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A comparative study of different kinds of iron therapy in treatment of mild to moderate iron deficiency anemia of pregnancy

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Abstract

Background and Objectives: Anemia is condition of low circulating hemoglobin (Hb) in which the Hb concentration has fallen below the threshold lying at two standards deviation below the median of a healthy population of same age, sex and stage of pregnancy, iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnancy prophylactic oral iron therapy is the most effective way of iron supplementation but in India, oral iron therapy, cannot meet the requirement because poor compliance and low baseline haemoglobin level. Resulting in high incidence of moderate to severe anaemia in pregnancy. This study was undertaken to evaluate the response and effect of intramuscular iron sorbitol given to pregnant women with IDA.

Methods: A prospective study was conducted (Feb 2014 to Feb 2016) in department of Obstetrics and Gynecology, JLN Medical College Ajmer, Rajasthan, a tertiary care hospital in India. A total 150 pregnant women in gestation period of 16-24 weeks, singleton pregnancy with mild to moderate IDA (Hb 8-11gm) attending antenatal clinic were divided into 3 groups by random number table Group A oral iron therapy of 100mg of elemental iron per day Group B (n=50) were given 250mg of intramuscular iron sorbitol, two dose at interval of 4-6 weeks (total dose of 500mg), Group C (n=50) patient taking oral iron irregularly were given a single IM injection of Iron (250mg).

Results: The mean Hb raised from 9.80 ± 0.70 gm% to 11.25 ± 0.9 gm% in Group A patients, From 9.61 ± 0.71 gm% to 10.99 ± 0.85 gm% in group B patients and from 9.34 ± 0.73 to 10.65 ± 0.88 gm% in Group C patients after iron supplementation, the rise in Hb in all three groups was statistically significant ($p<0.001$), final mean Hb in all three group was comparable ($p < 0.05$). There was significant rise in serum ferretin level in all the groups. The absolute rise in serum ferritin was statistically significant in parenteral group B. Other parameters including serum iron level and red cell indices were also improved significantly in all three groups.

Conclusion: Both oral and parental iron therapy was effective in increasing hemoglobin, serum ferritin and other hematological parameters in pregnant women with mild to moderate anaemia. Two high doses of parental iron have a role in developing countries like India, where poor compliance to oral therapy is a great Hindrance to effective eradication of anaemia in pregnant women. In India only 50% of women avail of antenatal care but most mothers are aware of the

availability of receiving a tetanus toxoid injection during pregnancy and will make a visit to hospital/health centre to receive that service. This visit could be used as an opportunity for intramuscular administration of iron.

Keywords: Iron therapy, anemia, hemoglobin, Iron deficiency anaemia (IDA)

Introduction

Iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnant women. According to WHO, the prevalence of IDA is about 18 per cent in developed countries and 35-75 per cent (average 56%) in developing countries[1]. Globally, the prevalence of anaemia is 55.9 per cent with variations between developed and developing countries. In India, prevalence ranges between 33-89 per cent[2]. About half of the global maternal deaths due to anaemia occur in South Asian countries; India contributes to about 80 per cent of this mortality ratio[3]. Many programmes have been introduced and implemented to reduce the burden of anaemia in the country but the decrease is lower than other South Asian countries[4]. Various surveys [National Family Health Survey (NFHS), District Level Household Survey (DLHS), and Indian Council of Medical Research (ICMR) Micronutrient Survey] have been conducted to calculate the prevalence of anaemia in India. During 10th Five Year Plan (2002-2007)[4], a study conducted by ICMR[5] showed that the prevalence of anaemia was highest among pregnant women (50-90%) and that of moderate (<8 g%) and severe anaemia (<5 g%) was persistently high. Prevalence was high in all States of the country with considerable variations in moderate to severe anaemia[6]. Other factors responsible for high incidence of anaemia in our country include early marriage, teenage pregnancy, multiple pregnancies, less birth spacing, phytate rich Indian diet, low iron and folic acid intake and high incidence of worm infections in Indian population[7].

WHO defines anaemia as hemoglobin (Hb) <11 g %[1] 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[4].

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*.).

A prospective study, therefore, was conducted in pregnant women with iron deficiency anaemia (haemoglobin between 8-11 g%) attending a tertiary care hospital in Ajmer to evaluate the response and effect of intramuscular (IM) iron sorbital in terms of improvement in haemoglobin status and other parameters and compares with oral iron therapy.

Material and methods

The prospective study was carried out in department of Gynecology and obstetrics, JLN Medical College, Ajmer Rajasthan, a tertiary care hospital in India. A total of 150 pregnant women, in a gestation period of 16-24 weeks singleton pregnancy with moderate anaemia (Hb 8-11gm%) attending antenatal clinic from Feb 2014 to Feb 2016 were enrolled in the study.

Inclusion criteria:

1. Singleton pregnancy in a gestation period of 16-24 weeks
2. Moderate anaemia (Hb 8-11 gm%)

3. Patient is willing for enrolment to the study

Exclusion criteria:

1. Women with anaemia due to causes other than iron deficiency eg. Folic acid or Vit. B12 deficiency, Haemoglobinopathies chronic bleeding, parasitosis, disease of liver, cardiovascular system, Kidney.
2. Medical disorders like tuberculosis, Diabetes mellitus
3. Women who had any form of parental iron therapy for anemia during pregnancy
4. Pregnant women with a hemoglobin less than 8gm% or more than 11gm%.
5. Patients of antepartum haemorrhage.
6. Any women with a history of allergy or abnormal reaction to iron therapy.

About 8-10 ml of venous blood was taken from the patient slides of the peripheral smears prepared in OPD itself. Then the sample was divided into two parts.

Part I: About 3 ml blood was transferred to vaccutainers containing EDTA solution. This sample was taken to haematology laboratory of pathology department, JLN Medical College, Ajmer along with the slides of the peripheral smears prepared in the OPD itself. The parameters done with the sample were Hemoglobin, Mean corpuscular volume, Mean corpuscular hemoglobin, Mean corpuscular hemoglobin concentration.

Peripheral smears were stained with Feishman's stain to look for the morphology of red blood cell.

Part II: The other part of sample was put into a clean, labeled test tube. This sample was later centrifuged at rate of 2000 rpm for 10 mm. The serum separated out was transferred to the microcentrifuge tubes and the aliquots of there were stored in deep freezer at a temperature of 80°C, for later proceeding. The parameters done with this sample were serum ferritin, serum iron, serum total iron binding capacity.

Haemoglobin: Hb estimation was performed by automated counters using haemoglobinocyanide (cyanmethaemoglobi) method.

The model of auto analyzer used was sysmex-F-820, Kobe, Japan and the model of autodilitor was sysmex AD-270, Sysmex Corporation.

Hematocrit MCV/PCV: It is determined on automated counters using principle of independence counting

$$MCV = \frac{\text{Hematocrit (\%) x 10}}{\text{Red cell count x } 10^6/\mu l}$$

$$MCH = \frac{\text{Hemoglobin (g/dl) x 10}}{\text{Red cell count x } 10^6/\mu l}$$

$$MCHC = \frac{\text{Hemoglobin (g/dl) x 10}}{\text{Haematocrit (\%)}}$$

Serum ferritin: Serum ferritin was determined by enzyme immune assays using pathozyme ferritin Kits united biotech INC, USA

Serum Iron/UIBC/TICBC: These were measured by calorimetric method using kits from RANDOY laboratories Ltd. U.K.

The study was conducted to compare the results of oral v/s parental iron supplementation on pregnant women. It was carried out in the antenatal OPD of JLN Medical College, Ajmer. 50 patients each were enrolled in 3 groups. Group A of 50 patients were started on 100mg elements iron per day. Group B of 50 patients were given 250mg of Iron intramuscularly two doses at an internal of 4 – 6 weeks. Group C of 50 patients on irregular oral iron were taken and effect of supplementary single

high dose, intramuscular iron 250mg was found out.

Pregnant female of cell three groups were followed in the antenatal clinic in routine manner, Evaluation of Hemoglobin (Hb), Hematocrit (PCV), MCHC, MCV, serum ferritin, serum iron, TIBC were done at the beginning a study and at 36 weeks on works to see the effect alter iron supplementation in the three groups.

Results

In this study 150 patients was enrolled in 3 groups (A,B,C) were evaluated. The mean age in Group A was 23.3 ± 2.87 years, group B 23.46 ± 2.92 years and group C was 23.96 ± 3.89 years.

The difference in the mean age was not significant in any two compare groups ($P > 0.05$). The difference in gestation age at first visit was not statistically significant in the first two group ($p = 0.063$). But difference was significant when comparing B & C ($p=0.00$) and A & C ($p=0.00$) due to requirements of patients in C group at a latter gestational age.

The difference in the distribution of parity was not significant statistically in any two compared group ($p = 0.433$)

Mean initial Hb of the group A was 9.80 ± 0.70 gm%, group B was 9.61 ± 0.71 gm%, group C was 9.34 ± 0.73 which was comparable. After treatment mean Hb in group A was 11.25 ± 0.91 gm%, group B 10.94 ± 0.85 gm%, group C was 10.65 ± 0.88 gm%.

The absolute charge and percentage increase in Hb was 1.26 ± 0.70 gm%, 14.30% respectively in group A, was 1.30 ± 0.74 gm%, 14.36% respectively in group B and 1.08 ± 0.57 gm%, 14.23% respectively in group C, which was not statistically significant in any two compared groups ($P>0.05$).

After Fe supplementation, the rise in Hb in all three groups was statistically significant ($p < 0.01$). Final mean Hb in all groups was comparable ($p<0.05$).

All the three groups, the improvement in haematocrit, MCNC, MCN, serum ferritin, serum iron were statistically significant after iron supplement ($P<0.001$). There was statistically significant fall in TIBC in both the groups after supplementation with iron ($P<0.001$).

Side effects: In oral group, there was dyspepsia in 6 patients (12%) constipation in 5(10%), diarrhea 3(6%) and vomiting in 1(2%) patients in parental group, local pain was present in 21(42%), staining in 20(40%), systemic ache 3(6%), arthralgia 3(6%), fever 3(6%) patients. There was no major side effects and anaphylactoid reaction.

Discussion

The total requirement of iron during pregnancy is approximately 1000mg (500mg for developing foetus and placenta and similar amount for red cell increment usually this iron is mobilized from iron stores. However women with poor iron stores become iron deficient during pregnancy.

As compared to western women whose iron store are sufficient and they need 30-40 mg elemental iron per day for anaemia prophylaxia in pregnancy, the stores in Indian women are deficient and may need 100mg elemental iron per day for prophylaxis. For treatment and anaemia, dose recommended is 200mg elemental iron per day. In present study, 8-11 gm%. Hb was taken as cut off. Iron supplementation oral or parental leads to definite improvement in all the blood parameters of iron status (Hb, PCV, MCNC, MCH, MCV, serum ferritin, serum iron, T1BC) during pregnancy. Serum ferritin, which 18 considered the best indicator of iron status in body showed statistically significant absolute rise alter parenteral iron supplementation as compared to oral iron supplementation.

Even a single high dose of parenteol iron (250mg) in a patient on irregular iron can prevent her from severe anemia.

In his study bhatt include a total of 100 patient, 50 each in parenteral and oral group group. Bhatt gave 250mg iron dextran in 2 doses at an interval of 3-4 weeks, giving total dose of 500mg. In his study, bhatt found that only 36% patient, in oral showed good compliance and in them, Hb showed a better rise after supplementation than other who were non-complaint, 32% in oral group had Hb > 9gm% and 8% had more than 11gm%, while in parenteral group, after supplementation 96% had Hb > 9gm% and 32% had Hb > 11gm%.

Study on intramuscular iron in zambia included 133 pregnant women. In the Zambian study mean initial haemoglobin was 12.3 ± 0.074 gm% and mean final haemoglobin was 12.6 ± 0.096 gm% in oral group, while in parenteral groups, mean initial Hb was 11.9 ± 0.103 gm% and mean final Hb was 13.0 ± 0.103 gm%. Thus change in Hb was + 1.026 gm% in parenteral group and ± 0.258 gm% in oral group the former had better rise in Hb that latter. The absolute change in Hb in our study was better in all three groups.

Hook worm is one of the well established causes of anemia in developing countries. Routine antibelmiphic therapy in pregnancy is not recommended. But due to high prevalence in developing countries including India, it is advisable to give antibelmiphic therapy to pregnant women presenting with anaemia.

Conclusion

The administration of 2 intramuscular doses of 250mg of iron sorbitol at 4-6 weeks internal is an alternative strategy with good efficacy and compliance for treating pregnancy Anemia in women who cannot take iron orally or those who are non-compliance and irregular in attending the antenatal clinics. However, further studies with large group of patients are required to establish the effect of different kind of treatment in mild to moderate IDA of pregnancy.

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