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COMPARISON OF THE SUCCESSFUL OUTCOME OF ORAL IRON AND INTRAVENOUS IRON SUCROSE FOR TREATMENT OF ANEMIA IN PREGNANCY AT BILAWAL MEDICAL COLLEGE (CDF HOSPITAL) HYDERABAD

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Abstract

OBJECTIVE: *To compare the successful outcome of oral iron and intravenous iron sucrose for treatment of anemia in pregnancy at Bilawal Medical College (CDF Hospital), Hyderabad.*

METHODOLOGY: *This randomized controlled trial was conducted over six months in the Department of Gynaecology and Obstetrics, Bilawal Medical College, Hyderabad, after obtaining ethical approval. A total of 100 anemic pregnant women aged 20-45 years, with gestational age ≥12 weeks, were enrolled using non-probability consecutive sampling and randomly allocated into two groups. Group A (n=50) received intravenous iron sucrose, while Group B (n=50) received oral ferrous sulfate. Both groups received equal folic acid supplementation. Hemoglobin levels were assessed at baseline and after four weeks of treatment. A hemoglobin level ≥11 g/dL at four weeks was considered a successful outcome. Data were analyzed using SPSS, and comparisons were made using appropriate statistical tests, with $p \leq 0.05$ considered significant.*

RESULTS: *The mean post-treatment hemoglobin level was significantly higher in the intravenous iron sucrose group compared to the oral iron group (11.6 ± 0.7 g/dL vs. 10.9 ± 0.8 g/dL; $p < 0.001$). Successful treatment outcomes were achieved in 92.0% of patients receiving intravenous iron sucrose, compared to 72.0% in the oral iron group ($p = 0.01$). Stratification analysis showed that intravenous iron sucrose remained superior across different demographic and clinical variables.*

CONCLUSION: *Intravenous iron sucrose is more effective than oral iron therapy in achieving rapid correction of anemia during pregnancy and should be considered a preferred treatment option, particularly when prompt improvement in hemoglobin levels is required.*

INTRODUCTION:

Iron deficiency anemia (IDA) is an important health condition common among pregnant women.[1] Pregnant women with IDA are exposed to increased risk of cardiovascular stress, fatigue, dizziness, exhaustion, pre-eclampsia, renal failure, antepartum hemorrhage, blood transfusion requirement, and even mortality.[2–4] IDA is also associated with risk of adverse perinatal

outcomes, such as intrauterine growth retardation, stillbirth, prematurity, and low birth weight [5]. Treatments for IDA in pregnancy include oral iron, parenteral iron therapy, and blood transfusion. The most common treatment is oral iron therapy [6]. However, it is associated with some drawbacks, such as gastrointestinal side effects, poor compliance, and treatment unresponsiveness due to poor iron absorption [7]. Gastrointestinal adverse effects are reduced with intravenous iron therapy [8].

Parenteral iron is an alternative treatment for IDA, indicated when the blood ferritin level drops to below 15 µg/L [9]. Parenteral iron is quicker in increasing the hemoglobin (Hb) level and replenishing iron stores than oral iron [10]. Several types of parenteral iron include intravenous iron sucrose complex (ISC) and low-molecular-weight iron dextran (LMWID). Both are effective, safe, fast, and convenient in treating maternal IDA [11-12]. However, ISC requires the patient to stay longer in the hospital due to divided dosage [13]. By contrast, LMWID can be administered in a short period as a total dose [14]. A study done by Tigga et al it was observed that the number of cases who attained the target Hb level at the end of 4 weeks was 82% (oral) versus 96% (IVIS) [15].

Anemia and the primary cause, iron deficiency, lead to reduced physical capacity, with consequences for both social and economic development. Women who become pregnant while anemic due to insufficient iron stores are at higher risk of preterm delivery. For a successful outcome of pregnancy and improvement in anemia treatment of its causes is of paramount importance. On the other front, treating nutritional anemia in pregnancy with oral iron is staggering due to its associated side effects, resulting in noncompliance for the same. Parenteral iron therapy is therefore considered an alternative for oral iron defaulters, which can also reduce the need for blood transfusion in antenatal period. Data from this study would help us in addressing anemia by adopting it our management plan. The objective of the study was to compare the successful outcome of oral iron and intravenous iron sucrose for treatment of anemia in pregnancy at Bilawal Medical College (CDF Hospital), Hyderabad.

METHODOLOGY:

This randomized controlled trial was conducted over a period of six months (from 1st-Mar-2024 to 31st-Aug-2024) in the Department of Gynaecology and Obstetrics at Bilawal Medical College, CDF Hospital Hyderabad. The study was initiated after obtaining approval from the College of Physicians and Surgeons Pakistan (CPSP). All eligible participants were informed in detail about the objectives, potential benefits, and possible risks of the study, and written informed consent was obtained before enrollment.

A total sample size of 100 pregnant women was included, with 50 participants allocated to each study group. The sample size was calculated using OpenEpi software, considering a 5% level of significance (α = 0.05) and 90% power ($1-\beta$ = 0.90). Based on the findings reported by Tigga et al., [15] the proportion of patients achieving target hemoglobin levels at four weeks was 82% in the oral iron group compared to 96% in the intravenous iron sucrose group. Women aged 20 to 45 years with gravida and parity of one or more, gestational age of at least 12 weeks (determined by last menstrual period or dating ultrasound), and diagnosed anemia were recruited through non-probability consecutive sampling. Anemia was defined according to World Health Organization criteria as hemoglobin concentration below 11 g/dL during pregnancy. Pregnant women with coagulopathies (evidenced by elevated INR), vitamin B12 or folic acid deficiency, history of peptic ulcer disease, inflammatory bowel disease, hypothyroidism, hematological malignancies, thalassemia, or celiac disease were excluded from the study.

Outcome Definition: Treatment success was evaluated after four weeks of therapy. Participants who achieved a hemoglobin level of ≥11 g/dL following treatment were classified as having a successful outcome.

Hypothesis: Intravenous iron sucrose therapy produces superior treatment outcomes

compared to oral iron supplementation in anemic pregnant women.

Data collection procedure: Eligible participants were enrolled from the Department of Gynaecology and Obstetrics. Baseline demographic and clinical information including age, gestational age, gravida, parity, occupation, educational status, and family monthly income was recorded by the principal investigator. Laboratory investigations were performed to confirm anemia prior to randomization.

Participants were randomly assigned into two groups using the sealed envelope method. Group A (intravenous iron sucrose group) received iron sucrose at a dose of 100 mg diluted in 100 mL of normal saline, administered on alternate days following a test dose. The minimum daily dose was 100 mg, with a maximum weekly dose of 300 mg. The total iron requirement was calculated using the formula:

Body weight (kg) × (target hemoglobin − baseline hemoglobin) × 2.4 + 500 mg, where the target hemoglobin level was set at 11 g/dL.

A test dose of 15 mL iron sucrose infusion was administered slowly, followed by a 15-minute observation period to monitor for any hypersensitivity or anaphylactic reactions. In the absence of adverse reactions, the remaining infusion was administered.

Group B (oral iron group) received oral ferrous sulfate tablets at a dose of 200 mg twice daily, with each tablet containing 60 mg of elemental iron. Both groups were given the same dose of folic acid supplementation.

Participants were instructed to return after four weeks for reassessment. At follow-up, blood samples were collected and sent to the hospital laboratory for hemoglobin estimation. Treatment outcomes were then evaluated and documented using a structured proforma (Annexure).

Statistical analysis: Data were analyzed using SPSS software. Quantitative variables such as age, gestational age, and post-treatment hemoglobin levels were summarized using mean and standard deviation for normally distributed data, as assessed by the Kolmogorov–Smirnov test. Median and interquartile range (IQR) were reported for variables with non-normal distribution. Qualitative variables including residence, parity, gravida, monthly family income, educational status, and occupation were expressed as frequencies and percentages.

Comparisons between the two groups were made using the Chi-square test or Fisher's exact test, where appropriate. Potential effect modifiers were controlled through stratification of demographic and clinical variables, followed by post-stratification application of Chi-square or Fisher's exact test. A p-value of ≤0.05 was considered statistically significant.

RESULTS:

A total of 100 anemic pregnant women were enrolled in the study and randomly allocated into two equal groups. Group A received intravenous iron sucrose (IVIS), while Group B received oral iron therapy. All participants completed the four-week follow-up and were included in the final analysis.

Baseline Characteristics:

The mean age of participants in Group A was 29.6 ± 5.4 years, while in Group B it was 30.1 ± 5.7 years. The mean gestational age at enrollment was 24.8 ± 4.6 weeks in the IVIS group and 25.2 ± 4.3 weeks in the oral iron group. Baseline demographic variables including age, gestational age, gravida, parity, occupational status, family monthly income, and educational status were comparable between the two groups, showing no statistically significant differences ($p > 0.05$).

TABLE 1: BASELINE CHARACTERISTICS OF STUDY PARTICIPANTS (N = 100)

Variable	Group A (IVIS) n=50	Group B (Oral Iron) n=50	p-value
Age (years), mean ± SD	29.6 ± 5.4	30.1 ± 5.7	0.64
Gestational age (weeks), mean ± SD	24.8 ± 4.6	25.2 ± 4.3	0.58
Gravida ≥ 2, n (%)	32 (64.0)	30 (60.0)	0.68

Variable	Group A (IVIS) n=50	Group B (Oral Iron) n=50	p-value
Parity ≥ 2, n (%)	29 (58.0)	27 (54.0)	0.69
Employed, n (%)	18 (36.0)	20 (40.0)	0.67
Monthly income ≤ 75,000 PKR, n (%)	34 (68.0)	36 (72.0)	0.66
Secondary or higher education, n (%)	31 (62.0)	29 (58.0)	0.68

Post-Treatment Hemoglobin Levels:

After four weeks of treatment, the mean post-treatment hemoglobin level was significantly higher in the IVIS group (11.6 ± 0.7 g/dL) compared to the oral iron group (10.9 ± 0.8 g/dL), and this difference was statistically significant ($p < 0.001$).

TABLE 2: COMPARISON OF POST-TREATMENT HEMOGLOBIN LEVELS

Parameter	Group A (IVIS)	Group B (Oral Iron)	p-value
Post-treatment Hb (g/dL), mean ± SD	11.6 ± 0.7	10.9 ± 0.8	<0.001

Treatment Outcome:
A successful outcome, defined as achieving hemoglobin ≥ 11 g/dL after four weeks of therapy, was observed in 46 patients (92.0%) in the IVIS group, compared to 36 patients (72.0%) in the oral iron group. The difference in successful outcomes between the two groups was statistically significant ($p = 0.01$).

TABLE 3: COMPARISON OF SUCCESSFUL TREATMENT OUTCOME BETWEEN GROUPS

Outcome	Group A (IVIS) n (%)	Group B (Oral Iron) n (%)	p-value
Successful	46 (92.0)	36 (72.0)	0.01
Not successful	4 (8.0)	14 (28.0)	0.09

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Stratification of Successful Outcome:
Stratification analysis showed that intravenous iron sucrose remained superior to oral iron across different age groups, gestational age categories, parity, educational status, and family income levels. The difference in treatment success remained statistically significant after stratification ($p \leq 0.05$), indicating that the observed effect was independent of these potential confounders.

TABLE 4: STRATIFICATION OF SUCCESSFUL OUTCOME BY SELECTED VARIABLES

Variable	Successful IVIS n (%)	Successful Oral n (%)	p-value
Age ≤ 30 years	24 (92.3)	18 (69.2)	0.04
Age > 30 years	22 (91.7)	18 (75.0)	0.05
Gestational age ≤ 24 weeks	21 (91.3)	17 (70.8)	0.04
Gestational age > 24 weeks	25 (92.6)	19 (73.1)	0.03
Secondary or higher education	29 (93.5)	22 (75.9)	0.04
Income ≤ 75,000 PKR	31 (91.2)	24 (66.7)	0.02

Intravenous iron sucrose demonstrated significantly better improvement in hemoglobin levels and a higher rate of successful treatment outcomes compared to oral iron therapy in pregnant women with anemia.

DISCUSSION: Anemia during pregnancy remains a significant public health concern in developing countries, contributing to adverse maternal and fetal outcomes. The present randomized controlled trial compared the effectiveness of oral iron supplementation

and intravenous iron sucrose in achieving successful treatment outcomes among anemic pregnant women. The findings of this study demonstrate that intravenous iron sucrose is superior to oral iron therapy in improving hemoglobin levels and achieving treatment success within a shorter duration.

In the current study, post-treatment hemoglobin levels were significantly higher in the intravenous iron sucrose group compared to the oral iron group after four weeks of therapy (11.6 ± 0.7 g/dL vs. 10.9 ± 0.8 g/dL, $p < 0.001$). This rapid rise in hemoglobin among patients receiving intravenous iron can be attributed to better bioavailability, avoidance of gastrointestinal absorption limitations, and improved patient compliance. Oral iron therapy, on the other hand, is often associated with poor absorption and gastrointestinal side effects, which may limit adherence and therapeutic response.

The proportion of women achieving a successful outcome (hemoglobin ≥ 11 g/dL) was significantly higher in the intravenous iron sucrose group compared to the oral iron group (92.0% vs. 72.0%, $p = 0.01$). These findings are consistent with the results reported by Tigga et al., [15] who observed a higher treatment success rate with intravenous iron sucrose compared to oral iron among pregnant women with iron deficiency anemia. Similar outcomes have also been reported by Bhandal and Russell, [16] who demonstrated faster hemoglobin correction and better tolerability with intravenous iron sucrose.

Several previous studies have highlighted the limitations of oral iron therapy, including poor gastrointestinal tolerance, non-compliance, and delayed hematological response. Breymann et al [17] reported that intravenous iron sucrose resulted in a more predictable and sustained increase in hemoglobin levels compared to oral iron preparations. Likewise, Khalafallah et al [18] showed that intravenous iron therapy led to better hematological outcomes and reduced the need for blood transfusion in pregnant women with moderate to severe anemia.

Stratification analysis in the present study revealed that the superiority of intravenous iron sucrose remained consistent across different age groups, gestational age categories, parity, educational status, and income levels. This suggests that the observed benefit of intravenous iron sucrose was independent of demographic and socioeconomic factors. These findings align with those of Bayoumeu et al., [19] who reported that intravenous iron sucrose was effective irrespective of gestational age and baseline hemoglobin levels.

The safety profile of intravenous iron sucrose in pregnancy has been well established in previous studies. In the present study, no serious adverse reactions were observed, further supporting the safety and tolerability of intravenous iron sucrose when administered under appropriate monitoring. This is in agreement with findings from Al-Momen et al., [20] who reported minimal adverse effects with iron sucrose infusion in pregnant women.

Despite its strengths, the study has certain limitations. The follow-up duration was limited to four weeks, and long-term maternal and neonatal outcomes were not assessed. Additionally, serum ferritin levels were not measured, which could have provided further insight into iron store replenishment. Future studies with longer follow-up and inclusion of iron indices are recommended.

CONCLUSION:

The intravenous iron sucrose is more effective than oral iron therapy in achieving rapid correction of anemia in pregnancy. Given its higher success rate, better tolerability, and faster hematological response, intravenous iron sucrose should be considered a preferred treatment option for pregnant women with moderate anemia, particularly when rapid correction is required or oral iron therapy is poorly tolerated.

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