

Abstract

Eur J Clin Nutr. 2010 Mar 10. [Epub ahead of print]

Effect of physiological doses of oral vitamin B(12) on plasma homocysteine: a randomized, placebo-controlled, double-blind trial in India.

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BACKGROUND AND OBJECTIVES: Vitamin B(12) (B(12)) deficiency is common in Indians and a major contributor to hyperhomocysteinemia, which may influence fetal growth, risk of type II diabetes and cardiovascular disease. The purpose of this paper was to study the effect of physiological doses of B(12) and folic acid on plasma total homocysteine (tHcy) concentration.

SUBJECTS AND METHODS: A cluster randomized, placebo-controlled, double-blind, 2 x 3 factorial trial, using the family as the randomization unit. B(12) was given as 2 or 10 mug capsules, with or without 200 mug folic acid, forming six groups (B(0)F(0), B(2)F(0), B(10)F(0), B(0)F(200), B(2)F(200) and B(10)F(200)). Plasma tHcy concentration was measured before and after 4 and 12 months of supplementation.

RESULTS: From 119 families in the Pune Maternal Nutrition Study, 300 individuals were randomized. There was no interaction between B(12) and folic acid ($P=0.14$) in relation to tHcy concentration change and their effects were analyzed separately: B(0) vs. B(2) vs. B(10); and F(0) vs. F(200). At 12 months, tHcy concentration reduced by a mean 5.9 (95% CI: -7.8, -4.1) $\mu\text{mol/l}$ in B(2), and by 7.1 (95% CI: -8.9, -5.4) $\mu\text{mol/l}$ in B(10), compared to nonsignificant rise of 1.2 (95% CI: -0.5, 2.9) $\mu\text{mol/l}$ in B(0). B(2) and B(10) did not differ significantly. In F(200), tHcy concentration decreased by 4.8 (95% CI: -6.3, -3.3) $\mu\text{mol/l}$ compared to 2.8 (95% CI: -4.3, -1.2) $\mu\text{mol/l}$ in F(0).

CONCLUSION: Daily oral supplementation with physiological doses of B(12) is an effective community intervention to reduce tHcy. Folic acid (200 mug per day) showed no additional benefit, neither had any unfavorable effects.

PMID: 20216560

