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ORAL IRON VERSUS PARENTERAL IRON SUCROSE IN A RURAL TERTIARY CARE HOSPITAL OF SOUTHERN INDIA

Obstetrics & Gynaecology

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ABSTRACT

Introduction: Nutritional iron deficiency is one of the most common deficiency disorders affecting more than one billion people, with pregnant women at particular risk. In pregnancy iron deficit attributable due to increased iron demand of the feto-placental unit and an increase in maternal red cell mass. 30% of anaemic women have haemoglobin levels below 10g/dl above 10% below 8g/dl. Irrespective of mode of delivery blood loss can also be a contributing factor postnatal. Oral iron therapy and intravenous iron sucrose are the main therapy of iron deficiency anaemia. The present study is aimed at comparing both their efficacy side effects.

METHOD : A prospective randomised control study was done from June 2019- September 2020, in the department of Obstetrics and gynaecology, Adichunchanagiri Institute of Medical Science, BG nagara. 253 women including antenatal women between 8-38 weeks gestational age were studied and postnatal women studied with no associated obstetrics and medical complication.

They were divided into Group A (Oral) and Group B(Intravenous) by randomization. The two groups were monitored clinically, and for an improvement in laboratory parameters after four weeks on day 30 haemoglobin and haematocrit were repeated in both the groups.

This study results were expressed as mean +/- standard deviation. And to test the significance of difference between Oral and IV mode of treatment, student T test was done to verify the statistical significance.

RESULTS: Out of 253 patients in the study the mean age of ANC patients was 24.7+/- 4.4years. Mean age of PNC patients was 24.15+/- 3.5years. The peripheral smear showed Dimorphic anaemia in 9.1% and Microcytic Hypochromic picture in 90.9 % of the patients. Initial haemoglobin of ANC patients was 9.8+/- 0.3g/dl. The initial haemoglobin of PNC patients was 9.73+/- 0.91g/dl. 59.3% of the patient had a haemoglobin between 7.1 and 10.0g/dl. Final haemoglobin of an ANC patient was 11.68+/-0.98g/dl, PNC patients 11.69+/-0.99g/dl. There was a substantial increase in Group A haemoglobin (oral iron) raising from 10.2+/-7.2g/dl to 12.0+/-0.92g/dl with a T value of 9.25. as well as in Group B (iron sucrose) raising from 9.3+/-8.5g/dl to 11.3+/-0g/dl with T value of 5.65. In both cases this raise in haemoglobin after four weeks had a p value less than 0.01 which was highly statistically significant.

Conclusion: Intravenous iron sucrose is more effective than oral iron for correction of anaemia with lesser side-effects.

KEYWORDS

anaemia, oral iron, intravenous iron sucrose, iron deficiency, pregnancy, postpartum.

INTRODUCTION :

Iron deficiency is one of the most common and most widespread essential element deficiencies. The overall mean global incidence of gestational anaemia is 25%.WHO has estimated its prevalence to be around 14% in developed countries, 51% in developing countries and in India around 65-70%[1]. More than 2/3rd of pregnant women in developing countries have anaemia and 95% of them are iron deficiency anaemia[2]. It's a direct cause of 20% of maternal mortality in India and indirectly leads to 20-40% of maternal deaths[1]. Iron deficiency anaemia is defined by WHO as haemoglobin less than 11g/dl. Postpartum haemoglobin less than 10g/dl are seen in about 30% of women and 10% have more severe anaemia with haemoglobin less than 8g/dl[3]. About 84% women are iron deficient in the first postpartum week[4] . This iron deficit is caused due to increased iron demand by the feto-placental unit and increase in maternal red cell mass. Irrespective of the mode of delivery, blood loss during delivery is also a contributing factor[2]. Iron deficiency anaemia causes a variety of morbidities such as lethargy lactation failure postpartum depression it also interferes with normal intrauterine growth leading to increased foetal loss and perinatal deaths. It is also associated with increased incidence of preterm labour(28%), preeclampsia(31%) and maternal sepsis[3].

Iron requirement during pregnancy is about 4-6 mg/day. At least 40-60mg of dietary iron is required to meet this demand since there is less than 10% iron absorption[3]. The Government of India recommends oral Iron Folic acid supplementation to antenatal and postpartum women. Decreased dietary availability and poor absorption of iron and closely spaced pregnancies continually decrease iron stores in pregnant women. The standard approach for treatment in the majority of Indian institutions is oral iron supplementation, injectable iron preparation, with blood transfusion for more severe or symptomatic cases. oral iron supplementation is one of the most widely practiced public health measures and it thought to be one of the best ways to replace iron stores but pregnant women do not always respond adequately to oral iron therapy due to its limited absorption and gastrointestinal side effects which are associated with ingestion of tablets which leads to reduce rates of complacence[4].

Also oral iron supplementation is unreliable in the treatment of severe anaemia because it requires several weeks about 0.7-1g/week to raise haemoglobins and takes months to replenish iron stores. When there is a need for faster rate of rise in haemoglobin levels parenteral iron therapy is preferred as it overcomes the problems of complacence and ensures that the patients receives the required dose of iron[5]. In recent years, parenteral iron therapy has developed from intramuscular injection which were painful and variable efficacy to intravenous iron sucrose which has better efficacy, complacence, safety, shorter hospital stay, it rapidly corrects anaemia in pregnancy and restore the stores, as the total dose can be given over a short duration of time.

The present study is aimed at comparing efficacy safety tolerability compliance and adverse effects of oral iron versus intravenous iron.

OBJECTIVE

1) To compare the efficacy of oral and parenteral iron in iron deficiency anaemia during antenatal and postpartum period for improving haematological indices i.e Hb and PCV
2) To compare the adverse effect of oral and parenteral iron.

MATERIAL AND METHODS

In the study written and informed consent was obtained from all participants. A prospective randomised control study was done from June 2019- September 2020, in the department of Obstetrics and gynaecology, Adichunchanagiri Institute of Medical Science, BG nagara. 253 women including antenatal women between 8-38 weeks gestational age were studied and postnatal women studied with no associated obstetrics and medical complication. Inclusion criteria haemoglobin less than 11g/dl, age group between 18-35years, singleton pregnancy. Exclusion criteria was women with very severe anaemia haemoglobin less than 4g/dl.

Anaemia due to any other cause other than iron deficiency, history of bleeding tendency, history of blood transfusion within the prior 120 days, haemoglobinopathy or other red cell disorder, asthma and other allergic conditions. Intolerance to iron derivatives and acute inflammatory state.

A detailed history was taken including socioeconomic and dietary history and detailed examination was done. Investigations done on inclusion (day 0) included haemoglobin, hematocrite(PCV), Peripheral smear was done to diagnosis iron deficiency anaemia, blood indices including mean corpuscular volume (MCV), mean corpuscular haemoglobin(MCH), mean corpuscular haemoglobin concentration(MCHC), urine routine and stool for occult blood.

All women recruited in the study were given Tab. Mebendazole 100mg twice daily for 3days for deworming and Folic acid 5mg daily along with a nutritious diet. Patients were allocated to two groups (Group A: Oral group and Group B: Intravenous group) by a simple randomisation method. Group A 125 patients in Group B 128 patients. In group A participants received Ferrous fumarate 2 tablets each containing 100mg of elemental iron daily on an outpatient basis for 4 weeks and 5mg of Folic acid/day was supplemented with this treatment. Treatment compliance was monitored by asking the women to bring back empty packs, and asking about intake of tablets carefully marked on a calendar, colour of stools to ensure that they are consuming the tablets.

In Group B the total dose of iron sucrose to be administered was calculated using the following formula. Total dose required= weight in Kg x (target Hb- actual Hb)x 2.4+500 rounded up to the nearest multiple of 100[1]. This dose of iron sucrose complex was administered as 200mg (elemental iron in 100ml 0.9% sodium chloride over 15-20 mints on alternate days upto total dose required and the patient was monitored for the signs of any evidence of reactions or significant change in vitals. Patients were observed for two hours following administration. This treatment was supplemented with 5mg of folic acid orally daily to prevent eventual folic acid deficiency and to ensure the elimination of its effect on the results. Additional oral iron was excluded during the four weeks of the study.

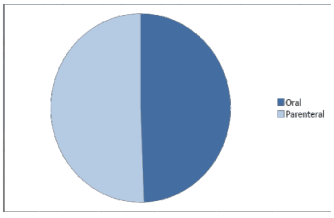
On each visit adverse reactions were likely to be linked with treatment such as headache, nausea ,heartburn ,constipation ,allergic reactions and discontinuation of therapy due to adverse events were noted.

The two groups were monitored clinically, and for an improvement in laboratory parameters. after four weeks on day 30 haemoglobin and haematocrit were repeated in both the groups

This study results were expressed as mean +/- standard deviation. And to test the significance of difference between oral and IV mode of treatment, student T test was done to verify the statistical significance.

RESULTS:

Out of 253 patients in the study 47.8% were between 21-25years of age and majority of them belong to SES class II (65.6%) and majority were multigravida(64.3%). The mean age of ANC patients was 24.7+/-4.4years. Mean age of PNC patients was 24.15+/- 3.5years. The peripheral smear showed Dimorphic anaemia in 9.1% and Microcytic Hypochromic picture in 90.9 % of the patients. Initial haemoglobin of ANC patients was 9.8+/- 0.3g/dl. The initial haemoglobin of PNC patients was 9.73+/- 0.91g/dl. 59.3% of the patient had a haemoglobin between 7.1 and 10.0g/dl. The mean PCV was found to be 30.9+/-2.7%. Final haemoglobin of an ANC patient was 11.68+/-0.98g/dl, PNC patients 11.69+/-0.99g/dl. Mean haemoglobin deficit was found to be 2.2+/-0.9g/dl. Body weight of women in Group A and Group B were comparable and the difference was not statistically significant (p <0.26) there was substantial increase in Group A haemoglobin (oral iron) raising from 10.2+/-7.2g/dl to 12.0+/-0.92g/dl with T value of 9.25. as well as in Group B (iron sucrose) raising from 9.3+/-8.5g/dl to 11.3+/-0g/dl with T value of 5.65. In both cases this raise in haemoglobin after four weeks had a p value less than 0.01 which was highly statistically significant. Mean total dose required is 1370.5+/-976.7mg. Overall 96% of the patient had no reaction and gastritis and sweating was seen in 2.8% and 1.2% respectively.



Pie chart showing distribution of study participant in oral and parenteral group

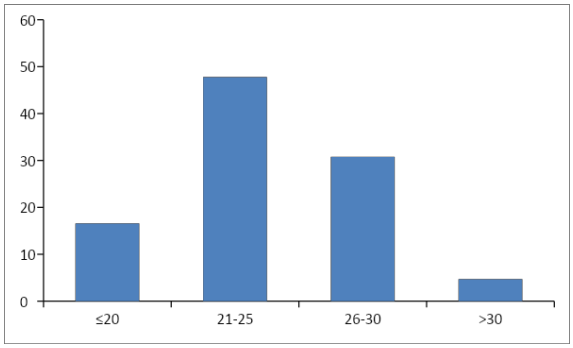


Table 1 Showing the age group of study participant

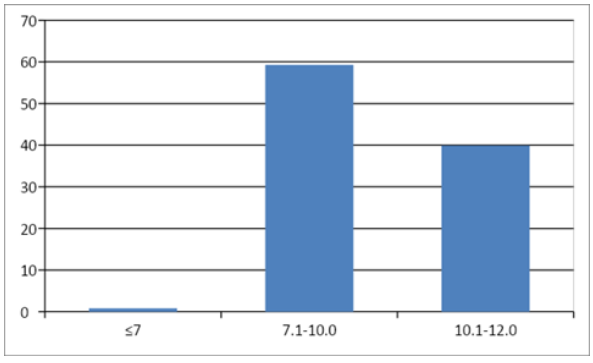


Table 2 Showing the haemoglobin level of study participant

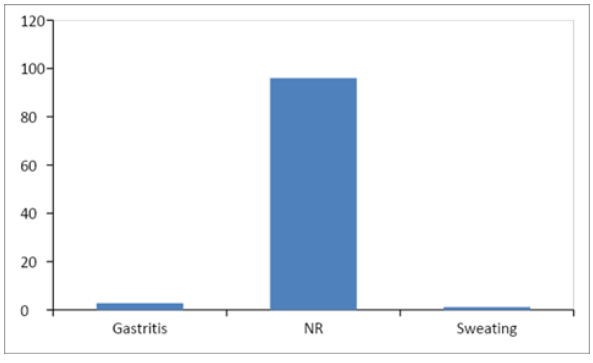


Table 3 Showing the incidence of side effect of iron sucrose infusion

DISCUSSION:

Iron deficiency is one of the leading causes of anaemia affecting over 500 million people around the world. Federation of obstetrics and gynaecological societies of India/ WHO. Study in 1997 on maternal mortality showed 64.4% of women who died haemoglobin less than 8 g/dl. Anaemia increases the risk of requirement of blood transfusion in the peripartum period as they are unable to cope up with blood losses during delivery so severe anaemia is associated with poor outcome which may be fatal.

The mean age of our study group was between 21-25 years of age (47.8%) which is comparable to Shruthi Bhavi et al.[1] 90% of our study iron deficiency anaemia similar to that found by Horowitz KM et al.[7]

Oral iron supplementation is the ideal way to replace iron stores because it uses the body's normal mechanism but are frequently associated with GI discomfort such as nausea bloating diarrhoea and constipation and also because the GI tract has a limited capacity for Iron absorption intravenous iron treatment can be used in patients with poor compliance to Oral iron or non responsive. As in cases of bowel operation or diseases and also in anaemia and high risk settings who require quick replacement of iron stores when blood transfusion is declined. The rise of haemoglobin is at a similar rate although stores are replenished more efficiently in intravenous iron due to the certainty of its administration to correct anaemia

In our study mean haemoglobin increase in the Group A (oral) was

found to be 1.8g/dl and Group B (Intravenous) was found to be 2.05g/dl which is comparable to the study by A. Khalafallah et al. which was 1.6g/dl and 1.9g/dl respectively[6].

Iron sucrose has excellent efficacy and minimum side effects and also leads to rapid rise in haemoglobin and can be administered without a test dose. This absence of side effects was partly due to lower allergenic effect of the sucrose complex due to the very slow release of elementary iron from the complex. In addition, the majority of iron sucrose undergoes metabolism in the liver within 5 minutes of administration. Less than 5% undergoes extra hepatic metabolism .

In our study 5% of our patients showed GE side effects and sweating. Which is comparable to a study by P. K. Kochhar et al.[4]

Although newborn anaemic mothers do not have iron deficiency anaemia their iron stores are related to maternal iron stores. Recent studies show adverse perinatal outcomes in neonates of anaemic mothers in the form of preterm stillbirth and small for gestational age babies, our study showed no statically significant difference in birth weight between babies born to the mother in both groups and neonatal outcome was comparable in both groups. However in our study sample size was insufficient to draw a definitive conclusion regarding obstetrics and neonatal outcomes.

CONCLUSION :

This study demonstrates that intravenous iron sucrose is more effective than oral iron therapy in pregnant and postpartum women with iron deficiency anaemia. It is a safe and effective alternative in the treatment of iron deficiency anaemia compared to oral iron.

REFERENCES :

1. Bhavi SB, Jaju PB. Intravenous iron sucrose v/s oral ferrous fumarate for treatment of anemia in pregnancy. A randomized controlled trial. BMC Pregnancy Childbirth. 2017;17:137.
2. Bhandal, N. & Russell, R. Intravenous versus oral therapy for postpartum anaemia. *BJOG*, 2006,113, 1248–1252.
3. Radhika AG, Sharma AK, Perumal V, et al. Parenteral versus oral iron for treatment of iron deficiency anaemia during pregnancy and post‒ partum: a systematic review. *J Obstet Gynaecol India*. 2019; 69(1): 13‒ 24.
4. 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 39. 3013; 504–510. pmid:22925176
5. Shi Q, Leng W, Wazir R, et al. Intravenous iron sucrose versus oral iron in the treatment of pregnancy with iron deficiency anaemia: a systematic review. *Gynecol Obstet Invest.* 2015;80:170–8.
6. Khalafallah AA, Dennis AE. Iron deficiency anaemia in pregnancy and post-partum: pathophysiology and effect of oral versus intravenous iron therapy. J Pregnancy 2012;2012:630519.
7. Horowitz KM, Ingardia CJ, Borgida AF. 2013, Anemia in pregnancy. *Clin Lab Med.* 2013;33:281–91.