Results Presented on Cleveland Clinic Trial on Bios Life 2®

Below is the published abstract of the Cleveland Clinic Trial on Bios Life 2® that has been published in the Official Abstract Book for International Academy of Cardiology in Washington, D.C. (attended by Dr. Dennis Sprecher from Cleveland Clinic, who oversaw the study).
Also included is a layman's explanation of the abstract from Unicity Network

Abstract

FIBER-MULTIVITAMIN BLEND:
AN OVER-THE-COUNTER LDL LOWERING PRODUCT
Dennis L. Sprecher MD, [1] Gregory L. Pearce, [1] Anita M.Boddie RD, PhD, [2]
Nader Fotouhi, PhD, [2] Vicki Horiatis RN[1]

[1]The Cleveland Clinic Foundation, Cleveland, Ohio
[2]Rexall Sundown, Inc., Boca Raton, Florida

Background: A commonly used 90% soluble fiber-blend product (Bios Life 2) has not been evaluated for lipid altering effect. Few data are available to describe the influence of fiber on serum ApoB levels. Further, as a fiber-vitamin combination agent, the potential claim of folate/B6 benefit in the setting of fiber intake has not been examined.

Methods: Patients (n=119) were randomized to either a fiber blend treatment, or placebo with 99 (50 treatment, 49 placebo) completing the study. Fasting lipid profiles (including ApoB), and homocysteine concentrations were obtained at weeks 4 and 8. Between group (Wilcoxon rank-sums test) and within group (paired t-tests) comparisons were used to evaluate treatment effect.

Results: Subjects in both groups showed similar baseline LDL levels (159mg/dl vs. 158mg/dl). The treatment group showed a 7.9% +/- 11.0 reduction ($p<0.001$) over 8 weeks. Placebo patients showed a slight increase in LDL over the same period (+2.4% +/- 11.7, $p=0.16$), for a 10.3% difference between groups ($p<0.001$). ApoB measured in a subset (n=53) revealed a 20% reduction with treatment ($p=0.004$). Treatment subjects showed a reduction in homocysteine (9.8 mg/dl to 8.7 mg/dl, $p=0.02$), while neither TG ($p=0.95$) nor HDL-c ($p=0.54$) changed.

Conclusions: Significant LDL and ApoB lowering effects are demonstrated. No adverse effects on triglyceride or HDL-c levels were noted, and folate/B vitamin derived benefits towards homocysteine reduction were preserved. This combination product could be used to reduce the need for concomitant lipid lowering prescription therapy, as well as for advancing self-styled primary prevention strategies.

Abstract explanation

Before medications are approved for widespread use, they are typically tested in a controlled clinical trial. Controlled trials are considered necessary to show that a medication's effects are not subjective (relying on the patient's or physician's interpretation). Otherwise, a researcher might (perhaps unintentionally) test the medication only in patients who already show signs of responding well to treatment. Or a patient, knowing that the medication is supposed to have a specific effect, could experience that effect due to some other factor, but attribute the relief solely to the new medication.

The preferred way to avoid subjectivity is to do a controlled study. In a controlled study, or trial, patients in one group receive the investigational product; while patients in another group-the control group-receive a placebo (an

inactive substance that is indistinguishable from the investigational product). This arrangement allows researchers to compare the health of the group receiving the new product with the control group. If the group receiving the new product shows clear and measurable improvements in symptoms, but the control group does not, researchers can reasonably conclude that the new product was responsible for improving the health of the treatment group. To ensure that comparisons between a treatment group and control group are scientifically valid, researchers select people for both groups who are similar in age, weight, health status, and other factors. The most common way to accomplish this is through randomization. Researchers first gather a group of people with similar characteristics. They then randomly assign each person to either the treatment group or the control group. This ensures that certain patients aren't "hand picked" for a group because of their characteristics.

The final step in ensuring that a research study is objective is blinding. Blinding is used to eliminate the effects of personal beliefs and biases (on the part of both researchers and patients). In a single-blind study, the patients do not know whether they are in the treatment group or the control group, but the researchers do know. In a double-blind study, no one involved-not the patients, researchers, or data analysts-know which patients are receiving the new product and which are not.

A controlled, randomized, double-blind clinical trial therefore produces the most objective and scientifically valid results.

The abstract explains the results of the controlled, randomized, double-blind clinical trial on the Bios Life 2Æ that was accomplished by the Cleveland Clinic.

The abstract states that 119 patients were randomized for the trial. All of the patients were required to eat the same low fat diet for the six weeks leading up to the trial and then continue on a controlled diet throughout the trial. This isolated the variable. In other words, the patients' diet would not have been the cause of any difference in serum cholesterol as all of the patients had been following the same diet.

Ninety-nine patients completed the trial (50 on the Bios Life 2 and 49 on the placebo). Blood work was done at the fourth and the eighth week of the trial. The values obtained from the blood work were then statistically analyzed. Accepted methods of mathematical analysis can determine whether a difference in treatment outcomes is statistically significant. A statistically significant difference means that the result is very unlikely to be due to chance alone. Researchers represent the degree of certainty in a result as what is called a "p value." A p value of less than 0.05 indicates that the results of the study are statistically accurate and did not occur by chance. Achieving a significant p value is heavily dependent on the number of people in the groups that are being compared.

LDL is "Low Density Lipoprotein". A lipoprotein substance (combination of a fat and a protein) acts as a carrier for cholesterol and fats in the bloodstream. High levels of low density lipoprotein (LDL) are considered a positive risk factor for the development of coronary artery disease. Less than 130 mg/dl is desirable, 130 to 159 mg/dl is borderline high, over 160 is considered high. The results showed that there was an average difference in LDL levels of 10.3% between the groups. This is statistically significant ($p<0.001$) and shows the difference being solely attributable to the Bios Life 2.

ApoB is "Apolipoprotein B". Apolipoproteins are proteins on the surface of the lipoprotein complex that bind to specific enzymes or transport proteins on the cell membranes; this directs the lipoprotein to the proper site of metabolism. ApoB is in LDL (low density lipoprotein). Unlike HDL and LDL measurements (which are indirect), apolipoprotein levels can be measured directly. Knowing a patient's ApoB levels may give a much more accurate picture of their health, including the risk for heart disease. The results showed a 20% reduction in ApoB with treatment. This value showed statistical significance ($p=0.004$).

Homocysteine is an amino acid produced by the body by altering another amino acid, methionine. In a healthy

system, homocysteine is usually converted into other amino acids. Elevated levels of homocysteine in the blood appear to make for an elevated risk of cardiovascular (heart and vessel) disease. Homocysteine can damage blood vessels in several ways. It injures the cells that line arteries and stimulates the growth of smooth muscle cells. Homocysteine can also disrupt normal blood clotting mechanisms, increasing the risk of clots that can bring on a heart attack or stroke. The results showed an 11.2% reduction in homocysteine levels in the patients taking Bios Life 2. This value has lower statistical significance (p=0.02) and the changes cannot be wholly attributed to the product.

TG represents "triglycerides". These are the storage units for fat in the body. Elevations of the triglyceride level (particularly in association with elevated cholesterol) have been correlated with the development of atherosclerosis, an underlying cause of heart disease and stroke. The results showed a reduction in triglycerides that was not statistically significant (p=0.95). As such, the article will represent that "triglycerides were unchanged". Even that is important as many other methods for lowering serum cholesterol may increase triglyceride levels.
HDL is "High Density Lipoprotein". Raised high density lipoprotein levels have been correlated with a lower risk for heart disease. Less than 35 mg/dl is considered a positive risk factor for coronary artery disease, over 60 mg/dl is considered a negative risk factor (reduces your risk of heart disease). The results showed an increase in HDL that was not statistically significant (p=0.54). As such, the article will represent that "HDL levels were unchanged". Again, even that is important as many other methods for lowering serum cholesterol may decrease HDL levels.
The most encouraging part of the abstract lies in the conclusion. Almost every study that is completed on complementary therapies states an ambiguity in the conclusion. Usually something to the effect of "These results suggest that more study is warranted." Dr. Sprecher never states anything like that. His simple conclusion is that the Bios Life 2 was effective in the clinical trial. He even states that the ***Bios Life 2 should be used for primary prevention of hypercholestremia***.