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Original Article

Conventional and Herbal Therapy for Hyperlipidemia: A Major Risk Factor for Coronary Artery Disease

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Abstract

Objective: To observe the effects of Nigella sativa and Gemfibrozil's hypolipidemic with on lipid profile.

Patients & Methods: It was a single blind placebo-controlled study done in two months' time. Hyperlipidemic patients of both sexes with age range from 20 to 70 years were enrolled after getting approved consent from them. Patients with renal dysfunction, any liver disease, hormonal disturbances, peptic ulcer disease, or with any metabolic disease were excluded from the study. In total 75 hyperlipidemic patients were selected from Jinnah Hospital Lahore and divided in three groups. Group-I was on Nigella sativa, Group-II was on Gemfibrozil 600 mg, and Group-III was placebo group. Patients were advised to use these medications for 8 weeks. Serum LDL-cholesterol was calculated by Friedwald formula. Data were expressed as the mean ± SD and "t" test was applied to determine statistical significance as the difference. A probability value of <0.05 was considered as significant and P<0.001 was considered as highly significant change in the results when pre and post-treatment values were compared.

Results: In two months' therapy, Nigella sativa decreased 30.30, 37.8, 31.7 mg/dl of total cholesterol, triglycerides, LDL cholesterol respectively and increased HDL cholesterol 4.7 mg/dl. Gemfibrozil decreased 43.6, 34.2, 38.2 mg/dl respectively and raised HDL cholesterol 7.5 mg/dl.

Conclusion: Conventional allopathic hypolipidemic drugs effects are nearly the same as that of herbal medicine Nigella sativa.

Key words: Hyperlipidemias, Lipid profile, Lipid lowering agents, Nigella sativa,

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Introduction

Both Primary as well as secondary hyperlipidemias are independent risk factor for development of coronary artery disease. Low density lipoprotein (LDL) causes oxidation in systemic circulation and in result atherosclerotic plaque get deposited in walls of blood vessels leading to narrowing of blood vessels which may result to development of Coronary Artery Disease (CAD).[1,2] Atherosclerosis is the underlying cause of most diseases of the heart and blood vessels, collectively referred to as cardiovascular disease, which is the leading cause of death in the U.S. According to the Centers for Disease Control and Prevention, cardiovascular disease accounted for nearly 1 in every 3 deaths in 2010.[3,5] Lipid lowering agents are used to treat CAD due to atherogenesis. These drugs have some adverse effects, so their low compliance have made cardiologist to choose herbal medicines like Nigella sativa (kalonji) which have low adverse effects.[1-4] Conventional treatment of hyperlipidemia include use of statins, fibrates, bile acid binding resins and niacin. Fibrate treatment results in the formation of Lipoprotein lipase with a higher affinity for the LDL receptor, which are thus catabolized more rapidly.[2] Fibrates increase the production of apoA-I and apoA-II in liver, which may contribute to the increase of plasma HDL concentrations and a more efficient reverse cholesterol transport.[2-6] Hypotriglyceridemic action of fibrates involves combined effects on lipoprotein lipase and apoC-III expression, resulting in increased lipolysis.[7] Many studies have shown good potential of hypoglycaemia, hypocholesterolemia and antioxidant effects of Nigella Sativa, which contribute to its cardioprotective effects.[8] The major mechanism this seems to be effective is simply by preventing the dietary cholesterol from being absorbed in the intestines where fat is digested. Another way that seems to work is by increasing the flow of bile acids, which binds

the cholesterol in the digestive track and excretes it in the feces.[1,7]

Patients and Methods

This was single blind placebo-controlled study, conducted at Jinnah Hospital, Lahore from February 2012 to July 2012.

Seventy-five newly diagnosed primary hyperlipidemic patients of either sex and age range from 20-70 years were selected. Permission was taken from ethical review board and written consent was taken from all patients. Specific Performa was designed for the research work. Patients with history of hypothyroidism, diabetes mellitus, alcoholism, peptic ulcer, any gastrointestinal upset, renal impairment, and any hepatic or cardiac problem were excluded from the study. All patients were divided in three groups (Group-A, Group-B, Group-C), 25 in each group. Their baseline experimental data was taken and filed in specifically designed Performa, at start of taking medicine, like fasting lipid profile, blood pressure and pulse rate. The study period was eight weeks. Twenty-five patients of Group-A were advised to take one tea spoon of Kalonji, twice daily, i.e.; one tea spoon after breakfast and one tea spoon after dinner. Twenty-five patients of Group-B were advised to take Gemfibrozil 600 mg tablets, one after breakfast and one after dinner. Twenty-five patients were provided placebo capsules, (containing grinded wheat), taking one capsule after breakfast and another before going to bed. All participants were advised to take these medicines for eight weeks. They were also advised for 20 minutes' brisk walk in the morning or evening time. Patients were called every 2 weeks for follow up to check blood pressure, weight, pulse rate and general appearance of the individual. Drug compliance to the regimen was monitored by interview and counseling at each clinical visits. Serum LDL-cholesterol was calculated by Friedwald formula[9] (LDL-Cholesterol = Total Cholesterol-(Triglycerides/5 +HDL-Cholesterol). Data were expressed as the mean ± SD and "t" test was applied to determine statistical significance as the difference. A probability value of <0.05 was considered as significant and P<0.001 was considered as highly significant in the results when pre and post-treatment values were compared.

Results

Two months' therapy by Nigella sativa decreased 30.30, 37.8, 31.7 mg/dl total cholesterol, triglycerides, LDL cholesterol respectively and increased HDL cholesterol 4.7 mg/dl. Gemfibrozil decreased 43.6, 34.2, 38.2 mg/dl respectively and raised HDL cholesterol 7.5 mg/dl.

This decrease in total-cholesterol, LDL-cholesterol, triglycerides and increase in HDL-cholesterol by Nigella sativa and Gemfibrozil compared to placebo treatment was statistically significant. Results are shown in table 1, 2 and 3.

Table 1: Lipid profile before and after treatment in group A (n=25)

Parameter	Before Treatment (Mean +SD)	After Treatment (Mean +SD)	p Value
TC (mg/dl)	231.21±1.12	200.90±3.11	<0.001
TG (mg/dl)	178.90±3.01	141.10±1.01	<0.001
LDL-C (mg/dl)	191.14±3.45	159.40±2.98	<0.001
HDL-C (mg/dl)	36.48±2.11	41.17±1.88	<0.001

Table 2: Lipid Profile before and after treatment in group B (n=25)

Parameter	**Before Treatment (Mean +SD)**	**After Treatment (Mean +SD)**	p Value
TC (mg/dl)	240.92±2.21	197.31±1.00	<0.001
TG (mg/dl)	204.31±1.26	170.14±2.93	<0.001
LDL-C (mg/dl)	197.77±3.91	159.62±2.20	<0.001
HDL-C (mg/dl)	32.97±3.10	40.45±2.22	<0.001

Table 3: Lipid Profile before and after treatment in group C (n=25)

Parameter	**Before Treatment (Mean +SD)**	**After Treatment (Mean +SD)**	p Value
TC (mg/dl)	213.11±2.32	210.10±2.91	>0.05
TG (mg/dl)	170.00±3.01	161.70±3.91	>0.05
LDL-C (mg/dl)	163.104±1.45	159.40±1.77	>0.05
HDL-C (mg/dl)	31.12±1.01	31.69±2.00	>0.05

*TC= serum total cholesterol, TG= serum triglycerides, LDL-C= low density lipoprotein cholesterol, HDL-C= high density lipoprotein cholestero*l

Discussion

Hyperlipidemia causes atherogenesis which lead to development of CAD, causing morbidity and mortality due to cardiac arrest or cardiac arrhythmias. Traditionally used hypolipidemic drugs have low patient's compliance due to their side effects. Medicinal herbs are going to get popularity due to their mild or no side effects. In this research we compared lipid lowering effects of Nigella sativa and Fibrates, when used in hyperlipidemic patients for eight weeks. Changes in all parameters of lipid profile (i.e.; serum cholesterol, triglycerides, LDL-cholesterol and HDL-cholesterol) were highly significant in two drug groups when they compared with placebo-controlled group, and serum total cholesterol in Nigella sativa group was highly significant with p value of <0.01. Our results regarding lipid lowering effects of Nigella sativa match with results of research work conducted by Hossein H et al who did see reduction of serum total cholesterol 13.01 %, triglycerides 9.1 %, LDL cholesterol 17.89 % and HDL-cholesterol increased 23.62 %.[10] Ghoneim MT et al proved highly significant changes in lipid parameters of hyperlipidemic rats when they used one teaspoon of Nigella sativa oil twice daily for 3 weeks.[11] These results are comparable with results of our work. Rahman A et al conducted a research on

hyperlipidemic patients and proved 12.76, 8 %, 15 % decrease in serum cholesterol, triglycerides, and LDL-cholesterol in 19 days when they used kalongi oil.[12] They have explained marked protective action of Nigella sativa against ischemic reperfusion-induced gastric mucosal lesions, an effect that was mediated by suppression in the level of lipid peroxide and lactic dehydrogenase and an increase in those in glutathione and superoxide dismutase. Burits M and Mand Bucar F observed 10.11 %, 12.51 %, 12.45 % reduction in total cholesterol, triglycerides, and LDL-cholesterol respectively, when they used kalongi oil for two months in hyperlipidemic patients.[13] Our results are in contrast with research work results of Rajmani K et al who observed (11%) increase in HDL-cholesterol with use of Kalonji for 4 weeks in 19 patients suffering from Hyperlipidemia.[14] This difference is surely due to large sample size in their study and duration of research study. Another observation was also made by Keech AC et-al reporting that treatment with fenofibrate in individuals with type 2 diabetes mellitus reduces the need for laser treatment for diabetic retinopathy.[15]

Conclusion

Hypolipidemic effects of Nigella sativa are nearly the same as traditionally used hypolipidemic agent Fibrates so it can be used safely without side effects.

Conflict of Interest

This study has no conflict of interest as declared by any author.

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