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Mild to Moderate Normalization of Lipid Profile, Blood Pressure and Body Weight of Obese and Hyperlipidemic Patients by Herbs and Allopathic Agents

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Abstract: The research study was planned to observe effects of Nicotinic acid (niacin) and psyllium husk on blood pressure, body weight, LDL-cholesterol and HDL-cholesterol. It was single blind placebo controlled research study, which was conducted at Lahore Journal Hospital, from April 2023 to December 2023. Forty male and female hyperlipidemic patients were included in the research study, among which 20 patients were on placebo as control group, and 20 were on tablet Niacin, 2.25 grams daily, in divided doses for the period of three months. Patients with diabetes mellitus, peptic ulcer, renal disease, hepatic disease, hypothyroidism and alcoholism were excluded from the study. Body weight and blood pressure of patients were recorded at fortnightly visit. LDL-Cholesterol was calculated by Friedwald formula (LDL= TC- (TG/5 + HDL-C). Serum HDL-cholesterol was determined by direct method. Serum cholesterol and triglycerides were estimated by the enzymatic calorimetric method. Data regarding results were expressed as the mean ± SD and "t" test was applied to determine statistical significance of results. A probability value of <0.05 was the limit of significance. Three patients were dropped from the study due to side effects of Niacin. In three months of treatment with 2.25 grams of niacin HDL-cholesterol increased from 36.41±1.96 to 43.70±1.81 mg/dl, which was highly significant change when analyzed statistically. Niacin has decreased LDL-Cholesterol from 182.58±8.74 mg/dl to 119.29±4.08 mg/dl, which was highly significant (P<0.001), when compared statistically by paired "t" test. Overall percentage (%) changes from day-0 to day-90 were 34.66. Triglycerides reduced from 169.64±7.60 to 137.35±6.31 mg/dl, which was highly significant (P value <0.001) reduction in three months. Niacin has also reduced Blood Pressure. Difference between mean values of systolic and diastolic blood pressure at day-0 and day-90 were found highly significant (P<0.001). Body weight was reduced from 66.29±194 kg to 64.79±1.82 kg in three months. This change was significant (P<0.01). We concluded from the research study that niacin decreases blood pressure, body weight and LDL-Cholesterol and increases HDL-cholesterol in primary hyperlipidemic patients. KEY WORDS: Blood pressure, diabetes, body weight, hyperlipidemia, herbs, allopathy.

Keywords: Nicotinic acid (Niacin), Hyperlipidemia, Blood Pressure, Dyslipidemia, B3 Vitamin.

Research Paper

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INTRODUCTION

Routine measurements that can help to diagnose dyslipidemia include total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol measurments [1]. The majority of cases of dyslipidemia in adults are not caused by primary disorders. They are most commonly due to secondary causes. The most common secondary cause of dyslipidemia in adults is a sedentary lifestyle coupled with excessive intake of saturated fat, cholesterol, and trans fats [2]. Other secondary causes of dyslipidemia include diabetes mellitus, hypothyroidism,

overuse of alcohol, and chronic kidney disease [3]. Although dyslipidemia usually doesn't cause symptoms, it can lead to symptomatic vascular disease, which includes coronary artery disease (CAD) and peripheral arterial disease [4]. Treatment of dyslipidemia is indicated for all patients who have cardiovascular disease and for some without. Treatment of dyslipidemia focuses primarily on reducing high levels of LDL cholesterol and secondarily on treating high levels of triglycerides, low levels of HDL cholesterol, and metabolic syndrome [5]. There are various drugs which decrease total cholesterol, triglycerides, LDL-Cholesterol and increase HDL-Cholesterol in primary hyperlipidemic patients, but nicotinic acid along with psyllium husk is the best LDL-Cholesterol lowering drug regimen among the lipid lowering agents. Nicotinic acid has another beneficial effect that it reduces body weight and blood pressure. Psyllium husk has more effects on cholesterol than triglycerides. When combinely administered in hyperlipidemic patients, these drugs can reduce 30% risk of developing atheroma, coronary artery disease and myocardial infarction in these patients [6]. Nicotinic acid acts as an antilipolytic agent in adipose tissue, reducing the supply of free fatty acids and hence the availability of substrate for hepatic triglyceride synthesis and the secretion of VLDL [7]. Psyllium husk is an oral anion-exchange resin, which binds bile acids in the intestine. Bile acids are formed from cholesterol in the liver, pass into the gut in the bile and are largely reabsorbed at the terminal leum. Most of the major bile acid transport proteins responsible for the enterohepatic circulation have been identified and include the Na+-dependent hepatocyte bile acid transporter, the Na+-independent bile acid and organic anion transporter, the ATP-dependent hepatocellular bile acid export pump, the apical sodium-dependent bile acid transporter, and the organic solute transporter α-β in the ileal enterocyte [8].

MATERIAL & METHODS

Research was conducted at Lahore Journal Hospital Lahore and duration of study was 3 months, starting from April 2023 to December 2023. 60 patients of primary hyperlipidemia were enrolled for the research, selected from ward and OPD of Lahore Journal Hospital. Male and female primary hyperlipidemic patients of 21 to 70 years age were selected. Patients with alcohol addiction, hypothyroidism, peptic ulcer, diabetes mellitus, renal disease, hepatic disease, were excluded from the study. Written consent was obtained from all participants. Research study was started after approval by RESEARCH ETHICS COMMITTEE, Lahore Journal Hospital PAKISTAN. The study period consisted of 90 days with fortnightly follow up visits. The required information like name, age, sex, occupation, address, previous medication, date of follow up visit and laboratory investigations, etc of each patient was recorded on a proforma, especially designed for this study. Initially a detailed medical history and physical examination of all patients were carried out. All the base line assessments were taken on the day of inclusion (Day-0) in the study and a similar assessment was taken on Day-90 of research design. After fulfilling the inclusion criteria patients were randomly divided into three groups, i.e. Drug-1 group, 65 patients (tab: Niacin 2.25gm), Drug-2 group, 65 patients (Niacin 2.25 gm + Psyllium 10 gm) and Placebo-group, 65 patients (placebo capsules, containing equal amounts of partly grinded wheat). Patients of drug-1 group were advised to take Tab: Niacin (250 mg), half tablet thrice daily, after meal for 2 days, then by increasing the dose one tablet, TID, after meal for 2 days, then 2 tablets, thrice daily after meal for 2 days, then the maintenance dose of 3 tablets, thrice daily, till end of the study period, i.e. up to day-90. This regimen of dose of drug (called titration of Niacin) was applied due to avoidance of it's adverse effects produced by starting with higher doses of the Niacin. 65 Patients of drug-2 group were provided Tab Niacin and 10 grams of psyllium husk to take 3 times daily in divided doses. For placebo group placebo capsules were given to take thrice daily in divided doses after each meal for the period of 90 days. 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. Data were expressed as the mean ± SD and "t" test was applied to determine statistical significance as the difference. For non significant results P-value >0.05 was used and for significant to highly significant results P-value <0.01 and <0.001 was used in the research. Serum LDL-cholesterol was calculated by Friedwald formula (LDL-Cholesterol = Total Cholesterol-(Triglycerides/5 +HDL-Cholesterol). The calculation of LDL-C by the traditional Friedewald's formula (F-LDL-C) is: F-LDL-C (mg/dl) = TC-HDLC - TG/5. The LDL-C calculated using Friedewald's formula correlates well with LDL-C measured by beta quantification, but doesn't come without any limitations.

RESULTS

Results explained in table 1, 2, and 3 are self explainatory showing parameters observed, pre and post-treatment values of parameters, and its statistical significance of change.

Table 1: Niacin Group

Parameter	Pre-Treatment	Post-Treatment	P-Value	Difference in Percentage
LDL-C	180.83±1.5	139.90±2.2	<0.001	-22.7 %
TG	201.22±5.8	170.66±2.0	<0.001	-15.3 %
Systolic-BP	140.99±3.3	137.98±2.2	<0.01	-2.2 %
Diastolic-BP	92.11±2.0	90.98±4.0	>0.05	-1.4 %
Body Weight	72.22±3.1	70.98±1.9	>0.05	-1.9 %
HDL-C	34.90±1.1	41.99±2.0	<0.001	+16.8 %

Table 2: Niacin+Psyllium Group

Parameter	Pre-Treatment	Post-Treatment	P-Value	Difference in Percentage
LDL-C	188.58±1.7	140.29±2.0	<0.001	-25.6 %
TG	180.77±3.9	146.88±3.3	<0.001	-18.9 %
Systolic-BP	131.12±2.3	128.11±2.0	<0.01	-2.3 %
Diastolic-BP	93.01±2.8	90.20±2.8	<0.01	-3.3 %
Body Weight	70.01±3.5	68.91±4.7	<0.01	-2.9 %
HDL-C	33.22±1.0	40.01±1.5	<0.001	+17.5 %

Table 3: Placebo Group

Parameter	Pre-Treatment	Post-Treatment	P-Value	Difference in Percentage
LDL-C	164.64±1.5	162.23±1.9	>0.05	-1.5 %
TG	178.22±1.7	176.90±1.1	>0.05	-0.8 %
Systolic-BP	130.11±1.8	129.29±1.4	>0.05	-0.7 %
Diastolic-BP	87.88±4.5	86.91±1.0	>0.05	-1.1 %
Body Weight	71.77±3.1	70.98±2.2	>0.05	-1.2 %
HDL-C	31.22±1.7	32.17±2.1	>0.05	+2.9 %

Key: (Mean values of all parameters are written here, ± indicates standard error of mean, LDL-C stands for low-density lipoproteins cholesterol, TG stands for triglycerides, BP stands for blood pressure, HDL-C stands for high-density lipoproteins cholesterol, P-value >0.05 indicates non significant, P-value <0.01 indicates significant and P-value <0.001 indicates highly significant change, minus sign (-) indicates reduction in values and plus (+) sign indicates increase in values, LDL-C, HDL-C and Triglycerides are measured in mg/dl, Blood pressure is measured in mm of Hg and body weight is measured in Kilograms)

DISCUSSION

Soluble fibers, including those from psyllium husk, have been shown to augment the cholesterol-lowering effects of a low-fat diet in persons with hypercholesterolemia. As evidence of this, the scitific authorities recommended that the use of health claims on food products containing soluble fiber from psyllium that state that they are associated with a decreased risk of coronary heart disease. In our research, HDL-cholesterol increased from 36.41±1.96 to 43.70±1.81 mg/dl and LDL-Cholesterol levels decreased by 34.66% in men and women with high LDL-C levels treated with 2.25 grams of Niacin. Reduction in body weight was 2.26%. Systolic blood pressure decreased 4.90% and diastolic blood pressure reduced 4.94% in three months of treatment with same dose of niacin as used in LDL lowering and HDL upraising dose. Triglycerides reduced from 169.64±7.60 to 137.35±6.31 mg/dl, which was highly significant (P value <0.001) reduction in three months. These results match with the results of study conducted by J. M. S. Lee *et al*., [9], who observed almost same changes in LDL-Cholesterol, body weight and blood pressure. HDL-cholesterol is not increased as much as in our research study. Their research proved only 11.09% increase in HDL cholesterol. In their study LDL-C reduced 29.75%, systolic BP 2.89%, diastolic BP 3.98% and body weight 2.94%, in 90 days of treatment with three grams of niacin in 47 primary hyperlipidemic patients. Results of study conducted by Allen J. Taylor *et al*., [10], also match with our study results. In their results LDL cholesterol reduced 31.98%, systolic blood pressure 3.87%, diastolic blood pressure 3.87% and body weight 2.91%. They observed remarkable increase in HDL cholesterol in 15 female hyperlipidemic patients when two grams of niacin was used for 4 months. Guyton JR [11], observed that niacin is very effective among all lipid lowering drugs, that can reduced LDL cholesterol and increase HDL cholesterol remarkably. They proved 30.12% reduction in low density lipoprotein cholesterol, 17% decrease in triglycerides and 20.56% increase in high density lipoprotein cholesterol when 3 grams of niacin was used in 20 hyperlipidemic patients for three months. These results also coincide with our results regarding LDL and HDL cholesterol. Results of research study conducted by Bays H E and McGovern ME [12], are in contrast with our results who observed only 12.99% decrease in LDL-Cholesterol by using three grams of niacin in 13 hyperlipidemic patients for the

period of three months. In their observation systolic and diastolic blood pressure was reduced 0.19 and 2.51% respectively. Body weight was reduced 2.90%. These findings do not match with our results, except body weight. The reason for difference may be due to small sample size and environmental factors. Their patients strictly followed step-I diet, along with taking drug. Taylor AJ *et al*., [13], proved 24.03% reduction in concentration of LDL cholesterol, 10.32% reduction in serum triglycerides and 11.87% increase in HDL cholesterol. Their observation is in contrast with our observation, probably due to small sample size and low dose of the drug in our study. They used 4.4 grams of niacin in 87 hyperlipidemic patients for the period of 8 months. F. A. Jaffer [14], used 2.5 grams of niacin in 30 hyperlipidemic patients for four months and observed 20% increase in HDL cholesterol and only 13% decrease in LDL cholesterol. Result of one of the parameter that is HDL cholesterol matches with our result but in another parameter that is LDL cholesterol results of his study and our research results are in contrast. The reason of this contrast may be the cases of secondary hyperlipidemia, they included in their study. Enterohepatic circulation allows for recycling of metabolized and non-metabolized compounds, and is of critical importance in toxicologic processes involving the gastrointestinal tract. This circulatory route is active when ingested compounds that are absorbed in the gastrointestinal tract enter the portal circulation, go to the liver, and then return to the gastrointestinal tract via biliary excretion. The enterohepatic circulatory pathway can also be utilized by dermally absorbed or inhaled materials that are excreted in the bile [15-19].

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