Deer Brand Sat Isabgol

Excellence in Quality Since 1948

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Messrs KAMAL & SONS have established dominance in supply of **Quality Sat-Isabgol** (Psyllium Husks) in highly purified form packed in consumer packs for supply in the Domestic market throughout India and the Gulf countries popularly marketed under the brand name and symbol of " DEER " . The company has well-established marketing network with stress on service and quality assurance.

Deer Brand Sat-Isabgol is the most preferred brand for over 60 years. A Natural vegetable product is highly purified form is Nature's highest soluble fibre obtained from Plantago Ovata (Isabgol) Seeds. **Deer Brand Sat-Isabgol** is processed in state of the art plant having modern computerized sorting machines under stringent quality control measures. Right from selection of raw materials to computerized cleaning, processing and packaging in hygienic plant, utmost care is taken to bring you 100 % Natural and Super Quality Sat Isabgol

The consumer packs are sealed and packed on fully automatic machines without hand touch in line with international standards. These are available in various sizes of 500gm, 200gm, 100gm, & 50gm packets and in convenient 10gm and 5gm sachets for the domestic and export markets.

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Deer Brand Sat Isabgol : Commenly known in trade as Psyllium Husks (Botanical: Plantago Ovata Forsk) is mainly grown in India was popularised with the advent of Arabians and Persians in India as early as 10th Century A.D. under the popular name of Fleawort or Flea Seed Husk. Its use as a mild bulk laxative spread to the United States and other European countries during middle of 19th century and increased substantially later on and has maintained an important place in therapeutics in spite of the development of many newer synthetic compounds.

Deer Brand Sat Isabgol is a 100% NATURAL , PURE and SAFE high fibre supplement for fibre deficient diet obtained from Isabgol Seeds - a cultivated agriculture crop from India. In indigenous medicine Ayurvedic and Unani the seeds and husk are used as emollient, demulcent and laxative and in the treatment of chronic constipation, amoebic and bacillary dysentery and diarrhea. The efficacy of Psyllium is due to the large quantity of mucilage, the action of which is purely mechanical as the husk swells into a jelly like mass with liquids. Recent advance research carried out in the United States and elsewhere shows that Psyllium Husks used as a dietary supplement has helped lowering the human serum cholesterol level. Consumption of Natural Fibre is known to help in effective control of diabetes.

Deer Brand Sat Isabgol has not side- effects. The daily intake can be upto 20 grams as per individual requirements taken once or twice in 10g dosage. Each gram of Sat-Isabgol swells upto 80 to 100% its volume and therefore when taken with lots of liquids is helpful in effective control of constipation.. Ideally taken during the day time - can be supplemented with several glasses of liquids during the day. For acute Dysentery (loose motions) Sat Isabgol intake is recommended with curd (Yoghurt) and reduced liquid intake.

Please feel free to post your queries at www.facebook.com/SATISABGOL or e-mail to us at deersatisabgol@gmail.com

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FAQs

Q. **What is Sat Isabgol?**

A. Sat Isabgol contains the husk of seeds of the plantago ovata, popularly known as isabgol. This time-tested herb has been described in ancient Ayurvedic literature as an emollient, gentle laxative, cooling and diuretic, hence, it is a popular household remedy for constipation.

Deer Brand Sat Isabgol is superior to other isabgol preparations because the isabgol husk used in its manufacture is triple refined using latest technology. This process enhances the swelling property of isabgol and at the same time retains its natural therapeutic properties. Hence, Sat Isabgol is the perfect natural laxative. The entire manufacturing and packaging process is carried out in clean and hygienic conditions. Stringent quality control is maintained throughout the manufacturing process to ensure a quality product.

Being a purely Ayurvedic product it is perfectly safe and free from harmful side effects. Nor is it habit forming, unlike chemical laxatives.

Q. **How does it work?**

A. The Superior Quality Deer Brand Sat Isabgol contains large quantities of a gelatinous substance, which absorbs water and due to its enhanced swelling properties, forms an emollient gel that facilitates the passage of intestinal contents and stimulates bowel movement. As Sat Isabgol forms a bulk on swelling, it is classified as a bulk-laxative. It is usually effective within 8-12 hours.

Since SatIsabgol is unaffected by the digestive enzymes and not absorbed into the system, it does not affect the absorption of other nutrients. It passes unchanged through the intestines. Therefore the action of Satisabgol is purely mechanical, as it relives constipation by mechanically stimulating bowel movement. This process closely approximates the body's internal mechanism.

The Jelly-like substance has, in addition, a remarkable capacity to absorb bacterial and other toxins in the intestines.

In short, Sat Isabgol works partly by lubrication and partly by increasing the bulk of the intestinal contents, which stimulates bowel movement.

Q. **What are the advantages of Sat Isabgol?**

A. Sat Isabgol is free from many of the disadvantages of mineral- based liquid paraffin, which acts in a similar fashion but causes malignant diseases of the colon and paraffin cramps. In addition, Sat Isabgol is more economical.

The regular and prolonged use of Sat Isabgol as a laxative is considered very safe. It does not produce any harmful side effects.

Q. **What precautions should you take?**

A. Sat Isabgol should be stirred in a full glass of fluid, such as water or fruit, just before ingestion. Failure to consume sufficient fluid with a bulk laxative decreases its efficacy. Intake of the husk without fluids should be avoided.

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Q. **When can you take Sat Isabgol?**

A. Due to its bulk forming and emollient properties Sat Isabgol is indicated in the following conditions.

1. In constipation
2. Useful in piles and rectal disorders
3. Irritable bowel syndrome
4. Chronic diarrhea and dysentery
5. For preventing post-operative constipation

Q. **When should you not take Sat Isabgol?**

A. Bulk laxative should not be given in cases of intestinal ulceration, stenosis or adhesions where they may cause obstruction.

Q. **What is the dosage?**

A. Adults : 7.0 g (Two teaspoonful) 1 to 3 times a day with water
Children : 3.5 g (One teaspoonful) 1 to 3 times a day with water

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No time to take care of your health?
Fed up with constipation?

Experience

DEER BRAND ® SAT ISABGOL

100 % Magic

When it comes to relief for constipation, you have a wide choice of artificial products to choose from. But why go for artificial products when you've got ***Deer Brand® SatIsabgol*** *– the tried and tested remedy for over 6 decades.*

Deer Brand® Sat Isabgol *– produced from prime quality Isabgol is a 100 % Natural, Pure and Safe, high fibre supplement for fibre deficient diet which works in the effective treatment of chronic constipation, amoebic and ancillary dysentery and diarrhoea.*

Recent advance research carried out in the United States and elsewhere shows that Sat Isabgol used as a dietary supplement helps lowering the human serum cholesterol levels. The Natural fibre is useful in effective control of diabetes.

Try for yourself and experience the magic. You can take up to 10g twice every day with lots of liquids and enjoy the health benefits.

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Kudrat Ka Uphaar Guno Ka Bhandar

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Fiber

Eating fiber may be one of the easiest and least expensive ways to practice preventive health care. These days, people seem to be concerned with what kind of and how many carbohydrates, proteins, and fats they ingest. The reason is simple—carbohydrates, proteins, and fats attribute to how we look on the outside. But as most health-conscious people know, what's going on in the inside matters more.
And what's going on in the inside—from our digestive health to measures of whole body health—can often be equated to the amount of fiber in our diets.

Fiber

Fiber is the elongated, threadlike structures in fruits, vegetables, and grains that cannot be digested. It has long been recognized as one of the best food ingredients for maintaining bowel regularity and preventing constipation. And because it acts to normalize bowel movements, it can also be used to treat and manage chronic diarrhea (Murray 1996). Consuming fiber reduces transit time and results in a more thorough evacuation of waste materials. It is thought to improve all aspects of colon function.

There are two types of fiber: water-soluble and insoluble.

Water-soluble fiber

Water-soluble fiber dissolves in water and is found in oat bran, legumes, Psyllium (SatIsabgol) , nuts, beans, pectins, and various fruits and vegetables. It forms a bulky gel in the intestine that regulates the flow of waste materials through the digestive tract.

Water-soluble fiber may lower cholesterol by preventing the reabsorption of bile acids. Bile acids are made from cholesterol, and after they aid fat digestion, fiber binds with them and escorts them out of the body. The liver then has to pull more cholesterol from the blood. In a meta-analysis of 67 controlled trials, it was found that some water-soluble fibers lower the total cholesterol and the bad cholesterol (LDL) without affecting the good cholesterol (HDL) (Brown 1999). A similar double-blind study found that Psyllium (SatIsabgol) lowered LDL cholesterol without affecting HDL cholesterol (Anderson 1999).

Water-soluble fiber may also stabilize blood sugar by slowing down the absorption of carbohydrates into the blood. Plus, it can lower blood sugar levels. Researchers have found that increasing fiber intake results in a decrease in the body's need for insulin (Nuttall 1993). Psyllium (SatIsabgol) supplementation, in particular, has been shown to improve blood sugar levels in diabetics (Anderson 2000).

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Insoluble fiber

Insoluble fiber cannot be dissolved in water, meaning that our bodies cannot digest it. This type of fiber includes the undissolvable parts of plant walls and is found in greatest amounts in cereals, brans, and vegetables. The primary function of insoluble fiber is to collect water that increases stool bulk in the large intestine. This promotes bowel movement, and as the bulk works through the intestine, it scours the intestinal walls of waste matter, reducing the risk of colon-related problems.

Fiber in the diet

Most nutritionists recommend consuming 25 to 40 grams of fiber per day.

A variety of epidemiological (disease and population) studies have found that in populations with high-fiber diets, the incidences of colon cancer, appendicitis, and diverticulosis are very low. Industrialized countries, which largely have diets high in fat and low in fiber, have high incidences of these diseases.

Because fiber is low in calories, it can be added to your diet, providing a greater feeling of satiety without significantly increasing your caloric intake. In addition, fiber's ability to stabilize blood sugar may also curb the desire to snack. In other words, you may find yourself eating less. This is beneficial in weight-loss programs.

Psyllium (Sat Isabgol)

Psyllium (SatIsabgol), a soluble fiber grown in India, has more than eight times the bulking power of oat bran. In 1998, the U.S. Food and Drug Administration approved the health claim that foods containing Psyllium (SatIsabgol) may reduce the risk of coronary heart disease. This is due to its cholesterol-lowering effect.

Manufacturers of foods containing Psyllium (SatIsabgol) may use the claim with certain restrictions. When making the claim, they must state that it is in conjunction with a diet low in saturated fat and cholesterol, that adequate amounts of fluids must be consumed with the food, that there is a potential for choking if fluids are not consumed with the food, and that people with difficulty swallowing should avoid consumption of the food. As well, the food must provide at least seven grams of soluble fiber per day.

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Adding fiber to your diet

Once you understand what fiber is and what it does, the next step is changing your diet to make sure you increase your fiber intake.

- Eat at least five servings of fruits and vegetables per day. Fruits and vegetables that are high in fiber include apples, oranges, broccoli, cauliflower, berries, pears, Brussels sprouts, lettuce, figs, prunes, carrots, and potatoes.
- Switch from white bread to whole-grain breads and cereals. Switch from white rice to brown rice.
- Eat dry bran cereals for breakfast. Be sure to check the label to see how much fiber the cereals contain. Some have less fiber than you would think.
- Add a fiber supplement (SatIsabgol) to your diet.

Remember, as you increase your fiber intake, increase the amount of water you drink. To experience the benefits of fiber, adequate water/liquid is necessary.

Experience and research indicate that fiber is an indispensable part of your diet. Including adequate fiber in your diet can help prevent many of today's prevalent health care concerns.

Soluble fiber intake at a dose approved by the US Food and Drug Administration for a claim of health benefits: serum lipid risk factors for cardiovascular disease assessed in a randomized controlled crossover trial[1–3]

David JA Jenkins, Cyril WC Kendall, Vladimir Vuksan, Edward Vidgen, Tina Parker, Dorothea Faulkner, Christine C Mehling, Marcella Garsetti, Giulio Testolin, Stephen C Cunnane, Mary Ann Ryan, and Paul N Corey

ABSTRACT

Background: The US Food and Drug Administration (FDA) approved health claims for 2 dietary fibers, β-glucan (0.75 g/serving) and psyllium (1.78 g/serving), on the assumption that 4 servings/d would reduce cardiovascular disease risk.

Objective: We assessed the efficacy of this dose of fibers in reducing serum lipid risk factors for cardiovascular disease.

Design: Sixty-eight hyperlipidemic adults consumed a test (high-fiber) and a control low-fat (25% of energy), low-cholesterol (<150 mg/d) diet for 1 mo each in a randomized crossover study. The high-fiber diet included 4 servings/d of foods containing β-glucan or psyllium that delivered 8 g/d more soluble fiber than did similar, unsupplemented foods in the control diet. Fasting blood samples and blood pressure readings were obtained at baseline and weeks 2 and 4, and the subjects' weight was monitored weekly.

Results: Compared with the control diet, the high-fiber diet reduced total cholesterol (2.1 ± 0.7%; $P = 0.003$), total:HDL cholesterol (2.9 ± 0.8%; $P = 0.001$), LDL:HDL cholesterol (2.4 ± 1.0%; $P = 0.015$), and apolipoprotein B:A-I (1.4 ± 0.8%; $P = 0.076$). Applying the Framingham cardiovascular disease risk equation to the data confirmed a reduction in risk of 4.2 ± 1.4% ($P = 0.003$). Small reductions in blood pressure were found after both diets. The subjects reported no significant differences in palatability or gastrointestinal symptoms between the diets.

Conclusions: The reduction in serum lipid risk factors for cardiovascular disease supports the FDA's approval of a health claim for a dietary fiber intake of 4 servings/d. Although relatively small in terms of patient treatment, the reduction in cardiovascular disease risk is likely to be significant on a population basis. *Am J Clin Nutr* 2002;75:834–9.

KEY WORDS Soluble fiber, psyllium, oats, β-glucan, LDL cholesterol, HDL cholesterol, coronary artery disease, National Cholesterol Education Program, Food and Drug Administration, health claim, functional foods

INTRODUCTION

The US Food and Drug Administration (FDA), which assesses health claims for foods, has approved health claims for the viscous fibers oat β-glucan and psyllium as cholesterol-lowering agents that in the context of a good diet may reduce the risk of cardiovascular disease (1, 2). Furthermore, national agencies concerned with cardiovascular health have for the first time recommended viscous fiber intake (3, 4). Much interest has been shown internationally by the general public, the scientific community, and federal regulators in the medical application of these food components in so-called functional foods, foods that favorably modify physiologic function. There is therefore a need to substantiate the validity of current regulations that govern health claims in this area (1, 2, 5, 6). To address this need, we tested the effects of psyllium and β-glucan intake, in the amounts approved by the FDA for a fiber health claim, on serum lipid risk factors for cardiovascular disease (1, 2).

SUBJECTS AND METHODS

Ninety-one hyperlipidemic subjects were recruited and 82 were available for random assignment. Of these, 68 (83%; 37 men and 31 postmenopausal women) completed both 1-mo dietary phases, separated by a 2-wk washout period in a randomized crossover study. The subjects' mean (±SE) age was 60 ± 1 y (range: 33–82 y) and their mean body mass index (in kg/m^2) was 25.6 ± 0.3 (range:

[1] From the Clinical Nutrition and Risk Factor Modification Center, St Michael's Hospital, Toronto (DJAJ, CWCK, VV, EV, TP, DF, and CCM); the Departments of Nutritional Sciences (DJAJ, CWCK, VV, EV, SCC, and MAR) and Preventive Medicine and Biostatistics (PNC), Faculty of Medicine, University of Toronto; and the Department of Food Science Technology and Microbiology, Division of Human Nutrition, University of Milan, Milan, Italy (MG and GT).

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TABLE 1
Calculated macronutrient intakes from week 4 dietary records with the high-fiber and control ad libitum diets[1]

	Control diet		High-fiber diet	
	Baseline	Week 4	Baseline	Week 4
Energy				
(MJ/d)	7.05 ± 0.22	7.47 ± 0.21	7.08 ± 0.24	7.42 ± 0.20
(kcal/d)	1686 ± 53	1787 ± 50	1694 ± 57	1774 ± 48
Total protein				
(g/d)	75 ± 3	73 ± 3	77 ± 3	74 ± 3
(% of energy)	17.9 ± 0.3	16.3 ± 0.3	18.3 ± 0.4	16.6 ± 0.3
Available carbohydrate				
(g/d)	230 ± 7	268 ± 7	229 ± 8	258 ± 6[2]
(% of energy)	55.0 ± 0.8	60.7 ± 0.7	54.4 ± 0.9	58.9 ± 0.8[2]
Total dietary fiber (g/d)	23 ± 1	20 ± 1	22 ± 1	30 ± 1[3]
Soluble fiber (g/d)	6 ± 0	4 ± 0	6 ± 0	13 ± 0[3]
Total fat				
(g/d)	52 ± 3	47 ± 2	52 ± 3	50 ± 3
(% of energy)	27.1 ± 0.9	23.1 ± 0.6	27.4 ± 0.8	24.5 ± 0.7[2]
SFA				
(g/d)	16 ± 1	13 ± 1	16 ± 1	15 ± 1[2]
(% of energy)	8.2 ± 0.3	6.5 ± 0.2	8.2 ± 0.4	7.4 ± 0.3[3]
MUFA				
(g/d)	21 ± 1	19 ± 1	21 ± 1	20 ± 1
(% of energy)	10.9 ± 0.4	9.0 ± 0.3	11.1 ± 0.4	9.6 ± 0.4[4]
PUFA				
(g/d)	11 ± 1	10 ± 1	11 ± 1	10 ± 1
(% of energy)	5.5 ± 0.2	5.1 ± 0.2	5.6 ± 0.2	5.0 ± 0.1
Dietary cholesterol				
(mg/d)	179 ± 11	127 ± 9	185 ± 13	144 ± 10
(mg/MJ)	25 ± 2	17 ± 1	26 ± 2	19 ± 1[2]
Alcohol				
(g/d)	8 ± 1	7 ± 1	7 ± 1	7 ± 1
(% of energy)	3.1 ± 0.6	2.5 ± 0.5	2.7 ± 0.5	2.7 ± 0.5

[1] $\bar{x}$ ± SE; n = 68. SFA, saturated fatty acid; MUFA, monounsaturated fatty acid; PUFA, polyunsaturated fatty acid.
[2–4] Significance of the treatment difference assessed by analysis of covariance with the general linear model procedure in SAS (11): [2] $P < 0.01$, [3] $P < 0.001$, [4] $P < 0.05$.

20.0–33.8). At baseline, all subjects had elevated serum LDL-cholesterol concentrations (>4.1 mmol/L) (7). One subject started with triacylglycerol concentrations >4.0 but <6.0 mmol/L. None had clinical or biochemical evidence of diabetes, liver disease, or renal disease, and none were taking hypolipidemic agents. Dosages of medications and level of physical activity were held constant for both study periods. Blood samples were obtained and blood pressure was measured with the subjects seated after they had fasted 12–14 h overnight before the start and at the end of weeks 2 and 4 of each phase. Serum was stored at −70°C until analyzed. Body weight was measured at the start and during biweekly clinic visits in both phases, and the subjects were also asked to monitor their weight on a home scale weekly.

For the last 7 d of each phase, the subjects recorded their diets after weighing food items on self-tarring electronic scales. During week 4 of each phase the subjects noted their number of bowel movements and rated flatulence, bloating, and abdominal pain on a 9-point bipolar scale. At each biweekly visit, subjects also rated their feelings of satiety with the use of a 9-point scale on which −4 represented extremely hungry, 0 neutral, and +4 completely satiated. The study was approved by the Ethics Committee of the University of Toronto. All the subjects gave informed consent.

Diets

At least 1 mo before the start of the study, the subjects were instructed on the principles of a National Cholesterol Education Program Step II diet (total fat <30% of energy, saturated fat <7% of energy, and dietary cholesterol <200 mg/d) (3). The subjects were instructed to follow these guidelines throughout the course of the study. Test (high-fiber) and control study foods consisted of a variety of breakfast cereals, breads, pasta-based frozen dinners, tea cakes, cookies, potato chips, and smoothie beverages. On average these contributed 36.2% of total daily energy intake. The test foods contained 1.8–2.5 g psyllium or 0.75 g β-glucan/serving (The Kellogg Co, Battle Creek, MI). Each subject selected 4 servings/d from the available foods, with the stipulation that one breakfast cereal and one frozen dinner must be chosen. On average, 7.2 g psyllium and 0.75 g β-glucan were consumed daily from these products (**Table 1**). The control diet provided similar commercial foods without the added fiber. The foods provided replaced similar foods in the subjects' diets such that they maintained their weight. Supplements were recorded when eaten, and any uneaten supplements were returned at the end of the dietary phase.

Analyses

Serum was analyzed in a single batch for total cholesterol, triacylglycerols, and HDL cholesterol after dextran sulfate–magnesium chloride precipitation in accordance with the guidelines of the Lipid Research Clinics Program (8). LDL cholesterol was calculated by using the Friedewald equation. Serum apolipoprotein A-I and B were measured by nephelometry.

TABLE 2
Body weight, serum lipid, and blood pressure data for the high-fiber and control ad libitum diet periods[1]

	Control diet		High-fiber diet		Mean treatment difference[2]	P[3]
	Baseline	Mean treatment	Baseline	Mean treatment		
					%	
Body weight (kg)[4]	71.7 ± 1.5	71.6 ± 1.4	71.7 ± 1.5	71.6 ± 1.4	0.1 ± 0.1	0.494
Cholesterol (mmol/L)						
Total	6.90 ± 0.10	6.78 ± 0.09	6.78 ± 0.10	6.63 ± 0.09	−2.1 ± 0.7[5]	0.001
LDL	4.75 ± 0.09	4.57 ± 0.08	4.67 ± 0.09	4.48 ± 0.08	−1.7 ± 0.9	0.064
HDL	1.30 ± 0.04	1.25 ± 0.03	1.26 ± 0.03	1.26 ± 0.03	1.3 ± 0.9	0.304
Triacylglycerols (mmol/L)	1.96 ± 0.11	2.15 ± 0.11	1.88 ± 0.09	2.00 ± 0.10	−5.2 ± 2.4[6]	0.005
Apo A-I (g/L)	1.64 ± 0.03	1.60 ± 0.03	1.60 ± 0.03	1.58 ± 0.03	−1.3 ± 0.6	0.033
Apo B (g/L)	1.70 ± 0.03	1.69 ± 0.03	1.69 ± 0.03	1.64 ± 0.03	−2.9 ± 0.8[5]	0.001
Total-C:HDL-C	5.53 ± 0.15	5.66 ± 0.15	5.58 ± 0.15	5.47 ± 0.14	−2.9 ± 0.8[5]	0.000
LDL-C:HDL-C	3.79 ± 0.12	3.81 ± 0.11	3.86 ± 0.13	3.70 ± 0.11	−2.4 ± 1.0[6]	0.003
Apo B:apo A-I	1.06 ± 0.03	1.07 ± 0.03	1.08 ± 0.03	1.06 ± 0.03	−1.4 ± 0.8	0.016
Blood pressure (mm Hg)						
Systolic	124 ± 2	122 ± 1	124 ± 2	121 ± 1	−0.7 ± 0.4	0.061
Diastolic	80 ± 2	76 ± 1	79 ± 2	77 ± 2	−0.3 ± 0.6	0.406
CAD risk (%)[7]	11.6 ± 0.7	11.7 ± 0.7	11.7 ± 0.7	11.1 ± 0.7	−4.2 ± 1.4	0.003

[1] $\bar{x}$ ± SE; n = 68. Apo, apolipoprotein; C, cholesterol; CAD, coronary artery disease. To convert cholesterol and triacylglycerols to mg/dL, multiply by 38.67 and 88.57, respectively. To convert apo A-I and apo B values to mg/dL, multiply by 100.

[2] Treatment difference (%) = [(high-fiber − control) × 100/control], where high-fiber and control represent the mean of the absolute values from weeks 2 and 4.

[3] Calculated from the absolute means of the values from weeks 2 and 4 with the general linear model procedure in SAS (11).

[4] Mean treatment data are week 4 values.

[5] $P < 0.01$.

[6] $P < 0.05$.

[7] The Framingham predictive equation for cardiovascular disease risk was used to assess the likelihood of angina, myocardial infarction, or death during a 10-y period.

Macronutrient intakes were assessed from the 7-d dietary records with the use of a database derived from food-composition tables of the US Department of Agriculture (9) and with food labels for the few foods that were not analyzed directly. The supplements used in the study were analyzed with the use of Association of Official Analytical Chemists methods for fat, protein, and fiber, with available carbohydrate determined by difference (10). The fatty acid composition was determined by gas chromatography.

Statistical analysis

The results are expressed as means ± SEs. The mean of weeks 2 and 4 for each phase was used in calculating treatment differences because no significant differences were found between weeks 2 and 4 in any measurement except LDL cholesterol, for which a significant treatment effect was seen only at 2 wk. Furthermore, this difference was not reflected in a corresponding difference in non-HDL cholesterol; the mean of the LDL-cholesterol values from weeks 2 and 4 was therefore used in analysis of the data. The significance of the percentage difference between treatments was assessed by two-tailed Student's t test for paired data. The absolute difference between treatments was assessed by analysis of covariance with the use of the general linear model procedure and SAS software (PROC GLM/SAS) (11), with the response variable as the mean of the measurements from weeks 2 and 4 and the main effects of diet, sex × sequence interaction, and a random term representing the subject nested within the sex × sequence interaction and the baseline value as a covariate. Analysis with an alternative statistical model, with diet, sex, diet × sex, and the random term described above as main effects and dietary cholesterol and starting value as covariates, yielded similar results.

The Framingham predictive equation for cardiovascular disease risk was also applied to the data by using the total:HDL cholesterol and systolic blood pressure results. The equation also includes age, sex, the presence or absence of left ventricular hypertrophy, and whether the individual is a smoker or has diabetes (12). Our subjects did not have diabetes and were nonsmokers. Left ventricular hypertrophy was not assessed. Cardiovascular disease risk is expressed in the text as the percentage of individuals who would be predicted to have angina, have a myocardial infarction, or die during a 10-y period (12).

RESULTS

The diets were well accepted and compliance was good. With both the control and high-fiber diets, subjects consumed 96 ± 1% of the supplements provided. Both diets had high and similar palatability scores (high-fiber diet: 3.4 ± 0.1; control diet: 3.2 ± 0.1) and satiety scores (high-fiber diet: 0.6 ± 0.1; control diet: 0.5 ± 0.1). There was no significant body weight change with either the high-fiber diet (−0.1 ± 0.1 kg) or the control diet (−0.1 ± 0.1 kg; **Table 2**).

Blood lipids and apolipoproteins

Significant reductions from pretreatment values were seen in blood lipids after both diets (Table 2). There were no significant differences in pretreatment values between the high-fiber and control diets (Table 2). Mean values were significantly lower after the high-fiber diet than after the control diet for total cholesterol [percentage difference between treatments: 2.1 ± 0.7%;

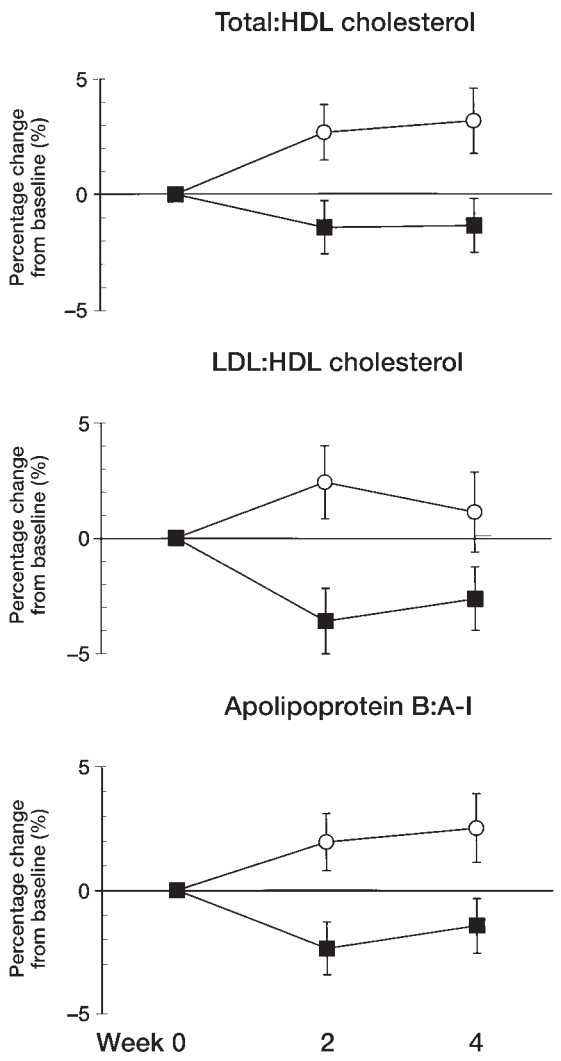

FIGURE 1. Percentage change in blood lipid, lipoprotein, and apolipoprotein ratios from week 0 to weeks 2 and 4 of the high-fiber (■) and control (○) diets.

$P = 0.003$ (Students's t test)]; triacylglycerols (5.2 ± 2.4%; $P = 0.037$); apolipoprotein B (2.9 ± 0.8%; $P < 0.001$); total:HDL cholesterol (2.9 ± 0.8%; $P = 0.001$); and LDL:HDL cholesterol (2.4 ± 1.0%; $P = 0.015$), with a nonsignificant reduction in apolipoprotein B:A-I of 1.4 ± 0.8% ($P = 0.076$). There were no other significant differences. The percentage treatment differences in the lipid and lipoprotein ratios at week 2 were similar to the respective values at week 4. The percentage changes from baseline for the high-fiber and control treatments are shown in **Figure 1**. The significance of the effect of diet on serum lipids was confirmed by using the mean of the lipid values from weeks 2 and 4 and the general linear model procedure (for total cholesterol, triacylglycerol, apolipoprotein B, total:HDL cholesterol, LDL:HDL cholesterol, and apolipoprotein B:A-I; Table 2).

There were no significant differences between the sexes in response to diet. In addition, neither age nor body mass index influenced the treatment effect. Controlling for weight change or differences in dietary carbohydrate, saturated or polyunsaturated fat, the ratio of polyunsaturated to saturated fatty acids, or dietary cholesterol in the general linear model procedure did not alter the pattern of significance in treatment differences of blood lipids.

Cardiovascular risk estimation

Application of the Framingham cardiovascular disease risk equation to the data confirmed a 4.2 ± 1.4% treatment difference in cardiovascular disease risk ($P = 0.003$) (12).

Blood pressure

Systolic and diastolic blood pressures tended to be reduced after both dietary phases but were not significantly different between treatments (Table 2).

Gastrointestinal symptoms

No significant differences were seen between the high-fiber and control diets in bloating, flatulence, or abdominal pain. Bowel movements were more frequent during the high-fiber than during the control diet (9.6 ± 0.5 compared with 8.6 ± 0.5 movements/wk; $P = 0.005$).

DISCUSSION

Our data show that incorporation of viscous fibers into a wide range of foods resulted in small but significant reductions in total cholesterol and in the ratio of LDL to HDL cholesterol. These data add support to the FDA-approved health claim that in the context of a low-fat, low-cholesterol diet, 4 servings/d of foods containing the viscous fibers psyllium and oat β-glucan can be expected to reduce serum lipids and the risk of cardiovascular disease.

The FDA was one of the first national agencies to recognize a role for fiber in cardiovascular disease risk reduction. Products that contain 0.75 g β-glucan or 1.78 g psyllium/serving are permitted to carry a health claim stating that the product "will reduce the risk of coronary heart disease" (1, 2). The FDA further determined that 4 servings of these foods is likely to provide the effective daily dose (1, 2).

There is considerable international interest in health claims, both to encourage industry to produce foods with specific health benefits (functional foods) and to ensure efficacy of action (1, 2, 5, 6, 13). Validation of health claims is therefore important, especially in the case of soluble fiber, because national agencies concerned with cardiovascular health have only recently acknowledged a role for fiber in cholesterol reduction (4, 14). The ability of viscous soluble fibers to lower serum cholesterol has been recognized for more than a quarter of a century (15, 16). At first the dietary fibers of interest were pectin and guar (15, 17); later attention focused on oat β-glucan and psyllium, which in most but not all studies were shown to reduce serum cholesterol concentrations (15, 16, 18–20).

The present study assessed the effects of consuming 8 g/d of a combination of the viscous fibers psyllium and β-glucan, an amount that meets the FDA requirements for a health claim for cardiovascular disease risk reduction. Although the cholesterol reduction was modest, estimated cardiovascular disease risk was reduced. In addition, the ratios of total to HDL cholesterol and of LDL to HDL cholesterol were also reduced in our study, which was not previously reported with the consumption of fiber in studies achieving these modest levels of cholesterol reduction. Although glycemic index data are not available on the foods used in the present study, it is possible that part of the beneficial effect on the lipid and lipoprotein ratios was caused by a general

lowering of the glycemic index of the diet. Incorporation of viscous fibers into a range of carbohydrate foods eaten over the day would tend to reduce the dietary glycemic index, as has been shown for individual foods and meals (21). Studies of low–glycemic index diets reported varied effects on serum cholesterol: some showed reductions (22–24) and others did not (25, 26). On the other hand, low-glycemic-index diets appear to lower serum triacylglycerols in subjects with raised triacylglycerol concentrations (27, 28).

In cohort studies, low-glycemic-index diets were associated with higher HDL-cholesterol concentrations (29, 30) and reduced risk of cardiovascular disease (31). The changes in lipoprotein ratios observed in the present study are considered key indicators of cardiovascular disease risk reduction and are central to equations predicting coronary artery disease risk (12). In this respect our data suggest a potential advantage of distributing fiber over the day in a range of carbohydrate foods.

The viscous nature of the types of dietary fiber that are most effective in reducing serum lipids has been a major barrier to their use in foods. Their clinical relevance has been questioned because of the extreme unpalatability of some of the products tested (32). The finding that palatable diets can be produced by incorporating lower amounts of fiber into more foods while retaining effectiveness is therefore important.

Foods containing sufficient psyllium and oat β-glucan per serving to justify a health claim for cardiovascular disease risk reduction reduce serum lipids and are as palatable as their low-fiber counterparts. Spreading the fiber intake over the day may be responsible for reducing the ratio of total to HDL cholesterol and of LDL to HDL cholesterol, through lowering of the glycemic index of the carbohydrate portion of the diet. The palatability of and lack of side effects from these foods suggest that consumption of more servings of fiber-supplemented foods will also prove acceptable in clinical situations where larger reductions in lipid risk factors for cardiovascular disease are required. The present level of supplementation is likely to be of benefit on a population basis as one of several dietary strategies to reduce lipid risk factors for cardiovascular disease (33).

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Effects of psyllium on glucose and serum lipid responses in men with type 2 diabetes and hypercholesterolemia[1–3]

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ABSTRACT

Background: Water-soluble dietary fibers decrease postprandial glucose concentrations and decrease serum cholesterol concentrations. This study examined the effects of administering psyllium to men with type 2 diabetes.

Objective: The objective was to evaluate the safety and effectiveness of psyllium husk fiber used adjunctively to a traditional diet for diabetes in the treatment of men with type 2 diabetes and mild-to-moderate hypercholesterolemia.

Design: After a 2-wk dietary stabilization phase, 34 men with type 2 diabetes and mild-to-moderate hypercholesterolemia were randomly assigned to receive 5.1 g psyllium or cellulose placebo twice daily for 8 wk. Serum lipid and glycemic indexes were evaluated biweekly on an outpatient basis and at weeks 0 and 8 in a metabolic ward.

Results: In the metabolic ward, the psyllium group showed significant improvements in glucose and lipid values compared with the placebo group. Serum total and LDL-cholesterol concentrations were 8.9% ($P < 0.05$) and 13.0% ($P = 0.07$) lower, respectively, in the psyllium than in the placebo group. All-day and postlunch postprandial glucose concentrations were 11.0% ($P < 0.05$) and 19.2% ($P < 0.01$) lower in the psyllium than in the placebo group. Both products were well tolerated, with no serious adverse events related to treatment reported in either group.

Conclusion: The addition of psyllium to a traditional diet for persons with diabetes is safe, is well tolerated, and improves glycemic and lipid control in men with type 2 diabetes and hypercholesterolemia. *Am J Clin Nutr* 1999;70:466–73.

KEY WORDS Psyllium, type 2 diabetes, serum lipids, hypercholesterolemia, postprandial glucose, glycemic response, fiber, men

INTRODUCTION

Psyllium husk fiber is a viscous, mostly water-soluble fiber prepared by mechanical removal of the husk from blonde psyllium seed (*Plantago ovata*). Early or uncontrolled studies suggested that psyllium improved glycemic and lipid control in individuals with type 2 diabetes (1–3). Although a more recent and carefully controlled study reported reduced postprandial glucose and insulin concentrations with psyllium supplementation in type 2 diabetes (4), other studies found no effect on glycemic control (5) or an effect only when psyllium was sprinkled onto or incorporated into a cereal meal (6).

Psyllium has been shown to significantly reduce postprandial serum glucose and insulin concentrations in nondiabetic individuals (7). Numerous studies of nondiabetic individuals indicate that psyllium significantly lowers both total and LDL-cholesterol concentrations (8–12). However, the safety and effectiveness of psyllium for individuals with type 2 diabetes and hypercholesterolemia has not been well documented. The Diabetes Control and Complications Trial convincingly showed that maintaining good glycemic control delayed the onset and slowed the progression of complications in individuals with type 1 diabetes (13). Many healthy individuals with type 2 diabetes may also benefit from improved glycemic control (14). Furthermore, type 2 diabetes dramatically increases the risk of atherosclerotic cardiovascular disease (15, 16) and reductions in atherogenic lipids could greatly reduce mortality and morbidity from cardiovascular disease in individuals with type 2 diabetes.

The purpose of this study was to investigate the safety and effectiveness of psyllium husk fiber consumed for 8 wk adjunctively to a standard diet for diabetes in the treatment of men with type 2 diabetes and mild-to-moderate hypercholesterolemia. Effects of psyllium on glycemic and serum lipid indexes were examined in both an outpatient and metabolic ward setting.

SUBJECTS AND METHODS

Subjects

A total of 56 men with type 2 diabetes and hypercholesterolemia were recruited initially. After a 2-wk dietary stabilization phase, 34 of these men qualified for random assignment to treatment. The Human Investigation Subcommittee of the

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University of Kentucky reviewed and approved the study and informed consent was obtained from each subject.

Individuals were eligible for the study if they were men aged 30–70 y; had a body mass index (in kg/m^2) of ≤30; had a history of stable type 2 diabetes meeting the criteria of the National Diabetes Data Group (17), with a fasting blood glucose concentration of 8.33–11.10 mmol/L and a serum glycated hemoglobin (Hb A_{1c}) concentration of ≤9% (mean of values taken in weeks −2 and −1 of the study); and had mild-to-moderate hypercholesterolemia, with a stable serum total cholesterol concentration of 5.17–7.76 mmol/L and triacylglycerol concentration of ≤5.65 mmol/L (mean of weeks −2 and −1). Individuals whose diabetes was controlled with diet only or diet plus oral sulfonylurea agents were eligible for study. Individuals were excluded from the study if they had medical conditions or were taking medications or supplements that might have interfered with glucose, insulin, or lipid measurements. Individuals with a history of myocardial infarction or major surgical procedures within the previous 6 mo were excluded from the study, as were individuals with a history of alcohol abuse, allergy to aspartame or psyllium seed, or phenylketonuria.

Experimental design

This study was double-blind, placebo-controlled, and parallel. The study consisted of a 2-wk dietary stabilization phase during which subjects followed a diet for diabetes followed by an 8-wk treatment phase in which subjects continued the diet but were also randomly assigned to receive either 5.1 g psyllium (psyllium group) or cellulose placebo (control group) twice daily. Subjects were instructed to consume the test products 20–30 min before the morning and evening meals.

All subjects underwent 2-d metabolic ward studies at weeks 0 and 8. During these studies, standardized meals were used to more accurately measure the effects of psyllium on glycemic and lipid control. After an overnight insulin infusion, a random subset of 8 subjects in the psyllium group and 8 subjects in the placebo group underwent a euglycemic clamp procedure during the third day of each metabolic ward evaluation to more fully evaluate glucose metabolism and peripheral insulin sensitivity.

Diets and test products

During the dietary stabilization phase, subjects received instruction on a traditional weight-maintaining diabetes exchange diet providing ≤30% of total energy as fat, ≤10% of energy as saturated fat, and ≥55% of energy as carbohydrate. Diet was not the major focus of this intervention and the main goal of dietary instruction was to encourage subjects to maintain their same dietary patterns throughout the study. Subjects continued with this diet and received ongoing dietary counseling throughout the remainder of the study.

During the treatment phase, subjects in the psyllium group received an orange-flavored, sugar-free product (Metamucil; Procter & Gamble Co, Cincinnati); subjects in the placebo group received an insoluble fiber, microcrystalline cellulose (Avicel, PH-101; FMC Corp, Philadelphia). Both test products included the same psyllium-product excipients and were given in two 8.7-g doses daily; each dose provided 5.1 g of either psyllium or cellulose. Both products were orange-flavored powders and were packaged in identical foil packets. Subjects were instructed to mix each packet in 240 mL liquid and to drink the mixture immediately before (20–30 min) the morning and evening meals each day for 8 wk.

During the metabolic ward evaluations, subjects received standardized meals low in fiber to enhance detection of the effects of fiber on glucose and lipid metabolism, as described previously (8). Subjects consumed a low-fat, low-fiber meal (65% of energy as carbohydrate, 15% as protein, 20% as fat, and 50 mg cholesterol/MJ) on the evening of the first day of the metabolic ward evaluation. On day 2 of the metabolic-ward evaluation, subjects consumed 3 meals providing 40% of energy as carbohydrate, 15% as protein, 45% as fat, 50 mg cholesterol/MJ, and 0.8 g dietary fiber/kJ.

Measurements

Dietary compliance throughout the study was monitored by using 3-d food records collected at weeks −1, 4, and 8. Dietary data were analyzed for energy, total fat, polyunsaturated fat, saturated fat, carbohydrate, protein, total fiber, soluble fiber, and cholesterol contents by using a computerized nutrient database (18) with revised fiber values (19). Compliance with test product use was monitored by subject interviews and by counting unopened packets at follow-up visits. Reports of any treatment-related adverse experience were solicited at each follow-up visit. A brief physical exam, a complete serum lipid profile, and fasting blood glucose and glycated hemoglobin (Hb A_{1c}) concentrations were taken at week −2 to establish eligibility for the study and were repeated at weeks −1, 0, 2, 4, 6, and 8. Fasting glycated albumin concentrations were measured at weeks −1, 0, 2, 4, 6, and 8 of the study. Thyroid function tests were also measured at week −1 of the study. Clinic visits were scheduled in the morning after a minimum 12-h fast. Subjects were instructed not to take their test medication on the morning of the study visits.

At weeks 0 and 8, all subjects were admitted to the metabolic ward for 2–3 d of evaluation. A complete physical examination, routine clinical chemistry and hematologic evaluations, and urinalyses were performed on day 1. Fasting serum lipid, C-peptide, Hb A_{1c}, and glycated albumin concentrations were some of the indexes measured.

On day 2 of the metabolic ward evaluation, serum lipids, glucose, insulin, fatty acids, apolipoproteins, and lipoprotein fractions by a vertical auto profile (VAP) were measured immediately before breakfast after a 14-h fast. Postprandial lipids, glucose, and insulin concentrations were measured at 9 intervals throughout the day; postprandial fatty acids were measured at 7 intervals; and postprandial apolipoproteins and VAP lipoproteins were measured at 3 intervals. A catheter was inserted into an antecubital vein to limit the number of venipunctures.

On the morning of day 3 of the metabolic ward evaluation, 16 randomly selected subjects also underwent a euglycemic hyperinsulinemic clamp procedure (20, 21). To standardize basal serum glucose concentrations, subjects received an overnight insulin infusion (W Duckworth, unpublished observations, 1992). Briefly, a 12-h intravenous insulin infusion (Novolin R in 1 L isotonic saline; Squibb & Co, Princeton, NJ) was started in these subjects on the evening of day 2. The insulin delivery rate was initiated and adjusted hourly according to a predetermined algorithm based on capillary blood glucose. Insulin was infused at $\approx 1\ mU \cdot kg^{-1} \cdot min^{-1}$ for 3 h after an appropriate priming dose. Glucose (20% wt:vol, or 1.1 mol/L) was infused to maintain blood glucose at 5.55 mmol/L. Blood was drawn every 5 min throughout the procedure to monitor blood glucose concentrations, and 6 evaluations of serum

insulin were made at regular intervals during the procedure. Subjects who underwent the euglycemic clamp were discharged after the postclamp meal. All other subjects were discharged after breakfast on day 3.

Analytic methods

Serum glucose concentrations were measured by using glucose oxidase (22). Serum insulin concentrations were measured with an insulin radioimmunoassay kit (ICN Micromedic Systems, Horsham, PA). Serum cholesterol, triacylglycerol, and HDL-cholesterol concentrations were determined with enzymatic methods by using the Abbott VP Analyzer (Abbott Laboratories, North Chicago). Serum cholesterol concentrations were measured with a sterol esterase–cholesterol oxidase assay (23). Serum triacylglycerol concentrations were determined by hydrolyzing the triacylglycerol and measuring the released glycerol (24). Serum HDL-cholesterol concentrations were measured with the same method used for serum cholesterol after removal of LDL and VLDL cholesterol by magnesium–dextran sulfate precipitation (25). Apolipoprotein A-I and B-100 concentrations were measured by radioimmunodiffusion with Tago-Diffu-Gen Kits (Tago, Burlingame, CA). Samples were sent to the University of Alabama Lipoprotein Laboratory (Birmingham) for VAP measurements (26). Other lipid measurements were done locally. Serum LDL-cholesterol, intermediate-density-lipoprotein (IDL), VLDL-cholesterol, HDL_2, and HDL_3 concentrations were available from VAP analysis. LDL cholesterol was also calculated with the Friedewald formula (27). Fasting serum C-peptide concentrations were measured as described previously (28). Glycated albumin was measured by using a boronated affinity column (Nichols Institute Reference Laboratories, San Juan Capistrano, CA), with expected values of 0.9–1.9%.

Statistical analyses

Two-sample *t* tests confirmed by Wilcoxon rank-sum tests were used to determine the comparability of values for the psyllium and placebo groups at baseline, to compare changes and percentage changes from baseline between treatment groups, and to compare dietary analyses indexes between groups. One-sample *t* tests were used to determine whether mean changes from baseline within each treatment group were significant. For the final values of body weight and each of the glycemic and lipid profile indexes, analysis of covariance was also completed with baseline values as covariates.

For outpatient evaluations, baseline values were defined as the average of all values taken at weeks −2, −1, and 0. Final values were defined as those measured at week 8. For metabolic ward evaluations, baseline and final values were defined as an average of values taken on day 2 of the metabolic ward evaluation at weeks 0 and 8, respectively. Values measured during the euglycemic clamp procedure were analyzed separately from other metabolic ward evaluations. Mean and peak serum glucose and insulin values were calculated separately for the postprandial periods after breakfast, lunch, and dinner.

All subjects were included in the safety analyses, whereas only subjects meeting all inclusion and exclusion criteria were included in the efficacy analyses. Two-tailed *P* values <0.05 were considered statistically significant, whereas *P* values between 0.05 and 0.10 were considered to be nearly significant. All analyses were performed by using the SAS package (29).

TABLE 1
Baseline characteristics of subjects in the psyllium and control groups[1]

Variable	Control (n = 14)	Psyllium (n = 15)
Age (y)	63.8 ± 1.6	62.0 ± 1.6
Height (cm)	178.6 ± 2.0	176.8 ± 1.4
Body weight (kg)	87.1 ± 3.3	89.6 ± 2.4
Body mass index (kg/m^2)	27.4 ± 1.1	28.7 ± 0.9
C-peptide (nmol/L)	1.16 ± 0.10	1.32 ± 0.10

[1] $\bar{x}$ ± SEM of values taken at weeks −2, −1, and 0 during the dietary stabilization phase. There were no significant differences between groups.

RESULTS

Of the 56 men who entered the dietary stabilization phase, 19 failed to meet study inclusion and exclusion criteria and 3 withdrew their consent to participate. Of the 34 subjects randomly assigned to treatment (18 to the psyllium group and 16 to the placebo group), 29 (15 in the psyllium group and 14 in the placebo group) completed the study and were considered evaluable. In the psyllium group, one subject withdrew consent, one subject was discharged by the study investigator because of back pain due to a spinal infection unrelated to treatment, and one subject was deemed unevaluable because of a baseline fasting blood glucose concentration in violation of the study protocol. In the placebo group, one subject withdrew consent and one subject was discharged by the study investigator because of noncompliance. On the basis of the number of returned, unopened packages and subject interviews, compliance was determined to be excellent. Subjects consumed 99.6% of the psyllium and 95.3% of the placebo given.

Baseline characteristics

Baseline characteristics of subjects in the psyllium and placebo groups are summarized in **Table 1**. Subjects were well matched according to age, height, body weight, and body mass index. Baseline C-peptide concentrations were not significantly different between groups.

Baseline and final dietary nutrient intakes in the psyllium and placebo groups are shown in **Table 2**. Except for the significantly higher total energy intake in the psyllium group than in the placebo group at baseline, dietary intakes did not differ significantly between groups throughout the study. The low energy intakes reported by both the psyllium and placebo groups in this study indicated that subjects substantially underreported their food intakes. More intensive training of subjects is required to ensure accurate self-reported intakes for careful dietary studies.

Outpatient responses

Changes from baseline in the glycemic and lipid indexes of the 2 groups during the outpatient and metabolic ward portions of the study are summarized in **Table 3**. At week 8, serum LDL-cholesterol concentrations decreased 4.9% in the psyllium group but increased 2.8% in the placebo group. This 7.7% difference in serum LDL-cholesterol concentrations was nearly significant ($P = 0.09$). The change in serum HDL-cholesterol concentrations was significantly different between the psyllium and placebo groups at week 8, although the change in the ratio of LDL to HDL cholesterol was significantly different. Other than these exceptions, there were no significant differences in the change in glycemic and lipid indexes between the psyllium and placebo groups during outpatient evaluations.

TABLE 2
Daily nutrient intakes of subjects in the psyllium and control groups[1]

	Control (n = 14)		Psyllium (n = 15)	
Nutrient	Baseline	Final	Baseline	Final
Energy (MJ)	4.62 ± 0.40	4.71 ± 0.40	5.88 ± 0.32[2]	5.39 ± 0.26
Carbohydrate (% of energy)	43.8 ± 1.8	48.5 ± 1.7	48.2 ± 2.3	48.3 ± 2.3
Protein (% of energy)	22.6 ± 1.7	22.6 ± 0.9	20.2 ± 0.9	20.2 ± 1.1
Total fat (% of energy)	33.6 ± 1.5	28.8 ± 1.4	31.4 ± 2.1	31.2 ± 1.7
Saturated fat (% of total fat)	35.1 ± 1.2	32.7 ± 1.4	34.4 ± 1.6	32.0 ± 2.1
P:S[3]	0.61 ± 0.08	0.68 ± 0.09	0.69 ± 0.09	0.65 ± 0.10
Cholesterol (mg)	262.1 ± 36.4	194.9 ± 33.4	269.2 ± 39.5	280.3 ± 35.8
Total fiber (g)	11.4 ± 1.7	13.7 ± 1.7	17.0 ± 2.2	15.1 ± 1.9
Soluble fiber (g)	4.2 ± 0.6	4.7 ± 0.6	5.3 ± 0.6	4.9 ± 0.7

[1] $\bar{x}$ ± SEM. Baseline and final values were measured at weeks −1 and 8, respectively.
[2] Significantly different from control group, $P < 0.05$.
[3] Ratio of polyunsaturated to saturated fat.

All subjects maintained their body weights within ±5% during the study. As shown in Table 3, body weight decreased 0.3% in the psyllium group but increased 1.5% in the placebo group at week 8. Although this 1.8% difference in change in body weight between the psyllium and placebo groups was significant at week 8, no consistent trends in body weight were seen during the study. Changes in body weights did not differ significantly between groups at weeks 2, 4, or 6.

Metabolic ward responses

Changes from baseline in serum glucose with treatment are illustrated in **Figure 1**. During the first 180 min of treatment, values for subjects in the placebo group did not differ significantly from baseline, but values were consistently higher than baseline beginning at 270 min and beyond, being significantly different at 420 and 480 min. In contrast, values for psyllium-treated subjects were consistently below baseline values and differed significantly from values in the placebo group at 420 and 480 min.

Changes from baseline in glycemic and lipid indexes during the metabolic ward and outpatient evaluations are also shown in Table 3. There were significant differences in changes from baseline between the 2 groups for both glycemic and lipid indexes, with the psyllium group showing improved metabolic control compared with subjects in the placebo group. Of the glycemic indexes measured in all subjects in the metabolic ward, the percentage change in all-day postprandial serum glucose concentrations and postlunch serum glucose concentrations differed significantly between the psyllium and placebo groups. Compared with baseline concentrations, all-day postprandial serum glucose concentrations declined 4.2% in the psyllium group but rose 6.8% in the placebo group ($P < 0.05$). Postlunch serum glucose concentrations declined 6.5% in the psyllium group but rose 12.7% in the placebo group ($P < 0.01$). Thus, all-day and postlunch postprandial glucose concentrations were 11.0% and 19.2% lower, respectively, in the psyllium than in the placebo groups. Although mean baseline and peak serum insulin concentrations were significantly different between the psyllium and placebo groups, percentage changes from baseline in insulin did not differ significantly between groups (data not shown).

Glycemic indexes measured during the insulin clamp studies were not significantly different before and after treatment in the psyllium and placebo groups. After an overnight insulin infusion, baseline serum glucose values averaged 7.6 ± 0.6 and 7.5 ± 0.5 mmol/L in the psyllium and placebo groups, respectively; these values did not differ significantly between groups after the 8-wk treatment period. Mean serum glucose concentrations during the baseline insulin clamp procedure were 6.2 ± 0.1 and 6.1 ± 0.2 mmol/L in the psyllium and placebo groups, respectively; these values did not differ significantly between groups after treatment. Mean serum insulin concentrations during the baseline insulin clamp procedure were 517.4 ± 17.4 pmol/L (74.5 ± 2.7 mU/mL) and 470.2 ± 38.9 pmol/L (67.7 ± 5.6 mU/mL) in the psyllium and control groups, respectively; these values did not differ significantly between groups at baseline and did not change significantly after treatment. Glucose infusions during the baseline insulin clamp procedure averaged 2.3 ± 0.7 and 2.4 ± 0.5 $mg \cdot kg^{-1} \cdot min^{-1}$ in the psyllium and control groups, respectively; these values decreased by 4.4 ± 5.3% and 4.2 ± 13.8%, respectively, during treatment. Thus, there were no significant differences in these glycemic indexes nor in percentage changes in these indexes between the psyllium and control groups at baseline or after treatment.

Of the lipid indexes measured in the metabolic ward, percentage changes in serum total cholesterol concentrations differed significantly between the psyllium and placebo groups ($P = 0.012$). Differences in percentage changes between groups were nearly significant for calculated LDL-cholesterol concentrations ($P = 0.068$) and VAP LDL-cholesterol concentrations ($P = 0.068$). Serum total cholesterol concentrations declined 2.1% from baseline in the psyllium group but increased 6.9% in the placebo group, resulting in a net difference in serum total cholesterol concentrations of 9.0% between the 2 groups.

Safety analyses

Safety analyses were performed on all 34 subjects randomly assigned to treatment. Test products were well tolerated by most subjects. There were no significant differences between treatment groups in the incidence of adverse events or in the type of event reported. Respiratory system disorders were the most commonly reported adverse event. No serious adverse events related to treatment were reported by either the placebo or psyllium group.

Except for increased total protein and γ-glutamyltransferase concentrations and significant changes in some of the leukocyte indexes in the placebo group compared with baseline, no

TABLE 3
Serum glycemic and lipid responses in metabolic ward and outpatient settings in subjects in the psyllium and control groups[1]

	Control (n = 14)		Psyllium (n = 15)	
	Baseline	Percentage change	Baseline	Percentage change
Outpatient				
Body weight (kg)	87.1 ± 3.3	1.5 ± 0.7	89.6 ± 2.4	−0.3 ± 0.4[2]
Glucose (mmol/L)	10.74 ± 0.56	2.8 ± 4.6	10.02 ± 0.41	−6.1 ± 4.5
Hb A_{1C}	0.075 ± 0.002	−0.8 ± 4.3	0.073 ± 0.003	−6.3 ± 3.1
Glycated albumin	0.0222 ± 0.0010	−5.6 ± 6.2	0.020 ± 0.001	−3.1 ± 4.1
Total cholesterol (mmol/L)	5.89 ± 0.15	2.8 ± 2.3	6.08 ± 0.18	−2.3 ± 2.2
LDL cholesterol (mmol/L)	3.80 ± 0.17	2.8 ± 3.4	4.00 ± 0.23	−4.9 ± 2.4
HDL cholesterol (mmol/L)	0.94 ± 0.05	8.8 ± 2.3	0.97 ± 0.07	−0.9 ± 3.0[2]
Triacylglycerols (mmol/L)	2.50 ± 0.20	−0.4 ± 5.3	2.71 ± 0.35	−7.0 ± 13.3
Metabolic ward				
Glucose (mmol/L)				
Postbreakfast	13.54 ± 0.95	3.8 ± 4.7	13.44 ± 0.82	−3.0 ± 4.6
Postlunch	10.43 ± 0.83	12.7 ± 5.6	10.75 ± 0.69	−6.5 ± 4.2[3]
Postdinner	10.89 ± 0.61	2.2 ± 3.9	11.80 ± 0.75	−5.7 ± 4.5
All day	11.53 ± 0.76	6.8 ± 3.9	11.90 ± 0.70	−4.2 ± 3.3[2]
Total cholesterol (mmol/L)	5.39 ± 0.17	6.9 ± 2.4	5.69 ± 0.20	−2.1 ± 2.3[2]
LDL cholesterol (mmol/L)	3.39 ± 0.17	8.3 ± 5.3	3.81 ± 0.19	−4.7 ± 4.3
HDL cholesterol (mmol/L)	0.85 ± 0.05	2.0 ± 2.2	0.88 ± 0.07	0.6 ± 3.1
Triacylglycerols (mmol/L)	2.50 ± 0.23	13.7 ± 7.3	2.54 ± 0.31	6.5 ± 6.8
VAP lipoprotein cholesterol (mmol/L)				
LDL	3.39 ± 0.14	2.7 ± 3.5	3.70 ± 0.20	−7.0 ± 3.7
HDL	0.86 ± 0.05	−2.6 ± 3.6	0.85 ± 0.07	−0.1 ± 4.2
HDL_2	0.14 ± 0.02	−19.2 ± 9.2	0.12 ± 0.04	8.7 ± 15.9
HDL_3	0.72 ± 0.03	1.4 ± 4.3	0.72 ± 0.05	−3.1 ± 4.2
Apolipoprotein B (g/L)	1.45 ± 0.08	5.7 ± 2.3	1.46 ± 0.08	−1.5 ± 3.7
Apolipoprotein A (g/L)	1.064 ± 0.032	2.5 ± 3.0	1.047 ± 0.079	2.2 ± 4.4

[1] $\bar{x}$ ± SEM. Baseline values were measured at weeks −2, −1, and 0; final values were measured at week 8. VAP, verticle auto profile; Hb A_{1C}, glycated hemoglobin.
[2,3] Significantly different from control group: [2] $P < 0.05$, [3] $P = 0.01$.

clinically significant changes occurred in clinical chemistry, hematology, or urinalysis indexes as a result of treatment in either group. Although the difference in changes from baseline between the psyllium and placebo groups was significant for total protein, γ-glutamyltransferase concentrations, and some leukocyte indexes, none of these indexes changed significantly from baseline in the psyllium group.

DISCUSSION

This study was designed to evaluate the safety and effectiveness of psyllium compared with a cellulose placebo used adjunctively to a traditional diabetes diet in men with type 2 diabetes and mild-to-moderate hypercholesterolemia. Significant differences in changes from baseline between treatment groups were seen in both glycemic and lipid indexes evaluated in the metabolic ward, with the psyllium group showing improved metabolic control compared with the placebo group. Although most changes in glycemic and lipid indexes during the outpatient evaluations were not significantly different between treatment groups, directional changes also suggested improved metabolic control in the psyllium group.

The magnitude of serum total and LDL-cholesterol reductions seen in this study were similar to reductions reported in studies of nondiabetic individuals. Sprecher et al (10) reported significant net decreases (psyllium minus placebo) in total and LDL cholesterol-concentrations of 3.5% and 5.1%, respectively, after 8 wk of psyllium treatment (5.1 g twice daily) in subjects consuming a low-fat diet. In a similar study with an 8-wk dietary stabilization phase, Bell et al (12) reported significant net decreases in total and LDL-cholesterol concentrations of 4.8% and 8.2%, respectively, after psyllium and placebo supplementation.

In large-scale studies of nondiabetic individuals with hypercholesterolemia, 8–16 wk of psyllium treatment after a dietary stabilization phase reduced serum total cholesterol concentrations by 3.5–5.6% and serum LDL-cholesterol concentrations by 5.1–8.8% compared with placebo treatment (8, 10–12). This smaller-scale study may not have had sufficient statistical power to detect all significant treatment effects of psyllium. Additional larger-scale studies are needed to confirm the preliminary results of this study.

Earlier studies reported that psyllium reduced fasting serum glucose concentrations (1) or decreased postprandial serum glucose concentrations (30) in individuals with type 2 diabetes. In another study, psyllium reduced the glycemic response of diabetic individuals to a flaked bran cereal test meal only when psyllium was incorporated into or sprinkled onto the cereal (6). In a carefully controlled crossover study of the effects of psyllium taken immediately before breakfast and dinner compared with the effects of cellulose placebo supplementation in individuals with type 2 diabetes, postprandial serum glucose values were 14% lower after breakfast, 31% lower after lunch, and 20% lower after dinner with psyllium (4). The ability of soluble fibers to reduce the postprandial glucose response to meals eaten

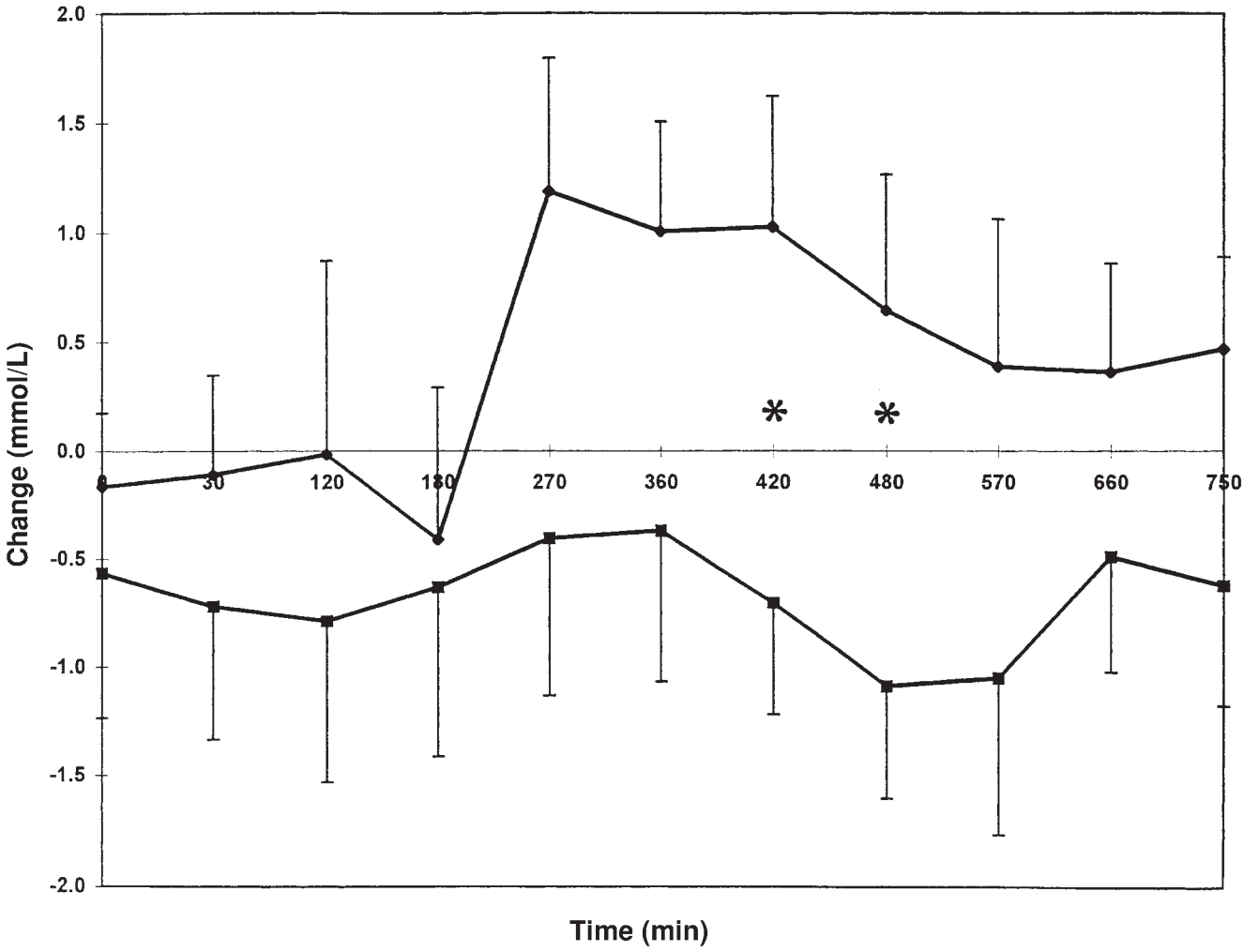

FIGURE 1. Mean (±SEM) changes (final values at week 8 − initial values at week 0). in serum glucose concentrations before and after meals for subjects in the placebo (◆) and psyllium (■) groups. *Significant difference between groups, $P < 0.05$.

several hours after fiber ingestion (eg, the so-called second meal effect) was shown previously in nondiabetic individuals (31, 32).

The second-meal effect of psyllium was also evident in the present study. Two doses of psyllium taken immediately before breakfast and dinner resulted in significantly lower metabolic ward measurements of all-day postprandial glucose and postlunch serum glucose concentrations in the psyllium than in the placebo group. All-day and postlunch postprandial glucose concentrations were 11.0% and 19.2% lower, respectively, in the psyllium than in the placebo group.

It is unlikely that the steady improvements in metabolic indexes seen in the psyllium group in this study were due to weight changes. Although body weights were 1.8% lower in the psyllium group than in the placebo group at week 8 ($P < 0.05$), no consistent trends in body weight were seen during this study.

Except for higher energy intakes in the psyllium group at baseline, dietary intakes were not significantly different between groups during the study. The low energy intakes reported by both groups indicated that subjects underreported their food intakes, as was documented in other clinical studies (33). The present study was not intended to be a careful dietary study but, rather, the purpose of dietary instruction and monitoring in this study was to ensure that dietary intake did not change significantly and that there were no significant differences in dietary intake between treatment groups during the study. Careful dietary studies require intensive instruction and monitoring beyond the scope of this study.

Psyllium is a viscous water-soluble fiber that has long been used as a bulk laxative with a good safety record. Although the role of dietary fiber in nutrition therapy for type 2 diabetes remains controversial (34, 35), several studies indicate that high-fiber diets (36–40) or diets supplemented with soluble fibers such as guar gum (41), soy (42), or pectin (43) improve metabolic control in many individuals with type 2 diabetes. The practical applications for some soluble fiber sources, however, are limited because of the lack of palatable forms. In this study, psyllium was well tolerated, was associated with no serious adverse events, and improved metabolic control compared with a cellulose placebo.

Medical nutrition therapy in type 2 diabetes must be individualized to reflect personal lifestyle and management goals (44). Because type 2 diabetes markedly increases the risk of atherosclerosis and its complications (45), achievement and maintenance of normal serum lipid concentrations is a primary goal of diabetes

management that could greatly reduce death and disability in this population. Results of this study suggest that the addition of psyllium to a standard diet for diabetes is safe, is well tolerated, and offers an additional dietary tool to improve metabolic control in individuals with type 2 diabetes and hypercholesterolemia.

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