Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVitA): a cluster-randomised, placebo-controlled trial

Kirkwood BR *et al.*, for the Obaapa Trial Team. Lancet 375: 1640-49, 2010.

Introduction

In this issue of Nutrition News for Africa (NNA) we report on the results of a large-scale trial of weekly vitamin A supplementation (VAS) conducted among women of reproductive age in the Brong Ahafo Region in Ghana. This trial was designed to follow up on the results of an earlier study in Nepal, which found that providing either pre-formed vitamin A or beta-carotene supplements to women of reproductive age reduced their pregnancy-related mortality by 44% (West, 1999). Whereas there is now general consensus, based on the results of eight large trials, that VAS reduces mortality among under-five children (Beaton, 1993), less information is available on the effects of VAS among women. Hence, the present study was carried out to provide additional policy-relevant information for this population sub-group. Because vitamin A deficiency is considered a public health problem in much of sub-Saharan Africa (WHO, 2009), these results are of potential interest to the readership of NNA.

Methods

The ObaapaVitA study was a cluster-randomised, masked intervention trial which provided either vitamin A capsules containing 25,000 IU (7.5 mg) vitamin A in soybean oil or placebo capsules containing only oil for weekly consumption by women 15-45 years of age. The capsules were delivered every four weeks, at which time information was collected on all pregnancies, births, and deaths of the women and their children. The main study outcomes were pregnancy-related mortality (maternal deaths occurring during pregnancy or within 42 days of delivery), all-cause female mortality, and peri-natal and infant mortality.

Results and Conclusions

A total of 104,484 women in 544 clusters were assigned to receive VAS, and 103,297 women in 542 clusters received placebo capsules. The characteristics of the women in each study group were similar, as were their rates of refusal and migration. Adherence to supplementation, which was monitored both by history of consumption and intermittent home visits for inspection of remaining capsules, was greater than 70% and did not differ by study group.

81,385 women were examined early in the course of the trial, and ~2% reported problems with their vision. None of the 124 women with reported visual problems who were subsequently examined had clinical signs of xerophthalmia, although four women provided histories that were compatible with night blindness. A sub-study of both pregnant and non-pregnant women was completed during the final year of the trial to assess their serum retinol concentrations. Notably, fewer than 10% of the non-pregnant women examined in the placebo group had serum retinol concentrations <0.70 µmol/L, and there was no measurable impact of the intervention on the mean serum retinol concentration of women in the VAS group.

Nearly 80,000 pregnancies were recorded, and there were no significant effects of the intervention on pregnancy-related deaths, all-cause female deaths, pregnancy-related hospital admissions, stillbirths, or peri-natal, neonatal or infant mortality. The authors concluded that weekly VAS had no beneficial effect on the survival of rural Ghanaian women of reproductive age or of their infants, and they offered several possible reasons for the differences between the studies in Nepal and Ghana. Of these possible reasons for the observed differences, the

most likely explanation seems to be that the Ghanaian women were not sufficiently vitamin A deficient to be able to benefit from the intervention.

Program and Policy Implications

The impact of VAS of women of reproductive age seems to vary according to the vitamin A status of the population. Decisions on whether to invest in delivering VAS to this population sub-group should be based on prior assessment of the women's vitamin A status.

NNA Editors' comments*

This was a very well designed, carefully implemented, and expertly analyzed intervention trial with negative results. These results are not entirely surprising in view of the women's apparent lack of severe vitamin A deficiency, and the findings emphasize the importance of conducting nutritional status assessment before deciding on the need for particular nutrition intervention programs. Additional trials of VAS of women of reproductive age may be worthwhile in other African countries where the prevalence of vitamin A deficiency and maternal mortality ratios approximate those observed previously in Nepal.

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* Note that the Editors' comments and discussion of program and policy implications have been added by the editorial team and are not part of the cited publication.

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