

PRISM

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Is the Tolerable Upper Intake Level (UL) useful for risk managers?

Editorial

After the discovery of indispensable nutrients that are essential for the proper performance of the human metabolism, the US Food and Nutrition Board (FNB) proposed the first Recommended Daily Allowances (RDA) in 1941. Ten editions have defined the RDAs according to the same definitions up to 1989 aiming at the elimination of deficiencies. However, as early as 1953 the RDA committee was considering the potential health benefits of nutrient intakes above minimum requirements. Data mainly from observational studies pointed at properties of nutrients beyond deficiency. But nutrients, too, follow the rule of Paracelsus who stated in the 16th century: "All things are poison and nothing is without poison, only the dose permits something not to be poisonous". Indeed, numerous studies revealed unexpected results using high doses of nutrients usually above the RDA. Combining the results of several trials in meta-analyses increased the awareness and widespread coverage in the media, but the general public became confused and concerned about the use of vitamins. As a matter of fact, authors concluded in a critical review that the medical community and the general public may have over reacted to recently published meta-analyses showing less favorable effects of vitamin E (How safe is vitamin E supplementation? Bell SJ, Grochoski GT. *Crit Rev Food Sci Nutr.* 2008; 48: 760-74). Limitations of meta-analyses, particularly their application for proving the efficacy or safety of nutrients, led to an over interpretation of study results. Nevertheless, health care professionals and persons in charge of the risk management regarding the security of nutrients have to rely on meaningful lower and upper limits of exposure. Therefore, in 1994 the FNB presented a new concept for the reassessment of the RDAs (Institute of Medicine 2000; *Dietary Reference Intakes: Applications in Dietary Assessment.* National Academy Press Washington D.C.) including upper levels of intake (UL) where data existed regarding risk of adverse effects. The setting of ULs for vitamins and minerals has been undertaken by a number of bodies internationally besides the FNB including the former EU Scientific Committee on Food (SCF), the European Food Safety Authority (EFSA), and the UK Expert Group on Vitamins and Minerals (UK EVM). However, the task of setting maximum amounts of vitamins and minerals in food supplements in the EU falls to risk managers in the European Commission and the Member States.

The basis for setting the UL is the risk assessment elaborated by several scientific panels. The approach consists of deriving the no observed adverse effect level (NOAEL) or, in case of insufficient data, the lowest observed adverse effect level (LOAEL) from available databases on micronutrients corrected by an uncertainty factor (UF): $UL = NOAEL \text{ (or LOAEL)} / UF$

The major drawback of this method is the lack of reliable human data that necessitates the definition of large UFs. As a consequence, an acceptable intake of vitamins and minerals could be very close to levels that cause deficiency. Or, an UL cannot be set that might pretend a false security (Risk assessment of micronutrients. Renwick AG, Walker R. *Toxicol Lett.* 2008; 180: 123-30).

A true way-out of this dilemma could be the use of observed safe levels (OSL) that is defined as "the highest intake with convincing evidence of safety, even if there are no established adverse effects at any level". Or, instead, the highest observed intake (HOI) could be elaborated from observational trials as recently proposed (Expanded approach to tolerable upper intake guidelines for nutrients and bioactive substances. Hathcock JN, Shao A. *J Nutr.* 2008; 138: 1992S-1995S). This method would not only eliminate the apparent quantitative arbitrariness of the UL but it could also be used for other nutrients besides vitamins and minerals that are claimed to provide a health benefit.

U. Moser, Editor

SUPPLEMENTS: HAZARDOUS FOR SMOKERS?**Supplement use increased all-cause mortality risk among smokers****Observation**

The aim of the study was to determine whether supplement use was associated with all-cause mortality in participants of the SENECA study. Baseline measurements were carried out in 1988/89 among 75 to 80-year-old people living in 15 European small towns who were not suffering from ischemic heart diseases, stroke or cancer. All-cause mortality was followed up to April 30, 1999. At baseline, 13% of participants (920 men and 980 women) used nutritional supplements, and 19% were smokers. During the ten years of follow-up 445 men and 252 women died. There was no association between supplement use and mortality among non-smokers. Among smokers the use of any type of supplements (HR: 1.52; 95% CI: 1.02-2.28), vitamin B₁ (HR: 1.57; 95% CI: 1.00-2.48) and vitamin B₂ (HR: 1.60; 95% CI: 1.00-2.56) were associated with higher risk of all-cause mortality if adjusted for sex, age, education, physical activity, body mass index, chronic diseases, Mediterranean Diet Score, alcohol use, and latitude.

Conclusion

Supplementation practice had no beneficial effect on mortality among 70 to 75-year-old European participants of SENECA population. The results indicated that some supplements should be used with special caution, and further studies are necessary, which also would allow for explanation of the mechanisms of harmful effects of supplements among smoking subjects

Editor's comment

The unadjusted Kaplan-Meier survival curves demonstrate clearly the high risk of smoking: 67% of non-smokers survived the observational period versus 47% of smokers. The use of supplements significantly increased the survival rate of non-smokers from 67% to 75% (HR=0.72; 95% CI: 0.52-0.97), but not of smokers (HR: 1.37; 95% CI: 0.97-1.94). Adjustment for 9 parameters reversed the significance of the result, the benefit in non-smokers became non significant and the increase of mortality in smokers significant. Unfortunately, it is not stated which of the 9 parameters contributed the most to this turnaround. A limitation of the study is the uncertainty about the beginning of the use of supplements. Smokers might start using them after realizing first health problems which might be too late.

Source

Supplement use and mortality: the SENECA study. Brzozowska A, Kaluza J, Knoop KT, de Groot LC. Eur J Nutr. 2008 Apr;47(3):131-7.

VITAMIN D DEFICIENCY IN CHILDREN AND ADULTS**Vitamin D supplementation in early childhood inversely associated with risk of type 1 diabetes****Meta-analysis**

A systematic review and meta-analysis using Medline, Embase, Cinahl, Cochrane Central Register of Controlled Trials and reference lists of retrieved articles has been performed to assess whether vitamin D supplementation in infancy reduces the risk of type 1 diabetes in later life. The main outcome measure was development of type 1 diabetes. Five observational studies that had assessed the effect of vitamin D supplementation on risk of developing type 1 diabetes met the inclusion criteria and were included in the analysis. Meta-analysis of data

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from the 4 case-control studies showed that the risk of type 1 diabetes was significantly reduced in infants who were supplemented with vitamin D compared to those who were not supplemented (pooled odds ratio 0.71, 95% CI 0.60 to 0.84). The result of the cohort study was in agreement with that of the meta-analysis. There was also some evidence of a dose-response effect, with those using higher amounts of vitamin D being at lower risk of developing type 1 diabetes. Finally, there was a suggestion that the timing of supplementation might also be important for the subsequent development of type 1 diabetes.

Conclusion

Vitamin D supplementation in early childhood may offer protection against the development of type 1 diabetes. The evidence for this is based on observational studies. Adequately powered, randomized controlled trials with long periods of follow-up are needed to establish causality and the best formulation, dose, duration and period of supplementation.

Source

Vitamin D supplementation in early childhood and risk of type 1 diabetes: a systematic review and meta-analysis. Zipitis CS, Akobeng AK. Arch Dis Child. 2008 Jun;93(6):512-7.

Calcium & vitamin D supplement beneficial for postmenopausal women

Intervention

23 postmenopausal women (mean age 61.2 yrs) with vitamin D deficiency received in an open-label study a combined oral Ca-D3 supplement (500 mg elemental calcium and 500 IU (12.5 µg) of cholecalciferol) The dosing regimen comprised a loading dose of 1000 IU of cholecalciferol per day for one month (two tablets) and thereafter a maintenance dose of 500 IU of cholecalciferol per day for 2 months (one tablet). Serum 25OHD3 levels normalized in all 21 subjects who completed the study with 18 (86%) subjects achieving values of greater than 70 nmol/L. Serum 25OHD3 levels increased from 36 (31-41; 95% range) to 91 (79-102; 95% range) nmol/L ($p = 0.0001$) over the 3-month period. There was a corresponding 38% decrease in serum PTH concentrations at 3 months (5.1 ± 0.6 pmol/L), compared with baseline (8.0 ± 1.0 pmol/L) ($p = 0.001$). No subject developed hypercalcemia, but an elevated urinary Ca/creatinine excretion index occurred in one subject.

Conclusion

A combined oral calcium-vitamin D3 product is effective for treating vitamin D deficiency and is adequately tolerated.

Source

The effect of a combined oral calcium and vitamin D supplement for treating mild to moderate vitamin D deficiency in postmenopausal women. Golombick T, Diamond T. Clin Interv Aging. 2008;3(1):183-6.

Calcium, vitamin D and vitamin K important for osteoporosis prevention

Review

Throughout the life cycle the skeleton requires optimum development and maintenance of its integrity to prevent fracture. Bones break because the loads placed on them exceed the ability of the bone to absorb the energy involved. It is now estimated that one in three women and one in twelve men aged >55 years will suffer from osteoporosis in their lifetime and at a cost in

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the UK of $>£1.7 \times 10^9$ per year. The pathogenesis of osteoporosis is multifactorial. Both the development of peak bone mass and the rate of bone loss are determined by key endogenous and exogenous factors. Ca supplements appear to be effective in reducing bone loss in women late post menopause (>5 years post menopause), particularly in those with low habitual Ca intake ($<400\text{mg/d}$). In women early post menopause (<5 years post menopause) who are not vitamin D deficient, Ca supplementation has little effect on bone mineral density. However, supplementation with vitamin D and Ca has been shown to reduce fracture rates in the institutionalized elderly, but there remains controversy as to whether supplementation is effective in reducing fracture in free-living populations. Re-defining vitamin D requirements in the UK is needed since there is evidence of extensive hypovitaminosis D in the UK. Low vitamin D status is associated with an increased risk of falling and a variety of other health outcomes and is an area that requires urgent attention. The role of other micronutrients on bone remains to be fully defined, although there are promising data in the literature for a clear link between vitamin K nutrition and skeletal integrity, including fracture reduction.

Conclusion

There are genetic, environmental, lifestyle and dietary determinants of risk of osteoporotic fracture, as well as interactions between them. Ca and vitamin D are clearly key nutrients for optimal bone health. Ca supplementation alone does not appear to be effective in reducing fracture. In recent years, evidence has emerged for a role for vitamin K in bone health. Further data are urgently required to enable a fuller understanding of the complex interaction between dietary factors and bone health.

Source

Importance of calcium, vitamin D and vitamin K for osteoporosis prevention and treatment. Lanham-New SA. Proc Nutr Soc. 2008; 67: 163-76

LESS COGNITIVE DECLINE WITH VITAMINS

Less cognitive decline in elderly taking antioxidant vitamins C and E in combination with anti-inflammatory drugs

Observation

Studies have shown less cognitive decline and lower risk of Alzheimer's disease (AD) in elderly individuals consuming either antioxidant vitamins or nonsteroidal anti-inflammatory drugs (NSAIDs). The potential of added benefit from their combined use has not been studied. We therefore analyzed data from 3,376 elderly participants of the Cache County Study, a prospective study of the elderly residents of Cache County, Utah, who were given the Modified Mini-Mental State examination up to three times during a period of 8 years. Those who used a combination of vitamins E and C supplements and NSAIDs at baseline declined by an average 0.96 fewer points every 3 years than nonusers ($P < .05$). This apparent effect was attributable entirely to participants with the APOE epsilon 4 allele, a genetic risk factor for AD, whose users declined by 2.25 fewer points than nonusers every 3 years ($P < .05$). These results suggest that among elderly individuals with an APOE epsilon 4 allele, there is an association between using antioxidant supplements in combination with NSAIDs and less cognitive decline over time.

Conclusion

Using a combination of antioxidant vitamins E and C supplements plus NSAIDs is associated with less cognitive decline among elderly APOE epsilon4-carriers. The reason might be the contribution of oxidative stress and inflammation in neurodegeneration. However, the results of the study are based on a relatively small number of participants.

Source

Better cognitive performance in elderly taking antioxidant vitamins E and C supplements in combination with nonsteroidal anti-inflammatory drugs: the Cache County Study. Fotuhi M, Zandi PP, Hayden KM, Khachaturian AS, Szekely CA, Wengreen H, Munger RG, Norton MC, Tschanz JT, Lyketsos CG, Breitner JC, Welsh-Bohmer K. *Alzheimers Dement.* 2008; 4: 223-7.

N-3 PUFAS IMPROVE HEALTH OF INFANTS AND ADULTS**Higher maternal docosahexaenoic acid intake is associated with positive neurodevelopmental outcomes****Review**

Long-chain n-3 fatty acids are essential for the developing fetus. Docosahexaenoic acid, the most important n-3 fatty acid, is an essential component of neural and retinal membranes, and rapidly accumulates in the brain during gestation and the postnatal period. Positive associations have been shown between maternal intake of fish, seafood and n-3 fatty acids during pregnancy and/or lactation and visual and cognitive development. Observational and interventional studies indicate a significant association with prolonging gestation and reducing the risk of preterm delivery both in low-risk and in high-risk pregnancies. Further benefits have been suggested for intrauterine growth restriction, preeclampsia and postpartum depression, but the evidence is inconclusive. Higher maternal docosahexaenoic acid intake both in pregnancy and lactation is associated with positive infant neurodevelopmental outcomes. Women of reproductive age should achieve an average dietary docosahexaenoic acid intake of at least 200 mg/day.

Conclusion

The studies published to date and reviewed herein strongly suggest that the dietary intake of n-3 fatty acids, and, in particular, of DHA, during pregnancy and lactation has biologically important effects on gestation length and the risk of preterm delivery, and may have an effect on other pregnancy outcomes such as fetal growth, preeclampsia and postpartum depression. Similarly, DHA supply to the fetus and the neonate is associated with beneficial effects on later cognitive development and visual function. The resulting effects might be related to background diversity of dietary supplies. Dietary advice should be given to women of childbearing age in order to achieve a regular intake of adequate amounts of DHA in their diets.

Source

Long-chain omega-3 fatty acid supply in pregnancy and lactation. Cetin I, Koletzko B. *Curr Opin Clin Nutr Metab Care.* 2008; 11: 297-302.

Omega-3 PUFAs improve endothelial function in patients with systemic lupus erythematosus

Intervention

The objective was to determine the clinical effect of dietary supplementation with low-dose n-3-polyunsaturated fatty acids on disease activity and endothelial function in patients with systemic lupus erythematosus. A 24-week randomized double-blind placebo controlled parallel trial of the effect of 3 g of n-3- polyunsaturated fatty acids on 60 patients with systemic lupus erythematosus was performed. Serial measurements of disease activity using the revised Systemic Lupus Activity Measure (SLAM-R) and British Isles Lupus Assessment Group index of disease activity for systemic lupus erythematosus (BILAG), endothelial function using flow-mediated dilation (FMD) of the brachial artery, oxidative stress using platelet 8-isoprostanes and analysis of platelet membrane fatty acids were taken at baseline, 12 and 24 weeks. In the fish oil group there was a significant improvement at 24 weeks in SLAM-R (from 9.4 ± 3.0 to 6.3 ± 2.5 , $p < 0.001$); in BILAG (from 13.6 ± 6.0 to 6.7 ± 3.8 , $p < 0.001$); in FMD (from 3.0% (-0.5 to 8.2) to 8.9% (1.3 to 16.9), $p < 0.001$) and in platelet 8-isoprostanes (from 177 pg/mg protein (23–387) to 90 pg/ mg protein (32–182), $p = 0.007$).

Conclusion

Low-dose dietary supplementation with n-3 fish oils in systemic lupus erythematosus not only has a therapeutic effect on disease activity but also improves endothelial function and reduces oxidative stress and may therefore confer cardiovascular benefits.

Source

A randomised interventional trial of omega-3-polyunsaturated fatty acids on endothelial function and disease activity in systemic lupus erythematosus. Wright SA, O'Prey FM, McHenry MT, Leahey WJ, Devine AB, Duffy EM, Johnston DG, Finch MB, Bell AL, McVeigh GE. *Ann Rheum Dis.* 2008; 67: 841-8.

Intake of fish or omega-3 fatty acids from fish may decrease the risk for colorectal cancer

Observation

The association between intakes of fish and n-3 fatty acids from fish and colorectal cancer risk in men enrolled in the Physicians' Health Study has been examined. Fish intake was assessed at the 12-month follow-up with an abbreviated food-frequency questionnaire. Cox proportional hazards models were used to estimate multivariate relative risks for colorectal cancer for the categories of fish intake and quartiles of n-3 fatty acid intake. During 22 years of follow-up, 500 men had a confirmed diagnosis of colorectal cancer. Fish intake was inversely associated with colorectal cancer risk [multivariate relative risk (95% confidence interval) for highest versus lowest category, 0.60 (0.40-0.91); $P_{\text{trend}} = 0.01$]. The inverse association was observed for both colon and rectal cancers. Our findings for n-3 fatty acids were similar to those for fish; the multivariate relative risk (95% confidence interval) of total colorectal cancer for the highest versus lowest quartile of n-3 fatty acids was 0.74 (0.57-0.95; $P_{\text{trend}} = 0.01$).

Conclusion

The results from this long-term prospective study suggest that intakes of fish and long-chain n-3 fatty acids from fish may decrease the risk for colorectal cancer.

Source

A 22-year prospective study of fish, n-3 fatty acid intake, and colorectal cancer risk in men. Hall MN, Chavarro JE, Lee IM, Willett WC, Ma J. *Cancer Epidemiol Biomarkers Prev.* 2008; 17: 1136-43. Erratum in: *Cancer Epidemiol Biomarkers Prev.* 2008; 17: 2901

LUTEIN AND ZEAXANTHIN MAY BE EFFECTIVE IN THE PREVENTION OF AGE-RELATED EYE DISEASES

Plasma levels of lutein and zeaxanthin are associated with macular pigment optical density

Review

Age-related macular degeneration (AMD) is a disorder of the macula, the area associated with the sharpest visual acuity. AMD is classified as dry (nonneovascular) or wet (neovascular) and is associated with several risk factors, the most important being age. The pathogenesis of AMD is unknown. Like many chronic illnesses, prevention is a key factor for managing AMD. Lutein and zeaxanthin, natural xanthophylls not synthesized by the human body, have been investigated for their use in promoting visual health. Lutein and zeaxanthin are dietary Carotenoids that are components of a normal diet. The mechanism of protection that they confer is unknown, but two mechanisms have been hypothesized. Several studies have been conducted to assess the relationship between plasma levels of lutein and zeaxanthin and the risk of developing AMD and have yielded conflicting results. Increased dietary intake of or supplementation with lutein and zeaxanthin was found to result in increased plasma levels, which were positively and significantly associated with macular pigment optical density. Limited data have suggested that supplementation may also improve visual function. The optimal dose of lutein and zeaxanthin for the prevention or treatment of AMD has not yet been defined.

Conclusion

A definite association between lutein and zeaxanthin supplementation and clinical benefit has yet to be shown; however, it may still be an appropriate cautionary measure for patients at high risk for developing AMD.

Source

Lutein and zeaxanthin for macular degeneration. Zhao L, Sweet BV. *Am J Health Syst Pharm.* 2008; 65: 1232-8.

Lutein and zeaxanthin may contribute to improved vision in patients with AMD

Review

The number of people with age-related diseases like age-related macular degeneration (AMD) will increase due to demographic changes. Currently, AMD is incurable and only a few therapeutic strategies are available. Therefore, prevention becomes more important. Protective effects related to eye health are discussed for the two carotenoids lutein and zeaxanthin. Meanwhile both substances are offered as food supplements to a great extent. The two carotenoids are accumulated in the retina, especially in the macula lutea. They are able to

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absorb blue light, which damages photoreceptors and pigimentary epithelium. Due to their antioxidative properties they can reduce changes in membrane permeability via quenching reactive oxygen species and free radicals. Research studies suppose that lutein and zeaxanthin may contribute to the improvement of vision in patients with AMD and other eye diseases. Based on the scientific rationale, these carotenoids may be effective in the prevention of age-related eye diseases. However, this issue has to be examined in a differentiated way.

Conclusion

Lutein and zeaxanthin are important for the physiology of the eye. Based on current studies it is evident that the carotenoids play a role in the prevention of eye diseases and may even delay the progression of diseases. However, data are still missing for the determination of the required amount.

Source

Lutein and eye health--current state of discussion. Hahn A, Mang B. Med Monatsschr Pharm. 2008; 8: 299-308. German

GLUCOSAMINE ATTENUATES OSTEOARTHRITIS

Glucosamine sulfate may prevent total joint replacement in patients with knee osteoarthritis

Observation

The objective of this study was to assess the incidence of Total Joint Replacement (TJR) during the long-term follow-up of patients with knee osteoarthritis (OA) formerly receiving treatment with glucosamine sulphate or placebo. Knee OA patients participating in two previous randomized, placebo-controlled, double-blind, 3-year trials of glucosamine sulphate and receiving treatment for at least 12 months, were systematically contacted to participate in a long-term follow-up retrospective assessment of the incidence of total knee replacement. Out of 340 patients with at least 12 months of treatment, 275 (i.e., 81%) could be retrieved and interviewed for the present evaluation: 131 formerly on placebo and 144 on glucosamine sulphate. There were no differences in baseline disease characteristics between groups or with the patients lost to follow-up. The mean duration of follow-up was approximately 5 years after trial termination and treatment discontinuation, making up a total of 2178 patient-years of observation (including treatment and follow-up). Total knee replacement had occurred in over twice as many patients from the placebo group, 19/131 (14.5%), than in those formerly receiving glucosamine sulphate, 9/144 (6.3%) ($P = 0.024$, chi-square test), with a Relative Risk of 0.43 (95% confidence interval (CI): 0.20 - 0.92), i.e., a 57% decrease compared with placebo. The Kaplan Meier/Log-Rank test survival analysis confirmed a significantly decreased ($P = 0.026$) cumulative incidence of total knee replacements in patients who had received glucosamine sulphate. A pharmacoeconomic analysis in a subgroup of subjects suggested that patients formerly on glucosamine sulphate had recurred to less symptomatic medications and use of other health resources than those from the placebo group during the last year of follow-up.

Conclusion

Long-term treatment (1-3 years) of knee OA with glucosamine sulphate may prevent TJR in the longer run, according to the results of this overall 8-year observation. This outcome might be explained by the preservation of radiographic joint space during treatment and by the overall well-being that seems to result in a lower consumption in health resources. These findings would deserve confirmation in a prospective and carefully standardized study setting.

Source

Total joint replacement after glucosamine sulphate treatment in knee osteoarthritis: results of a mean 8-year observation of patients from two previous 3-year, randomised, placebo-controlled trials. Bruyere O, Pavelka K, Rovati LC, Gatterová J, Giacobelli G, Olejarová M, Deroisy R, Reginster JY. *Osteoarthritis Cartilage*. 2008; 16: 254-60.

COENZYME Q10 IMPROVES FATIGUE SENSATION**Coenzyme Q10 improves subjective fatigue sensation and physical performance****Intervention**

The effects of coenzyme Q10 administration on physical fatigue has been examined. In a double-blinded, placebo-controlled, three crossover design, 17 healthy volunteers were randomized to oral coenzyme Q10 (100 or 300 mg/d) or placebo administration for 8 d. As a fatigue-inducing physical task, subjects performed workload trials on a bicycle ergometer at fixed workloads twice for 2 h and then rested for 4 h. During the physical tasks, subjects performed non-workload trials with maximum velocity for 10 s at 30 min (30-min trial) after the start of physical tasks and 30 min before the end of the tasks (210-min trial). The change in maximum velocity from the 30- to the 210-min trial in the 300-mg coenzyme Q10-administered group was higher than that in the placebo group. In addition, subjective fatigue sensation measured on a visual analog scale in the 300-mg coenzyme Q10-administered group after the fatigue-inducing physical task and recovery period was alleviated when compared with that in the placebo group.

Conclusion

Oral administration of coenzyme Q10 improved subjective fatigue sensation and physical performance during fatigue-inducing workload trials and might prevent unfavorable conditions as a result of physical fatigue.

Source

Antifatigue effects of coenzyme Q10 during physical fatigue. Mizuno K, Tanaka M, Nozaki S, Mizuma H, Ataka S, Tahara T, Sugino T, Shirai T, Kajimoto Y, Kuratsune H, Kajimoto O, Watanabe Y. *Nutrition*. 2008 Apr;24(4):293-9. Epub 2008 Feb 13. Erratum in: *Nutrition*. 2008 Jun;24(6):616.