

Evaluation of Intravenous Iron Sucrose Therapy for Iron Deficiency Anaemia in Pregnancy

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Abstract: Iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnancy. Prophylactic oral iron is recommended during pregnancy to meet the increased requirement. In India, women become pregnant with low baseline haemoglobin levels resulting in high incidence of moderate to severe anaemia in pregnancy, where oral iron therapy cannot meet the requirement. Pregnant women with anaemia are to be treated with parenteral iron therapy. An Observational Prospective study was conducted to evaluate the safety and efficacy of IV Iron Sucrose therapy in the treatment of Iron Deficiency Anaemia. In this study two hundred pregnant women with haemoglobin levels between 5-11 gm. /dl attending antenatal clinic were given intravenous iron sucrose complex in a dose of 200 mg twice weekly schedule, after calculating the dose requirement. The mean haemoglobin raised from 7.63 ± 0.61 to 11.20 ± 0.73 gm. /dl after six weeks of therapy. No major side effects or anaphylactic reactions were noted during study period. IV Iron Sucrose therapy was effective in increasing haemoglobin levels in pregnant women with anaemia in hospital settings and tertiary urban hospitals. Further, long-term comparative studies are required to recommend its use at peripheral level.

Key Words: Iron Deficiency Anaemia, Parenteral Iron Therapy, Iron Sucrose Complex, Pregnant women.

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I. Introduction

IDA occurs when the body does not have enough iron to produce haemoglobin it needs. Our Body needs iron to make haemoglobin. When there isn't enough iron in your blood stream, rest of your body can't get the amount of oxygen it needs. In women of child bearing age, the most common cause of iron deficiency anaemia is a loss of iron in the blood due to heavy menstruation or pregnancy. A poor diet or certain intestinal diseases that affect how the body absorbs iron can also cause iron deficiency anaemia. WHO defines IDA as Haemoglobin (Hb) less than 11gm/dl¹. ICMR Classification of IDA is 8-11 gm. /dl as mild, 5-8 gm. /dl as moderate, and less than 5 gm. /dl as severe anaemia¹. The signs and symptoms of iron deficiency anaemia are Extreme fatigue, weakness, pale skin, brittle nails, inflammation or soreness of tongue, dizziness, head ache, etc². There is clear evidence to support prompt treatment in all patients with iron deficiency anaemia because it is known that treatment improves quality of life and physical condition as well as alleviates fatigue and cognitive deficits. Initial treatment is usually with oral iron (Ferrous Sulphate, Ferrous Gluconate or Ferrous Fumarate). Intestinal iron absorption is limited. The maximum rate of absorption of 100mg of oral iron is 20% to 25% and is reached only in the late stage of iron deficiency. Latent iron deficiency and iron deficiency anaemia correspond to mean absorption rates of 10% and 13% respectively, where as healthy males absorb 5% and healthy females 5.6%³. Patients who are intolerant of oral iron can be considered for IV iron replacement therapy. Doses typically range from 100 to 200 mg of elemental iron per day, successful repletion can be achieved with doses as low as 15 to 30 mg of elemental iron daily. Compared to oral iron, the use of IV iron has shown superior efficacy in the treatment of IDA. IV Iron Sucrose has been shown to be safe during pregnancy and is more effective than oral iron⁴⁻¹⁰. It enables rapid correction of anaemia with minimal side effects.

II. Materials and Methods

Inclusion Criteria:

- Pregnant women with IDA.

Exclusion Criteria:

- Pediatric patients.
- Geriatric patients.
- Pregnant women with cause other than IDA.

Study Design:

- Observational prospective study.

Sample Size:

- 200 pregnant women with IDA.

Study Site:

- The study has been conducted in the department of Obstetrics and Gynecology at Malla Reddy Health City, Medak Road, Suraram, Hyderabad, Telangana, India.

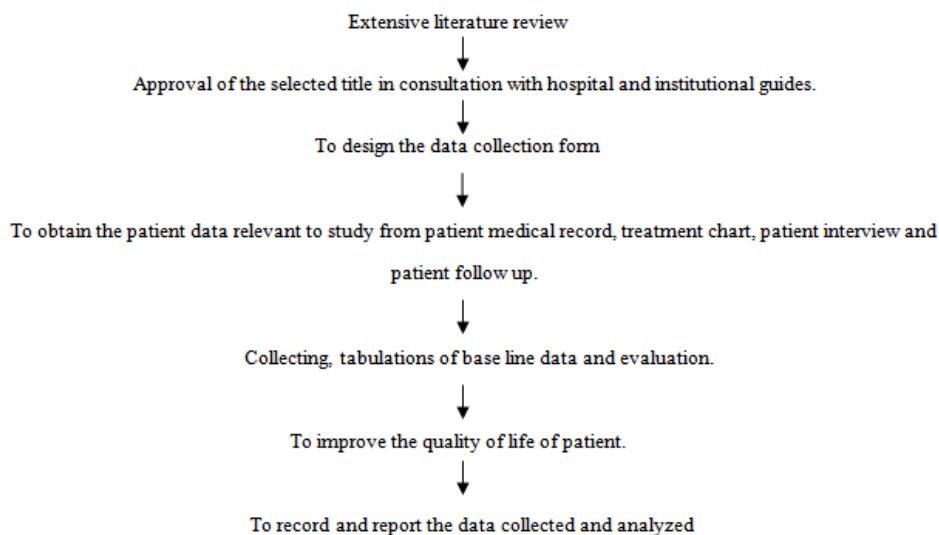
Study Period:

- Study period was from August 2018 to February 2019.

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

Required iron dose (mg) = (2.4 × (target Hb-actual Hb) × pre-pregnancy weight (kg)) + 500 mg for replenishment of stores¹¹.

Plan:



The prescribed doses of IV Iron Sucrose for Iron Deficiency Anaemia patients were as follows:

2.5 ml Ampule: 50 mg undiluted slow IV over 2-5 minutes.

5 ml Ampule : 100mg undiluted slow IV over 2-5 minutes.

10 ml Ampule:200 mg undiluted slow IV over 2-5 minutes.

Max dose is 200 mg not more than 3 times for week; dose must be 24hrs apart.

III. Results

Patient Population Demographics:

We have collected 200 cases of pregnant women with Anaemia taking IV Iron Sucrose Therapy. These patients were divided into Mild, Moderate, Severe Anaemia patients. They were given IV Iron Sucrose therapy for 6 weeks.

The mean age of women was 24.77yrs.

Table No 1: The baseline hemoglobin and effect of IV Iron Sucrose was as follows.

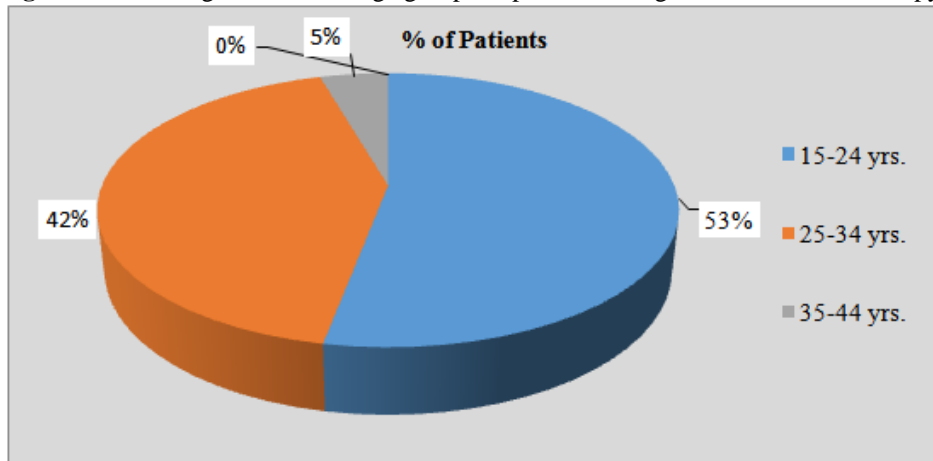
Parameter	Baseline	2 nd week	4 th week	6 th week
MeanHb(gm./dl)	7.8705 gm./dl	8.978 gm./dl	10.237 gm./dl	11.561 gm./dl

Table No 2: Distribution of patients taking IV Iron Sucrose Therapy based on their age groups.

Age Groups	15-24 yrs.	25-34 yrs.	35-44 yrs.
No of patients	106	85	9

Interpretation: IV Iron Sucrose therapy was given to more number of patients in the age group of 15-24 yrs.

Figure 1: Percentage of different age groups of patients taking IV Iron Sucrose Therapy.

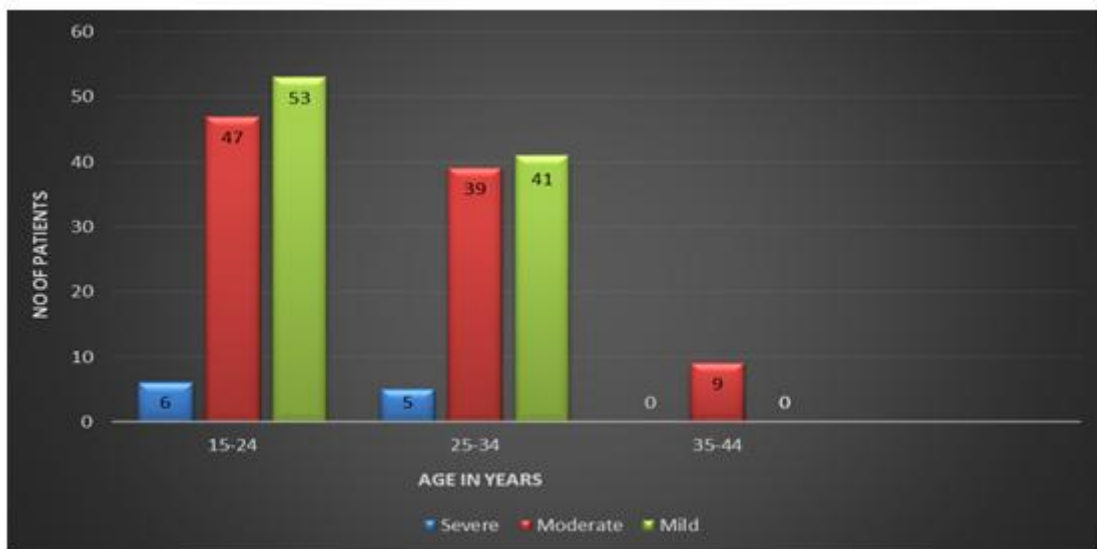


Interpretation: Patients with age group 15-24 yrs. were found to be highest with 53% followed by 25-34 yrs. of patients with 42%.

Table 3: Distribution of patients taking IV Iron Sucrose therapy based on age groups and Hb levels.

Haemoglobin Levels	Age Groups:			
	15-24 yrs.	25-34 yrs.	35-44 yrs.	
<=5 Hb (gm./dl) Severe Anaemia	6	5	0	
5-8 Hb (gm./dl) Moderate Anaemia	47	39	9	
8-11 (gm./dl) Mild Anaemia	53	41	0	

Figure 2: Graphical representation of patients taking IV Iron sucrose therapy, based on age groups and Hb levels.

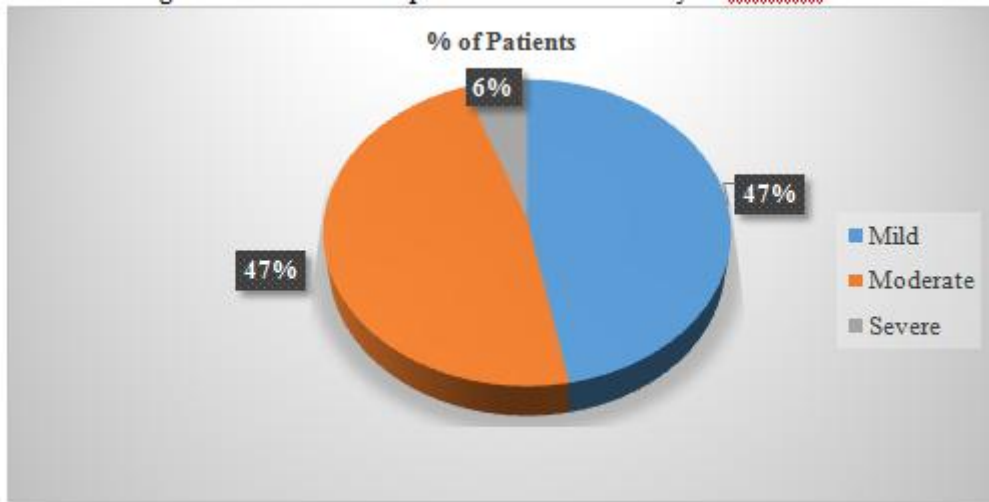


Interpretation: Mild anaemia patients are highest in age group of 15-24 yrs. and in the age group of 25-34 Mild anaemia patients are slightly higher than Moderate anaemia patients. In the age group of 35-44 only moderate anaemia patients are present.

Table 4: Distribution of patients based on severity of Anaemia:

Severity of Anaemia	No of Patients
Mild Anaemia(Hb = 8-11gm./dl)	94
Moderate Anaemia (Hb = 5-8gm./dl)	95
Severe Anaemia (Hb <=5)	11

Figure 3: Distribution of patients based on severity of anaemia

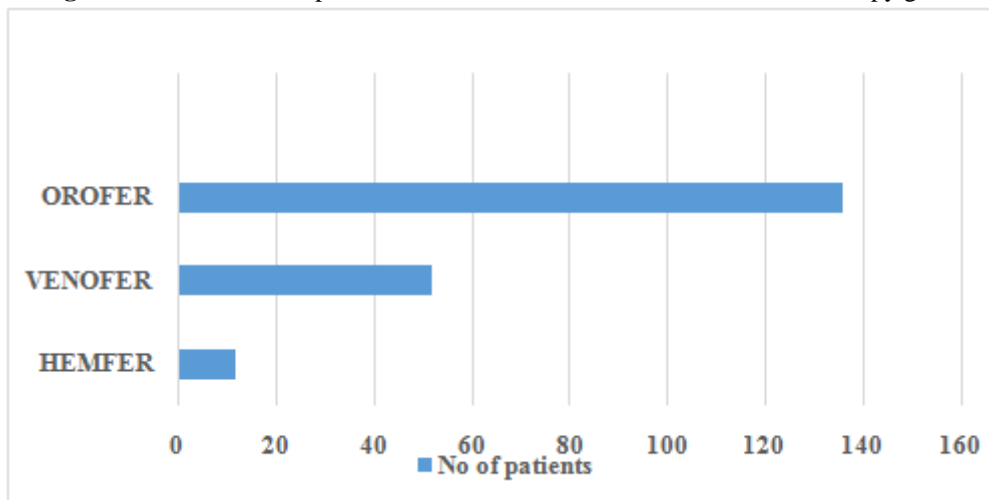


Interpretation: Patients with Mild and Moderate Anaemia were found to be highest with 47%.

Table 5: Distribution of patients based on brands of IV Iron Sucrose given.

Brands of IV Iron Sucrose	No of patients
OROFER	136
VENOFER	52
HEMFER	12

Figure 4: Distribution of patients based on the brand of IV Iron Sucrose therapy given.



Interpretation: OROFER is the Brand of IV Iron Sucrose that was prescribed to highest number of patients i.e. 136 patients.

III. Discussion

The total requirement of iron during pregnancy is approximately 1000 mg (500 mg for developing fetus and placenta and similar amount for red cell increment)¹². Usually, this iron is mobilized from iron stores. However, women with poor iron stores become iron deficient during pregnancy. Studies have shown that Hb levels <8 gm./dl (moderate to severe anaemia) in pregnancy are associated with higher maternal morbidity^{12,13,14}. Hb less than 5 gm./dl is associated with cardiac decompensating and pulmonary edema. Blood loss of even 200 ml in third stage of labor can cause sudden shock and death in these women.

As compared to western women whose iron stores are sufficient and they need 30-40 mg elemental iron per day for anaemia prophylaxis in pregnancy^{15, 16}, the stores in Indian women are deficient and they need 100 mg elemental iron per day for prophylaxis. For treatment of anaemia, dose recommended is 200 mg elemental iron per day²⁷. In the present study, 5-11gm/dl Hb was taken as cut-off. Intravenous iron is superior to oral iron with respect to faster increase in Hb and faster replenishment of body iron stores¹⁷. Also, it reduces the need of blood transfusions²⁹, and it can be given at outpatient basis.

In this observational prospective study, the effect of IV iron sucrose therapy for anemia in pregnancy was evaluated in a total of 200 patients. Among them, 47% were mild and moderate anemia patients and 6% were severe anemia patients. The mean age of women was 24.77 years. Mild anaemia patients were highest in 15-24 age group. In the age group of 25-34 Mild anaemia patients were slightly higher than Moderate anaemia patients. In the age group of 35-44 only moderate anaemia patients were present. At the beginning, baseline Hb levels were 7.8705 gm. /dl. After the initiation of therapy with IV Iron Sucrose, there was found to be a consecutive increase in the mean Hb levels. The second week mean Hb levels were 8.978 gm. /dl, fourth week mean Hb levels were 10.237 gm. /dl and sixth week mean Hb levels were 11.561 gm. /dl which indicates that the patients were showing an excellent response with IV Iron Sucrose and the results were satisfactory without any major side effects.

OROFER is the Brand of IV Iron Sucrose that was prescribed to highest number of patients i.e. 136 patients followed by VENOFER and HEMFER in 52 and 12 patients respectively.

This study also emphasizes on the safety of the IV Iron sucrose injection. None of the patients required any emergency care. Among 200 patients who received IV Iron Sucrose therapy, minor general adverse effects were noticed in very few cases. These effects includes metallic taste, flushing of the face and burning at the site of injection. The high tolerance of the drug has been attributed to slow release of Iron from the complex and also due to low allergenicity of Sucrose. Iv Iron Sucrose was given according to a calculated dose as either IV push over 5-10 mints or IV infusion over 20-30 mints.

IV. Conclusion

Based on the results obtained, it is clear that IV Iron Sucrose therapy was effective in the treatment of anaemia in pregnancy. Intra muscular preparations are known to be associated with local side effects such as metallic taste, flushing of the face and burning at the site of injection. IV Iron Sucrose complex was associated with few negligible side effects. It caused rapid rise in Hb levels and replacement of Iron stores was faster. Long term comparative studies are required to assess if it can be used at peripheral levels. Therefore Intravenous Iron sucrose is a safe and effective treatment for the rapid reversal of iron deficiency anaemia in obstetric and gynaecological settings. It enables rapid correction of anaemia with minimal side effects.

References

- [1]. Dutta Dc. Text book of obstetrics including perinatology & contraception. 6th ed. Calcutta: New Central Book Agency (P) Ltd; 2004. Anaemia in pregnancy; pp. 262-7.
- [2]. Kalaivani K. Prevalence & consequences of anaemia in pregnancy. Indian J Med Res. 2009; 130:627-33. [PubMed]
- [3]. Iron-deficiency anemia. American Society of Hematology. <http://www.hematology.org/Patients/Anemia/Iron-Deficiency.aspx>. Accessed Oct. 16, 2016.
- [4]. Seril DN, Liao J, Ho KL, Warsi A, Yang CS, Yang GY. Dietary iron supplementation enhances DSS-induced colitis and associated colorectal carcinoma development in mice. -Dig Dis Sci. 2002; 47(6):1266-1278. [PubMed].
- [5]. Koutroubakis IE, Oustamanolakis P, Karakoidas C, Mantzaris GJ, Kouroumalis EA. Safety and efficacy of total-dose infusion of low molecular weight iron dextran for iron deficiency anemia in patients with inflammatory bowel disease. Dig Dis Sci. 2010; 55(8):2327-2331. [PubMed]
- [6]. Onken JE, Bregman DB, Harrington RA et al. A multicenter, randomized, active-controlled study to investigate the efficacy and safety of intravenous ferric carboxymaltose in patients with iron deficiency anemia. Transfusion. 2014; 54(2):306-315. [PubMed]
- [7]. Rozen-Zvi B, Gafter-Gvili A, Paul M, Leibovici L, Shpilberg O, Gafter U. Intravenous versus oral iron supplementation for the treatment of anemia in CKD: systematic review and meta-analysis. Am J Kidney Dis. 2008; 52(5):897-906. [PubMed]
- [8]. Lindgren S, Wikman O, Befrits R et al. Intravenous iron sucrose is superior to oral iron sulphate for correcting anaemia and restoring iron stores in IBD patients: a randomized, controlled, evaluator-blind, multicentre study. Scand J Gastroenterol. 2009; 44(7):838-845. [PubMed]
- [9]. Khalafallah A, Dennis A, Bates J et al. A prospective randomized, controlled trial of intravenous versus oral iron for moderate iron deficiency anaemia of pregnancy. J Intern Med. 2010; 268(3):286-295. [PubMed]

- [10]. Schroder O, Mickisch O, Seidler U et al. Intravenous iron sucrose versus oral iron supplementation for the treatment of iron deficiency anemia in patients with inflammatory bowel disease—a randomized, controlled, open-label, multicenter study. *Am J Gastroenterol.* 2005; 100(11):2503–2509. [PubMed]
- [11]. Adamson JW. Iron deficiency and other hypoproliferative anemias. In: Braunwald E, Fauci AS, Kasper DL, editors. *Harrison's textbook of internal medicine.* 17th ed. New York: McGraw Hill; 2008. pp. 628–33.
- [12]. Rome: FAO; 1988. FAO/WHO Joint Expert Consultation Report. Requirements of vitamin A, iron, folate and vitamin B12 (FAO Food and Nutrition series 23)
- [13]. Toteja GS, Singh P, Dhillon BS, et al. Prevalence of anemia among pregnant women and adolescent girls in 16 districts of India. *Food Nutr Bull.* 2006; 27:311–5.
- [14]. Prema K, NeelaKumari S, Ramalakshmi BA. Anaemia and adverse obstetric outcome. *Nutr Rep Int.* 1981; 23:637–43.
- [15]. Milman N. Iron prophylaxis in pregnancy - general or individual and in which dose? *Ann Hematol.* 2006;85:821–8
- [16]. Milman N, Bergholt T, Eriksen L, Byg KE, Graudal N, Pedersen P, et al. Iron prophylaxis during pregnancy - how much iron is needed? A randomized dose- response study of 20-80 mg ferrous iron daily in pregnant women. *ActaObstetGynecol Scand.* 2005; 84:238–47.
- [17]. Bashiri A, Burstein E, Sheiner E, Mazor M. Anaemia during pregnancy and trHallakM, Sharon A, Duikman R, Auslender R, Abramovici H. Supplementing iron intravenously in pregnancy

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