

Correspondence

Regarding Double-Blind Medical Trials

I am writing to support your contention that double-blind medical trials create only the illusion of scientific credibility.¹ Indeed, despite the enormous weight given to them by most conventional medical researchers, it is relatively easy to show that the statistics they provide are of dubious validity and are only likely to get poorer.

Throughout the Western world and beyond, ethics committees demand that informed consent be obtained before any individual is admitted into a double-blind study. To achieve this, potential participants must be told the nature and dose of the substance to be tested and the probability that he, or she, will receive a placebo. Each possible participant, therefore, realizes that this substance may be of some value in either preventing or curing a disease or disorder that threatens them. The individual also understands that there is a strong possibility, often 50%, that they will receive only a useless placebo. Potential participants, therefore, are often asked to risk death to improve the acceptability of a research team's statistics. It has been my experience that it is extremely difficult to persuade members of the public to make small financial contributions to medical research. To expect that most of them are willing to risk their lives for the same cause seems naive in the extreme.

The substance to be tested either may be easily obtained elsewhere, such as a vitamin or mineral, or may be unavailable in the country conducting the double-blind study. In the first instance, many of the participants are likely to purchase the substance under trial at the local health food store, or pharmacy. This means that many of those supposedly limited to the placebo also will be taking the substance being tested. In addition, many of the study participants already prescribed it, will be taking their own and will receive higher doses than the researchers anticipate. Such self-medication

blurs the distinction between the placebo and the substance under study. All related statistics, therefore, will be virtually meaningless and will tend to underestimate any beneficial effects of the nutrient or drug involved.

Does this mean that only esoteric substances, that are very difficult to obtain, can be evaluated using the double-blind approach? Experience from recent testing of AIDS - related drugs shows that such studies also have minimal validity. In this case, participants formed self-help groups which met to pool prescribed medications.² All received, therefore, a mixture of both the placebo and the substance(s) being tested. The end result, of course, was that these multimillion dollar double-blind studies were virtually worthless. Indeed, their value was undermined further by smuggling co-operatives that bought the drugs being tested in the study in other countries and then made them freely available to members of the trial.³

In summary, whether the substance(s) being evaluated in a double-blind trial is widely available, or esoteric, there are simple ways in which participants can ensure that they receive it. The more educated and politically astute the study's participants, the less likely it is that they will passively accept the risk that their treatment is a useless placebo. The end result of this process is that, as the size of the true placebo group declines, it become more and more difficult to prove that anything has medicinal value. An alternative approach is to provide the substance under study to the entire group of participants and then to compare their subsequent health status and survival rates against historical data. It must be admitted that it is still possible that some of the patients, whose records are used for comparison, also may have been taking the tested substance, especially if it is orthomolecular. However, it is obvious that the double-blind approach, especially when

used in developed countries, currently provides only a very thin veneer of credibility.

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Foods as Stressors in Essential Hypertension

George O'Clock, Ph.D., in his article "Treatment of Hypertension from an Orthomolecular Standpoint"¹ lists physical and emotional stressors capable of adversely influencing renal function and vascular (cardiac and blood vessel) functions. This list includes foods as stressors. However, his article made no reference to food as a stressor.

How is it that wholesome, non-toxic and nutritious foods used to produce human life energy can become stressors? The secret lies in the observed fact that foods used two times a week or more have the potential of developing metabolically maladaptive, symptom-producing reactions. Essential hypertension is one of these symptoms produced by maladaptive reactions to foods. These maladaptive reactions have been observed to have the following associated causes:

1) Immunologic. These immunologic reactions can produce antibodies and also disordered complement. Occasionally, these disorders are IgE. More frequently, they are IgG in origin. Acidification accompanies any and all immunologic symptom producing reactions.

2) Addiction. Food addiction develops when the stress of the frequently used food evokes a stress reaction evoking self-made opiate polypeptides (endorphins) and serotonin. The human body's basic response to stressors is that of evoking the biological response of producing endorphins and serotonin as a protective defense. This rise in endorphins and serotonin equally apply to foods as well as to other stressors. Addiction with its rise in endorphin-serotonin complex applies equally to immunologic and other nonimmunologic food stress types.

3) Enzyme deficiencies. In a state of nutritional deficiencies, the nutritional precursors to the oxidoreductase enzyme family of enzymes is not met and thus there is a reduced capacity to produce adenosine triphosphate (ATP) by oxidation phosphorylation and also a reduced ability to process (detoxify) free radicals, peroxides, acids, alcohols and aldehydes. Acid-hypoxia develops when these end-products of oxidation phosphorylation (free radicals, acids, peroxides, alcohols and aldehydes) are not quickly enzymatically processed. Acidity (acidhypoxia) is always present in oxidoreductase enzyme deficiency.

4) Enzyme inhibition. The oxidoreductase enzymes can be present in adequate supply and still not be optimally functional. This can occur because their response has been trained down by the presence of acidity or other enzyme inhibitors. These enzymes are alkaline-dependent. The presence of acidity can block and thus also train down the function of these enzymes. These oxidoreductase enzymes are not activated by ATP but instead are activated by a static electric field which, when the catalytic reactions occur, produces a negative magnetic field. A negative magnetic field also serves as an activator of oxidoreductase enzymes. A negative magnetic field also acts on the bicarbonate buffer system making it more active thus producing the necessary alkalinity for the enzymes to function.

5) Toxicity. Foods nearly always con-

tain some level of toxins which would be enzyme inhibiting. Eating a food frequently with these toxins can exceed the human body's capacity for enzyme detoxification. This again, is a reason to not use the same food twice a week or more.

Theron G. Randolph¹ was the first to observe acidity as a common denominator in all types (immunologic and non-immunologic) of maladaptive symptom reactions (maladaptive, symptom producing, hypersensitive food reactions). My research has consistently confirmed Dr. Randolph's initial observations.²³ The common denominator of all immunologic and nonimmunologic symptom producing reactions to foods is acidity. Acidity ties up oxygen and thus the result is acid-hypoxia. The numerous metabolic disorders including vascular and kidney maladaptive responses to acid-hypoxia are well established.

Case Histories

A forty-five year old woman with severe chronic headaches and hypertension was studied. Her headache was so severe that she resorted to narcotics for relief and had become an addict. Her blood pressure was 180/110 despite the medication she was on for hypertension. She was fasted on water only for five days, at which time she was also taken off of her hypertension medication. By the fifth day, she was headache free and her blood pressure normalized to 130/80. She was then tested by eating single meals of foods. Soy beans evoked both her headaches and her hypertension. Soy beans had been used on a daily basis for many years.

An eighteen year old insulin dependent diabetic was examined. His blood pressure was 180/110. He had 4+ protein in the urine. He was on 60 units of insulin a day and in spite of this, had a widely fluctuating blood sugar. His eyes were already deteriorating and he had received laser treatment for the vascular disorder in his eyes secondary to his diabetes. He could not be fasted as usual since

he was insulin dependent. The foods that he used twice a week or more were removed from his diet. By the fifth day, his blood pressure was 130/80. There was no protein in the urine. His insulin requirements had dropped from 60 to 20 units. His blood sugar was in good control on 20 units of insulin a day.

The above are simply two cases. I have repeated the same thing numerous times with essential hypertensive patients. The ones that did not behave this way, had marked deterioration of the kidneys. It is my impression that foods as stressors should be the first examination made for essential hypertension. Of course, nutrition should be made optimum both for kidney function and vascular function and nutritional enzyme precursors. However, reliance should not be made on providing these nutrients and ignoring foods as stressors that are known to be capable of evoking hypertension.

George O'clock is rightfully interested in Dr. Bjorn Nordenstrom's closed loop theory of electromagnetism. It is my hope that Dr. O'clock will become interested in comparing Dr. Nordenstrom's low level DC circuit response with a static magnetic field response from a static field magnet. Through the years, before I understood the role of magnetism, I made extensive use of electricity including over 70,000 electric shock treatments and over 50,000 nonconvulsive cerebral stimulation treatments and a very extensive use of TENS instruments. These all had value. However, my work has demonstrated that it is the negative magnetic field that is present in these electrical treatments that is of value. There are side effects to the electric current. The negative magnetic field has no side effects and the therapeutic response is even more predictable than it is with the electric current treatments. I recently received a request from a basic scientist to express magnetic biological response in terms of mathematics. I think this is correct. I hope that Dr. O'clock will work out

a mathematical parallel between Dr. Nordestrom's use of a direct current circuit and the static magnetic field treatment from a static field magnet.

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Reassessing the Role of Sugar in the Etiology of Heart Disease

Regarding Dr. Grant's article,¹ I have two comments:

1. Although you hint at the fact that sucrose becomes a precursor to triglycerides more so than glucose, this fact is clearly if not unequivocally demonstrated by the experiments by Winitz, Seedman and Graff² regarding chemically defined diets in which pure glucose (not starch) at 88% of total calories (TC) was found to lower total cholesterol while 25% glucose replacing sucrose (equivalent to 11% TC fructose) was found to raise total cholesterol.

2. The two parameters for heart disease considered are fats and sweeteners which are, as you indicate, macro nutrients. You do not elaborate on the hypothesis that it may not in fact be these macro nutrients themselves that are causally related to the observed statistical (or factual) link to infarction and CHD but that the causal link may be the absence of micro nutrients in fats

and sweeteners.

I would suggest that fats and sweeteners have always been consumed in some amount but that the processing and refining of these macro nutrients are new to the human diet, and that more likely the resulting lack of phytochemicals, vitamins and minerals are the main causal pathway to heart and vascular diseases.

It is urgent to determine through clinical and population studies if lack of micro-nutrients rather than excess of some selected macro nutrients are the true cause of vascular diseases.

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Dr. Grant replies:

In answer to your first comment regarding glucose and sucrose, I think it is the fructose that raises TGs.

In your second comment, you mention that it may be the absence of micro nutrients in fats and sweeteners, rather than the macro nutrients themselves which are causally related to the observed statistical (or factual) link to infarction and CHD. I totally agree. In fact, I have published a second paper in which I find that lactose has the highest statistical association with IHD for men of all ages and postmenopausal women.

I have found fats to have a relatively low statistical association with IHD, and are probably there mainly as confounding factors. The second step, beyond the development of TGs and VLDL cholesterol is the oxidation of fats. That is why wine, especially red wine,

vitamins A,C and E, and selenium are important as antioxidants.

Regarding the investigation of a micro-nutrient deficiencies as the primary cause of vascular disease, I have written to half a dozen researchers suggesting that they look at existing or future case control or cohort study data to examine lactose and fructose/ sucrose. There seems to be some gentleman's agreement" not to study these macro-nutrients.

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Linus Pauling and Albert Szent-Gyorgyi

Albert Szent-Gyorgyi's statements in 1939 on vitamins, health, and disease, serendipitously discovered and reported by Jack Chalem in a recent issue of the Journal of Orthomolecular Medicine, are marvelously prescient.¹ In his paper "Albert Szent-Gyorgyi and Vitamin C" (Search and Discovery: A Tribute to Albert Szent-Gyorgyi, 1977), Linus Pauling cited another remark by Szent-Gyorgyi from the same 1939 text:

"I have a strong faith in the perfection of the human body, and I think that vitamins are an important factor in its coordination with its surroundings. Vitamins, if properly understood and applied, will help us to reduce human suffering to an extent which the most fantastic mind would fail to imagine."

While Pauling often credited Szent-Gyorgyi, Abram Hoffer, Humphry Osmond, Roger Williams, Irwin Stone, the Shutes, and Geoffrey Bourne (who pointed out in 1949 that our closest biological relatives consume about 4.5 grams/day of vitamin C in their wild-type diet, corresponding to about 2 grams/day for humans) as the seminal figures in orthomolecular medicine, it is clear that his thinking in the 1930s paralleled

Szent-Gyorgyi's. At the dedication of the Crellin Laboratory at the California Institute of Technology in May, 1938, Pauling made the following statement, which aptly demonstrates his early interest in the health effects of natural substances:

"Organic chemistry was developed into a great science during the nineteenth century, and it seems probable that all or nearly all its fundamental principles have now been formulated. There is, however, a related field of knowledge of transcendent significance to mankind which has barely begun its development. This field deals with the correlation between chemical structure and physiological activity of those substances, manufactured in the body or ingested in foodstuffs, which are essential for orderly growth and the maintenance of life, as well as of the many substances which are useful in the treatment of disease."

This statement precedes by three decades Pauling's introduction of the term "orthomolecular", first published in "Orthomolecular Psychiatry" (Science 160:265-271, 1968) and subsequently codified in "Some Aspects of Orthomolecular Medicine" (Journal of the International Academy of Preventive Medicine 1:1-30,1974) as follows:

"Orthomolecular medicine is the preservation of health and the treatment of disease by the provision of the optimum molecular constitution of the body, especially the optimum concentration of substances that are normally present in the human body and are required for life. The adjective orthomolecular is used to express the idea of the right molecules in the right concentration."

In his 1970 paper, "Evolution and the Need for Ascorbic Acid" (Proceedings of the National Academy of Sciences 67:1643-1648), Linus Pauling provided an answer, at least for several water-soluble vitamins, to the issue raised in 1939 by Szent-Gyorgyi, who believed that "for any vitamin, the D. O. Q. [dosis optima quotidiana] will be found to be the quantity the animal consumes normally in his natural habitat." Pauling calculated the

quantity of thiamin, riboflavin, nicotinic acid, and vitamin C present in the amount of 110 raw plant foods that provide the average daily food energy requirement for humans of 2,500 kcal. For thiamin, riboflavin, and nicotinic acid, the vitamin content was found to be 3.8, 3.0, and 2.4 times, respectively, the RDAs. The average amount of vitamin C in the raw foods providing 2,500 kcal of food energy was 2,300 mg, or 35 times the 1970 RDA of 66 mg. Based on these calculations and the arguments advanced by Bourne on the amount of vitamin C consumed in wild-type diets, Pauling concluded that the optimal intake of vitamin C for humans (Szent-Gyorgyi's D. O. Q.) is at least 2,300 mg/day. Of course, the therapeutic benefit of these substances is likely to be fully realized at much higher levels.

Pauling experienced a life-saving benefit of orthomolecular medical practice in 1940 when he was diagnosed with glomerular nephritis. On the advice of a New York physician, he decided to be treated by Dr. Thomas Addis at the Stanford Medical School in San Francisco, rather than go to the Mayo

Clinic for conventional therapy. Addis, who was interested in the quantitative assessment of renal function and the relation of function to anatomical structure, put Pauling on a dietary regimen to reduce edema and rest the kidneys, consisting of a salt-free diet for four months, a minimum protein diet that Pauling followed for fourteen years, plenty of water, and supplementary vitamins and minerals. Pauling's successful recovery certainly influenced his subsequent ideas about the relation of nutrition to health and disease,

It is now apparent that the excellent work of these pioneers in orthomolecular medicine was critical in focusing the attention of the public and medical professionals on the value of micronutrients, phytochemicals, and microconstituents of the diet in the promotion of health and treatment of disease.

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