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Original Research Article

Study of effectiveness, tolerability and safety of intravenous iron sucrose in moderate anaemia in pregnancy

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ABSTRACT

Background: Iron deficiency is the most common cause of anaemia in pregnancy. The first choice in the treatment of iron deficiency anaemia for almost all patients is oral iron replacement because of its effectiveness, safety and low cost. Intravenous iron therapy is recommended during the second and third trimesters for women with moderate anaemia and those with noncompliance or intolerance to oral iron. This study aimed to assess the effectiveness, tolerability and safety of intravenous iron sucrose in moderate anaemia in pregnancy.
Methods: A longitudinal prospective study was conducted at a tertiary care center. The pregnant women with moderate anaemia with gestational age between 28 weeks and 34 weeks were administered intravenous iron sucrose in precalculated doses and rise in haemoglobin and other indices were measured after 3 weeks.
Results: Among 163 cases, baseline mean Hb level of 8.09±1.1 g/dl and serum ferritin level of 7.74±6.1 µg/l showed a statistically significant change to 12.07±1.4 g/dl and 89.12±62.43 µg/l respectively three weeks after treatment with intravenous iron sucrose. In addition, mean PCV, MCH and MCHC also improved significantly.
Conclusions: Parental iron therapy is safe and effective in increasing haemoglobin, serum ferritin and other hematological parameters in pregnant women with moderate anaemia. It can be used as a treatment of choice in patients with intolerance or non- compliance to oral iron therapy. Intravenous iron sucrose injection is found to be safe and tolerable with good efficacy in the treatment of moderate anaemia.

Keywords: Iron deficiency anaemia, Injection iron sucrose, Moderate anaemia in pregnancy

INTRODUCTION

WHO defines anaemia as a haemoglobin <11 g/dl or haematocrit <33% at any time during pregnancy.[1] According to WHO, 30.7% of women aged 15-49 years suffered from anaemia in 2023 and the prevalence of anaemia in pregnant women in the same age group was 35.5%.[2] The physiological changes occurring during pregnancy, including accelerated erythropoiesis and disproportionate plasma volume expansion compared to red cell volume result in haemodilution. These changes mask the severity of anaemia, delay diagnosis and complicate the management of anaemia.

According to statistics from the National Family Health Survey (NFHS-5), 52.2% of pregnant women in the country between the ages of 15 and 49 years are considered anaemic.[3] During pregnancy, approximately 1000 mg of iron is needed for the developing fetal-placental unit and the expansion of maternal erythrocyte mass. Out of this amount, one- third of the iron is utilized to establish sufficient iron stores in neonates at birth. Iron deficiency anaemia (IDA) results from inadequate iron intake, poor absorption, or increased iron requirements during pregnancy. Folate deficiency and vitamin B12 deficiency are also significant contributors to anaemia in pregnant women. Additionally, haemolytic anaemias, caused by genetic disorders such as sickle cell disease and thalassemia, pose unique challenges in the management of

anaemia during pregnancy.[4] IDA during pregnancy is also influenced by the mother's preexisting iron stores and the amount of iron absorbed during gestation.

Anaemia during pregnancy is associated with a range of maternal complications that can have severe consequences. These include an increased risk of maternal mortality, heightened susceptibility to infections, preterm labour, preterm premature rupture of membranes, postpartum haemorrhage, and cardiac complications. Fetal complications arising from maternal anaemia are equally concerning. The reduced oxygen-carrying capacity of the blood in anaemic mothers can lead to inadequate oxygen supply to the fetus, affecting fetal growth and development. Fetal growth restriction, preterm birth, perinatal mortality, and long-term neurodevelopmental impairments are some of the adverse outcomes associated with anaemia in pregnancy. Each of these complications can significantly impact the health and well-being of the mother and fetus, underscoring the importance of early detection and effective management of anaemia in pregnant women.[5]

The primary treatment for IDA is oral iron supplementation, which is safe and cost-effective. However, it is associated with gastrointestinal side effects such as nausea, abdominal pain, diarrhoea, and constipation, leading to non-adherence in up to 40% of patients.[6] In cases of moderate anaemia or when oral iron is poorly tolerated, intravenous (IV) iron therapy is recommended.[7] IV iron sucrose offers a better safety profile and faster onset of action compared to older agents like high molecular weight iron dextran.

IV iron sucrose has been shown to be effective in improving Hb and serum ferritin levels in pregnant women with IDA. It is administered intravenously, with doses calculated based on the patient's weight and Hb levels. The treatment is generally well-tolerated, with a lower incidence of adverse reactions compared to oral iron therapy.[8]

METHODS

Study setting

A hospital based longitudinal follow up study was conducted for 18 months from November 2022 to May 2024 in a tertiary health care center after obtaining clearance from Institutional Ethical Committee. All pregnant women with gestational age of 28 weeks to 34 weeks with moderate anaemia with haemoglobin levels between 7-9 gm/dl were included in the study after taking informed consent. Pregnant women with anaemia due to causes other than iron deficiency anaemia such as haemoglobinopathies like sickle cell disease and thalassemia and acute blood loss were excluded from the study. The patients who refused to participate and follow up during study and those with history of recent blood transfusions and allergy to iron containing medications were also not included.

The women were subjected to thorough history taking using a questionnaire. Demographic profile of the patients was assessed including age, socioeconomic status and education. A detailed general and obstetric examination was carried out. Blood investigations like CBC, Hb electrophoresis, serum ferritin and peripheral blood smear were conducted in all patients. The Ganzoni's formula was used for calculation of dose of iron sucrose required to correct anaemia:

Required iron (mg) = 2.4 x (target Hb-actual Hb) x body weight (kg)+ replenishment of stores.[9]

Iron stores (mg): An estimation of the iron needed to replenish the body's reserves. For patients weighing 35 kg or more, 500 mg was added. For patients under 35 kg, the amount was calculated as 15 mg per kg of body weight.

Injection iron sucrose was administered in a dose of 200 mg intravenously in 100ml normal saline given over a period of 15-20 min on alternate days depending on the precalculated dose of iron. The first dose was given in the ward where facilities for cardiopulmonary resuscitation were available. The patients were observed for major or minor side effects or anaphylactic reactions and they were documented accordingly.

CBC and serum ferritin levels were repeated after 3 weeks and the outcome was determined by rise in haemoglobin and serum ferritin levels. If rise in haemoglobin and serum ferritin levels was as expected then patients were shifted on oral iron. The patients in whom the rise in Hb was not satisfactory, they were treated with second dose of iron sucrose or blood transfusions depending on gestational age and severity of anaemia.

Statistical analysis

All the data were recorded in a pre- designed study proforma. The recorded data were entered and compiled in Microsoft excel 2021. Descriptive data were represented in the form of frequencies, means and percentages. Association between categorical variables was assessed by using chi square test and for continuous variables paired t-test was used. P value of <0.05 was considered significant. SPSS version 26.0 was used for statistical analysis of data.

RESULTS

Total 163 patients were registered in our study. The highest proportion of the patients i.e. 83(50.93%) were in age group of 26-30 years, 48(29.44%) were between 21-25 and rest 32(19.63%) were above 30 years of age (Table 1). The mean age of patients was 27.8 years. Total 95 (68.9%) patients in our study were primigravida and 68 (31.1%) were multigravida (Table 2).

The distribution of patients in terms of socioeconomic status showed that the highest proportion of the patients (54.60%) were in upper lower socioeconomic status,

28.84% in lower middle, 11.04% in lower and rest 5.52% belonged to upper middle class (Table 3).

Table 1: Distribution of patients according to age group.

Age group (in years)	Number of patients	Percentage (%)
25	48	29.44
26-30	83	50.93
>30	32	19.63
Total	163	100.00

Table 2: Distribution of patients according to parity.

Parity	Number of patients	Percentage (%)
Primigravida	95	68.9
Multigravida	68	31.1
Total	163	100.00

Table 3: Distribution of patients according to socioeconomic status.

SES category	Number of patients	Percentage (%)
Lower	18	11.04
Lower middle	47	28.84
Upper lower	89	54.60
Upper middle	09	5.52
Total	163	100.00

The weight distribution and BMI in our study showed that 55.82% of patients were in normal BMI category followed by 29.44% in overweight, 10.45% in obese and 4.29% in underweight categories respectively (Table 4).

Table 4: Distribution of patients according to socioeconomic status.

BMI category	Number of patients	Percentage (%)
Underweight (<18.5)	7	4.29
Normal weight (18.5-24.99)	91	55.82
Overweight (25-30)	48	29.44
Obese (>30)	17	10.45
Total	163	100.00

Baseline mean Hb level was 8.09±1.1 g/dl, and the mean serum ferritin was 7.74±6.1 µg/l. Three weeks after treatment with iron sucrose, both parameters showed significant improvement. The mean Hb increased to 12.07±1.4 g/dl, and serum ferritin rose to 89.12±62.43 µg/l. The p values for both Hb and ferritin were 0.0001 and 0.000 respectively, indicating statistically significant changes (Table 5).

Table 5: Distribution of patients on basis of mean haemoglobin and serum ferritin levels before and after intravenous iron sucrose.

Parameter	Baseline (Mean±SD)	After 3 weeks (Mean±SD)	P value
Mean Hb (g/dl)	8.09±1.1	12.07±1.4	0.0001
Serum ferritin (µg/l)	7.74±6.1	89.12±62.43	0.000

The baseline values of mean PCV were 22.17±2.94%, mean MCH 21.17±2.07 pg and mean MCHC was 25.67±2.97 g/l. These values when repeated after the treatment were significantly improved. The mean PCV increased to 35.87±2.71%, the mean MCH rose to 29.21±2.14 pg, and the mean MCHC elevated to 36.37±2.14 g/l. The p values for all three indices were 0.001 which were statistically significant (Table 6).

Table 6: Distribution of patients based on red blood cell indices before and after intravenous iron sucrose therapy.

Parameter	Baseline (Mean±SD)	After 3 weeks (Mean±SD)	P value
Mean packed cell volume (%)	22.17±2.94	35.87±2.71	0.0001
Mean MCH (pg)	21.17±2.07	29.21±2.14	0.0001
Mean MCHC (g/L)	25.67±2.97	36.37±2.14	0.0001

Among the 163 patients registered in our study, 92% patients reported no side effects. The remaining patients experienced only minor adverse effects, with nausea being the most common (4.29%), followed by headache (1.84%), chills and rigor (2.45%), and vomiting (0.61%). Notably, there were no reports of pain at the injection site or anaphylactic reactions (Table 7).

Table 7: Distribution of patients according to adverse effects.

Adverse effects	No. of patients	Percentage (%)
Headache	3	1.84
Nausea	7	4.29
Vomiting	1	0.61
Chills and rigor	4	2.45
Thrombophlebitis	1	0.61
Pain at injection site	0	0.00
Anaphylactic reaction	0	0.00
No side effects	150	92.02
Total	163	100.00

DISCUSSION

Iron deficiency anaemia (IDA) remains a significant

public health concern during pregnancy, with prevalence rates varying globally. In India, approximately 53.7% of pregnant women are affected by anaemia, predominantly due to iron deficiency. This condition is associated with adverse maternal and fetal outcomes, including increased risks of preterm labor, low birth weight, and maternal mortality.[10]

Our study observed that the majority of patients (50.93%) were in the 26–30 years age group, followed by 29.44% in the 21–25 years group and 19.63% above 30 years. This distribution aligns with findings of study of Rudra S et al who reported a mean age of 25.08 ± 3.32 years among their study participants.[11]

In terms of parity, 68.9% of the patients were primigravida and 31.1% were multigravida in our study. In a study conducted by Singh A et al most of the patients were aged between 21 and 30 years (74.5%). Almost equal number of primigravida (48.1%) and multigravida (58.9%) patients was reported in their study.[12]

The highest proportion of the patients (54.60%) in our study belonged to upper lower socioeconomic status followed by 28.84% from the lower middle class. Similar results were seen in study conducted by Niranjana et al in 2018 and found that 84% belonged to the class V socio economic status who were more prone for deprivation and 16% belonged to the class IV socio economic status and none belonged to the class I, II and class III.[13]

The distribution of BMI in our study showed 55.82% of patients to be in normal BMI category followed by 29.44% in overweight, 10.45% in obese and 4.29% in underweight categories respectively. Similarly, Rudra et al noted a mean BMI of 22.18±2.42 in their study.[11]

Our study demonstrated a significant improvement in hematological parameters following intravenous iron sucrose therapy. The mean haemoglobin level increased from 8.09±1.1 g/dL at baseline to 12.07±1.4 g/dL after three weeks. Serum ferritin levels rose from 7.74±6.1 µg/L to 89.12±62.43 µg/L, and other red cell indices such as PCV, MCH, and MCHC also showed significant improvements. These findings are in line with studies by Cancado et al and Niranjana et al, who reported similar increases in haemoglobin and ferritin levels following intravenous iron therapy.[14,13]

Among the 163 patients registered in our study, 92% patients reported no side effects and the rest had only minor adverse effects. Notably, none of the patients had anaphylactic reactions. Similar results were seen in a study by Nanthini et al where iron sucrose therapy was well-tolerated with very few local side effects such as pain and burning at the injection site and there were no treatment-related serious adverse events. None of the adverse events required further medical intervention.[15]

CONCLUSION

Parental iron therapy is safe and effective in increasing haemoglobin, serum ferritin and other hematological parameters in pregnant women with moderate anaemia. It can be used as a treatment of choice in patients with intolerance or non- compliance to oral iron therapy. Intravenous iron sucrose injection is found to be tolerable with no gastrointestinal side effects and also safe with no life- threatening side effects, at the same time proving to be an efficient treatment modality for moderate anaemia.

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