
BIOS LIFE 2[®] NATURAL

CLINICAL STUDY

THE LOWERING OF SERUM CHOLESTEROL WITH A PATENTED DIETARY FIBER SUPPLEMENT

RESEARCH BRIEF SYNOPSIS



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INTRODUCTION

Since the 1950s, there has been a tremendous amount of research investigating the link between serum cholesterol and coronary heart disease (13,20). The higher the total plasma cholesterol concentration, the greater the risk (10). Data from the Lipid Research Clinic study showed convincingly that reductions in serum low density lipoprotein (LDL) were associated with reductions in myocardial infarction and sudden cardiac death (21). Serum LDL was reduced by a combination of diet and drug therapy. The authors concluded that for every 1% reduction in total cholesterol (TC), there was an approximate 2% reduction in the risk of myocardial infarction and sudden cardiac death (21). This study established the necessity for reducing serum cholesterol and LDL in the hope of reducing coronary heart disease (CHD) in the general population. A more recent study conducted at Harvard University Medical School tested 43,000 middle aged males for a duration of more than 6 years, and showed that increasing fiber intake to 30gm daily resulted in a 41% reduction of MI (Myocardial Infarction) regardless of cholesterol level (33). It further showed significant reductions in cancer of the colon, breast cancer, diabetes and diverticulitis. While impressive, the obtaining of 30gm of fiber per day associated with diet alone is far from practical. Recently, the National Cholesterol Education Program (NCEP) listed guidelines for treating adults with high cholesterol (25).

Epidemiological evidence suggests that dietary fiber intake reduces CHD in certain populations. Individuals consuming a diet high in fiber tended to exhibit a lower incidence of myocardial infarction and sudden cardiac death (20,24). This initial research suggested that cholesterol-lowering benefits were found mostly with diets high in oat fiber or bran. However, clinical studies investigating blood glucose maintenance with high-viscosity resins like guar gum and pectin showed demonstrable reductions in TC and LDL as well (22,32,36).

Drug intervention has been the most common form of intervention therapy. This therapy relies upon a two-phase model (37). Phase one utilizes diet modification and exercise for reducing circulating serum TC and LDL. Phase two incorporates cholesterol-inhibiting drugs like pravastatin, lovastatin, and fluvastatin for lowering serum levels along with phase one components. The resurgence of natural medicine and the mounting evidence showing the success of fiber-based therapy for lowering serum TC and LDL have prompted the suggestion of a three-phase model. This model incorporates the use of fiber therapy in between diet and exercise, and drug-based therapy for lowering serum TC and LDL (37). Considering the higher costs and adverse side effects associated with drug-based therapy and the trend for medical cost containment, it is prudent that more cost-effective steps for reducing serum TC and LDL be examined. Dietary supplementation is therefore becoming an increasingly important and practical means of addressing this important issue.

Therefore, the present study was designed to investigate the effect of a patented fiber supplement on circulating levels of cholesterol and lipoproteins (LDL and HDL). The study examined serum changes in patients, (N=66) without the requirement of a control group, at risk for CHD, but not currently on cholesterol-lowering medication. It was hypothesized that reductions in circulating cholesterol and LDL using fiber supplementation, as part of an overall diet, would be similar in magnitude to that produced via medications used to treat high cholesterol.

ABSTRACT

High levels of serum cholesterol have been linked with coronary heart disease (CHD) for over 30 years. Early interventions included the prescription of drugs that inhibited the production of cholesterol and a reduction in the dietary intake of cholesterol. In recent years prescription therapy has advanced in the fight against CHD. But this does not fully address the associated dangers. These include dangerous but manageable side effects, drug interactions, excessive costs and insurance claims. There is accumulating evidence suggesting that dietary fiber can reduce serum cholesterol. The current study was designed to investigate the serum cholesterol lowering effect of a patented dietary fiber supplement. This fiber supplement is manufactured by Rexall Showcase International under the trade name *Bios Life 2^o Natural*. Subjects (n=66) were taken from a random blinded pool of patients currently at risk for CHD. Patients were monitored for total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL), triglyceride (TG) and cardiac risk (HDL:LDL). Fasting blood samples were obtained at the beginning of the study and then monthly for three months. The results indicate that highest significant reductions in serum TC (14.9%) and serum LDL (17.9%) were achieved within the first 60 days of using the fiber supplement.

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HDL increased (30.1%) significantly while TG decreased (30.7%). These statistics show overall highly significant results in (TC), (HDL), (LDL), (TG). The most notable of these results is in the highly significant reduction of cardiovascular risk (36%) in the HDL:LDL risk ratio. TC reduction was seen as high as 45% with LDL decreases as low as 59% and HDL increases as high as 48%. This variability is consistent with blood sampling and lack of diet and exercise restrictions. In conclusion, the use of a natural dietary fiber supplement, as part of an overall diet, proved highly successful in lowering risk factors associated with Coronary Heart Disease (CHD). However, no assurances should be inferred as to the individual results a patient may obtain with the use of this dietary supplement.

DISCUSSION

The use of a patented dietary fiber supplement proved highly successful in reducing serum total cholesterol (TC) and low density lipoprotein (LDL). The degree of these reductions falls within levels normally associated with anti-cholesterol drugs. The present study has great implication for individuals interested in lowering their serum cholesterol naturally with limited side effects.

Coronary heart disease (CHD) is one of the leading causes of death in the population (26,31). While factors like obesity, diabetes, smoking and hypertension have been shown to influence CHD risk, serum cholesterol seems to show the strongest correlation (1,11,12). In 1950, Moreton demonstrated the relationship between chylomicronemia (the soluble cholesterol and fat fraction in the intestine) and the incidence of atherosclerosis (24). Since then there have been numerous studies showing the prevalence of CHD in those individuals with high levels of TC and LDL (13). Data from the Lipid Research Clinic (21) established the final link between cholesterol and the incidence of CHD risk. This study investigated 3,806 men over seven years and showed convincingly that a 1% reduction in TC resulted in a 2% reduction in myocardial infarction and sudden cardiac death. Later, the National Institutes of Health Consensus Conference on Cholesterol advocated the aggressive identification and treatment of individuals suffering from elevated blood cholesterol (26).

This medical mandate gave rise to a tremendous amount of research on cholesterol. Basically, after consumption, dietary cholesterol and fat appear in the bloodstream and are immediately transported to the liver. Dietary cholesterol has a very small influence on circulating cholesterol (less than 15%), but nevertheless should be reduced (6,14). It is the consumption of fat (e.g. triglycerides) that has a tremendous impact on circulating cholesterol. The ingestion of dietary fats gives rise to elevated cholesterol levels in the circulation. After traveling to the liver these globules are converted into the various cholesterol fractions (14). The enzyme regulating the production of cholesterol and bile acids in the liver is 3-hydroxy-3-methylglutaryl-CoA reductase (9). The preponderance of drug-related therapy is based upon inhibiting this enzyme for reducing serum cholesterol levels.

During this same time, a substantial body of evidence was accumulating regarding the low incidence of CHD in certain populations. Further investigation indicated that one of the main correlated items was the ingestion of a diet high in fiber (20). These findings soon led to further research regarding the turnover of cholesterol within the GI tract. It soon became evident that the majority of cholesterol is excreted into the GI tract from the bile duct, as bile salts.

The understanding of cholesterol-GI recycling led to the discovery that certain products could bind up bile salts, and thus reduce the ability for cholesterol to be reabsorbed back into circulation (5,8). The actual mechanism of action for dietary fiber is still unclear (5). It has been purported that dietary fiber combines with the bile salt-cholesterol molecule for transport out of the body. Some products like guar gum and pectin have a greater affinity for bile salts and therefore have a greater ability to reduce circulating cholesterol. Guar gum and pectin have been purported to exert their effect due to their viscosity (5,19,36). These two resins may increase the resistance for cholesterol absorption at the intestinal wall by altering the unstirred water micro-layer (19). Regardless of the mechanism, there is accumulating evidence in both animal and human studies regarding dietary fiber's influence on reducing serum TC and LDL.

In the present study, serum TC was significantly reduced after three months of dietary fiber supplement ingestion. The 15% reduction in TC achieved using a natural dietary fiber is as aggressive as that found using cholesterol-lowering drugs. In a controlled study using 40 mg pravastatin per day, Milani et al. (23) reported a decrease in serum TC by 23% after four weeks. Serum LDL was decreased by 31%. Similar findings have been reported in other studies (16, 23, 27).

In summary, patients at risk for coronary heart disease exhibited significant reductions in serum cholesterol after using a natural dietary fiber supplement. This fiber supplement is manufactured by Rexall Showcase International under the trade name *Bios Life 2[®] Natural*. The magnitude in change was as initially anticipated and the current findings support the use of a natural dietary supplement for cholesterol management in adults.

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