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RESEARCH ARTICLE

SINGLE BLIND PLACEBO-CONTROLLED STUDY ON COMPARISION OF EFFECTS OF ZINGIBER OFFICINALE BEFORE AND AFTER TREATMENT IN HYPERLIPIDEMIA

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ABSTRACT

Hyperlipidemia had have proved in many research studies causing atherosclerosis, coronary artery disease, angina and myocardial infarction. Hypolipidemic drug's low compliance made medicinal herbs to replace conventional hypolipidemic agents for treating primary or secondary hyperlipidemic patients. Zingiber Officinale (Ginger) is one of those medicinal herbs. This research was conducted at General Hospital Lahore Pakistan from March to May 2015. It was single-blind placebo controlled study. Inclusion criteria was primary and secondary hyperlipidemic patients age range from 18 to 65 years. Male and female patients were included in this work. Randomly selected eighty patients were divided in two equal numbers. Group-I was tested group and Group-II was on placebo therapy. Their base line values of LDL-cholesterol and plasma total cholesterol were measured in Biochemistry laboratory of the Hospital. When used in 40 hyperlipidemic patients this herb's paste preparation reduced LDL-cholesterol and plasma total cholesterol significantly. Mean values of LDL-cholesterol and plasma total cholesterol with SEM before and after treatment were calculated and analyzed biostatistically by using SPSS version 5.0. P-values >0.05 were used for non-significant change in parameters. P-values <0.01 and <0.001 were used for significant and highly significant changes respectively.

INTRODUCTION

Metabolic syndrome is combination of disorders related with altered state of metabolism of Carbohydrates, Proteins and Lipids in human body. HYPERLIDEMIA is one of these disorders. High plasma level of lipids taken by food or synthesized in form of cholesterol by liver are risk factors to development of HYPERLIPIDEMIA[1-3]. Total cholesterol and LDL-cholesterol are main factors causing oxidation of LDL leading to formation of atherosclerotic plaques, which causes coronary artery disease, hypertension, CCF, angina and cardiac arrhythmias[4]. Conventionally used Antihyperlipidemic drugs include HMG-CoA reductase inhibitor STATINS, Niacin, Bile acid binding resins, and Fibrates. Their compliance is low due to their unwanted effects in different parts of body or their therapeutic dose recommended[5]. Zingiber Officinale (Ginger) contains Carbohydrates, fats, proteins, dietary fibers, zinc, sodium, potassium, phosphorus, manganese, magnesium, iron, calcium, vitamin C, E, and B-1,2,3,5,6, and vitamin B-9[6-10]. Dietary fibers, vitamin C, vitamin E and vitamin B-3 (Niacin) in Zingiber Off. are responsible to cause hypolipidemic effects of this herb[11]. These vitamins are responsible for hypolipidemic effects of the herb, which act as antioxidant. In many research studies it has been proved that free radical formation (ROS) is lowered by using these vitamins. In various studies it has also been proved that vitamin B-3, C and E utilize these Reactive Oxygen Species (ROS) synthesized in many metabolic pathways leading to lowering of oxidative stress, atherosclerosis, CAD and its consequences like hypertension, CCF, angina, MI, and cardiac arrhythmias[12].

SUBJECTS & METHODS

The research work was conducted from March 2015 to May 2015. Eighty male and female patients age range from 18 to 65 years with high lipid profile were selected in the research work conducted at General Hospital, Lahore-Pakistan.

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The study was single blind placebo controlled. Duration of study was 12 weeks. Explained and written consent was taken from all participants. Research work on human beings and its objectives were approved from Ethical Committee of the Hospital. Exclusion criteria was peptic ulcer disease, alcohol abuse, cigarette smoking, any liver, or renal disease and thyroid dysfunction. Patients were divided in two groups, i.e. group-I (n=40) was advised to take equally divided dose of 5 grams of Pasted Ginger with each meal thrice daily for three months. Group-2 was on placebo therapy, provided Capsules containing grinded wheat, to take thrice daily for three months. To be tested parameters of LDL-cholesterol and Total-cholesterol were determined in Biochemical laboratory of the Hospital. Serum total cholesterol was estimated by the enzymatic calorimetric method. Serum LDL-cholesterol was calculated by Friedwald formula[5] (LDL-Cholesterol = Total Cholesterol-(Triglycerides/5 +HDL-Cholesterol). Data were expressed as the mean ± SEM and paired "t" test was applied to determine statistical significance as the difference. A probability value of <0.05 was considered as non-significance and P<0.001 was considered as highly significant change in the results, while p<0.01 was labeled as significant alteration in tested parameter.

RESULTS

After three months, when data were ready to analyze, it was observed that 3 patients withdrew to take Ginger due to their personal problems, and low compliance of the drug. In three months therapy by Ginger, LDL-cholesterol reduced from 199.08±2.29 mg/dl to 187.56±1.96 mg/dl, which is highly significant change in the parameter. Serum total cholesterol at baseline was 279.66±1.22 mg/dl which reduced to 268.95±1.11 mg/dl after three months therapy. These changes are significant statistically. In placebo group LDL-Cholesterol, and serum total cholesterol reduction was 0.7 mg/dl, and 0.2 mg/dl respectively. All these changes are non-significant (p-value >0.05). Detailed changes are shown in table.

Table Explaining changes in parameters before and after treatment with Zingerber Officinale

	ZINGEBER Off **(n=37)**	Placebo **(n=40)**
Before	TC 279.66±1.22 LDL-c 199.08±2.29	Tc 268.95±1.11 Ldl-c 187.56±1.96
After	TC 267.21±1.09 LDL-c 178.29±1.08	Tc 267.01±1.11 Ldl-c 177.64±1.34
Change	TC 12.5 LDL-c 20.8	Tc 0.2 Ldl-c 0.7
Change in %	TC 4.5 LDL-c 10.4	Tc 0.1% Ldl-c 0.4%
p-value	TC <0.01 LDL-c <0.001	Tc >0.05 Ldl-c >0.05

KEY: P-value <0.001 = highly significant, P-value <0.01= significant, p-value >0.05 = non-significant changes in lipid profile. Total-cholesterol-c and LDL-c values are measured in milligrams per DL. 'n' indicates number of patients (sample size) in tested and placebo group. All parameter's mean values and their difference between before/ after treatment values are measured in mg/dl. TC stands for total plasma cholesterol, LDL-C stands for low density lipoprotein cholesterol.

DISCUSSION

Simply, dyslipidemia is related with morbidity and mortality though out the world due to its complication like atheroma formation, CAD, hypertension, angina and myocardial infarction. In allopathy Hyperlipidemia either secondary or primary is simple to treat, but broad canvas of pharmacological effects of allopathic drugs made them unpopular in human population. Simply it is low drug-compliance. Herbal medicinal preparations are on way to replace unpopular allopathic drugs for treating Hyperlipidemia. Medicinal herb Zingiber Off. contain vitamin C, vitamin E, and vitamin B-3 which act as antioxidant agents. In our research work LDL-cholesterol reduction by three months treatment by Zingiber Off. was 10.4%. When anlalysed statistically it was highly significant change. In total cholesterol this reduction in 37 hyperlipidemic patients was 4.5%, which is significant when analyzed biostatistically. Our results are being supported when we compare these changes with results of work conducted by Bordia A et al[13] who proved that Ginger can reduce LDL-cholesterol higher than plasma total cholesterol when used in primary or secondary sufferer patients of Hyperlipidemia. Janssen P et al[14] has also explained being main target of LDL oxidation which is independent risk factor for development of coronary artery disease. Srivastava KC[15] proved lesser effects of Ginger utilization by 50 hyperlipidemic patients suffering from secondary Hyperlipidemia. He proved that Ginger can reduce only five to six percent LDL-cholesterol and plasma Total-cholesterol, respectively in secondary Hyperlipidemia. Reason for this contrast in two studies are obviously due to selective sample i.e. patients suffering from secondary Hyperlipidemia. Shoji N et al[16] have explained that patients enjoying sedentary

life, alcohol abusers, cigarette smokers and fond of eating junk foods are more prone to develop too much oxidative stress as compared to patients of primary Hyperlipidemia. For most patients, the root causes of the metabolic syndrome are thought to be poor nutrition, inadequate physical activity, and subsequent increases in body weight. Obesity is associated with insulin resistance and the syndrome's cluster of other metabolic disorders. However, there are many interrelated factors that are thought to be important in the development of metabolic syndrome.

CONCLUSION

It was concluded from this research work that hypolipidemic herbal medications can play major role in prevention of atherosclerosis, coronary artery disease (CAD), Congestive Cardiac Failure, Angina, and Myocardial Infraction if taken in specific amount by primary or secondary hyperlipidemic patients. It is also recommendation for pharmaceutical industries that isolated active ingredients of Ginger can be used to prepare new generation of hypolipidemic drugs.

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