European Journal of Clinical Nutrition (2006) 60, 62–68

0954-3007/06 $30.00
www.nature.com/ejcn

ORIGINAL ARTICLE

A randomized controlled trial of dietary fiber intake on serum lipids

J Chen[1,2], J He[1,2], RP Wildman[2], K Reynolds[2], RH Streiffer[3] and PK Whelton[1,2]

[1]*Department of Medicine, Tulane University School of Medicine, New Orleans, LA, USA;* [2]*Department of Epidemiology, Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA and* [3]*Department of Family and Community Medicine, Tulane University School of Medicine, New Orleans, LA, USA*

Objective: Clinical trials have indicated that water-soluble fiber from oats reduces serum cholesterol among hypercholesterolemic patients on a low-fat diet. We examined the effect of dietary fiber intake on serum lipids among persons without hypercholesterolemia.
Design: Randomized controlled trial.
Setting and subjects: We recruited 110 participants who were aged 30–65 years and had a serum cholesterol level <240 mg/dl from community.
Intervention: Study participants were randomly assigned to receive 8 g per day of water-soluble fiber from oat bran or a control intervention.
Results: At baseline, the mean levels of serum cholesterol and other measured variables were comparable between the high-fiber and control groups. Over the 3-month intervention, mean changes (95% confidence interval (CI)) in total, HDL-, and LDL-cholesterol were −2.42 mg/dl (−8.90 to 4.05 mg/dl; $P=0.46$), −0.24 mg/dl (−2.19 to 1.71 mg/dl; $P=0.81$), and −1.96 mg/dl (−7.32 to 3.40 mg/dl; $P=0.47$) in the fiber group and −0.02 mg/dl (−5.29 to 5.26 mg/dl; $P=0.99$), 1.42 mg/dl (−0.74 to 3.59 mg/dl; $P=0.19$), and −0.64 mg/dl (−5.30 to 4.03 mg/dl; $P=0.79$) in the control group, respectively. The net changes (95% confidence interval) in total, HDL-, and LDL-cholesterol were −2.40 mg/dl (−10.6 to 5.81 mg/dl; $P=0.56$), −1.66 mg/dl (−4.55 to 1.22 mg/dl; $P=0.26$) and −1.33 mg/dl (−8.33 to 5.68 mg/dl; $P=0.71$), respectively.
Conclusions: Our study does not support the hypothesis that water-soluble fiber intake from oat bran reduces total and LDL-cholesterol in study participants with a normal serum cholesterol level.
European Journal of Clinical Nutrition (2006) **60,** 62–68. doi:10.1038/sj.ejcn.1602268; published online 31 August 2005

Keywords: dietary fiber; cholesterol; glucose; clinical trials

Introduction

Coronary artery disease is the major cause of death in the United States and in most Western countries (American Heart Association, 2003). Observational epidemiologic studies have indicated that elevated serum cholesterol is the most common and important modifiable risk factor for coronary heart disease (Stamler *et al*., 2000; Sharrett *et al*., 2001; Greenland *et al*., 2003). Clinical trials have documented that reductions in total and LDL-cholesterol by dietary and pharmacologic interventions decrease the risk of coronary events (Gould *et al*., 1998; LaRosa *et al*., 1999). Therapeutic lifestyle changes, including dietary intervention are the first-line approach for the prevention and treatment of hypercholesterolemia (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001).

Prospective cohort studies have reported a significant inverse association between total fiber intake and the risk of coronary heart disease (Pietinen *et al*., 1996; Rimm *et al*., 1996; Wolk *et al*., 1999; Bazzano *et al*., 2003). Part of this phenomenon may reflect the accompanying inverse

Correspondence: Professor J He, Department of Epidemiology, Tulane University School of Public Health and Tropical Medicine, 1430 Tulane Avenue SL18, New Orleans, LA 70112-2699, USA.
E-mail: jhe@tulane.edu
Guarantor: J He.
Contributors: JC and JH contributed to conception and design of the study, conduct of the study, analysis and interpretation of the data, drafting of the article, and critical revision of the article for important intellectual content. RPW contributed to analysis and interpretation of the data and critical revision of the article for important intellectual content. KR contributed to conduct of the study, and critical revision of the article for important intellectual content. RHS and PKW contributed to conception and design of the study and critical revision of the article for important intellectual content. In addition, JH contributed to Obtaining of funding.
Received 20 December 2004; revised 26 June 2005; accepted 12 July 2005; published online 31 August 2005

association that is often observed between fiber and fat intake (Anderson *et al*., 1992). Numerous studies comparing vegetarians and nonvegetarians have reported lower levels of serum cholesterol and risk of coronary heart disease in the former, but whether fiber is the active agent involved or simply a reflection of greater intake of complex carbohydrates and vegetable protein and less saturated fat is not easily deciphered (Sacks *et al*., 1975; Burslem *et al*., 1978; He *et al*., 1996). Randomized controlled trials have indicated that dietary fiber intake decreases serum cholesterol concentration, especially LDL-cholesterol (Ripsin *et al*., 1992; Van Horn, 1997; Brown *et al*., 1999). Most previously published trials, however, have been conducted in patients with hypercholesterolemia (Ripsin *et al*., 1992; Brown *et al*., 1999). In addition, many studies reduced dietary saturated fat and cholesterol intake in the fiber supplementation intervention group. Therefore, it remains inconclusive whether dietary fiber intake reduces serum lipids among persons who do not have hypercholesterolemia and who consume usual American diets. We conducted a randomized controlled trial to test the effects of water-soluble fiber intake from oat bran on serum lipid levels among participants without hypercholesterolemia.

Methods

Study participants
Healthy adult men and women aged 30–65 years were recruited from the New Orleans area by worksite/community-based screenings, mass mailing of brochures, and radio, television, and newspaper advertisements. The main study eligibility criteria included the following: (1) fasting serum total cholesterol <240 mg/dl and no use of cholesterol-lowering medications; (2) systolic blood pressure <160 mmHg and diastolic blood pressure <95 mmHg and no use of antihypertensive medications; (3) fasting serum glucose <140 mg/dl and no use of insulin or oral hypoglycemic agents; (4) body mass index <35 kg/m^2; (5) no history of cardiovascular diseases and cancer; (6) serum creatinine <2.0 mg/dl and no history of chronic renal failure; (7) consumption of less than 21 alcoholic beverages per week; (8) not on a vegetarian diet and no current use of fiber supplementation; and (9) good compliance during a run-in phase (intake of more than 85% of the assigned study foods).

In all, 419 persons were deemed eligible to participate in a screening visit based on their response to a brief medical history questionnaire (Figure 1). Of these, 154 met the trial eligibility criteria after the screening visit and participated in a 2-week run-in period. In all, 110 study participants were eligible and willing to participate in the main trial after the run-in period. Of this group, 54 participants were randomly assigned to intervention and 56 to the control group. The main reason for excluding the 44 participants was poor compliance (taking less than 85% of their dietary supplements) during the 2-week run-in period. The randomization was stratified by race (African-Americans/others) and gender, with a block size of four persons within each stratum. The assignment schedule was concealed in an ordered set of sealed, opaque envelopes, opened only after the study coordinator had confirmed eligibility. Apart from the study coordinator, all research personnel, including the laboratory technicians and dietitians, were unaware of the treatment assignment, as were the study participants. Age, weight, serum cholesterol, glucose, and blood pressure levels were similar between the trial participants and those who were excluded prior to randomization. In addition, baseline characteristics were similar between the eight participants who were lost to follow-up and those who finished the study.

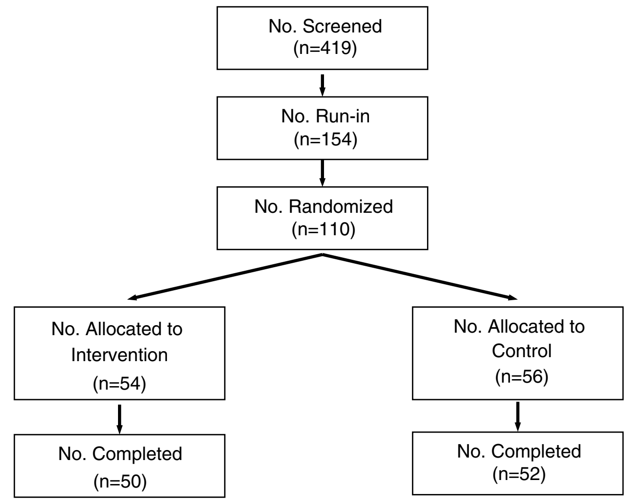

Figure 1 Flow of study participants through the trial.

Data collection
Data were collected at three screening visits, a run-in visit, a randomization visit and three termination visits conducted at week 12. Information on personal medical history, cigarette smoking, alcohol consumption, physical activity, and use of lipid-lowering medication was obtained using structured questionnaires at the baseline and termination visits. Information on side effects of fiber intake was also assessed using a questionnaire at the termination visits. A 24-h dietary recall was conducted at the baseline and termination visits by trained, certified technicians who were masked to the intervention assignment. A computerized questionnaire and food models were employed and nutrient calculations were performed using the Minnesota Data System software (NDS93-Vision 2.9), developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis (Schakel *et al*., 1988). Data from the 24-h recalls were used to determine macronutrient, micronutrient, and energy intake in the randomized groups at baseline and during follow-up visits.

Overnight fasting blood samples were drawn by venipuncture to measure serum total cholesterol, HDL-cholesterol, triglycerides, glucose, and plasma insulin. Total cholesterol, HDL-cholesterol, and triglycerides were analyzed enzymatically on a Hitachi 7060 Clinical Analyzer (Hitachi High-Technologies Corporation, Japan) using commercial reagents (Allain *et al*., 1974). Serum control pools were obtained from Solomon Park Research Laboratories. LDL-cholesterol levels were calculated using the Friedewald equation for participants who had triglyceride levels <400 mg/dl: LDL-cholesterol = total cholesterol−HDL-cholesterol−triglycerides/5 (Friedewald *et al*., 1972). Serum glucose was measured using a modified hexokinase enzymatic method (Hitachi 7060 Clinical Analyzer, Hitachi High-Technologies Corporation, Japan). Plasma insulin was measured in duplicate by radioimmunoassay using the double antibody method (Soeldner and Slone, 1966).

Blood pressure, height, weight, and waist circumference measurements were obtained by trained and certified observers who were masked to the intervention assignment. Systolic blood pressure was defined as the appearance of the first Korotkoff sound and diastolic blood pressure as the disappearance of the fifth Korotkoff sound. At each visit, three blood pressure measurements were obtained while the participant rested quietly in a seated position for at least 5 min. Random-zero sphygmomanometers were used to minimize observer bias. Body weight and height and waist circumference were measured according to a standard protocol.

Intervention

Study participants who were assigned to the active intervention (high fiber) group received a daily serving of 60 g (approximately three-fourths of a cup) of Quaker oat bran concentrate as a muffin and 84 g (approximately one and one-half cups) of Quaker Oatmeal Squares for 12 weeks. Participants in the control (low fiber) group consumed 93 g (approximately three-fourths of a cup) of refined wheat as a muffin and 42 g (one and one- half cups) of Kellogg's Corn Flakes daily during the same period. The nutritional content of the daily portion of muffins and cold cereals is presented in Table 1. Cold cereals were provided in a coded, labeled package which allowed for identification by study coordinator but preserved blinding of the contents to participants and other study staff. Study participants came to the study clinic biweekly to pick up their assigned packages of muffins and cold cereals. They were instructed to return any unused packages at their next study visit, and returned muffins and cereals were recorded by study staff members. In addition, study participants kept a daily muffin and cereal calendar that was reviewed by study staff members to help determine compliance.

During the intervention, study participants were instructed to reduce other high carbohydrate food intake by a study dietitian so that their total energy intake would be constant during the course of the trial. They were also instructed to remain at their usual level of physical activity and dietary habits. However, this trial was not designed as a feeding study, therefore, we did not try to control the total energy intake of our study participants. Each participant's body weight was monitored biweekly during the study and dietary consultation was provided when more than a 2 kg weight gain was observed. The presence of side effects was assessed by study staff using a standard questionnaire at the 12-week follow-up visit.

Table 1 Composition of dietary supplements per day

Nutrients	*High fiber*		*Low fiber*	
	Muffins	*Cereals*	*Muffins*	*Cereals*
Energy (kcal)	328	324	414	153
Protein (g)	13.1	10.9	8.0	2.8
Fat (g)	9.8	3.9	10.7	0.3
Saturated fat (g)	1.7	0.7	1.4	0.1
Monounsaturated fat (g)	3.8	1.2	5.0	0.0
Polyunsaturated fat (g)	4.0	1.6	3.6	0.2
Cholesterol (mg)	3.2	0	2.8	0
Carbohydrate (g)	48.3	65.0	72.1	36.3
Total fiber (g)	9.5	6.4	1.5	1.2
Water-soluble fiber (g)	5.5	2.6	0.8	0.1
β-glucan (g)	5.2	2.1	0	0
Water-insoluble fiber (g)	3.9	3.8	0.5	1.0

Statistical methods

Baseline characteristics were compared between the intervention and control groups using Student's *t*-tests for continuous variables and χ^2 tests for categorical variables. Changes in dietary nutrient intake, body weight, or waist circumference during the intervention were defined as the measures at the termination follow-up visit minus those at the baseline visit. Changes from baseline in 24-h dietary nutrient intake, body weight, and waist circumference were compared between the intervention and control groups using Student's *t*-tests.

The primary outcome of interest was net changes in mean total, HDL- and LDL-cholesterol, triglycerides, glucose, and insulin during the 12 weeks of intervention, defined as the measures at the termination follow-up visit minus those at the baseline visit. Initially, changes in serum lipids, glucose, and insulin from baseline to the 12-week follow-up visit were compared between the high- and low-fiber groups using paired *t*-tests. Next, mean changes in study outcomes over the 12 weeks of follow-up were compared between the intervention and control groups using two-way analysis of variance. The analyses of lipids and glucose change were based on intention-to-treat. For individuals who were lost to follow-up, outcome values were imputed assuming no effect of intervention. All statistical tests were two-tailed. Data analyses were performed using SAS version 8.2 (SAS Institute Inc., Cary, NC, USA).

The present study was approved by the Institutional Review Board of the Tulane University Health Sciences

Center. Written informed consent was obtained from each study participant at the first screening visit and at the randomization visit.

Results

Baseline characteristics

In all, 110 study participants took part in the trial. Their baseline characteristics are presented in Table 2, according to intervention assignment. On average, study participants in the high-fiber group were 3.6 years older and had a slightly higher systolic blood pressure compared to their counterparts in the low-fiber group. Serum lipids, glucose, and other baseline variables were similar in the two groups.

Table 2 Baseline characteristics of the 110 study participants according to intervention assignment

	High fiber (n = 54)	Low fiber (n = 56)	P-value
Age (years)	49.7±8.2	46.1±8.6	0.03
Female (%)	59.3	60.7	0.9
African-Americans (%)	51.9	53.6	0.9
Current cigarette smoking (%)	7.4	7.1	0.9
Weekly alcohol drinking (%)	59.3	57.1	0.8
College education (%)	75.9	83.9	0.3
Weight (kg)	82.1±16.0	83.6±15.7	0.6
Body mass index (kg/m^2)	28.5±5.0	29.3±4.1	0.4
Waist circumference (cm)	95.4±14.3	96.7±12.4	0.6
Systolic blood pressure (mmHg)	129.8±10.2	126.4±10.0	0.08
Diastolic blood pressure (mmHg)	81.1±6.4	79.6±6.6	0.2
Glucose (mg/dl)	91.2±8.1	91.4±12.8	0.9
Insulin (μIU/ml)	19.8±9.8	21.3±10.3	0.4
Total cholesterol (mg/dl)	197.9±36.8	200.4±33.3	0.7
HDL-cholesterol (mg/dl)	51.7±16.8	47.5±13.8	0.2
LDL-cholesterol (mg/dl)	123.6±33.1	128.6±31.8	0.4
Triglyceride (mg/dl)	112.5±65.0	121.6±56.2	0.4

All data are mean±s.d. or proportion.

Changes in dietary intake

Mean baseline and changes from baseline to 12-week values for dietary nutrient intake are presented in Table 3, according to intervention assignment. Overall, the mean dietary nutrient intakes at baseline were similar in the two groups. Over the 12-week period of intervention, the mean changes in dietary intake of total energy, protein, fat, cholesterol, carbohydrate, sodium, and potassium were not significantly different among participants in the two groups. However, mean dietary intake of total, water-soluble and water-insoluble fiber increased by 10.6, 5.8, and 4.9 g/day in the high-fiber group, and −0.1, 0.2, and −0.5 g/day in the low-fiber group, respectively. The net difference in dietary intake was 10.7, 5.6, and 5.4 g/day for total, water-soluble, and water-insoluble fiber, respectively (all $P<0.001$).

Changes in serum lipids

Within group analyses indicated that mean reductions in total cholesterol, LDL-cholesterol and triglycerides were not statistically significant in either the high-fiber intervention or low-fiber control groups (Table 4). In addition, mean HDL-cholesterol did not significantly change over the intervention period in either group. The net changes (95% confidence intervals (CI)) in mean total cholesterol, HDL-cholesterol, LDL-cholesterol and triglycerides between the high-fiber intervention and low-fiber control groups were −2.40 mg/dl (−10.6 to 5.82, $P=0.56$), −1.66 mg/dl (−4.55 to 1.22, $P=0.26$), −1.33 mg/dl (−8.33 to 5.68, $P=0.71$), and 3.76 mg/dl (−12.4 to 19.9, $P=0.65$), respectively.

During the intervention period, the net reduction in body weight was −0.74 kg (95% CI −1.56 to 0.07; $P=0.07$). The net changes in waist circumference, glucose, and insulin were not statistically significant (Table 4).

Compliance

Compliance was excellent in both the high-fiber intervention and low-fiber control groups. For example, on average,

Table 3 Mean changes from baseline in 24-h dietary intake of nutrients, according to intervention assignment

Nutrients	High fiber, Mean±s.d.		Low fiber, Mean±s.d.		Net change (95% CI): high fiber – low fiber
	Baseline	Change	Baseline	Change	
Energy (kcal)	2143±941	75±776	2034±811	112±757	−37 (−343, 269)
Protein (g)	88.5±49.8	0.0±42.0	79.6±39.4	−1.1±37.2	1.1 (−14.7, 16.9)
Fat (g)	80.9±48.0	−3.7±51.7	75.8±43.1	−5.0±44.2	1.3 (−17.9, 20.4)
Saturated fat (g)	26.9±16.6	−4.9±14.5	24.6±15.0	−4.1±14.2	−0.8 (−6.5, 5.0)
Monounsaturated fat (g)	30.6±18.3	−0.4±23.9	29.7±17.8	−2.0±16.4	1.6 (−6.6, 9.7)
Polyunsaturated fat (g)	16.9±12.8	2.0±15.4	15.4±10.9	1.5±15.5	0.6 (−5.6, 6.7)
Cholesterol (mg)	242±132	−35.1±175	241±142	−32.9±212	−2.2 (−81.8, 77.4)
Carbohydrate (g)	266±109	32.0±95.9	259±98	41.3±106.8	−9.3 (−49.9, 31.3)
Total fiber (g)	20.3±18.5	10.6±12.5	16.1±7.0	−0.1±8.9	10.7 (6.4, 15.0)*
Water-soluble fiber (g)	6.8±5.4	5.8±5.3	5.6±2.5	0.2±3.4	5.6 (3.8, 7.4)*
Water-insoluble fiber (g)	13.2±13.2	4.9±8.6	10.3±5.2	−0.5±6.1	5.4 (2.5, 8.4)*

*$P<0.001$.

Table 4 Mean changes (95% confidence interval) from baseline in body weight, glucose, insulin, and lipids according to intervention assignment

Variants	*High fiber*		*Low fiber*		*High fiber – low fiber*	
	Effect (95% CI)	P-*value*	*Effect (95% CI)*	P-*value*	*Effect (95% CI)*	P-*value*
Body weight (kg)	0.08 (−0.49, 0.66)	0.77	0.82 (0.24, 1.41)	0.01	−0.74 (−1.56, 0.07)	0.07
Waist circumference (cm)	−0.75 (−1.83, 0.32)	0.16	−0.18 (−1.44, 1.08)	0.78	−0.58 (−2.22, 1.07)	0.49
Glucose (mg/dl)	−0.74 (−3.43, 1.95)	0.58	−0.81 (−4.11, 2.49)	0.63	0.07 (−4.16, 4.29)	0.97
Insulin (μIU/ml)	−0.12 (−1.94, 1.70)	0.90	2.08 (−1.07, 5.21)	0.19	−2.19 (−5.84, 1.45)	0.23
Total cholesterol (mg/dl)	−2.42 (−8.90, 4.05)	0.46	−0.02 (−5.29, 5.26)	0.99	−2.40 (−10.6, 5.82)	0.56
HDL- cholesterol (mg/dl)	−0.24 (−2.19, 1.71)	0.81	1.42 (−0.74, 3.59)	0.19	−1.66 (−4.55, 1.22)	0.26
LDL- cholesterol (mg/dl)	−1.96 (−7.32, 3.40)	0.47	−0.64 (−5.30, 4.03)	0.79	−1.33 (−8.33, 5.68)	0.71
Triglyceride (mg/dl)	−0.80 (−10.1, 8.50)	0.86	−4.56 (−17.9, 8.75)	0.49	3.76 (−12.4, 19.9)	0.65

study participants reported taking 87.8% (95% CI, 81.5–94.1%) and 93.7% (91.0–96.4%) of the study foods in the high- and low-fiber groups, respectively, at the 12-week termination visits.

Side effects were similar in both groups. For example, percentages of self-reported change in appetite (20.8 vs 15.7%, $P=0.51$), stomach upset or nausea (8.3 vs 7.8%, $P=0.93$), belching (12.5 vs 9.8%, $P=0.67$), stomach pain or burning (4.2 vs 7.8%, $P=0.44$), constipation (4.2 vs 5.9%, $P=0.70$), excessive gas (14.6 vs 7.8%, $P=0.29$), and excessive thirst (6.3 vs 7.8%, $P=0.76$) were similar in the high- and low-fiber groups. The percentage of diarrhea was slightly higher in the high fiber group compared to the low fiber group (10.4 vs 2.0%; $P=0.07$).

Discussion

The present study was conducted to determine the efficacy of water-soluble fiber intake from oat bran in lowering serum lipid and glucose levels in a free-living population of healthy persons. In this study, water-soluble fiber from oat bran did not significantly lower serum total cholesterol, LDL-cholesterol, triglyceride, or glucose in participants without hypercholesterolemia or diabetes. Unlike most previously published studies, this randomized, double-blinded controlled trial was designed to minimize the changes in dietary saturated fat and cholesterol intake during the fiber supplementation.

There is debate regarding the value of increased dietary fiber intake in reducing serum cholesterol, especially in persons with a normal serum cholesterol level (Kris-Etherton *et al*., 1988; Swain *et al*., 1990). In a meta-analysis conducted by Ripsin *et al*. (1992), the effects of dietary fiber intake from oat bran on total cholesterol varied among clinical trials from −27.0 to 8.3 mg/dl . Reasons for such large variations may include relatively small sample sizes in some trials, various dosages of dietary fiber intake, concurrent other lifestyle interventions, variation in dietary intakes of saturated fat and cholesterol, and different preintervention levels of serum cholesterol among study participants. Of the 19 clinical trials included in the meta-analysis, only four of them reported a statistically significant reduction in serum cholesterol level associated with increased dietary fiber intake. Furthermore, all of the four trials were conducted among patients with hypercholesterolemia. The clinical trials of fiber supplementation with oat bran conducted in participants with a normal level of serum cholesterol did not show a significant reduction in serum cholesterol (Ripsin *et al*., 1992). After the meta-analysis, several additional clinical trials showed a small but statistically significant reduction in serum total and LDL-cholesterol levels associated with increased dietary fiber intake from oat bran among patients with hypercholesterolemia (Uusitupa *et al*., 1992; Braaten *et al*., 1994; Anderson *et al*., 1995; Jenkins *et al*., 2002). The current study was conducted among 110 healthy volunteers who had a serum total cholesterol level less than 240 mg/dl. Our study showed that 8 g of water-soluble fiber from oat bran did not significantly reduce serum total or LDL-cholesterol levels.

It has been suggested that the reported cholesterol-lowering effect of dietary fiber intake may result from a substitution of carbohydrates for dietary saturated fat and cholesterol intake rather than by a direct action of the soluble fiber (Swain *et al*., 1990). In many studies, dietary saturated fat and cholesterol intake was replaced by high-fiber food intake in the intervention group while this was not replaced in the comparison group due to lack of a low-fiber food as the control (de Groot *et al*., 1963; Van Horn *et al*., 1986, 1988, 1991; Demark-Wahnefried *et al*., 1990). For example, Van Horn *et al*. (1991) randomly assigned 80 patients with hypercholesterolemia to an intervention group who received two servings per day of instant oats (approximately two ounces dry weight) or control group who maintained regular diet . After an 8-week intervention, the net reduction in serum total and LDL-cholesterol was 4.9 and 5.4%, respectively. Compared to the control group, however, the dietary Key score, a measure of dietary intake of saturated fat and cholesterol ($1.35 \times (2 \times$ % of kcal for saturated fat$-$% of kcal for polyunsaturated fat$) + 1.5 \times$ square root of dietary cholesterol, mg/100 kcal), was reduced by 12.8% in the intervention group (Van Horn *et al*., 1991). Ripsin *et al*. (1992) demonstrated a high correlation ($r=0.63$, $P=0.001$) between the observed change in total serum cholesterol level and the expected change as determined by the Key scores among the fiber supplementation trials . In our study, dietary intake of saturated fat and cholesterol were comparable between the high-fiber intervention and low-fiber control groups. Therefore, the effect due to replacing dietary saturated fat and cholesterol intake with dietary complex carbohydrate intake on lowering serum cholesterol level was minimized. Our study indicated that increasing dietary water-soluble fiber intake alone did not significantly reduce serum total and LDL-cholesterol in persons without hypercholesterolemia.

Swain *et al*. (1990) compared the effect of isocaloric supplements of high-fiber oat bran (87 g per day) and a low-fiber refined-wheat product on the serum lipoprotein cholesterol levels of 20 healthy subjects aged 23–49 years old. After a 1-week baseline period during which they consumed their usual diets, the subjects were given each type of supplement for 6-week periods in a double-blind, crossover trial. Both types of supplements lowered the mean baseline serum cholesterol level by 7–8%. The subjects ate less saturated fat and cholesterol and more polyunsaturated fat during both periods of supplementation than at baseline. Those changes in dietary fats were sufficient to explain all of the reduction in serum cholesterol levels caused by the high- and low-fiber diets (Swain *et al*., 1990).

Although our study had a larger sample size compared to most previous trials, it may not have provided sufficient statistical power to detect a small but potentially important serum cholesterol reduction between the high-fiber intervention and low-fiber control groups. For example, our study had 80% statistical power to detect only a 9.7 mg/dl reduction in total serum cholesterol and an 8.6 mg/dl reduction in LDL-cholesterol. In addition, the dosage of water-soluble fiber in the present study may not have been sufficient to produce a large enough reduction in serum cholesterol level. Furthermore, an intervention duration longer than 12 weeks might increase the chance to observe a significant reduction in serum cholesterol level.

The present study indicated that increasing dietary fiber intake from oat bran did not significantly reduce serum cholesterol level among individuals without hypercholesterolemia. These findings have important public health implications. The documented dietary intervention approaches including reduction in dietary saturated fat and cholesterol intake should be the main focus on the prevention of high blood cholesterol in the US general population. The increased dietary fiber intake should be accompanied by rigorous efforts to reduce dietary saturated fat and cholesterol intake in order to achieve the optimal effect.

Acknowledgements

This study was supported by a grant (HL60300) from the National Heart, Lung, and Blood Institute of the National Institutes of Health and partially by Tulane-Charity-LSU General Clinical Research Center (RR05096). Drs J Chen and RP Wildman were supported by Building Interdisciplinary Research Careers in Women's Health Scholarship (K12 HD43451) from the National Heart, Lung, and Blood Institute, National Institutes of Health Bethesda, Maryland. The Quaker Oats Company provided oat bran concentrate and cold cereal for the study.

The authors would like to express their appreciation to all study participants and study staff members, including study coordinator, Sara Bienvenu, RN, Kenya Morris-Brooks, MPH, Liying Hao, MD, Timir Paul, MD, MPH, Rhonda Fontenot, RN, Patricia Early, RN, Angela Cemo, RD, and Rosanne Farris, RD.

Conflicts of interest

None.

References

Allain CC, Poon LS, Chan CS, Richmond W, Fu PC (1974). Enzymatic determination of total serum cholesterol. *Clin Chem* **20**, 470–475.

American Heart Association (2003). *Heart disease stroke statistics – 2004 update*. Dallas, TX: American Heart Association.

Anderson JW, Garrity TF, Wood CL, Whitis SE, Smith BM, Oeltgen PR (1992). Prospective, randomized, controlled comparison of the effects of low-fat and low-fat plus high-fiber diets on serum lipid concentrations. *Am J Clin Nutr* **56**, 887–894.

Anderson JW, O'Neal DS, Riddell-Mason S, Floore TL, Dillon DW, Oeltgen PR (1995). Postprandial serum glucose, insulin, and lipoprotein responses to high- and low-fiber diets. *Metabolism: Clin Exper* **44**, 848–854.

Bazzano LA, He J, Ogden LG, Vupputuri S, Loria C, Myers L *et al*. (2003). Dietary fiber intake and reduced risk of coronary heart disease in US men and women. *Arch Intern Med* **163**, 1897–1904.

Braaten JT, Wood PJ, Scott FW, Wolynetz MS, Lowe MK, Bradley-White P *et al*. (1994). Oat beta-glucan reduces blood cholesterol concentration in hypercholesterolemic subjects. *Euro J Clin Nut* **48**, 465–474.

Brown L, Rosner B, Willett WW, Sacks FM (1999). Cholesterol-lowering effects of dietary fiber: a meta-analysis. *Am J Clin Nutr* **69**, 30–42.

Burslem J, Schonfeld G, Howald MA, Weidman SW, Miller JP (1978). Plasma apoprotein and lipoprotein lipid levels in vegetarians. *Metabolism* **27**, 711–719.

de Groot AP, Luyken R, Pikaar NA (1963). Cholesterol-lowering effect of rolled oats. *Lancet* **2**, 303–304.

Demark-Wahnefried W, Bowering J, Cohen PS (1990). Reduced serum cholesterol with dietary change using fat-modified and oat bran supplemented diets. *J Am Diet Assoc* **90**, 223–229.

Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (2001). Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol (Adults Treatment Panel III). *JAMA* **285**, 2486–2497.

Friedewald WT, Levy RI, Fredrickson DS (1972). Estimation of the concentration of low density lipoprotein cholesterol in plasma without the use of the preparative ultracentrifuge. *Clin Chem* **18**, 499–502.

Greenland P, Knoll MD, Stamler J, Neaton JD, Dyer AR, Garside DB *et al*. (2003). Major risk factors as antecedents of fatal and nonfatal coronary heart disease events. *JAMA* **290**, 891–897.

Gould AL, Rossouw JE, Santanello NC, Heyse JF, Furberg CD (1998). Cholesterol reduction yields clinical benefit: impact of statin trials. *Circulation* **97**, 946–952.

He J, Klag MJ, Wu Z, Qian MC, Chen JY, Mo PS *et al*. (1996). Effect of migration and related environmental changes on serum lipid levels in southwestern Chinese men. *Am J Epidemiol* **144**, 839–848.
Jenkins DJ, Kendall CW, Vuksan V, Vidgen E, Parker T, Faulkner D *et al*. (2002). 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. *Am J Clin Nutr* **75**, 834–839.
Kris-Etherton PM, Krummel D, Russell ME, Dreon D, Mackey S, Borchers J *et al*. (1988). The effect of diet on plasma lipids, lipoproteins, and coronary heart disease. *J Am Diet Assoc* **88**, 1373–1400.
LaRosa JC, He J, Vupputuri S (1999). Effect of statins on risk of coronary disease: a meta-analysis of randomized controlled trials. *JAMA* **282**, 2340–2346.
Pietinen P, Rimm EB, Korhonen P, Harman AM, Willett WC, Albanes D *et al*. (1996). Intake of dietary fiber and risk of coronary heart disease in a cohort of Finish men: The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study. *Circulation* **94**, 2720–2727.
Rimm EB, Ascherio A, Giovannucci E, Spiegleman D, Stampfer MJ, Willett WC (1996). Vegetable, fruit, and cereal fiber intake and risk of coronary heart disease among men. *JAMA* **275**, 447–451.
Ripsin CM, Keenan JM, Jacobs DR, Elmer PJ, Welch RR, Van Horn L *et al*. (1992). Oat products and lipid lowering: a meta-analysis. *JAMA* **267**, 3317–3325.
Sacks FM, Castelli WP, Donner A, Kass EH (1975). Plasma lipids and lipoproteins in vegetarians and controls. *N Engl J Med* **292**, 1148–1151.
Schakel SF, Sievart YA, Buzzard IM (1988). Sources of data for developing and maintaining a nutrient database. *J Am Diet Assoc* **8**, 1268–1271.
Sharrett AR, Ballantyne CM, Coady SA, Heiss G, Sorlie PD, Catellier D *et al*. (2001). Atherosclerosis Risk in Communities Study Group. Coronary heart disease prediction from lipoprotein cholesterol levels, triglycerides, lipoprotein(a), apolipoproteins A-I and B, and HDL density subfractions: The Atherosclerosis Risk in Communities (ARIC) Study. *Circulation* **104**, 1108–1113.
Soeldner JS, Slone D (1966). Critical variables in the radioimmunoassay of serum insulin using the double antibody technic. *Diabetes* **14**, 771–779.
Stamler J, Daviglus ML, Garside DB, Dyer AR, Greenland P, Neaton JD (2000). Relationship of baseline serum cholesterol levels in 3 large cohorts of younger men to long-term coronary, cardiovascular, and all-cause mortality and to longevity. *JAMA* **284**, 311–318.
Swain JF, Rouse IL, Curley CB, Sacks FM (1990). Comparison of the effects of oat bran and low-fiber wheat on serum lipoprotein levels and blood pressure. *N Engl J Med* **322**, 147–152.
Uusitupa MI, Ruuskanen E, Makinen E, Laitinen J, Toskala E, Kervinen K *et al*. (1992). A controlled study on the effect of beta-glucan-rich oat bran on serum lipids in hypercholesterolemic subjects: relation to apolipoprotein E phenotype. *J Am Coll Nutr* **11**, 651–659.
Van Horn L (1997). Fiber, lipids, and coronary heart disease. A statement for healthcare professionals from the Nutrition Committee, American Heart Association. *Circulation* **95**, 2701–2704.
Van Horn LV, Liu K, Parker D, Emidy L, Liao YL, Pan WH *et al*. (1986). Serum lipid response to oat product intake with a fat-modified diet. *J Am Diet Assoc* **86**, 759–764.
Van Horn L, Emidy LA, Liu KA, Liao YL, Ballew C, King J *et al*. (1988). Serum lipid response to a fat-modified, oatmeal-enhanced diet. *Prev Med* **17**, 377–386.
Van Horn L, Moag-Stahlberg A, Liu K, Ballew C, Ruth K, Hughes R *et al*. (1991). Effects on serum lipids of adding instant oats to usual American diets. *Am J Public Health* **81**, 183–188.
Wolk A, Manson JE, Stampfer MJ, Colditz GA, Hu FB, Speizer FE *et al*. (1999). Long-term intake of dietary fiber and decreased risk of coronary heart disease among women. *JAMA* **281**, 1998–2004.