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Original Research Article

Parenteral Iron Sucrose Transfusion in Pregnant Women with Iron Deficiency Anaemia and its Outcome

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Abstract:

Introduction: Iron deficiency anaemia (IDA) is common in pregnancy, characterized by reduced red blood cells or haemoglobin due to low iron levels. Pregnancy increases iron demand to support fetal development and the mother's blood volume. Insufficient iron intake or absorption can lead to IDA, causing complications like low birth weight, postpartum bleeding, and maternal mortality. Iron Sucrose, an IV preparation, due to its efficacy and safety profile become widely used in patients unable to take oral iron preparation.

Materials and Methodology: This was a prospective, observational study conducted in the obstetrics and gynecology department of Parul Sevashram Hospital over four months. A total of 30 pregnant women with IDA undergoing parenteral iron sucrose therapy were enrolled. Haemoglobin level and its severity were measured on 4^{th} and 8^{th} weeks from last dose of iron sucrose. Data were recorded in predesigned case record forms, entered in Microsoft Excel, and analyzed using appropriate statistical methods.

Results: In present study most participants were aged 26-30 years, with a majority having an education level of 1st to 9th grade and being housewives. The mean age was 25.2 years. There was significant increase in haemoglobin levels from 8.11 ± 0.88 gm/dL at baseline to 10.28 ± 0.66 gm/dL after eight weeks ($p<0.001$). Haemoglobin levels increased significantly across all severity levels of anaemia (mild, moderate, severe) over the eight weeks. Adverse drug reactions included one case of anaphylactic reaction and two cases of skin rashes.

Conclusion: The study shows that intravenous iron sucrose is a safe and effective treatment for IDA in pregnant women. Haemoglobin levels significantly increased over eight weeks, with 20% of participants reaching normal levels. Adverse reactions were minimal. These findings support intravenous iron sucrose as a reliable option, especially for those intolerants to oral supplements and reducing pregnancy-related anaemia complications.

Keywords: Iron deficiency Anaemia, Iron sucrose, Pregnancy, Haemoglobin.

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Introduction

Iron deficiency anaemia (IDA) is a prevalent condition during pregnancy, marked by a reduction in red blood cells or haemoglobin in the blood caused by inadequate iron levels. Iron is crucial for the production of haemoglobin, which transports oxygen in the blood. Pregnancy significantly raises the body's need for iron to support the developing fetus and manage the mother's increased blood volume. When iron intake or absorption is inadequate to meet these demands, iron deficiency Anaemia can develop. Complications linked to anaemia in pregnancy include low birth weight, post-partum bleeding, maternal mortality, stillbirths, and premature births etc. [1]. According to the World Health Organization (WHO), globally around 40% of pregnant women and a third of all women of reproductive age are affected by anaemia [2]. According to the National Family Health Survey, 2019-2021 (NFHS-5) in India, 52.2% of pregnant women were found to be anaemic, with higher rates in rural areas (54.3%) compared to urban areas (45.7%) [3]. Iron deficiency is the

primary reason for anaemia and is believed to be responsible for around half of all anaemia cases in both non-pregnant and pregnant women globally [4]. Anaemia can worsen during pregnancy due to the greater need for iron, if it left untreated. In recent times, various types of iron formulations administered orally, intramuscularly and intravenously have been used to treat anaemia [5].

Oral iron supplements are the preferred option due to their effectiveness, safety and affordability. Nevertheless, iron taken by mouth is not well tolerated and can lead to different gastrointestinal side effects such as vomiting, nausea, abdominal pain, constipation, and diarrhoea. Iron gluconate and iron dextran preparations are commonly utilized for intravenous iron treatment, however their usage is restricted due to high incidence of adverse reactions. Iron sucrose, a newly developed intravenous iron preparation, is being used more often due to its effectiveness, safety with minimal side effects and becoming a top choice for patients unable to take oral iron supplements [5-7]. Therefore, this research aimed to assess the efficacy and safety of intravenous iron sucrose in the treatment of iron deficiency anaemia in pregnant women, focusing on improvements in Hb% levels and potential complications.

Materials and Methodology: This was a prospective, longitudinal, observational, single centre study, conducted in obstetrics and gynaecology department (Patients attending ANC clinic) of Parul Sevashram Hospital for 4 months of duration. Total 30 patients were enrolled over a period of 4 months from 1st September 2023 to 31st December 2023. Written informed consent was obtained from each subject. Haemoglobin level and its severity were repeated on follow-up at 4th and 8th weeks from the last dose of I.V. Iron sucrose.

In the context of this study, inclusion criteria encompass pregnant individuals afflicted with iron deficiency anaemia who are undergoing parenteral iron sucrose therapy. Conversely, exclusion criteria delineate individuals suffering from any forms of anaemia other than iron deficiency anaemia, those who have undergone blood transfusion within the preceding month, those with documented hypersensitivity to Iron Sucrose, those concurrently afflicted with additional medical conditions such as hypertension, gestational diabetes, thalassemia, among others, as well as individuals who decline participation. As this study adopts an observational design, inherent risks are not anticipated. The envisaged benefits center on ameliorating iron deficiency anaemia during pregnancy, achieved through the augmentation of haemoglobin levels and the restoration of maternal iron reserves via intravenous administration of iron sucrose. The anticipated outcome pertains to the evaluation of effectiveness and safety in pregnant cohorts, as evidenced by the rectification of anaemia.

Data were recorded in predesigned case record form. Data entry was done in Microsoft excel and evaluated with appropriate Statistical method.

Result: During the study period a total of 30 study participants were enrolled according to inclusion and exclusion criteria. Their demographic details were presented in below table.

Table 1: Demographic detail of study participants

Parameters		**Study participants (n=30)**	**Percentage**
Age (in years)	18 – 20	7	23.33
	21 – 25	8	26.67
	26 – 30	9	30
	31 – 35	5	16.67
	36 - 40	1	3.33
Education	10th Pass	2	6.67
	1 to 9th Pass	22	73.33
	Illiterate	6	20
Occupation	Working	10	33.33
	Housewife	20	66.67
Gravida	1	6	20
	2	13	43.33
	3	6	20
	4	5	16.67
Abortion	0	22	73.33
	1	5	16.67
	2	3	10
Gestational week	15 - 20	10	33.33
	21 - 25	7	23.33
	25 - 30	13	43.33
Mean Age		25.2 ± 4.70	

Data are expressed as n and %. Mean age expressed as Mean ± SD.

Table 1 displays the demographic and obstetric characteristics of the study group. Most participants are in the 26-30 age group (30%), with the next largest group being 21-25 years old (26.67%). In terms of education, the majority (73.33%) reached the 1st to 9th grade, with a small percentage (6.67%) finishing the 10th grade. In terms of job status, the majority (66.67%) were housewives, while the rest (33.33%) held jobs. The status of pregnancy shows a relatively equal spread among different groups, with 43.33% indicating that they had two pregnancies. Regarding the history of abortions, the majority of participants (73.33%) said that they had not found any abortions before. The gestational week at enrolment ranged, with the majority (43.33%) occurring between weeks 25-30 of gestation. Participants had an average age of 25.2 years, with a standard deviation of ± 4.70.

Table 2: Comparison of level of haemoglobin at baseline, at 4 week and 8 weeks.

Parameters	Baseline	4 weeks	8 weeks	P value
Hb gm/dL	8.11 ± 0.88	9.67 ± 0.71*	10.28 ± 0.66*#	<0.001

Data were presented as Mean ± SD. * p<0.05 is statistically significant as compared to baseline by using ANOVA, #p<0.05 is statistically significant as compared to 4 weeks by using ANOVA.

Table 2 shows a comparison of the haemoglobin levels at the start, after 4 weeks, and after 8 weeks. The original measurement of haemoglobin (Hb) was 8.11 ± 0.88 gm/dL. After four weeks of treatment, there was a significant increase in Hb from 8.11 ± 0.88 gm/dL to 9.67 ± 0.71 gm/dL ($p<0.05$) which indicates a statistically significant improvement. After 8 weeks there was a further increase in Hb levels from 9.67 ± 0.71 gm/dL to 10.28 ± 0.66 gm/dL ($p<0.05$), which is statistically significant (Figure 1).

This data shows a consistent and significant rise in haemoglobin levels over the course of the study.

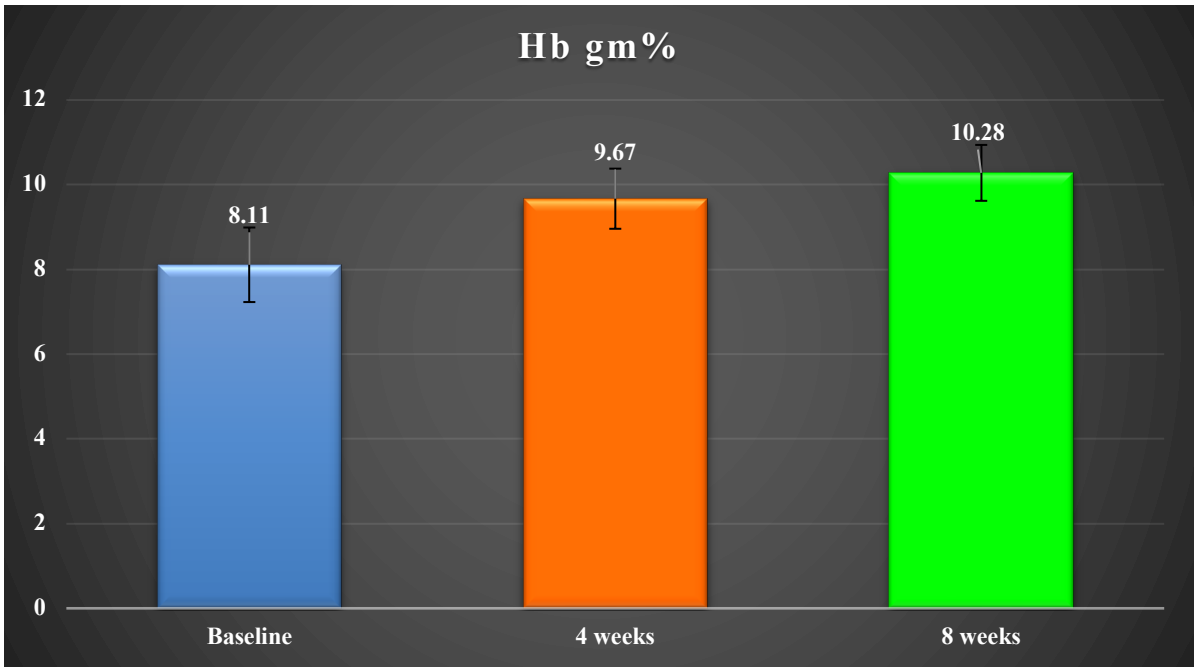

Figure 1: Comparison of level of haemoglobin at baseline, at 4 week and 8 weeks

Table 3: Comparison of Hb level based on severity classification

Hb Severity	Baseline	4 weeks	8 weeks	P value
Mild (n=6)	9.23 ± 0.33	10.51 ± 0.23	11 ± 0.28	0.0008
Moderate (n=21)	8 ± 0.62	9.60 ± 0.55	10.22 ± 0.54	<0.0001
Severe (n=3)	6.63 ± 0.11	8.5 ± 0.10	9.23 ± 0.25	<0.0001

Data were expressed as Mean ± SD. $P<0.05$ considered as statistically significant by using repeated measure ANOVA. Table 3 present a comparison of haemoglobin levels classified by severity at the beginning, 4 weeks, and 8 weeks. The information is categorized into three levels of severity: mild, moderate and severe iron deficiency anaemia. In the mild group (n=6), the average Hb level rose from 9.23 ± 0.33 g/dL initially to 10.51 ± 0.23 g/dL at 4 weeks and 11 ± 0.28 g/dL at 8 weeks, showing a significant P value of 0.0008.

Within the moderate group (n=21), the haemoglobin levels increased from 8 ± 0.62 g/dL initially to 9.60 ± 0.55 g/dL at 4 weeks, then to 10.22 ± 0.54 g/dL at 8 weeks, demonstrating a P value below 0.0001, which is statistically significant. In the severe group (n=3), Hb levels rose from 6.63 ± 0.11 g/dL initially to 8.5 ± 0.10 g/dL at 4 weeks, and 9.23 ± 0.25 g/dL at 8 weeks, with a P value of less than 0.0001, showing statistically significant difference.

These results show a gradual and statistically notable increase in Hb levels for all severity categories during the 8-week duration (Figure 2).

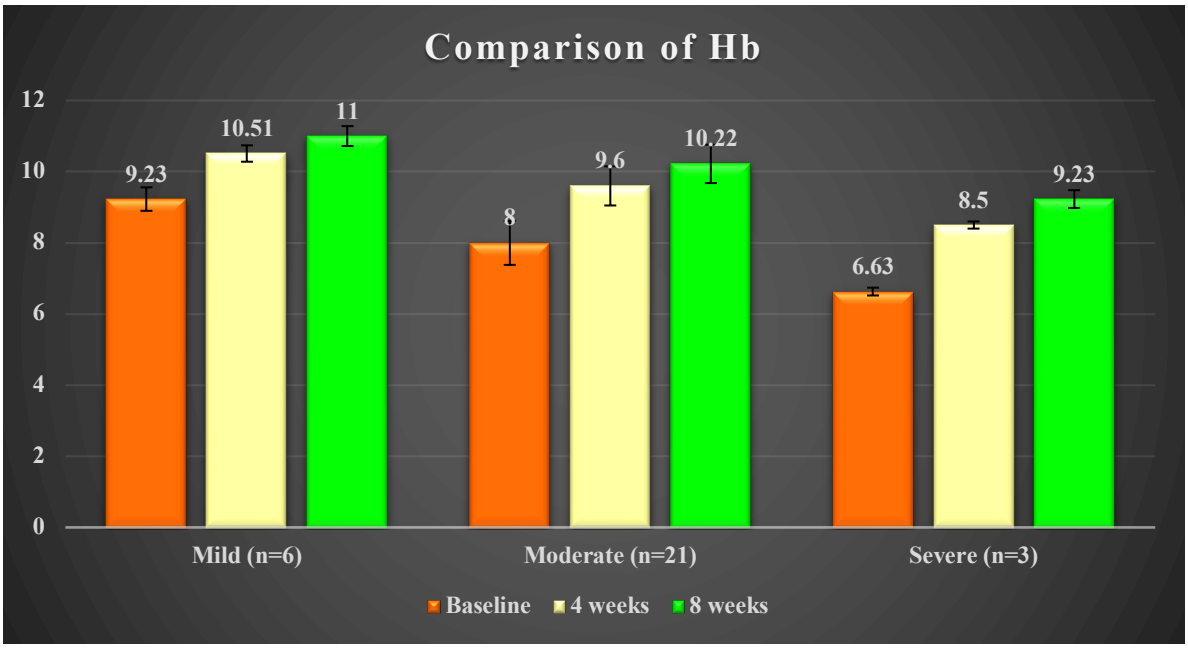

Figure 2: Comparison of Hb level based on severity classification

Table 4: Adverse drug reactions following parenteral Iron Sucrose Therapy

Adverse Drug Reaction	No. of patients
Anaphylactic Reaction	1
Rashes	2

Table 4 displays the cases of adverse drug reactions that occurred after receiving Iron Sucrose Therapy via injection. Only single instance of anaphylactic reaction was found and two instances of skin rashes on hand and chest. No any other adverse drug reactions were observed during the study period.

Discussion:

In present times, intravenous iron sucrose is one of the preferred methods of treatment for Iron deficiency anaemia (IDA). We had found that the mean Hb levels following iron sucrose therapy for 4 and 8 weeks were 9.67 ± 0.71 gm/dL & 10.28 ± 0.66 gm/dL respectively, showing mean difference of 1.56 ± 0.17 gm/dL at 4 week compared to base line and 2.17 ± 0.22 gm/dL at 8 week compared to baseline, consistent with results from earlier research studies like Lakshmikantha G et al., having mean increase of 2.5 gm/dL [8], 3.59 gm/dL in G.D. Abhilashini, et al. study [9], and 3.0 ± 0.4 gm/dL in Srivastava D et al., study [10]. The recorded increase in Hb level following IV Iron Sucrose treatment in Al RA et al., study is 2.1 gm/dL [11], in Halder et al., mean Hb increase is 1.35 gm/dL [12], and in GD Abhilashini et al., mean Hb increase is 3.59 gm/dL [9]. The broad range could be a result of differences in patient characteristics, dosage, and timing of administering IV Iron Sucrose, along with the method and timing of measuring Hb levels. In our study, 20% of pregnant women achieved normal Hb levels after eight weeks of getting their last IV Iron Sucrose treatment. Our findings are consistent with a study done by Thakor et al. [13], where they also found the nearby percentage to be 24%. The baseline Hb levels reported by Thakor N. et al. [13] and Kriplani A. et al. [14] are 7.8 ± 0.61 gm/dL and 7.63 ± 0.61 gm/dL, respectively, whereas the present study recorded a higher baseline level of 8.11 ± 0.88 gm/dL. At the conclusion of their respective studies, Thakor N. et al. observed an Hb level of 10.1 ± 0.73 gm/dL [13], while Kriplani A. et al. reported 11.20 ± 0.73 gm/dL [14], and the present study documented an Hb level of 10.28 ± 0.66 gm/dL.

The mean increase in Hb levels from baseline to the end of the study was 2.3 ± 0.12 gm/dL in Thakor N. et al., [13] 3.57 ± 0.12 gm/dL in

Kriplani A. et al., [14] and 2.17 ± 0.22 gm/dL in the present study, indicating varied responses in haemoglobin improvement across the studies.

It appears that the difference observed could be linked to differences in the characteristics of the participants, particularly their starting Hb level (Table 5).

Table 5: Comparison of present study with different studies at various parameters

Referral studies	Baseline Hb(gm/dL)	End of study Hb (gm/dL)	Mean increase in Hb level at end of study compared to baseline (gm/dL)	Mean Dose
Lakshmikantha et al., [8]	6.15 ± 0.75	8.625 ± 0.66	2.47 ± 0.09	600 mg
Haldar et al., [12]	7.85 ± 0.80	9.62 ± 1.30	1.76 ± 0.5	400 mg
Thakor N. et al. [13]	7.8 ± 0.61	10.1 ± 0.73	2.3 ± 0.12	800 mg
Kriplani A et al., [14]	7.63 ± 0.61	11.20 ± 0.73	3.57 ± 0.12	1700 mg
Kaur et al., [15]	8.5 ± 0.88	10.3 ± 1.24	1.8 ± 0.36	996 mg
G. Perewusnyk et al., [16]	7.3 ± 0.9	10.5 ± 0.9	3.2	800 mg
	8.6 ± 0.10	11.5 ± 0.10	2.9	400 mg
	8.8 ± 0.8	11.1 ± 0.7	2.3	100 mg
Present study	8.11 ± 0.88	10.28 ± 0.66	2.17 ± 0.22	866 mg

Thakor N. et al. reported an increase in Hb from 7.8 ± 0.61 gm/dL to 10.1 ± 0.73 gm/dL, with a mean increase of 2.3 ± 0.12 gm/dL at a mean dose of 800 mg [13]. Kriplani A. et al. observed a more substantial increase from 7.63 ± 0.61 gm/dL to 11.20 ± 0.73 gm/dL, resulting in a mean increase of 3.57 ± 0.12 gm/dL with a higher dose of 1700 mg [14]. The present study documented an initial Hb level of 8.11 ± 0.88 gm/dL, which rose to 10.28 ± 0.66 gm/dL, showing a mean increase of 2.17 ± 0.22 gm/dL at a mean dose of 866 mg (Table 5).

Ravneet Kaur's study showed a baseline Hb of 8.5 ± 0.88 gm/dL and an endpoint Hb of 10.3 ± 1.24 gm/dL, with a mean increase of 1.8 ± 0.36 gm/dL at 996 mg [15]. Lakshmikantha G. reported a baseline Hb of 6.159 ± 0.75 gm/dL, which increased to 8.625 ± 0.66 gm/dL, resulting in a mean increase of 2.47 ± 0.09 gm/dL at 600 mg [8] (Table 5). G. Perewusnyk conducted three different dosages: 800 mg with an increase from 7.3 ± 0.9 gm/dL to 10.5 ± 0.9 gm/dL (mean increase 3.2 gm/dL), 400 mg from 8.6 ± 0.10 gm/dL to 11.5 ± 0.10 gm/dL (mean increase 2.9 gm/dL), and 100 mg from 8.8 ± 0.8 gm/dL to 11.1 ± 0.7 gm/dL (mean increase 2.3 gm/dL) [16]. Lastly, Haldar et al. reported an increase from 7.85 ± 0.80 gm/dL to 9.62 ± 1.30 gm/dL, with a mean increase of 1.76 ± 0.5 gm/dL at a dose of 400 mg [12].

In summary, it illustrates that variations in dosages across studies result in differing increments in Hb levels, highlighting the dose-dependent nature of Hb improvement (Table 5). The present study's findings align closely with Thakor N. et al. [13] and Kaur et al. [15] though it utilizes a moderate dose of 866 mg compared to the higher and lower dosages in the other studies (Table 5). After looking more closely at earlier studies, it can be inferred that there is a weekly rise of 0.8 - 1gm% after iron sucrose is administered [8]. This rise in levels has the potential to improve the patient's appetite and overall well-being, ultimately disrupting the cycle of poor health and Anaemia. The main reason for the improved compliance is a decrease in the number of appointments and side effects. Although our study did not discover any major negative effects, other extensive studies have revealed that roughly 6.66% of subjects reported mild side effects like rashes and anaphylactic reaction.

In a clinical setting, the increase in Hb levels for pregnant women with severe Anaemia was notable. In our study above 20 % participants no longer suffered from Anaemia. All of this was achieved in a short amount of time, precisely 8 weeks after the last IVIS infusion. Hence, we consider that IV iron supplementation infusion may be a viable choice for pregnant females with intense Anaemia if blood transfusion is unavailable or rejected.

In Naqash et al. study showed adverse events ranged from 6.8% to 24.2% for IS therapy [17], while in our research, it was 10%. No serious adverse drug reactions necessitating hospitalization were reported by any of the patients. In study, Aggarwal and co-authors [18] found patients receiving IS therapy experienced fever, arthritis, dyspepsia, and anaphylaxis Grade I, while our study observed adverse events such as rashes and anaphylactic reaction. In their study 0.1 to 2% of patients experience severe anaphylactic reactions, such as sudden cardiovascular collapse, respiratory failure, and death, from intravenous iron dextran. Additionally, 30% of patients who received iron dextran treatment experienced negative effects such as fever, arthritis, and urticaria [19]. Injecting iron in the form of an iron–sorbitol citric acid complex into the muscle can lead to different side effects such as a metal taste in the mouth, nausea, vomiting, and discomfort at the injection site [19]. Different parenteral iron options, such as ferric

gluconate and ferric citrate, have been linked to causing serious and prolonged liver necrosis [19].

Our study was limited by a small number of cases, preventing the use of advanced tools to assess the response.

Conclusion:

The present research proves that intravenous iron sucrose is safe and effective in pregnant women, in treating iron deficiency Anaemia. Findings establish a substantial and steady rise in haemoglobin levels throughout an 8-week period, with 20% of subjects reaching standard levels. The occurrence of minor adverse reactions, like skin rashes and anaphylactic reaction was minimal (10%).

These results endorse the utilization of intravenous iron sucrose as a reliable and efficient remedy, especially in cases where oral iron supplements are not successful or well-tolerated. The findings also support the past research, highlighting the significance of IV iron supplementation in enhancing haemoglobin levels and decreasing complications associated with Anaemia in pregnancy. The research emphasizes the importance of detecting and treating issues early, suggesting intravenous iron sucrose as a suitable initial treatment option.

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