



PRESUMPTIVE TREATMENT WITH MEBENDAZOLE AND THE PREVALENCE OF PERIPARTUM ANAEMIA AMONG PREGNANT WOMEN AT THE UNIVERSITY OF CALABAR TEACHING HOSPITAL, CALABAR, NIGERIA

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ABSTRACT

WHO recommends antenatal deworming of pregnant women living in areas where the prevalence of helminthes infection exceeds 20-30%. However, mass deworming is not yet included in routine antenatal care protocols in Calabar and in many other countries. The prevalence of helminthes infection in Calabar was reported at 28.3% in previous study. In this study, presumptive treatment of pregnant women in their second trimester with oral Mebendazole (500mg), a broad-spectrum anthelmithic drug, was carried out. The aim of the study was to establish the impact of ante-natal deworming on the prevalence of peripartum anaemia in pregnancy. This was a placebo controlled study where 560 pregnant women in their second trimester were randomized to receiving single dose mebendazole (500mg) and placebo. They were followed-up to term and haemoglobin levels were determined pre-treatment and at term. Anaemia was considered for hemoglobin values of less than 11g/dl or Packed cell volume (PCV) of less than 33% according to WHO. The prevalence of anaemia in the treatment group was 12.6% compared with 29.9% in the placebo ($p < 0.001$). Anaemia was recorded more among women with high parity (OR=5.063, 95% CI=1.531-16.743). Inclusion of anthelminthics in routine antenatal care programme can significantly improve maternal health.

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INTRODUCTION

It is estimated that there are over one billion people infected with Nematodes globally.^{1,2} The burden is considered to be more significant in children and pregnant women because of increased requirement for macro and micro nutrients.^{2,3} Previously most mass deworming programmes were focused on school aged children and pregnant women were exempted because of safety concerns.³ However, in many African societies with low contraceptive usage, where women are pregnant or lactating for over half of their reproductive lives, this may result in treatment delays and morbidity.³ In considering the detrimental effects of helminths on maternal anaemia, fetal growth, risk of neonatal mortality, World Health Organization in 1994 recommended the treatment of hookworm during pregnancy in areas where the infection is endemic.⁴

Furthermore, Anaemia in pregnancy is one of the most common health problems that women face worldwide. Anaemia affects about 20% of the world's population and is a significant cause of morbidity and mortality.⁵ Majority of women have depleted or borderline iron stores due to menstruation and the demands of previous pregnancies, and

only few women enter into pregnancy with sufficient iron stores.^{5,6} Combined with the increased iron demands in pregnancy due to the expansion in red cell mass and the requirement of the developing foetus, many women become iron deficient.^{4,5}

The common causal agents of soil-transmitted helminthiasis include the following: *Ascaris lumbricoides*, *Trichuris trichura* and the hookworms. Infection is caused by ingestion of eggs from contaminated soil (*Ancylostoma duodenale* and *Necator americanus*) or by active penetration of the skin by larvae in the soil (hookworms). These helminths may produce a wide range of symptoms including intestinal manifestations (diarrhoea, abdominal pain), general malaise and weakness, which may affect the quality of life and impair physical growth.² Hookworms may cause chronic intestinal blood loss that result in anaemia and the infection is therefore regarded as, a major contributor to the high prevalence of anaemia in women of child bearing age, particularly in areas of high prevalence⁶⁻⁸

Presumptive treatment with anthelminthics in the early second trimester of pregnancy may also improve food intake and availability of essential nutrients by relieving the symptoms of

anorexia and vomiting caused by the infections, thus, improved food intake, nutrient absorption and reduced blood loss, along with iron and folate supplementation over a longer period of time, would result in a better haematological response. So far most of the evidence for the inclusion of deworming in antenatal care packages in hookworm-endemic areas is mostly observational in nature. Hence this research is directed towards strengthening the evidence base on empirical data from randomized controlled trial.

MATERIALS AND METHODS

Study Area and Study Site

The University of Calabar Teaching Hospital, where this study was conducted is a Federal Government tertiary health facility in Calabar, the capital of Cross River State which is located in South-South Zone of Nigeria. Calabar has an area of 406 KM² and a recent population projection of 431200 according to the GeoNames geographical database.⁹ Calabar is located at 4.95893 (latitude in decimal degrees), 8.32695 (longitude in decimal degrees) at an elevation/altitude of meters (Google Earth). The indigenes are mainly of Efik and Quas extraction. A little above have of the population are non indigenes from Ibibio, Annang, Oron, Ejagham, Igbos and others.

The study population comprised all consenting women attending antenatal care at the university of Calabar teaching hospital who were attending antenatal clinic during the period..

Determination of Sample Size

In a recent study at Enugu⁷, a state capital in South-East Nigeria, the prevalence of helminthiasis among antenatal women was 23.6%. The sample size is thus calculated using Leslie Kish formula:

$$n = \frac{Za^2 Pq}{d^2}$$

where n = minimum sample size

Za = standard deviate, a value at 95% confidence interval (= 1.96 t-test)

P = prevalence of presence of the condition = 23.6% from a previous study

q = probability of absence of the condition

d = precision at 5% substitution: P here = 23% i.e (0.236)

q = i-p = 0.764 d = 5% = 0.05

$$n = \frac{Za^2 Pq}{(0.05)^2} = \frac{1.96^2 \times 0.236 \times 0.764}{(0.05)^2}$$

The sample size of 280 was chosen for the mebendazole group. This was made up to 300 to allow for dropped-out. More than 80% of this number (260) was chosen for the placebo.

Recruitment of Subjects

Women who presented for antenatal care at the university of Calabar teaching hospital during the study period were recruited in their second trimester for the study. The research and its purpose and expected benefits to the patient and the community were explained and consent was obtained from the willing participants..Consenting women were assured of confidentiality. They were informed that no money would be charged for the test performed or for the anthelmintic/placebo drugs.

Data Collection

Qualitative data were collected using pretested interviewer administered questionnaire. Information obtained include socio-demographic characteristics, obstetric and gynaecological history, drug history and previous drug reaction or allergy, past and present medical and surgical history of the subjects.

Study Design

This was a randomized placebo controlled study consisting of two groups of pregnant women, the treatment and the placebo group. The study design was suitable for this particular research because the placebo group constituted the baseline of what can be assumed to be expected outcome in normal circumstances. Presumptive treatment was adopted in this study due to ethical issues. The ideal would have been to obtain stool microscopy for ova of worms then administer treatment to some people infected and offer no treatment to some as controls, but this was ethically binding in leaving infected women untreated..

The women were randomized to receive either a single 500mg dose of Mebendazole plus a daily iron supplement, ferrous sulphate (60mg elemental iron) and folic acid or a single dose placebo plus a daily iron supplement (60mg elemental iron) and folic acid. The administration of the anthelmintics was done by directly observed therapy to ensure 100% compliance. Snacks and drinks were provided in the clinic for eligible women who came to the clinic with empty stomach. All the participants received intermittent preventive treatment for malaria according to schedules. The baseline PCV was noted at recruitment. All the participants in both the treatment and the placebo groups were then followed up to term. Then the packed cell volume was determined preferably on their scheduled clinic days at term.

Data Processing and Analysis

Data were analyzed using SPSS version 19. Description of means, frequency, proportions and rates of given data for each variable was calculated. Bivariate analysis was done to see the association of each independent variable with the outcome variable. Multivariate logistic regression model was used to identify the effect of each independent variable with outcome variable. A p value of less than 0.05 was considered statistical significant

Eligibility Criteria

Consenting women with singleton pregnancy were recruited in the second trimester (14 to 28 weeks gestational ages). Women with history of vaginal bleeding in the index pregnancy, haemoglobinopathy, moderate to severe anaemia, ingestion of anthelmintics in the preceding 6 months, and allergy to anthelmintics were excluded.

Ethical Consideration

Formal approval was obtained from the research ethics committee of the University of Calabar Teaching Hospital before the research was commenced. Written informed consent was obtained from each study participant after introduction to the purpose of the study and informed about their right to interrupt the researcher or withdraw at any time. Women who were detected to be anaemic were given appropriate treatment. Confidentiality was maintained at all levels of the research.

RESULTS

Socio-Demographic Characteristics of Respondents

Table 1 shows the socio-demographic characteristics of respondents. The mean age of respondents in both groups were similar; 29.3±4.4 years for the study group and 29.7±4.6 years for the control group. A little above half of the respondents in both groups were aged 30 years and above. Almost all participants in both study and control groups were residing in the urban area.

The social classes of the respondents in both groups were determined using the classification by Olusanya and Okpere¹⁰ based on the highest educational attainment of the woman and the occupation of her spouse as demonstrated below. Slightly above half of respondents belong to the higher social classes 1 and 2.

Table 1 Socio-demographic characteristics of respondents by group

Variable	Study n=286 Freq(%)	control n=244 Freq(%)	Total N=530 Freq(%)	X2	p-value
Age(years)					
<20	4(1.4)	1(0.9)	5(0.9)	Fisher's Exact	0.062
20-29	136(47.6)	118(48.4)	254(47.9)		
30-39	146(51.0)	120(49.2)	266(50.2)		
≥40	0(0.0)	5(2.0)	5(0.9)		
Mean ±SD	29.3±4.4	29.7±4.6	29.5±4.5		
Residence					
Urban	276(96.5)	234(95.9)	510(96.2)	Fisher's Exact	0.825
Rural	10(3.4)	20(3.8)	10(4.1)		
Parity					
0	96(33.6)	49(20.1)	145(27.4)	14.269	0.001*
1-4	187(65.4)	187(76.6)	374(70.6)		
>4	3(1.0)	8(3.3)	11(2.1)		
Social class					
1	54(18.9)	57(23.4)	11(20.9)	2.753	0.600
2	88(30.8)	73(29.9)	161(30.4)		
3	90(31.5)	64(26.2)	154(29.1)		
4	39(13.6)	37(15.2)	76(14.3)		
5	15(5.2)	13(5.3)	28(3)		

Prevalence of anaemia in the study and control groups

Figure 1 demonstrates the prevalence of anaemia at term in the study and control groups. A higher proportion of participants in the control group (29.9%) compared with the study group (12.6%) had anaemia at term.

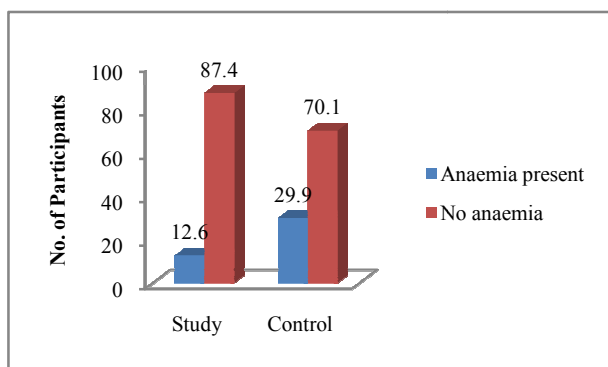


Figure 1 Prevalence of anemia study and control group

PCV Difference of Respondents by Group

Table 2 shows PCV difference of respondents in the study and control groups. Participants with positive difference were more (57.0%) in the mebendazole group compared with (29.9%) in

the placebo group. Those with either no difference or negative difference were more (22% and 61.1% respectively) in the control group compared with the study group (6.3% and 36.7% respectively). These differences were statistically significant ($p < 0.001$). Those with PCV at term above 40% were significantly more (6.3%) in the study group compared with (1.6%) in the control group ($p=0.007$). In the mebendazole group, 64.3% of the anaemic women had mild anaemia (Hb=10 to 10.9g/dl) while the remaining (35%) had moderate anaemia (7 to 9.9g/dl). There was no incidence of severe anaemia in the treatment arm (Hb<7.0g/dl). One case of severe anaemia was noted in the placebo group while 79.2% and 19.4% of the reported anaemia in this group was mild and moderate respectively.

Table 2 PCV difference (PCV at term - PCV at recruitment) of respondents, including those with PCV above 40; Post-intervention

Variable	Study (n=286) Freq (%)	Control (n=244) Freq(%)	Total χ^2 (N=530) Freq (%)	P-value
No difference	18(6.3)	22(9.0)	40(7.5)	236(44.5) 39.212 <0.001
Positive difference	163 (57.0)	73(29.9)		
Negative difference	105(36.7)	149(61.1)	254(47.9)	22(4.21) 7.169 0.0007*
Total PCV>40	286(100.0)	244(100.0)	530(100.0)	
Yes	18(6.3)	4(1.6)		508(95.8)
No	268(93.7)	240(98.4)		
TOTAL	286 (100.0)	244(100.0)	530(100.0)	

*Statistically significant

Genotype of Respondents

Table 3 shows the genotype of respondents by study group. Majority of participants (80.0%) have AA genotype. Although slightly higher in the control (81.1%) compared with the study (79.0%), the difference was not statistically significant ($p=0.813$).

Table 3 Genotype of respondents by study group

Variable	Study (n=286) Freq (%)	Control (n=244) Freq(%)	Total χ^2 (N=530) P-value
Genotype			
AA	226(79.0)	198(81.1)	424(80.0)
AS	59(20.6)	46(18.9)	105(19.8)
*Others	1(0.9)	0(0.0)	1(0.2)

*Others include-- HC

Social class and GA were correlated with anaemia at term in the study group. There was a consistent very weak negative correlation between social class and anemia, and also between GA and anaemia in the study group. The negative correlations were not statistically significant in the two variables.

Bivariate Analysis between Socio-Demographic Characteristics and Anemia In The Study Group

Table 4 shows the bivariate analysis between socio-demographic characteristics and anaemia in study group. Participants who did not have anaemia at term were significantly higher than those who had anaemia. However, those that had anaemia at term were more in the 30 to 39 years age group (17.1%) compared with all the other age groups put together (8.1%). No significant difference was found regarding anaemia across the different social classes. Gestational age showed no significant relationship with anaemia. Those with

parity above 4 who had anaemia (66.7%) were significantly higher compared with (18.6%) those with parity less than 4. This difference was statistically significant ($p < 0.0001$). Respondents who had anaemia at term were slightly higher among those that resides in urban (12.7%) compared with rural respondents (11.1%). This was not statistically significant ($p = 0.722$).

Table 4 Bivariate analysis between socio-demographic characteristics and anemia in study group

Variable	Total		χ^2	p-value
	Has anemia (n=36) (12.6%)	Yes (n=250) (87.4%) No (N=286) (100.0%)		
Age/years				
<20	0(0.0)	4(100.0)		
20-29	11(8.1)	125(91.0)		
30-39	25(17.1)	121(82.9)		
Social class				
1	7(13.0)	47(87.0)		
2	14(15.9)	74(84.1)		
3	10(11.1)	80(88.9)		
4	4(10.3)	35(89.7)		
5	1(6.7)	14(93.3)		
GA				
≤20	10(13.7)	63(86.3)		
21-25	10(13.9)	62(86.1)		
26-32	16(11.3)	125(88.7)		
Parity				
0	3(3.0)	93(96.9)		
1-4	31(16.6)	156(83.4)		
>4	2(66.7)	1(33.3)		
Genotype				
AA	29(12.8)	197(87.2)		
AS	7(11.9)	52(88.1)		
*Others	0(0.0)	1(100.0)		
Residence				
Urban	35(12.7)	241(87.3)		
Rural	1(11.1)	9(88.9)		

*Statistically significant

*Others include---HC

Multivariate Logistic Regression of Factors Associated With Anemia among Study Respondents

Table 5 shows the multivariate logistic regression of factors associated with anemia among study respondents. Only parity (OR= 5.063, 95% CI=1.531-16.743) was found to be an independent predictor of anemia among the study group. Those with parity above 3 were significantly more likely to have anemia at term.

Table 5 Determinants of anemia among respondents in study group

Characteristic	Odds Ratio	95% Confidence interval	P-value
Age			
≤29	1.815	0.816-4.039	0.144
>29	1		
Parity >3	5.063	1.531-16.743	0.008
Yes	1		
No	5.063		
Social class			
1 to 2		0.324-1.485	0.346
3 to 5	1		
Gestational age at term			
<24	0.829	0.396-1.736	0.618
>24	1		
Residence			
Urban	1.091	0.128-9.291	0.937
Rural	1		

DISCUSSION

Out of the 300 women recruited in the treatment group, 286 (95.3%) continued antenatal care to term. Loss to follow-up (drop-out) rate was 4.7%. This was significantly lower than 7% obtained in a similar randomized trial in Uganda.¹¹ Health education regarding continuity and adherence may be yielding positive results.

The prevalence of anaemia at term (after intervention) in the study group was 12.6% and was significantly lower than the prevalence of 29.9% among the control/ placebo arm ($p = 0.0001$). This shows that elimination of intestinal parasites has significantly contributed to the reduction in the incidence of anaemia at term among the treated women. Several studies have found a strong association between anaemia and intestinal parasitic infestations.^{1,7}

In a previous randomized placebo controlled trial in Sierra Leone, after controlling for baseline haemoglobin concentration (obtained during the first trimester), the mean benefit of deworming relative to the placebo group on the change between baseline and third trimester was 6.6g/dl haemoglobin.¹²

However, the prevalence of anaemia (29.9%) among the untreated (placebo) group was lower than 46.2% by Oladeinde *et al*¹³ in South-south Nigeria and 46.0% by Dim *et al*¹⁴ (Eastern Nigeria) among pregnant women in the 3rd trimester of pregnancy. This decreased prevalence in this study can be attributed to advancement in the quality of antenatal care and living condition. Every woman who participated in this study was given standard dose of iron supplementation and intermittent preventive treatment for malaria. Generally during antenatal classes women were also educated on good nutrition and hygiene.

Among the anaemic women in both groups, majority of them had mild anaemia (64.3% and 79.2% in the study and placebo group respectively). Although women with mild anaemia may go through pregnancy and labour without any adverse consequences, they may experience decreased work capacity and subsequently unable to cope with jobs involving manual labour and therefore may not be able to earn their livelihood.⁵ Women with moderate anaemia are at increased risk of premature births, lower birth weight and perinatal mortality is higher. They may not be able to withstand blood loss during delivery and are at risk of dying from antepartum and postpartum haemorrhage, puerpal sepsis and pregnancy induced hypertension.⁷ Untreated severe anaemia in pregnancy may be associated with tachycardia, tachypnea, palpitation, heart failure, pulmonary oedema and death. Anaemia pregnant women are therefore high risk obstetric group and should be treated as such.

In comparing the difference in PCV at term and at recruitment in both arms, women in the treatment group were significantly more likely to have positive difference compared with the placebo group (18 v 4, $p = 0.007$). Similar finding has been reported.¹² The significance of this is that in case of obstetric haemorrhage during delivery, the treated women are more likely to survive and are also not likely to be given blood transfusion with its associated complication. Furthermore, religious group that forbids blood transfusion stand to benefit from this.

About 20% of the participants have AS genotype while the remaining 80% were AA. Homozygous haemoglobinopathy (SS or HS) were excluded for obvious reasons. The study did not show any significant difference in anaemia at term between AA and AS individuals. In a previous study on risk factors for anaemia in pregnancy, AS genotype was associated with low malaria parasitaemia and less maternal anaemia as the AS trait offers some protection against malaria in pregnancy.¹⁵ As stated before, every participant in this study was given intermittent - preventive treatment for malaria in pregnancy (IPT), using sulphadoxine-pyremethamine according to our National guidelines. Also in the hospital Long Lasting Insecticide Nets (LLINs) are usually distributed free to pregnant women.

There was no strong positive correlation between social class and anaemia at term. This is not in keeping with a study by Owolabi *et al*¹⁶ which found that low socio-economic status was significantly associated with increased prevalence and severity of anaemia. As this study was done in a tertiary hospital, women attending antenatal care are better informed through antenatal classes of micronutrient rich foods that are affordable and there is abundance of sea foods in Calabar.

The parity of the respondents had a clear effect on the prevalence of anaemia at term. The women with more than three pregnancies had significantly higher rate of anaemia. Other studies in Africa and Latin America¹⁷ have found similar results while a study in south India¹⁸ reported higher rate of anaemia for the parity index more than four. This might be due to the increase of women's nutritional needs during pregnancy in the setting of low iron store especially due to short inter-pregnancy intervals. This further highlights the role of contraceptives in improving maternal health.

Furthermore, anaemia was recorded more among respondents age 30 and above: 17.1% vs 8.1% (Fischer's < 0.001). This was in keeping with finding in a study in Ethiopia³⁷ which reported the age group of 25-39 years as the highest prevalence while a study in India⁴⁰ considered age group 41 -45 years for the highest prevalence. In the Ethiopian study the relationship of anaemia and age was different for various locations and rural dwellers were more likely to be anaemic. As a good number of them were involved in fanning, helminthic infection was a significant risk factor. However, this hospital based study in a tertiary institution in an urban area with the participants mainly town dwellers, the positive association with maternal age may be attributed to increased parity with advancing maternal age as most of the primigravidas in this study were in their twenties.

CONCLUSION

The results of this research provide evidence of the benefits of antenatal deworming for the mothers in preventing maternal anaemia. Therefore, cumulative evidence to date, including WHO policy statements based on several consultations over a number of years would suggest inclusion of deworming in antenatal care packages. However, more studies may be necessary to evaluate benefits on perinatal outcome.

Limitations

The study relies in part on information obtained with a preceded questionnaire and history obtained from the patients. Some important facts might not have been volunteered. Also, this study relies on results obtained from laboratory

procedures; errors may arise from the human element or the equipment used.

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