

Evaluation of the Efficacy of Flaxilip Capsule for Hypercholesterolemic Patients

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Summary

Clinical trial of the Flaxilip Capsule was carried out for the treatment of hypercholesterolemia associated cardiac disorders; the efficacy was reviewed on the basis on lipid profile. The trial conducted in total 51 patients and significant results were observed in elevated lipid profile compared to control group. Flaxilip capsule was found undoubtedly effective and safe for the majority of patients with hypercholesterolemia associated cardiac disorders.

Key Words: Flaxilip, hyper cholestrolemic, cardiac disorder, angina, hyperlipidemia and clinical study.

Introduction

Cholesterol is one type of fat or lipid; this fatty substance present normally in our body and is essential for normal functioning of the body. Any excess cholesterol that is not used by the body can negatively affect our arteries over the time. This fatty material begins to adhere as plaque to the walls of the arteries. High cholesterol increases risk for cardiovascular disease and stroke. Medical conditions such as diabetes mellitus, hypothyroidism, kidney disease, liver disease, alcoholism, as well as certain medications, can cause elevated lipid levels. Family history of high cholesterol may also mean that a person is genetically at risk for high lipids.

There are several types of fat of which high density lipoprotein (HDL), low density lipoprotein (LDL) and Triglycerides (TG) are most important. HDL is known as good cholesterol while LDL as bad cholesterol. Excessive levels of this LDL accumulate on the walls of the arteries; reduce the blood flow leading to diseases like heart attacks, atherosclerosis, and ischemic heart diseases etc.

There are many herbs which have been described in Indian system of medicine which help in reducing lipid level. Flaxlip is a perfectly blended formulation Linseed oil, *Commiphora mukul*, *Allium sativum* and *Trigonella foenum graecum*. It helps in managing the cholesterol levels in the body by naturally and safely improving cholesterol synthesis and thereby regulates lipid metabolism. It reduces LDL and increases the HDL level.

***Linum usitatissimum* (Flaxseed, Linseed)** contains a substance called alpha linolenic acid, which is known as an omega-3 fatty acid, it appears to reduce the risk of heart disease and numerous ailments¹. Alpha-linolenic acid is a biologic precursor to omega-3 fatty acids such as eicosapentaenoic acid. Although omega-3 fatty acids have been associated with improved cardiovascular outcomes, evidence from human trials is mixed regarding the efficacy of flaxseed products for coronary artery disease or hyperlipidemia². Several studies indicate that flaxseed oil, as well as ground flaxseeds, can lower cholesterol, thereby significantly reducing the risk of heart disease. Taking flaxseed oil may also protect against angina (chest pain) and high blood pressure. In addition, a five-year study done recently at Boston's Simmons College found that

flaxseed oil may be useful in preventing a second heart attack. It may also help prevent elevated blood pressure by inhibiting inflammatory reactions that cause artery-hardening plaque and poor circulation¹. Flaxseed is lowering cholesterol levels in people with high cholesterol. Various flaxseed preparations seem to significantly reduce total cholesterol and the “bad cholesterol”, low-density lipoprotein (LDL) cholesterol. Flaxseeds have much effect on “good cholesterol,” high-density lipoprotein (HDL) cholesterol³.

Allium sativum (**Garlic**) is having hypolipidemic, antiplatelet and pro-circulatory effect. Allium lowers total- and LDL-cholesterol and triglyceride concentrations without affecting HDL-cholesterol concentrations. Garlic has a protective effect from atherogenic diets, both in human and animals. The garlic preparations showed significant reduction on serum cholesterol level in clinical as well as experimental studies^{4, 5}. Allium sativum has been reported to exhibit beneficial effects in atherosclerosis and ischemic heart disease in experimental animals and human beings^{6, 7}. Garlic is typically used to prevent heart disease (including atherosclerosis, high cholesterol), Cancer, Infections, Colds conditions. Garlic supports the cardiovascular system and helps to lower high cholesterol. It helps decrease the risk factors for developing atherosclerosis. It may help decrease the fatty deposits on blood vessels and has a mild blood thinning effect⁸.

Commiphora mukul decreases LDL cholesterol and triglycerides by 15% to 20%. It inhibits liver cholesterol synthesis. At the same time it increases blood levels of HDL cholesterol. *Commiphora mukul* helps reduce high cholesterol by lowering harmful low-density lipoproteins while elevating the beneficial high-density lipoproteins. It helps prevent blood platelet aggregation and breaks up already formed blood clots. Guggul helps reduce high cholesterol, because it lowers harmful low-density lipoproteins while elevating the beneficial high-density lipoproteins. It helps prevent blood platelet aggregation and breaks up ready formed blood clots. Thus, it helps prevent heart disease and stroke⁹. It is known to prevent heart disease and stroke, treat weight gain, enhance thyroid function, stimulate the activity of white blood cells in the body, boost immune system, and its lipid helps eliminate and expel dead tissues, wastes, and toxin from the body. The usefulness of Guggul for treatment of obesity and other disorders of fat,

including coating and obstruction of channels have been described in Ayurveda medical text in details. The results of the various studies indicated guggul as a natural cholesterol lowering substance, safe and more effective than many cholesterol-lowering conventional drugs¹⁰. The guggulsterones are the main steroidal component isolated from the crude extract responsible for lowering elevated lipid profile. Studies indicated reduction in triglycerides and cholesterol (including both LDL and VLDL) and a raise in HDL cholesterol after its regular use¹⁰. The active ingredient responsible for the use of the plant in maintenance of healthy cholesterol levels is guggulsterones [4, 17(20)-pregnadiene-3, 16-dione], specifically guggulsterones E and guggulsterone Z¹¹.

Trigonella foenum graecum (**Fenugreek**) is used as a spice and traditionally as medicine. Fenugreek is having hypocholesterolemic effect. Fenugreek is currently available commercially in encapsulated forms and is being prescribed as dietary supplements for the control of hypercholesterolemia and diabetes by practitioners of complementary and alternative medicine¹². Fenugreek finds its uses in treating hyperglycemia, hyperlipidemia and disorders of gastro-intestinal and cardiovascular systems¹³. The well documented therapeutic uses of fenugreek are its hypoglycemic and hypolipidemic activity¹⁴; Fenugreek is rich in steroidal (furostanol) saponins – notably trigoneosides and diosgenic – which appear responsible for its healthful effects on blood fat and cholesterol levels. Serum total cholesterol, LDL and VLDL (bad) cholesterol, as well as triglyceride levels, can be significantly reduced, while HDL (good) cholesterol levels remained unchanged¹⁵.

Material and Methods

The purpose of this study was to evaluate the effect of Flaxilip capsule in hyperlipidemia and hypercholesterolemic disorders associated with cardiac disorders. Total 51 patients were enrolled in the study with an age group of 20-75 years. Fifty one diagnosed cases of hypercholesterolemia were selected for this clinical trial. Most of the cases had evidence of angina pectoris, hypertension and obesity. Diabetic cases were excluded from this study. For comparable results, apparently normal individuals with no evidence of lipid disorders were selected to serve controls.

A comprehensive clinical examination was carried out. A part of routine investigations, obesity index were also measured. The overnight fasting blood sample was taken and the lipid profile was measured. One Flaxilip capsule was administered two times a day for the period of twelve weeks. The normal as well as hypercholesterolemia cases were advised a prescribed regimen of diet and exercise during the entire course of study. At the end of twelve weeks all the investigations were repeated. Those cases who could not follow up the prescribed regimen diet and therapy were excluded from the study. The initial findings were compared with those after 12 weeks of follow up.

RESULTS AND DISCUSSION

Out of the 51 patients completed the trial, 13 patients were noted for complaint of Angina pectoris, 12 patients for Hypertension while 26 patients were obese.

Table 1: Clinical Diagnosis of Cardiac disorders and number of patients

Clinical Diagnosis	No. of Patients
Angina Pectoris	13
Hypertension	12
Obesity	26
Total	51

Table 2: Control Group Cholesterol Level

Group	Total cholesterol (mg/dl)	LDL cholesterol (mg/dl)	HDL cholesterol (mg/dl)	TC/HDL-C (risk factor)
Initial	255.10 ± 16.84	231.82 ± 11.82	51.60 ± 6.4	4.96 ± 0.77
After 12 weeks	268.80 ± 20.30	201.82 ± 16.32	49.80 ± 5.26	5.39 ± 0.72
P Value	P< 0.05	P< 0.05	P< 0.05	P< 0.05

Table 3: Effect of Flaxilip capsule on Cholesterol Level

Group	Total cholesterol (mg/dl)	LDL cholesterol (mg/dl)	HDL cholesterol (mg/dl)	TC/HDL-C (risk factor)
Initial	280.09 ± 46.68	220.82 ± 13.72	49.05± 11.72	6.19 ± 2.30
After 12 weeks	204.08 ± 40.66	131.82 ± 12.62	54.07± 11.89	4.03 ± 1.43
P Value	P< 0.001	P< 0.001	P< 0.05	P< 0.001

A significant elevated level of total cholesterol and LDL cholesterol was noticed in the present study. After 12 weeks of Flaxilip capsule treatment reverse trend was observed. Total cholesterol and LDL cholesterol showed a decreasing trend and the ratio also decreased to a significant extent. In the normal control series no significant changes in either the total cholesterol and LDL cholesterol or TC/ HDL ratio. Thus it is evident that Flaxilip has a capacity to modify the increased lipid profile. HDL is the one of the most important risk factors for the development of coronary heart disorders. High HDL cholesterol prevents atherosclerosis and reduces the risk of coronary heart diseases. Alcohol and moderate exercise are responsible for increasing the level of HDL cholesterol level. The hypolipidemic drug generally does not elevate the level of HDL cholesterol. The drug which can increase the level of HDL cholesterol may be considered as cardio protective. Flaxilip contains Linseed oil and combined effect of other ingredients may be responsible for cardio protective action. The continuous oral administration of Flaxilip may prevent the development of coronary heart disorders. The present study is preliminary in nature and requires a bigger sample size to prove the beneficial effect of Flaxilip capsule.

CONCLUSION

We performed this study to evaluate the effect of Flaxilip Capsule on hypercholesterolemia. The positive influence of Flaxilip Capsule observed on the hypercholesterolemia and cholesterol related cardiac disorders. Flaxilip Capsule was helpful in providing significant change in elevated lipid profile. No adverse effects were reported by the patients. Thus, Flaxilip Capsule can be considered a useful and safe remedy for hypercholesterolemia and related cardiac disorders.

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