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ABSTRACT

Objective: **To evaluate the efficacy of a multiple micronutrient fortified beverage containing eleven nutrients at physiological levels in prevention of anaemia and improving iron and vitamin A status during pregnancy.**
Design: **A randomised double blind placebo controlled study.**
Setting: **Mpwapwa and Kongwa Districts in Dodoma Region of Tanzania.**
Subjects: **Five hundred and seventy nine pregnant women were screened for entry into the study and 439 women who met the study criteria were enrolled.**
Interventions: **Study participants received either a fortified (F) or non-fortified (NF) orange flavoured drinks identical in appearance, provided in two self administered servings per day for an eight week period.**
Main outcome measures: **Comparison of haemoglobin (Hb), serum ferritin (SF) and serum retinol (SR) at baseline and follow up.**
Results: **After eight weeks of supplementation, the F group (n=129) had a significantly higher Hb increase of 0.86g/dL compared to 0.45g/dL in the NF group (n=130) p<0.0001. Gestational age at entry into the study, moderated the effect on Hb of the fortified drink. Women at earlier gestational age upon entry, had a higher rise in Hb than women of late gestational age (0.8g/dL versus 0.04 g/dL rise respectively, p=0.038, n=188). The risk of being anaemic at the end of the study for those in the F group was reduced by 51% (RR=0.49, CI=0.28 to 0.85). Iron stores (by serum ferritin levels) increased by 3µg/L in the F group (p=0.012) and a decrease of 2µg/L in the NF group (p=0.115). The follow up ferritin concentration depended on initial ferritin level. Regardless of treatment group, serum retinol concentrations were significantly higher in mothers who had delivered. Mothers who had adequate levels at entry benefited more from the supplement than those with low levels (0.26 µmol/L versus no significant difference).**
Conclusions: **The multiple micronutrient-fortified beverage given for eight weeks to pregnant women improved their haemoglobin, serum ferritin and retinol status. The risk for anaemia was also significantly reduced. The important predictors of Hb increase at follow up were the fortified beverage, baseline Hb, serum retinol, baseline ferritin and gestational age at entry into study. Anthropological research showed that the beverage was highly acceptable and well liked.**

INTRODUCTION

The World Health Organisation (WHO) estimates that 35% to 75% of pregnant women in developing countries and 18% of women from industrialised countries become anaemic during pregnancy(1). In Tanzania, the prevalence of anaemia lies between 36% to over 75% of pregnant women, and it is shown to vary with altitude, being very prevalent along the coastal belt(2-5).

The common cause of nutritional anaemia is iron deficiency, although there is evidence to suggest that deficiencies of B12, folate, vitamin A and zinc contribute either singly or in combination to maternal anaemia(6-8). Furthermore dependence on cereal and legume based diets, which often lack animal protein as well as fruits and vegetables that enhance absorption of non-haem iron aggravate the condition. Increased iron requirements during pregnancy, and prevalence of parasitic infections such as hookworm and schistosomiasis further predisposes to severe anaemia in the poor countries. Malaria also contributes to anaemia in childbearing women. As a result maternal mortality and adverse pregnancy outcomes such as foetal loss, prematurity and low birth weight are increased(9,10). This calls for correction of pregnancy induced iron deficiency anaemia otherwise women will suffer the described consequences.

In Tanzania prophylaxis against nutritional anaemia have focussed on mainly combating iron deficiency anaemia. Use of iron supplements as recommended by the WHO guidelines(11) has been implemented throughout the country. Iron tablets are distributed free of charge in government clinics that provide antenatal care. Despite this measure the prevalence of anaemia during pregnancy has remained high due to low compliance, logistic problems and inadequate knowledge of primary health worker on how to instruct women on use of haematinics(12-14). Since women with anaemia during pregnancy also suffer multiple nutritional deficiencies, the use of multiple micronutrient supplements is being advocated as an alternative measure(15-17). The objective of this study was to evaluate the efficacy of one such multiple micronutrient-fortified beverage in improving haemoglobin level in two rural districts of central Tanzania.

MATERIALS AND METHODS

The study was conducted between the months of August and December 1999 in study subjects predominantly the Wagogo and Wakaguru of Mpwapwa and Kongwa Districts of Dodoma Region, Tanzania. The area is semi-arid and agricultural production is usually seasonal.

The study subjects were mothers of gestational age between 10 and 34 weeks. A maximum gestational age of 34 weeks was chosen to ensure that mothers had at least eight weeks of supplementation before delivery. Eligibility criteria included Hb greater than or equal to 8.0g/dL and absence of a serious medical disorder during the current pregnancy. Out of 579 pregnant women who were screened for enrolment, only 439 met the study criteria.

The study was approved by the Research and Ethics Committee of the Tanzania Food and Nutrition Centre, as well as by Cornell University Committee on human Subjects. Informed consent was obtained from the study participants.

The study design was a double blind placebo controlled trial with two groups. Sample size was calculated using a haemoglobin difference of 0.8g/dL, with a power of 80% and a confidence level of 95%. After adjusting for a 25% potential drop out rate each of the two groups required 211 participants. At each of the study centres a block randomisation (ten subjects in each block) was used to assign the pregnant women to one of the two study groups i.e., receiving fortified beverage (F group) and receiving non-fortified beverage (NF group).

The micronutrient fortified beverage produced by food technologists at the Procter & Gamble Company, contained eleven nutrients. Most of the doses of micronutrients in the beverages were lower than recommended daily allowances for supplements during pregnancy. The nutrients include: iron, vitamin A, iodine, zinc, vitamin C, riboflavin, folic acid, vitamin B12, vitamin B6, Niacin and vitamin E, shown in Table 1 with reference to the FAO/WHO recommended levels, under results. The content of one sachet was added to 250 ml of clean previously boiled water to produce a single serving. Each subject was asked to drink two sachets daily, one with the morning meal and another with an evening meal. The women collected their supplies fortnightly. All the empty packages were returned and counted before providing a new supply every two weeks.

Table 1

Quantities of nutrients in the fortified beverage consumed daily compared with the FAO/WHO recommended daily allowances during third trimester of pregnancy

Nutrient	Amount (2 servings)	RDA FAO/ WHO[1]
Iron (low bioavailability)[2] (mg)	10.8	92-152
Vitamin A (µg RE)	1050	600
Iodine (µg)	90	200
Zinc (mg)	10.5	2
Vitamin C (mg)	144	50
Riboflavin (mg)	1.2	1.5
Folic Acid (µg)	280	370-470
Vitamin B12 (µg)	6	1.4
Vitamin B6 (µg)	1400	-
Niacin (mg NE)	10	12.6
Vitamin E (µg RE)	21	-

[1]FAO/WHO Recommended dietary allowances (RDA) and intakes for pregnant women.
[2]Low iron bioavailability=diet categorised as having iron absorption of about 5%.

NB: The beverage had less iron content than RDA by the WHO/FAO
RE=Retinol equivalent, TE= (-tocopherol equivalents, NE=Niacin equivalents

Laboratory measurements were taken at baseline and after eight weeks. Whole blood collected by venepuncture was used for haemoglobin determination. Haemoglobin was measured by a portable haemoglobinometer (HemoCue AB, Angelholm, Sweden). Serum ferritin (SF) was assayed via an enzyme-linked immunosorbent assay according to the method described by Flowers *et. al.*, 1989 using commercial kits (Ramco Laboratories, Houston, Texas, USA). Accuracy was assessed using a quality control sera (Ramco Laboratories, Houston, Texas, USA and Lyphochek Immunoassay Plus Controls from Bio-rad Laboratories, Hercules, California). For all assays, samples were assayed in duplicate to measure within-run precision, and aliquots of pooled serum were used to measure inter-assay precision. Liquid Nitrogen was used to transport frozen sera from field to the laboratory for storage until analysis. Fresh urine and stool samples were collected for Schistosomiasis and hookworm ova examination. Stool preparations and urine deposits after centrifugation were examined microscopically.

Weight, height, height of the fundus and gestational age were established by a medical doctor. A questionnaire was administered to collect information on health, nutrition, morbidity and demographic factors.

Data was analysed in SPSS programme (SPSS 1999).