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Original Research Article

A Hospital Record Based Study Outcome of IV Iron Sucrose in the Treatment of Iron Deficiency in Pregnancy

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Abstract

Introduction: Intravenous iron sucrose is a promising therapy for increasing haemoglobin concentration; however, its effect on clinical outcomes in pregnancy is not yet established. The present study was aimed to assess the outcome of intravenous iron sucrose in the treatment of iron deficiency in pregnancy.

Methodology: This prospective observational study was conducted at a tertiary level care hospital. The research included 125 patients who were diagnosed as anaemia (less than 11 gm/dl) and received intravenous iron sucrose while receiving prenatal care at our institution between November 2020 and October 2022. 200 mg of iron sucrose injection was administered intravenously twice a week in 200 ml of normal saline over the course of 15 to 20 minutes.

Results: It was observed that mean hemoglobin increased from 8.77 ± 1.32 to 11.74 ± 1.44 gm/dl (p value < 0.01), mean hemtocrit increased from 26.5 ± 4.4 to 44.7 ± 12.7% (p value < 0.01), mean MCV increased from 75.3 ± 10.9 to 78.2 ± 11.5 fl (p value < 0.01) and mean ferritin increased from 19.21 ± 2.4 to 48.7 ± 8.7 ng/ml (p value < 0.01). Before treatment, 77.6% of the patients had moderate anemia and 22.4% had severe anemia. Post-treatment, of those with moderate anemia, 54.6% had mild anemia and 18.5% had no anemia, while of those with severe anemia, post-treatment 64.2% had moderate anemia and rest 35.8% had mild anemia. At the time of delivery, 2% had postpartum hemorrhage, 2% needed blood transfusion and 1% was admitted to the ICU. Low birth weight was present in 22%, 16% were preterm and there was one intrauterine death.

Conclusions: Intravenous iron sucrose has a clinically acceptable safety profile, improves haemoglobin and ferritin levels in pregnant women with anemia.

Keywords: Iron Deficiency Anemia; Iron Sucrose; Serum Ferritin; Hemoglobin.

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Introduction

In 2011, it was estimated that 38% of pregnant women worldwide had anaemia. [1] India has a 40% to 60% prevalence of moderate-to-severe anaemia in pregnancy in 2015. [2] On average, iron deficiency is thought to be the cause of more than 60% of instances of anaemia. [3] For pregnant women with mild-to-moderate anaemia, oral iron is the most often prescribed treatment [4]; however, compliance with oral iron is poor due to gastrointestinal side-effects. For pregnant women who don't

react to oral medication, parenteral iron preparations such iron dextran, iron sucrose, sodium ferric gluconate, and ferric carboxymaltose are advised as an additional treatment option. [5] Blood transfusions continue to be the major medical intervention for instances of severe anaemia. [6] After multiple randomised controlled studies confirmed the safety and efficacy of intravenous iron sucrose, it was first used to treat refractory anaemia in individuals with chronic renal disease. [7] Improvements in haematological parameters with intravenous iron sucrose have been seen in a number of modest experimental investigations in pregnant women. [8]

Even when pregnant women are given oral iron supplements, not all patients benefit from oral iron treatment. While patients can choose whether or not to have a blood transfusion, doing so carries risks of transfusion responses, mismatched transfusions, infections—particularly hepatitis and HIV—as well as lung damage connected to transfusions. In order to increase compliance and to quickly replenish iron reserves and treat anaemia during pregnancy, intravenous iron sucrose may be utilised.

The present study was aimed to assess the outcome of intravenous iron sucrose in the treatment of iron deficiency in pregnancy.

Methodology

Study Design and Sampling

This prospective observational study was conducted in the Department of at a tertiary level care hospital in Pune. The research included all patients who were diagnosed as anaemia (less than 11 gm/dl) and received intravenous iron sucrose while receiving prenatal care at our institution between November 2020 and October 2022. Other than iron deficiency anaemia, exclusion criteria included multiple pregnancies, premature labour at high risk, recent blood transfusions, thalasaemia, and other illnesses. As reported in a previous study [9], with an expected 0.25 gm/dL minimal mean difference in Hb levels between baseline and endline, the minimum determined sample size was 104 women with a standard deviation (SD) of 1.3 and a power of 95%. Initial tests were performed on the liver and kidneys, urine (using standard microscopy and culture sensitivity), and stool (looking for ova and cysts). Mebendazole 100 mg tablets were administered to all of the ladies for three days as part of their antihelminthic medication. During treatment, folic acid tablets were provided to every woman. All patients provided informed written permission before to the study's launch, which was approved by the institution's ethics committee.

Treatment details

The formula used for calculation of iron sucrose dose was as follows:

Required iron dose (mg) = (2.4 x (target Hb-actual Hb) x pre- pregnancy weight (kg)) + 1000 mg for replenishment of stores. [10]

The required iron dose varied depending upon index Hb level and pre-pregnancy weight. Average dose requirement was 1825 ± 135.2 mg (1450-2050 mg). Mean duration to complete total therapy was 4.2 weeks.

200 mg of iron sucrose injection was administered intravenously twice a week in 200 ml of normal saline over the course of 15 to 20 minutes. The first dosage was administered in the ward, where there was equipment for cardiac resuscitation. The subsequent dosages were administered on an outpatient basis. For side effects or anaphylactic responses, patients were watched. Any adverse effects, big or small, were recorded.

Data Collection and Data Analysis

Using a pre-designed semi-structured study proforma, patients' demographic information were noted. Obstetric history included gravida status and period of

gestation at the start of treatment. Apart from the routine investigations ordered by the treating doctor, the four hematological parameters noted for all patients were hemoglobin, hematocrit, mean corpuscular volume and ferritin levels. These parameters were noted before the start of treatment and after finishing the treatment. All cases were followed up till the time of delivery to note for any adverse events.

The data were analysed using SPSS

version 23. Patient variables were described as frequency distribution. Mean values of hematological parameters at the end of treatment were compared with those before the start of the treatment using independent t test. A p value less than 0.05 was considered as statistically significant.

Results

During the study period, 125 patients were included in the study and no patient was lost to follow up. The mean age of the patients was 24.3 years and 60% of them were educated till secondary level (Table 1).

Table 1: Baseline characteristics of the patients included in the study

Variables	N	%
Age groups		
18 to 20	28	22%
21 to 25	66	53%
26 to 30	31	25%
Education level		
Primary	37	30%
Secondary	37	30%
Matric	23	18%
Intermediate	24	19%
Graduate	4	3%
Gravity		
1	44	35%
2	51	41%
3	18	14%
4 or more	12	10%
Abortions		
0	92	74%
1	25	20%
2 or more	8	6%
Period of gestation		
12 to 28 weeks	92	74%
29 to 32 weeks	16	13%
32 weeks or more	17	14%
Comorbidity		
Gestational diabetes	15	12%
Hypertension	10	8%
Asthma	8	6%
Chronic kidney disease	5	4%
Genitourinary infection	5	4%
Total	125	100%

In addition, 41% were gravida 2 and 20% had one abortion. In our study sample, 74% of the patients had POG of 12 to 28 weeks, 13% had 29 to 32 weeks and 32 weeks or more in 14%. The most common comorbidity was gestational diabetes, reported in 12% of the patients. Compared to baseline (before treatment), we observed a significant increase in all four hematological parameters (Table 2).

Table 2: Change in haematological parameters before and after treatment

Anemia indices	Day 0	At term	p value*
Hemoglobin (gm/dl)	8.77 ± 1.32	11.74 ± 1.44	< 0.01
Hematocrit (%)	26.5 ± 4.4	44.7 ± 12.7	< 0.01
Mean corpuscular volume (fl)	75.3 ± 10.9	78.2 ± 11.5	< 0.01
Ferritin (ng/ml)	19.21 ± 2.4	48.7 ± 8.7	< 0.01
*analyzed using independent t test			

It was observed that mean hemoglobin increased from 8.77 ± 1.32 to 11.74 ± 1.44 gm/dl (p value < 0.01), mean hemtocrit increased from 26.5 ± 4.4 to 44.7 ± 12.7% (p value < 0.01), mean MCV increased from 75.3 ± 10.9 to 78.2 ± 11.5 fl (p value < 0.01) and mean ferritin increased from 19.21 ± 2.4 to 48.7 ± 8.7 ng/ml (p value < 0.01). Before treatment, 77.6% of the patients had moderate anemia and 22.4% had severe anemia (Table 3).

Table 3: Change in anemia status after receiving treatment

Category of anemia before treatment	Category of anemia post treatment				
	No anemia (Hb ≥ 11gm/dl)	Mild (Hb 10 to 10.9 gm/dl)	Moderate (Hb 7 to 9.9 gm/dl)	Severe (Hb < 7 gm/dl)	Total
No anemia (Hb ≥ 11gm/dl)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0
Mild (Hb 10 to 10.9 gm/dl)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0
Moderate (Hb 7 to 9.9 gm/dl)	18 (18.5%)	53 (54.6%)	26 (26.9%)	0 (0%)	97
Severe (Hb < 7 gm/dl)	0 (0%)	10 (35.8%)	18 (64.2%)	0 (0%)	28

Post-treatment, of those with moderate anemia, 54.6% had mild anemia and 18.5% had no anemia, while of those with severe anemia, post-treatment 64.2% had moderate anemia and rest 35.8% had mild anemia. At the time of delivery, 2% (n=3) had postpartum hemorrhage, 2% (n=3) needed blood transfusion and 1% (n=1)was admitted to the ICU. Low birth weight was present in 22%, 16% were preterm and there was one intrauterine death (Table 4).

Table 4: Adverse maternal and fetal outcomes after treatment

Outcome	N	%
Maternal		
Postpartum hemorrhage	3	2%
Shock	0	0%
Prolonged hospitalization	2	2%
Need for blood transfusion during delivery	3	2%
ICU admission	1	1%
Fetal		

Low birthweight	27	22%
Preterm labor	20	16%
IUD	1	1%
Total	125	100%

Discussion

We observed that compared to baseline (before treatment), a significant increase in all four hematological parameters. It was observed that mean hemoglobin increased from 8.77 ± 1.32 to 11.74 ± 1.44 gm/dl (p value < 0.01), mean hematocrit increased from 26.5 ± 4.4 to 44.7 ± 12.7% (p value < 0.01), mean MCV increased from 75.3 ± 10.9 to 78.2 ± 11.5 fl (p value < 0.01) and mean ferritin increased from 19.21 ± 2.4 to 48.7 ± 8.7 ng/ml (p value < 0.01). In addition, before treatment, 77.6% of the patients had moderate anemia and 22.4% had severe anemia. Post-treatment, of those with moderate anemia, 54.6% had mild anemia and 18.5% had no anemia, while of those with severe anemia, post-treatment 64.2% had moderate anemia and rest 35.8% had mild anemia. Because of their relative significance in the hemodynamics of the pregnant lady, haemoglobin and ferritin levels were employed in the current investigation to track the hemopoietic system's reaction to iron sucrose. Despite being the gold standard for iron deficient anaemia, bone marrow analysis is invasive and not recommended for use during pregnancy. Haemoglobin, hematocrit, and red blood cell count all fall during pregnancy as a result of hemodilution, but MCV is unaffected. Haemoglobin levels often increased following therapy by 2.9 gm/dl on average. Similar improvements in hemoglobin levels were observed in previous studies. Ragip et al had seen a rise of 1.2 gm/dl [11], Kriplani et al. 2.27gm/dl [12] and Gupta et al. had seen a rise of 2gm/dl [13]. Our observed finding almost correlated with findings of the studies of Dewen Bhupesh et al (2.2gm/dl) [14], and Hallak M et al. (2.3gm/dl) [15]. Following the delivery of iron sucrose intravenously or orally to 200 pregnant women, Dubey et al. conducted another randomised investigation and found that iron sucrose substantially (p < 0.001) increased haemoglobin levels and iron storage more quickly than oral iron. [16]

At the time of delivery, 2% (n=3) had postpartum hemorrhage, 2% (n=3) needed blood transfusion and 1% (n=1) was admitted to the ICU. Low birth weight was present in 22%, 16% were preterm and there was one intrauterine death. When it comes to significant and severe adverse events associated with infusions, Neogi et al. showed that intravenous iron sucrose is safe. Only one individual experienced an adverse event that required stopping future infusions during the period of 4651 treatments. Similar to earlier research, 13% of women had immediate and 24% reported late self-limiting mild side effects. [17] In comparison to the usual treatment group, the chance of experiencing any mild side effects was 22% lower in the intravenous iron sucrose group. This outcome suggests that iron sucrose may be suggested in primary care settings with qualified staff. In our investigation, we saw a tendency that larger dosages were associated with a higher prevalence of foetal adverse effects. The investigation lacked the necessary power to identify this difference. [18]

There are a few limitations of this study. Despite the fact that intravenous iron sucrose considerably raised serum ferritin, patients were not monitored in the postpartum period to see if haemoglobin levels were preserved throughout breastfeeding. Second, and this was a drawback of the study, serum ferritin was not repeated at the end of pregnancy or at the postnatal check-up to see how long the reserves persist. In modern environments, vitamin B12 deficiency is a significant contributor to anaemia. Since it was outside

the purview of our investigation, we were unable to evaluate how vitamin B12 supplementation affected the overall outcomes. Moreover, the doctor had the choice to give albendazole, calcium, and vitamin supplements. Thus, we were unable to document the precise amounts of concurrent medications that were taken.

Conclusion

This study came to the conclusion that giving pregnant women iron sucrose intravenously is a good treatment for iron deficiency anaemia, especially for those who did not respond well to oral iron supplements. Intravenous iron sucrose has a clinically acceptable safety profile, improves haemoglobin and ferritin levels, and reduces pregnancy-related problems brought on by iron deficiency anaemia. To prove the therapeutic benefit of intravenous iron sucrose above normal therapy for the treatment of anaemia in pregnancy, more convincing data is needed.

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