Plasma Lipid Response and Nutritional Adequacy in Hypercholesterolemic Subjects on the American Heart Association Step-One Diet

Chul-Young Bae, MD, MS, MPH; Joseph M. Keenan, MD; Patricia Fontaine, MD; Joyce Wenz, RD, MS; Cynthia M. Ripsin, MS, MPH; David J. McCaffrey

Objectives: To determine the efficacy of the American Heart Association Step-One Diet for lowering blood lipid levels and to assess its nutritional adequacy in younger (<50 years old) and older (≥50 years old) subgroups.

Study Design: A prospective cohort study; 383 subjects were instructed in the American Heart Association Step-One Diet. Adherence to the diet was assessed at 6 weeks. Eighty-seven subjects continued the diet for an additional 12 weeks.

Setting: General community participants: volunteers from community cholesterol screening programs and chart reviews at family practice clinics.

Study Participants: Men and women, aged 20 to 70 years, with baseline low-density lipoprotein cholesterol levels between the 50th and 95th percentile, and excluded if receiving any medications that affect blood lipid levels or if there was a history of diabetes, gout, peptic ulcer, or liver disease.

Intervention: Instruction by a registered dietitian and adherence to the American Heart Association Step-One Diet for 6 (n=383) and 18 weeks (n=87). This diet involves an intake of total fat not to exceed 30% of calories, saturated fatty acids not to exceed 10% of calories, and dietary cholesterol limited to 300 mg/d.

Results: Subjects aged 50 to 70 years averaged a reduction in total cholesterol level and low-density lipoprotein cholesterol level of 4% after 6 weeks. At the end of 18 weeks, mean total cholesterol and low-density lipoprotein cholesterol levels in subjects younger than 50 years exceeded their baseline levels, and in those older than 50 years returned to baseline lipid levels. Inadequate intake of several micronutrients were reported, notably, zinc, calcium, and vitamins A, D, and E.

Conclusions: When recommending the American Heart Association Step-One Diet to persons with hyperlipidemia, baseline dietary behavior should be assessed to determine whether that diet offers therapeutic advantage over the person's self-selected diet. Follow-up should include monitoring of lipid response and nutritional adequacy. Special emphasis should be placed on selection of foods with appropriate micronutrient content.

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Throughout the second half of this century, heart disease has been the leading cause of death in the United States. An elevated serum cholesterol level is one of the principal modifiable factors contributing to coronary heart disease (CHD). The association of serum cholesterol level with the incidence of CHD is well understood: low-density lipoprotein cholesterol (LDL-C) levels are the main contributor to this relationship and high-density lipoprotein cholesterol (HDL-C) levels are inversely related to the incidence of CHD.

Data from clinical trials of middle-aged adult men demonstrate that the relationship between serum cholesterol level and CHD death rate is continuous, graded, and strong and that each 1% reduction in serum cholesterol levels is associated with a 2% decrease in CHD rates.

Early studies of serum cholesterol levels and CHD mortality in older persons failed to identify an association between the two. More recent studies, however, includ-

See Subjects and Methods on next page
Subjects and Methods

Subjects

Approximately 12,000 individuals were initially contacted to take part in trials of lipid-lowering interventions (oat bran, nicotinic acid). They were identified from persons who underwent a recent cholesterol screening at the University of Minnesota, Minneapolis, family practice clinics (approximately 4000) or who responded to a public invitation issued at community-based health fairs (approximately 8000). Individuals were invited by letter to be further screened if they were between 20 and 70 years of age and had previously recorded total cholesterol (TOTAL-C) values between the 50th and 95th percentile for age and sex, as outlined by the Lipid Research Clinics. Exclusion criteria included a history of diabetes, drug or alcohol abuse, use of any medication known to affect blood lipid levels, previous surgical treatment to lower blood lipid levels, weight more than 20% above or below the norm for height and sex, and pregnancy.

Subjects were further evaluated using two additional complete fasting lipid profiles that included TOTAL-C, LDL-C, HDL-C, and triglycerides. Those whose LDL-C values were between the 50th and 95th percentile for age and sex and triglyceride values below 400 mg/dL based on the mean of the baseline measurements were invited to participate in the study. The resulting sample (n=416) was grouped for this analysis into younger (20 to 49 years, n=204) and older (50 to 70 years, n=212) subgroups.

The report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults provided the rationale for dietary change to lower blood lipid levels, outlined the vehicle for that change (ie, the American Heart Association [AHA] Step-One and Step-Two Diets), recommended treatment goals, and suggested ways of monitoring behavioral change. Diet therapy is now considered a key component in treating hypercholesterolemia for adult men and women, including elderly patients, in spite of the fact that most dietary intervention studies involving qualitative and quantitative modification of fat intake have been conducted in middle-aged men.

The issue of adequate nutrition by diet modification in older persons is an important one. When considering dietary therapy for such patients with hypercholesterolemia, the value of diet modification for improvement in blood cholesterol levels must be balanced against the possibility of inadequate nutrition, which is often a problem in older persons.

This study, while not exclusively targeted at older subjects, compared younger (20 to 49 years) and older (50 to 70 years) free-living hypercholesterolemic men and women in their response to the AHA Step-One Diet. Specifically, subjects' improvement in serum lipid levels, dietary adherence, and nutritional adequacy were assessed.

Subjects gave written informed consent for this study, which was approved by the Committee for the Use of Human Subjects in Research of the University of Minnesota.

study design

Diet instruction and follow-up were planned to be comparable to that offered in a typical clinical setting. Subjects attended a 2-hour nutrition education session on the AHA Step-One Diet taught by a registered dietitian (J.W.).

Throughout the study, the dietitian was available by telephone to answer diet-related questions. To encourage compliance, recipes were included in one mailing to all subjects during each 6-week treatment period, and the dietitian called each subject to review his or her diet during the third or fourth week of each 6-week period.

The recommended eating pattern for the AHA diet provided guidelines for isoenergetic reduction in intake of total fat not to exceed 30% of total energy, saturated fatty acids limited to 10% of total energy, and dietary cholesterol limited to 300 mg/d. Subjects were instructed in the maintenance of food records and asked to try to maintain present physical activity and body weight throughout the study period, although a slight weight loss was expected due to anticipated reduction of fat intake.

Of the 416 subjects entered in this study, 383 continued the AHA diet for 6 weeks. Of these, 260 were then randomly placed in cohorts to test other lipid-lowering interventions and...
120 were randomized to continue the AHA diet for an additional 12 weeks.

MEASUREMENTS

All fasting blood samples for lipid measurements were obtained using a standardized protocol for phlebotomy technique and specimen handling. Lipid measurements were performed in duplicate on plasma samples at the University of Minnesota Lipid Research Laboratory, a facility certified by the Centers for Disease Control and Prevention. Total cholesterol and triglyceride levels were determined by enzymatic methods using a Roche COBAS analyzer (Roche Diagnostics Systems, Nutley, NJ). The HDL-C levels were measured in the supernatant after plasma was precipitated with heparin-manganese. The LDL-C levels were calculated as described by Friedewald et al.\(^22\) Lipid values were obtained by averaging the results of fasting morning samples drawn on three consecutive days. Baseline dietary intake was measured by a semiquantitative food-frequency questionnaire that has been validated by comparison with yearlong diet records.\(^23\) Four-day food records that included one weekend day were collected every 6 weeks to assess dietary adherence and nutritional adequacy. Food records were coded by nutritionists trained in the method of the Nutrition Coordinating Center, University of Minnesota, and analyzed by the University of Minnesota Nutrient Data System Version 1.3. Body weight was measured in indoor clothing without shoes at baseline and at 6-week intervals for the duration of the study.

DIETARY ADHERENCE

Table 3 shows the mean baseline values of daily nutrient intake as assessed by the baseline semiquantitative food-frequency questionnaire. There were no significant differences between the younger and older age groups on any of the baseline dietary variables. Of note, both age groups reported relatively low baseline intake of total fat and dietary cholesterol. As assessed by the 4-day food records, both age groups reported continued good adherence to the AHA diet without significant differences between them except for monounsaturated fatty acid intake at the sixth week. During the 18-week study period, the older age group had a greater loss of body weight than did the younger age group (P<.05).

BLOOD LIPID RESPONSE

Baseline characteristics and blood lipid levels for the initial 6-week diet group are presented in Table 1. The mean baseline levels of TOTAL-C (P<.01), LDL-C (P<.01), and HDL-C (P<.05) in the older age group were significantly higher than those in the younger age group. The younger subjects were taller than the older subjects (P<.05), but there was no significant difference in baseline body weight. For the group that was observed for 6 weeks, there were modest reductions in TOTAL-C and LDL-C levels. When the subset of subjects who continued to the end of week 18 were considered separately (Table 2), only the older subjects demonstrated a beneficial response to the AHA diet after 6 weeks. At the end of week 18, older subjects' TOTAL-C and LDL-C levels had drifted back toward baseline, and younger subjects actually finished the 18 weeks with TOTAL-C and LDL-C levels that exceeded their baseline values.

STATISTICAL ANALYSES

For dietary and lipid variables, two-sample, two-tailed \(t\) tests were used to assess significant differences between younger and older age groups. Variables for TOTAL-C, LDL-C, HDL-C, and triglyceride levels were calculated as the percentage of change from baseline. To evaluate nutritional adequacy of the AHA diet, two thirds of the recommended dietary allowance (RDA) was used as a reference standard for each nutrient.\(^24\) \(\chi^2\) Analysis or Fisher's Exact Test was performed to compare the proportion of subjects reporting nutrient intake less than two thirds of the RDA according to the dichotomized age variable. A cutoff level of \(P<.05\) (two-tailed) was chosen for each statistical test to assess significance.

Underreporting frequently occurs when written food records are used as a measure of dietary intake.\(^25\) Therefore, reported micronutrient values were corrected by making the following assumptions: subjects maintained usual activity levels as instructed, underreporting was constant across food groups (ie, subjects were as likely to underreport carbohydrates as fats), and all body weight was lost as fat. Recorded change in body weight was then compared with reported change in energy intake, and the discrepancy between actual weight loss and the weight loss expected by the change in energy intake was taken as the measure of underreporting. The percentage of energy intake underreported was then used to correct reports of individual micronutrient intake.

NUTRITIONAL ADEQUACY

Tables 4 and 5 show the mean values (after correction for underreporting of nutrients) for selected micronutrients. There were no significant differences in the mean values between older and younger subjects for the group that was observed for 6 weeks or for those that were observed for 18 weeks. The mean value for each nutrient was at or above the RDA with the following exceptions: for the group that was observed for 6 weeks, zinc in men of both age groups (the RDA for zinc is 15 mg for males) was lower than the RDA value;\(^24\) for the group that was observed for 18 weeks, zinc in younger men and in men and women aged 50 years or older (the RDA for zinc is 12 mg for wom-
Values are reported as mean±SD at baseline except where noted. TOTAL-C indicates total cholesterol; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; and ellipses, values do not change with time.

COMMENT

SERUM LIPID RESPONSE AND DIETARY ADHERENCE

In their review of 16 controlled trials of dietary interventions for the purpose of lowering blood cholesterol levels,
Values are reported as mean±SD except where noted.
†No significant difference in baseline values between younger vs older subjects.
§Significant difference (P<.05) between younger vs older subjects for the 18-week group.
¶Significant difference (P<.05) between younger vs older subjects for the 6-week group.

five of which used diets resembling the AHA Step-One Diet, Ramsay et al\(^\text{10}\) concluded that the benefits achieved by intervention with the AHA Step-One Diet parameters were minimal and suggested a review of dietary guidelines to address their findings. In our study, the initial reductions in the levels of TOTAL-C and LDL-C at 6 weeks for the larger group of subjects were modest but encouraging. By week 18, however, reductions in the levels of TOTAL-C and LDL-C initially achieved were no longer evident. This was in spite of apparently good dietary adherence reported by both older and younger subjects; the reported intake of fat as a percentage of energy intake was close to that recommended by the AHA diet, and the cholesterol intake was well below AHA guidelines.

A reasonable explanation for the modest lipid response to the AHA diet—and an important limitation to the dietary intervention of this study—is that subjects at baseline were already on a relatively prudent diet. These subjects had been recruited in large part from cholesterol screening programs. Since subjects were selected because their cholesterol levels made them potential candidates for further treatment, they may, in fact, represent a somewhat diet-resistant group of hyperlipidemics. Alternatively, since they were previously aware of their hypercholesterolemia, they had likely initiated some appropriate dietary changes before the study. Thus, the initiation of the AHA Step-One Diet did not produce much additional change in lipid levels. Although prestudy dietary behavior was assessed at baseline, subjects were not included or excluded on the basis of diet but rather on the basis of

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**Table 3. Baseline Values and Mean Changes From Baseline in Daily Nutrient Intake of Younger (<50 y) and Older (≥50 y) Subjects**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline†</th>
<th>Baseline to End of Week 6</th>
<th>Baseline to End of Week 18</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;50 y</td>
<td>≥50 y</td>
<td>&lt;50 y</td>
</tr>
<tr>
<td>Total kilojoules per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>9215±3650</td>
<td>8702±2873</td>
<td>1432</td>
</tr>
<tr>
<td>18-wk group</td>
<td>8316±2171</td>
<td>8274±2898</td>
<td>353</td>
</tr>
<tr>
<td>Body weight, kg†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>78.3±15.0</td>
<td>76.5±12.6</td>
<td>−0.4</td>
</tr>
<tr>
<td>18-wk group</td>
<td>77.4±17.0</td>
<td>74.2±12.6</td>
<td>−0.4</td>
</tr>
<tr>
<td>% Kilojoules of total fat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>32.4±6.1</td>
<td>32.6±6.2</td>
<td>−2.3</td>
</tr>
<tr>
<td>18-wk group</td>
<td>31.4±6.2</td>
<td>32.1±6.0</td>
<td>−1.2</td>
</tr>
<tr>
<td>% Kilojoules of saturated fat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>11.3±2.6</td>
<td>10.8±2.6</td>
<td>−1.6</td>
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<tr>
<td>18-wk group</td>
<td>11.0±2.5</td>
<td>10.4±2.2</td>
<td>−1.3</td>
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<tr>
<td>% Kilojoules of polyunsaturated fat</td>
<td>6.8±1.8</td>
<td>6.8±1.8</td>
<td>+0.1</td>
</tr>
<tr>
<td>18-wk group</td>
<td>6.3±1.5</td>
<td>7.1±1.6</td>
<td>+0.4</td>
</tr>
<tr>
<td>% Kilojoules of monounsaturated fat§</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>11.6±2.5</td>
<td>12.0±2.6</td>
<td>−0.3</td>
</tr>
<tr>
<td>18-wk group</td>
<td>11.4±2.7</td>
<td>11.7±2.7</td>
<td>+0.1</td>
</tr>
<tr>
<td>% Kilojoules of carbohydrates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>49.1±7.5</td>
<td>49.1±7.7</td>
<td>+2.6</td>
</tr>
<tr>
<td>18-wk group</td>
<td>49.9±7.0</td>
<td>50.4±6.9</td>
<td>+1.7</td>
</tr>
<tr>
<td>% Kilojoules of protein</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6-wk group</td>
<td>16.8±2.8</td>
<td>16.7±2.8</td>
<td>+0.5</td>
</tr>
<tr>
<td>18-wk group</td>
<td>17.0±2.8</td>
<td>16.8±2.7</td>
<td>+0.6</td>
</tr>
<tr>
<td>Cholesterol, mg/d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>274±154</td>
<td>256±118</td>
<td>−75</td>
</tr>
<tr>
<td>18-wk group</td>
<td>243±98</td>
<td>229±96</td>
<td>−41</td>
</tr>
<tr>
<td>Water-soluble fiber, g/d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-wk group</td>
<td>6.5±3.3</td>
<td>6.4±2.5</td>
<td>+0.1</td>
</tr>
<tr>
<td>18-wk group</td>
<td>5.7±2.2</td>
<td>6.0±2.2</td>
<td>+0.9</td>
</tr>
</tbody>
</table>

*Values are reported as mean±SD except where noted.
†No significant difference in baseline values between younger vs older subjects.
§Significant difference (P<.05) between younger vs older subjects for the 18-week group.
¶Significant difference (P<.05) between younger vs older subjects for the 6-week group.
their blood cholesterol levels. It was our expectation that even if subjects reported appropriate prestudy dietary behavior, formal instruction by a dietitian in the AHA Step-One Diet would have added positive results. Individuals had improvements in blood lipid levels, especially those with higher prestudy dietary fat intake and higher baseline cholesterol levels. However, consistent with the assessment of their prestudy eating behavior, the groups’ overall lipid improvements were modest at 6 weeks and even less impressive for the 18-week group.

With cholesterol level testing widely available to the lay public in drugstores and shopping malls and with books on heart-healthy life-styles showing up on the nation’s best-seller lists, physicians should suspect that their patients with hyperlipidemia may have already made many of the dietary modifications recommended in the AHA diet. It would appear advisable in the clinical setting, before ordering dietary instruction in the AHA diet, to perform a brief baseline dietary assessment. The advantages and disadvantages of several methods of dietary assessment in the clinical setting have been discussed.26 If the patient is already close to the AHA Step-One Diet recommendations, proceeding to instruction in the Step-Two program could avoid the discouragement of apparent dietary failure and the tendency to resort to drug therapy before an adequate trial of diet can take effect.

Older persons demonstrated a somewhat better reduction in the levels of TOTAL-C and LDL-C than did younger subjects. This may have been due, in part, to better dietary compliance, since it appeared that the older subjects were less likely to underreport energy intake even though there was no significant difference in compliance as measured by food records. Older persons also had higher baseline levels of TOTAL-C and LDL-C; thus, they would be expected to experience a greater reduction of their cholesterol levels.

**NUTRITIONAL ADEQUACY**

Although mean values of reported (and corrected) micronutrient intake were largely in line with RDA values, the finding that a relatively high proportion of subjects reported an intake less than two thirds of the RDA for several micronutrients is disturbing. Bianchetti et al27 assessed the nutritional adequacy of 1201 elderly men and women who lived at home and found that at least 30% reported deficient intake in vitamins A, C, and B12, niacin, calcium, and iron, and greater than 90% reported dietary deficiencies in vitamin B6 and thiamin. Compared with these figures, older subjects in our study demonstrated better nutritional adequacy. However, subjects in the study by Bianchetti et al were following a self-selected diet, whereas our subjects had been instructed in a diet assumed to be providing adequate nutritional balance.

Patients with hyperlipidemia as a cardiovascular risk factor are advised to adopt the AHA diet as a lifelong eating pattern, and, according to National Cholesterol Ed-

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**Table 4. Characteristics of Selected Nutrients and Percentage of Subjects Reporting Micronutrient Intake Less Than Two Thirds of the Recommended Dietary Allowance (RDA) After 6 Weeks on the American Heart Association Step-One Diet**

*Values are reported as mean ± SD except where noted, and are corrected for underreporting.
†Statistically significant difference (P < .05) in percentage of younger vs older subjects reporting inadequate intake.

![Table](https://www.archfammed.com)
ucation Program guidelines, up to 60 million Americans are candidates for this dietary intervention. Unquestionably, the AHA diet has adequate food choice options for a healthy and well-balanced diet. The dietician in our study emphasized the importance of balance in the diet, as well as modification of fat and cholesterol intake. Yet, it appears from the records of eating behavior that subjects tended to simplify their approach to dieting by largely eliminating red meats, eggs, and dairy products. Thus, the deficiencies observed in their diets were the micronutrients found primarily in those eliminated food sources. Red meats and dairy products, especially cheese, are important sources of zinc,28 the micronutrient found to be most insufficient in the diets of our subjects. A greater variety of foods in the diet is associated with a higher intake of micronutrients.29 Since elderly people are already at risk of dietary insufficiency in many micronutrients, especially calcium, zinc, potassium, vitamin B6, magnesium, and folate,29 recommending a diet where the tendency is to eliminate foods to stay within the diet parameters may further increase the risk of micronutrient insufficiency.

It is apparent from these data not only that nutritional balance must be stressed by dietitians and physicians but also that assessment of the diet after initiation—perhaps at the time of the blood lipid recheck—must be part of management and follow-up. Patients may need to be specifically reminded to include low or nonfat dairy products and occasional lean, red meat selections in their eating plan.

The results of this study are completely generalizable only to clinic patients who resemble the study subjects: essentially healthy, mildly hypercholesterolemic persons who have the resources and have demonstrated the intent and motivation to make the necessary dietary changes. An important limitation in terms of generalizing these results to the elderly is that the older subjects in this study did not represent a truly elderly population: only 20% of the older group were 65 years old or older. Our older study group might be better characterized as old middle aged and young elderly. However, as cited by Munro,30 both the National Health and Nutrition Examination Survey II and the Baltimore Longitudinal Study on Aging demonstrated a linear and inverse relationship between caloric intake and age, and at least one trial of elderly women living alone has shown that reductions in nutrient and caloric intake accelerate between the ages of 70 and 80 years. This strongly suggests that a group of "true" elderly (ie, at least age 65 years) persons would demonstrate even greater dietary deficiencies than those reported by our subjects.

An important question that this study raises but does not answer is whether the micronutrient inadequacies described were created by the implementation of the AHA diet or simply maintained by the diet. We used a food-frequency questionnaire at baseline that has been validated for quantification of fewer than half the micronutrients chosen for analysis in this study.23 Thus, an analysis of the micronutrients for the baseline diet of these subjects would not yield a valid conclusion.
The AHA Step-One Diet is recommended to millions of persons as part of a lifelong approach to modify cardiovascular risk. Findings from this study suggest that physicians should assess baseline dietary behavior of patients before recommending dietary instruction. Such an approach can avoid apparent diet failure in those persons who have already initiated a relatively prudent diet on their own and can appropriately direct the dietitian to recommend the more advanced Step-Two Diet, if indicated. For individuals similar to those in this study, older persons do as well as, if not better than, younger ones in serum lipid level improvement on the AHA diet, but both groups appear to demonstrate similar dietary deficiencies as a result of unbalanced food choices. The specific micronutrients lacking in their reported diets could place persons—particularly those who are older—at increased risk for immune dysfunction and osteoporosis. Follow-up is recommended to monitor not only lipid response but also nutritional balance and adequacy.

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Reprint requests to the Department of Family Practice and Community Health, University of Minnesota Medical School, 825 Washington Ave SE, Box 25, Minneapolis, MN 55414-3034 (Dr Keenan).

REFERENCES


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