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## REDUCTION OF PLASMA CHOLESTEROL LEVELS IN NORMAL MEN ON AN AMERICAN HEART ASSOCIATION STEP 1 DIET OR A STEP 1 DIET WITH ADDED MONOUNSATURATED FAT

HENRY N. GINSBERG, M.D., SUSAN L. BARR, M.S., R.D., AME GILBERT, B.A.,  
WAHIDA KARMALLY, M.S., R.D., RICHARD DECKELBAUM, M.D., KAREN KAPLAN, M.D., PH.D.,  
RAJASEKHAR RAMAKRISHNAN, SC.D., STEVE HOLLERAN, B.A., AND RALPH B. DELL, M.D.

**Abstract** The design of diets to achieve optimal changes in plasma lipid levels is controversial. In a randomized, double-blind trial involving 36 healthy young men, we evaluated the effects on plasma lipid levels of both an American Heart Association Step 1 diet (in which 30 percent of the total calories were consumed as fat: 10 percent saturated, 10 percent monounsaturated, and 10 percent polyunsaturated fats, with 250 mg of cholesterol per day) and a monounsaturated fat-enriched Step 1 diet (with 38 percent of the calories consumed as fat: 10 percent saturated, 18 percent monounsaturated, and 10 percent polyunsaturated fats, with 250 mg of cholesterol per day). The effects of these diets were then compared with those of an average American diet, in which 38 percent of the total calories were consumed as fat: 18 percent saturated, 10 percent monounsaturated, and 10 percent polyunsaturated fats, with 500 mg of cholesterol per day. The men consumed the average American diet for 10 weeks before random assignment to one of the two Step 1

diets or to continuation of the average diet for an additional 10 weeks. Caloric intake was adjusted to maintain a constant body weight.

As compared with the mean ( $\pm$ SD) change in the plasma total cholesterol level in the group that followed the average American diet throughout the study ( $-0.05 \pm 0.36$  mmol per liter), there were statistically significant reductions ( $P < 0.025$ ) in the plasma total cholesterol level in the group on the Step 1 diet ( $-0.37 \pm 0.27$  mmol per liter) and in the group on the monounsaturated fat-enriched Step 1 diet ( $-0.46 \pm 0.36$  mmol per liter). There were parallel reductions in the plasma low-density lipoprotein cholesterol levels in these two groups. Neither the plasma triglyceride levels nor the high-density lipoprotein cholesterol concentrations changed significantly with any diet.

We conclude that enrichment of the Step 1 diet with monounsaturated fat does not alter the beneficial effects of the Step 1 diet on plasma lipid concentrations. (*N Engl J Med* 1990; 322:574-9.)

**A**LTHOUGH the relation between dietary intake of fatty acid and plasma cholesterol levels has been studied for more than 20 years,<sup>1-3</sup> the most effective dietary approach for reducing plasma concentrations of total cholesterol while achieving an optimal relation between plasma levels of low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol remains controversial.<sup>4,5</sup> There are limited data on the ability of diets similar in both fat and cholesterol content to the American Heart Association "Step 1" diet to reduce plasma levels of total and LDL cholesterol in healthy, noninstitutionalized persons who follow practical diets for long periods.<sup>6-8</sup> In addition, the relative efficacy of reducing the total fat in-

take by reducing only the intake of saturated fat as compared with replacing the saturated fat with monounsaturated fat or polyunsaturated fat is unclear.<sup>9-13</sup>

Recent studies by Grundy and his colleagues<sup>11,13,14</sup> and by Mensink and Katan and their colleagues<sup>12,15</sup> have suggested that the substitution of monounsaturated fats for saturated fats results in reductions in the plasma total and LDL cholesterol levels that are at least equivalent to the reductions attained by the simple removal of saturated fats. In addition, the consumption of the monounsaturated fat-enriched diets in those studies was not associated with decreases in plasma concentrations of HDL cholesterol, a frequent concomitant of diets with reduced content of total fat. Although these studies provided interesting results, formula diets containing very high absolute amounts of polyunsaturated fatty acids<sup>13</sup> or diets with marked reductions in total fat (with 20 to 25 percent of the total calories consumed as fat)<sup>11,12,14,15</sup> were used in the comparison with the monounsaturated fat-enriched diets. The rather extreme nature of these diets makes extrapolation of the results to practical dietary recom-

From the Departments of Medicine (H.N.G., S.L.B., A.G., K.K.) and Pediatrics (R.D., R.R., S.H., R.B.D.), and the Irving Center for Clinical Research (W.K.), Columbia University College of Physicians and Surgeons, New York. Address reprint requests to Dr. Ginsberg at the Department of Medicine (P&S 9-501), College of Physicians and Surgeons, Columbia University, 630 W. 168th St., New York, NY 10032.

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recommendations difficult.<sup>16,17</sup> In addition, some of the studies were carried out with hospitalized subjects whose diet and lifestyle were rigidly controlled, so that the effects of such diets on noninstitutionalized subjects were unclear.

We decided, therefore, to conduct a randomized, double-blind trial of the effects on plasma levels of lipids and lipoproteins in normal men of a diet similar to the 30 percent-fat Step 1 diet that has been recommended recently<sup>17</sup> and of a monounsaturated fat-enriched version of the Step 1 diet that contains 38 percent fat. The diets in our study consisted of ordinary foods prepared daily in a research kitchen. Our subjects were selected from among a free-living student population, and their lifestyles were unaltered during the course of the study.

## METHODS

### Subjects

Thirty-nine normal male medical and dental students 22 to 32 years of age were recruited from an initial population of 300 male students with nonfasting plasma levels of total cholesterol between the 30th and 80th percentiles. None of the men had serious medical problems or were taking any medications that might affect plasma lipid levels. Before the men were accepted into the study, five-day dietary records, including records of ethanol consumption, were obtained from the potential subjects by a registered dietitian. Men with extreme dietary habits before the study (such as a vegetarian diet, a very low fat intake, or multiple intolerances to food) were excluded because it was thought that they would not be able to follow the study diets. The nutrient composition of the recorded diets and the research diets was determined with Nutritionist III software (N-Squared Computing, Silverton, Oreg.), with a data base expanded to include data on fatty acid composition from Handbook 8 of the U.S. Department of Agriculture.<sup>18</sup> Patterns of physical activity were also ascertained from the history, and together with each man's height, weight, and dietary history, these patterns were used to estimate daily caloric requirements. Routine laboratory tests were performed at several points during the study to ensure normal health status.

### Protocol

The study design included a control period of 10 weeks during which all the men consumed an average American diet, in which 38 percent of the total calories were consumed as fat, with 18 percent saturated fatty acids, 10 percent monounsaturated fatty acids, and 10 percent polyunsaturated fatty acids. The average American diet also contained 500 mg of cholesterol per day. The control period began in early September 1987, shortly after the start of the academic year, and was completed just before the students' Christmas vacation. On their return from this 14-day vacation, the students continued to follow the average American diet for one week before beginning the randomized component of the study. After randomization, one third of the men (the control group) continued to follow the average American diet, one third switched to a Step 1 diet similar to that recommended by the American Heart Association and the Adult Treatment Panel of the National Cholesterol Education Program,<sup>17</sup> and one third switched to the "Mono" diet — a monounsaturated fatty acid-enriched modification of the Step 1 diet. In the Step 1 diet, 30 percent of the total calories were consumed as fat, with 10 percent each of saturated fatty acids, monounsaturated fatty acids, and polyunsaturated fatty acids. In the Mono diet, 38 percent of the total calories were consumed as fat, with 10 percent saturated fatty acids, 18 percent monounsaturated fatty acids, and 10 percent polyunsaturated fatty acids. Both the Step 1 and the Mono diets contained 250 mg of cholesterol per day. The randomized portion of the study lasted 10 weeks. The participants were urged to maintain their usual level of physical activity throughout the study.

Analyses of the men's plasma total cholesterol concentrations during the control period indicated a normal distribution of values; therefore, no stratification criteria were used in the randomization. Only the dietary staff engaged in meal preparation and a single statistician were aware of the group assignments.

Blood samples were obtained for the determination of plasma lipid and serum apolipoprotein concentrations 2, 4, 6, and 9 weeks after the start of the control period and 2, 4, 7, and 10 weeks after the start of the randomized diet period. All samples were obtained between 8 a.m. and 9 a.m., after a 12-hour overnight fast. The blood samples were drawn into tubes containing EDTA (1.0 mg per milliliter) for plasma, or into empty tubes for serum. The samples were placed immediately on ice and were centrifuged at 2000 rpm for 20 minutes at 4°C within one hour of sampling. The plasma samples were assayed for total cholesterol, triglyceride, and HDL cholesterol levels within 48 hours and then stored at 4°C after the addition of aprotinin (Trasylol, FBA Pharmaceuticals, New York) and azide. The serum samples were stored in multiple aliquots at -70°C until they were assayed for apolipoproteins B and A-I.

### Diets

The study diets consisted of foods prepared from fresh ingredients in accordance with computer-analyzed recipes and menu plans. The composition of each day's meals in terms of protein, carbohydrate, fat (including the ratios of polyunsaturated fatty acids to saturated fatty acids and polyunsaturated fatty acids to monounsaturated fatty acids) and cholesterol matched the research protocol for the particular diet. We used a two-week menu cycle and served a mixed diet consisting of red meat (beef), poultry, fish, dairy products, eggs, fruits, vegetables, and a variety of complex carbohydrates and desserts. The meals were designed so that the men were unaware of their own dietary group assignments. For example, a menu consisting of a poultry entrée with rice and vegetables was prepared with three types of marinades and condiments. Thus, each diet had a distinct fatty acid and carbohydrate composition (the protein composition was the same for the three diets). In addition, the subjects received packaged snacks with a nutrient composition that mirrored the research protocol for their particular diets. On the basis of estimated daily caloric requirements, the men were assigned to one of three different caloric groups and were weighed every other week. Caloric intake was adjusted as necessary to maintain body weight.

The study subjects were served lunches and dinners, Monday through Friday, in the student dining facility. Evening snacks and the next day's breakfasts were packaged and distributed at dinner. Except for one dinner, all weekend meals were packaged and distributed on Saturdays. We also advised the men about choices for their one self-selected weekend dinner, and they were instructed to keep a record of the meal they selected and of their weekend ethanol consumption, if any. The subjects received nutritional counseling if their weekend food or beverage choices were excessive. They also had daily contact with either the principal investigator or the supervising dietitian, which expedited the management of any problems with compliance.

Food samples from each of the three research diets were prepared for compositional analysis by homogenizing all the food from each week of the two-week menu cycle. Six composite samples, two for each research diet, were sent to Hazleton Laboratories America (Madison, Wis.) for an analysis of the protein, carbohydrate, total fat, and cholesterol content.<sup>19</sup> Analyses of fatty acids were performed on separate aliquots by Dr. M.A. Bieber at Best Foods (Union, N.J.), using capillary gas chromatography. The compositions of our research diets, as determined by analysis, were very close to those calculated (Table 1). In addition, the determination of the individual fatty acid content revealed the expected pattern of distribution for each diet (Table 2).

### Laboratory Analyses

Plasma concentrations of total cholesterol and triglycerides were measured by enzymatic methods with an ABA-100 automated spectrophotometer (Abbott Laboratories, North Chicago). HDL cholesterol was measured in the same manner after the precipitation of

Table 1. Composition of the Three Study Diets.\*

	AVERAGE AMERICAN DIET		STEP 1 DIET		MONO DIET	
	CALCULATED	ACTUAL	CALCULATED	ACTUAL	CALCULATED	ACTUAL
<b>Week 1 menu</b>						
Fat (%)	38	37.5	30	30.1	38	37.8
Saturated	18	16.5	10	8.9	10	9.1
Monounsaturated	10	11.5	10	10.7	18	18.0
Polyunsaturated	10	9.5	10	10.5	10	10.7
Carbohydrate (%)	47	45.3	55	52.5	47	46.4
Protein (%)	15	17.3	15	16.7	15	16.1
Cholesterol (mg/day)	500	358	250	319	250	215
<b>Week 2 menu</b>						
Fat (%)	38	36.8	30	31.5	38	37.3
Saturated	18	15.2	10	9.9	10	9.2
Monounsaturated	10	11.8	10	11.3	18	17.8
Polyunsaturated	10	9.8	10	10.3	10	10.3
Carbohydrate (%)	47	46.3	55	51.7	47	46.2
Protein (%)	15	17.3	15	16.6	15	16.2
Cholesterol (mg/day)	500	420	250	241	250	215

\*The Step 1 diet was similar to that recommended by the American Heart Association and the Adult Treatment Panel of the National Cholesterol Education Program. The Mono diet was a monounsaturated fatty acid-enriched version of the Step 1 diet. "Calculated" denotes the composition calculated on the basis of Nutritionist III software and U.S. Department of Agriculture Handbook 8.<sup>18</sup> "Actual" denotes the actual composition based on food analysis. The values shown are percentages of the total calories consumed daily, except those for cholesterol.

apolipoprotein B-containing lipoproteins with magnesium and phosphotungstate, with use of reagents supplied by Sigma (St. Louis).<sup>20</sup> LDL cholesterol levels were estimated by the Lipid Research Clinics method.<sup>21</sup> Our laboratory participates in the Lipid Research Clinics quality-control program administered by the Centers for Disease Control, Atlanta. The interassay coefficients of variation were less than 3 percent for the determinations of both cholesterol and triglycerides.

The concentrations of serum apolipoproteins B and A-I were measured by specific fluid-phase radioimmunoassays.<sup>22</sup> Our laboratory participates in the Apolipoprotein Standardization Program administered by the Centers for Disease Control.<sup>23</sup> All samples were assayed with single radioiodinated LDL and apolipoprotein A-I tracers for the serum apolipoprotein B and A-I determinations, respectively. All samples from the same subject were analyzed in the same assay for each apolipoprotein. The intraassay coefficients of variation were 10 percent and 8 percent for apolipoprotein B and apolipoprotein A-I, respectively.

### Statistical Analysis

For each subject, the mean values for lipid and apolipoprotein levels obtained at weeks 4, 6, and 9 of the control period and weeks 4, 7, and 10 of the randomized diet period were used to determine

the changes in concentration of each lipid or apolipoprotein. The means of the values at weeks 4, 6, and 9 of the control period were taken as the base-line values. For each variable, the changes in the three groups were analyzed by analysis of variance.<sup>24</sup> If there was a significant effect of diet at a P value of 0.05, two (two-tailed) comparisons were made, each at a P value of 0.025 — one between the Step 1 diet group and the control group, and the other between the Mono diet group and the control group. No comparison was attempted between the Step 1 diet group and the Mono diet group.

### RESULTS

The clinical characteristics of the men in each of the three diet groups, including their base-line lipid levels, are shown in Table 3. There were no significant differences in age or body-mass index among the three groups. The mean base-line plasma levels of total cholesterol and triglycerides were slightly but not significantly higher in the group randomly assigned to the Mono diet. Because of these base-line differences, an analysis of covariance was performed to determine whether the plasma lipid levels during the diet period were affected by the base-line values. This analysis did not demonstrate any relation between the base-line plasma cholesterol concentrations and the responses to diet, possibly because of the relatively narrow range of plasma cholesterol levels in our study population.

Thirty-six of the 39 men completed the study. One man left the study during the first week of the control period, when it became apparent that he was allergic to several foods in the diet. Two men were asked to leave the program at the start of the diet period because of poor dietary compliance. Compliance in the remaining men, as assessed by an inspection of the lunch and dinner trays and the weekend dietary records, was estimated to be between 85 and 90 percent. Body weight did not change by more than 3 percent throughout the study in any man.

Figure 1 shows the plasma total cholesterol levels in each group during the study as the mean percentage of change from base line at each sampling. Plasma cholesterol levels were stable during the control period. During the diet period, both the Step 1 diet group and the Mono diet group had decreases in plasma total cholesterol levels, as compared with the group that continued on the average American diet. There was an increase in the plasma concentration of total cholesterol in all three groups at week 7 of the diet period (week 17 of the total study period). This change was qualitatively similar in all three groups and occurred at the time of midterm examinations.

The reductions in plasma total cholesterol levels in both the Step 1 diet group (mean  $\pm$ SD,  $-0.37 \pm 0.27$  mmol per liter) and the Mono diet group ( $-0.46 \pm 0.36$  mmol per liter) were statistically significant as compared with the reduction in total cholesterol in the group that continued to follow the average American diet throughout the study ( $-0.05 \pm 0.36$  mmol per liter) (Fig. 2). These reductions were equal to 8.0 percent, 10.4 percent, and 1.1 percent of the values for the control period in the respective groups. Plasma concentrations of LDL cholesterol also fell significantly in the Mono diet group, and there was a nonsignificant

Table 2. Proportions of Major Fatty Acids in the Three Study Diets.

FATTY ACID*	AVERAGE AMERICAN DIET	STEP 1 DIET	MONO DIET
	percent of total fat		
12:0	9.1	2.1	2.0
14:0	5.9	2.9	2.1
16:0	15.9	15.5	12.8
16:1	1.1	1.0	1.0
18:0	7.2	7.6	5.7
18:1	29.5	33.6	45.8
18:2	24.1	31.5	26.3
18:3	1.6	2.3	1.7

\*Values are the ratios of the number of carbon atoms constituting the structural chain of the fatty acid molecule to the number of double bonds within the carbon chain.

Table 3. Characteristics of the Men in the Three Study Groups.\*

GROUP	AGE	BODY-MASS INDEX†	PLASMA LIPIDS‡			
			TOTAL CHOLESTEROL	TOTAL TRIGLYCERIDES	HDL CHOLESTEROL	LDL CHOLESTEROL
			millimoles per liter			
Average American diet (n = 12)	23.4±1.9	24.6±2.0	4.58±0.51	0.89±0.40	1.32±0.15	3.08±0.55
Step 1 (n = 12)	22.8±1.1	23.9±1.8	4.71±0.46	0.92±0.30	1.24±0.20	3.28±0.47
Mono (n = 12)	24.2±2.2	25.0±3.0	4.95±0.29	1.23±0.45	1.26±0.21	3.44±0.30

\*Plus-minus values are means ±SD.

†Measured before the start of the control period as the weight in kilograms divided by the height in meters squared.

‡Values shown are the means of the values at weeks 4, 6, and 9 of the control period. To convert values to milligrams per deciliter, multiply by 38.67.

trend toward a reduction in LDL cholesterol levels in the Step 1 diet group as well.

The plasma levels of HDL cholesterol did not change significantly in either the Step 1 or the Mono diet group as compared with the average-American-diet group (Fig. 2). The plasma triglyceride concentrations tended to fall in all three diet groups during the diet period, as compared with the control period, but there were no significant differences in the changes in either experimental group as compared with the control group.

The serum apolipoprotein B levels fell in both experimental groups during the diet period (16.7 percent and 21.9 percent in the Step 1 and the Mono diet groups, respectively), but these changes did not differ significantly from the decrease in the average-American-diet group (14.7 percent). The serum apolipoprotein A-I concentrations did not change significantly in any of the groups (Table 4).

## DISCUSSION

Reducing plasma levels of total and LDL cholesterol by dietary modification was a central theme of the recently published report of the Adult Treatment Panel of the National Cholesterol Education Program.<sup>17</sup> Although large reductions in dietary fats are clearly associated with reduced plasma cholesterol levels, there is still controversy about the effects of individual fatty acids. This controversy focuses on the degree of reduction of total saturated fatty acids needed, the optimal level of polyunsaturates, and the role of monounsaturates. Both Keys et al.<sup>2</sup> and Hegsted et al.<sup>3</sup> concluded that monounsaturated fatty acids appeared to be neutral components of the diet in regard to plasma cholesterol levels, whereas polyunsaturated fatty acids seemed to lower plasma cholesterol levels. Some recent studies have suggested, however, that diets high in monounsaturated fatty acids actually lower plasma concentrations of total and LDL cholesterol,<sup>11,13</sup> whereas polyunsaturated fatty acids, in addition to their LDL-lowering activity, reduce plasma concentrations of HDL cholesterol.<sup>8,9,13</sup>

In this randomized, controlled trial, we found that reductions in dietary consumption of saturated fat consistent with the recommended Step 1 diet<sup>17</sup> significantly reduced the plasma concentration of total cho-

lesterol in a group of normal, free-living men. The reduction in the plasma total cholesterol level was less than might have been expected on the basis of the regression equations of Keys et al.<sup>2</sup> and Hegsted et al.<sup>3</sup> This difference may be due to the fact that although we estimated compliance to be 85 to 90 percent, we could not achieve the 100 percent compliance attainable in studies of hospitalized subjects.<sup>2,3</sup> It is noteworthy that all three groups had increases in plasma total cholesterol levels coincident with mid-

term examinations (Fig. 1, week 18); whether these increases were associated with reduced compliance or with effects of stress is not clear. Although studies of diet in free-living populations are difficult, studies that are used as a basis for public health recommendations must be conducted with free-living subjects.

Lewis et al.<sup>6</sup> achieved a much larger reduction in the plasma total cholesterol level. The nearly perfect compliance by the monks in that study and their rigid lifestyle, along with the lower ratio of polyunsaturated to saturated fats in their "Western" diet as compared with our average American diet, may account for this difference from our results. A lower ratio of polyunsaturated to saturated fats was used in the control diet in the studies by Weisweiler et al.<sup>7</sup> and Grundy et al.,<sup>8</sup> in which the subjects had larger reductions in the total cholesterol level than we observed in our subjects. The importance of the base-line ratio was also evident in the study by Denke and Breslow,<sup>25</sup> in which a slightly larger decrease in total cholesterol was achieved during a three-week period of consumption of a diet like

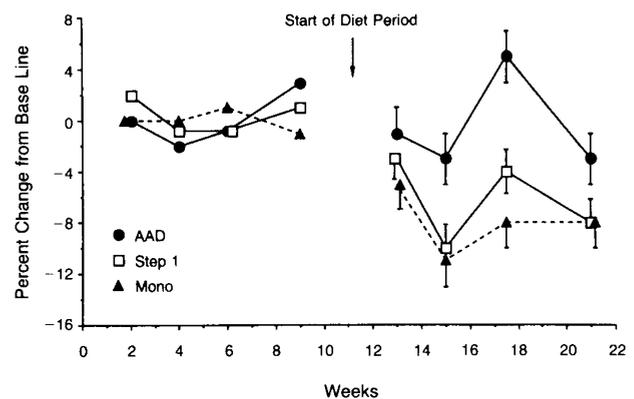


Figure 1. Effects of Diet on Plasma Total Cholesterol Concentration in the Three Study Groups.

The values plotted are the mean ( $\pm$ SE) percent differences of the plasma levels of total cholesterol from the respective averages for weeks 4, 6, and 9 of the control period. The three groups had stable plasma levels of total cholesterol during the 10-week control period. After the start of the randomized diet period, the levels decreased in the Step 1 and Mono groups, but not in the average-American-diet (AAD) group. The differences between the AAD group and both the Step 1 and Mono groups were maintained during the last six weeks of the study.

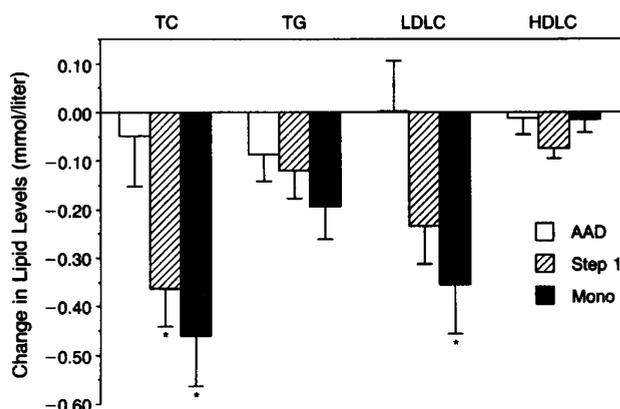


Figure 2. Mean Changes in Plasma Lipid Concentrations in the Three Study Groups.

Each bar represents the mean ( $\pm$ SE) difference between the mean of the values obtained at weeks 4, 7, and 10 of the diet period and the mean of the values obtained at weeks 4, 6, and 9 of the control period. Asterisks indicate significant differences ( $P < 0.025$ ) between the changes in the average-American-diet (AAD) and Step 1 groups, and between those in the AAD and Mono groups. TC denotes total cholesterol, TG triglycerides, LDLC low-density lipoprotein cholesterol, and HDLC high-density lipoprotein cholesterol.

that of the American Heart Association. Overall, our results support the view that dietary modifications consistent with the recommendations of the Adult Treatment Panel of the National Cholesterol Education Program<sup>17</sup> and the American Heart Association<sup>16</sup> should reduce plasma levels of total and LDL cholesterol in healthy subjects.

We also found that the consumption of a diet to which monounsaturated fatty acids were added, in a quantity equal to the amount of saturated fatty acids removed from that diet, resulted in significant reductions in plasma total cholesterol levels. The addition of monounsaturates did not add substantially to the cholesterol-lowering effect of the Step 1 diet. Our study, however, was not designed to have the statistical power needed to attempt direct comparisons between the effects of the Step 1 diet and those of the Mono diet, and future studies with larger groups of subjects will be required to address this issue. Our results are in accord with the original studies of Keys et al.<sup>2</sup> and Hegsted et al.,<sup>3</sup> in which monounsaturated

fatty acids had no independent effect on plasma cholesterol levels. Hence, we believe it reasonable to conclude that the decrease in the plasma total cholesterol level in our subjects during consumption of the Mono diet occurred in response to the removal of saturated fatty acids. This conclusion is consistent with the results of the studies in which monounsaturated fatty acids replaced saturated fatty acids,<sup>11-13</sup> and with the recent study of Mensink and Katan.<sup>26</sup> In that study, a diet very similar to our Mono diet was as effective as a diet enriched with polyunsaturated fatty acids in lowering plasma total and LDL cholesterol levels when compared with a diet similar to our average American diet.

The results of this study also suggest that within the guidelines of the Step 1 diet, the reduction of levels of total and saturated fats is not necessarily associated with biologically important reductions in the plasma HDL cholesterol concentrations. The small number of men participating in these studies, however, makes any definitive conclusions about small changes in HDL cholesterol levels tenuous. The trend toward lower HDL cholesterol levels in the Step 1 group suggests that further studies with more subjects may show a small but statistically significant decrease in the plasma concentration of HDL cholesterol.

The lack of effect of the Step 1 diet on plasma concentrations of HDL cholesterol would not necessarily contradict several recent studies in which HDL cholesterol levels fell during the consumption of diets low in fat or high in polyunsaturated fat. In those studies, the subjects consumed very low levels of total dietary fat<sup>9,11,12,14,15,27</sup> or very high absolute amounts of polyunsaturated fatty acids.<sup>8,9,13,27-29</sup> The extreme reductions in dietary cholesterol levels in some of those studies<sup>11,13,28,29</sup> may also have affected the plasma HDL cholesterol levels.

In the studies of diets with very low total fat content, the reductions in plasma concentrations of HDL cholesterol were consistent with the effects of diets very high in carbohydrates. Although the mechanisms underlying the induction of hypertriglyceridemia by carbohydrates have not been completely defined, it is clear that the consumption for several weeks of diets high in simple carbohydrates is associated with increased levels of both hepatic secretion of very-low-density lipoprotein triglyceride<sup>30,31</sup> and fractional catabolism of plasma HDL apolipoprotein A-I.<sup>32</sup> In the absence of any change in the production of HDL apolipoprotein A-I, the latter change will result in lower plasma concentrations of HDL cholesterol. In studies in which large absolute quantities of polyunsaturates were consumed, the reductions in plasma HDL cholesterol were consistent with the reported ability of diets very high in polyunsaturates to decrease the production of HDL apolipoprotein A-I.<sup>33</sup>

Because the plasma total cholesterol concentration appeared to fall slightly more in the Mono group than in the Step 1 group, whereas the HDL cholesterol level tended to fall more in the Step 1 group, we compared the effects of these two diets on the ratio of total

Table 4. Serum Apolipoprotein Levels in the Three Study Groups during the Control and Diet Periods.\*

GROUP	APOLIPOPROTEIN B		APOLIPOPROTEIN A-I	
	CONTROL PERIOD	DIET PERIOD	CONTROL PERIOD	DIET PERIOD
<i>grams per liter</i>				
Average American diet (n = 12)	0.68 $\pm$ 0.15	0.58 $\pm$ 0.12	1.00 $\pm$ 0.09	1.01 $\pm$ 0.10
Step 1 (n = 12)	0.66 $\pm$ 0.13	0.55 $\pm$ 0.11	0.99 $\pm$ 0.12	0.99 $\pm$ 0.13
Mono (n = 12)	0.73 $\pm$ 0.14	0.57 $\pm$ 0.10	1.00 $\pm$ 0.10	1.00 $\pm$ 0.13

\*Plus-minus values are means  $\pm$ SD. The changes in levels of apolipoprotein B and apolipoprotein A-I in the Step 1 and Mono groups during the diet period did not differ significantly from those in the average-American-diet group during that period.

cholesterol to HDL cholesterol with that of the average American diet. This ratio fell by a mean ( $\pm$ SD) of  $0.43 \pm 0.40$  in the Mono group and  $0.10 \pm 0.27$  in the Step 1 group. The reduction in the ratio in the Mono group was statistically significant as compared with the change in the average-American-diet group ( $-0.03 \pm 0.27$ ;  $P < 0.01$ ). The reduction in the Step 1 diet group was not different from that in the average-American-diet group. Because there are no epidemiologic data based on the changes in this ratio after dietary modification, and because this was a post hoc analysis, we are uncertain of the meaning of these findings.

In conclusion, the consumption of a diet consistent with Step 1 guidelines recommended by both the American Heart Association and the Adult Treatment Panel of the National Cholesterol Education Program<sup>17</sup> can significantly reduce the plasma total cholesterol level in healthy young men. The addition of substantial quantities of monounsaturated fatty acids to the Step 1 diet did not appear to affect the ability of the diet to reduce the plasma total cholesterol level in this population. This finding, together with previous reports indicating the neutrality of monounsaturates relative to the plasma cholesterol concentration, suggests that the diversification of menus by the addition of foods that are sources of monounsaturated fatty acids may be possible for nonobese persons who are attempting to lower their plasma cholesterol levels. Of course, appropriate correction must be made for the difference in caloric density between fats and carbohydrates if weight maintenance or weight loss is desired. Finally, in this group of healthy men, neither the Step 1 diet nor the Mono diet altered the plasma concentrations of HDL cholesterol or triglycerides significantly.

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