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THE TRUTH ABOUT THE VITAL STUDY ON OMEGA-3 and VITAMIN D

There have been two recent publications regarding the findings from the VITAL study that have gotten a lot of media attention because of their conclusions that there was no benefit to supplementation of omega-3 fatty acids or vitamin D. Here are the conclusions of the two papers recently published in the New England Journal of Medicine:

“Supplementation with vitamin D did not result in a lower incidence of invasive cancer or cardiovascular events than placebo.” (Manson, J.E. et al. Vitamin D Supplements and Prevention of Cancer and Cardiovascular Disease. NEJM November 10, 2018 DOI: 10.1056/NEJMoa180994)

“Supplementation with n-3 fatty acids did not result in a lower incidence of major cardiovascular events or cancer than placebo.” (Manson, J.E. et al. Marine n-3 Fatty Acids and Prevention of Cardiovascular Disease and Cancer. November 10, 2018 DOI: 10.1056/NEJMoa1811403).

Do these conclusions accurately portray the data from the studies? Do these conclusions accurately represent a valid determination of the value of supplementation with omega-3 fish oil and/or vitamin D?

Well, let's have a closer look and I will let you decide.

Let's start with some quotes from the studies themselves and then some quotes from the VITAL study website.

From the Vitamin D paper,

“In both an analysis that excluded 1 year of follow-up and an analysis that excluded 2 years of follow-up, neither of which was specified in the protocol, the rate of death from cancer was significantly lower with vitamin D than with placebo.”

Interesting, there was a significantly reduced chance of death from cancer in those taking vitamin D. This seems something worth reporting and it certainly seems like a significant benefit to me.

From the Omega-3 Fatty Acid paper,

“In an analysis that excluded the first 2 years of follow-up, the hazard ratio for major cardiovascular events in the n-3 group, as compared with the placebo group, was 0.89 (95% CI, 0.76 to 1.05), and the lower incidence of myocardial infarction in the n-3 group persisted.”



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In other words, if you took out the first two years when the low amount of omega-3 supplementation had probably not had time to raise blood levels enough, and just analyze the last 3 years of the study, you see that the omega-3 group had a lower risk of major cardiovascular events!

“Subgroup analyses showed a possible lower incidence of the primary cardiovascular end point with n-3 supplementation than with placebo among participants with low fish consumption.”

In other words, people who were getting less omega-3 in their diet benefited more from supplementation – of course! In other words, the more deficient you are the more you are at risk and the less deficient you are the less you are at risk.

From the VITAL study website www.vitalstudy.org under the heading Study Findings in the left-hand margin:

Vitamin D:

“Supplemental vitamin D also did not reduce the occurrence of breast, prostate, or colorectal cancers. However, there was a suggestive 17% reduction in cancer deaths, **which became a 25% reduction in analyses that excluded the first two years of follow-up.** Excluding early follow-up is a common practice in analyzing data from trials of dietary supplements and cancer because effects of nutritional factors on risk of cancer, a slow-developing disease, typically become clear only after several years.”

So, in reality, with only 2000 IUs of vitamin D per day, an amount not enough to reach sufficiency, there was:

A 25% reduction in cancer deaths!

Omega-3 Fatty Acids:

“Upon closer examination, this result was due almost entirely to a reduction in heart attacks without a reduction in strokes. Specifically, the omega-3 fatty acid intervention lowered the risk of heart attack by 28% and the risk of fatal heart attack by 50% but had no benefit on stroke or cardiovascular deaths not related to heart disease. Additionally, omega-3 fatty acids reduced the rate of angioplasty procedures by 22%.”

So, in reality, with less than 1 g of essential fatty acids in ethyl ester not triglyceride form and no DPA there was:



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A 28% reduced risk of heart attack, a 50% reduced risk of fatal heart attack and a 22% reduced rate of angioplasty procedures!!!

“Presently, according to the American Heart Association, 1.3 million coronary angioplasty are performed annually [at an average cost of more than 30,000.00 per procedure for a total cost of \$39 Billion per year].”

Fish oil supplementation can reduce the costs of angioplasties alone by \$8.6 Billion. And fish oil actually works, unlike angioplasties....

“Despite these costs, many studies, including one last month in the New England Journal of Medicine, reveal that angioplasties and stents do not prolong life or even prevent heart attacks in stable patients (i.e. 95% of those who receive them).” (Hyman et al. Lifestyle Medicine: Treating the Causes of Disease. Alternative Therapies in Health and Medicine Nov/Dec 2010).

In other words, there are 1.235 million USELESS angioplasties performed each year at an annual cost of \$37 Billion.

I think it is fair to say that there is indeed, even from the VITAL study, ample evidence to support supplementation with Omega-3 fatty acids and Vitamin D. Let's not stop here, let's critique the study design and look at some important facts with regard to essential nutrients in general, and omega-3 and vitamin D supplementation specifically.

Study Description:

“The VITamin D and OmegA-3 Trial (VITAL) is an ongoing randomized clinical trial in 25,871 U.S. men and women investigating whether taking daily dietary supplements of vitamin D3 (2000 IU) or omega-3 fatty acids (Omacor® fish oil, 1 gram) reduces the risk of developing cancer, heart disease, and stroke [over a 5-year period] in people [average age 72.3 years at end of 5-year study] who do not have a prior history of these illnesses.”

***Average age of subjects was 67.1 years at beginning of study and 72.3 years at follow-up.**

***Omacor is an ethyl ester concentrate and which delivered a daily amount of 460 mg EPA and 380 mg DHA (EPA and DHA only – NO DPA (see studies on importance of DPA).**

***Subjects only received 2000 IU of Vit D per day!! (see studies showing requiring 5000 IUs and that as blood levels increase the effects MUCH greater – dose responsive up to point of sufficiency)**



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***Innate Choice® OmegA+D Sufficiency delivers 2360 mg of Omega-3 (1060 mg EPA; 920 mg of DHA; Additional Omega-3 (including DPA) – 380 mg and 4120 IUs of Vit D per daily serving.**

So, to put this study in perspective. It is a primary prevention study that is choosing to measure the value of omega-3 and vitamin D supplementation based on a select few outcome measures of invasive cancer and major cardiovascular events.

Keep in mind, the average age of subjects at baseline was 67.1 years of age and 72.3 years at approximately 5-year follow-up. Does this not seem like a very short duration of time and a strange cohort or group of people to use to look at primary prevention of cancer and heart disease, two chronic illnesses that take years if not decades to develop?

Perhaps most important to keep in mind is the FACT that sufficient intake of essential nutrients such as omega-3 and vitamin D has already, beyond any reasonable doubt, been PROVEN to be required for the expression of health and that deficient intake has been PROVEN to result in the expression of reduced health. By scientific and biochemical definition, essential nutrients are nutrients that are required in sufficient amounts for proper cell function and health and are nutrients which humans cannot make so must ingest in sufficient amounts.

Does this mean that simply being sufficient in these nutrients can erase all other risk factors for cancer and heart disease or any other chronic illness? Of course not! WRONG QUESTIONS! These diseases, like all chronic diseases, are multi-factorial! Most importantly, whether or not supplementing with fish oil and vitamin D can prevent any individual disease is NOT a valid measure of whether or not supplementation is beneficial for health. Exercise is beneficial whether it prevents blindness or not. Eating more vegetables is beneficial whether it prevents liver disease or not. There are a multitude of benefits other than cancer and heart disease prevention. However, when you look at the actual data from this study you see that there are even significant benefits with respect to these two diseases!

The main point to remember is that the mere classification as essential nutrients means that omega-3 fatty acids and vitamin D are required in sufficient amounts by every human and that deficient intake is detrimental to every human.

The only question remaining is what constitutes sufficient intake. Sadly, the VITAL study does not seem to recognize the latest scientific research regarding human requirements for sufficiency. The amounts of these nutrients delivered in this study do NOT represent sufficient intake!



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SUFFICIENT INTAKE/ BLOOD LEVELS

Sufficient Intake of Vitamin D:

The Vitamin D Council (www.vitamindcouncil.org) recommends 5000 IUs per day for adults to maintain a MINIMUM blood level of 50 ng/ml. In reality this averages out to 1000 IUs per 40 lbs of body weight which is exactly what we recommend.

*“At levels below 40-50 ng/mL the body diverts most or all of the ingested or sun-derived vitamin D to immediate metabolic needs, signifying chronic substrate starvation (deficiency).”
“The above studies indicate that few modern humans living in temperate latitudes – of any age – now achieve levels of 50 ng/mL.” (Cannell et al. (2009) Athletic Performance and Vitamin D. *Medicine and Science in Sports and Exercise*. 41 (5) 1102-1110).*

****In the VITAL study the vitamin D supplementation group only received 2000 IUs per day and only reached an average blood level of 41.8 ng/ml – the supplementation group was in substrate starvation – they were still deficient!***

*“In a subgroup of 1644 participants with repeat measurements after 1 year, mean 25-hydroxyvitamin D levels increased from 29.8 ng per milliliter (74 nmol per liter) at baseline to 41.8 ng per milliliter (104 nmol per liter) at 1 year (a 40% increase) in the vitamin D group.” (Manson. J.E. et al. Vitamin D Supplements and Prevention of Cancer and Cardiovascular Disease. *NEJM* November 10, 2018 DOI: 10.1056/NEJMoa180994).*

Further, research shows that the higher the vitamin D levels the greater the benefit!

*“High serum vitamin D was associated with lower mortality from breast cancer.” “Patients with the highest concentration of Vitamin D had approximately half the fatality rate compared to those with the lowest concentration.” (Mohr SB et al. Meta-analysis of Vitamin D sufficiency for improving survival of patients with breast cancer. *Anticancer Research*. 2014;34:1163-1166).*

*“Women with sufficient vitamin D levels had an 80% reduction in breast cancer incidence compared to those who had deficient vitamin D levels.” (Lowe, LC et al. Plasma 25-hydroxy vitamin D concentrations, vitamin D receptor genotype and breast cancer risk in a UK Caucasian population. *Eur J Cancer*. 2005;41:1164-9).*

A four year study on vitamin D supplementation showed a 77% reduction in all invasive breast cancers in women who received vitamin D supplementation versus those who did not



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supplement. (JM et al. Vitamin D and calcium supplementation reduces cancer risk: results of a randomized trial. *Am J of Clin Nutr* 2007;85:1586-1591).

Also, it is very important that sufficient vitamin A intake accompanies vitamin D intake as the two vitamins (actually hormones) work synergistically and actually up-regulate each other's cell receptors. The VITAL study makes no mention of this.

“Vitamin A and vitamin D balance, enhance, and contain each other through the retinoid X receptor (RXR).” “Because they share a receptor, if we supplement either vitamin D or vitamin A in an unbalanced fashion, we create a functional deficiency of the one not supplemented.” “Low blood levels of vitamin D, vitamin A, and carotenoids are all correlated with greater risk of heart disease.” (Levine, SA. The importance of a balanced approach to vitamin D supplementation. *Journal of Orthomolecular Medicine*. 2011;26(1):15-20).

“Vitamins A and D each increase the genetic expression of cell receptors for the other. Together, vitamins A and D cause a three-fold increase in production of receptors compared to either vitamin alone.” “This would imply that the policy of giving vitamin D supplement alone in pregnancy instead of cod liver oil would need adjustment. Cod liver oil, as natural supplement of vitamin A and vitamin D, is well known for its beneficial effects on the growth of infants and children.” (Ng et al. Vitamin D and vitamin A receptor expression and the proliferative effects of ligand activation of these receptors on the development of pancreatic progenitor cells derived from human fetal pancreas. 2011 *Stem Cell Rev* 7 (1): 53–63).

****Innate Choice® OmegaA+D Sufficiency contains fish oil AND cod liver oil with extra vitamin D added to provide both sufficient and synergistic amounts of omega-3 fatty acids, vitamin D, and vitamin A. I formulated this product specifically for this reason based on the research. It is the only such product in the world.***

Sufficient Intake of Omega-3 Fatty Acids:

First, according to the peer-reviewed literature, it is not just the amount of omega-3 fatty acids that is significant but also the ratio of omega-3 to omega-6 fatty acid ingestion which this study completely ignores. This is why most humans require 2 grams of natural triglyceride fully fatty acid complement fish oil (EPA, DPA, DHA) per day in order to balance out the intake of Omega-3 and Omega-6 fatty acids.

“Western diets are deficient in omega-3 fatty acids, and have excessive amounts of omega-6 fatty acids compared with the diet on which human beings evolved and their genetic patterns were established.” (Simopoulos, AP. The importance of the ratio of omega-6/omega-3 essential fatty acids. *Biomed Pharmacother*. 2002;56:365–379).



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The VITAL study also ignores the importance of the fatty acid DPA which has been removed from the EPA and DHA ethyl ester concentrate delivered in this study but called fish oil. Omacor is NOT fish oil. No such oil is found in any fish or any other animal on the planet. Ethyl esters are the product of chemical labs not nature. Nature supplies omega-3 fatty acids in natural triglyceride, fully fatty acid complement form NOT artificial ethyl esters. Real fish oil contains DPA because fish contain DPA; Innate Choice® Omega+D Sufficiency contains DPA!

“For cause-specific deaths, all 3 PUFAs were associated with lower CVD mortality and their combined levels were associated with 35% lower risk across quintiles.” “Among CVD subtypes, DHA seemed most strongly related to CHD death (40% lower risk), especially arrhythmic CHD death (45% lower risk), **whereas DPA was most strongly related to stroke death (47% lower risk).**” (Muzaffarabad et al. Plasma phospholipid long chain n-3 fatty acids and total and cause-specific mortality in older adults. Ann Intern Med. 2013;158:515-525).

Interesting to note that this study showed a markedly low effect on stroke; something commented on by the authors. Yet, the omega-3 supplement they provided contained NO DPA; something they seem completely unaware of. This is the problem when essential nutrients are studied like drugs instead of food, the expertise of these authors was not in the field of genome-specific nutrition, it was in the field of disease treatment.

I hope this article has provided you some deeper insight and some more detailed information so that you can make a scientific research informed choice rather than a headline informed choice regarding the benefits of supplementation with omega-3 fatty acids and vitamin D.

The cost is minimum and the proven benefits are many. These essential nutrients are not panaceas for disease treatment or prevention; anyone who claims they are is being dishonest. They are however panaceas for solving deficient intake and deficient intake is unhealthy – period. Further, sufficient intake does improve your health because it is required for the expression of health – period!

If you would like more information please visit www.innatechoice.com