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A Comparative Study to determine the Effect of Oral Iron and Parentral Iron Sucrose in the Treatment of Iron Deficiency Anaemia in Pregnant Women

Anupam Sharma[1], Mridula Sharma[2]

[1]Associate Professor, Department of Medicine, Rajshree Medical Research Institute, Bareilly, UP, India.
[2]Assistant Professor, Department of Obstetrics and Gynaecology, Rajshree Medical Research Institute, Bareilly, UP, India.

Abstract

Background: To determine the effect of parentral iron sucrose and oral iron in the treatment of iron deficiency anaemia in pregnant women.**Material and Methods:**There were two Category of 45 patients each, with 45 patients in each Category. Category A ladies were given IV iron sucrose. To restore iron reserves, sucrose was administered at a rate of 10 mg/kg. The whole determined dosage was administered in split doses on alternate days or twice weekly. For 6 weeks, the women in Category B were given ferrous sulphate as an oral iron BD. The pills were to be taken on an empty stomach, either two hours before or after a meal. All initial investigations, including haemoglobin, red blood cell count, reticulocyte count, PCV, MCHC, serum iron, serum ferritin, and total iron binding capacity of serum, were completed after six weeks. All haematological markers were checked at the moment of delivery and again one week afterwards.**Results:**In the current research, the baseline mean Hb level in the oral iron treatment Category was 9.11±0.22g/dl and 9.02±0.21g/dl in the parental iron therapy Category, which was shown to be statistically insignificant between the Categorys. The Hb level in both the oral and injectable iron Categorys changed significantly ($p<0.05$) 6 weeks after commencing the medication. The mean Hb increase in the injectable iron Category was 3.30 g/dl (p 0.05), and 1.34 g/dl in the oral iron Category ($p <0.05$).The increase in serum iron, serum ferritin, and TIBC was also significant ($p<0.05$) in two Categorys A and B in our study, whereas the rise in other haematological parameters such as red cell count, packed cell volume, mean corpuscular haemoglobin concentration, and reticulocyte counts were non-significant. Indicate that the IV Category outperforms the oral Category ($p<0.05$).**Conclusion:**With no major adverse medication reactions, intravenous iron sucrose addressed iron deficient anaemia of pregnancy quicker and more efficiently than oral iron treatment.

Keywords: Iron sucrose, Haemoglobin, Anaemia.

Corresponding Author: Dr. Mridula Sharma, Assistant Professor, Department of Obstetrics and Gynaecology, Rajshree Medical Research Institute, Bareilly, UP, India.
Email: drmridu@gmail.com

Introduction

Iron deficiency anaemia (IDA) is a serious public health issue worldwide. Because of the effects on maternal and neonatal morbidity and death, pregnant women are the most susceptible. According to the WHO study, the prevalence of IDA in pregnancy is predicted to be 35-75 percent (average 56 percent) in non-industrialized nations and 18 percent in industrialised ones.[1] It is directly or indirectly responsible for 40-60% of maternal deaths in non-industrialized nations.[2,3] According to the National Family Health Survey-3 (NFHS), the prevalence of IDA in pregnancy in India is 57.9 percent (54.6 percent in urban areas and 59 percent in rural areas), with a large range in incidence from state to state.[4] According to WHO statistics provided at the Federation of International Obstetrics and Gynecology

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(FIGO) congress in Chile in 2003, iron deficiency anaemia causes around 500,000 maternal fatalities and 20,000,000 maternal morbidity cases each year. According to a FOGSI – WHO research on maternal morbidity, 64.4 percent of women who died had haemoglobin less than 8 gm percent, and 21.6 percent had haemoglobin less than 5 gm percent.[2]
Mismatched transfusions, infections, notably HIV and hepatitis, and transfusion-related acute lung damage are all possibilities. As an option to raising haemoglobin in iron deficiency anaemia, parenteral iron formulations might be considered. Early parenteral formulations have been linked to several adverse events and have been removed in a number of countries. They were exceeded with the development of iron sucrose and modified iron dextran and ferric gluconate formulations. These formulations have significantly enhanced safety profiles, lower incidence of adverse events, and reduced the frequency of hospital or clinic visits by patients.[5,6] When compared to blood transfusions, intravenous (IV) iron treatment is both safe and cost efficient for restoring haemoglobin and iron reserves in the body.[7] In several countries, IV iron sucrose formulations are utilised for this purpose. Although another IV iron preparation, ferric carboxymaltose, is now available and promises to be safe, it is highly expensive and out of reach for many people. Our research will assist primary care providers in prioritising IV iron sucrose as a safe and cost-effective treatment for iron deficient anaemia.

Materials and Methods

After receiving clearance from the protocol review committee and the institutional ethics council, this prospective, randomised, comparative research was carried out at the Department of Medicine & Obstetrics & Gynaecology. This research recruited 90 pregnant women with gestational ages ranging from 26 to 34 weeks with mild to severe iron deficiency anaemia (Hb 7-10 g/dl). We established a Hb goal of 11 g/dl. Clinical and laboratory exams were used to determine the woman's initial iron status. Low red cell count, MCHC, reticulocyte count, serum ferritin and serum iron, and elevated TIBC were all signs of iron insufficiency. Pregnant women with gestational ages between 26 and 34 weeks, anaemia owing to reasons other than iron deficiency, and any other medical or obstetric complicating factors such as hypertension, diabetes, or a response to IV iron sucrose are ineligible from the research.

Methodology

Other causes of anaemia were ruled out after meticulous history taking, clinical examination, and basic testing. There were two Categorys of 45 patients each, with 45 patients in each Category. Category A ladies were given IV iron sucrose. The iron sucrose dosage was determined as follows: 2.4Body mass index (in kg) (target Hb- actual Hb). To restore iron reserves, sucrose was administered at a rate of 10 mg/kg. The whole determined dosage was administered in split doses on alternate days or twice weekly. The maximum dosage is 200 mg per dose given intravenously over 1 hour. Iron sucrose has been demonstrated to be stable in normal saline at concentrations ranging from 0.5 to 2 mg/ml for 24 hours in tests. As a result, 100 mg iron sucrose dissolved in 100 mL saline (1 mg/mL) is stable and should be administered within 15-20 minutes. So the dilutions and delivery were as follows: 5 ml iron sucrose (100 mg iron) in 100 ml 0.9 percent NaCl infused for at least 15 minutes. There was no test dosage administered.
For 6 weeks, the women in Category B were given ferrous sulphate as an oral iron BD. The pills were to be taken on an empty stomach, either two hours before or after a meal. As salt, each pill contained 200 mg (60 mg elemental iron). Every patient in these two Categorys was followed up on once a week for six weeks. All initial investigations, including haemoglobin, red blood cell count, reticulocyte count, PCV, MCHC, serum iron, serum ferritin, and total

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iron binding capacity of serum, were completed after six weeks. All haematological markers were checked at the moment of delivery and again one week afterwards.

Statistical Evaluation

SPSS 25.0 was used to analyse the data. A P<0.05 value was deemed statistically significant.

Results

In this prospective trial, 90 pregnant women were chosen at random and randomly allocated to one of two Categorys: iron sucrose (Category A, n = 45) or ferrous sulphate (Category B, n = 45). At 6 weeks, 44 pregnant women from the iron sucrose Category (two had hypersensitive response) and 38 pregnant women from the ferrous sulphate Category were eligible for the study. In both the oral and intravenous Categorys, the majority of the patients were between the ages of 25 and 30. The mean age of the patients in the oral Category was 26.11±4.03 years, while the mean age of the patients in the intravenous Category was 26.25± 4.57 years.

In the current research, the baseline mean Hb level in the oral iron treatment Category was 9.11±0.22g/dl and 9.02±0.21g/dl in the parental iron therapy Category, which was shown to be statistically insignificant between the Categorys. The Hb level in both the oral and injectable iron Categorys changed significantly (p<0.05) 6 weeks after commencing the medication. The mean Hb increase in the injectable iron Category was 3.30 g/dl (p 0.05), and 1.34 g/dl in the oral iron Category (p <0.05).

The increase in serum iron, serum ferritin, and TIBC was also significant (p<0.05) in two Categorys A and B in our study, whereas the rise in other haematological parameters such as red cell count, packed cell volume, mean corpuscular haemoglobin concentration, and reticulocyte counts were non-significant. Indicate that the IV Category outperforms the oral Category (p<0.05).

The independent sample t-test was used to compare the haematological parameters of two Categorys (Categorys A and B). Hb, serum iron level, and total iron binding capacity showed significant variations (p<0.05), but other parameters were determined to be non-significant (p<0.05) [Table 2 and 3].

The independent sample t-test was used to compare the weekly change in haemoglobin levels in two Categorys. In all weeks, two Categorys vary substantially (p<0.05) in terms of haemoglobin percentage change [Table 4].

There were no significant differences in pregnancy outcomes between the two Categorys. The parenteral iron Category had more systemic adverse effects, while the oral iron Category saw more gastrointestinal side effects.

Table 1: Demographic profile

Characteristics	IV Categorys (A)= 45	Oral Categorys (B)= 45	P-value
Age	26.25 ± 4.57	26.11 ±4.03	0.77
Multigravida	35	33	0.68
BMI (Kg/m^2)	21.89 ± 3.22	21.98 ± 3.02	0.65
POG (weeks)	28.11 ±3.65	28.42 ±3.44	0.55

Table 2: Haemoglobin level before and after treatment

Category	Hb level (g/dl)	
	Before treatment	After treatment
Category A	9.02±0.21	12.32±0.19
Category B	9.11±0.22	10.45±0.24

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Table 3: Change in various Haematological parameters

Parameters	Change in haematological parameters after treatment		P value
	Category- A	Category- B	
Haemoglobin level (g/dl)	3.30	1.34	0.001
Red cell count (million/ mm^3)	0.97	1.08	4.33
Packed cell volume (%)	10.05	11.89	4.88
Mean corpuscular haemoglobin concentration (%)	5.05	4.49	3.63
Reticulocyte counts (%)	0.83	0.65	2.21
Serum iron level (µg %)	71.05	43.38	0.048
Serum ferritin (µg/l)	66.05	16.25	0.0015
Total iron binding capacity (µg %)	-327.76	-153.38	0.0015

Table 4: Weekly change in level of haemoglobin

Weeks	Category-A average %	Category-B average %	P - Value
1st	14.11 ± 0.71	10.74 ± 0.69	0.0001
2nd	19.12 ± 0.87	6.15± 0.48	0.0001
3rd	5.41 ± 0.54	1.82 ± 0.22	0.006
4th	2.92 ± 0.35	1.42 ± 0.15	0.0039
5th	1.24 ± 0.06	0.74 ± 0.09	0.0004
6th	0	0.39 ± 0.04	0.0000
At time of delivery	45.10 ± 3.11	28.22 ± 1.58	0.0014
One week after delivery	33.58 ± 2.38	17.12 ± 1.38	0.014

Discussion

One of the most common dietary deficits affecting pregnant women is anaemia.8 Iron supplementation is critical during pregnancy because the mother's and fetus's requirement for iron rises. The overall maternal demand for additional iron averages about 800 mg (elemental iron), with around 300 mg going to the foetus and placenta and the rest going to maternal haemoglobin mass increase.[9] This increased requirement cannot be addressed without the use of iron supplements. A pregnant woman requires between 2–4.8 milligrammes of iron each day. To absorb this amount of iron daily, the woman must eat 20–48 mg of dietary iron. As a result, iron supplementation during pregnancy is always advised, even in nonanemic women. Iron supplementation may be accomplished via a variety of means, including oral iron treatment, parenteral therapy, and blood transfusion.[9] Iron deficiency anaemia during pregnancy is the most frequent medical disease in underdeveloped countries and demands particular attention due to the possible repercussions.[10-12] Despite the fact that oral iron supplementation is routinely used to treat IDA, not all patients react well to it. Previously, the administration of intravenous iron was linked with unfavourable and sometimes severe side effects, and as a result, it was underutilised. However, in recent years, novel type II and III iron complexes with improved compliance and tolerability, as well as strong effectiveness and a low risk profile, have been produced. There have been few studies that compare intravenous iron sucrose to oral iron for the management of iron deficient anaemia in pregnancy.[13,14]

In the current research, the baseline mean Hb level in the oral iron treatment Category was 9.11±0.22g/dl and 9.02±0.21g/dl in the parental iron therapy Category, which was shown to be statistically insignificant between the Categorys. The Hb level in both the oral and injectable iron Categorys changed significantly ($p<0.05$) 6 weeks after commencing the

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medication. The mean Hb increase in the injectable iron Category was 3.30 g/dl (p 0.05), and 1.34 g/dl in the oral iron Category ($p<0.05$). Earlier researchers found comparable results of elevated Hb percent in the oral and IV Categorys.[15,16] The increase in serum iron, serum ferritin, and TIBC was also significant ($p<0.05$) in two Categorys A and B in our study, whereas the rise in other haematological parameters such as red cell count, packed cell volume, mean corpuscular haemoglobin concentration, and reticulocyte counts were non-significant. Indicate that the IV Category outperforms the oral Category ($p<0.05$). Other researchers observed a rise in blood iron in both Categorys, but there was no statistically significant difference between the oral and IV Categorys.[17,18] When the data was evaluated over time, it was discovered that the haemoglobin percent change in two Categorys differed substantially ($p<0.05$) in all weeks. Similar to other studies, patients who received intravenously administered iron sucrose (Category A) were significantly more likely to have higher haemoglobin from baseline than those who received orally administered iron at every point of measurement (at 1st week, 2nd week, and at term) throughout the course of the study.[19]

Conclusion

With no major adverse medication reactions, intravenous iron sucrose addressed iron deficient anaemia of pregnancy quicker and more efficiently than oral iron treatment.

References

1. WHO global database on child growth and malnutrition, Geneva: WHO programme on nutrition. 1997.
2. Bhatt RV. Maternal mortality in India, FOGSI- WHO study. J Obstet Gynecol India. 1997;47:207-14.
3. Viteri FE. The consequences of iron deficiency and anaemia in pregnancy. Adv Exp Med Biol. 1994;352:127-39.
4. National Family Health Survey (NFHS-3), Ministry of health and family welfare (Government of India). 2005-2006.
5. Agarwal KN, Agarwal DK, Sharma A, Sharma K, Prasad K, Kalita MC, et al. Prevalence of anaemia in pregnant and lactating women in India. Indian J Med Res 2006;124:173 84.
6. Peebles G, Fenwick S. Intravenous iron administration in a short stay hospital setting. Nurs Stand 2008;22:35 41.
7. Westad S, Backe B, Salvesen KA, Nakling J, Okland I, Borthen I, et al. A 12 week randomised study comparing intravenous iron sucroseversus oral ferrous sulphate for treatment of postpartum anemia. Acta Obstet Gynecol Scand 2008;87:916 23
8. Thangaleela T, Vijayalakshmi P. Prevalence of anaemia in pregnancy. Indian J Nutr Diet 1994;31:26-32.
9. Mukherji J. Iron deficiency anemia in pregnancy. Rational Drug Bull 2002;12:2-5.
10. Govan AD, Scott JM. Intravenous iron in the treatment of anemia of pregnancy. Eur J Obstet Gynecol Reprod Biol. 2005;123(2):S33-S35
11. Beard JL. Effectiveness and strategies of iron supplementation during pregnancy. Am J Clin Nutr 2000;71:1288-1294.
12. Murray CJL, Lopez AD. Global and regional causes of death patterns in 1990. Bull. World Health Organ 1994;72:447-480.
13. Al-Memon, Almeshari Al, Saddique N, Abotalib A, Khashogu Z. Intravenous iron sucrose complex in treatment of iron deficiency and anaemia in pregnancy. Eur J Obstet Gynacol Repord Bio 1996;69:121-4.

ISSN: 0975-3583,0976-2833 VOL12, ISSUE 05, 2021

14. Kochhar PK, Kaundal A, Ghosh P. Intravenous iron sucrose versus oral iron in treatment of iron deficiency anemia in pregnancy: a randomized clinical trial. J Obstet Gynaecol Res 2012;39(2):504-10.
15. Divakar H. Iron-deficiency anaemia in pregnant women: what preventing practitioners from using IV iron sucrose. International Journal of infertility Fetal Medicine 2012;3(1):1.
16. Aggarwal R, Mishra V, Panchal N, Patel N, Deshchougule V, Jasani A. Comparison of oral iron and IV iron sucrose for treatment of anemia in postpartum Indian women. Natl J Community Med 2012;3(1):48-54.
17. Kumar A, Jain S, Singh NP, Singh T. Oral versus high dose parenteral iron supplementation in pregnancy. Int J Gynaecol Obstet 2005;89(1):7-13.
18. Raja KS, Janjua NB, Khokhar N. Intravenous iron sucrose complex therapy in iron deficiency anemia in the pregnant women. Rawal Medical Journal 2003;28:40-43.
19. Ragip A, Unlubilgin E, Kanderim O, Yalvac S, Cakir L, Haberal A. Intranenous versus oral iron treatment of anemia in pregnancy: A randomized trial. Obst Gynecol 2005;106:1335-1340.