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# A PROSPECTIVE COMPARATIVE STUDY TO COMPARE THE EFFICACY, SAFETY, AND COMPLIANCE OF INTRAVENOUS IRON SUCROSE VERSUS ORAL IRON THERAPY IN THE TREATMENT OF IRON DEFICIENCY ANEMIA IN PREGNANCY.

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## ABSTRACT

**Background:** Iron deficiency anemia (IDA) is one of the most common nutritional disorders complicating pregnancy and is associated with increased maternal and perinatal morbidity. Oral iron therapy is traditionally used for treatment; however, poor compliance, gastrointestinal side effects, and inadequate absorption often limit its effectiveness. Intravenous iron sucrose has emerged as a promising alternative with better efficacy and tolerability.**Objectives:** To compare the efficacy, safety, and compliance of intravenous iron sucrose with oral iron therapy in the treatment of iron deficiency anemia during pregnancy.**Methods:** A hospital-based prospective comparative study was conducted in the Department of Obstetrics and Gynecology of a tertiary care center. Hundred pregnant women between 16–32 weeks of gestation with hemoglobin levels of 7–10.9 g/dL were enrolled and divided into two groups. Group A received oral ferrous sulfate (200 mg twice daily) for four weeks, while Group B received intravenous iron sucrose calculated according to iron deficit. Hematological parameters including hemoglobin, packed cell volume, serum ferritin, transferrin saturation, MCV, and MCHC were assessed before and after treatment. Adverse effects and treatment compliance were also evaluated. **Results:** Baseline mean hemoglobin was 8.2±0.8g/dL in the oral iron group and 7.8±0.7 g/dL in the intravenous iron sucrose group. After four weeks, mean hemoglobin increased to 9.8±0.86g/dL and 10.5±0.88g/dL, respectively (p=0.01). Significant improvement in ferritin levels, transferrin saturation, PCV, and MCHC was observed in the intravenous group. Gastrointestinal adverse effects such as nausea, constipation, and gastritis were significantly higher in the oral iron group.**Conclusion:** Intravenous iron sucrose is a safe, effective, and well-tolerated treatment for iron deficiency anemia in pregnancy, producing a greater rise in hemoglobin and better replenishment of iron stores with fewer adverse effects compared to oral iron therapy.

## KEYWORDS

Iron Deficiency Anemia, Pregnancy, Intravenous Iron Sucrose, Oral Iron Therapy

## INTRODUCTION

Iron deficiency anemia (IDA) remains one of the most common nutritional deficiencies affecting pregnant women worldwide. According to the World Health Organization (WHO), nearly half of all pregnant women suffer from anemia, with a substantially higher burden in developing countries. Pregnancy increases maternal iron requirements because of expansion of maternal blood volume, fetal growth, placental development, and blood loss during delivery. When these increased requirements are not met, iron deficiency develops, leading to anemia.[1,2]

Maternal anemia is associated with significant adverse maternal and fetal outcomes including preterm labor, low birth weight, intrauterine growth restriction, postpartum hemorrhage, increased susceptibility to infections, poor lactation, and increased maternal mortality. It also affects neonatal iron stores, resulting in impaired cognitive and physical development of infants.[2,3]

Oral iron supplementation has traditionally been considered the first-line treatment for iron deficiency anemia during pregnancy due to its affordability and ease of administration. However, gastrointestinal side effects such as nausea, constipation, abdominal discomfort, and gastritis frequently reduce compliance. Furthermore, impaired intestinal absorption and poor adherence often limit its effectiveness.[4,5]

Intravenous iron sucrose has emerged as an effective alternative for the treatment of moderate iron deficiency anemia during pregnancy. It bypasses gastrointestinal absorption, rapidly replenishes iron stores, and achieves faster correction of hemoglobin levels. Modern formulations of iron sucrose have demonstrated excellent safety profiles with a lower incidence of severe adverse reactions compared with older parenteral preparations.[6,7]

The present study was undertaken to compare the efficacy, safety, and compliance of intravenous iron sucrose and oral iron therapy in pregnant women with iron deficiency anemia. Understanding the relative benefits of these treatment modalities can help optimize antenatal care and improve maternal and fetal outcomes.[4,6]

## MATERIALS AND METHODS :

Study Design: Hospital-based prospective comparative study

Study Setting:Department of Obstetrics and Gynaecology, Tertiary Care Hospital, India.

Study Duration:18 months

Study Population : Pregnant women diagnosed with iron deficiency anemia between 16 and 32 weeks of gestation.

Sample Size : A total of 100 pregnant women were included and divided into two groups:

Group A (n=50): Oral Iron Group
Group B (n=50): Intravenous Iron Sucrose Group

Inclusion Criteria: Singleton pregnancy , Gestational age 16–32 weeks, Hemoglobin 7–10.9 g/dL, Willingness to participate

Exclusion Criteria: Hemoglobin <7 g/dL , Non-iron deficiency anemia, Known hypersensitivity to iron sucrose, not willing to participate

Treatment Protocol: Group A: Oral Iron Therapy :Ferrous sulfate tablets containing 60 mg elemental iron were administered twice daily for four weeks.

Group B: Intravenous Iron Sucrose Therapy

Iron sucrose dose was calculated using: Maximum dose per infusion: 200 mg diluted in 100 mL normal saline.

**Data Collection:**

Baseline evaluation included: Detailed history, General and obstetric examination, Hemoglobin estimation, Packed Cell Volume (PCV), Serum ferritin, Transferrin saturation, Mean Corpuscular Volume (MCV) , Mean Corpuscular Hemoglobin Concentration (MCHC), Reticulocyte count

Patients were reassessed after 4 weeks of treatment.

Outcome Measures:. Rise in hemoglobin level,. Improvement in iron stores, Safety profile,Patient compliance

## RESULTS:

### 1)Demographic Characteristics

Both groups were comparable regarding age, parity, education, and socioeconomic status. No statistically significant difference was observed in baseline demographic characteristics indicating that both groups were well matched before treatment.

**Table 1: Demographic data**

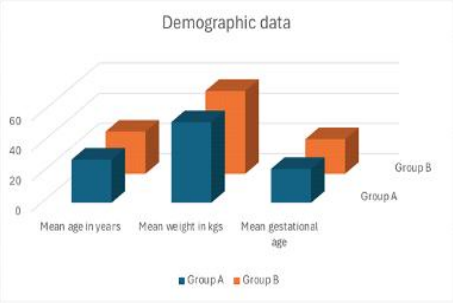
| Parameter | Group A | Group B | P value |
|---|---|---|---|
| Mean age in years | 28.6+1.60 | 28.0+2.00 | 0.4 |
| Mean weight in kgs | 53.5+5.8 | 54.9+7.4 | 0.001 |
| Mean gestational age | 22.5+4.10 | 22.9+4.30 | 0.55 |

**Distribution of Parity:**

Oral group: 23primigravida, 27multigravida

IV group: 19primigravida, 31 multigravida

**Graph 1: Demographic data**



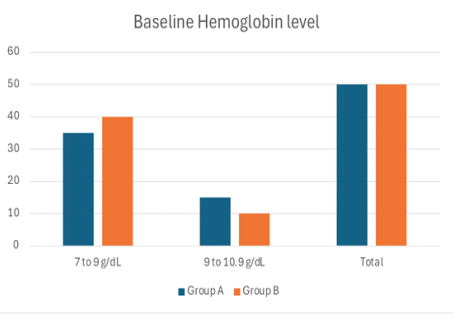

### 2)Baseline Hemoglobin level

Among group A at baseline mean Hb was 8.2±0.8 and majority 35 had Hb in 7 to 9g/dl range and in group B at baseline mean Hb was 7.8±0.7 and majority 40 had Hb in 7 to 9g/dl range. P=0.01 showed statistical significance.

**Table 2: Base line Hemoglobin level**

| Hemoglobin level | Group A | Group B | P value |
|---|---|---|---|
| 7 to 9 g/dL | 35 | 40 | 0.01 |
| 9 to 10.9 g/dL | 15 | 10 | |
| Total | 50 | 50 | |
| Mean +SD | 8.2+0.8 | 7.8+0.7 | |

**Graph 2 : Base line Hemoglobin level**




### 3)Hemoglobin level after 4weeks of respective treatment

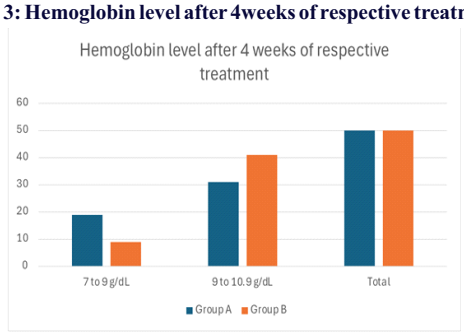
after 4 weeks of respective treatment in group A mean Hb was 9.8±0.86 and majority 31 had Hb in 9 to 10.9g/dl range and in group B after respective treatment mean Hb was 10.5±0.88 and majority 41 had Hb in 9 to 10.9g /dl range. P=0.01 showed statistical significance.

**Table 3 : Hemoglobin level after 4weeks of respective treatment**

| Hemoglobin level | Group A | Group B | P value |
|---|---|---|---|
| 7 to 9 g/dL | 19 | 9 | 0.01* |
| 9 to 10.9 g/dL | 31 | 41 | |
| Total | 50 | 50 | |
| Mean +SD | 9.8+0.86 | 10.5+0.88 | |

Among group A mean PCV % was 33.3±2.4, mean ferritin m/l was 211.34±1.6, mean transferrin saturation % was 26.4±2.8, mean reticulocyte count was 4.37±1.6, mean MCHC was 34.4±2.5 and Mean MCV was 91.5±1.9 and Among group B mean PCV % was 39.9±3.9, mean ferritin m/l was 215±2.5, mean transferrin saturation % was 28.9±2.6 mean reticulocyte count was 4.7±2.4, mean MCHC was 37.9±3.1and Mean MCV was 83.4±1.1. Statistical significance was seen for transferrin saturation and MCHC. Statistical significance was seen for all parameters except reticulocyte count.

**Graph 3: Hemoglobin level after 4weeks of respective treatment**

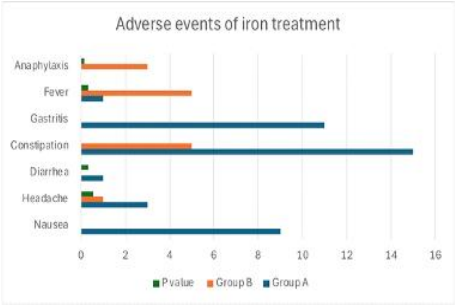



### 4)Adverse events of iron treatment

**Table 4: Adverse events of iron treatment**

| Adverse events | Group A | Group B | P value |
|---|---|---|---|
| Nausea | 9 | 0 | 0.005 |
| Headache | 3 | 1 | 0.55 |
| Diarrhea | 1 | 0 | 0.31 |
| Constipation | 15 | 5 | 0.02 |
| Gastritis | 11 | 0 | 0.001 |
| Fever | 1 | 5 | 0.31 |
| Anaphylaxis | 0 | 3 | 0.15 |

**Graph 4: Adverse events of iron treatment**




On Adverse events, majority were in Group A as compared to Group B. among group A 9 had nausea, 3 had headache, 1 had diarrhea, 15 had constipation, 11 had gastritis, 1 had fever and among group B 1 had headache, 5 had constipation, 5 had fever and 3 had anaphylaxis. Statistical significance was seen for nausea ($p<0.005$), constipation ($p<0.02$), and gastritis ($p<0.001$).

## DISCUSSION:

The present study compared oral iron therapy with intravenous iron sucrose in pregnant women with moderate iron deficiency anemia. The demographic characteristics of both groups were comparable, ensuring valid comparison of treatment outcomes.[6,8]

Baseline hemoglobin levels were similar between groups, indicating comparable severity of anemia. After four weeks of treatment, both groups demonstrated significant improvement; however, the increase was substantially greater among women receiving intravenous iron sucrose.[6,9]

The rapid rise in hemoglobin observed in the IV iron group can be explained by direct delivery of iron into circulation, bypassing gastrointestinal absorption barriers. This finding is consistent with studies by Mishra et al., Kochhar et al., and Verma et al., who reported superior hematological responses with intravenous iron therapy.[6,9,10]

Iron store parameters such as ferritin, transferrin saturation, PCV, and MCHC improved significantly in both groups but were more pronounced in the IV iron sucrose group. Restoration of iron stores is clinically important because it reduces the likelihood of recurrent anemia during late pregnancy and the postpartum period.[3,9]

Patient compliance was better in the intravenous group because treatment was administered under medical supervision. Oral iron therapy requires prolonged daily intake and is frequently associated with gastrointestinal side effects that reduce adherence.[4,5]

Regarding safety, oral iron therapy produced a significantly higher incidence of nausea, constipation, and gastritis. Although two patients in the IV group developed mild hypersensitivity reactions, no severe life-threatening complications occurred. Overall, intravenous iron sucrose demonstrated a favorable safety profile.[7,9]

The findings suggest that intravenous iron sucrose provides faster correction of anemia, better replenishment of iron stores, and improved compliance compared with oral iron supplementation. These findings are consistent with previous studies and support the use of intravenous iron sucrose as an effective alternative for the treatment of moderate iron deficiency anemia during pregnancy.[6,9,10]

## CONCLUSION

Iron deficiency anemia remains a major public health problem among pregnant women and contributes significantly to maternal and fetal morbidity.

The present study demonstrates that:
1. Both oral iron and intravenous iron sucrose improve hemoglobin levels.
2. Intravenous iron sucrose produces a significantly greater rise in hemoglobin within four weeks.
3. Iron stores are replenished more effectively with intravenous therapy.
4. Gastrointestinal adverse effects are considerably lower with intravenous iron sucrose.
5. Compliance is superior with intravenous treatment because administration occurs under supervision.
6. Intravenous iron sucrose is a safe and effective alternative to oral iron therapy.

Therefore, intravenous iron sucrose should be considered the preferred treatment for moderate to severe iron deficiency anemia during pregnancy, especially when rapid correction is required or oral therapy is poorly tolerated.

**Conflict of interest**: no

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