

# **Beneficial effects of Bios Life 2 (Dietary Fiber Supplement) in patients with dyslipidemia.**

**Balajadia E., Valerio A., and Yumul N.**

## **Abstract**

**The importance of dietary fibers in lowering cholesterol levels is not well recognized by the general public and medical practitioners. The lipid and sugar-lowering effects of dietary fibers, particularly the BioSphere fiber matrix, have been investigated in the Caucasian population but not in Asians. This study was done to determine the cholesterol-lowering effect of dietary fibers in adult patients.**

**This is an experimental, uncontrolled study involving a total of 103 patients. Baseline total cholesterol determination was done after which subjects were given six grams of the BioSphere fiber blend for four weeks and were advised to follow a low fat diet. A repeat total cholesterol determination was done after four weeks.**

**Most patients who are dyslipidemic are hypertensive, which comprised 68.9 percent of the study population. Hypercholesterolemia is more common in the female group compared with males. Sex has a relation on the levels of baseline total cholesterol with computed X2 value of 9.94 compared to the tabular value at five percent with two degrees of freedom (df), of 5.99. Female response to the treatment is significantly greater than male, with a computed X2 of 9.92 and tabular X2 value at five percent with 2 df of 5.99.**

**HYPERCHOLESTEROLEMIA is the elevation of fasting plasma total cholesterol in the presence of normal levels of triglycerides and is associated with increased concentrations of plasma LDL cholesterol. LDL carries about 65 to 75 percent of total plasma cholesterol [1]. The normal range for total blood cholesterol is less than 200 mg/dL. For higher levels, the risk of heart disease begins to rise. Given the high-stake consequences of high cholesterol being heart attacks and strokes, estimates are that 102.3 million American adults have total blood cholesterol values of 200 mg/dL and higher, and about 41.3 million American adults have levels of 240 mg/dL or higher.**

**In adults, total cholesterol levels of 240 mg/dL or higher are considered high, and levels from 200 to 239 mg/dL are considered borderline-high [2].**

**Objectives of the study:**

- To determine if there will be a significant reduction in the total cholesterol levels of patients with dyslipidemia given the BioSphere fiber blend for four weeks.**
- To determine if sex, age, and severity of hypercholesterolemia are factors affecting baseline and post-treatment total cholesterol levels.**
- To determine the frequency of dyslipidemic patients who have hypertension, diabetes, and coronary artery disease in our study population.**

**Significance of the Study**

**The inclusion of fibers in the diet of persons**

---

*From Angeles Medical Center, Angeles University, Angeles City, The Philippines.*

*Presented at 34<sup>th</sup> Annual Convention of the Philippine College of Physicians., May 4—7, 2004.*

at risk of developing cardiovascular disease is normally not emphasized by clinicians. Focus has been on the prescription of synthetically manufactured medicines like lipid-lowering agents, antihypertensive medicines, and sugar-lowering agents. The general public is not aware of the beneficial effects of fibers, thus consumption of more fiber is not advocated by most physicians. Most studies on fibers have been done on Caucasians. No study has been done on Asians to evaluate cholesterol-lowering effects of dietary fibers. There is growing awareness of risk of having elevated cholesterol levels among Filipinos and the high prices of lipid-lowering agents, coupled with their side effects. This study was done to evaluate if dietary fiber will be effective among other race groups than Caucasians in lowering the serum cholesterol level since a reduction would prevent complications like diabetes, hypertension, and coronary artery disease.

A study has been performed by the Cleveland Clinic Foundation using the BioSphere fiber blend of Bios Life which is a unique, fiber-rich nutrient drink mix that can support healthy cholesterol and blood sugar levels when combined with a healthy lifestyle. A total of 119 patients was 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 of diet. In other words, the patients' diets could 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 Bios Life and 49 on placebo). Blood work was done at the fourth and the eighth week of the trial. Significant LDL- and ApoB-lowering effects were demonstrated. No adverse effects on triglyceride or HDL-c levels were noted, and folate/B vitamin-derived benefits toward homocysteine reduc-

tion 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 [4].

The randomized controlled trial done at Cleveland Clinic using Bios Life has yielded significant recommendations for the beneficial effects of the fiber supplement. Bios Life is one of the fiber products that seems superior to other fiber supplements because it contains a mixture of different kinds of dietary fibers such as guar gum, locust bean gum, pectin, oat fiber, gum acacia, barley, and stevia.

Lipoprotein substances (combination of a fat and a protein) act as carriers 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. Blood levels of less than 130 mg/dL are desirable, 130 to 159 mg/dL are borderline high, over 160 mg/dL are considered high.

The mechanism of action of statins (3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors) is different from fibers, but their effects are comparable. This was demonstrated by a study done in July 2003 where a portfolio of cholesterol-lowering foods versus lovastatin showed comparable reduction in the lipid levels of the study subjects [5].

## MATERIALS AND METHODS

### Study Design

The study followed the experimental uncontrolled design. This involves one group of intervention users that was evaluated pre- and post-intervention.

### Subjects

#### Inclusion Criteria

Adult patients, age 18 years and above, diagnosed of dyslipidemia who are not taking

any lipid-lowering agent were included in the study. Patients who have stopped taking lipid-lowering agent for at least one month were also included in the study.

#### Exclusion Criteria

Patients who are azotemic, have active liver disease, or are patients with malabsorption syndrome were excluded from participating.

#### Scope and Limitation of the Study

The study is an uncontrolled experimental study. The compliance of patients was monitored through telephone calls. They were advised regarding their diet and intake of the fiber supplement.

#### Patient Follow-up and Instructions

The patients were given six grams of Bios Life daily for four weeks. They were advised to remain on their usual low-fat diet. Baseline serum total cholesterol was determined prior to the administration of Bios Life. After four weeks, the serum total cholesterol measurement was repeated. No attempt was made to blind the subjects or the study personnel. Patients were classified according to age, sex, and the presence of hypertension, diabetes, and coronary artery disease and/or myocardial infarction was noted.

#### Definition of Terms

Hypercholesterolemia – total cholesterol level of 200 mg/dL or greater.

Desirable cholesterol – total cholesterol level of less than 200 mg/dL.

Borderline cholesterol – total cholesterol between 200 to 239 mg/dL.

Undesirable cholesterol – total cholesterol level of 240 mg/dL or greater.

#### Time and Place of Study

The study was conducted at Angeles University Foundation Medical Center from May 1, 2003, to October 30, 2003, on an out-patient basis; 103 patients were included in the

study.

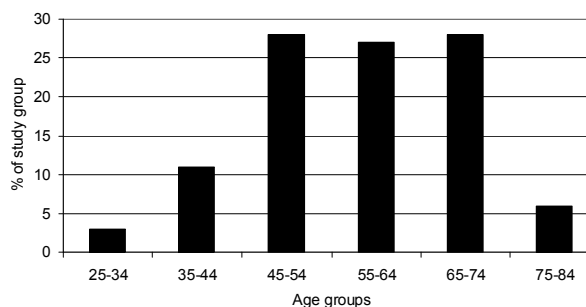
#### Statistical Analysis

Patients' levels of total cholesterol were classified as desirable, borderline, and undesirable. The mean, percentage, and frequency were used in describing the age, sex, and clinical profile of the patients while the pre- and post-treatment total cholesterol levels were analyzed by using the students' T-test (two-tailed) and expressed as means +/- standard error of the mean. To test the correlation between age and sex and the baseline and post-treatment total cholesterol levels, the Chi square test was used.

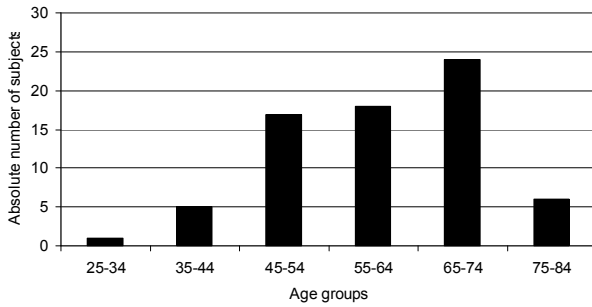
## RESULTS

Included in the study were 103 patients who had their baseline cholesterol determined and were followed up until four weeks of treatment with Bios Life.

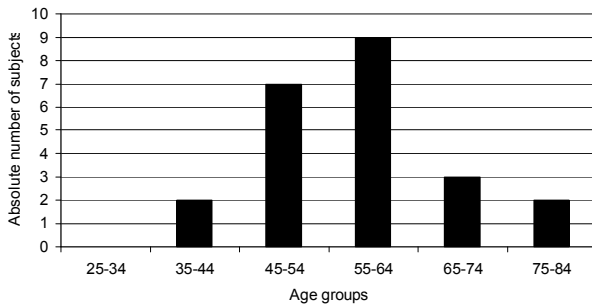
Figure 1 shows the age distribution of the subjects. Patients' ages ranged from 25 to 84 years. There is an increase in frequency among age group 65 to 74 years, which totaled 28 patients, and the smallest age group was the 25 to 34 group, which accounted for three subjects. Twenty-seven percent of the subjects were male, and 73 percent were female.



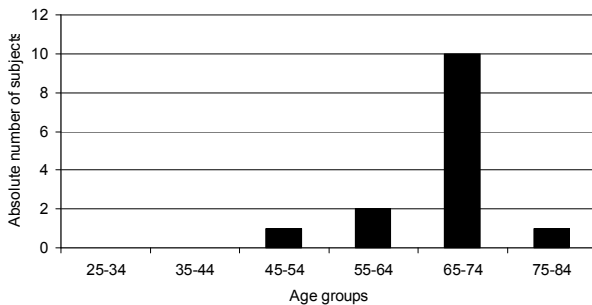
**Figure 1. Age distribution of the included subjects.**



**Figure 2. Absolute number of hypertensive subjects.**



**Figure 3. Absolute incidence of diabetes in the subject group.**



**Figure 4. Absolute incidence of CAD or previous MI in the subject group.**

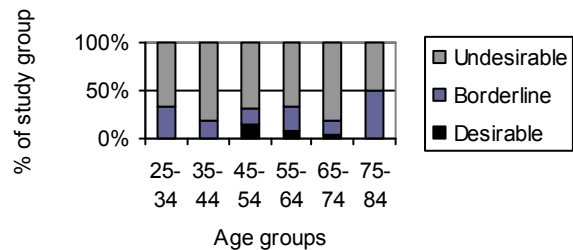
Figure 2 shows that about 68 percent of the patients are hypertensive, of whom most are in the age group of 65 to 74 years. Figure 3 shows that 22 percent of the patients are diabetic. Most are in the age group of 55 to 64 years. In Figure 4, it was shown that most patients with CAD (coronary artery disease) or previous myocardial infarction are in the age group of 65 to 74 years, comprising ap-

proximately 10 percent of the patient population.

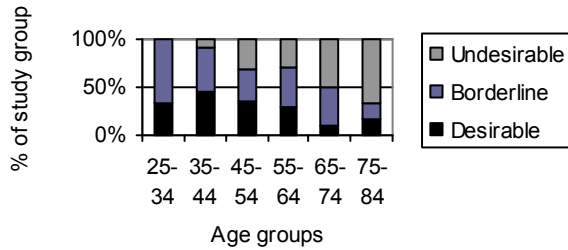
Most of the hypertensive patients are female, comprising 48 percent of the study group. Also most of the diabetics (14 percent) and those with CAD (12 percent) or previous myocardial infarction are female.

The incidence of hypertension is high in patients who have dyslipidemia. Of the study population 68.9 percent are hypertensive, 22.3 percent are diabetic, and 13.59 percent have a history of myocardial infarction or coronary artery disease.

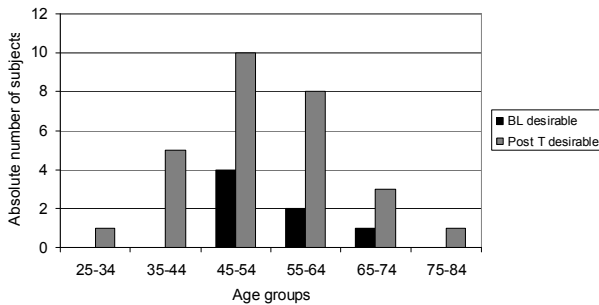
Figure 5 shows that the frequency of having undesirable cholesterol levels is highest in the age group of 65 to 74 years with 23 patients, and smallest in the 25 to 34 age group, accounting for two patients. Statistical analysis using chi-square was then applied to determine if age affects cholesterol levels. Analysis revealed a computed  $X^2$  of 8.89 which is not statistically significant as compared to the tabular  $X^2$  value at five percent with 10 degrees of freedom, which equals to 18.31. This shows that although there is an increasing trend noted among the age group of 65 to 74, age has no correlation with the levels of cholesterol. Also after four weeks of intervention, this correlation did not exist.



**Figure 5. Baseline LDL level distribution among the study subjects, according to the NCEP guidelines.**



**Figure 6. LDL cholesterol levels post treatment in the subject group according to NCEP guidelines.**



**Figure 7. Baseline desirable versus post-treatment desirable LDL.**

Sex has a significant effect on the levels of cholesterol, both in the baseline and post-treatment phase with computed X2 value of 9.94 compared to the tabular value at five percent with 2 df, of 5.99. Treatment applied among all age groups revealed a computed X2 of 9.92 as compared with tabular X2 value at five percent with 2 df of 5.99. In conclusion, there is a statistical significant greater reduction in the total cholesterol levels in the female population compared to the male population.

Statistical analysis using student T test revealed a significant effect of Bios Life in lowering total cholesterol with a computed T value of 10.040 and tabular T value of 1.986 at five percent with 102 degrees of freedom. In summary, the percentage decrease in the baseline total cholesterol of all the subjects combined is 15.9 percent.

## DISCUSSION

Hypercholesterolemia has shown to be one of the major risk factors for atherosclerosis. Over the past three decades a variety of epidemiological, animal, and human trials has demonstrated the preventive and therapeutic benefits of dietary fibers on hypercholesterolemia and reduction of the mortality rate of CAD.

The mechanism of the reduction of plasma cholesterol by dietary fibers is controversial. The increase in the bile acid excretion among patients increasing fiber intake probably explains most of the reduction, and a reduction in cholesterol absorption may have contributed to this finding [6].

In our study we were able to demonstrate the cholesterol-lowering effect of the BioSphere fiber matrix of Bios Life in four weeks' time. Most likely our patients also have increased excretion of bile acids in their stools, but we did not determine this.

Diversifying the content of a cholesterol-lowering diet is the key in obtaining significant reduction of lipid levels since the various types of fibers have different functions. Some absorb water, making the stool softer and increasing the transit time of feces in the colon, and this is particularly true for the non water-soluble dietary fibers.

A high intake of dietary fiber, particularly the soluble type, above the level of the recommendations of the American Diabetic Association (25 to 30 g), improves glycemic control, decreases hyperinsulinemia, and lowers plasma lipid concentration in patients with type II diabetes. Among patients with established coronary artery disease and who are post-myocardial infarction, dietary fibers could reduce the serum total and LDL cholesterol levels and delay the progression and increase the overall regression of coronary artery disease [7].

Non water-soluble fibers increase stool bulk by absorbing water and making the stool

softer, which prevents constipation and possibly diverticulosis.

The combination of soluble and insoluble fibers as in Bios Life works in the intestinal tract by binding fats ingested during a meal and by “pulling” cholesterol, especially LDL cholesterol, from the circulatory system into the bowel. These two functions lower blood cholesterol, LDL cholesterol, and serum triglyceride levels simultaneously.

In our study there is increased frequency of females with elevated cholesterol with hypertension, diabetes, and coronary artery disease. There is ample evidence that women with coronary heart disease and hypercholesterolemia should be treated as aggressively as men. An elevated serum cholesterol level in women is as predictive of later CHD events as it is in men. The prognosis for women with CHD (coronary heart disease) is similar to or worse than that of men. Therefore, the old idea of women being at lower risk vanishes when CHD is documented. It is not surprising that trials of lipid-lowering agents show similar levels of effectiveness.

There is a great deal of evidence that people with high blood pressure and/or blood cholesterol levels have a greater risk of developing cardiovascular diseases. The higher the blood pressure and/or cholesterol level, the greater the risk.

### CONCLUSIONS

In our study group, hypertension was most prevalent, followed by diabetes and coronary artery disease. An increase in the incidence of dyslipidemia was noted in the elderly subjects, but statistical analysis revealed this is not significant. Young and elderly patients can develop hypercholesterolemia just as effectively.

As to gender, there is a greater number of females who have increased cholesterol levels but when treatment was applied using Bios Life, they showed greater reduction in

cholesterol levels compared to males. There was a 15.9 percent reduction in the total cholesterol of the subject group, showing that Bios Life is beneficial in patients with dyslipidemia in lowering total cholesterol levels. Bios Life, therefore, prevents atherosclerosis, which leads to a decrease in prevalence of hypertension, diabetes mellitus, and coronary artery disease and/or angina pectoris.

### RECOMMENDATIONS

It is recommended that further studies be conducted, preferably randomized controlled trials, and that the clinical outcomes like mortality, morbidity, and other co-morbid factors will be evaluated in patients receiving Bios Life.

Patients with elevated total cholesterol should take Bios Life if their diet is not sufficient to meet the daily intake of 20 to 35 grams of fiber as recommended by the American Dietetic Association.

### REFERENCES

1. Fauci, A., *Principles of Internal Medicine, 14th Edition*. 1998.
2. *National Health and Nutrition Examination Survey III*. 1988 - 1994, Centers for Disease Control / National Center for Health Statistics.
3. *Doctors Guide to Rexall Showcase International*. 1998.
4. Sprecher, D.L. and P. Gregor, *Fiber Multivitamin Blend: An Over the Counter LDL Lowering Product*. 2001, Cleveland Clinic Foundation: Cleveland, Ohio.
5. Jenkins, D.J., et al., *Effects of a dietary portfolio of cholesterol-lowering foods vs lovastatin on serum lipids and C-reactive protein*. *Jama*, 2003. **290**(4): p. 502-10.

6. Chandalia, M., *Beneficial Effects of High Density Fiber Intake In Patients with Type II Diabetes mellitus*. New England Journal of Medicine, 2000. **342**: p. 1392-8.
7. Freed, S., *Diabetes in Control Newsletter*. Diabetes in Control, 2000(15 (1)): p. 12-18.