

Press Release

Lancet makes type 2 error in dismissing vitamin D

D deficiency is probable cause of many diseases - evidence robust

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The Lancet, the world's best known medical journal, has published two articles¹ which contain serious errors in scientific reasoning. The articles containing these errors argue that the association between vitamin D deficiency and various diseases, including cancer, is not caused by the deficiency but is the result of "reverse causation". That is people with these diseases spend less time in the sun and so their vitamin D level is low.

The Lancet's reasoning is in error because a negative result in a clinical trial of vitamin D supplementation only shows that the vitamin cannot heal a particular group of people. It does not allow for the possibility that vitamin D deficiency may have caused irreversible damage many years earlier, argues scientist and writer, Oliver Gillie, in an article² published in the journal, Public Health Nutrition.

The Lancet authors point to clinical trials of vitamin D in a number of diseases, all with negative findings. They argue that negative clinical trials show that vitamin D cannot be the cause of any of these diseases. The Lancet and its authors insist that their trials are "gold standard" evidence and The Lancet backs up their authors with an editorial called "Vitamin D: chasing a myth?"

"They have made a mistake in scientific reasoning known to statisticians as type 2 error. I call it the gold standard fallacy", said Dr Gillie. The Lancet errors are explained in a peer reviewed article for the scientific journal Public Health Nutrition and from November 5 the article will be available online at: <http://journals.cambridge.org/phn/vitaminD>. The Lancet and its authors overlook the fact that adult disease may be caused by deficiency of vitamin D occurring in childhood or teenage years and that such disease may not be remedied by giving the vitamin later. This is the case with rickets, a bone deformation in children caused by lack of sunshine and lack of vitamin D. Rickets may be corrected if vitamin D is given in childhood when growth is still occurring. But once bones stop growing in adulthood deformities become fixed and cannot then be changed by giving vitamin D.

A number of other diseases are known or believed to be caused by insufficient vitamin D in childhood. It is well known that multiple sclerosis is more common in northern countries with short summers giving less exposure of people to the sun. For a long time experts researching multiple sclerosis resisted the suggestion that vitamin D might be a factor in the disease. But now much more evidence has accumulated and experts believe that deficiency of vitamin D is the major cause of MS.

However the Lancet authors point to clinical trials in which adults with MS have been given vitamin D without any clear improvement in their health and they argue from this that D deficiency cannot be the cause of the disease. This is mistaken scientific reasoning, a type 2 statistical error; because statistical tests specify very precise conditions and can never prove a lack of difference between two groups to be true for all conditions and all groups.

Causality may be proved in a Gold Standard clinical trial when supplementation succeeds in correcting a defect, but not when it fails to do so. A null result may be obtained simply because the trial took place too long after an irreversible insult occurring at a much earlier time, possibly during a critical period in youth, or alternatively over a long period of deprivation. Vitamin D might have prevented or cured the condition at an earlier stage but after gap of many years it has become fixed and is no longer remediable by supplementation.

An important example is diabetes type 1 (T1D), the type occurring in children and requiring insulin injections. T1D is now believed by experts to be caused by vitamin D deficiency that may begin in the womb. A deficiency of vitamin D in the foetus during pregnancy, in infancy or even teenage may produce irreversible changes in biochemistry, immune status, or organ structure that cannot be remedied by supplying the missing vitamin in adulthood. For example, the action of the immune system is partly determined by escape of T cells (lymphocytes) from deletion in the thymus, an irreversible process which may be influenced by vitamin D. This may explain why many immune system diseases are influenced by vitamin D as may be seen from the list below.

The Lancet authors have ignored many years of high quality research which have elucidated the causes of MS and T1D. "They put the clinical trial on a pedestal, exalting it as "gold standard". They have failed to explore scientific evidence of other kinds from specialist fields. This failure to fully review the research they write about has inevitably led to mistaken conclusions," said Oliver Gillie.

Other diseases for which vitamin D deficiency may be a possible or probable cause include: osteomalacia, Paget's disease of bone, Perthes' disease of bone, fractures, certain heart problems, chronic lymphocytic leukaemia, schizophrenia, autism, Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease, Addison's disease, ankylosing spondylitis, autoimmune hemolytic anemia, chronic active hepatitis, celiac disease, Crohn's disease, pemphigoid, pernicious anemia, primary biliary cirrhosis, rheumatoid arthritis, Sjogren's syndrome, systemic lupus erythematosus, thyrotoxicosis, rheumatoid arthritis, ulcerative colitis.

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1. Phillippe Autier of the international Agency for Research on Cancer, Lyon, et al. *Vitamin D status and ill health: a systematic review*. The Lancet Diabetes and Endocrinol, 2 (1) 76-89, Jan2014. Mark Bolland of the University of Auckland et al. *The effect of vitamin D supplementation on skeletal, vascular, or cancer outcomes: a trial sequential meta-analysis*. The Lancet Diabetes and Endocrinology, 2(4), 307-320, April 2014.
2. Oliver Gillie, Health Research Forum, London. *Controlled trials of vitamin D, causality and type 2 statistical error*. Public Health Nutrition. In press.