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Vitamin B_{12}

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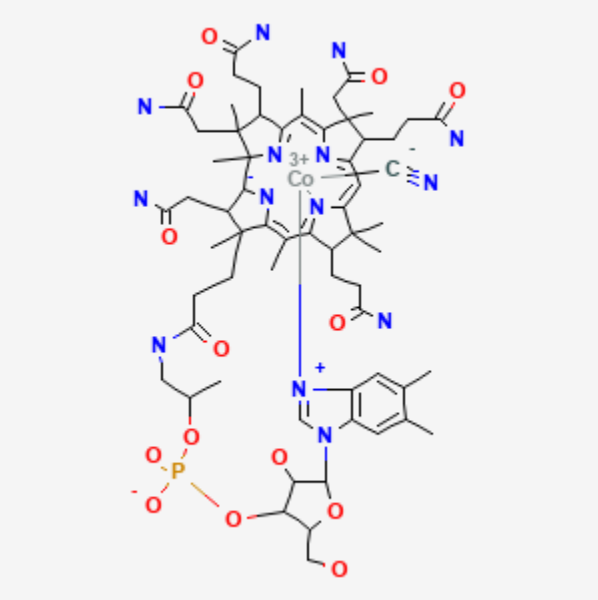

Drug Levels and Effects

Summary of Use during Lactation

Vitamin B_{12} is a normal component of human milk.[1] The recommended daily intake in lactating women is 2.8 mcg and for infants aged 6 months or less is 0.4 mcg.[2] Some authorities recommend 5.5 mcg per day during lactation.[3] Supplementation may be necessary to achieve these recommended daily intakes or to correct a known deficiency. Low doses (1 to 10 mcg) of vitamin B_{12} found in B complex or prenatal vitamins increase milk levels only slightly. Higher daily doses of 50 to 250 mcg are needed in cases of maternal deficiency. The breastfed infant is not exposed to excessive vitamin B_{12} in such cases, and their vitamin B_{12} status should improve if it was previously inadequate.

Poor health outcomes in infants with vitamin B_{12} deficiency include anemia, abnormal skin and hair development, convulsions, weak muscle tone, failure to thrive, mental developmental delay, and possibly abnormal movements.[4-7] One well-recognized at risk group are exclusively breastfed infants of mothers with B_{12} deficiency due to minimal or no dietary intake of animal products[8-19] or pernicious anemia caused by a maternal malabsorption of B_{12}.[17,20] Infant vitamin B_{12} status can be improved through maternal B_{12} supplementation during pregnancy and lactation.[21-24] Deficient mothers who miss the opportunity to supplement during pregnancy should still be encouraged to supplement during early lactation since infant vitamin B_{12} status correlates with milk vitamin B_{12} levels in breastfed infants up to 6 months of age.[25-28] Although there are cases reported of exclusively breastfed infants with vitamin B_{12} deficiency having biochemical and clinical improvement through adequate maternal supplementation alone,[8] direct supplementation of the infant is recommended when such treatments are available.[29-31]

Drug Levels

Methylcobalamin is the major form of vitamin B_{12} in milk. Deoxyadenosylcobalamin, hydroxocobalamin and cyanocobalamin are minor forms.[1] When measured in milk, all forms or "total" vitamin B_{12} levels are reported. Breastmilk vitamin B_{12} levels are correlated with maternal intake and maternal blood levels.[32,33] Infant vitamin B12 levels are correlated with maternal blood and milk levels.[34] Infant vitamin B_{12} blood levels are significantly lower, and the rate of vitamin B_{12} deficiency is significantly higher, in exclusively breastfed infants compared to those who are exclusively formula fed.[35]

A vitamin B_{12} blood level <150 pmol/L (<203 ng/L) is considered a biochemical indicator of deficiency.[36] A blood level >220 pmol/L (>298 ng/L) indicates adequate vitamin B_{12} status, and values between 150 and 220 pmol/L are considered marginally adequate.[21,37] These are traditional epidemiological cutoffs and not necessarily diagnostic. Numerous laboratory tests in addition to vitamin B_{12} blood levels and clinical examination are used to diagnose vitamin B_{12} deficiency.[38,39]

Maternal Levels. Average milk levels in mature milk are 200 to 700 pmol/L (270 to 950 ng/L) during the first 28 weeks postpartum in healthy, lactating women with known or presumed adequate vitamin B_{12} status and not taking a supplement.[25,26,40-43] Levels are highest during the first 4 weeks postpartum and gradually decrease thereafter.[23,26,27,40-45] Hindmilk levels are 20% to 30% higher than foremilk.[27]

In populations with a high prevalence of vitamin B_{12} deficiency or insufficient dietary vitamin B_{12} intake, reported median or average milk levels are 120 to 160 pmol/L (160 to 220 ng/L) at 6 months postpartum.[28,44] In one study of 210 lactating women from different regions of Cameroon, rates of maternal vitamin B_{12} deficiency were 15% to 25% and median milk levels were between 47 and 236 pmol/L (64 and 320 ng/L). Levels were lowest in regions with the highest rates of maternal vitamin B_{12} deficiency. In women with confirmed deficiency, milk levels are typically less than 100 pmol/L (135 ng/L).[8,11,37] A lower milk level threshold of 310 pmol/L (420 ng/L) for adequate infant B_{12} intake has been suggested.[26]

Three mothers in India with vitamin B_{12}deficiency due to very low dietary intake were given a single 50 mcg intramuscular injection of vitamin B_{12}. Their milk levels increased from 40 to 70 pmol/L (54 to 95 ng/L) prior to the dose to around 1,000 pmol/L (1,350 ng/L) later that same day or the next day. Levels then decreased each day thereafter to baseline 3 to 5 days after the dose.[8] Based on the milk levels reported, the three infants in this study received approximately 0.1 mcg/kg daily of extra vitamin B_{12} in breastmilk for 4 to 5 days after the maternal dose.

Three hundred sixty-six pregnant women in India received 50 mcg oral vitamin B_{12} or placebo once daily beginning during their first trimester of pregnancy and continuing until 6 weeks postpartum. Three quarters of all mothers had less than adequate vitamin B_{12} blood levels at baseline and there were no differences between the two groups. Among 141 mothers who provided milk samples, the median breastmilk vitamin B_{12} level at 6

weeks postpartum was 136 pmol/L (184 ng/L) in the supplemented group and 87 pmol/L (118 ng/L) in the placebo group. After treatment discontinuation, milk levels decreased to 97 and 68 pmol/L (131 and 92 ng/L), respectively, at 3 months and 106 and 80 pmol/L (144 and 108 ng/L), respectively, at 6 months postpartum. Only the 6-week levels were significantly different between the two groups.[21] Based on the 49 pmol/L (66 ng/L) difference in median milk levels reported at 6 weeks, exclusively breastfed infants would receive an extra 0.01 mcg/kg daily of vitamin B_{12} from maternal 50 mcg once daily oral supplementation.

Sixty-eight pregnant women in Bangladesh received 250 mcg oral vitamin B_{12} or placebo once daily beginning during their first trimester of pregnancy and continuing until 3 months postpartum. At baseline, 67% of all enrolled women had less than adequate vitamin B_{12} blood levels and there were no differences between the two groups. Median vitamin B_{12} levels were significantly higher in the supplemented mothers compared to placebo. Colostrum levels were 778 and 320 pmol/L (1,054 and 434 ng/L), respectively, and at 3 months postpartum were 235 and 170 pmol/L (318 and 230 ng/L), respectively.[23] Based on the 65 pmol/L (88 ng/L) difference in median milk levels reported at 3 months, exclusively breastfed infants would receive an extra 0.013 mcg/kg daily of vitamin B_{12} from maternal 250 mcg once daily oral supplementation.

One hundred twenty-four pregnant women in Canada received 12 mcg of oral vitamin B_{12} once daily beginning at 13 to 22 weeks gestation and continuing through 8 weeks postpartum when blood and breastmilk were sampled for vitamin B_{12} measurement. None of the mothers had deficient blood vitamin B_{12} levels and only one mother had a marginal level. The average breastmilk vitamin B_{12} level was 452 pmol/L (612 ng/L). These findings were compared to 69 mothers in Cambodia who were not given a vitamin B_{12} supplement during pregnancy or lactation, and who had blood and milk collected one time between 3 and 27 weeks postpartum. Only one had a deficient vitamin B_{12} blood level and one mother had a marginal level. The average milk vitamin B_{12} level was 317 pmol/L (430 ng/L). The lower milk level in the Cambodian study group was possibly related to most of the samples being collected at later postpartum time points. A subanalysis determined that milk sampled on or before 8 weeks postpartum had an average level of 427 pmol/L (579 ng/L) compared to 286 pmol/L (388 ng/L) when sampled after 8 weeks.[26]

Ten women in Texas received an oral multivitamin tablet supplement containing 8 mcg of vitamin B_{12} beginning on the day of delivery. Foremilk was sampled once daily on postpartum days 5 to 7 and again on days 43 to 45. Maternal blood was sampled on day 7 and 45. Seven women who were not given a supplement served as a control group. All of the mothers had adequate vitamin B_{12} status and blood vitamin B_{12} levels were not different between the two groups at baseline. At the first measurement, average milk levels were approximately 1,200 pmol/L (1,650 ng/L) in the supplemented group and 900 pmol/L (1,220 ng/L) in the nonsupplemented group. At the second measurement, average levels were 800 and 450 pmol/L (1,100 and 610 ng/L), respectively.[38] Based on the 6 week postpartum results, an exclusively breastfed infant would receive an extra 0.07 mcg/kg daily of vitamin B_{12} in milk from the maternal supplement. The same research group conducted a similar study in 12 different postpartum women beginning 1 to 3 months after delivery; 6 received the daily supplement and 6 did not. At 6 months postpartum, average milk vitamin B_{12} levels were 640 and 470 pmol/L (866 and 642 ng/L), respectively, and were not significantly different.[46]

Average milk vitamin B_{12} levels in 25 Danish mothers ranged from 300 to 700 pmol/L (405 to 950 ng/L) from 2 weeks to 9 months postpartum. Most (>50%) mothers were taking a daily multivitamin supplement containing a low dose of 1 to 4.5 mcg vitamin B_{12}.[27]

One hundred eighty-three mothers in Malawi were given a daily multinutrient supplement containing 2.6 mcg vitamin B_{12} beginning during the first week postpartum. A control group of 177 mothers was given no supplement. The median milk level at a composite time period of 2 or 6 weeks postpartum was 410 pmol/L (555 ng/L) in the supplemented group and 330 pmol/L (447 ng/L) in the control group. At 24 weeks postpartum the levels were 320 and 240 pmol/L (434 and 325 ng/L), respectively. Mothers who also took antiretroviral drugs for HIV infection had vitamin B_{12} milk levels similar to control.[47] Based on these reported milk levels, an

exclusively breastfed infant would receive an extra 0.016 mcg/kg daily of vitamin B_{12} from the daily maternal supplemental 2.6 mcg.

One hundred seventy-three breastfeeding mothers in Norway provided samples of foremilk and hindmilk, each collected twice by manual expression after a morning and afternoon meal on a single day. The total of four samples from each mother were pooled and analyzed for vitamin B_{12} content. All had adequate vitamin B_{12} intake and were well nourished. The average milk B_{12} level among all the participants was 327 pmol/L (443 ng/L) ranging from 140 to 1089 pmol/L (190 to 1476 ng/L). The average postpartum date of collection was 11 weeks and ranged from 1 to 6 months. The average milk level was highest in mothers at 1 month postpartum, 402 pmol/L (545 ng/L), and lowest at 6 months, 299 pmol/L (405 ng/L). Levels did not significantly differ between those mothers who, according to a dietary questionnaire, took vitamin supplements containing B_{12} compared to those who did not, although the B_{12} supplemental dose was only 3 mcg per day.[43]

Four hundred ninety-one pregnancy women in Dar-es-Salaam, Tanzania were randomized to receive a daily multivitamin supplement containing 50 mcg vitamin B_{12} or placebo from 20 weeks gestation. At six weeks postpartum, when a single breastmilk sample was collected for vitamin B_{12} analysis. The median milk level was 229 pmol/L (309 ng/L) in the multivitamin group and 198 pmol/L (267 ng/L) in the placebo group, which were not significantly different. The proportion of milk samples below 310 pmol/L were 67% and 74%, respectively, which were also not significantly different. Mothers in this study were not undernourished, consumed animal protein, and had adequate vitamin B_{12} intake during pregnancy and postpartum according to responses given to dietary questionnaires. The authors considered the unexpected equivocal results possibly due to undocumented deficient maternal B_{12} liver stores or gastrointestinal malabsorption.[48]

Forty-eight vegan and vegetarian mothers in the U.S. had a single milk vitamin B_{12} level measured after 2 weeks postpartum. The median level in the group was approximately 500 pmol/L (678 ng/L). Eighty percent were taking a vitamin B_{12} supplement. Twenty-six nonvegetarians had a similar median milk value, and 69% used a supplement, but fewer were taking single ingredient B_{12} supplements. Among all participants, the use of individual vitamin B_{12} supplements with a daily dose range between 100 and 5000 mcg was a significant positive predictor of milk vitamin B_{12} concentration. The use of B complex or prenatal vitamins was not predictive.[22] This study raises the possibility that mothers with dietary restrictions limiting vitamin B_{12} intake can achieve milk vitamin B_{12} levels equal to nonlimited mothers if they are sufficiently supplemented.

Infant Levels. Three hundred sixty-six pregnant women in India received 50 mcg of oral vitamin B_{12} or placebo capsules once daily beginning during their first trimester of pregnancy and continuing until 6 weeks postpartum. Three quarters of all mothers had less than adequate vitamin B_{12} blood levels at baseline. Among the 77 infants tested at 6 weeks of age, the median blood vitamin B_{12} level was 199 pmol/L (270 ng/L) in the supplemented group and 139 pmol/L (188 ng/L) in the placebo group.[21]

Sixty-eight pregnant women in Bangladesh received 250 mcg oral vitamin B_{12} capsules or placebo once daily beginning during their first trimester of pregnancy and continuing until 3 months postpartum. At baseline, 66% of all enrolled women had less than adequate vitamin B_{12} blood levels and there were no differences between the two groups. The median cord blood vitamin B_{12} level was 555 pmol/L (752 ng/L) in the supplemented group and 208 pmol/L (282 ng/L) in the placebo group. At 3 months postpartum, the median infant blood levels were 328 and 200 pmol/L (444 and 271 ng/L), respectively. At 3 months of age, 85% of infants in the supplemented group had adequate vitamin B_{12} blood levels compared to 36% in the placebo group.[23]

One hundred twenty-four pregnant women in Canada received 12 mcg oral vitamin B_{12} once daily beginning at 13 to 22 weeks gestation and continuing through 8 weeks postpartum. None of the mothers had deficient blood vitamin B_{12} levels and only one had a marginal level. All self-reported exclusive breastfeeding. The average infant blood vitamin B_{12} level at 8 weeks postpartum was 506 pmol/L (686 ng/L).[26]

Three hundred fifty-three infants born to women in Bangladesh taking a daily multinutrient supplement containing 2.6 mcg vitamin B_{12} from the first trimester of pregnancy through 3 months postpartum had a median blood vitamin B_{12} level at 6 months postpartum of 221 pmol/L (299 ng/L). Six hundred eighty other infants whose mothers took one of two different supplements that did not contain vitamin B_{12} during the same time period had median blood vitamin B_{12} levels of approximately 190 pmol/L (257 ng/L). The percentage of infants with vitamin B_{12} deficiency was 26% in those born to supplemented mothers, which was significantly lower than the 31% to 37% reported in those not given a vitamin B_{12} supplement. An equivalent percentage of infants were exclusively breastfed in each group.[49]

Effects in Breastfed Infants

Twelve exclusively breastfed infants between 4 and 11 months of age had biochemical, hematological and clinical findings consistent with vitamin B_{12} deficiency. Their mothers received a 50 mcg single dose of intramuscular vitamin B_{12}. Within 5 to 8 days after the dose, the infants experienced significantly increased hemoglobin and reticulocyte counts, normoblastic erythropoiesis, improved mental status, regression of abnormal skin pigmentation, and reduction in tremors.[8]

Three hundred sixty-six pregnant women in India received 50 mcg of oral vitamin B_{12} or placebo capsules once daily beginning during their first trimester of pregnancy and continuing until 6 weeks postpartum. Among 218 infants that underwent neurodevelopment testing at 30 months of age, those born to mothers randomized to vitamin B_{12} had higher expressive language scores than the placebo group when adjusted for baseline maternal vitamin B_{12} deficiency. Cognitive, receptive language and motor scores were not different between the two groups.[24] Neurophysiological assessments were then conducted at 6 years of age and there were no differences in the measured brain activity between the two groups.[50]

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

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Substance Identification

Substance Name

Vitamin B_{12}

CAS Registry Number

68-19-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Vitamin B Complex

Vitamins