e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(12); 728-731

Original Research Article

A Hospital-Based Study to Evaluate the Efficacy of Intravenous Iron Sucrose for the Treatment of Iron Deficiency Anemia in Pregnancy

Sweta Kumari[1], Simpi Shilpa[2], Seema Singh[3]

[1]Senior Resident, Department of Obstetrics and Gynaecology, Bhagwan Mahavir Institute of Medical Science, Pawapuri, Nalanda, Bihar, India

[2]Senior Resident, Department of Obstetrics and Gynaecology, Bhagwan Mahavir Institute of Medical Science, Pawapuri, Nalanda, Bihar, India

[3]Assistant Professor and HOD, Department of Obstetrics and Gynaecology, Bhagwan Mahavir Institute of Medical Science, Pawapuri, Nalanda, Bihar, India

Received: 08-07-2023 Revised: 19-08-2023 / Accepted: 21-09-2023
Corresponding Author: Dr. Simpi Shilpa
Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to evaluate the efficacy of intravenous iron sucrose for the treatment of iron deficiency anemia in pregnancy.

Methods: The present study carried out in Department of Obstetrics and Gynaecology. The duration of the study was about 12 months. 100 pregnant women were enrolled for this study.

Results: The study results showed that the mean age of the pregnant women was 24.76±5.08 years, their mean weight was 58.52±11.29 kg, their mean gestational week was 27.83±4.08, 15 (15%) of them had gestational diabetes, 12 (12%) of them had hypertension, 7 (7%) of them had hyperthyroidism, 6% had asthma and 5% genitourinary infection whereas 4 (4%) of them had chronic kidney disease. The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$).

Conclusion: This study concluded that the administration of iron sucrose intravenously (Orofer S) is a secure and effective choice in the management of iron deficiency anemia in pregnant women particularly for those who had inadequate response to oral iron supplementation. Intravenous iron sucrose is well accepted along with controllable safety profile clinically and enhanced Hemoglobin and ferritin level both and thus decrease complications during pregnancy due to iron deficiency anemia.

Keywords: Iron deficiency anemia, intravenous iron sucrose, Efficacy, Safety

Introduction

Anemia during pregnancy is associated with complications such as post-partum hemorrhage, low birth weight, premature births, stillbirths, and maternal deaths. [1] The World Health Organization (WHO) estimates that nearly 40% of pregnant women and one-third of all women of reproductive age worldwide are anemic. [2] In India, the National Family Health Survey, 2019-2021 (NFHS-5) reported that 52.2% of pregnant women in India were anemic, the prevalence being higher in rural areas (54.3%) than in urban areas (45.7%). Iron deficiency is the most common cause of anemia and is estimated to contribute to approximately 50% of all cases of anemia among non-pregnant and pregnant women worldwide. [3] Oral iron supplementation (iron-folic acid tablets) is the therapy of choice for prophylaxis and treatment of mild and moderate iron deficiency anemia in pregnancy. [4] However, oral iron therapy requires a prolonged duration of treatment, which is often beset with poor compliance. [5] Therefore, parenteral iron therapy is an alternative treatment modality for pregnant women with moderate anemia. [6]

WHO defines anaemia as haemoglobin (Hb) <11 g %. [7] In India, the ICMR classification of iron deficiency anaemia is: 8-11 g% as mild, 5-8 g % as moderate and <5 g% as severe anaemia. In absence of interfering factors, serum ferritin <12-15 µg/l is considered as iron deficiency. [8] The first choice for prophylaxis and treatment of mild iron deficiency anaemia in pregnancy is oral iron therapy. But in patients with moderate and severe anaemia, oral therapy takes long time and

compliance is a big issue in our country. Thus, pregnant women with moderate anaemia should be better treated with parentral iron therapy and/or blood transfusion depending upon individual basis (degree of anaemia, haemodynamic status, period of gestation, etc.). Various parenteral iron preparations are available in the market which can be given either intravenously or intramuscularly. Initially, iron dextran and iron sorbitol citrate was started. But test dose was required to be given before these injections as severe anaphylactic reactions were reported with intravenous iron dextran. Iron sucrose has been reported to be safe and effective during pregnancy. [9] The injection can be given without test dose. [10]

A variety of parenteral iron preparations are accessible that can be administered either intramuscularly or intravenously. In the beginning, iron dextran and iron sorbitol citrate was administered. Severe adverse anaphylactic reactions were observed with intravenous iron dextran so test dose was required before these injections. Therefore, iron sucrose has been projected to be harmless and effectual throughout pregnancy. [11] The advantage of iron sucrose is that there is no need of test dose before injection. [12] Iron sucrose complex (ISC) is a comparatively innovative preparation that is given intravenously for the improvement of iron deficiency anemia. This complex increases the Hb to acceptable level particularly injected in severe iron deficiency anemia in pregnant women. [13]

The aim of the present study was to evaluate the efficacy of intravenous iron sucrose for the treatment of iron deficiency anemia in pregnancy.

Materials and Methods

The present study carried out in Department of Obstetrics and Gynaecology, Bhagwan Mahavir Institute of Medical Science, Pawapuri, Nalanda, Bihar, India. The duration of the study was about 12 months. 100 pregnant women were enrolled for this study.

Pregnant women with Hb level equivalent to or <10 g/dl, Serum ferritin level equivalent to or <15 ng/l, with the age ranging from 18-40 years, gestational age of 16 weeks till at term were included in the study while identified allergic reaction to any active component, anemia not caused by lack of iron (such as hemolytic anemia), chronic or acute bacterial infection, pregnant women with gestational age <16 weeks, excess of iron or interruption in consumption of iron (such as haemosiderosis, haemochromatosis), liver cirrhosis and hepatitis, treated with iron products intravenously or transfusion of blood in 4 weeks were excluded from the study.

Demographic data and co-morbidities were recorded at the time of registration. A two times-weekly dose of 200 mg of iron sucrose (Orofer s) intravenously were infused to pregnant women, until the aim of Hb level of patient accomplished. The total collective dose of iron sucrose, equal to the total iron deficit (mg) can find out by the hemoglobin level (Hb) and body weight (BW). The dose of iron sucrose was individually calculated for each patient according to the total iron deficit with this formula.

Data Analysis

SPSS version 22 was applied to analyze the data. Frequency and percentages were calculated for categorical variables such as gender, co-morbidities and adverse effects etc. Mean±Standard deviation was calculated for numerical variables such as age, Hb and Ferritin level. Wilcoxon rank- test was used to compare mean Hb and ferritin level at, baseline and at term. P<0.05 were taken as statistically significant level.

Results

Table 1: Baseline profile of pregnant females

Variables	N (%)/Mean±SD
Age (years)	24.76±5.08
Maternal weight (kg)	58.52±11.29
Gestational week	27.83±4.08
Gestational diabetes	15 (15)
Hypertension	12 (12)
Hyperthyroidism	7 (7)
Asthma	6 (6)
Chronic kidney disease	4 (4)
Genitourinary infection	5 (5)

The study results showed that the mean age of the pregnant women was 24.76±5.08 years, their mean weight was 58.52±11.29 kg, their mean gestational week was 27.83±4.08, 15 (15%) of them had gestational diabetes, 12 (12%) of them had hypertension, 7 (7%) of them had hyperthyroidism, 6% had asthma and 5% genitourinary infection whereas 4 (4%) of them had chronic kidney disease.

Table 2: Comparison of baseline and term of hematological values

Variables	Day-zero	at Term	P value
	Mean±SD	Mean±SD	
Hb (mg/dl)	9.04±0.76	12.88±11.07	<0.001
Ferritin (ng/ml)	9.81±12.48	51.77±58.42	<0.001
Mean corpuscular volume (fl)	75.45±12.24	78.42±12.08	<0.001
Pack cell volume (%)	29.91±5.16	39.28±40.06	<0.001

The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$).

Discussion

Globally, one of the most frequent nutritional deficiencies is anemia. Even though, both the genders and all the ages are affected by nutritional anemia, the dilemma is more wide spread in women that lead to maternal morbidity and death, in addition to low weight of their babies at birth. [14] In developing countries, it has been predicted that about two-third of pregnant women are affected by the nutritional anemia. Though, in developing countries mostly women were anemic at the time of conception by a projected occurrence of anemia approximately 50% amongst non-pregnant women. Multiple factors are involved in anemia in pregnant women in the developing countries that vary by topographical areas.[15] Globally, deficiency of iron is the major cause of anemia throughout pregnancy, while the secondary cause is the constant insufficient intake and menstruation, increased requirement of the fetus and increase volume of maternal blood in pregnancy, physiologically. [15,16]

Generally, this iron is activated from iron stores. Moreover, women with already deprived stores of iron, develop deficiency of iron during pregnancy. One of the study has revealed that Hb levels less than 8 g% (moderate to severe anemia) in pregnancy are related to higher maternal morbidity whereas Hb <5 g% is linked with cardiac de- compensation and edema of lungs. Loss of even 200 ml of blood in third phase of labor leads to abrupt shock and fatality in these women. [17] The study results showed that the mean age of the pregnant women was 24.76±5.08 years, their mean weight was 58.52±11.29 kg, their mean gestational week was 27.83±4.08, 15 (15%) of them had gestational diabetes, 12 (12%) of them had hypertension, 7 (7%) of them had hyperthyroidism, 6% had asthma and 5% genitourinary infection whereas 4 (4%) of them had chronic kidney disease. Multiple studies have proposed that IV iron sucrose is harmless and effective substitute to oral iron in the management of Iron deficiency anemia. [18-20]

The study results further showed that both the hemoglobin ($p<0.001$) and ferritin levels ($p<0.001$) of females were significantly increased at term after receiving intravenous iron sucrose as compared to the baseline. Furthermore, significant difference was observed in PCV ($p<0.001$) and MCV as well ($p<0.001$). A randomized control assessment reported by Neeru et al [21], utilized iron sucrose intravenously in contrast with oral iron for management of iron deficiency anemia and observed that efficacy of iron sucrose was more in raising hemoglobin level significantly (23.62% vs 14.11% in oral iron) ($p<0.05$). In another randomized study by Dubey et al [22] after administration of iron sucrose intravenously or oral iron in 200 pregnant women, it was observed that iron sucrose augmented hemoglobin level and iron stores more rapidly as compared to oral iron significantly ($p<0.001$). The high acceptance of the drug has been partially accredited to sluggish discharge of iron from the iron sucrose complex and also because of low tendency to cause allergic reaction of sucrose. [23] The finding of the above study was contradictory to present study, where no major side effect was reported.

Conclusion

This study concluded that the administration of iron sucrose intravenously (Orofer s) is a secure and effective choice in the management of iron deficiency anemia in pregnant women particularly for those who had inadequate response to oral iron supplementation. Intravenous iron sucrose is well accepted along with controllable safety profile clinically and enhanced Hemoglobin and ferritin level both and thus decrease complications during pregnancy due to iron deficiency anemia.

References

1. Rahman MM, Abe SK, Rahman MS, Kanda M, Narita S, Bilano V, Ota E, Gilmour S, Shibuya K. Maternal anemia and risk of adverse birth and health outcomes in low-and middle-income countries: systematic review and meta-analysis, 2. The American journal of clinical nutrition. 2016 Feb 1;103(2):495-504.
2. World Health Organization. Prevalence of anaemia in women aged 15–49, by pregnancy status. Geneva: Who. 2021.
3. Chaparro CM, Suchdev PS. Anemia epidemiology, pathophysiology, and etiology in low-and middle-income countries. Annals of

the new York Academy of Sciences. 2019 Aug ;1450(1):15-31.
4. Ministry of Health and Family Welfare, Government of India. Guidelines for control of iron deficiency anaemia. (2013).
5. Cook JD: Diagnosis and management of iron-deficiency anaemia . Best Pract Res Clin Haematol. 2005, 18:319-32.
6. Ministry of Health and Family Welfare. Government of India. Anemia Mukt Bharat operational guidelines. (2019).
7. Dutta Dc. Anaemia in pregnancy. Text book of obstetrics including perinatology & contraception, 6th ed. Calcutta: New Central Book Agency (P) Ltd.; 2004. p. 262-7.
8. Kalaivani K. Prevalence & consequences of anaemia in pregnancy. Indian Journal of Medical Research. 2009 Nov 1;130(5):627-33.
9. Silverstein SB, Rodgers GM. Parenteral iron therapy options. American journal of hematology. 2004 May;76(1):74-8.
10. Charytan C, Levin N, Al-Saloum M, Hafeez T, Gagnon S, Van Wyck DB. Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anemia: North American clinical trial. American Journal of Kidney Diseases. 2001 Feb 1;37(2):300-7.
11. Silverstein SB, Rodgers GM. Parenteral iron therapy options. Am J Hematol. 2004;76(1): 74-8.
12. Van Wyck DB, Cavallo G, Spinowitz BS, Adhikarla R, Gagnon S, Charytan C, Levin N. Safety and efficacy of iron sucrose in patients sensitive to iron dextran: North American clinical trial. American journal of kidney diseases. 2000 Jul 1;36(1):88-97.
13. Kriplani A, Mahey R, Dash BB, Kulshreshta V, Agarwal N, Bhatla N. Intravenous iron sucrose therapy for moderate to severe anaemia in pregnancy. The Indian journal of medical research. 2013 Jul;138(1):78.
14. WHO. Maternal Health and Safe Motherhood Programme & World Health Organization. Nutrition Programme. The prevalence of anaemia in women : a tabulation of available information, 2021.
15. van den Broek N. Anaemia in pregnancy in developing countries. Br J ObstetGynaecol. 19 98;105(4):385-90.
16. Gopalan C. Current food and nutrition situation in south Asian and south-east Asian countries. Biomed Environ Sci. 1996;9(2-3): 102-16.
17. Toteja GS, Singh P, Dhillon BS, Saxena BN, Ahmed FU, Singh RP et al. Prevalence of anemia among pregnant women and adolescent girls in 16 districts of India. Food Nutr Bull. 2006;27(4):311-5.
18. Al RA, Unlubilgin E, Kandemir O, Yalvac S, Cakir L, Haberal A. Intravenous versus oral iron for treatment of anemia in pregnancy. Obstet Gynecol. 2005;106(6):1135-40.
19. Cançado RD, Novis de Figueiredo PO, AlbeOlivatoMS,Chiattone CS. Efficacy and safety of intravenous iron sucrose in treating adults with iron deficiency anemia. Rev Bras HematolHemoter. 2011;33(6):439-43.
20. Bhandal N, Russell R. Intravenous versus oral iron therapy for postpartum anaemia. BJOG. 2006;113(11)1248-52.
21. Neeru S, Nair NS, Rai L. Iron sucrose versus oral iron therapy in pregnancy anemia. Indian J Comm Med. 2012;37(4):214-8.
22. Dubey S, Suri V, Aggarawal N, Das R. Is it safe to use intravenous iron sucrose during pregnancy? a randomized controlled trial. Int J ReprodContraceptObstet Gynecol. 2013;2(4): 544-9.
23. Perewusnyk G, Huch R, Huch A, Breymann C. Parenteral iron therapy in obstetrics: 8 years experience with iron-sucrose complex. Br J Nutr. 2002;88(1):3-10.