Hematological responses to oral administration of iron polymoltose complex in anemic and normal pregnant women: A comparative study

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Abstract

Anemia is a common medical disorder affecting a lot of women in pregnancy in the developing countries. Daily oral iron supplementation during pregnancy reduces the prevalence of anemia. In the present study we have compared the hematological responses to oral iron therapy using the formulation of iron poly maltose complex in anemic and normal pregnant women. The haemoglobin(Hb) level and other blood parameters were studied in anemic and non-anemic pregnant women both before and after oral iron therapy. Hemoglobin, iron indicators improved significantly with oral iron therapy and appear to have good compliance and efficacy. This helps us to assess the varied comparative responses in both the categories. The study will be indicative about the rational use of iron in iron deficiency anemia.

Key words: Anemia, blood, hemoglobin, deficiency.

Introduction

At the beginning of 19th century the word Anemia was a clinical term referring to pallor of the skin & mucous membranes. Anemia is the commonest medical disorder in pregnancy. This is particularly a major health problem in developing countries. Prevalence in non-industrialized countries varies between 35–75 %, with the average being 56 %.[1] The prevalence is very high in Central Asia, reported as being 90 % in India. [2, 3]In India 90% of anemia cases is estimated to be due to iron deficiency, because high iron requirements during pregnancy are not easily fulfilled by dietary intake, especially when iron bioavailability is poor. Because of religious reasons, poverty, or both, the Indian population observes dietary patterns that are largely vegetarian. Diet alone cannot supply the 30–40 mg Fe that is required for absorption of the 4–6 mg Fe/d needed during the latter stages of pregnancy. Ignorance, poverty and gender bias significantly contribute to this high prevalence. [4, 5, 6,7]

WHO defines anemia in pregnancy as hemoglobin (Hb) concentration of < 11 g / dl and hematocrit of < 0.33.[8] A typical iron deficiency anemia shows the following blood values. Hb: less than 10gm%, Red blood cells: less than 4 million/mm^3, PCV: less than 30%, MCHC: less than 30%, MCV: less than 75mm^3, MCH: less than 25pg. Iron supplementation is strongly recommended for all pregnant women in developing countries. Oral iron intake is the treatment of choice,

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and almost all women can be treated effectively with oral preparations.

In the present study we have compared the hematological responses to oral iron therapy using the formulation of iron polymaltose complex. The Hb level and other blood parameters were studied in anemic and non-anemic pregnant women both before and after oral iron therapy. This helps us to assess the varied comparative responses in both the categories. The study will be indicative about the rational use of iron in iron deficiency anemia.

Materials and methods

The study was done in the Physiology Department of Prathima Institute of Medical sciences, Kariminagar (A.P), India and included subjects based on the following criteria. We decided to enroll 23 pregnant women in non-anemic and 21 women in anemic group in the age group of 15-24. Similarly 16 pregnant women in anemic and 14 women in non-anemic group under the age group of 25-34 and 9 pregnant women in anemic and 7 women in non-anemic group under the age group of 35 and above. The loss of follow-up was very high in the non-anemic pregnant women. Characteristics such as age, parity, weeks of gestation and literacy did not differ between the anemic pregnant women and non-anemic pregnant women.

The women in the oral Iron group were given daily oral doses of 100 mg Iron Poly maltose Complex tablets which were provided every month and the women were asked to take 90 such tablets per month. They had to bring back empty packs and were also asked about the intake of their tablets and the colour of their stools to ensure that they had consumed the tablets.

A detailed history was taken from all the women, and a complete physical examination and an obstetric examination were performed at the time of recruitment. At enrollment 3ml venous blood was taken from each of the patients. This blood was transferred to an evacuated tube containing EDTA solution. Peripheral blood smears were performed along with estimation of Hb%, MCV, MCH, MCHC. A peripheral smear was stained with Leishman's stain to look for the morphology of the blood cells. Hb% was determined by using the cyanomethaemoglobin method. Haematocrit and Red cell count were determined by using hemocytometry.

Blood indices were calculated. The values for RBC count, Hb count and PCV can be used to obtain certain RBC indices (also called absolute values of blood index). These indices indicate the size and hemoglobin concentration within the RBCs and thus help in diagnosing the type of anemia.

All the women were followed up routinely until the delivery. All the tests were repeated at term (37-41 weeks) or during labour if patients went into pre term labour. Resource constraints precluded more frequent hematological estimations, which may have been able to detect any difference in the timing of hematologic responses between the 2 groups. However a woman's hematologic status at term is more important for pregnancy outcome, especially from the perspective of risks associated with child birth.

Results

Age group	No of Patients	Ist trimester		IInd trimester		IIIrd trimester		No. of Patients	Ist trimester		IInd trimester		IIIrd trimester	
		MEAN	SD	MEAN	SD	MEAN	SD		MEAN	SD	MEAN	SD	MEAN	SD
15-24	21	3.70	±0.37	3.70	±0.39	3.80	±0.36	23	3.86	±0.34	3.83	±0.33	3.86	±0.33
25-34	16	3.63	±0.38	3.69	±0.32	3.74	±0.34	14	3.78	±0.4	3.9	±0.37	3.90	±0.39
35 & Above	9	3.56	±0.47	3.77	±0.43	3.82	±0.43	7	3.57	±0.36	3.59	±0.32	3.61	±0.26
15-24	21	7.74	±0.52	8.27	±0.62	9.27	±0.65	23	10.82	±0.74	11.00	±0.86	11.49	±0.75
25-34	16	7.74	±0.38	8.63	±0.57	9.42	±0.77	14	11.11	±0.95	11.29	±1	11.43	±0.83
35 & Above	9	8.10	±0.70	9.08	±0.75	10.11	±0.72	7	9.94	±0.51	10.07	±0.53	10.37	±0.56
15-24	21	78.30	±5.47	80.76	±5.98	83.39	±6.02	23	88.08	±4.76	89.66	±4.66	91.12	±3.84
25-34	16	77.79	±2.67	80.35	±3.13	82.47	±3.28	14	82.58	±2.71	83.47	±3.15	84.53	±3.51
35 & Above	9	79.49	±2.98	80.86	±2.56	84.25	±3.42	7	81.21	±4.13	83.03	±4.21	86.44	±4.7
15-24	21	21.15	±2.56	22.56	±2.81	24.61	±2.9	23	28.11	±2	28.79	±2.13	29.89	±1.93
25-34	16	21.57	±2.75	23.60	±2.75	25.37	±3.05	14	29.66	±3.67	29.2	±3.65	29.51	±2.98
35 & Above	9	23.03	±2.96	24.41	±3.68	26.83	±3.6	7	28.16	±3.68	28.32	±3.69	28.92	±2.88
15-24	21	27.12	±3.79	28.02	±3.64	29.61	±3.63	23	32.01	±2.97	32.2	±3.01	32.86	±2.51
25-34	16	27.67	±2.81	29.24	±2.78	30.72	±3.02	14	35.88	±3.94	34.97	±4.12	34.92	±3.25
35 & Above	9	28.97	±3.52	30.16	±4.21	31.00	±3.69	7	34.61	±3.55	34.02	±3.11	34.42	±2.25

Table-1: The subjects selected for the project were 90 pregnant women of which 44 are non-anemic & 46 are anemic pregnant women. These women were sub divided into 3 groups depending upon the age group I (15 – 24), group II (25 – 34), group III (35 & above) .All the groups of women were healthy. Both normal pregnant women and anemic pregnant women were given oral iron therapy.

The hematological examinations conducted in these groups of people were RBC (Red blood cells) million/mm^3, Hemoglobin%, Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC). The results are shown in master table & individual tables. The laboratory tests were done at the beginning before and after oral therapy, during I^{st}, II^{nd} and III^{rd} trimesters of pregnancy. The results of various tests showed significant difference in hematological parameters as assessed statistically. Data were analyzed, quantitative data were expressed as mean ± SDs or as medians. The results of the study are as follows.

Table -II : Red Blood cell counts in different age groups of Pregnant Women (trimester Wise)

Particulars	R.B.C. IN ANEMIC mil/mm^3				R.B.C. IN NON ANEMIC mil/mm^3				P.Value
(Age group)	No.s	I	II	III	No.s	I	II	III	
15-24	21	3.70	3.70	3.80	23	3.86	3.83	3.86	0.16
25-34	16	3.63	3.69	3.74	14	3.78	3.90	3.90	0.48
35 & above	9	3.56	3.77	3.82	7	3.57	3.59	3.61	0.51

P. value _ Insignificant
P. value _ greater than .01

Red blood cells (RBC): The increase RBC count was about 0.1, 0.11 and 0.26 in the age groups of I, II & III respectively in anemic pregnant women. Whereas the increment in normal pregnant women was about nil, 0.12 & 0.07 in the respective groups (Table II).

Table-III: Hemoglobin concentrations in different age groups of pregnant women (trimester wise)

Particulars		Hb% IN ANEMIC (gm/dl)			Hb%. IN NON ANEMIC (gm/dl)				P.Value
(Age group)	No.s	I	II	III	No.s	I	II	III	
15-24	21	7.74	8.27	9.27	23	10.82	11.00	11.49	0.01
25-34	16	7.74	8.63	9.42	14	11.11	11.29	11.43	0.01
35 & above	9	8.10	9.08	10.19	7	9.94	10.07	10.37	0.10

P. value:Insignficant

Hemoglobin % : There is an increase in hemoglobin % by 1.53%, 1.68% & 2.09% in the I, II & III age groups of anemic pregnant women respectively and in the normal pregnant women the increment of 1.67%, 0.32% & 0.43% in I, II & III group respectively. The findings are significant with 'P' value of 0.01, 0.01 & 0.1 respectively in the three groups (Table III).

Table - IV :MCV in different age groups of pregnant women (trimester wise)

Particulars	M.C.V. IN ANEMIC (mm^3)				M.C.V. IN NON-ANEMIC (mm^3)				P.Value	
(Age group)	No.s	I	II	III	No.s	I	II	III		
15-24	21	78.30	80.76	83.39	23	88.08	89.66	91.12	0.89	Insignificant
25-34	16	77.79	80.35	82.47	14	82.58	83.47	84.53	0.1	Significant
35 & above	9	79.49	80.86	84.25	7	81.21	83.03	86.44	0.92	Insignificant

P. value _ Insignificant
P. value _ greater than .01

Mean corpuscular volume (MCV) : The MCV showed an increase after the oral therapy in anemic pregnant by 5.09, 4.68 & 4.76 in groups I, II & III respectively. In the normal pregnant women, the increment was 3.04, 1.95 & 5.2 in the groups of normal pregnant women respectively (Table – IV).

Table - V : MCH in different age groups of pregnant women (trimester wise)

Particulars	M.CH. IN ANEMIC (pgm)				M.C.H. IN NON-ANEMIC (pgm)				P.Value	
(Age group)	No.s	I	II	III	No.s	I	II	III		
15-24	21	21.15	22.56	24.61	23	28.11	28.79	29.89	0.05	Significant
25-34	16	21.57	23.60	25.37	14	29.66	29.20	29.51	0.1	Significant
35 & above	9	23.03	24.41	26.83	7	28.16	28.32	28.92	0.58	Insignificant

Mean corpuscular hemoglobin (MCH): There was an improvement in the MCH by 3.46, 3.90 & 3.80 in anemic pregnant women of age groups I, II & III respectively. In the normal pregnant women the increment in the group I, II & III were 1.78 and a decrease of 0.15 and an Increase of 0.76 respectively. (Table V)

TABLE - VI: MCHC in different age groups of pregnant women (trimester wise)

Particulars	M.C.V. IN ANEMIC (%)				M.C.V. IN NON-ANEMIC (%)				P.Value	
(Age group)	No.s	I	II	III	No.s	I	II	III		
15-24	21	27.12	28.02	29.61	23	32.01	32.20	32.86	0.1	Significant
25-34	16	27.67	29.24	30.72	14	35.88	34.97	34.92	0.62	Significant
35 & above	9	28.97	30.16	31.00	7	34.61	34.02	34.42	0.63	Significant

Mean corpuscular hemoglobin concentration (MCHC): The improvement in the MCHC of anemic pregnant women in group I,II &III were 2.49, 3.05 & 2.03 respectively. Among the normal pregnant women, the Ist group showed an increase of 0.85,whileII and III group showed a decrease of 0.96, 0.19 respectively. (VI)

Discussion

Anemia was defined according to criteria proposed by the Centers for Disease Control (CDC)[9] and refined by the National Academy of Sciences (NAS) panel on nutrition and pregnancy. For all anemias, these criteria include hemoglobin values below the 5th percentile of CDC standards for gestation. During pregnancy, there are variation of hemoglobin at different trimester, the lowest values meeting this definition were 110g/L (first trimester), 105 g/L (second trimester), and 110 g/L (third trimester). Anemia accompanied by a low serum ferritin concentration, that is, < 12ng/L, was considered by the NAS panel to reflect iron-deficiency anemia. [10]

Bentley ME reported 2.2% severely anemic pregnant women in Andhra Pradesh.[11] Porenterol

administration of iron has been used by many investigators, especially in Asia and Africa, with good results.[12] Sood et al observed a greater increase in hemoglobin concentration with intramuscular administration of iron with oral or intravenous administration.[13]

Jai B Sharma et al observed 2 types of iron treatment(oral and parenteral) were equally effective at improving the various iron indicators in the pregnant anemic and non pregnant anemic women.[14]The main problem with oral iron supplementation is poor compliance because of side effects or other reason. Alternate strategies, such as weekly or twice weekly iron supplementation, have been developed to improve compliance .[15]

But in the present study red blood cell values showed a better increase after the oral iron therapy in anemic pregnant women than in non anemic pregnant women who also had oral iron therapy, though not significant. Though there is increase in RBC in anemic pregnant women, it is not significant probably due to increase in the plasma volume and reduced erythropoiesis that results in physiological anemia in pregnancy.

Hemoglobin % also improved to a greater extent in the anemic pregnant women after oral iron therapy as compared with the improvement of hemoglobin % in normal pregnant women after the oral iron therapy. It has been shown to be of significance, may be due to the rate of absorption being increased, which may be probably due to decrease in the stored iron in the body of anemic pregnant women.

There is increase in the Mean corpuscular volume (MCV) in anemic pregnant women after oral iron therapy as compared with that of normal pregnant women during 1st & 2nd trimester. In 3rd trimester as compared with the anemic pregnant women the 1st age group only, showed 'P' value of significance (0.1). This is probably due to physiological anemia, decreased stored iron and reduced erythropiesis.

The improvement in Mean Corpuscular Hemoglobin (MCH) in anemic pregnant women was more as compared with that of normal pregnant women in all the age group but the 'P' value was of significant only in the 1st two age groups. This is probably due to increased absorption of iron due to decrease in iron storage. The third group anemic women are mostly multiparity probably this may be the cause for the result of not being significant.

There was improvement in the Mean Corpuscular Hemoglobin Concentration (MCHC) of anemic pregnant women in all the three age groups. Where as in normal pregnant women there was only slight improvement in the 1st age group, the other two age groups showed a fall in the MCHC. The 2nd age group results were significant. The reason for the fall in the normal pregnant women in the 2nd & 3rd group probably was due to multiparity as the iron demand in multiparous women is 2 folds while iron ininake is less.

Conclusion

It is a comparative study of hematological response to oral iron in anemic pregnant women and normal pregnant women.

The object of the study was to find out the changes in the hematological parameters with oral iron therapy during pregnancy. The various hematological parameters used for this purpose are RBC, Hb, MCV, MCH & MCHC and a comparison of these between pregnant women of both anemic & non anemic with 3 different age groups. The results of various tests

showed that there was a significant increase in RBC, Hb% with oral administration and this is an important finding for developing nations like India where the prevalence of anemia during pregnancy is very high. This condition is further complicated by malnutrition and repeated pregnancies separated by short intervals.

The results of the present study showed that the 2 types of women with iron treatment, increased storage of iron are important for further iron status. The change in the iron status achieved with supplementation of iron is better in all the age groups of anemic pregnant women. In this study we included women with moderate anemia only, but not those with severe anemia because, for severe anemia patients, they should get the full treatment with adequate repeated intramuscular injections or blood transfusion according to the hospitals protocol.

The above study does not include the causes for the anemia. We have not taken steps to correct the cause of anemia. The extent to which maternal hemoglobin level can be increased by recommended parenteral supplementation is limited and has uncertain physiological benefits.

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