e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(6); 621-625

Original Research Article

Comparative Effectiveness of Oral Iron Supplements Vs Intravenous Iron Sucrose in Managing Iron Deficiency Anemia in Pregnant Women

Shilpa Shekhar Ingle

Assistant Professor, Department of Obstetrics and Gynecology, Parbhani Medical College and R P Hospital and Research Institute, Parbhani

Received: 25-03-2024 / Revised: 23-04-2024 / Accepted: 26-05-2024
Corresponding Author: Dr. Shilpa Shekhar Ingle
Conflict of interest: Nil

Abstract:

Introduction: Iron deficiency anaemia (IDA) has emerged as general health issue affecting world-wide population during pregnancy, its impact on health of mothers and newborns, as well as subsequent generations is observed. India with increasing population, it also has the highest prevalence of iron-deficiency anaemia in comparison to worldwide population, particularly affecting rural populations due to poverty and inadequate nutrition. Anemia can be short-lived or constant and ranges from mild to severe. Focusing on creating an anaemia-free India is achievable by raising awareness. Present study is focused on comparative analysis and record the effectiveness of oral iron supplementation during pregnancy.

Aim: Aim of present study is to systematically record and compare the effectiveness of oral iron supplementation versus intravenous iron sucrose in treating iron deficiency anemia during pregnancy.

Materials and Methods: A prospective study was conducted at a tertiary care center over a period of 2 years, involving 100 pregnant participants diagnosed with mild to moderate iron deficiency anaemia, on the basis of inclusion and exclusion criteria.

Study Design: This comparative study involved two groups, with 50 participants allocated to each group. One group received intravenous (IV) iron treatment, while the other group received oral iron supplementation. The study aimed to evaluate treatment effects based on outcomes such as initial and final hemoglobin levels.

Result: Initially hemoglobin levels were found to be statistically significantly lower in the Oral Rx group of participants compared to the IV Rx group, with a p-value of 0.001**. This indicates that participants who received intravenous iron treatment had higher final hemoglobin levels compared to those who received oral iron supplementation.

Conclusion: Present study aimed to evaluate the safety and effectiveness of oral iron compared to intravenous (IV) iron on hematological parameters in pregnant women with iron deficiency anemia. Our findings confirm that IV iron resulted in a rapid and significant improvement in hematological parameters compared to oral iron supplementation.

Keywords: Oral Iron Supplements, Intravenous Iron Sucrose, Iron Deficiency Anemia and Pregnant Women.

Introduction

Iron deficiency anaemia (IDA) has emerged as general health issue affecting world-wide population duringpregnancy [1], its impact on health of mothers and newborns, as well as subsequent generations is observed. India with increasing population, it also has the highest prevalence of iron-deficiency anaemiain comparison to worldwide population, particularly affecting rural populations due to poverty and inadequate nutrition. Anemia can be short-lived or constant and ranges from mild to severe. Focusing on creating an anaemia-free India is achievable by raising awareness about its consequences and promoting effective prevention and treatment strategies, it has been essential to spread awareness in rural population as compared to urban areas. Maternal mortality has been ranging in between 350-450per 100000 live birth in India, which was comparable to European population two centuries ago from present day [2,3]. Anaemia contributes to about 20% of maternal deaths and significantly increases the risk of perinatal mortality by nine times8. The odds of delivering a low-birth-weight baby triple, while the risk of preterm birth more than doubles in association with iron deficiency anaemia (IDA) during pregnancy [4]. Anaemia and iron deficiency in pregnancy are also linked to increased placental weight and a higher ratio of placental weight to birth weight, both of which are predictors of hypertension in adulthood [5, 6]

A study revealed deficiency in serum iron level and iron deficiency anemia in pregnant women from rural India. Anemia in rural pregnant is more common, it has been increasing as 43.5% experienced moderate anemia in rural population, while in urban they had mild anemia, accounting for 35.7%.

IDA has also been related to below par scores of the Bayley Mental Development Index in newborns [7]; an aspect that highlights the effect of the condition on mental and motor development. Nevertheless, the effect of iron supplementation on these developmental aspects has been affirmed to reduce these adverse impacts within iron-deficient infants who are over 12-18 months of age,[8]. Contributory factors such as nutritional perturbations weaning, and other related factors while not as prominent, are becoming less apparent as investigations have linked IDA during infancy and early childhood to maternal iron deficiency during pregnancy. According to the current studies, babies born out of iron supplemented mothers possess more than double the levels of iron content in their body than the mother as early as in two months.

Eradicating iron deficiency anemia therefore entails identifying and extending the iron status of the mother to the infant and early childhood age group. The decision appears to be rational and economical at this stage if all the factors are viewed superficially. Although there still has been controversy over iron supplementation during pregnancy in France [9], treatment of iron deficiency anaemia with iron supplement is well-known. However, when delivered orally in the long-term, untoward GI symptoms may surface and can negatively impact patient compliance. There is intramuscular injection of iron supplement is also available, but it is quite painful and not very effective all the time. The intravenous iron therapy by using iron sucrose solutions has existed and some EU countries and in other countries. A comparative analysis [10] has further used iron sucrose both intravenous show better results in comparison with oral iron during pregnancy. Present study is focused on comparative analysis and record the effectiveness of oral iron supplementation during pregnancy.

Aims and Objectives

1. To systematically record and compare the effectiveness of oral iron supplementation versus intravenous iron sucrose in treating iron deficiency anemia during pregnancy.
2. To pilot the response to intravenous iron sucrose.

Materials and Methods

A prospective study was conducted at a tertiary care center over a period of 2 years, involving 100pregnant participants diagnosed with mild to moderate iron deficiency anaemia. Participants willing to take part in the study were included if they were between 14 to 34 weeks of gestation and had hemoglobin levels ranging from less than 11 mg/dl to greater than 7 mg/dl, indicating iron deficiency anaemia.

Inclusion Criteria

Participants voluntarily consented to join the study. Participants had uncomplicated pregnancies. Gestational age ranged from 14 to 34 weeks, with confirmed iron deficiency anaemia defined by hemoglobin levels between less than 11 mg/dl and greater than 7 mg/dl. No complicating factors were present in the participants. All participants had confirmed iron deficiency anaemia.

Exclusion Criteria

The study excluded participants with the following criteria: anaemia not attributed to iron deficiency, severe anaemia defined by hemoglobin levels below 7 g/dl, and several medical conditions like, pulmonary diseases asthama, COPD, Tuberculosis, Livel diseases (Liver cirrhosis, Viral hepatitis, multiple pregnancy, acute or chronic infection, treatment on iron supplementation, and participants who did not provide informed consent.

Study Procedure

Participant selected for the study were aware about the study procedures, every aspect of study was explained well to them, informed consent form was also obtained in written format.

All the participants were selected only after clinical examinations, comprehensive history was taken, detailed general as well as obstetrics examination was done. Participants were selected after special attention, to ensure that none of the exclusion criteria were present.

Participant's hemoglobin estimation was done, using Sahli's method of hemoglobinometry following peripheral smear examination, and RBC indices. The sufficient amount of iron needed by an individual was calculated using formula below:

Total iron deficient (mg) = Amount of iron deficit + Amount to refill stores

Amount of iron deficit (mg) = Pre-pregnancy BW (Kg) X Hb deficit X 2.4

Hb deficit = target Hb – initial Hb

Amount of iron to replenish = BW (Kg) X 10

In present study targeted level was, 11 mg/dl.

The participants divided into two groups, namely Group I and group II

Participants received ferrous sulfate 100 mg tablets three times daily, with each tablet containing 100 mg of elemental iron.

Group II: participants received iron sucrose administered as a bolus injection intravenously over 10 minutes.

Initially, 2 ampoules (100 mg each) were given, and if no allergic reaction occurred, the same dose was repeated on alternate days until the total prescribed dose was administered. Oral iron supplements were withheld during this treatment. After completing the prescribed course of treatment, participants were monitored every 2 weeks for side effects, compliance with the treatment regimen, and laboratory response, assessed by repeating hemoglobin (Hb) level measurements.

Results

Study Design: This comparative study involved two groups, with 50 participants allocated to each group. One group received intravenous (IV) iron treatment, while the other group received oral iron supplementation. The study aimed to evaluate treatment effects based on outcomes such as initial and final hemoglobin levels.

Table 1: The initial hemoglobin levels were measured and observed to be distributed as follows in the two groups of participants studied

Initial level of hemoglobin	IV Rx group		Oral Rx group	
	No	%	No	%
<7	05	10.0	05	10.0
7-8	17	34.0	30	60.0
8-9	28	56.0	15	30.0
>9	0	0.0	00	0.0
Total	50	100.0	40	100.0

The initial hemoglobin levels were found to be statistically similar between the two groups studied, with a p-value of 0.624. This indicates that there was no significant difference in the baseline hemoglobin levels between the group receiving intravenous (IV) iron treatment and the group receiving oral iron supplementation.

Table 2: The distribution of final hemoglobin levels in the two groups of participants studied is as follows

Final level of hemoglobin	IV Rx group		Oral Rx group	
	No	%	No	%
<7	-	-	-	-
7-8	-	-	-	-
8-9	-	-	-	-
9-10	2	5.0	18	45.0
>10	38	95	22	55.0
Total	40	100.0	40	100.0

The final hemoglobin levels were found to be statistically significantly lower in the Oral Rx group of participants compared to the IV Rx group, with a p-value of 0.001**. This indicates that participants who received intravenous iron treatment had higher final hemoglobin levels compared to those who received oral iron supplementation.

Table 3: The comparison of hemoglobin levels between the two groups of participants studied showed the following results

Hemoglobin	IV Rx group	Oral Rx group	P value
Initial level of hemoglobin	7.55±0.59	7.82±0.55	0.616
Final level of hemoglobin	10.67±0.72	0.55±0.64	<0.001**
Hb deficit	3.11±0.58	3.01±0.54	0.722

Initially hemoglobin levels were found to be statistically significantly lower in the Oral Rx group of participants compared to the IV Rx group, with a p-value of 0.001**.

This indicates that participants who received intravenous iron treatment had higher final hemoglobin levels compared to those who received oral iron supplementation.

Discussion

Iron deficiency anemia in pregnancy is common and varied from 5 % - 45 % in the world, pregnant women and lactating mother need more iron and this increases the risk of developing this condition. Iron deficiency anemia risk have high effects to the lives of mothers and infants which again point to its high menace in India. [11,12] This study was intended to compare iron sucrose with the oral iron treatment in pregnant women with iron deficiency anemia as to its safety and impacts to the hematological profile of the participants. Randomisation of participants involved the assignment of participants to the calculated doses of iron sucrose IV or 300 of

elemental iron dose of oral iron therapy on a day basis.

Socio economic majority of participants in this study fall under II class which is in conformity with tribal pregnant women of rural Haryana with multiple micronutrient deficiencies [13]. The study conducted on 283 participants, pregnant women with an average age of 22.9 years revealed that 31.8% of the participants were illiterates and 81.9% of participants belonging to lower middle and middle class.

Another point, associated with the above mentioned, was that all the participants who underwent intravenous iron sucrose improved their hematological parameters during the final follow up compared to the oral iron. Iron sucrose not only came as a supplement to address deficiencies in hemoglobin but also replenished iron levels because overall there were raised hemoglobin levels. These results are in accordance with those reported by Al Momen et al., the participants in the iron sucrose group seemed to have higher Hemoglobin level (128.5 ± 6.6 g/L Vs 11.4 ± 12.4 g/L of control group ($P < 0.001$, higher duration (6.9 ± 1.8 weeks Vs 14.9 ± 3.1weeks of control On the other hand, the group in this study receiving oral iron, specifically ferrous sulfate, were intolerant, with many reporting side effects such as gastrointestinal problems and low compliance.[14]

The findings of a study by Ragip et al. regarding 90 anemic women whose hemoglobin levels were 8-10.5 g/dL with low ferritin values showed the same-regardless oral iron polymaltose complicated or intravenous iron bulked [15]. The continuous infusion group demonstrated higher increments in hemoglobin levels at each evaluation, especially on days 14 and 28, and ferritin levels were both during pregnancy. Françoise Bayoumeu et al. Prospective open study of 50 participants undergoing surgery, in whom the initial haemoglobin level was between 8 and 10 g/dL and ferritin was less than 50 µg/L.The authors noted the changes in haemoglobin levels that were measured at 30 days: increase from baseline 11.11 ± 1.3 g/dL for IV iron group compared to the one of 9.7 ± 0.5 g/dL increased to 11 ± 1,25 g/dL ($p < 0,001$) for oral iron group But there was no meaningful difference in this group.[16] IV iron sucrose efficiently increases hemoglobin and replenishes iron stores and is better tolerated than oral iron in the treatment of iron deficiency anemia during pregnancy.

Conclusion

Present study aimed to evaluate the safety and effectiveness of oral iron compared to intravenous (IV) iron on hematological parameters in pregnant women with iron deficiency anemia. Our findings confirm that IV iron resulted in a rapid and significant improvement in hematological parameters compared to oral iron supplementation. Given the higher prevalence of iron deficiency anemia during pregnancy in our country, particularly in rural areas, this treatment approach may offer a cost-effective management option for these participants.

Through rigorous research and evaluation, iron sucrose has demonstrated its efficacy and potential, suggesting it could be a viable solution.

References

1. World Health Organization (WHO). The global prevalence of anaemia in 2011. Geneva, Switzerland: WHO; 2015.
2. Stevens GA, Finucane MM, De-Regil LM, et al. Global, regional, and national trends in haemoglobin concentration and prevalence of total and severe anaemia in children and pregnant and non-pregnant women for 1995-2011: a systematic analysis of population-representative data. Lancet Glob Health. 2013;1(1).
3. Kalaivani K. Prevalence & consequences of anaemia in pregnancy. Indian J Med Res. 2009;130(5):627-633.
4. Fernández-Gaxiola AC, De-Regil LM. Intermittent iron supplementation for reducing anaemia and its associated impairments in menstruating women. Cochrane Database Syst Rev. 2011;(12).
5. Allen LH. Anemia and iron deficiency: effects on pregnancy outcome. Am J Clin Nutr. 2000;71(5 Suppl):1280S-1284S.
6. Kalaivani K. Prevalence & consequences of anaemia in pregnancy. Indian J Med Res. 2009;130(5):627-633.
7. Milman N. Iron and pregnancy--a delicate balance. Ann Hematol. 2006;85(9):559-565.
8. Pena-Rosas JP, De-Regil LM, Garcia-Casal MN, et al. Daily oral iron supplementation during pregnancy. Cochrane Database Syst Rev. 2015;(7).
9. Shobeiri F, Begum K. Prevalence of anemia and its epidemiological determinants in pregnant women. J Health Res Rev. 2015;2(3):105-110.
10. Goswami R, Goswami D, Kabra M, et al. Prevalence of anemia among pregnant women and its socio-demographic associates in a rural area of Delhi. Indian J Community Med. 2009;34(3):227-231.
11. WHO. Worldwide prevalence of anaemia 1993-2005: WHO global database on anaemia. Geneva: World Health Organization; 2008.
12. WHO. Daily iron and folic acid supplementation during pregnancy. Geneva: World Health Organization; 2012.
13. Pathak P, Kapil U, Yajnik CS, Kapoor SK, Dwivedi SN, Singh R. Iron, folate, and vitamin B12 stores among pregnant women in a rural area of Haryana state, India. Food NutrBull.

2007;28(4):435-438.
14. Al Momen AK, Al Serouri AW, Al-Momen MM, Dandash K. Intravenous versus oral iron for treatment of iron deficiency anaemia in pregnancy: a randomized controlled trial. J ObstetGynaecol Res. 2009;35(3):514-521.
15. Ragip S, Dal T, Resim S, et al. Comparison of intravenous iron sucrose and oral iron in the treatment of iron deficiency anemia in pregnancy: a randomized controlled study. J Matern Fetal Neonatal Med. 2012;25(6):930-934.
16. Bayoumeu F, Subiran-Buisset C, Baka NE, et al. Iron therapy in iron deficiency anemia in pregnancy: intravenous route versus oral route. Am J Obstet Gynecol. 2002;186(3):518-522.