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Research Article

DEWORMING IN PREGNANCY – YES OR NO? - A DOUBLE BLIND, RANDOMIZED, CONTROLLED TRIAL

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Hence, every pregnant woman should be offered an anthelminthic, whatever her baseline Hb%, in the second or third trimester of pregnancy.

ABSTRACT

Background & Objectives: This study was conducted to observe the change in Hb % after iron supplementation, with and without a single dose of anthelminthic Albendazole (400 mg), in two groups of pregnant women.
Materials & Methods: This is a double blind, randomized (simple randomization) controlled study, carried out among 134 consenting pregnant women attending the antenatal clinics of a University Medical College in South India. The confidence interval of the study was 95 % with a power of 20 %. The Study group A was prescribed 300 mg Ferrous Fumarate tablet daily for 30 days PLUS Single, stat dose of 400 mg Albendazole. The Control group B was prescribed 300 mg of Ferrous Fumarate tablet per day for 30 days PLUS a single, stat dose of a chewable antacid tablet (placebo).
Results: The mean Hb (Hemoglobin) level prior to treatment for Group A was 9.257 g %(with deworming) and for Group B(without deworming) was 9.924 g % (p> 0.05-NS). Post treatment, the mean Hb level for group A was 10.775 g % and that in Group B was 10.037 g % (p<< 0.001-HS).Hence a significant rise in the Hb level has been observed in group A post treatment.
Conclusion: Pregnant women benefit significantly from deworming in pregnancy with the improvement of anemia and without causing any adverse effects on the growing fetus. Hence, every pregnant woman should be offered an anthelminthic, whatever her baseline Hb%, in the second or third trimester of pregnancy.

INTRODUCTION

Nutritional deficiency anemia is probably the main cause of anemia in pregnancy[1]. However, intestinal parasitic, especially hookworm, infections contribute to anemia to a great extent by causing blood loss and by affecting the absorption of nutrients necessary for erythropoiesis. Hookworm infection is considered to be a leading cause of pathological blood loss in tropical and subtropical areas. In 1996, the WHO recommended that deworming be given to pregnant women after the first trimester of pregnancy in those areas where hookworm infections are endemic[2]. A few studies showing the safety and efficacy of deworming in pregnancy have been done. Universal deworming in pregnancy, however, stays a simple, achievable, yet unattained goal for a hookworm endemic country like ours. This study adds more evidence to the invaluable contribution of one simple, sensible and inexpensive additive to the treatment of anemia in pregnancy.

MATERIALS AND METHODS

This was a double blind randomized controlled study carried out in pregnant women in late second trimester and third trimester of pregnancy, who were anemic and consented to be a part of the study. Simple randomization, by lottery system was done. The following ladies were excluded from the study- Multiple gestations, Uncorrected bleeding hemorrhoids, Hemoglobinopathies, untreated UTI, Antitubercular treatment, Baseline Hemoglobin levels of more than 11.0 g% or less than 7.0 g% or a patient already on Iron supplementation. Group A was the study group. The women were given a tablet of 300 mg Ferrous Fumarate, once a day, for 30 days, along with a single, stat dose of Albendazole 400 mg, at the beginning of the study. Group B, the control group, was given 300 mg of Ferrous Fumarate for 30 days, along with a single, stat dose of an antacid tablet, at the beginning of the study, as a placebo.

All the women had

1. Baseline Hb% estimation.
2. Answered a questionnaire
3. Were counseled regarding diet and nutrition in simple terms and local language.
4. Were asked to come for follow-up after two weeks or four weeks, depending upon the period of gestation.
5. Repeat questionnaire was given.
6. Repeat Hb% estimation was done after four weeks of starting the treatment.
7. Iron supplementation was continued till delivery.

The following outcome measures were observed

The comparison of the rise in Hb% in the two groups
Cure rates of anemia in the mild and moderate anemia groups.

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OBSERVATIONS AND RESULTS

134 pregnant women, between 26 to 34 weeks of gestation were enrolled into the study. They were randomized by simple lottery system. (26 weeks- safely two to four weeks after the complete development of the last organ system-CVS; 34 weeks- anticipating a minimum four weeks interval to delivery)

No difference was observed among the groups with respect to age, gestational age and pretreatment Hb% level, thus making the two groups comparable [**Table 1**]

	Group A (deworming)	Group B (placebo)	t Test	Statistical significance
Age(years)	23.82	24.60	0.33	
Gestational Age(weeks)	28.89	30.29	2.62	NS
Baseline Hb%	9.26	9.92	0.15	

Post treatment Hb levels of both the groups A and B were analyzed.

In Group A, the Hb level was 9.2567g% pretreatment and 10.7746 g% posttreatment. There was a statistically significant rise of 1.518 g % (p= 0.000) [**Table 2**]

Group A (deworming)	MEAN Hb% g/dl	Standard Deviation of Hb%	Standard Error	Test Applied	Result
Pre-Treatment	9.257	0.963	0.118	t = 11.26	HS
Post Treatment	10.775	1.053	0.129	p = 0.000	

In Group B, the rise in Hb level from pre- to post treatment period was 0.113 g%. This was found to be statistically not significant (p= 0.478) [**Table 3**]

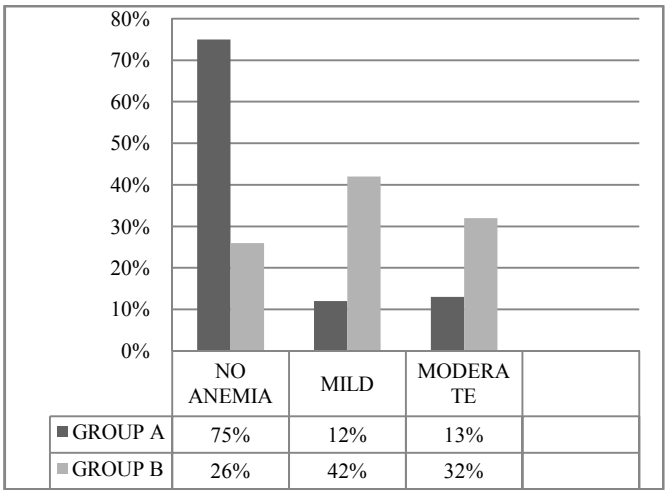
Group B (placebo)	MEAN Hb % g/dl	Standard Deviation of Hb%	Standard Error	Test Applied	Result
Pre-Treatment	9.924	0.924	0.113	t = 0.71	NS
Post Treatment	10.037	1.129	0.138	p = 0.478	

There was an average rise of 1.5 g% in Hb levels above the baseline in the Group A, compared to 0.11 g % in Group B. (p= 0.0001).95.5 % of women in Group A had a rise in Hb% (64/67) compared to 61.2 % (41/67) in Group B (p=0.0001). Moreover, 4.5% women in group A had a fall in Hb% levels in Group A (3/67), compared to Group B, in which there was a fall in Hb % levels in 37.31 % of women (25/67, p = 0.0001) [**Table 4**].

Parameter	Group A (deworming)	Group B (placebo)	t	p	Statistical Significance
Av. Increase in Hb% [g/dl] (n=67)	1.518(16.4%)	0.113(1.1%)	3.30	0.0001	HS
No. with Hb Increase	64(95.5%)	41(61.2%)	5.66	0.0001	HS
No. with Hb Decrease	3(4.5%)	25(37.3)	5.41	0.0001	HS

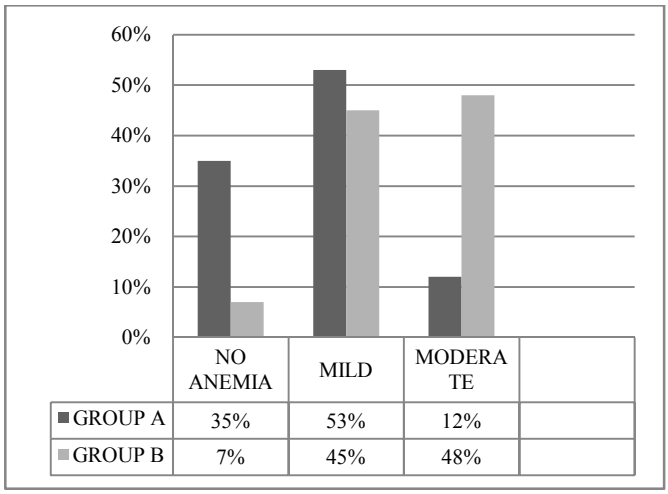
In patients with mild anemia, the cure rate with deworming was 75% while that with no deworming was 26.3%; 12.5 % women with deworming and 42.1% women without deworming continued to have mild anemia. Deterioration, that is, worsening of anemia was observed in 12.5% women with deworming and 31.6 % of women without deworming. Of the two ladies with deworming and worsening of anemia, one was found to have Malaria (Vivax positive), and the other had urinary tract infection. No such medical condition was found in the non-deworming group [Figure 1].

Post Treatment Status of Patients With Mild Anemia



Of the patients with moderate anemia, in the Deworming group A, the cure rate was found to be 35.3 % (51/67), while in the non-deworming group B, it was 6.9 % (29/67); 52.9% and 44.9 % women went over to the mild anemia group in Group A and Group B respectively. No change in the degree of anemia was seen in 11.8 % of women in Group A and 48.2 % women in Group B (even though an increase in Hb percentage was observed [Figure 2]

Post Treatment Status of Patients With Moderate Anemia



Overall, a higher cure rate was found in women given a single, stat dose of Albendazole (Group A), compared to women where this was withheld, that is, Group B,44.8% and 17.9 % respectively [Figure 3]

The rate of improvement to a lesser degree of anemia, that is, moderate to mild anemia was also higher in the deworming group A compared to the non-deworming group B, 43.3 % and 38.8 % respectively [Figure 3]

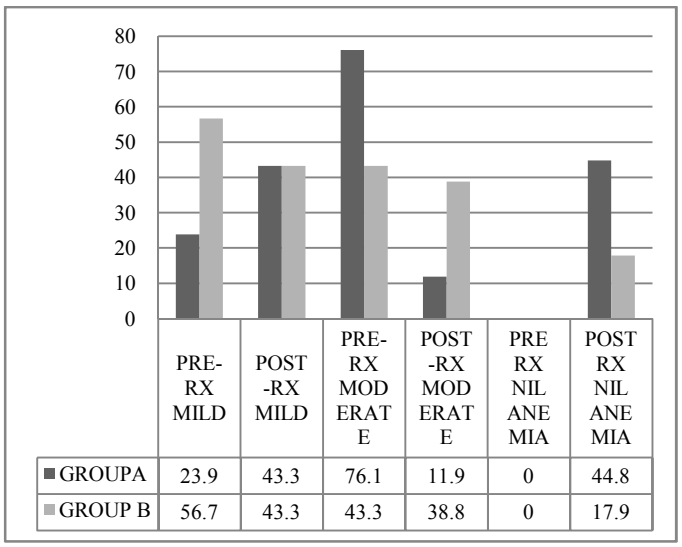


Figure 3 overall anemia status in group a (with deworming) and group b (without deworming) pre- and post treatment

DISCUSSION

Evidence based medicine is divided on the beneficial effects of deworming in pregnancy. Our study results are consistent with those of M Kiwou *et al*[3] who concluded in their study that administration of a combination of Albendazole and Praziquantel for two doses, during the second and third trimesters of pregnancy, decreases the prevalence of anemia significantly. Larocque and Gyorkos[4] concluded from their review that deworming in pregnancy was beneficial to both maternal and infant outcomes. Ndibazza *et al*[5] however concluded that there was no beneficial effect of deworming in pregnancy. It did not affect the maternal anemia, birth weight of the babies, perinatal outcomes or congenital anomalies.

The balance tips in favor of deworming with a single dose of Albendazole or Mebendazole in the second or third trimester of pregnancy. WHO recommends preventive chemotherapy as a public health intervention for pregnant women where both (1) the baseline prevalence of hookworm and/or *T trichiura* infection is 20% or more among pregnant women and (2) where anemia is a severe public health problem with a prevalence of 40% or higher. The incidence of anemia in a developing country like ours ranges from 35 % to 75 %. Many states in India have also included deworming as a part of the ANC package like West Bengal, Orissa and Tamil Nadu.

According to the WHO, in the developing countries, about two billion people are infected with soil transmitted helminths causing anemia and stunted physical growth. These worm infestations are mostly asymptomatic. Treatment for anemia will not be effective in the presence of worm infestation. In our study too, most of the cases, when treated with only iron supplementation, showed only a slight improvement or even deterioration; when deworming was included in the antenatal care package, there were significant rise in the Hb levels.

CONCLUSION

The clear-cut conclusion drawn from this study is that with the same level of pre-existing Hb%, iron supplementation, awareness and nutrition, there is a higher rise in the Hb% level when pregnant women with anemia are given deworming treatment besides iron supplementation. Hence this small but significant prescription of a deworming agent should always be included in the treatment of anemia in pregnancy to get the full benefits of iron supplementation in any form.

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