

Comparison of the Effects of Lean Red Meat vs Lean White Meat on Serum Lipid Levels Among Free-living Persons With Hypercholesterolemia

A Long-term, Randomized Clinical Trial

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Background: Patients with hypercholesterolemia are often counseled to limit or eliminate intake of red meats, despite evidence that lean red meats (LRMs) are not hypercholesterolemic in comparison with lean white meats (LWMs). The objective of this study was to evaluate the long-term effects on serum lipids of incorporating LRM (beef, veal, and pork) vs LWM (poultry and fish) into a National Cholesterol Education Program (NCEP) Step I diet in free-living individuals with hypercholesterolemia.

Methods: Subjects included 191 men and women with a serum low-density lipoprotein cholesterol level of 3.37 to 4.92 mmol/L (130-190 mg/dL) and triglyceride level less than 3.96 mmol/L (350 mg/dL). After a 4-week baseline phase, subjects were counseled to follow an NCEP Step I diet including 170 g (6 oz) of lean meat per day, 5 to 7 days per week. Based on random assignment, subjects were instructed to consume at least 80% of their meat in the form of LRM or LWM. Fasting serum lipid

levels were assessed 4, 12, 20, 28, and 36 weeks after randomization.

Results: After randomization, mean concentrations of total cholesterol (6.09 mmol/L [235.7 mg/dL] vs 6.08 mmol/L [235.2 mg/dL]) and low-density lipoprotein cholesterol (3.99 mmol/L [154.1 mg/dL] vs 4.01 mmol/L [154.7 mg/dL]) were nearly identical in the LRM and LWM groups (1%-3% below baseline) during treatment. Mean triglyceride levels remained similar to baseline values and high-density lipoprotein cholesterol concentrations increased by approximately 2% in both groups.

Conclusions: The NCEP Step I diets containing primarily LRM or LWM produced similar reductions in low-density lipoprotein cholesterol and elevations in high-density lipoprotein cholesterol levels, which were maintained throughout 36 weeks of treatment.

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EPIDEMIOLOGICAL studies have shown a strong positive association between serum total and low-density lipoprotein cholesterol (LDL-C) levels and risk for coronary heart disease.¹⁻⁴ Several large-scale clinical trials have also demonstrated that reducing elevated LDL-C lowers the risk of coronary heart disease morbidity and mortality.^{3,5} Diet intervention is recommended by the National Cholesterol Education Program (NCEP) guidelines as first-line therapy for the management of high blood cholesterol levels.^{6,7} The NCEP Step I diet limits intake of fat to 30% or less of energy intake, saturated fatty acids to 8% to 10% of energy, and cholesterol to less than 300 mg/d.⁶

To achieve NCEP dietary goals, individuals are often counseled to reduce the amount and frequency of red meat consumption.⁸⁻¹¹ However, controlled feeding studies have shown that the choles-

terol-raising influence of some red meats appears to result from the cholesterol-raising fatty acids they contain.^{8,12,13} Therefore, lean red meats (LRMs) that provide small amounts of these fatty acids would not be expected to adversely influence the blood lipid profile compared with lean white meats (LWMs). In fact, studies directly comparing the effects of lean beef with chicken, or with chicken and fish, indicate that these meats are interchangeable with regard to their influence on serum lipid levels.^{9,14} Since lean cuts of red meat are now readily available to consumers, the common practice of advising patients to avoid or severely limit red meat intake may be unnecessarily restrictive and adversely affect long-term dietary adherence.

The present study was undertaken to compare the long-term effects of diets in which LRM (beef, veal, pork) or LWM (poultry and fish) comprised the principal meat sources within the context of an

SUBJECTS AND METHODS

SCREENING AND DIET STABILIZATION

This was a randomized, multisite study with participants recruited from the Chicago, Ill (Chicago Center for Clinical Research); Minneapolis, Minn (The University of Minnesota Hospital and Clinics); and Baltimore, Md (The Johns Hopkins University Lipid Clinic), metropolitan areas. The study protocol was reviewed and approved by an institutional review board for each investigative site. Men and women aged 18 to 75 years were screened by telephone interview. Individuals who met the initial screening criteria were asked to discontinue all lipid-lowering drugs or therapies, with approval from their physicians, for at least 6 weeks prior to an orientation and screening visit at their respective clinical research center. Volunteers were excluded from the study if they were pregnant or lactating, vegetarians, current smokers, abused alcohol (>14 drinks per week), or used illicit drugs. At the time of the baseline measurements, eligible subjects were not allowed to be using hypolipidemic drugs, or therapeutic doses of fish oil supplements, niacin/nicotinic acid (>250 mg/d), psyllium (>10 g/d), or oat bran (>1/3 cup/d).

At screening (week -4), the conditions and procedures of the study were explained and a written consent form was signed by each participant. Participants completed a medical history questionnaire and underwent a physical examination and laboratory procedures including hematological assessment, blood chemistry studies, urinalysis (including a urine pregnancy test for women of childbearing potential), and a blood lipid profile (total cholesterol, high-density lipoprotein cholesterol [HDL-C], LDL-C, and triglycerides). Persons with a body mass index (calculated as weight in kilograms divided by the square of height in meters) of 35 or greater; diabetes mellitus; atherosclerotic disease; cancer; hypothyroidism or other endocrine disorder; or any hematological, hepatic, gastrointestinal, or immune disorder were excluded from the study. All individuals who met the inclusion criteria were administered the Oregon Health Sciences Diet Habit Survey, an indicator of typical eating habits,¹⁵ and were instructed to maintain their usual diets throughout a 4-week diet stabilization period.

Subjects returned to their respective clinical research center 2 weeks after the screening visit (week -2) to have

vital signs and body weight checked, and for another blood lipid profile measurement. Lipid criteria for inclusion in the study, based on the average of the 2 measurements obtained at weeks -4 and -2, included LDL-C level between 3.37 and 4.92 mmol/L (130-190 mg/dL) and serum triglyceride level less than 3.96 mmol/L (<350 mg/dL). If LDL-C concentrations varied by more than 15% between visits at week -4 and -2 (larger value as the denominator), an additional lipid profile clinic visit at week -1 was scheduled. If values from week -2 and week -1 did not meet the lipid eligibility criteria, the subject was dropped from the study. At the week -2 visit, subjects were asked to continue their usual diets for the remaining 2 weeks of the diet stabilization period, and were instructed to complete a 3-day diet record (including 1 weekend day) during this period. A nutritionist instructed the subjects on how to complete the diet records, using Nasco food models to illustrate portion sizes.

RANDOMIZATION AND DIET INSTRUCTION

Of the 382 persons who were screened, 202 men and women met all inclusion criteria and were randomly assigned to either the LRM (n = 95) or (LWM) (n = 107) treatment group. At the randomization visit (week 0), subjects assigned to the LRM group were instructed to consume 170 g (6 oz) of meat, 5 to 7 days per week, for 36 weeks as part of an NCEP Step I diet. Subjects in the LRM group were instructed to consume at least 80% of their total meat in the form of lean beef, veal, or pork. Subjects randomized to the LWM group were similarly instructed, except that at least 80% of their meat consumption was to be LWMs defined as poultry or fish. Lamb was included in the 20% of other meat consumed by both groups during the treatment period.

Baseline 3-day diet records and the results of the baseline Diet Habit Survey were reviewed with each subject at the randomization visit. Detailed instructions were provided on following an NCEP Step I diet. An American Heart Association booklet, food scales, handouts, and videotapes were also provided as aids to help subjects understand and comply with the prescribed diet. Participants were also counseled by a nutritionist on selection and preparation of appropriate meats and completion of meat consumption daily logs used to record information on meat intake, cuts of meat consumed, methods of preparation, and portion sizes.

NCEP Step I diet among free-living subjects with mild to moderate hypercholesterolemia.

RESULTS

SUBJECTS AND DEMOGRAPHICS

Two hundred two subjects met all inclusion criteria and were randomly assigned to the LRM (n = 95) or LWM (n = 107) treatment groups. Forty-two subjects dropped out of the study prior to its completion. Of these, 18 were in the LRM group and 24 in the LWM group. Reasons reported for study discontinuation included inability to follow the diet (n = 15), schedul-

ing problems (n = 11), loss to follow-up (n = 7), private medical advice or newly prescribed medications (n = 5), personal reasons (n = 2), surgery (n = 1), and relocation (n = 1).

At least 1 postrandomization blood specimen was obtained from 191 subjects. Subjects for whom no postrandomization blood samples were obtained (n = 11) were excluded from all analyses. Baseline anthropometric and demographic characteristics of each treatment group are shown in **Table 1**. Treatment groups did not differ significantly in mean age or body mass index at baseline and were comparable with respect to sex and race distribution, as well as median weekly consumption of alcoholic beverages.

TREATMENT PERIOD

Subjects returned to the clinic at weeks 4, 12, 20, 28, and 36 of the treatment period. Vital signs, body weight, and fasting serum lipid profiles were measured at each clinic visit. Additionally, at week 36, safety measurements (hematology, blood chemistry, and urinalysis) were obtained. Throughout the treatment period, subjects maintained meat consumption daily logs. Three-day diet records (2 weekdays and 1 weekend day) were collected and analyzed at baseline (week 0) and at each subsequent clinic visit. Diet records and results of the computerized analysis of the diet record from the previous clinic visit were reviewed with the subject at each visit. Counseling and feedback were provided to assist patients with dietary adherence. Between clinic visits at weeks 8, 16, 24, and 32, telephone interviews were conducted to further monitor and encourage subject compliance with the study protocol. The Diet Habit Survey was administered during the telephone interviews at weeks 16 and 32.

ANALYSES

Lipids and Lipoproteins

Fasting (≥ 12 hours) blood collection was completed at each clinical research site according to previously described procedures.¹⁶ Serum total cholesterol, HDL-C, and triglyceride concentrations were measured enzymatically by a central laboratory (Medical Research Laboratories, Cincinnati, Ohio) that participates in the Centers for Disease Control and Prevention lipid measurement standardization program.¹⁷ Low-density lipoprotein cholesterol in milligrams per deciliter was calculated using the Friedewald equation: [LDL-C = total cholesterol - HDL-C - (triglycerides/5)].¹⁸ Results were blinded from investigators throughout the treatment period, though clinic sites were notified by the central laboratory if the LDL-C concentration of any subject exceeded 5.69 mmol/L (220 mg/dL).

Compliance

A subject was deemed compliant with their assigned treatment if at least 80% of total meat intake during each 1-month period came from the appropriate meat, and if the subject consumed an average of 795 to 1306 g (28-46 oz) of meat per week. Subjects whose average meat consumption was out

of this range were not dropped from the study, but were strongly encouraged to follow the specified guidelines.

Compliance with the fat and cholesterol recommendations of the NCEP Step 1 diet was determined using the cholesterol-saturated fat index of the Diet Habit Survey administered at baseline and at 16 and 32 weeks of the treatment period. A value of 60 or higher is consistent with the recommendations for intakes of less than 30% of total energy (calories) from fat and less than 300 mg/d of cholesterol.

Three-day diet records were analyzed using the University of Minnesota Nutrition Data System, version 2.7 software. Three-day averages were calculated for intake of selected nutrients at weeks 0 (baseline), 4, 20, and 36. Nutrient analyses were completed at the Chicago Center for Clinical Research Nutrient Analysis Center according to standard operating procedures, including blinded reentry of data on a randomly selected portion of the records. Diet records from the Minnesota and Maryland sites were sent by facsimile to the Chicago site, and the nutrient intake results were sent back to each clinical site prior to the next clinic visit for use in dietary counseling.

Statistical Procedures

Analyses were conducted using the JMP 3.1 (SAS Institute, Cary, NC) and Statview 4.5 (Abacus Concepts, Berkeley, Calif) statistical analysis packages. $P \leq .05$ (2-sided) was used to denote statistical significance.

Analysis of variance and χ^2 tests were used to assess comparability of baseline characteristics between treatment groups. Outcome analyses were conducted using data from all subjects who provided at least 1 postrandomization blood specimen for lipid analysis. The initial statistical models contained terms for treatment, time, treatment \times time interaction, study center, and treatment \times study center interaction. No evidence of treatment \times time or treatment \times study center interactions was detected ($P > .10$). Therefore, data from the 3 sites were pooled and mean blood lipid levels during treatment were used in the final statistical models. Blood lipid variables examined were the mean concentrations of total cholesterol, LDL-C, HDL-C, triglycerides, and the total cholesterol/HDL-C ratio during treatment, as well as the changes in these values from baseline (mean of 3 or 4 baseline measurements) to treatment (mean of all postrandomization measurements).

SERUM LIPIDS

Serum lipid values at baseline and during treatment are summarized in **Table 2**. No differences between groups were observed for any of the serum lipid measures assessed at baseline. Mean baseline total cholesterol and LDL-C values were near the cut points for high-risk classification as defined by the NCEP, 6.20 mmol/L (240 mg/dL) and 4.13 mmol/L (160 mg/dL), respectively.

During treatment, mean concentrations of total cholesterol (6.09 mmol/L [235.7 mg/dL] vs 6.08 mmol/L [235.2 mg/dL]) and LDL-C (3.99 mmol/L [154.1 mg/dL] vs 4.01 mmol/L [154.7 mg/dL]) were nearly identical in the LRM and LWM groups, respectively (Table 2

and **Figure 1**). Compared with baseline, total cholesterol concentration declined by 1.0% in the LRM group ($P > .05$) and 1.8% in the LWM group ($P = .003$). Levels of LDL-C decreased 1.7% in the LRM group ($P = .01$) and 2.9% in the LWM group ($P < .001$). No significant differences in total cholesterol or LDL-C responses were present between treatment groups. A pooled SD of 0.3 mmol/L (11.6 mg/dL) was observed for the absolute change in LDL-C. Accordingly, this study had approximately 80% power to detect a difference of 5 mg/dL (3%) in LDL-C response between treatment arms.

No between-group differences were observed for HDL-C, although HDL-C concentration increased by approximately 2% relative to baseline in both the LRM

($P = .01$) and LWM ($P = .004$) groups (Table 2 and **Figure 2**). The total cholesterol/HDL-C ratio did not differ between groups, and was maintained at a level 3% to 4% below the baseline value in both groups (LRM, $P = .002$; LWM, $P < .001$). No significant differences were observed within or between groups for triglyceride concentration at baseline or during treatment.

DIETARY DATA

Randomly selected consecutive 7-day periods between each clinic visit were chosen for evaluation of daily meat logs (**Table 3**). During the first 4 weeks of the treatment phase, mean reported total meat intake was 167.7 g/d in the LRM group and 160.7 g/d in the LWM group. These values were not significantly different and suggest that subjects were generally meeting the treatment compliance goal of consuming an average of 120 to 170 g/d of meat. In both groups, 84.2% of the reported meat

intake was in the form of red meat (LRM group) or white meat (LWM group). The mean proportion of meat consumed from the appropriate category did not vary significantly during the treatment period for either group and stayed above 80% at each measurement point. Total meat intake declined in both groups over time, but this trend was more pronounced in the LWM group. Compared with the first 4 weeks of the intervention period, reported meat intake had declined by approximately 5% in the LRM group and about 10% in the LWM group. During the final 16 weeks of the study, reported weekly meat intake was significantly lower in the LWM group than in the LRM group ($P < .01$).

Mean values of the Diet Habit Survey cholesterol-saturated fat index in the 2 treatment groups were 64.9 (LRM group) and 62.1 (LWM group) at baseline and were not statistically different (**Table 4**). After 16 and 32 weeks of treatment, scores were elevated significantly ($P < .001$) from baseline in both groups (LRM: 72.0 and 73.7; LWM: 72.0 and 75.0 for weeks 16 and 32, respectively) and values in the 2 treatment groups did not differ significantly from one another. Examination of the relationship between baseline scores and change in lipid levels during the treatment period indicated that subjects compliant with the NCEP Step I diet at baseline (score >60) had significantly smaller reductions of total cholesterol and LDL-C during treatment than did noncompliant subjects (score <60) ($P < .05$) (**Table 5**).

Results of diet record analysis at baseline and during treatment (mean of values from weeks 4 to 36) are shown in **Table 6**. No significant differences between groups were observed for intakes of any major dietary components at baseline ($P > .05$ for all comparisons). Both treatment groups had significantly lower intakes of energy ($P = .006$ and $P < .001$ for LRM and LWM groups, respectively), total fat ($P = .001$ and $P < .001$), monounsaturated fatty acids ($P = .02$ and $P < .001$), and protein

Table 1. Baseline Characteristics of the Study Sample

Variable	Treatment Group	
	Lean Red Meat (n = 89)	Lean White Meat (n = 102)
Age, mean \pm SEM, y	56.9 \pm 1.0	54.8 \pm 1.2
Sex, %		
Male	53.9	58.3
Female	46.1	41.7
BMI, mean \pm SEM, kg/m ³	27.6 \pm 0.37	27.1 \pm 0.37
Race, %		
White	91.0	86.4
Other	9.0	13.6
Alcoholic drinks per week		
Median	2	1
25th-75th percentile	0-4	0-4

Table 2. Serum Lipid Values at Baseline and During the Treatment Period*

Lipid Variable, Treatment Group	Mean \pm SEM Values, mmol/L (mg/dL)		Mean % Δ §	P for Mean Δ (Within Treatment)
	Baseline†	Treatment Period‡		
Total cholesterol				
Lean red meat	6.17 \pm 0.04 (238.3 \pm 1.6)	6.09 \pm 0.05 (235.7 \pm 1.9)	-1.0 \pm 0.6	.07
Lean white meat	6.21 \pm 0.05 (239.6 \pm 2.0)	6.08 \pm 0.05 (235.2 \pm 2.1)	-1.8 \pm 0.6	.003
LDL cholesterol				
Lean red meat	4.07 \pm 0.04 (157.0 \pm 1.6)	3.99 \pm 0.05 (154.1 \pm 1.8)	-1.7 \pm 0.7	.01
Lean white meat	4.13 \pm 0.04 (159.5 \pm 1.5)	4.01 \pm 0.05 (154.7 \pm 1.8)	-2.9 \pm 0.8	<.001
HDL cholesterol				
Lean red meat	1.33 \pm 0.03 (51.3 \pm 1.2)	1.36 \pm 0.03 (52.6 \pm 1.3)	2.3 \pm 0.8	.01
Lean white meat	1.31 \pm 0.03 (50.4 \pm 1.1)	1.33 \pm 0.03 (51.5 \pm 1.2)	2.4 \pm 0.7	.004
Triglycerides				
Lean red meat	1.69 \pm 0.08 (149.9 \pm 6.7)	1.66 \pm 0.08 (146.9 \pm 6.7)	1.3 \pm 2.6	.50
Lean white meat	1.68 \pm 0.06 (148.7 \pm 5.1)	1.65 \pm 0.07 (146.2 \pm 5.8)	-0.5 \pm 2.1	.41
Total/HDL cholesterol ratio				
Lean red meat	4.9 \pm 0.1	4.7 \pm 0.1	-2.8 \pm 0.9	.002
Lean white meat	5.0 \pm 0.1	4.8 \pm 0.1	-3.7 \pm 0.8	<.001

*LDL indicates low-density lipoprotein; HDL, high-density lipoprotein.

†Baseline and treatment period: lean red meat group, n = 89; lean white meat group, n = 102.

‡Values represent the average of lipid levels at each clinic visit during the treatment period (weeks 4-36). There were no significant differences between groups.

§Values represent the percentage change in lipid levels from baseline to the average of the values during the treatment period. There were no significant differences between groups.

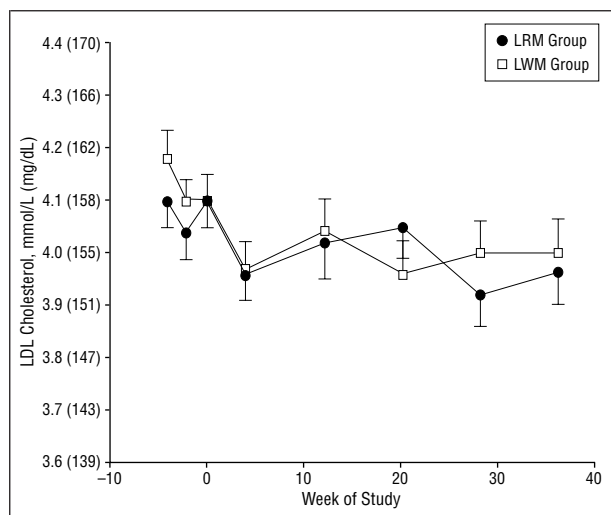


Figure 1. Mean \pm SEM low-density lipoprotein (LDL) cholesterol concentrations from screening to the end of the 36-week treatment period. Results represent all subjects included in the intent-to-treat analyses. Sample sizes for the lean red meat (LRM) group at weeks -2, -1, 0, 4, 12, 20, 28, and 36 were 88, 11, 88, 88, 79, 77, 76, and 75 subjects, respectively. Sample sizes for the lean white meat (LWM) group at each time point were 103, 8, 103, 103, 94, 90, 87, and 83 subjects. Week -1 represents results from only those subjects who required an additional lipid eligibility measurement.

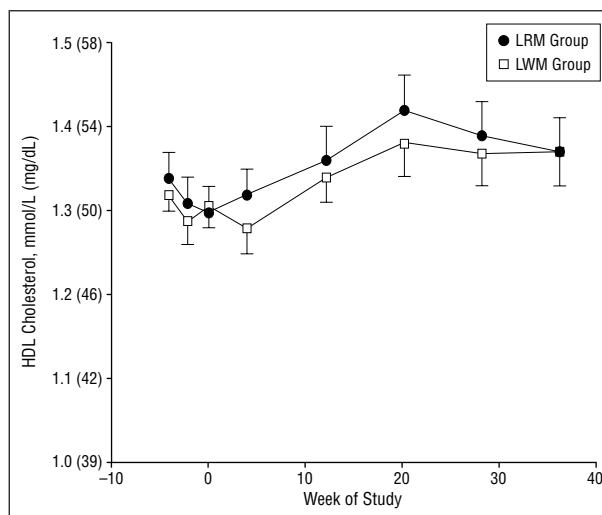


Figure 2. Mean \pm SEM high-density lipoprotein (HDL) cholesterol concentrations from screening to the end of the 36-week treatment period. Sample sizes for the lean red meat (LRM) group at weeks -2, -1, 0, 4, 12, 20, 28, and 36 were 88, 11, 88, 88, 79, 77, 76, and 75 subjects, respectively. Sample sizes for the lean white meat (LWM) group at each time point were 103, 8, 103, 103, 94, 90, 87, and 83 subjects. Week -1 represents results from only those subjects who required an additional lipid eligibility measurement.

Table 3. Daily Intake of Meat and Percentage of Red or White Meat Consumed According to Meat Log Entries*

Group	Weeks 0-4 (Days 19-25)	Weeks 5-12 (Days 76-82)	Weeks 13-20 (Days 118-124)	Weeks 21-28 (Days 182-188)	Weeks 29-36 (Days 246-252)
Lean red meat	n = 87	n = 81	n = 78	n = 76	n = 75
Total meat, g/d	167.7 \pm 5.1	158.3 \pm 4.8	159.9 \pm 4.6	161.2 \pm 3.7†	158.0 \pm 3.2†
Red meat, %	84.2 \pm 1.8	84.1 \pm 1.5	83.2 \pm 1.8	81.5 \pm 1.5	86.6 \pm 1.3
Lean white meat	n = 99	n = 92	n = 88	n = 85	n = 84
Total meat, g/d	160.7 \pm 4.7	152.2 \pm 4.3	149.3 \pm 3.6	144.6 \pm 3.2	144.2 \pm 3.7
White meat, %	84.2 \pm 1.5	84.4 \pm 1.8	85.4 \pm 1.4	87.3 \pm 1.2	84.9 \pm 1.8

* Values represent mean \pm SEM of daily intake from randomly selected meat log entries for 7 consecutive days during each of the specified time periods.
† Significantly different from lean white meat group ($P < .01$).

($P < .001$ for both) during the treatment period than at baseline. Additionally, the LWM group had reduced intake of 18:0 and 12:0-16:0 fatty acids ($P < .001$) and cholesterol ($P = .02$), whereas the LRM group had a reduction from baseline in polyunsaturated fatty acid intake ($P < .001$). Diet records collected during the treatment period suggest that daily consumption of fat ($P = .003$), stearic acid (18:0) ($P < .001$), cholesterol-raising (12:0-16:0) fatty acids ($P < .001$), and monounsaturated fatty acids ($P < .001$) were higher, and carbohydrate ($P = .005$) and polyunsaturated fatty acid intakes ($P < .001$) were lower during the treatment phase in the LRM group than in the LWM group. Total energy ($P = .06$) and cholesterol intakes ($P = .10$) tended to be lower in the LWM group. Reported consumption of protein, dietary fiber (including soluble fiber), and iron did not differ significantly between treatment groups.

BODY WEIGHT

Mean body weight in the 2 treatment groups was similar at baseline and did not change significantly during the treatment period. The LRM group had a mean \pm SEM

baseline body weight of 79.9 \pm 14.5 kg and the corresponding level in the LWM group was 80.2 \pm 14.6 kg. At the end of the treatment period, the mean body weight of the LRM group was 80.8 \pm 14.9 kg and the LWM group was 79.7 \pm 14.8 kg. Mean weight change during the treatment period was less than 1 kg in both groups ($P > .05$).

COMMENT

The participants of the present trial were free-living adult volunteers with hypercholesterolemia, for whom dietary modification is the first line of therapy. This long-term, randomized, multisite trial showed that serum lipid responses did not differ between groups consuming primarily LRM or LWM, as part of an NCEP Step I diet. In shorter studies conducted under highly controlled conditions, blood lipid responses to consuming lean beef were equivalent to responses to consumption of chicken, or chicken and fish.^{9,14} Scott and colleagues^{9,14} directly compared blood lipid responses with consumption of lean beef vs chicken and fish, or chicken alone, among men with hypercholesterolemia in 2 randomized, controlled feeding studies. These meats were incorporated into diets con-

taining less than 30% of energy from fat and less than 10% of energy from saturated fatty acids, and all foods consumed by the participants were prepared by the investigators. In both trials, total cholesterol and LDL-C responses during the 4- to 5-week treatment periods were similar in the lean beef, chicken, and chicken and fish treatment groups. Similar findings have also been reported for normocholesterolemic subjects.⁸ Our trial extends these findings to a group of hypercholesterolemic men and women who were free to make their own choices regarding food selection and preparation over a 9-month period. Together, these studies provide compelling evidence to support the view that instructing patients with hypercholesterolemia to eliminate or markedly reduce all red meat intake is unnecessarily restrictive. Replacement of high-fat meats with leaner red or white meat selections has the potential to improve long-term dietary adherence by increasing food choices.

Table 4. Oregon Health Sciences Diet Habit Survey Cholesterol-Saturated Fat Index Scores by Week of Study*

Treatment Group and P Value	Baseline	Week 16	Week 32
Lean red meat	64.9 ± 1.3 (n = 89)	72.0 ± 1.1† (n = 79)	73.7 ± 1.1† (n = 73)
Lean white meat	62.1 ± 1.2 (n = 102)	72.0 ± 1.2† (n = 93)	75.0 ± 1.2† (n = 85)
Red vs white P	.12	.99	.45

*Values represent mean ± SEM. A value of 60 or higher in the cholesterol-saturated fat index of the Oregon Health Sciences Diet Habit Survey is consistent with National Cholesterol Education Program Step I diet recommendations for intakes of less than 30% of total energy from fat, less than 10% of energy from saturated fat, and less than 300 mg/d of cholesterol.

†Significantly different from baseline value (P < .001).

Nearly all of the energy in meats is derived from protein and fat. The available data suggest that meat protein, per se, is not hypercholesterolemic.^{8,12,14} The blood cholesterol-raising potential of meat products appears to be a function of their fat and cholesterol contents. Red meats vary considerably in fat content. An 85-g (3-oz) serving of regular ground beef contains approximately 22 g of fat and 8 g of cholesterol-raising (12:0-16:0) fatty acids.⁸ The same size serving of ground round provides only 3 to 4 g of fat and less than 2 g of cholesterol-raising fatty acids. Therefore, substituting lean selections for higher fat cuts of red meat should favorably influence serum total cholesterol and LDL-C levels.

Controlled feeding trials provide important information regarding the biological effects of dietary components. However, such information will have limited clinical utility if practical barriers exist that prevent translation into dietary choices for free-living persons. If, for example, LRMs were not readily available to consumers in supermarkets and restaurants, findings from controlled feeding studies would be of little relevance to patients and health care professionals. In recent years, consumers have had access to a wider variety of lean meat products.

In the present study, the degree of lipid lowering after dietary counseling was modest for both treatment groups. Total cholesterol and LDL-C remained 1% to 3% below the baseline levels for the duration of the 36-week treatment period, suggesting that adherence to the NCEP Step I diet did not deteriorate over time. Participants were hypercholesterolemic on entry into the study while on a self-selected diet, although many had received prior counseling and were already consuming a diet similar to that recommended by the NCEP. Mean baseline cholesterol-saturated fat scores on the Diet Habit Survey were above 60 in both groups, suggesting that many subjects were con-

Table 5. Lipid Changes During the Treatment Period According to Baseline Oregon Health Sciences Diet Habit Survey Cholesterol-Saturated Fat Index Scores*

Lipid Variable, Treatment Group	Mean ± SEM Values, mmol/L (mg/dL)		P for Interaction‡
	NCEP Compliant at Baseline†	Not NCEP Compliant at Baseline†	
Total cholesterol			
Lean red meat	-0.05 ± 0.04 (-1.87 ± 1.69)	-0.10 ± 0.06 (-3.82 ± 2.31)	.04
Lean white meat	-0.04 ± 0.05 (-1.34 ± 1.79)	-0.21 ± 0.06 (-8.18 ± 2.38)	
LDL cholesterol			
Lean red meat	-0.05 ± 0.03 (-1.72 ± 1.30)	-0.13 ± 0.05 (-5.14 ± 2.09)	.009
Lean white meat	-0.06 ± 0.04 (-2.13 ± 1.48)	-0.21 ± 0.05 (-7.90 ± 2.04)	
HDL cholesterol			
Lean red meat	0.02 ± 0.01 (0.92 ± 0.51)	-0.04 ± 0.02 (1.64 ± 0.95)	.67
Lean white meat	0.03 ± 0.02 (1.15 ± 0.51)	-0.03 ± 0.02 (0.95 ± 0.60)	
Triglycerides			
Lean red meat	-0.03 ± 0.05 (-3.01 ± 4.55)	-0.02 ± 0.09 (-2.05 ± 7.70)	.68
Lean white meat	-0.001 ± 0.058 (-0.09 ± 5.15)	-0.06 ± 0.05 (-5.54 ± 4.33)	
Total/HDL cholesterol ratio			
Lean red meat	-0.13 ± 0.05	-0.19 ± 0.09	.05
Lean white meat	-0.10 ± 0.06	-0.28 ± 0.06	

*A value of 60 or higher in the cholesterol-saturated fat index of the Oregon Health Sciences Diet Habit Survey is consistent with the National Cholesterol Education Program (NCEP) Step I diet recommendations for intakes of less than 30% of total energy from fat, less than 10% of energy from saturated fat, and less than 300 mg/d of cholesterol. LDL indicates low-density lipoprotein; HDL, high-density lipoprotein.

†Lean red meat group: high baseline score (n = 59), low baseline score (n = 29); lean white meat group: high baseline score (n = 55), low baseline score (n = 46).

‡P value is for comparison between high and low baseline score subgroups (combined red and white meat groups). There were no significant differences between lean red meat and lean white meat treatments in the high or low baseline score groups.

Table 6. Results of 3-Day Diet Record Analysis

Dietary Component, Treatment Group	Mean ± SEM Value		P‡ (Treatment Group Main Effect)	P§ (Within Treatment)
	Baseline*	Treatment Period† (Weeks 4-36)		
Energy, kJ/d (kcal/d)				
Lean red meat	8678 ± 314 (2076 ± 75)	7641 ± 364 (1828 ± 87)	.06	.006
Lean white meat	8009 ± 259 (1975 ± 62)	6897 ± 184 (1650 ± 44)		<.001
Total fat, % of energy				
Lean red meat	31.7 ± 0.9	29.3 ± 0.7	.003	.001
Lean white meat	32.2 ± 0.8	26.7 ± 0.6		<.001
18:0 Fatty acids, % of energy				
Lean red meat	2.8 ± 0.1	2.7 ± 0.8	<.001	.57
Lean white meat	2.9 ± 0.1	2.1 ± 0.6		<.001
12:0-16:0 Fatty acids, % of energy				
Lean red meat	6.9 ± 0.2	6.6 ± 0.2	<.001	.12
Lean white meat	7.0 ± 0.2	5.3 ± 0.2		<.001
Monounsaturated fatty acids, % of energy				
Lean red meat	12.3 ± 0.4	11.5 ± 0.3	<.001	.02
Lean white meat	12.5 ± 0.4	9.9 ± 0.3		<.001
Polyunsaturated fatty acids, % of energy				
Lean red meat	6.2 ± 0.2	5.1 ± 0.2	<.001	<.001
Lean white meat	6.3 ± 0.2	6.5 ± 0.2		.23
Cholesterol, mg/d				
Lean red meat	256 ± 15	236 ± 10	.10	.27
Lean white meat	245 ± 14	209 ± 13		.02
Carbohydrate, % of energy				
Lean red meat	50.2 ± 0.9	50.2 ± 0.7	.005	.65
Lean white meat	51.6 ± 0.9	53.2 ± 0.7		.10
Protein, % of energy				
Lean red meat	16.9 ± 0.4	19.3 ± 0.3	.30	<.001
Lean white meat	16.0 ± 0.4	19.9 ± 0.4		<.001
Total fiber, g/d				
Lean red meat	18.9 ± 0.9	19.4 ± 1.6	.60	.45
Lean white meat	19.3 ± 0.7	18.5 ± 0.7		.17
Soluble fiber, g/d				
Lean red meat	6.5 ± 0.3	6.9 ± 0.6	.40	.37
Lean white meat	6.5 ± 0.3	6.3 ± 0.2		.46
Iron, mg/d				
Lean red meat	16.9 ± 0.9	17.0 ± 1.1	.54	.60
Lean white meat	15.7 ± 0.7	19.3 ± 3.4		.29

*Baseline: lean red meat, n = 88; lean white meat group, n = 99.

†Treatment period: lean red meat group, n = 84; lean white meat group, n = 94.

‡P value is for the between-treatment comparison of nutrient intakes during the treatment period.

§P value is for the within-treatment comparison of nutrient intakes at baseline and during the treatment period.

suming diets conforming to the NCEP recommendations.⁶ Further subgroup analysis of subjects with baseline scores above vs below 60 indicated that individuals compliant with the NCEP diet had less lipid lowering during treatment than did persons who were not compliant at baseline. In fact, non-compliant subjects (red and white combined) had a 3% to 5% LDL-C reduction from baseline. Thus, the lipid-lowering response in this group was close to the 5% to 10% lipid reduction expected from NCEP Step I diet intervention.^{6,19}

Meat consumption logs indicated that both groups maintained their meat consumption according to their appropriate treatment; however, total meat consumption declined over time, particularly in the LWM group. During the final 12 weeks of the treatment period, the LWM group had a reported meat intake of approximately 10% less than during the first 4 weeks of the intervention period compared with the LRM group, which had only approximately a 5% decline. Many of the participants had been following a cholesterol-lowering diet

prior to enrollment in the study and thus may have been restricting red meat intake at baseline. For these subjects, the LRM diet may have had higher palatability because it represented a greater change from the dietary pattern followed prior to entry into the trial.

According to diet records, mean intakes (approximate) of total fat, saturated fats, and cholesterol at baseline were 32% of energy, 10.5% of energy, and 255 mg/d, respectively. Average fat consumption reported by US adults who participated in the third National Health and Nutrition Examination Survey was 34% of energy, while saturated fats comprised 12% of energy intake.²⁰

Diet records suggest that subjects in the LRM group consumed more fat and cholesterol-raising fatty acids during the treatment phase. In addition, the LRM group showed a trend toward increased energy consumption compared with the LWM group. Although these differences were not large, they were statistically significant and are not fully consistent with the lack of difference in body weight and lipid

responses between treatment groups. Food records are among the best tools for estimating dietary intake, particularly in a free-living population, yet subjects frequently underreport or overreport their intakes.²¹ Further difficulties arose from the Nutrition Data System assumptions for red meat selections, which may no longer be valid with the now widely available leaner cuts of meat. Red meats vary more in their fat content than do white meats. These variations may not be fully reflected by the Nutrition Data System, which has limited options for cuts of red meat and different external fat (trim) widths. Thus, limitations inherent in the methods available for collection of dietary data from free-living subjects may explain the differences observed. The data obtained from administration of the Diet Habit Survey suggest that there were no marked differences in cholesterol-saturated fat intakes between the 2 groups after 16 and 32 weeks of treatment.

To further assess the potential impact of dietary differences between groups, predicted changes from baseline LDL-C concentration were calculated for each group using the equation published by Kris-Etherton and Yu²²:

$$\Delta\text{LDL-C (mmol/L or mg/dL)} = 1.46 \Delta 12:0-16:0 + 0.07 \Delta 18:0 - 0.69 \Delta M - 0.96 \Delta P,$$

where 12:0-16:0 is the percentage of energy intake from cholesterol-raising fatty acids, 18:0 is the percentage of energy from stearic acid, M is the percentage of energy from monounsaturated fatty acids, and P is the percentage of energy from polyunsaturated fatty acids. Using this equation, the predicted change in LDL-C was -0.08 mmol/L (-3.0 mg/dL) for the LRM group compared with -0.13 mmol/L (-5.2 mg/dL) for the LWM group. Because this equation has no term for differences in cholesterol intake, an additional calculation was performed using a factor of 0.01 mmol/L (0.44 mg/dL) to account for the influence of each 1-mg/d difference of dietary cholesterol intake per 4184 kJ (1000 kcal) of energy, from the equation of Hegsted and colleagues.²² This resulted in predicted changes in LDL-C of -0.07 mmol/L (-2.9 mg/dL) vs -0.15 mmol/L (-5.7 mg/dL) for the LRM and LWM groups, respectively.²² Comparison of the mean actual vs predicted mean changes in LDL-C showed that they were nearly identical ($P > .95$). Therefore, these data support the view that differences between groups in the intake of nutritional components known to influence blood cholesterol levels were small and not clinically significant.

CONCLUSIONS

The results of this 36-week dietary intervention trial indicate that the serum lipid profile was similarly improved by implementation of an NCEP Step I diet when the primary sources of meat consumed were lean cuts of red meat (beef, veal, and pork) vs white meat (poultry and fish). Therefore, with instruction regarding meat selection and preparation, free-living persons can effectively incorporate LRMs into their diets on a long-term basis, without compromising the lipid-lowering benefits of the diet. Counseling patients to replace high-fat meats with leaner red and white meat selections allows a greater range of food choices, which may improve patient acceptance and long-term dietary adherence.

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