Efficacy And Tolerance of Iron Sucrose in the Management of Iron Deficiency Anemia Patients in a Tertiary Care Hospital

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Abstract: *Iron deficiency anemia (IDA) remains one of the most common nutritional disorders worldwide, particularly in developing countries. Intravenous iron sucrose is frequently administered in patients with intolerance or inadequate response to oral iron therapy. Objective: To compare the efficacy and tolerability of iron sucrose injection in improving hematological parameters among IDA patients in a tertiary care centre. Methods: 100 patients receiving iron sucrose injections were enrolled in this study. Hemoglobin, hematocrit, MCV, MCH, MCHC, and RDW levels were determined before and after treatment. Symptomatic relief and investigator ratings of efficacy and tolerance were determined. Statistical tests used were paired t-test, ANOVA, correlation, and regression. Results: Hemoglobin levels increased significantly from 5.4 ± 1.91 g/dL to 7.8 ± 1.39 g/dL ($p < 0.001$), and there was equal improvement in other haematological parameters. Improvement in mean hemoglobin was approximately 38.2% ± 21.5%. Correlation analysis showed moderate positive correlation between the doses administered and hemoglobin improvement (Pearson's $r = 0.343$, $p < 0.001$). No adverse effects were severe. Most of the patients showed improvement within 1–2 weeks, and tolerance to injection was good to excellent. Conclusion: Iron sucrose injection did not produce any serious adverse effects and is highly effective in enhancing hematological parameters in IDA patients, offering a safe alternative to patients with intolerance to oral iron.*

Keywords: **Iron deficiency anemia, Iron sucrose, Intravenous iron therapy, Hemoglobin improvement, Tolerance, Adverse effects**

1. Introduction

The human body requires iron to perform various physiological activities, mainly to synthesize hemoglobin, which plays a vital role in transporting oxygen. Iron deficiency anemia (IDA) is the most common nutritional disorder in the world and a major cause of morbidity, especially in the developing world [1]. Iron deficiency anemia (IDA) is a consequence of depleted iron stores, resulting in insufficient hemoglobin production. This is a global health problem, especially in pregnant women and in patients with CKD, GI disorders, and malnutrition [2,3]. It presents with symptoms such as fatigue, pallor, dyspnoea, dizziness, and decreased exercise tolerance.

Dietary intake, absorption, storage, and recycling are ways to maintain iron homeostasis. Iron deficiency occurs when iron intake is inadequate or iron loss exceeds absorption. Iron is tightly regulated by the body because both iron deficiency and overload can be harmful. The most relevant laboratory factors used to evaluate iron status include serum ferritin level, transferrin saturation (TSAT), and serum iron level.

Historically, the standard first-line therapy for IDA has been an oral iron supplement. However, its effectiveness is limited in many patients owing to gastrointestinal side effects, such as nausea, constipation, and poor absorption [4,5]. In addition, diseases such as CKD and inflammatory conditions limit iron absorption, forcing the need for parenteral iron therapy for the prompt repletion of iron stores.

Iron sucrose is one of the most commonly used intravenous iron formulations. It is an iron sucrose complex that has a high safety profile due to controlled iron release circulation with a lower risk of toxicity than older formulations [6,7]. Among the parenteral iron formulations, intravenous iron sucrose has a favorable safety profile, is effective in correcting anemia, and can rapidly increase hemoglobin. Iron sucrose is less likely to cause acute hypersensitivity reactions and anaphylaxis than high-molecular-weight iron dextran [8,9].

Iron sucrose is largely considered safe with acceptable tolerability; however, some patients may observe side effects that are mild in severity such as: nausea, hypotension, dizziness, and infusion-site reactions. In rare circumstances, hypersensitivity reactions may arise after administration; therefore, careful assessment of the patient is necessary before administering iron sucrose. Tolerability and safety may vary depending on the dose, infusion rate, and clinical status of the patient.

This study aimed to determine the effectiveness and tolerability of iron sucrose injection in patients with IDA by improving hemoglobin levels, iron parameters, and adverse events following administration. The outcomes of this study can enhance the management of anemia, especially in patients who cannot tolerate or are non-responders to oral iron.

2. Materials and Methods

2.1 Setting and Study Design

This study was designed as a prospective observational analysis conducted in the General medicine department of Cuddalore Medical college and Hospital, Chidambaram, Tamil Nadu.

2.2. Duration of study

The research was conducted over six months, spanning from November 2024 to April 2025.

2.3 Study Subjects

The study included hospitalized patients who were receiving treatment for iron deficiency anemia with iron sucrose injection. A total of 100 patients were enrolled based on predefined inclusion and exclusion criteria. Patients who did not provide informed consent were excluded from the study. Ethical clearance for the study protocol was taken from the Ethics Committee of the institute.

2.4 Inclusion Criteria

- Patients of all age group of both sexes admitted with a confirmed diagnosis of iron deficiency anemia.
- Patients not responding to oral iron therapy.
- Patients without any inflammatory diseases or active infections that could impair iron metabolism.

2.5 Exclusion Criteria

- Patients with hypersensitivity to iron sucrose.
- Patients with anemia not caused by iron deficiency and those receiving concurrent iron therapy (oral or parenteral) other than iron sucrose.
- Patients receiving blood transfusion.

2.6 Study Materials

A structured data collection form was used to record patient details, including demographic information (age, gender, IP number), Hemoglobin and red cell indices value (before and after treatment), dose requirement of an individual patients based on their weight according to Ganzoni's Formula, dosage and frequency of iron sucrose administration and occurrence of adverse drug reaction.

2.7 Study drug and dosing schedule

Iron Sucrose was provided as a solution for Intravenous (IV) infusion in 5-ml ampoules (20 mg iron/ml). We have taken 1 dose of Iron Sucrose is equal to 100mg of Iron Sucrose. The patient receives iron either once, twice or thrice weekly until their hemoglobin level >9 g/dl. The total dose of iron required by an individual was estimated by Ganzoni's formula [body weight (kg) * 0.24* (11-Patient's Hb [g/dl]) + 500 mg (for stores)] [10]. Each dose was administered as 200 mg aliquots in 100 ml normal saline (NS) on alternate days. A test dose (20 mg of elemental iron or 1ml of the solution dilute in 10mL NS, administered Intravenously via slow infusion over 5-10 min) was performed before the first treatment [11]. Patients were observed for drug reaction for up to 30 mins after each dose. Blood pressure was monitored before 15 and 30 min after the initiation of infusions.

3. Observation and Results

3.1 Gender wise distribution

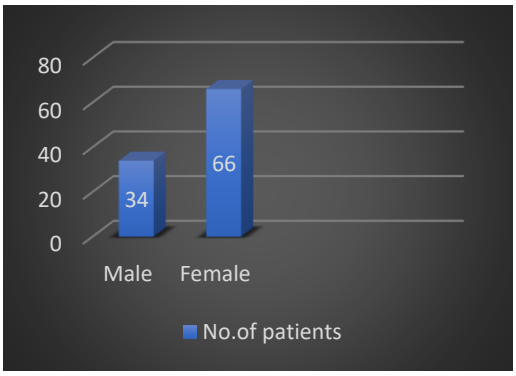

Figure 1: Gender wise distribution of patients receiving iron sucrose injection

The demographic data shows that among the patients a high prevalence of iron deficiency anemia occurred in females at about 66%.

3.2 Age wise distribution

Table 1: Age wise distribution of patients receiving iron sucrose

Age (years)	No. of Participants (n=100)	Percentage (%)
≤30	27	27%
31-50	38	38%
51-70	27	27%
>70	8	8%

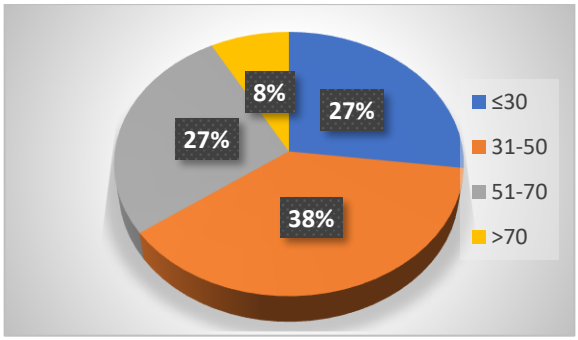

Figure 2: Age wise distribution of patients receiving iron sucrose

The majority of patients receiving iron sucrose were aged 31–50 years (38%), followed by ≤30 and 51–70 years (27% each). Only 8% of patients were above 70 years, indicating a higher prevalence of IDA in middle-aged adults.

3.3 Severity of Anemia

Table 2: Distribution of patients based on severity of Anemia

Severity of Anemia	No. of Participants (n=100)	Percentage (%)
Mild	21	21%
Moderate	33	33%
Severe	46	46%

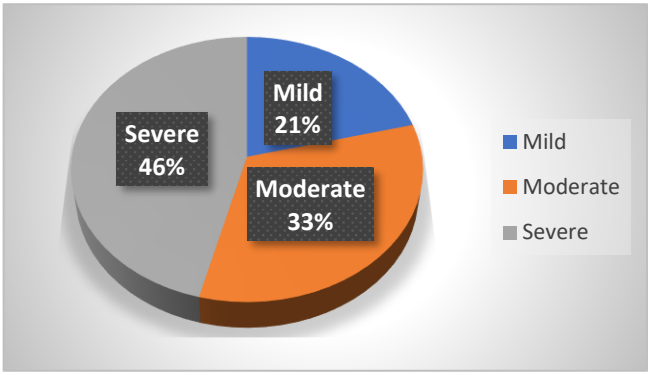

Figure 3: Distribution of patients based on severity of anemia

Of the 100 patients, 21% had mild anemia, 33% had moderate anemia, and 46% had severe anemia. This highlights the need for quick and efficient treatment, such as intravenous iron therapy, as the majority (79%) had moderate to severe anemia.

3.4 Distribution of comorbidities in patients

Among the 100 subjects that were studied, 62 had no comorbidity and 38 of them had comorbid conditions, as can be seen from Fig 4. The pie chart shows that heart disease, diabetes, and liver disease are the most common comorbidities among patients, each accounting for 20% of all cases. Besides this, lung disease (17%) and hypertension (16%) are also highly common. Less common ones are hypothyroidism, chronic kidney disease (CKD), and cerebrovascular accident (CVA), each accounting for 5%–12% of cases.

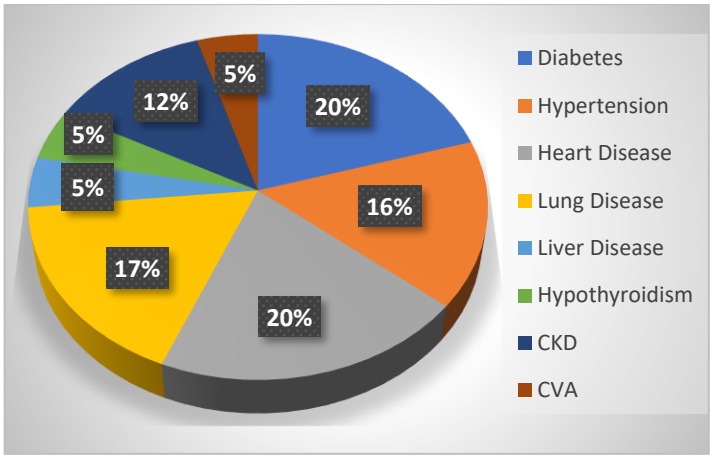

Figure 4: Distribution of patients based on comorbidities

3.5 Distribution of patients based on severity of Anemia

Table 3: Distribution of patients based on severity of Anemia

Severity of Anemia	Percentage of patients
Mild	21
Moderate	33
Severe	46

Most of the patients (46%) had severe anemia, followed by moderate anemia (33%) and mild anemia (21%), which shows a greater prevalence of severe iron deficiency in the study group.

3.6 Distribution of Patients based on Dose (mg) of Iron Sucrose Administered

Table 4: Distribution of patients based on total no. of dose administered

Total no. of Dose Administered	No. of Participants (n=100)		Total
	100 mg	200 mg	
1	3	6	9
2	8	24	32
3	6	34	40
4	9	0	9
5	2	0	2
6	8	0	8
Total	36	64	100

The table shows that the majority of the patients received 200 mg of iron sucrose in the first three doses, whereas 34 patients received it in the third dose. In the fourth to sixth doses, only 100 mg was utilized, which reflects the decrease to the lower dose in the subsequent treatment.

3.7 Distribution of patients based on ADR

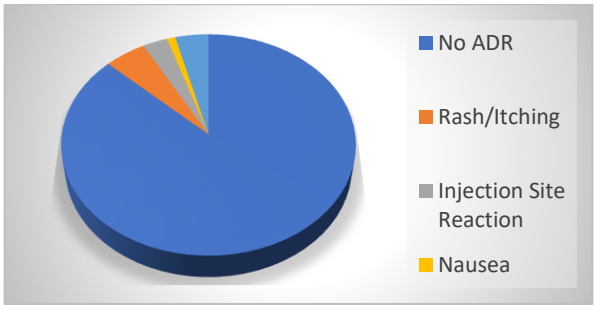

Figure 5: Distribution of patients based on ADR following Iron Sucrose Injection

Pie chart shows 87% of the patients had no ADRs after iron sucrose infusion, while 13% had ADRs: rash/itching (5%), injection site reaction (3%), nausea (4%), and others (1%), indicating good tolerability.

3.8 Distribution based on time required for symptom improvement (in days) following Iron Sucrose

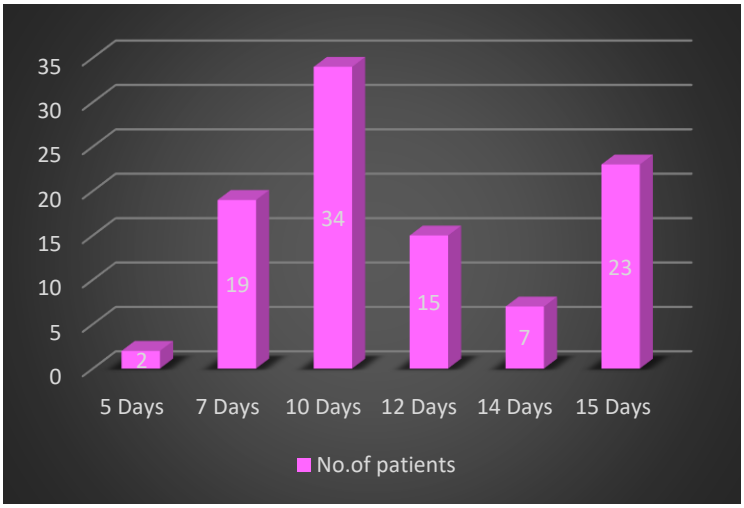

Figure 6: Distribution based on time requirement for symptom improvement (in days)

The Figure 6 indicates symptom improvement time after iron sucrose therapy. There was improvement in 34 patients on day 10 and 23 patients on day 15. Improvement mostly occurred between 7 and 15 days.

3.9 Distribution based on Investigator's assessment of Efficacy and Tolerance of Iron Sucrose Injection

The graph illustrates the researcher's evaluation of iron sucrose injection tolerance and efficacy. Most patients experienced good efficacy and tolerance, with subsequent excellent ratings, and a few experienced moderate or poor tolerance.

Figure 7: Distribution based on Investigator's assessment of Efficacy and Tolerance

3.10 Distribution based on changes in Quality of life after treatment

Table 5: Changes in quality of life

Changes in QOL	Percentage of Patients (%)
Improved	66%
Markedly Improved	24%
No Change	10%
Worsened	0%

Iron sucrose injection enhanced quality of life in 100 patients. 66% were better, and 24% were much better. 10% did not change, and none got worse. Treatment usually made most patients better.

3.11 Improvement in Hemoglobin and Red Cell Indices Following Iron Sucrose Administration

Table 6: Paired t-test of Comparison of average Hematological parameters of study population before and after Iron Sucrose Therapy

Laboratory Data	Pre-Treatment (Mean ±Standard Deviation)	Post Treatment (Mean± Standard Deviation)	P value
Hemoglobin	5.4 ± 1.91	7.8 ± 1.39	< .001
Hematocrit	20.7 ± 6.75	34.6 ± 7.02	< .001
MCV	68.9 ± 10.91	81.3 ± 7.09	< .001
MCH	20.2 ± 5.03	27.0 ± 3.02	< .001
MCHC	27.9 ± 3.67	35.2 ± 3.04	< .001
RDW	19.2 ± 3.02	21.0 ± 4.26	< .001

Laboratory findings show significant improvement in hematological values following iron sucrose treatment. Hemoglobin increased from 5.4 ± 1.91 to 7.8 ± 1.39 g/dL, and hematocrit increased from 20.7 ± 6.75% to 34.6 ± 7.02% (p <.001), reflecting adequate hematinic correction of anemia. Red cell indices

such as MCV, MCH, MCHC, and RDW also improved significantly (all p <.001), reflecting quality of red blood cells and iron absorption following treatment.

3.12 ANOVA Analysis for Improvement in Hemoglobin Value Post Iron Sucrose Injection

Table 7: Improvement in Hb Value post treatment between severity of anemia

Improvement of Hemoglobin Value	Sum of Squares	df	Mean Square	F	Sig. (p value)
Between Groups	48.298	2	24.149	25.870	< .001
Within Groups	90.547	97	.933		

The ANOVA results indicate a statistically significant hemoglobin change between 3 groups (mild, moderate and severe anemia) ($F = 25.870$, $p < 0.001$). This indicates that the iron sucrose treatment significantly influenced hemoglobin levels among groups compared.

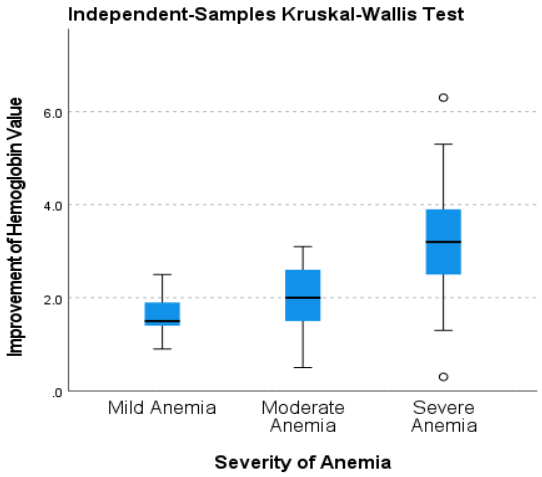

Figure 8: Independent Samples Kruskal-Wallis test for improvement of Hemoglobin Value across Severity of Anemia

According to the boxplot, patients with severe anemia responded more widely to treatment and saw the biggest improvement in hemoglobin levels. The least improvement was seen in cases of mild anemia. A statistically significant difference in hemoglobin improvement across anemia severity groups is suggested by the Kruskal-Walli's test.

3.13 Dose-Response Relationship (Iron Dose vs Hb Improvement)

The table 8 suggest that there is a moderate positive correlation between the number of doses of iron sucrose received and hemoglobin improvement (Pearson's $r = 0.343$; Spearman's $\rho = 0.379$, $p < 0.001$), suggesting that larger numbers of doses are associated with greater hemoglobin improvement, with a 95% confidence interval of 0.191 to 0.539.

Table 8: Correlation between total no. of dose administered vs Improvement of hemoglobin value

	Pearson's rho	Spearman's rho	Significance (2-tailed)	95% Confidence intervals	
				Lower	Upper
Total No. of dose administered – Improvement of Hemoglobin Value	.343	.379	< .001	.191	.539

3.14 Regression Analysis for Predictors of Hemoglobin Improvement

Table 9: Multiple Linear Regression Analysis for Predictors of Hemoglobin Improvement

	B	t	Sig.	95% Confidence Interval for B		Correlations		
				Lower Bound	Upper Bound	Zero Order	Partial	Part
Constant	3.764	9.379	< .001	2.967	4.561	-	-	-
Patient's Age	.140	1.967	.052	.000	.020	.158	.197	.138
Total no. of Dose Administered	.164	2.247	.027	.018	.293	.343	.223	.158
Baseline Hb	-.651	-8.989	< .001	-.492	-.314	-.690	-.676	-.631

The regression equation indicates that total doses predict hemoglobin improvement (B = 0.164, p = 0.027). Baseline hemoglobin is highly associated with increased improvement (B = -0.651, p < 0.001). Patient age is marginally significant (p = 0.052), suggesting a possible influence on hemoglobin response.

4. Discussion

We conducted a prospective observational study to assess the effectiveness and tolerance of intravenous (IV) iron sucrose therapy for patients with iron deficiency anemia (IDA). Results indicated an increase in hemoglobin (Hb) and hematocrit, along with red cell indices (MCV, MCH, MCHC, RDW) following treatment, suggesting effective correction for anemia and red blood cell regeneration.

Our findings align with the work done by Rathi et al. (2023), who observed a mean increase in hemoglobin of 2.4 ± 0.8 g/dL within 4 weeks of IV iron sucrose treatment among women with moderate to severe IDA [12]. In our study, we noted an average increase in hemoglobin of 2.6 ± 1.1 g/dL, confirming the effectiveness of IV iron sucrose in promptly correcting anemia, particularly in those who are either intolerant to or do not respond to oral iron therapy.

Significant improvements in red cell indices were also observed in our study. For instance, MCV increased from 68.9 to 81.3 fL, and MCHC improved from 27.9 to 35.2 g/dL, reflecting normalized erythropoiesis and enhanced iron availability. These findings align with those of Kaur et al. (2021) and Mujawar & Gite (2023), who both reported statistically significant increases in MCV, MCH, and RDW following IV iron sucrose therapy, particularly by the second week of treatment [13,14].

Moreover, similar trends were shown in the case of adult IDA patients by Ramesh & Sinha (2022), where both MCV and RDW values were effectively corrected by administering IV iron sucrose, demonstrating an improvement in red cell morphology and uniformity [15]. Consistent with our findings, Meena et al. (2020) also demonstrated significant improvement in MCHC and RDW values post parenteral iron in both IDA and anemia of chronic disease patients [16].

The increase of RDW in our study, although mild, is a classic feature of effective iron therapy, resulting from bone marrow returning to active erythropoiesis. These findings were supported by Saxena & Joshi (2023), who compared pregnant with pregnant non-patients with IDA, and demonstrated sustained improvements in MCV and MCHC over 30 days following treatment [17].

We also observed a low incidence of ADRs (13%) of which none were serious. This is consistent with prior work by Sharma et al. (2022) also demonstrated the high tolerability of iron sucrose with mild side effects in some 3% of patients. The overall therapy were well tolerated and augured impressive clinical and hematological recoveries [18].

Overall, this study further validates the role of IV iron sucrose in providing not only the hemoglobin increase but also an accelerated response concerning red cell indices in IDA patients. These results are consistent with several recent results and indicate that iron sucrose is a valuable treatment option, especially in patients with moderate to severe anemia or oral iron intolerance.

5. Conclusion

Intravenous iron sucrose is thus highly effective and well tolerable for the treatment of iron deficiency anemia. Results showed major improvements in hemoglobin, hematocrit, MCV, MCH, MCHC and RDW levels after treatment. Most patients had substantial clinical improvement with minimal adverse effects, suggesting an acceptable safety profile. Iron sucrose therapy was evaluated by investigator assessments as effective and tolerable as well. These results are in accordance with previous studies and support the use of IV iron sucrose as a well-tolerated alternative for iron supplementation in iron-deficient individuals, particularly among those with poor GI tolerance or severe anemia necessitating prompt correction. Therapeutic outcomes can be improved and the risk of complications can be reduced using tailored dosing and appropriate monitoring. This makes iron sucrose injection a safe and effective option for treating iron deficiency anemia, especially in inpatients or high-risk patients.

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