	Serum iron	69.1	41.2	0.0471
7	Serum ferritin (reported in $\mu\text{g/L}$)	64.73	14.28	0.0012
8	Total iron-binding capacity	-310.22	-150.09	0.0012

Source: Kumari et al. [1]. Some units and the direction of change need confirmation. In particular, the values printed as 4.2021, 4.9721, 3.5412 and 2.1210 cannot be valid *p*-values because *p*-values must lie between 0 and 1. These entries must be checked against the original statistical output; they should not be interpreted as valid significance tests.

The numerical values supplied for serum iron and ferritin suggest greater reported changes in the intravenous group. Nevertheless, the values alone are insufficient to establish the precision or reliability of the between-group differences without confirmation of the units, measurements, analytical population and statistical calculations.

Reported weekly haemoglobin changes

The published results also presented percentage changes in haemoglobin at weekly intervals and at later obstetric assessments.

Table 4. Weekly and subsequent haemoglobin changes as reported in the source

Assessment point	Intravenous group (%)	Oral group (%)	P-value printed in source
First week	13.42 ± 0.74	9.80 ± 0.60	0.0001
Second week	18.81 ± 0.83	5.91 ± 0.44	0.0001
Third week	4.72 ± 0.31	1.66 ± 0.11	0.0077
Fourth week	2.70 ± 0.23	1.17 ± 0.09	0.0047
Fifth week	1.33 ± 0.08	0.74 ± 0.07	0.0005
Sixth week	0	0.37 ± 0.04	0.0000
At delivery	45.60 ± 2.33	27.97 ± 1.29	0.0010
One week postpartum	33.45 ± 2.22	16.40 ± 1.33	0.0140

Source: Kumari et al. [1]. The supplied report does not clearly define how these percentages were calculated. The sixth-week value in the intravenous group and the p-value printed as 0.0000 particularly require examination of the original analysis output. A displayed value of 0.0000 should not be interpreted as a probability equal to zero.

The weekly figures should not be treated as a reliable longitudinal comparison until their definitions and calculations are confirmed. The number of participants contributing measurements at each interval should also be stated.

Pregnancy outcomes

The source report stated that pregnancy outcomes did not differ significantly between the groups. However, the supplied material did not contain numerical data for individual maternal, obstetric or neonatal outcomes.

Without the event counts, denominators and statistical comparisons, it is not possible to independently verify this statement or determine how precisely the study excluded clinically important differences.

Treatment tolerability

The source described a different pattern of treatment-related difficulties across the groups. Systemic adverse effects were reported more frequently in the intravenous group, whereas gastrointestinal complaints were described as more frequent in the oral group. Two hypersensitivity reactions were reported in the intravenous group, and irregular tablet intake was reported in 15 participants in the oral group.

Discussion

The published study describes a greater numerical increase in haemoglobin concentration with intravenous iron sucrose than with oral ferrous sulfate during the reported treatment period. This observation is consistent with the direction of findings in some comparative studies of intravenous and oral iron preparations during pregnancy. However, results across studies are not interchangeable because the populations, iron formulations, treatment protocols, follow-up periods and outcome definitions may differ [2–4].

Interpretation of the reported haemoglobin response

The source reported an increase of 3.22 g/dL in the intravenous group compared with 1.66 g/dL in the oral group. These values suggest a larger haematological response in the intravenous group among the participants included in the reported analysis.

Intravenous treatment delivers iron without relying on intestinal absorption, whereas the effectiveness of oral treatment depends in part on regular intake, absorption and tolerability. These differences provide a plausible clinical explanation for variation in response. They do not, by themselves, prove that the route of administration caused the entire observed difference.

The unequal numbers included in the reported final analysis are especially relevant. If participants who did not tolerate treatment or did not adhere to therapy were omitted, the analysed groups may no longer fully represent the randomized groups. A comparison restricted to participants with available follow-up may be affected by attrition and selection bias.

The original dataset should therefore be checked before the reported change scores are interpreted as a definitive estimate of comparative efficacy.

Relationship to other published studies

Earlier studies have evaluated intravenous iron sucrose against oral iron during pregnancy. Syal and colleagues reported greater improvements in selected haematological measures and iron stores with intravenous treatment in their comparative trial [2]. Kochhar and colleagues also evaluated the efficacy and tolerability of these treatment approaches in pregnant women [3]. Bhavi and Jaju reported a randomized comparison in which the intravenous group demonstrated a greater short-term increase in haemoglobin and serum ferritin than the oral ferrous fumarate group [4].

These publications provide a basis for discussing the clinical plausibility of the results reported by Kumari and colleagues. They do not validate the specific numerical values in the source table, nor can differences among studies be

resolved without considering their individual protocols and findings.

Evidence concerning pregnancy outcomes requires particular care. A greater improvement in a laboratory measurement does not automatically mean that a treatment produces better neonatal or obstetric outcomes. For example, a randomized trial evaluating clinical outcomes and the relative cost-effectiveness of intravenous iron sucrose reported that the clinical benefits should not be inferred solely from haematological improvement [5].

Iron stores and additional laboratory measurements

Serum ferritin and serum iron provide complementary information when assessing iron status. Nevertheless, their interpretation depends on the analytical method, units, sampling conditions and relevant clinical context. Total iron-binding capacity also requires correct units and a clearly specified definition of change.

The supplied source reported larger numerical changes in serum iron and ferritin in the intravenous group. These findings warrant attention but cannot be regarded as conclusive until the reported measurements and statistical calculations have been verified.

The p-values exceeding 1 in the supplied table are a major reporting concern. No conclusion about statistical significance should be drawn from those entries. Correcting them requires consultation of the original output or access to the underlying data; substituting plausible-looking values would be inappropriate.

Adherence and adverse effects

The source identified irregular oral tablet intake and hypersensitivity reactions associated with intravenous treatment. These findings highlight different practical considerations for the two strategies.

Oral iron can be convenient for outpatient care, but gastrointestinal symptoms may discourage consistent use. Intravenous iron avoids daily tablet intake but requires supervised administration and appropriate readiness to manage infusion-related reactions.

The supplied information does not quantify the frequency or severity of most adverse effects. Therefore, a quantitative claim that one treatment is safer than the other is not justified on the basis of these results alone. A meaningful comparison would require consistent event definitions, event counts, denominators, severity grading and documentation of treatment interruption.

Interpretation of pregnancy outcomes

The report stated that pregnancy outcomes were not significantly different between the groups. In the absence of outcome counts, this claim cannot be evaluated independently.

Furthermore, a nonsignificant p-value does not establish that two treatments are equivalent. Demonstrating equivalence or non-inferiority requires an appropriate prespecified design and analysis. Future reports should provide actual outcome frequencies, effect estimates and confidence intervals for clinically important maternal and neonatal endpoints.

Statistical reporting and reproducibility

The source tables contain values described as p-values that fall outside the permitted range. The weekly data also lack a clear definition of the percentage-change calculation. These issues reduce confidence in the precision and reproducibility of the reported comparisons.

A transparent reanalysis would require the participant-level dataset, a documented analysis plan and clarification of how missing measurements were handled. Baseline and follow-up values within a participant should be analysed with methods suitable for paired measurements, while comparisons between randomized groups should follow the intended trial estimand. Repeated weekly measurements require methods that account for their correlation within each participant. Until these issues are resolved, the reported numerical findings should be discussed descriptively rather than treated as independently validated evidence of superiority.

Strengths and Limitations

Strengths

The published study compared two clinically used approaches to iron replacement in pregnancy. It considered several laboratory outcomes rather than haemoglobin concentration alone and included observations related to treatment adherence, adverse effects and later pregnancy assessments. The equal initial allocation to the two treatment groups is also reported in the supplied source.

Limitations

Several limitations affect the interpretation of the supplied findings:

1. The numbers included in the six-week analysis differed between the treatment groups.
2. The information available for this appraisal did not fully describe the disposition of all participants or the analysis approach for missing follow-up.
3. Several entries presented as p-values are mathematically invalid and require verification.
4. The statistical meaning of the reported variability estimates was not established in the supplied material.

5. The calculation method for the reported weekly percentage changes was unclear.
6. Numerical counts for individual adverse effects were unavailable.
7. Detailed maternal, obstetric and neonatal outcome data were not supplied.
8. The findings presented here are drawn from a published report and have not been independently reanalysed using participant-level data.
9. This narrative appraisal was not conducted as a systematic review and does not claim exhaustive identification or formal grading of all available evidence.

CONCLUSION

The published comparative study reported a greater increase in haemoglobin concentration in pregnant women treated with intravenous iron sucrose than in those treated with oral ferrous sulfate. It also described differences in treatment-related difficulties, including hypersensitivity reactions in the intravenous group and irregular tablet intake in the oral group.

The findings require cautious interpretation. Unequal numbers of participants were included in the reported six-week analysis, several statistical entries cannot be valid p-values, and numerical data for pregnancy outcomes were unavailable in the supplied material. These issues prevent independent confirmation of the full magnitude and clinical significance of the reported differences.

The evidence reviewed supports further careful evaluation of the effectiveness and tolerability of different iron replacement approaches during pregnancy. It does not, without verification of the underlying statistics and complete outcome data, establish that one treatment is categorically superior across all clinically relevant outcomes.

Recommendations for Reporting and Further Research

Future comparative studies should prespecify their primary outcome and analysis approach, report participant flow transparently and explain missing follow-up data. Haemoglobin and iron-store measurements should be accompanied by clearly defined units, variability measures and appropriate statistical comparisons.

Adverse events should be documented using consistent definitions and reported with counts, denominators, severity and management. Pregnancy outcomes should be presented quantitatively, with confidence intervals where appropriate. Where possible, analyses should retain participants according to their original randomized allocation and include sensitivity analyses for missing data.

For any manuscript that uses findings from a prior publication, the source should be cited clearly. A paper claiming to be original clinical research must instead be supported by the authors' own study protocol, genuine participant records and independently verified analysis.

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