Serum Lipids in Hypercholesterolemic Men and Women Consuming Oat Bran and Amaranth Products[1]

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ABSTRACT

One hundred-eighty hypercholesterolemic subjects following the National Cholesterol Education Program Step One Diet were randomly divided into six groups (30 ± 2/group). Group 1 served as the control and received no fiber supplements. The fiber supplemented groups received 50 g/day of oat bran or amaranth from various sources: Group 2 (oat bran muffins); Group 3 (amaranth muffins); Group 4 (Oat Bran O's); Group 5 (Oat Bran Flakes); and Group 6 (a variety of oat bran products). Fasting serum total cholesterol (FSTC), low density-, very low density-, and high density-lipoprotein cholesterol (LDL-C, VLDL-C, and HDL-C) and serum triacylglycerols were measured before and after the 28-day intervention. Three-day diet records were completed before and after intervention. Subjects reduced ($P < 0.05$) the mean intake of total and saturated fat, and cholesterol. FSTC dropped more than twice as much ($P < 0.05$) as was observed with fat modification alone (Group 1 = –0.31 mmol/L), when oat bran was provided as flakes (Group 5 = –0.86 mmol/L) or in a variety of forms (Group 6 = –0.75 mmol/L). If the initial ratio of HDL-C to FSTC was low, then supplementation did not decrease FSTC to the extent observed when the initial ratio was high. Compliance with the dietary interventions was best when the subjects gave the product a rating of ≤2.0 (on a 1–4 hedonic scale, with 1 being excellent). We can conclude from these data that fiber supplementation to reduce serum cholesterol is most effective in hypercholesterolemic individuals that have a greater proportion of HDL-C. In addition, not all the oat bran products evaluated were able to lower cholesterol to the same extent, indicating that the ability of soluble fiber to reduce FSTC can be compromised by other dietary factors such as insoluble fiber.

Coronary heart disease (CHD) was responsible for nearly one-third of all deaths in the United States and cost over $56 billion in direct and indirect costs in 1994 (Anonymous 1996b, Oster and Thompson 1996). Because of this, extensive research has focused on modifying CHD risk factors, particularly elevated serum cholesterol concentrations (Anonymous 1984a, 1985, 1988; NCEP 1987b). The National Cholesterol Education Program (NCEP 1987a) recommends that dietary treatment should be the cornerstone of therapy for hypercholesterolemia and should be undertaken for a minimum of six months before deciding whether to initiate drug treatment. The specific NCEP Step One diet limits total fat to <30% of energy (with fat relatively equally distributed between saturated [SFA], monounsaturated [MUFA] and polyunsaturated [PUFA]), and cholesterol intake to <300 mg/day (NCEP 1987a).

Although no recommendation is made as to fiber intake as part of the NCEP diet, many Americans supplement their diets with soluble fiber products, particularly oat bran, because research has shown that the water-soluble fiber (primarily β-glucan) (Lee et al 1997) further reduces serum cholesterol in response to a fat-modified diet (De Groot et al 1963, Anderson et al 1981, 1984; Behall et al 1984; Storch et al 1984; Van Horn et al 1986; Gold and Davidson 1988; Van Horn et al 1988). Subsequent to the federal approval of a health claim that oat bran can reduce cholesterol (Anonymous 1996a), the American Dietetic Association (ADA 1997) issued a position statement on the health implications of dietary fiber that describes the potential mechanisms whereby dietary fiber reduces blood cholesterol. However, the independent effect of oat bran in lowering cholesterol has been challenged (Swain et al 1990).

A review of oat bran and serum lipid studies shows that a number of factors may influence the effectiveness of oat bran in lowering serum cholesterol. Of primary importance is the rest of the diet: total energy, total fat, saturated fat, and cholesterol. Also important is the initial degree of hypercholesterolemia in the subject population. Van Horn (1986, 1988) has reported on two clinical trials in a normolipidemic population using moderate fat modification and found a slight enhancement of the cholesterol lowering effect with oat bran supplementation. Anderson et al (1981, 1984) achieved more dramatic results but with more restrictive diets and with hypercholesterolemic subjects. The purpose of the current study was to determine the effect of supplementation with 50 g/day of oat bran or amaranth from a variety of products in a hypercholesterolemic population using NCEP diet recommendations. To determine whether oat bran conferred an added benefit to fat modification alone, results were compared with the NCEP diet without fiber supplementation.

MATERIALS AND METHODS

Selection of Study Population

Before beginning the study, protocols were approved by the Institutional Review Board for Human Subjects and Research at Texas A&M University, College Station, TX. Participants were selected from 1,500 men and women who attended a free cholesterol screening, which was advertised in the local newspaper. Individuals who attended the screening were eligible if they had blood cholesterol concentrations >6.24 mmol/L (Reflotron dry chemistry analyzer, Boehringer Mannheim Diagnostics, Indianapolis, IN); if they were willing and able to fulfill the responsibilities of the study; if they were within 30% of ideal body weight (IBW) for height and sex (Metropolitan Life Insurance Co., 1959); if they were between the ages of 20 and 70, not pregnant, and had no personal history of diabetes mellitus, hypo- or hyperthyroidism, liver, or kidney problems, alcohol or drug abuse, or use of cholesterol-lowering agents or diets. One hundred eighty individuals met the selection criteria. Each participant who completed the study received $50.

Dietary Intervention

Study participants were randomly assigned to one of the six treatment groups (30 ± 2/group). Treatment groups were stratified by serum cholesterol concentration at screening, age, number of smokers vs. nonsmokers (nine smokers total), and number of individuals with a history of CHD (five total). Family members were assigned to the same group to prevent sharing of fiber-supplemented foods among different diet groups.

Each participant was required to attend a 1-hr diet lesson each week of the study. The lessons focused on implementation of the NCEP Step One Diet recommendations. The NCEP diet limits total

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fat intake to 30% of total energy (NCEP 1987a). Saturated fatty acids and PUFA are limited to <10% of total energy, and MUFA provide 10–15% of total energy. In addition, dietary cholesterol is limited to <300 mg/day, and carbohydrates and protein provide 50–60% and 10–20% of total energy, respectively.

Group 1 subjects were instructed to follow the NCEP Step One Diet recommendations and asked to not add any oat or amaranth products to their diets. In addition to following the NCEP diet, subjects in Groups 2–6 consumed 50 g/day of oat bran or amaranth from either oat bran muffins, amaranth muffins, Oat Bran O's, Oat Bran Flakes, or a variety of products (Table I). The purpose of using a variety of products in Group 6 was to determine whether a variety of oat bran products was more acceptable and conducive to compliance with the prescribed diet than oat bran from a single source. All of the fiber-supplemented foods were provided by Health Valley Foods (Irwindale, CA), and were distributed to participants on a weekly basis.

Diets for the five fiber-supplemented groups were designed to provide 50 g/day of oat bran or amaranth. As a result of the different products used for the diet intervention groups, we were able to achieve different ratios of soluble (SF) to insoluble fiber (IF), as well as different total fiber (TF) intakes (Table I). Total fiber intake from the supplements ranged from 7.3 to 12.4 g, which was a realistic level of supplementation. The combination of the supplement and the rest of the diet was within the suggested daily intake for fiber (ADA 1997). The supplements were analyzed for TF and IF (Prosky et al 1988). Soluble fiber was estimated as the difference between TF and IF. The diet of the variety group contained more TF and SF than did the other groups, and the amaranth muffin diet contained more IF than the other diets. Beyond solubility, very little is known about amaranth fiber characteristics. Budin et al (1996) did report that in contrast to oat bran, amaranth does not contain β-glucans. The ratio of SF to IF was calculated to be higher in the Oat Bran O's group (0.91), followed by the Oat Bran Flakes group (0.58) and the variety group (0.56).

TABLE I
Fiber Content of Intervention Foods[a]

Intervention Group[b]	Total Soluble Fiber (g)	Total Insoluble Fiber (g)	Soluble to Insoluble Fiber Ratio	Total Dietary Fiber (g)
Oat bran muffins (3 = 170.1 g)	3.57	7.47	0.48	11.07
Amaranth muffins (3 = 170.1 g)	2.55	8.85	0.29	11.40
Oat bran O's (99.2 g)	4.17	4.56	0.91	8.73
Oat bran flakes (99.2 g)	2.68	4.66	0.58	7.34
Variety of products[c]	4.42	7.96	0.56	12.39

[a] Values in each column are for the total fiber-containing foods to be consumed each day. Only the National Cholesterol Education Program (NCEP) diet group received no fiber supplements.

[b] All products obtained from Health Valley Foods (Irwindale, CA), except for oat bran and amaranth muffins which were developed specifically for this study.

[c] Oat bran muffin (1 = 56.7 g); Oat bran O's (56.7 g); oat bran graham crackers (3 = 14.2 g); fancy fruit chunk cookies (2 = 21.3 g); and oat bran fruit jumbo cookie (1 = 14.2 g).

Data Collection

Physical data collected before and after the four-week intervention trial included height and body weight. Serum lipid measurements made before and after the intervention included fasting serum total cholesterol (FSTC), triacylglycerols, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and very-low-density lipoprotein cholesterol (VLDL-C). Total cholesterol was determined enzymatically using the methods of Flegg (1973) and Richmond (1973) as modified by Allain et al (1974) and Roeschlau et al (1974), and HDL-C concentrations were determined by the method of Finley et al (1978). Serum triacylglycerols were determined enzymatically (Bucolo and David 1973), and LDL-C and VLDL-C were calculated using the equations of Friedewald et al (1972).

Three-day diet records were kept before the onset of the study and during the final week of the study, and 24-hr recalls were completed after 7, 14, 21, and 28 days of intervention. Diet records were analyzed using the Nutritionist III (N-Squared Computing, Silverton, OR) software and database after the nutrition information on the fiber-supplement foods was added into the database. The analysis of each diet record included total energy, total fat, SFA, PUFA, MUFA, dietary cholesterol, total dietary fiber, vitamin A, vitamin B-6, calcium, and iron. Vitamin A, vitamin B-6, calcium, and iron have been identified as index nutrients (Jenkins and Guthrie 1984) and were used to establish diet quality. Subjects in the fiber-supplemented groups were asked to rate the products and to document the quantity of the required fiber-supplemented foods they had consumed.

Data Analysis

One-way analysis of variance (ANOVA) was used to detect significant differences within the six diet treatments with respect

TABLE II
Demographics of the Cohort at Baseline[a,b]

Variable	NCEP Diet	Oat Bran Muffin	Amaranth Muffin	Oat Bran O's	Oat Bran Flakes	Variety	Cohort
Number	28	29	28	31	30	31	177
Age (years)	48 ± 12	49 ± 11	48 ± 12	48 ± 11	48 ± 14	47 ± 12	48 ± 12
Sex (M:F)	14:14	15:14	17:11	14:17	14:16	17:14	91:86
Fasting total serum cholesterol (mmol/L)	6.53 ± 0.98	6.41 ± 0.55	6.41 ± 0.75	6.27 ± 0.93	6.54 ± 0.71	6.49 ± 0.57	6.44 ± 0.76
Body weight (kg)	75.7 ± 15.7	72.8 ± 12.1	75.5 ± 15.0	76.1 ± 12.0	71.9 ± 13.2	78.4 ± 10.7	75.1 ± 13.1
Height (cm)	67 ± 5	67 ± 4	68 ± 4	68 ± 4	67 ± 4	68 ± 3	67 ± 4
BMI	26 ± 3	25 ± 2	25 ± 3	26 ± 3	25 ± 3	26 ± 3	25 ± 3
Smokers (yes:no)	1:27	3:26	1:27	2:29	1:29	1:30	9:168
CHD history (yes:no)	0:28	1:28	1:27	1:30	1:29	1:30	5:172
HDL-C (mmol/L)	1.09 ± 0.26	1.07 ± 0.23	1.07 ± 0.26	1.09 ± 0.23	1.20 ± 0.08	1.12 ± 0.26	1.12 ± 0.26
LDL-C (mmol/L)	4.39 ± 1.07	4.37 ± 0.60	4.34 ± 0.78	4.13 ± 0.83	4.42 ± 0.70	4.32 ± 0.49	4.32 ± 0.75
VLDL-C (mmol/L)	0.96 ± 0.47	0.99 ± 0.39	0.96 ± 0.44	1.01 ± 0.42	0.96 ± 0.39	0.96 ± 0.44	0.96 ± 0.42
Triacylglycerols (mmol/L)	2.31 ± 1.45	2.27 ± 1.03	2.26 ± 1.18	2.37 ± 1.16	2.41 ± 1.82	2.96 ± 2.00	2.43 ± 1.49

[a] Values are expressed as mean ± standard deviation.

[b] National Cholesterol Education Program (NCEP); body mass index (BMI); coronary heart disease (CHD); low density, very low density, and high density lipoprotein cholesterol (LDL-C, VLDL-C, and HDL-C).

to changes in several variables: FSTC, triacylglycerols, HDL-C, LDL-C, VLDL-C, weight, and body mass index (BMI). In addition, one-way ANOVA was used to detect differences between the diet treatments for changes in intake of energy, protein, carbohydrate, total fat, SFA, PUFA, MUFA, alcohol, fiber, vitamin A, vitamin B-6, calcium, and iron resulting from diet modification. When differences were detected, means were separated using Duncan's multiple range test using the SAS general linear model (SAS Institute, Cary, NC). The univariate test was used to determine whether changes in any of the lipid, weight, or nutrient parameters measured were significant for the total cohort. The relationship between changes in FSTC and LDL-C, and between compliance and product rating were determined by Pearson's correlation coefficients.

RESULTS

Participation and Baseline Data

Only three subjects dropped out of the study, giving a 98.3% completion rate. The mean age of the participants was 48 years, and each group had approximately equal numbers of males and females (Table II). Initial mean FSTC, LDL-C, HDL-C, VLDL-C, and triacylglycerols were 6.44, 4.32, 1.12, 0.96, and 2.43 mmol/L, respectively. Both FSTC and LDL-C were in the range identified as high risk for CHD by the NCEP. No significant differences were detected among the diet groups for demographic data, or initial serum lipids, weight or BMI (Table II).

Nutrient Analyses

Analysis of the pretreatment (three day) diet records indicated that the mean intake of total fat (TF), SFA, and PUFA were 32.8, 9.1, and 4.7% of energy, respectively. In addition, the mean PUFA to SFA ratio was 0.6, and intake of cholesterol was 222 mg/day. After four weeks on the NCEP diet, the three-day diet record revealed the cohort reduced ($P < 0.05$) intake of TF and SFA to 25.7 and 6.0% of total energy, respectively, and cholesterol declined to 141 mg/day. All intervention diets reduced TF, SFA, and cholesterol, but no differences in the magnitude of the reduction were observed among the groups (Table III). Mean PUFA to SFA ratio for the cohort increased from the initial value to 0.8 at the last assessment. Although the ratio increased for all six groups, the increase in PUFA to SFA ratio was greater ($P < 0.05$) for subjects receiving the amaranth muffins or a variety of oat products, when compared to the Oat Bran Flakes (Table III). Total fiber intake of the cohort increased from an initial value of 15.6 g/day to 22.4 g/day by the end of the study. Even though there were differences in the quantity of fiber consumed by the groups, this variable alone explained only a small amount of the variation in the changes in serum cholesterol ($R^2 = 0.17$). Mean carbohydrate intake (as a percentage of total energy) increased from 50% at baseline to 58%. Carbohydrate intake increased more for individuals consuming either the oat bran muffins or the variety of products, than those consuming the Oat Bran Flakes or those only on the NCEP diet.

Groups consuming either the oat bran or amaranth muffins had reduced ($P < 0.05$) calcium intakes, while the Oat Bran Flakes or NCEP only groups had increased ($P < 0.05$) calcium intake (Table III), relative to the Oat Bran O's and the variety group. Furthermore, subjects consuming a variety of products increased iron intake by 2.2 mg/day, which was different ($P < 0.05$) from the Oat Bran O's and oat bran muffin groups. The changes in vitamin A and vitamin B-6 intake did not differ among the groups. Energy intake of each group was reduced, with the greatest reduction occurring in the Oat Bran O's group compared with the groups consuming either a variety of products or the NCEP diet only.

Acceptability of Fiber-Containing Foods

At the end of the study each participant self-reported compliance (0–100% in 5% increments) and rated the fiber-containing products (1 = excellent, 2 = good, 3 = fair, or 4 = poor) (Table IV). The variety group rated all five products individually and an average rating was calculated. Mean consumption of the required fiber-containing foods for the entire cohort (excluding NCEP only) was 96.4%. Seventy-five percent of the subjects consumed at least 95% of the foods, and 90% consumed at least 90%. Mean group compliance ranged from 94.3% in the amaranth muffin group to 97.8% in the Oat Bran Flakes group (Table IV).

The overall acceptability rating for the fiber-containing foods was 2.0 (good). The amaranth muffins were the least acceptable (2.3), and the Oat Bran Flakes were the most acceptable (1.9). A significant correlation between product rating and compliance ($r = -0.292$, $P = 0.0003$) was found.

Weight, BMI, and Serum Lipid Responses to Intervention

Weight and BMI. Weight loss for the overall cohort was 0.64 kg, and each group had a lower mean weight after intervention than at initiation of diet intervention ($P < 0.05$). However, there were no differences in weight loss or BMI among the diet groups.

Total serum cholesterol. After the 28-day dietary intervention, the mean FSTC for the entire cohort decreased ($P < 0.0001$) by 0.44

TABLE III
Group Mean Nutrient Intake[a]

	NCEP Diet			Oat Bran Muffin			Amaranth Muffin			Oat Bran O's			Oat Bran Flakes			Variety		
Nutrient (per day)[b]	B	A	A – B	B	A	A – B	B	A	A – B	B	A	A – B	B	A	A – B	B	A	A – B
Energy (kJ)	7.47	6.72ab	–0.54a	8.75	6.90ab	–1.70ab	8.87	7.59bc	–1.28ab	8.74	6.53ab	–2.21b	7.64	6.11a	–1.53ab	9.11	8.48c	–0.50a
Fat (% kJ)	32.1	27.6a	–4.6	34.2	26.3ab	–8.7	32.2	26.4ab	–5.8	32.3	22.9b	–9.4	33.0	24.9ab	–8.1	33.1	24.7ab	–8.1
SFA (% kJ)	9.0	6.9a	–2.3	9.4	6.3ab	–3.2	8.8	5.7ab	–3.1	9.0	5.2b	–3.8	8.8	6.7ab	–2.2	9.5	5.5ab	–3.8
PUFA (% kJ)	5.2	4.1abc	–1.0	5.4	4.5ab	–1.1	4.5	5.0a	0.5	4.3	3.2c	–1.1	4.4	3.6bc	–0.8	4.8	5.1a	0.3
MUFA (% kJ)	7.5	7.6a	.0a	8.5	6.6ab	–2.2b	7.9	7.1ab	–.9ab	7.9	5.5b	–2.4b	8.0	6.0ab	–2.0ab	8.4	6.9ab	–1.3ab
PUFA:SFA ratio	0.6	0.7a	0.13ab	.6	.8ab	.20ab	.6	1.0b	0.43a	0.6	0.7a	0.13ab	0.6	0.6a	0b	0.6	1.1b	0.4a
Carbohydrate (% kJ)	51.5	54.9ab	4.0a	49.4	59.7cd	–10.5b	51.0	59.3acd	8.3ab	48.9	57.8ac	8.8ab	49.5	53.2b	3.7a	49.7	63.5d	13.5b
Protein (% kJ)	16.3	18.2a	1.6a	16.1	18.4a	2.4	16.5	16.9a	0.4a	16.5	20.7b	4.2bc	15.5	20.7b	5.2c	16.0	17.9a	1.9ab
Alcohol (% kJ)	1.6	2.5	.2	2.4	1.8	0.0	2.2	1.5	–0.6	3.6	2.7	–0.9	3.6	1.4	–2.2	2.1	0.8	–1.4
Cholesterol (mg)	171a	144	–32	213ab	138	–64	225ab	137	–88	241ab	139	–101	199a	129	–70	274b	160	–111
Fiber (g)	15.4ab	16.5a	1.5a	17.3ab	26.3bc	9.2b	17.8a	24.2cd	6.4bc	15.5ab	20.1ad	4.6ac	13.1b	18.0a	4.9abc	14.7ab	29.4b	15.3d
Vitamin A (IU)	8,025	10,767a	2,673	8,685	6,219b	–2,490	6,702	7,045b	343	8,282	6,823b	–1,459	8,897	7,909ab	–988	6,986	6,111b	–781
Vitamin B-6 (mg)	1.62ab	1.7ab	0.1	2.12a	1.9ab	–0.2	1.83ab	2.0a	0.2	1.66ab	1.7ab	0.0	1.57b	1.5b	–0.1	1.98ab	1.9a	0.0
Calcium (mg)	675a	688	40a	780ab	612	–167b	892b	736	–156b	840ab	781	–59ab	650a	718	68a	729ab	678	–28ab
Iron (mg)	13.2a	13.2a	0.4ab	19.6b	16.4b	–3.4a	17.2ab	15.7ab	–1.5ab	14.9a	12.9a	–2.0a	13.9a	12.9a	–1.0ab	15.2a	17.3b	2.2b

[a] Values derived from average of diet records for three days taken before (B) and after (A) intervention. Comparisons are made across all diet groups for each nutrient at each time point (B, A, and difference A – B). Mean values followed by different letters are significantly different ($P < 0.05$). Differences cannot be calculated directly from means of B and A because of missing observations in the surveys taken after diet intervention (individuals who dropped out of the study).

[b] Saturated (SFA), monounsaturated (MUFA) ,and polyunsaturated (PUFA) fat.

mmol/L (6.9%), while the group which only used the NCEP diet had a mean decrease (P = 0.001) of 0.31 mmol/L (4.8%) (Table V). Mean FSTC decreased for the amaranth muffin (4.5%), Oat Bran O's (9.1%), Oat Bran Flakes (13.1%), and variety (11.5%) groups. Mean FSTC for the oat bran muffin group was 0.18 mmol/L (2.8%) higher than before intervention (Table V), causing its change in FSTC to be different ($P < 0.05$) from those of all other groups. In addition, the Oat Bran Flakes and variety group had larger decreases in FSTC than either the NCEP only group or amaranth muffin groups. Surprisingly, there were relatively weak relationships between quantity of SF ($r = –0.10$, $R^2 = 0.01$) or ratio of SF to IF ($r = –0.39$, $R^2 = 0.15$) consumed and the reductions in FSTC. Although the relationship was not much stronger, these data indicated that the quantity of IF consumed had an adverse effect on FSTC reductions ($r = 0.47$, $R^2 = 0.22$). These data suggest that dietary IF can influence the ability of SF to reduce FSTC.

Change in FSTC for the entire cohort or any of the six groups was not affected by gender (results not shown). In the NCEP only group, women had a mean drop of 0.44 mmol/L and men had a drop of 0.18 mmol/L, while in the oat bran muffin group both men and women had a mean increase of 0.18 mmol/L. In the other four groups, the FSTC decreased more for men than for women, but the difference in responses between the genders was not significant.

Serum lipid fractions. ANOVA indicated significant differences between diet groups in overall changes in serum LDL-C and HDL-C, but not for serum VLDL-C or triacylglycerols (Table VI). Changes in LDL-C paralleled mean changes in FSTC. Dietary intervention reduced LDL-C for all groups, except for those consuming the oat bran muffins. The mean increase of 0.21 mmol/L LDL-C for the oat bran muffin group was different ($P < 0.05$) from all other groups, except for the group only on the NCEP diet.

Dietary intervention reduced overall HDL-C in all six diet groups. However, the decrease in HDL-C was greater for the variety group than for either the NCEP diet alone, the oat bran muffin, or the amaranth muffin groups (Table VI). In addition, the overall decrease in HDL-C was greater for the Oat Bran Flakes and Oat Bran O's groups than for the oat bran muffin group ($P < 0.05$).

Recently, the ratio of HDL-C to FSTC has been found to be a better predictor of CHD than either of these variables alone (Swan 1999). Therefore we determined the correlation between HDL-C to FSTC and the reduction in serum cholesterol. We found that the reduction in FSTC was strongly correlated ($r = –0.80$, $R^2 = 0.63$) with the initial ratio of HDL-C to FSTC. Of all the variables measured in this experiment, the relationship between this initial CHD risk factor and the subsequent reduction in serum cholesterol after a dietary intervention including oat bran or amaranth was the strongest. Therefore, these data indicate that a hypercholesterolemic individual with a larger fraction of HDL-C in FSTC will benefit more from the inclusion of fiber in the diet than an individual with proportionately less HDL-C.

TABLE IV
Participant Compliance and Product Rating[a]

Group	Compliance (0–100%)	Product Rating (1–4)
Oat bran muffin	94.4	2.0
Amaranth muffin	94.3	2.3
Oat bran O's	97.6	2.0
Oat bran flakes	97.8	1.9
Variety of products	97.3	2.0

[a] Compliance was reported from 0 to 100% in 5% increments. Values for product rating ranged from 1 (excellent) to 4 (poor).

DISCUSSION

Compliance

This study was designed to determine the hypocholesterolemic effectiveness of the NCEP Step One Diet alone in hypercholesterolemic men and women, and to determine whether the response was enhanced when a variety of oat bran products or amaranth were added to the diet to increase soluble fiber intake. Because group mean self-reported compliance ranged from 94.3 to 97.8% (Table IV) and all fiber-containing products received mean ratings of at least "good", except for the amaranth muffins, it seems that the commercial oat bran products used in this study and the muffins formulated for this study were acceptable means of supplementing the diet with oat bran. In a previously reported study to evaluate the effect of consuming oat products (60 g/day) on serum lipids, Van Horn et al (1986) noted that compliance was 65% in the oatmeal group and 58% in the oat bran group. Gold and Davidson (1988) reported that subjects assigned to groups receiving either wheat bran muffins, oat bran muffins, or muffins containing a combination of wheat bran and oat bran consumed 92% of their allotted muffins (two per day) during a 28-day study. Therefore, the new commercial sources of oat bran might be more acceptable for adding oat bran to the diet than the traditional means. The relationship between product acceptability and the amount of the product subjects were willing to consume stresses the importance of providing palatable foods that are associated with potential health benefits to enhance compliance.

Diet Quality

When individuals modify their diet to reduce intake of saturated fat and cholesterol, rich sources of iron and calcium (meat and milk) are often limited. However, there were no reductions in the intake of index nutrients (vitamins A and B-6, calcium, and iron) for the entire cohort. Even though energy, total fat, saturated fat, and cholesterol intake were reduced for the total cohort, the nutritional quality of the diet was not sacrificed.

Serum Lipid Responses

This study confirmed the results of Van Horn et al (1986, 1988) which showed that modest consumption of oat bran and oatmeal

TABLE V
Mean Fasting Serum Cholesterol (mmol/L) Before (B) and After (A) Diet Intervention[a,b]

Group	B	A	B – A	% Change[c]
NCEP diet	6.53 ± 0.98	6.21 ± 0.95ab	–0.31 ± 0.96a	–4.8
Oat bran muffin	6.41 ± 0.55	6.59 ± 0.82a	0.18 ± 0.71c	2.8
Amaranth muffin	6.41 ± 0.75	6.12 ± 0.82ab	–0.29 ± 0.62a	–4.5
Oat bran O's	6.27 ± 0.93	5.70 ± 1.25b	–0.57 ± 0.91ab	–9.1
Oat bran flakes	6.54 ± 0.71	5.69 ± 0.96b	–0.85 ± 0.71b	–13.1
Variety	6.49 ± 0.57	5.74 ± 0.94b	–0.75 ± 0.81b	–11.5
P-value	0.7714	0.0015	0.0001	

[a] Values derived from average of diet records for three days taken before (B) and after (A) intervention. Differences cannot be calculated directly from means of B and A because of missing observations in the surveys taken after diet intervention (individuals who dropped out of the study). National Cholesterol Education Program (NCEP).
[b] Mean ± standard deviation. Values followed by the same letter in the same column are not significantly different ($P < 0.05$).
[c] Mean difference in cholesterol (B – A) mean cholesterol at first full lipid panel × 100.

enhanced the hypocholesterolemic response to the AHA diet (similar to the NCEP diet) in free-living individuals. In the present study, oat bran supplied as Oat Bran Flakes, Oat Bran O's or as a variety of oat bran products reduced serum cholesterol. However, when oat bran muffins were used as the sole fiber source, FSTC and LDL-C were higher after intervention. Even though the variety group received the greatest quantity of total and soluble fiber in their supplements, when the diets of those in the variety group after intervention were compared with the oat bran muffin group, individuals in the variety group consumed an average of 6.1 g more total fiber than the oat bran muffin group. Therefore, individuals in the variety group must have included more fiber-containing foods in their modified diet, because there was no difference in compliance noted between these groups.

The current study also confirms earlier reports that LDL-C reductions parallel FSTC (Anderson et al 1981, 1984; Van Horn et al 1986, 1988; Olson et al 1997). Serum HDL-C (Anonymous 1984a,b) may be reduced when individual diets are changed to provide less fat and more carbohydrate (Truswell and Kay 1976). Anderson et al (1984) found that HDL-C was reduced after 21 days in subjects who consumed metabolic ward diets that supplied 100 g of oat bran (5.6%) or beans (12.7%). However, in a subgroup that continued to consume a fat-modified diet and rich sources of soluble fiber for 99 weeks, HDL-C was 9% higher than baseline, and FSTC and LDL-C were reduced by 22 and 29%, respectively (Chen and Anderson 1986). In a recent meta-analysis, Olson et al (1997) found that although total cholesterol and LDL cholesterol were reduced by diets containing psyllium, HDL-C was unaffected. Van Horn et al (1988) found slight, but not significant, reductions in HDL-C after subjects followed the AHA diet for four weeks. However, during the next eight weeks of intervention, HDL-C increased in both the group which continued to follow the AHA diet alone and the AHA + oatmeal group. Van Horn et al noted that their results support the hypothesis that adaptation to diet occurs after approximately four weeks, with an overall positive impact on the lipoprotein profile (Kelsay 1978). HDL-C was reduced in all six groups in the present study (Table VI).

Isoenergetic substitution of carbohydrates for fat has been assciated with elevation of triacylglycerols (Truswell and Kay 1976). For the total cohort in the present study, the percentage of total energy intake provided by carbohydrate was increased (50–58%), whereas the energy provided by fat decreased (32.8–25.4%) with a resultant decrease in triacylglycerols of 4.4% (0.11 mmol/L). In this study, only the dietary interventions with oat bran or amaranth muffins resulted in elevated triacylglycerol concentrations.

Serum Lipids Increase with Oat Bran Muffins

The mean increases in both FSTC and LDL-C (0.18 and 0.21 mmol/L, respectively) in the oat bran muffin group were surprising. Although the oat bran muffin group had a lower mean weight loss than the other groups, a weight loss in itself would predict a fall in serum cholesterol greater than the fall which would be predicted from the dietary fat modification which occurred in this group (NCEP 1987a). No differences existed among the fiber-supplemented groups with respect to mean changes in intake of energy, total fat, saturated fat, or polyunsaturated fat. In fact, the oat bran muffin group reduced mean fat intake (% of kJ) more than any group except for the Oat Bran O's group, and they reduced mean saturated fat intake (% of kJ) more than all groups except for the Oat Bran O's and variety groups. Although three-day diet records indicated that this group reduced energy intake more than any group except the Oat Bran O's group, they had the smallest mean weight loss.

The oat bran muffin group received more total fiber and insoluble fiber from the intervention foods than all other groups except for the variety and amaranth muffin groups, and the amount of soluble fiber provided by the oat bran muffins was greater than the amount provided by the Oat Bran Flakes or the amaranth muffins. Amaranth muffins had the lowest SF to IF ratio (0.29), followed by the oat bran muffins (0.48). Groups with mean serum cholesterol reductions greater than the group on the NCEP diet alone had SF to IF ratios >0.50, meaning that at least 33% of the total fiber was provided from SF. Perhaps there is a critical minimum SF to IF ratio required for a food to be hypocholesterolemic or a critical SF to IF ratio below which a food elicits a hypercholesterolemic response. Obviously the SF to IF ratio is not the only factor that determined serum cholesterol responses in this study because the amaranth muffin group received the lowest ratio of SF to IF, and this group experienced FSTC and LDL-C reductions similar to the group only on the NCEP diet.

At baseline, the oat bran muffin group had one of the lowest mean HDL-C and ratio of HDL-C to FSTC, while the Oat Bran Flakes group had the highest mean HDL-C and highest ratio. This difference was not significant, but when the correlation between the ratio of HDL-C to FSTC and the reduction in FSTC was determined, we found that to be the strongest relationship in this study. Perhaps the proportion of HDL-C in the baseline FSTC concentration determines how well an individual will respond to dietary intervention or whether the participant will respond at all.

There is no clear cut answer to the question of why the oat bran muffin group in this study elicited unfavorable serum lipid responses. All six treatment groups received the same NCEP Step One Diet training and modified their diets similarly. Neither weight loss, compliance, nor the amount or types of fiber provided to this group explains these results. Beyond the difference in baseline HDL-C to FSTC ratio, the most obvious potential answers are those that can not be determined posthoc. They include the possibility that other components in the diets of subjects consuming the variety of oat bran products promoted the hypocholesterolemic response to the fiber supplements, or that the processing used to produce the oat bran muffins and the other ingredients included in them may have prevented the reduction in cholesterol absorption expected from consumption of this amount of total and soluble fiber. Beer et al (1997) documented that 30–85% of the total β-glucan in oat bran muffins was extractable in an in vitro system, and that the wide degree of variability could be attributed to the different recipes used to produce the muffins. Beer et al (1997) also found that frozen storage would reduce extractability of β-glucan from muffins, and that all baked muffins had reduced extractability when compared with the original oat bran used for formulation.

CONCLUSIONS

Following the NCEP diet and consuming nearly all of the supplementary fiber products reduced FSTC of hypercholesterolemic men and women, especially when HDL-C constituted a greater proportion of FSTC. Factors that might cause some oat bran-containing foods to be hypercholesterolemic should be examined. This is

TABLE VI
Mean Changes in Serum Lipid Fractions (mmol/L) (Final – Baseline)[a]

Group	*n*	LDL-C	HDL-C	VLDL-C	TG
NCEP diet alone	28	–0.16ab[b]	–0.16ab	–0.05	–0.21
Oat bran muffin	29	0.21b	–0.08a	0.03	0.11
Amaranth muffin	28	–0.23a	–0.16ab	0.05	0.12
Oat bran O's	30	–0.36a	–0.23bc	0	–0.07
Oat bran flakes	31	–0.52a	–0.26bc	–0.10	–0.47
Variety	31	–0.49a	–0.31c	0.08	–0.10
SEM		0.15	0.04	0.07	0.21
P-value		0.0078	0.0009	0.3723	0.3124

[b] National Cholesterol Education Program (NCEP); low density, very low density, and high density lipoprotein cholesterol (LDL-C, VLDL-C, and HDL-C); triacylglycerols (TG). SEM = standard error of the means. P = probability.

[b] Values followed by the same letter in the same column are not significantly different ($P < 0.05$).

extremely important in light of the abundance of oat bran containing cereals, breads, muffins, waffles, etc., which can currently be found on the shelves of most supermarkets, and the approval of a health claim for oat bran by the FDA. Documentation that product preparation and other ingredients included in the product do not alter its desirable qualities should be provided for general classes of products.

In summary, oat bran in many forms may enhance the serum cholesterol reductions that many individuals experience when they fat-modify their diets. Oat bran should be consumed only as one component of a cholesterol-lowering diet, and the diet should also incorporate the principles of energy balance and fat-modification.

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