

Keep Heart Healthy by Normalising Body Weight, Blood Pressure and Weight Reduction

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ABSTRACT

Hyperlipidemia, if not controlled at its initial stage may lead to atherosclerosis and myocardial infarction, causing high rate of morbidity and mortality all over the world. Research study was conducted to examine the effects of Psyllium fibres on blood pressure, weight and lipid profile in hyperlipidemic patients. It was single blind placebo controlled research study. Study was conducted at Jinnah Postgraduate Medical Centre, Karachi, Pakistan from January to July 2010. Forty already diagnosed primary hyperlipidemic patients were selected from Cardiology OPD of Jinnah Hospital, Karachi, Pakistan. Exclusion criteria were patients suffering from hypothyroidism, renal dysfunction, any hepatic disease. Consent Form was designed and got approval for the research from Research Ethical Committee of Jinnah Postgraduate Medical Centre, Karachi. After explaining the limitations, consent was obtained from all study participants before they were enrolled in the study. They were divided in two groups, 20 patients were on Psyllium husk fibres, 10 gram daily in divided doses. And 20 patients were kept on placebo as control group. Lipid profile of all participants was estimated at day-0 and at day-90. All other vital functions of patients were also estimated and kept on record. They were advised to visit clinic every two weeks. Two patients discontinued taking drug given, due to metallic test of psyllium fibres. Psyllium fibers when used for 3 months, it was observed that weight, systolic and diastolic blood pressure of hyperlipidemic patients reduced 1.34%, 2.57% and 4.57% respectively. Psyllium decreased serum total cholesterol from 228.27±4.89 mg/dl to 199.22±2.30 mg/dl, triglycerides from 169.27±9.92 mg/dl to 164.5±8.56 mg/dl, LDL-Cholesterol from 159.72±5.70 to 129.55±2.81mg/dl, and increased serum HDL-Cholesterol from 34.61±1.85 to 36.77±1.96 mg/dl in three months of treatment. Data were expressed as the mean±SD and "t" test was applied to determine statistical significance of results. P- value lesser than 0.05 was the limit of significance. Results of all parameters of lipid profile, weight and blood pressure were significant when paired 't' test was applied for statistical analysis. It was concluded from the research study that psyllium is effective agent to maintain lipid profile parameters at normal limits in hyperlipidemic patients. These fibers also reduce weight and blood pressure in hyperlipidemic patients.

Key words: Myocardial Infarction. Hyperlipidemia. Atherosclerosis. Psyllium fibres.

INTRODUCTION

In 2002 a report of findings from the National Health and Nutrition Examination Survey indicated that 64.5% of American adults were overweight as defined by body mass index (BMI; in kg/m²) criteria (BMI between 25 and 30), and ~30.5% were obese (BMI >30). These percentages have been steadily increasing since the 1960s.¹ In 1999 the National Population Health Survey from Statistics Canada reported that 36.6% of Canadian men and 31.2% of Canadian women aged between 20 and 64 y had a BMI>27, an indication of either mild or more developed weight problems. Given the elevated risk

of mortality and morbidity associated with obesity, providing treatment and guidance to overweight individuals to improve their health status is an important responsibility of the medical community². Initial complication of hyperlipidemia is high blood pressure and weight gain³. Recent research studies have proved remarkable effects on reducing risk of coronary artery disease by decreasing serum lipids, blood pressure and body weight.⁴ For treating primary hyperlipidemic patients, their weight and blood pressure may also be treated concurrently to get good results⁵. Statins or HMG-CoA reductase inhibitors, fibrates or fibric acids, nicotinic acid, bile acid binding resins including psyllium husk fibres are main drug groups used for this purpose⁶. Since pre-historic times psyllium husk has been used as antidiarrheal and constipation relieving agents but it has been proved that psyllium fibers reduce bad

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cholesterol; i.e.; low density lipoprotein cholesterol and increase good cholesterol i.e.; high density lipoprotein cholesterol. These fibers has effects on serum total cholesterol too. Triglycerides are not reduced significantly. Psyllium is also being used as weight reduction and hypotensive agent.⁷ These fibers bind with bile acids and decrease their absorption from terminal ileum. This in turn stimulates the hepatic synthesis of bile acid from cholesterol and thus reduce the total and low density lipoprotein cholesterol levels. It also decreases the reabsorption of cholesterol from intestine by decreasing the micelle formation.⁸ High density lipoprotein cholesterol concentrations are also increased, when psyllium is added to the treatment regimen of patients who are already receiving HMG-CoA reductase inhibitors and niacin⁹.

MATERIAL AND METHODS

The study was conducted in the department of pharmacology and therapeutics, Jinnah Hospital Karachi, Pakistan from January to July 2010. Primary hyperlipidemic patients who were already diagnosed by physician or cardiologist of the Jinnah Hospital, Karachi were initially selected and enrolled in this study, referred from Medicine and Cardiology OPD of Jinnah Hospital, Karachi, on request. Male and female patients, age range from 21 to 65 years, were randomly selected. Patients with diabetes mellitus, peptic ulcer, renal disease, hepatic disease, hypothyroidism and chronic alcoholics were excluded from the study by getting past medical history, clinical examination and available laboratory investigations. Written consent was obtained from all participants. The study period consisted of 3 months with fortnightly follow up visits. The required information, e.g. name, sex, age, occupation, address, medicines used in past for any disease, date of follow up visit and laboratory investigations, etc of each patient was recorded on a Performa. Initially 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 two groups, i.e. Drug-I (Psyllium husk 10gm/day) and Drug-2 (placebo capsules) groups. Patients of drug-1 group were advised to take psyllium fibres 10 gm daily in three divided doses. Patients of drug-II group were provided placebo capsules, i.e. one capsule, three time a day, for 3 months. Patients were called fortnightly for follow up visit. Serum total cholesterol and triglycerides were estimated by the enzymatic calorimetric Method. Serum LDL-Cholesterol was

calculated by Friedwald formula (LDL-Cholesterol = Total Cholesterol-(Triglycerides/5 +HDL-Cholesterol). Serum HDL-cholesterol was determined by direct method, at day-0 and day-90. Data were expressed as the mean \pm SD and "t" test was applied to determine statistical significance in results comparing drug group with placebo group. P-value >0.05 was considered as insignificant, P-value <0.05 was considered significant and P-value < 0.001 was considered as highly significant.

RESULTS

For the period of 3 months, when psyllium used in 18 patients mean systolic blood pressure reduced from 129.72 ± 2.75 mm of Hg to 126.38 ± 2.35 mm of Hg, diastolic blood pressure reduced from 91.11 ± 1.31 mm of Hg to 86.94 ± 1.15 . When analyzed statistically reduction in systolic blood pressure is significant (P-value <0.05) and diastolic blood pressure reduction is highly significant (P-value <0.001). In three months treatment with psyllium fibers mean reduction in body weight was 1.34%. It is also significant when analyzed statistically (P-value <0.01). Mean serum total cholesterol decreased from 228.2 ± 4.8 mg/dl on day-0 to 199.2 ± 2.3 mg/dl on day-90. This reduction in total cholesterol was highly significant (P <0.001) when levels on day-0 and those on day-90 were compared. The average percentage reduction in total cholesterol was -12.7%. Two patients out of 20 discontinued taking psyllium due to its metallic taste. The mean serum triglycerides level of 18 patients treated with psyllium fibres was 169.2 ± 9.9 mg/dl on day-0 which reduced to 164.5 ± 8.5 mg/dl on day-90. These differences were highly significant (P <0.001) when levels on day-0 and those on day-90 were compared statistically. The percentage change between day-0 to day-90 was -2.81. In 18 primary hyperlipidemic patients, when started treatment with psyllium husk, their mean serum LDL-C level at day-0 was 159.7 ± 5.7 mg/dl. This level reduced to 129.5 ± 2.8 mg/dl at day-90. When compared between day-0 to day-90, this change was highly significant (P <0.001). The percentage change was -18.88. In 18 patients treated with psyllium husk, the mean HDL-C at day-0 was 34.6 ± 1.8 mg/dl, which increased to 36.7 ± 1.9 mg/dl on day-90. The result was highly significant (P <0.001) when values were compared at day-0 to day-90. The percentage increase in HDL-C from day-0 to day-90 was +6.24. In 20 patients treated with placebo, systolic blood pressure, diastolic blood pressure, and weigh are reduced, but reduction in all of these parameters is non-significant, when analyzed statistically. In this placebo group serum total cholesterol reduced from 215.95 ± 2.47 mg/dl to 208.70 ± 5.38 mg/dl, triglycerides reduced from

148.45±4.80 mg/dl to 146.20±4.20 mg/dl, LDL-cholesterol reduced from 150.75±2.67 mg/dl to 148.80± 2.28 mg/dl. HDL-cholesterol raised from 35.50±1.13 mg/dl to 35.75±1.07 mg/dl in three months of treatment period. All results of placebo group are non-significant when analyzed statistically. Results of all parameters are shown in table 1, 2, 3.

Table 1: Changes in lipid profile in psyllium husk group of patients (n =18)

Parameter	At day-0	At day-90	%Change
T-C	228.27±4.89	199.22±2.30	-12.72
TG	169.27±9.92	164.50±8.56	-2.81
LDL-C	159.72±5.70	129.55±2.81	-18.88
HDL-C	34.61±1.85	36.77±1.96	+6.24
Systolic BP	129.72±2.75	126.38±2.35	-2.57
Diastolic BP	91.11±1.31	86.94±1.15	-4.57
Weight	68.22±1.82	67.30±1.82	-1.34

Key: (All lipid parameters are measured in mg/dl, blood pressure is measured in mm of Hg, and figures in parentheses indicate number of patients, (±) indicates standard error of mean, (-) indicates decrease in percentage, (+) indicates increase in percentage, T-C stands for total cholesterol, TG stands for triglycerides,

LDL-C stands for low density lipoprotein cholesterol, HDL-C stands for high density lipoprotein cholesterol, BP stands for blood pressure)

Table 2: Changes in lipid profile of patients on placebo group (n =20)

Parameter	At day-0	At day-90	% Change
T-C	215.95±2.47	208.70±5.38	-3.35
TG	148.45±4.80	146.20±4.20	-1.51
LDL-C	150.75±2.67	148.80±2.28	-1.29
HDL-C	35.50±1.13	35.75±1.07	+0.70
Systolic BP	122.75±2.19	120.75±2.18	-1.62
Diastolic BP	84.25±1.99	82.00±1.82	-2.67
Weight	69.35±1.76	69.17±1.68	-0.25

Key: (All lipid parameters are measured in mg/dl, blood pressure is measured in mm of Hg, and figures in parentheses indicate number of patients, (±) indicates standard error of mean, (-) indicates decrease in percentage, (+) indicates increase in percentage, T-C stands for total cholesterol, TG stands for triglycerides, LDL-C stands for low density lipoprotein cholesterol, HDL-C stands for high density lipoprotein cholesterol, BP stands for blood pressure)

Table 3: Comparison of changes in lipid profile parameters between placebo and psyllium group of patients in 90 days of treatment.

PLACEBO GROUP (n =20)				PSYLLIUM HUSK GROUP (n =18)			
Parameter	Baseline	Post Treatment	P Value	Baseline	Post Treatment	P Value	% Difference in groups
T-C	215.95±2.47	208.70±5.38	>0.05	228.27±4.89	199.22±2.30	<0.001	9.37
TG	148.45±4.80	146.20±4.20	>0.05	169.27±9.92	164.50±8.56	<0.001	1.30
LDL-C	150.75±2.67	148.80±2.28	>0.05	159.72±5.70	129.55±2.81	<0.001	17.59
HDL-C	35.50±1.13	35.75±1.07	>0.05	34.61±1.85	36.77±1.96	<0.001	5.54
Systolic BP	122.75±2.19	120.75±2.18	>0.05	129.72±2.75	126.38±2.35	<0.05	0.95
Diastolic BP	84.25±1.99	82.00±1.82	>0.05	91.11±1.31	86.94±1.15	<0.001	1.90
Weight	69.35±1.76	69.17±1.68	>0.05	68.22±1.82	67.30±1.82	<0.01	1.09

Key: (Figures in parentheses indicate number of patients, all lipid parameters are measured in mg/dl, blood pressure is measured in mm of Hg, (±) indicates standard error of mean, T-C stands for total cholesterol, TG stands for triglycerides, LDL-C stands for low-density lipoproteins, HDL-C stands for high-density lipoproteins, BP stands for blood pressure, P-value >0.05 indicates non significant, P-value <0.01 indicates significant and P-value <0.001 indicates highly significant)

DISCUSSION

Psyllium was used for the period of 90 days, and in these 90 days psyllium fibers reduced body weight from 68, 22±1.82 to 67.30±1.82 kg, systolic blood pressure from 129.72±2.75 to 126.38±2.35 mm of Hg, diastolic blood pressure from 91.11±1.31 to 86.94±1.15 mm of Hg. Triglyceride reduction was 2.81%, LDL-cholesterol 18.88% and serum total cholesterol 12.72%. Increase in high density lipoprotein cholesterol was 6.24%. These results match with the results of study conducted by Reid R et al¹⁰ in all parameters of lipid profile. In their study change in high density lipoprotein cholesterol was higher than ours. This difference may be due to genetic variation in patients suffering from primary

hyperlipidemia. Different type of primary hyperlipidemia could respond in different manners with different drug regimen and duration of the treatment. Another study was conducted by Guido MA Van Rosendaal et al¹¹ on placebo controlled trials, in which 19 male primary hyperlipidemic patients were treated with six gram psyllium husk fibers in divided doses, thrice daily for the period of three months. Results of the trial almost match with our results. In their results total-cholesterol reduction was 15.71%, triglycerides reduced from 171.12±7.77 mg/dl to 161±3.23 mg/dl (P value <0.001). In percentage it was -3.7%. Observed low density lipoprotein cholesterol and very low density lipoprotein cholesterol reduction was -17.93% and

-10.29%, respectively. Blackwood et al¹² also observed same changes that psyllium has reduced body weight 2.00% kg, systolic blood pressure 2.39% and diastolic blood pressure 4.11% mm of Hg, in three months. Almost same changes in lipid profile of 31 hyperlipidemic patients, treated with 6 gram of psyllium thrice daily for ten weeks. Results of the study also match with results of Krempf M et al¹³, in which 57 primary hyperlipidemic patients were treated by psyllium husk fibers 12 gram daily in divided doses for the period of 8 weeks. In their observation triglycerides reduction was -7.12%, LDL-C was reduced to -10.31%. HDL-cholesterol raised upto +5.11%. Results of research by Carlos Poston et al¹⁴ are in contrast with our results. They used ispaghula fibers in twenty nine primary hyperlipidemic patients of both genders, i.e; male and female with age range from twenty eight to sixty years for the period of one month. They used psyllium husk fibers 12 gram daily, in divided doses with step I diet. They observed that psyllium husk has reduced low density lipoprotein cholesterol 19.99%, serum total cholesterol 19.00%, triglycerides 6.96%, and increased HDL-cholesterol 4.30%. These results are in contrast with our research work observations. The obvious reason for this contrast is step I diet, which was strictly followed by their patients recruited for this research especially on payment. They were stayed at Lipid Research Centre. Approach to conduct research work on nutrition and nutritional related works should be monitored separately like Stoy DB et al did at their Lipid Research Centre. Our study is in contrast with the study results of Torgerson JS et al¹⁵ who observed more changes in serum total cholesterol. It was -19.11%. Only change in low density lipoprotein cholesterol match with our study. They did not mention the mode of action of psyllium to reduce cholesterol. One of the agreed upon mechanisms is that psyllium stimulate bile acid synthesis through 7 α -hydroxylase activity. Another mode of action of psyllium fibers to reduce cholesterol is diversion of hepatic cholesterol synthesis to bile acid production. Effect of psyllium on absorption of cholesterol and fat appeared minimal but it is small contribution to cholesterol lowering effect.

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