

## Original Article

# Placebo controlled study of psyllium husk to increase HDL cholesterol

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## ABSTRACT

### Objective

To examine the effects of Psyllium husk on HDLCholesterol levels.

### Patient and Methods

This single blind placebo controlled study was conducted at Department of Pharmacology and Therapeutics, Basic Medical Sciences Institute (BMSI), Jinnah Postgraduate Medical Centre (JPMC), Karachi, from January 2006 to July 2006. Forty hyperlipidemic patients were included with 20 serving as control and 20 as treatment group who were given Psyllium husk, 9 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 a commercial kit (Eli Tech Diagnostic, France). Data were expressed as the mean±SD and “t” test was applied to determine statistical significance.

### Results

Two patients were dropped from the study due to low compliance of metallic taste of psyllium husk. Psyllium husk 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. Percentage change was 6.24%.

### Conclusion

Psyllium husk increased HDL cholesterol by 6% after 90days treatment. (Rawal Med J 2010;35: ).

### Key words

Psyllium husk, HDL cholesterol, atherosclerosis.

## INTRODUCTION

One in every 2.6 deaths in United States is caused by cardiovascular disease.<sup>1</sup>The American Heart Association recognizes both LDL cholesterol and HDL cholesterol as strong and independent risk factors of heart disease. However, raising HDL cholesterol levels is thought to provide greater protection than lowering LDL cholesterol, as every 1% increase in HDL cholesterol decreases the risk for heart disease by 2% in men and 3% in women.<sup>2</sup> 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 measures.<sup>3</sup> HDL cholesterol can be further categorized into specific subtypes. 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 health.<sup>4</sup> Many drug groups increase HDL cholesterol, including psyllium hydrophilic mucilloid.<sup>5</sup> Moreover, psyllium by decreasing LDL cholesterol changes the LDL-C/HDL-C ratio to normalize the arterial and venous health.<sup>6,7</sup> The aim of this study was to determine the effects of Psyllium husk on HDLCholesterol levels as compared to placebo.

## **PATIENTS AND METHODS**

This study was conducted in Jinnah Postgraduate Medical Centre, Karachi, from January to July 2006. Forty patients who were previously diagnosed and untreated primary hyperlipidemic patients of either gender, 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.<sup>8</sup> A written consent was obtained from all participants. The study period consisted of 90 days with fortnightly follow up visits. Factors like age, gender, occupation, address, previous medication, date of follow up visit and laboratory investigations of each patient were recorded. All the base line assessments were taken on the day of inclusion and on Day-90 of study.

Patients were divided in two groups, treatment (group 1) (3 gram of Psyllium husk TID) and Placebo (group 2) (capsules containing equal amounts of partly grinded wheat). A program of diet control and exercise for 40-60 minutes (brisk walk) was advised. This regimen was followed for 12 weeks. Twenty hyperlipidemic patients of group 2 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.

At every two weeks follow up, blood pressure, weight, pulse rate and general appearance of the individual were checked. Drug compliance to the regimen was monitored by interview and counseling at each clinical visits. HDL cholesterol was determined by using commercial kit (Eli Tech Diagnostic, France). Data were analyzed using “t” test a  $p < 0.05$  was considered to be statistically significant.

## **RESULTS**

Out of 40 patients, 38 completed the study. Two patients of group 1 discontinued to take medicine due to metallic taste of Psyllium husk. At the end of treatment, in Psyllium group, HDL cholesterol increased from  $34.61 \pm 1.85$  mg/dl to  $36.77 \pm 1.96$  mg/dl ( $P < 0.001$ ) with increase of 6.24%.

**Table. Changes in HDL Cholesterol between the groups.**

Parameter	Placebo group (n=20)			Psyllium group (n=18)			% Difference in groups
	Baseline	Post Treatment	P Value	Baseline	Post Treatment	P Value	
HDL-C (mg/dl)	35.50 $\pm 1.13$	35.75 $\pm 1.07$	>0.05	34.61 $\pm 1.85$	36.77 $\pm 1.96$	<0.001	5.54

± 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

In placebo group, the change was not significant statistically (P>0.05) (Table).

## DISCUSSION

HMG-Co reductase inhibitors (Statins), fibric acids, Niacin and psyllium hydrophilic mucilloids are important lipid lowering drugs.<sup>9</sup> Psyllium 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 norm.<sup>10</sup> In our study, psyllium increased HDL-Cholesterol by 6.24 % in three months. Our results are consistent with another study showing 5% change in HDL-Cholesterol, when 4.4 gram of psyllium husk was used for four months.<sup>11</sup> Results of our study, however, do not match with the study by Anderson who observed no significant change in HDL when 2 gram of psyllium husk, twice daily was given to 20 hyperlipidemic patients for three months.<sup>12</sup> This difference may be due to less concentration (dose) of the psyllium administered and different design of study.

Our results also do not agree with study by Bell et al who observed that psyllium increased HDL-Cholesterol by 1.79% with 4 gram of psyllium administration for the period of two months.<sup>13</sup> Difference in results may be less duration of psyllium 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 study of Turley et al 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.<sup>14</sup> They tried psyllium administration in rat like rodent animals (hamsters) with low doses, but our study was on human beings with primary hyperlipidemia.

## CONCLUSION

We conclude that Psyllium husk increased serum HDL-Cholesterol in primary hyperlipidemic patients when administered in appropriate doses for a period of three months.

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