

PSYLLIUM HUSK TO INCREASE HDL-CHOLESTEROL; PLACEBO CONTROLLED STUDY

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ABSTRACT... Objectives: To examine the effects of Psyllium husk on HDL-Cholesterol. **Design:** Single blind placebo controlled study. **Place and Duration of Study:** Study was conducted at department of Pharmacology and therapeutics at Basic Medical Sciences Institute (BMSI), Jinnah Postgraduate Medical Centre (JPMC), Karachi, from January 2006 to July 2006. **Patient and Methods:** Forty hyperlipidemic patients were included, among which 20 patients were on placebo as control group, and 20 were on Psyllium husk, 3 gram daily, in divided doses for the period of three months. Patients with peptic ulcer, renal disease, hepatic disease, hypothyroidism, diabetes mellitus, and alcoholism were excluded from the study. HDL- Cholesterol was determined by using kit Cat. # 303210040 by Eli Tech Diagnostic, France. Data were expressed as the mean \pm SD and "t" test was applied to determine statistical significance as the difference. A probability value of <0.05 was the limit of significance. **Results:** Two patients were dropped from the study due to low compliance of metallic taste of psyllium husk. Psyllium husk has increased HDL-Cholesterol, in 90 days of treatment, from 34.61 ± 1.85 to 36.77 ± 1.96 (mg/dl), which was highly significant statistically when paired "t" test was applied for results. Percentage change was +6.24. **Conclusions:** It is concluded from this study that Psyllium husk decreases the risk of CHD by increasing HDL-Cholesterol.

Key words:Psyllium Husk. HDL-Cholesterol. Atherosclerosis. Heart Attack

INTRODUCTION

"Heart attack" is the single largest killer in United States. Every 20 seconds, an American will suffer a heart attack. Every 34 seconds, an American will die of cardiovascular disease. One in every 2.6 deaths in United States is caused by cardiovascular disease¹. The American Heart Association recognizes both LDL-Cholesterol (Bad Cholesterol) and HDL- Cholesterol (Good Cholesterol) as strong and independent risk factors of heart disease. However, raising good cholesterol levels is thought to provide greater protection than lowering bad cholesterol. Every 1% increase in HDL-Cholesterol decreases the risk for heart disease by 2% in men and 3% in women². It is easy for nearly everyone to significantly lower LDL cholesterol and raise HDL levels with diet, exercise and supplements, that it seems extreme for health care

providers to prescribe cholesterol-lowering drugs until other; simpler measures have been taken and failed. The exception to this would be if you are in imminent danger of having a heart attack and need to take extreme measures³. HDL, which is famously known as "good" cholesterol, can be further categorized into specific subtypes. (1) HDL2 is a larger form, produced when cholesterol carried by HDL-3 is chemically modified (esterified). It transports cholesterol to liver for processing and elimination. (2) HDL3 is a smaller form, synthesized by the liver and intestine. HDL-2 moves cholesterol away from the arterial wall so it may provide greater cardiovascular protection. HDL possess antioxidant activity and it helps balancing the body's natural anti-inflammatory response, both of which are important for cardiovascular health.

Its most important function is the role it plays in cholesterol transport. High levels of HDL cholesterol are associated with reduced platelet activity, another key indicator of arterial and venous health⁴. Many drug groups increase HDL-Cholesterol, including psyllium hydrophilic mucilloid⁵. Psyllium by decreasing LDL-Cholesterol change the LDL-C/HDL-C ratio to normalize the arterial and venous health⁶. Bile acid sequestrants, like psyllium are the only hypocholesterolemic drugs currently recommended for children of 11 to 12 years of age, although data now are emerging that document the safety of statin therapy of children in this age range⁷.

PATIENTS & METHOD

Research study was conducted in Jinnah Postgraduate Medical Centre, Karachi, from January to July 2006. Forty patients of primary hyperlipidemia were enrolled in the study, selected from ward and OPD of National Institute of Cardiovascular Diseases (NICVD), Karachi. Previously diagnosed and untreated primary hyperlipidemic patients of either sex, age range from 21 to 60 years were randomly selected.

Patients with peptic ulcer, cigarette smoking, hepatic disease, alcoholism, hypothyroidism, diabetes mellitus, and renal disease were excluded from the study as these pathological conditions can mask hyperlipidemic abnormality of the patient⁸. After explaining the limitations, written consent was obtained from all participants. The study period consisted of 90 days with fortnightly follow up visits. Name, age, sex, occupation, address, previous medication, date of follow up visit and laboratory investigations, etc of each patient was recorded on a Performa, especially designed for the study. 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 divided in two groups, i.e. Drug-1 (3 gram of Psyllium husk) and Drug-2 (placebo capsules, containing equal amounts of partly grinded wheat) groups.

Twenty hyperlipidemic patients of group-1 were provided packets containing 3 gram of Psyllium husk and were advised to take one packet thrice daily along with diet

control and exercise for 40-60 minutes (brisk walk). This regimen was followed for 12 weeks. Twenty hyperlipidemic patients of drug-2 group were taken as control, and were advised to continue on isocaloric weight maintaining diet, i.e. step-1 diet and brisk walk for next three months. Patients of this group were provided capsules containing equal amount of partly grinded wheat and orange flavor, taken one capsule thrice daily after meal for three months.

Patients were advised to come in OPD, every two 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. HDL-Cholesterol was determined by using kit Cat. # 303210040 by Eli Tech Diagnostic, France. Data were expressed as the mean \pm SD and "t" test was applied to determine statistical significance as the difference. A probability value of <0.05 was the limit of significance.

RESULTS

Out of 40 patients, 38 completed the over all study period. Two patients of drug-1 group discontinued to take medicine due to metallic taste of Psyllium husk. Tables showing base line and post treatment values are self explanatory. When results were summed up and test parameters were compared, it was seen that, after 90 days of treatment with Psyllium, HDL-Cholesterol increased from 34.61 ± 1.85 mg/dl to 36.77 ± 1.96 mg/dl, which is highly significant statistically ($P < 0.001$). The overall percentage change from day-0 to day-90 was +6.24, as shown in table-I. In placebo group at day-0, HDL-Cholesterol level was 35.50 ± 1.13 mg/dl, which increased to 35.75 ± 1.07 mg/dl, which is non significant statistically ($P > 0.05$). The overall percentage increase in the parameter was +0.70, as shown in table-II. When compared difference in percentage change in two groups, it was 5.54, as shown in table-III.

DISCUSSION

There are various groups of drugs which are used for the treatment of hyperlipidemia. HMG-Co reductase inhibitors (Statins), fibric acids, Niacin and psyllium hydrophilic mucilloids are important lipid lowering drugs⁹. Psyllium is also used as fiber in many nutrients, to

Table-I. Changes in Mean HDL-cholesterol in psyllium group of patients (n=18)

Parameter	At day-0	At day-90	% Change
HDL-C (mg/dl)	34.61±1.85	36.77±1.96	+6.24
<ul style="list-style-type: none"> ▶ Key: ± indicates standard error of mean ▶ 'n' is sample size of research group of individuals 			

Table-II. Changes in mean HDL-cholesterol, in placebo group of patients (n=20)

Parameter	At day-0	At day-90	% Change
HDL-C (mg/dl)	35.50±1.13	35.75±1.07	+0.70
<ul style="list-style-type: none"> ▶ Key: ± indicates standard error of mean ▶ 'n' is sample size of research group of individuals 			

Table-III. Difference of changes in Mean HDL-Cholesterol between placebo and Psyllium group of patients in 90 days of treatment.

Parameter	Placebo group (n=20)		P-value
	Baseline	Post Treatment	
HDL-C (mg/dl)	35.50±1.13	35.75±1.07	> 0.05
Psyllium group (n=17)			
Baseline	Post Treatment	P-value	% Difference in groups
34.61±1.85	36.77±1.96	< 0.001	5.54
<ul style="list-style-type: none"> • Key: ± indicates standard error of mean • P-value > 0.05 indicates non significant • P-value < 0.001 indicates highly significant • 'n' is sample size of research group of individuals 			

regulate gastrointestinal motility. Since long, its use as hypolipidemic agent is well known to health care personals. It reduces serum total cholesterol, LDL-Cholesterol, VLDL, triglycerides. It's HDL-C raising mechanism is not known, but LDL-C/HDL-C ratio is changed to normal, which helps to keep arterial and venous health in norm¹⁰.

In our study, psyllium increased HDL-Cholesterol by 6.24 % in three months. In placebo group, HDL-Cholesterol was raised by 0.70 %. Our study matches with Alan T. Remaley et al¹¹ who observed almost same changes in HDL-Cholesterol, i.e. 5 % increase in HDL-Cholesterol when 4.4 gram of psyllium husk was used by patients for

four months. He does not describe the mechanism by which HDL-Cholesterol is increased. Results of our study also match with results of research study conducted by Jenkins DJA et al¹¹ who observed 4.90 % increase in HDL-Cholesterol, when 3 gram of psyllium was used thrice daily in 90 primary hyperlipidemic patients, for the period of four months. He described that bile acids, metabolites of cholesterol, are normally reabsorbed in the jejunum with about 95 % efficiency. Their excretion is increased up to tenfold when the resins are given. The increased catabolism of cholesterol reflects its enhanced conversion to bile acids in liver via 7 alpha hydroxylation, normally controlled by negative feedback by bile acids.

Cholesterogenesis is inhibited, an effect that persists when bile acid-binding resins are given. By this way decreased synthesis of cholesterol in liver can increase hepatic uptake of LDL in support of increased bile acid synthesis induced by the resins. The catabolic rate for HDL is decreased, with an associated increase in the HDL₂ subfraction and high levels of HDL-Cholesterol in blood. Results of our study do not match with the study of Anderson JW¹² who observed that no significant change was there in HDL when 2 gram of psyllium husk, twice daily was given to 20 hyperlipidemic patients for the period of three months, in double blind placebo controlled study. HDL-Cholesterol was increased up to 1.9 % only. He also included other parameters in his study, like systolic and diastolic blood pressure. Difference in his and our study results may be due to less concentration (dose) of the psyllium administered and different design of research study. Our results do not match with results of research study conducted by Bell LP et al¹³ who observed that psyllium has increased 1.79 % HDL-Cholesterol with 4 gram of psyllium administration for the period of two months in 80 hyperlipidemic patients. Difference in results may be less duration of drug used and exclusion criteria, in which they did not excluded diabetic, alcoholic and chain smoker patients. In our study design exact exclusion criteria was followed, in which diabetic, alcoholic, cigarette smokers, hypothyroidism, renal and hepatic diseased patients were excluded from the study.

Our results are in contrast with results of research study of Turley SC et al¹⁴ who observed only 0.78 % increase in

HDL-Cholesterol, when one gram of psyllium was used, daily in divided doses in 20 hamsters for the period of two months. Difference in our and their results in HDL-Cholesterol may be due to difference in animal species. They tried psyllium administration in rat like rodent animals (hamsters) with low doses, but our study was on human beings suffered from primary hyperlipidemia.

CONCLUSION

We concluded from this research study that Psyllium husk decreases the risk of Coronary Heart Disease by increasing serum HDL-Cholesterol in primary hyperlipidemic patients.

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