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HERBAL MEDICINE IS EFFECTIVE FOR LOWERING SERUM LIPIDS WITH LEAST SIDE EFFECTS

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ABSTRACT

In past 2 decades hyperlipidemia, hypertension and hyperglycemia has gained especial attention of medical researchers to combat with these morbid and mortal pathological conditions. These pathological states eventually leading to development of cardiovascular metabolic syndrome are leading cause of morbidity and mortality throughout the world. Various drug groups and regimen are being used to handle these problems but none is absolute satisfactory due to their widespread side effects and low compliance. Conventional use of nigella sativa for many diseases are now emerging in allopathic discipline of healthcare to cure various diseases with good compliance and no important side effects. This study was single blind placebo-controlled, conducted in Lipid Research Centre, Pakistan Institute of Cardiology, Lahore, Pakistan, from March to May 2011. Study period was one month. Sixty male and female hyperlipidemic patients age range from 22 to 65 years were included in the research with written explained and approved consent. All patients were divided in two equal groups. In Group-I, 30 male female patients were advised to take two spoons of kalonji after breakfast for the period of four weeks. In group-II, 30 male & female hyperlipidemic patients were advised to take placebo capsules after breakfast everyday for the period of four weeks. There baseline values of LDL-cholesterol, HDL-cholesterol, serum total cholesterol and body weight were noted in specially designed proforma. They were asked to come for follow-up, fortnightly. At the end of research work, mean values of all parameters with ±SD were analyzed statistically using paired 't' test. These results were compared with placebo therapy and observed that all parameters showed highly significant change, with p-value <0.001. We concluded from these results that kalonji is very effective herbal drug to maintain lipid profile in normal states without adverse effects and any low compliance reported.

Key words: *Kalonji. Serum lipids. Lipoproteins. Heart attacks. Morbidity and mortality. Kalonji.*

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INTRODUCTION

The use of plants as medicine is gaining prominence around the world. In addition to being very important in traditional herbal medicine, these herbs are very often used to develop prescription medications[1]. Experts estimate that over 50% of all current prescription drugs are derived from modified molecules extracted from plants. The best known examples include penicillin (from fungus), morphine and codeine (from the opium poppy seeds) and digoxin (from foxglove)[2]. Over 80% of the world population uses natural remedies as medicine and over 70% of doctors in Germany prescribe plant-based medicines[3]. In the last 20 years, natural medicine gained great popularity by many individuals around the world. The demand for information on herbs and supplements continues to increase[4]. There are as many health care professional in the practice of natural health as there are medical doctors. The demand is driven by many more individuals seeking holistic approach to health care prevention and treatment[5]. Dyslipidemia is a common risk factor for cardiovascular disease, the leading cause for morbidity and mortality among patients[6]. Nigella sativa is an easily available and acceptable remedy to treat dyslipidemia and at a low cost[7]. Nigella sativa is a small plant originating in the Middle East and is found abundantly, growing wild in Egypt, Asiatic Turkey and the Balkan States. The seed extracts from this plant are used by herbalists in the treatment of several medical disorders including dyslipidemia[8].

MATERIAL AND METHODS

Sixty patients with high lipid profile were included in the research work conducted at Pakistan Institute of Cardiology, Lahore, Pakistan. Study was conducted in LIPID CONCERNED CLINIC, at the Hospital. The study was single blind placebo controlled. Duration of study was four 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 alcoholics, chain smokers, patients suffering from any liver disease, renal disease, peptic ulcer, already on vital medicines for treating vital organs of the body. Gender of participants was both male and female patients, age range from 22 to 65 years. Patients were divided in two groups, i.e.; group-I was advised to take two tea-spoons of Kalonji after breakfast everyday for the period of four weeks. Group-2 was on placebo therapy. The research work was conducted from March 2011 to May 2011. All pretreatment values of LDL- cholesterol, serum total cholesterol, HDL-cholesterol and body weight were determined by laboratory investigations and clinical examination of patients. Serum total cholesterol was estimated by the enzymatic calorimatic method. High density lipoprotein cholesterol was estimated directly by using kit cat number 303489329. Serum LDL-cholesterol was calculated by Friedwald formula[5] (LDL-Cholesterol = Total Cholesterol-(Triglycerides/5 +HDL-Cholesterol). Body weight was determined by weight machine provided by Lipid Concerned Clinic of the hospital. Data were expressed as the mean ± SD 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.

RESULTS

In one month therapy by nigella sativa, LDL-cholesterol reduced from 185.21±2.01 to 157.72±1.90 mg/dl, which is highly significant change in the parameter. Serum total cholesterol at baseline was 251.11±2.00 mg/dl, which reduced to 230.71±1.77 mg/dl. HDL-cholesterol increased from 31.70 mg/dl to 36.01±1.80 mg/dl. Mean body weight decreased from 79.01± kg to 77.32±2.61 kg in four weeks therapy. All changes are highly significant statistically. In placebo group LDL-Cholesterol, serum total cholesterol and body weight reduction was 0.18, 0.77, and 0.22 % respectively. Increase in HDL-cholesterol was 0.11 % in one month by placebo therapy. All these changes are non-significant (p-value >0.005). Detailed changes are shown in TABLE NO 1.

TABLE NO: 1

Results of drug and placebo therapy on lipid profile and body weight, with statistical analysis in 60 hyperlipidemic patients

Values used in stats	LDL-C	T-C	HDL-C	Body weight
GP-1(On Drug)				
Baseline	185.21±2.01	251.11±2.00	31.70±3.11	79.01±3.01
Aftertreatment	157.72± 1.90	230.71±1.77	36.01±1.80	77.32±2.61
Change in %	17.41%	8.83%	11.94%	2.11%
Stat: Sign (P-value)	<0.001	<0.001	<0.001	<0.05
GP-2(On Placebo)				
Baseline	143.25±1.99	190.47±2.71	35.87±2.22	76.73±2.19
Aftertreatment	142.98±2.61	188.99±2.50	35.91±3.72	76.56±2.71
Change in %	0.18%	0.77%	0.11%	0.22%
Stat: Sign(P-value)	>0.05	>0.05	>0.05	>0.05

KEY: ± indicates standard error of mean, p-value >0.05 indicates non significant and P<0.001 indicates highly significant change in lipid profile. LDL-C means low density lipoprotein cholesterol mg/dl, T-C means total serum cholesterol mg/dl, HDL-C means high density lipoprotein cholesterol mg/dl, and body weight is measured in kg. GP (group) I is on drug and GP (group) 2 is on placebo. Aftertreatment values are in negative except HDL-C value, which is positive.

DISCUSSION

Taking two spoons of kalonji everyday for one month can reduce serum bad-cholesterol and increase good-cholesterol remarkably. Low density lipoprotein cholesterol is known as bad cholesterol because its accumulation in blood vessels cause oxidation which leads to develop atherosclerosis, eventually causing ischemic heart disease and heart attack. In our research study kalonji was used in thirty male and female hyperlipidemic patients for one month, which reduced bad-cholesterol from baseline value of 185.21±2.01 mg/dl to 157.72 ±1.90 mg/dl. It is 17.4% change in this parameter, which is highly significant change statistically with p-value of <0.001. These results match with views of Ramadan MF[9] who mentioned in his overview research article that nearly same effects of kalonji oil may be achieved when the drug is used for three months, one spoon twice daily regularly. He has mentioned detailed

explanations regarding effects of kalonji in hypertensive, hyperlipidemic and hyperglycemic conditions. These results are in contrast with study results of Mohd Anwar Buriro et al[10] who observed less effect on LDL-cholesterol, i.e.; from 179.57±2.29 mg/dl to 166.92±2.11 mg/dl when they used kalonji one spoon for the period of 6 months in 82 hyperlipidemic rats. These variations and too much contrast in these two comparable studies may be sample size, long duration of administration of chemical compound/drug especially used in animal model. In our observation serum total cholesterol reduced from 251.11±2.00 mg/dl to 230.71±1.77 mg/dl. El-Dakhakhani M et al[11] observed almost same changes in serum total cholesterol when he used one spoon of kalonji twice daily for the period of one month. In our results it is proved that HDL-cholesterol increased from 31.70 mg/dl to 36.01±1.80 mg/dl, when 2 spoons of kalonji were used for one month in 30 hyperlipidemic male and female patients. Paired "t" test was applied to analyzed these results. P-value was <0.001 for these parallel results which suggested significant changes in pretreatment and post treatment values. These results match with study by Morikawa T et al[12] who observed 9% increase in HDL-cholesterol when they used 2 spoons of kalonji in 40 hyperlipidemic patients. Two spoons of kalonji reduced body weight of 30 male/female patients from 79.01± kg to 77.32±2.61 kg by one month therapy in our research design. Qidwai W, and H.B. Hamza[13] also observed same changes by their research study. It proved same effectiveness of kalonji in both studies. Zaoui, A, Cherrah, Y. et al[5] described presence of various chemical ingredients which are responsible to decrease high levels of serum lipid levels and decreased blood pressure in rats. They explained that kalonji contains melanthin 1.4%, cellulose 8.32%, sugar 2.75%, arabic acid 3.41%, ash 4.14%, fixed oil 37%, volatile oil 1.64%, albumin 8.2%, mucilage1.9%, organic acid precipitated by copper 0.38%, and metarabin 1.36%. Our results are in contrast with study results of Zahida T et al[14] who proved that there is no effect on body weight when 2 spoons of kalonji are used for two months. They also mentioned that in some individuals' kalonji decrease appetite and in some it increases appetite. Possible reason for that paradox results may be due to genetic and environmental variations in these patients.

CONCLUSION

In allopathic discipline of medical profession, hypertension, hyperlipidemia and hyperglycemia leading to development of cardiovascular metabolic syndrome has many limitations regarding its complicated drug regimen and poor patient compliance. We concluded from this research work that Nigella Sativa (Kalonji) is best replacement and comparable regimen for the management of dyslipidemia.

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