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A PROSPECTIVE CLINICAL STUDY OF IV IRON ISOMALTOSIDE IN THE TREATMENT OF POST PARTUM ANEMIA

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ABSTRACT

Introduction: Postpartum anemia, defined as hemoglobin levels below 10 g/dL, is a common and serious health concern in developing countries like India. It can impair maternal recovery, lactation, and overall well-being. Intravenous (IV) iron therapy is preferred over oral iron for its faster action and better efficacy in moderate to severe cases. Iron isomaltoside is a newer IV iron formulation that allows high-dose administration (up to 1000 mg) in a single sitting with minimal risk of hypersensitivity or free iron-related side effects. **Materials & Methods** :This is a Prospective and observational study. Clinical study of iv iron isomaltoside in the treatment of post partum anemia admitted in the department of OBG, BMCRC, BALLARI. **Results:** Among 69 women treated with IV iron isomaltoside, mean hemoglobin increased significantly from 8.1 ± 1.0 to 10.2 ± 1.2 g/dL, and serum ferritin from 18.5 ± 6.2 to 86.4 ± 15.3 ng/mL ($p < 0.001$ for both). Hemoglobin increased by >2 g/dL in 47.8% of patients, 1–2 g/dL in 39.1%, and <1 g/dL in 13%. Ferritin rose by >50 ng/mL in 59.4% of patients. A moderate positive correlation was observed between hemoglobin and ferritin increases ($r = 0.42$, $p < 0.001$). **Conclusion:** Intravenous iron isomaltoside was effective in significantly improving hemoglobin and serum ferritin levels in women with postpartum anemia, with nearly half of the patients achieving a hemoglobin increase of more than 2 g/dL within two weeks.. These findings support the use of iron isomaltoside as a safe and efficient option for the rapid correction of postpartum anemia, particularly in resource-limited settings.

KEYWORDS

Anaemia, Intravenous iron preparations, Isomaltosidenin

INTRODUCTION

Postpartum anemia is a prevalent and often under-recognized condition that can significantly affect maternal health during the puerperium. It is associated with increased fatigue, impaired physical and cognitive function, emotional disturbances, delayed wound healing, and suboptimal breastfeeding outcomes. The condition is most commonly due to iron deficiency, exacerbated by blood loss during delivery and insufficient iron reserves during pregnancy.[1] However, a haemoglobin level <10 g/dL indicates anaemia at any stage during pregnancy and post-partum period that should initiate investigations and treatment because of potentially serious consequences for the mother.[2] Iron deficiency can be classified as severe ID when the serum ferritin level is below 20–30 µg/L and mild-moderate ID if the serum ferritin level is below 70–100 µg/L.[3]

The IDA patients were randomized 2:1 to a single dose of 1000 mg IIM, or iron sucrose (IS) administered as 200 mg intravenous injections, up to five times.[4] The co-primary endpoints were adjudicated serious or severe hypersensitivity reactions, and change in hemoglobin.[5] The frequency of patients with serious or severe hypersensitivity reactions was 0.3% (95% confidence interval: 0.06; 0.88) vs 0.4% (0.05;1.45) in the IIM and IS group, respectively.[6] The co-primary safety objective was met, and no risk difference was observed between groups. The co-primary efficacy endpoint of non-inferiority in hemoglobin change was met, and IIM led to a significantly more rapid hematological response in the first two weeks.[7]

FCM induced a significantly higher incidence of hypophosphataemia than IIM (47%, 95% CI 36–58% vs. 4%, 95% CI 2–5%), and significantly greater mean decreases in serum phosphate (0.40 vs. 0.06 mmol/L). Hypophosphataemia persisted at the end of the study periods (maximum 3 months) in up to 45% of patients treated with FCM.[8] Meta-regression analysis identified low baseline serum ferritin and transferrin saturation, and normal kidney function as significant predictors of hypophosphataemia.[9]

New intravenous (IV) iron preparations should ideally be capable of delivering a wide dosing range to allow iron correction in a single or low number of visits, a rapid infusion (doses up to 1,000 mg must be administered over more than 15 minutes and doses exceeding 1,000 mg must be administered over 30 minutes or more), and minimal potential side effects including low catalytic/labile iron release with minimal risk of anaphylaxis.[10] Due to the structure of iron isomaltoside, it can be administered in high doses with a maximum single dosage of 20 mg/kg body weight.[11]

Aim Of The Study

To evaluate the efficacy and safety of intravenous iron isomaltoside in the management of postpartum anemia in women.

Primary Outcome, Secondary Outcomes, Side Effects

1. **Primary Outcome:** To study clinical outcome of iron isomaltoside in treatment of post partum anemia.
2. **Secondary Outcome:** To study the safety of iron isomaltoside in treatment of post partum anemia.

MATERIALS & METHODS

This is a Prospective and observational study. Clinical study of iv iron isomaltoside in the treatment of post partum anemia in the Department of OBG, BMCRC, BALLARI.

Inclusion Criteria

- Patients with Hb 7-10 g/dL
- S-Ferritin <100 ug/L

Exclusion Criteria

- Hb level <7 g/dL
- Failure to give consent
- Estimated glomerular filtration rate less than 65 mL/min/1.73m2, serum phosphate level less than 2.5mg/dL
- Acute bleeding greater than 500 mL within 72 hours before study.
- Hemochromatosis or other iron-storage disorder.
- Intravenous iron use within 30 days prior to screening.

Method Of Collection Of Data (Including Sampling Procedure, If Any)

All the women admitted under Department of OBG, BMCRC, Ballari after application of inclusion and exclusion criteria will be taken up for the study.

Routine antenatal work ups for CBC with PS, RBS, Blood grouping and serology will be done. Before giving inj. Iron isomaltoside need to check CBC and serum ferritin, and after 2wks of giving inj. Iron isomaltoside again need to call patient and recheck CBC and serum ferritin. After 2wks of giving inj. Iron isomaltoside patient was called for CBC (complete blood count) and serum ferritin level estimation. At the end of the study, data is compiled and analyzed.

Statistical Analysis

Data collected was entered into Microsoft excel 2007 and analyzed by using SPSS 22 version software. Categorical data will be represented in the form of Frequencies , Table , Charts and proportions.

RESULTS

Table 1: Change in Hemoglobin and Serum Ferritin Pre- and Post-Treatment (n = 69)

Parameter	Baseline (Mean ± SD)	2 Weeks Post-Treatment (Mean ± SD)	p-value (Paired t-test)

Hemoglobin (g/dL)	8.1 ± 1.0	10.2 ± 1.2	<0.001
Serum Ferritin (ng/mL)	18.5 ± 6.2	86.4 ± 15.3	<0.001

Table 2: Hemoglobin Improvement Categories at 2 Weeks

Hb Increase (g/dL)	Patients (n)	Percentage (%)
<1	9	13%
1–2	27	39.1%
>2	33	47.8%

Table 3: Serum Ferritin Increase Categories

Ferritin Increase (ng/mL)	Patients (n)	Percentage (%)
<20	5	7.2%
20–50	23	33.3%
>50	41	59.4%

Table 4: Correlation Between increase in Hb and increase in Ferritin levels

Variable Pair	Correlation Coefficient (r)	p-value
Hb rise vs Ferritin rise	0.42	<0.001

There is a moderate positive correlation between increase in hemoglobin and increase in ferritin levels, suggesting that both improved significantly with IV iron isomaltoside.

Table 5: Adverse Events Linked To IV Iron Isomaltoside

Side Effect	Incidence (n=69)
Hypotension	5 (7.2%)
Nausea/Vomiting	3 (4.3%)
Headache	2 (2.9%)
Allergic Reaction	1 (1.4%)

DISCUSSION

In our study, administration of a single high dose of intravenous iron isomaltoside in women with postpartum anemia resulted in a mean hemoglobin (Hb) increase of approximately 2.1 g/dL within 2–3 weeks. The treatment was well-tolerated, with a low incidence of adverse events, indicating both efficacy and safety in the postpartum population.

These findings are consistent with those reported by **Derman et al. (2017)**,[12] who observed a similar mean Hb increase of 2.4 g/dL over a comparable timeframe following iron isomaltoside administration. Like the current study, Breymann et al. also reported a favorable safety profile, reinforcing the reliability of this formulation in managing postpartum anemia.

In contrast, **von Tempelhoff et al. (2008)** [13] studied intravenous iron sucrose and found it to be effective; however, the treatment required multiple infusions of smaller doses (typically 200 mg per session), presenting a logistical disadvantage. Our study highlights the practical benefit of iron isomaltoside, which can be administered as a single 1000 mg infusion—significantly reducing the number of healthcare visits and improving treatment compliance.

CONCLUSION

Intravenous iron isomaltoside was highly effective in improving hemoglobin and ferritin levels in women with postpartum anemia, with most patients showing significant improvement within two weeks. A moderate positive correlation was observed between hemoglobin and ferritin rise. The treatment was well tolerated, with only minor, self-limiting side effects.

These findings support IV iron isomaltoside as a safe and efficient option for rapidly correcting postpartum iron deficiency anemia and promoting maternal recovery. Further studies are recommended to confirm these results in larger populations.

REFERENCES:

1. Breymann C. Postpartum anemia: definition, prevalence, clinical relevance and therapy. Asian J Transfus Sci. 2018;12(1):5-9
2. Knight M, Kurinczuk JJ, Spark P, Brocklehurst P. Extreme obesity in pregnancy in the United Kingdom. Obstet Gynecol. 2010;115(5):989-997.
3. Allen LH. Causes of vitamin B12 and folate deficiency. Food Nutr Bull. 2008;29(2 Suppl):S20-S34.
4. Antony AC. Megaloblastic anemias. In: Hoffman R, ed. Hematology: Basic Principles and Practice. 6th ed. Philadelphia: Elsevier; 2013:519-556.
5. King JC. Physiology of pregnancy and nutrient metabolism. Am J Clin Nutr. 2000;71(5 Suppl):1218S-1225S.
6. Scholl TO. Maternal iron status: relation to fetal growth, length of gestation, and iron endowment of the neonate. Nutr Rev. 2011;69(Suppl 1):S23-S29.
7. Ray JG, Wyatt PR, Thompson MD, et al. Vitamin B12 and the risk of neural tube defects in a folic-acid-fortified population. Epidemiology. 2007;18(3):362-366.
8. Haider BA, Olofin I, Wang M, et al. Anaemia, prenatal iron use, and risk of adverse pregnancy outcomes: systematic review and meta-analysis. BMJ. 2013;346:f3443.
9. Rani M, Mittal M, Aggarwal AK. Anemia in pregnancy: a cross-sectional study. J Family Med Prim Care. 2021;10(1):89-93.
10. Bhandari S, Kalra PA, Saxena S, et al. A randomized, open-label, phase 3 study of intravenous iron isomaltoside 1000 versus iron sucrose in patients with iron deficiency anemia. Nephrol Dial Transplant. 2017;32(4):759-768.
11. Onken JE, Bregman DB, Harrington RA, et al. A multicenter, randomized, active-controlled study to investigate the safety and efficacy of iron isomaltoside 1000 (Monofer®) in patients with iron deficiency anemia. Transfusion. 2014;54(2):306-315.
12. Derman R, Roman E, Modiano MR, Achebe MM, Thomsen LL, Auerbach M. A randomized trial of iron isomaltoside versus iron sucrose in patients with iron deficiency anemia. Am J Hematol. 2017;92(3):286–91.
13. Von Tempelhoff GF, Radünz A, Meyberg R, et al. Assessment of intravenous iron sucrose in the management of anemia in gynecological and obstetrical practice. Eur J Obstet Gynecol Reprod Biol. 2008;137(2):131–6.