Lack of an Effect of Dietary Saturated Fat and Cholesterol on Blood Pressure in Normotensives

FRANK M. SACKS, M.D., GARY E. MARAIS, M.B.CH.B., GAIL HANDYSIDES, R.N., M.S., JORGE SALAZAR, LYNN MILLER, PH.D., JOHN M. FOSTER, PH.D., BERNARD ROSNER, PH.D., and EDWARD H. KASS, M.D., PH.D.

SUMMARY The effect on blood pressure (BP) levels of modifying the saturated fat and cholesterol content in the diet was studied in two separate protocols in normotensive volunteers. For 3 months, 19 men and women, aged 14 to 54 years, adhered to a diet that eliminated meat, poultry, eggs, and dairy fat from the subjects' customary nonvegetarian diet, which had included 71 g/day (35%) of dietary fat. The experimental diet reduced the consumption of saturated fat from 21 to 10 g, dietary cholesterol was lowered from 398 to 69 mg per day, but consumption of polyunsaturated fatty acids, carbohydrates, and dietary fiber was unchanged. Body weight and urinary sodium and potassium excretion were not significantly altered. Mean BP before and after the low fat diet was 116/74 and 115/74 mm Hg, respectively. A second double-blind study tested the effect on BP of dietary cholesterol at levels of 155 and 471 mg/day. Seventeen semivegetarian college students consumed one egg per day concealed in desserts for 3 weeks, and identical desserts containing no eggs for an additional 3 weeks. Mean BP at the end of the egg and eggless periods was 108/69 and 107/69 mm Hg, respectively. Thus, in short-term nutritional studies, dietary saturated fat and cholesterol at low-to-moderate levels of intake have no significant effects on BP in normotensive adults. (Hypertension 6: 193-198, 1984)

KEY WORDS • blood pressure • dietary fats • cholesterol • dietary cholesterol

The low BP levels present in many societies that consume small quantities of animal products and the relatively high BP levels found in industrialized societies where animal foods are prevalent in the diet suggest that nutrients found in animal foods may influence BP levels. Vegetarians in the USA and Australia have lower BP than nonvegetarian controls in the same geographical area. Within these vegetarian groups, consumption of general animal products, eggs, and saturated fat (author's unpublished observations) was significantly associated with increased BP levels even after adjustment for age, sex, and weight. However, when 250 g of lean beef per day was added isocalorically for 4 weeks to a strict vegetarian diet, the mean systolic BP increased significantly, but by only 3%; and diastolic BP did not change. In two trials lowered the saturated fat intake of normotensives; in one protocol, BP was unchanged, but in the other it declined.

We undertook two studies to assess the effect of dietary saturated fat and cholesterol on BP. The first study tested the effect of removing meat, poultry, and dairy fat from the diet of nonvegetarian adults for 3 months. The second study attempted to confirm the correlation between egg ingestion and BP previously found in a vegetarian population by adding one egg per day for 3 weeks to the lactovegetarian diet of college students, thereby increasing dietary cholesterol more than threefold.

Subjects and Methods

Study 1. Reduction of Saturated Fat and Cholesterol Subjects

Normal volunteers who were consuming a conventional diet unrestricted in animal products were sought among the employees of New England Memorial Hospital, Stoneham, Massachusetts, an institution operated by the Seventh Day Adventist Church. In addition,
persons not employed by the hospital were recruited by an advertisement in the local newspaper. The study group consisted of 19 normotensive persons, namely, six hospital employees and two spouses and 11 residents of the surrounding community. There were 4 men and 15 women, with a mean age of 33.4 years and a range of 14 to 54 years. No subject was taking medicine to lower BP. Nine persons had a first-degree relative with hypertension or stroke.

Dietary Protocol

The protocol consisted of a 3-week period of baseline measurement while the subjects were consuming their usual diets, followed by a 3-month experimental period, during which the subjects consumed a lacto-vegetarian diet containing no meat, poultry, eggs, or dairy fat, and consisting primarily of cereal products, vegetables, skim milk products, margarine, fruits, legumes, and nuts. Consumption of fish was permitted once per week. The nutritional objective was to lower the consumption of saturated fat and cholesterol. Increased consumption of polyunsaturated fatty acids or dietary fiber was not encouraged. Participants were instructed on how to select and prepare the prescribed diet in a series of four classes conducted by vegetarian cooks, dietitians, and the authors. After the participants began consuming the new diet, the adherence was encouraged by periodic telephone calls by a member of the study team, by monthly group meetings, and by counseling sessions when necessary. The subjects were studied in two groups. Eight persons took part in the study from October 1980 to January 1981, and 11 subjects from February to May 1981.

Measurements

Assessment of the diet was carried out by a 7-day record of food consumption compiled by each subject before and at the end of the 3-month intervention and by a semiquantitative food-frequency questionnaire. Subjects were instructed by a registered dietitian on the record keeping. The diet records were analyzed at the Harvard School of Public Health computing center using the Case Western Reserve University computerized nutrient data base.

Blood pressure was measured during the morning hours in a hospital conference room using a semiautomated device that minimized observer bias. Korotkoff tones were received by a microphone placed over the brachial artery under an inflatable cuff and displayed on paper tape as spikes superimposed on a calibration curve directly produced by the falling level of mercury in a manometer. With the subject in the sitting position for approximately 5 minutes, two consecutive measurements were taken from the right arm on each visit. The average systolic and diastolic BP of the two measurements was used in the analysis. Three visits were scheduled 1 week apart during the period before the new diet was begun and during the final 3 weeks of the low-fat diet for each subject. During the baseline and low-fat dietary phases, 3 days of BP measurements were obtained from 19/20 and 13/20 subjects, respectively. Two visits were carried out on the rest. Tapes were read according to criteria standardized to the auscultatory method.

During each dietary period, six pooled overnight specimens of urine were collected from the participants. Compliance during both periods was obtained from 17/19 subjects, and one pooled specimen was lost. Sodium, potassium, and creatinine were measured on the 16 paired sets of urines by autoanalyzer methods at the Core Laboratory of the Clinical Research Center, Brigham and Women's Hospital, Boston.

Statistical Analysis

Differences in mean BP of the group between the moderate and low-fat diets were assessed using a two-tailed generalization of the paired t test on the individual mean blood pressures. In this method, the paired differences in the individual mean blood pressures were weighted to account for different numbers of readings comprising the individual means. The power in this study to detect a 4 mm difference in BP was 85% for systolic and 86% for diastolic. This calculation used the estimated intrapatient standard deviation of the differences between mean BP at the end of the two dietary phases, which were 5.8 and 5.7 mm for systolic and diastolic BP, respectively.

Study 2. Modification of Dietary Cholesterol Intake

Subjects

Undergraduate students at Hampshire College, Amherst, Massachusetts, who were adhering to a semi-vegetarian diet containing a low level of dietary cholesterol, were studied; the group consisted of 17 normotensive persons, 4 men and 13 women, ranging in age from 18 to 24 years.

Dietary Protocol

The protocol tested the effect on BP levels of one egg as compared to no eggs per day. The subjects were divided into two groups who consumed in opposite sequence the egg and eggless foods for 21 days. The subjects were initially assessed for BP and nutrient composition of the diet while they were following their usual diet. They were then asked to incorporate two muffins, pieces of cake, or servings of custard into their daily diet for 6 weeks. Variations of these foods were prepared with and without eggs and flavored to make the egg and eggless foods indistinguishable by taste or texture. The daily ration of these items included one extra-large egg. Aside from cholesterol, the egg and eggless versions of the experimental foods contained nearly identical nutrient content as determined.
from standard tables of nutrient composition. These foods supplied per day a mean of 398 kcal, 12 g fat, 62 g carbohydrate, and 17 g protein. Neither the subjects nor the researchers involved in carrying out the protocol were told which foods contained egg. Subjects did not consume any eggs or foods that contained eggs in addition to the experimental foods during the study. Before the study, the subjects had consumed 3 eggs per week on the average. At the end of the protocol, the subjects were asked to guess which sequence of egg and eggless foods they were assigned to; the responses were nearly evenly divided between correct and incorrect guesses.

Measurements

The nutrient content of the subjects' diets before and during the protocol was calculated from a food frequency questionnaire filled out by the subjects. This technique has been validated using 7-day diet records. Compliance with the protocol was ascertained by contact three times per week by a member of the study team, and by inspection of diaries of 5 to 10 days during the protocol were told which foods contained egg. Subjects did not consume any eggs or foods that contained eggs in addition to the experimental foods during the study. Before the study, the subjects had consumed 3 eggs per week on the average. At the end of the protocol, the subjects were asked to guess which sequence of egg and eggless foods they were assigned to; the responses were nearly evenly divided between correct and incorrect guesses.

Blood pressure was taken according to methods described for Study 1. Two measurements on each of the baseline, egg, and eggless periods.

**Statistical Analysis**

The individual means of the blood pressure measurements from the egg and eggless phases were analyzed using a two-tailed paired t test. The power of detecting a 5 mm change in mean blood pressure between stages was 94% for systolic BP and 82% for diastolic BP. In use were the estimated intraindividual standard deviations of the differences in mean BP between the egg and no-egg phases which were 5.8 mm systolic and 7.2 mm diastolic and a two-tailed p value of 0.05.

Studies 1 and 2 were conducted in accordance with the standards of the Human Subjects Committee, Brigham and Women's Hospital.

Results

**Study 1. Reduction of Saturated Fat and Cholesterol**

Analysis of dietary records showed that the subjects receiving the low fat diet significantly reduced their daily customary intake of saturated fat from 21 to 10 g, cholesterol from 398 to 69 mg, and protein from 74 to 53 g. Consumption of polyunsaturated fatty acids, carbohydrates, sucrose, and dietary fiber was not significantly changed on the low fat diets (Table 1). Urinary

<table>
<thead>
<tr>
<th>Table 1. Blood Pressure, Nutrient Content of the Diet, Sodium and Potassium Excretion, and Body Weight of Subjects on Moderate Fat and Low-Fat Diets</th>
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<tbody>
<tr>
<td><strong>Systolic BP (mm Hg)</strong></td>
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<td><strong>Diastolic BP (mm Hg)</strong></td>
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<tr>
<td><strong>Body weight (kg)</strong></td>
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<tr>
<td><strong>Na excretion (g)</strong></td>
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<td><strong>(g/g creatinine)</strong></td>
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<td><strong>K excretion (g)</strong></td>
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<td><strong>(g/g creatinine)</strong></td>
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<tr>
<td><strong>Creatinine excretion (g)</strong></td>
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<tr>
<td><strong>Nutrient intake per day, g (%kcal) (n = 19)</strong></td>
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<tr>
<td><strong>Calories</strong></td>
</tr>
<tr>
<td><strong>Protein</strong></td>
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<td><strong>Fat</strong></td>
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<td><strong>Saturated fats</strong></td>
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<td><strong>Polyunsaturated fats</strong></td>
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<td><strong>Carbohydrate</strong></td>
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<td><strong>Sucrose</strong></td>
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<td><strong>Cholesterol (mg)</strong></td>
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<td><strong>Dietary fiber (g)</strong></td>
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</tbody>
</table>

Values are means ± sd. Excretion measurements of Na, K, and creatinine consist of, in each instance, the total excretion in six combined overnight collections of urine.
sodium excretion in six combined overnight specimens remained relatively constant, whereas there was a trend toward increased potassium excretion during the low lipid diet (Table 1). Urinary creatinine decreased from 1.7 to 1.4 g (p < 0.05) during the study, probably as a result of the decreased protein intake.27 Expressed in creatinine units, urinary sodium excretion was not significantly altered by the low lipid diet, whereas urinary potassium excretion increased significantly (Table 1).

Mean plasma cholesterol decreased during the low fat diet by 22 mg/dl ± 17 (SD) (p < 0.001) from a mean baseline level of 189 mg/dl. The equation of Keys and colleagues28 predicted a difference in plasma cholesterol of 25 mg/dl from the reported changes in dietary fats and cholesterol.

There were no significant changes in systolic or diastolic BP as a result of the dietary changes (Table 1). Mean BP of the eight subjects who had a family history of hypertension or stroke was 121.1/77.0 mm Hg on the moderate fat diet, and 118.7/75.0 mm Hg on the low fat diet (p = 0.2 for differences in both systolic and diastolic BP). The mean BP of the 8 persons who were in the study from October 1980 to January 1981 decreased from 113.1/71.9 to 111.9/69.5 mm Hg, whereas the mean BP of 11 subjects who completed the 3-month protocol in May 1981 was 117.6/76.2 and 117.6/76.4 mm Hg before and after the protocol, respectively.

Study 2. Modification of Dietary Cholesterol Intake

Before the start of the experiment, the subjects consumed in their usual diets a mean of 1579 kcal, 69 g protein, 52 g fat, and 208 g carbohydrate. During the 6 weeks of dietary intervention of egg and eggless foods, the subjects' mean daily nutrient intake was: 1626 kcal, 70 g protein, 44 g fat, 237 g carbohydrate. Thus, the basic structure of the diet was not changed to any important extent by the introduction of the experimental foods. Dietary cholesterol consumption before the study was 278 mg per day; during the eggless phase, it was 155 mg/day. The daily allotment of egg-containing foods supplied from one extra-large egg the cholesterol was calculated to be 316 mg from the most recent tables of nutrient composition.25 26

There were not significant differences in mean systolic or diastolic BP between the egg and eggless periods (Table 2). Neither the 10 subjects who consumed the eggs initially in the egg/no egg sequence, nor the seven subjects who consumed the eggs last showed any significant change in mean systolic or diastolic BP, p > 0.3 for each analysis. Urinary sodium excretion during the egg and eggless phases was 0.81 g/g creatinine and 0.83 g/g creatinine, respectively. Potassium excretion was 0.37 g/g creatinine during the egg phase and 0.36 g/g creatinine during the eggless phase.

**Discussion**

In our two studies of nutritional modification in adult subjects, increasing or decreasing the saturated fat and/or cholesterol intake had no effect on blood pressure levels. Multiple measurements of BP using objective methods were taken on each subject for several days during each dietary phase. In this way, the intrasubject variability of BP was reduced, and the sensitivity of the study to detect small changes in BP between dietary stages was high. The first study, in which participants changed from a customary omnivorous diet supplying moderate amounts of saturated fat and cholesterol to a low fat lactovegetarian diet, was conducted in an open, nonblinded design. Thus, a placebo effect in subjects who might have anticipated benefit from the diet would have biased the study in favor of a hypotensive dietary effect, which did not in fact occur. Although the experimental lactovegetarian diet required a major change in the subjects' previous dietary patterns, the only significant change in consumption of a nutrient other than saturated fat and cholesterol was a decrease in protein. There were no significant changes in polyunsaturated fatty acids, dietary fiber, sucrose, or carbohydrate.

There was a trend toward lower caloric intake during the vegetarian diet period (p = 0.07). The subjects probably did not consume fewer calories on the vegetarian diet, since no weight loss occurred over the 3-month period. The difference in caloric intake was due either to random error, since it was not statistically significant, or to underreporting of foods consumed during the vegetarian period. Underreporting probably occurred during both vegetarian and nonvegetarian periods, since the caloric intake was somewhat low for the mean weight of the group.

The second study tested the effect of dietary cholesterol from eggs, within the range of 155 to 471 mg/day. The protocol did not require the subjects to alter

<p>| Table 2. Blood Pressure, Body Weight, and Cholesterol Content of the Diet of 17 Subjects in Response to Ingestion of an Egg for 3 Weeks |
|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1 egg/day</th>
<th>Placebo</th>
<th>(Egg–placebo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>105.9 ± 7.0</td>
<td>108.0 ± 6.8</td>
<td>106.7 ± 6.7</td>
<td>1.2 ± 5.8</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>66.7 ± 6.9</td>
<td>68.5 ± 6.5</td>
<td>69.3 ± 6.7</td>
<td>0.7 ± 7.2</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>63 ± 8.8</td>
<td>64 ± 8.7</td>
<td>64 ± 8.6</td>
<td>0.3 ± 1.2</td>
</tr>
<tr>
<td>Dietary cholesterol (mg)</td>
<td>289 ± 154</td>
<td>471 ± 122</td>
<td>155 ± 122</td>
<td>316*</td>
</tr>
</tbody>
</table>

Values are means ± sd.

*Extra-large egg. 58 g edible food. 316 mg cholesterol; calculated from USDA Handbook 8-1 and 456 (see refs 25 and 26).
their usual dietary patterns and involved a daily nutritional supplement of about 400 kcal. The protocol was conducted in a two-group double-blind crossover design, leaving little likelihood that bias or secular trends in BP could have affected the results.

Since these studies were not conducted on a hospital ward where the diets could be precisely formulated and consumed under the direct supervision of the investigators, objective confirmation of the dietary compliance of the subjects in this report is desirable. In Study 1, the significant decline in urinary creatinine excretion probably reflected the removal of meat from the diet and the concomitant decrease in creatine intake.\(^{37}\) The decrease in plasma cholesterol levels predicted by the Keys equation\(^{28}\) on the basis of the decline in saturated fat and cholesterol consumption during the vegetarian period was nearly the same as the observed decrease in plasma cholesterol. In Study 2, the difference in dietary cholesterol between the egg and no egg periods is confirmed by the significant 12% increase in low density lipoprotein cholesterol that occurred during the egg ingestion (authors’ unpublished observations).

Both studies involved nutritional modifications within the low low-to-average range of intakes found in the general population. It is possible that shifts in consumption of saturated fat and/or cholesterol that are much larger than those studied here may affect BP. Such a finding, however, would have limited clinical relevance.

Iacono and colleagues\(^{18}\) have proposed that the ratio of polyunsaturated to saturated (P/S) fats in the diet is inversely related to BP levels. These two classes of fatty acids were supplied to the diet by different foods and had distinct metabolic effects. When the P/S ratio was increased by changes in polyunsaturated but not saturated fats, mean BP of normotensive and mildly hypertensive subjects decreased.\(^{18} \) However, studies of normotensive subjects in whom alterations in saturated fat intake produced the changes in the P/S ratio of the diet are not in agreement. No effect\(^{18}\) (and present study), slight effects on systolic BP only,\(^{19}\) and significant effects in both systolic and diastolic BP\(^{19}\) have all been observed. In one study of mild hypertensives, reduction of saturated fat intake lowered BP.\(^{18}\)

Depending on how a vegetarian diet is taught to subjects, changes in nutrient intake will vary. For example, the present study produced decreases mainly in saturated fats whereas that of Rouse et al.\(^{31}\) resulted in increases in polyunsaturated fats (Ian Rouse, personal communication). Interestingly, BP was unchanged in the former study, but decreased significantly in the latter study.

All of the prospective trials of diet modification utilized an investigation timespan of several weeks or months. Epidemiologic studies demonstrating low BP in vegetarians\(^{1-16}\) and positive associations between animal products and BP\(^{15} \) involved persons who had followed dietary practices for years. Follow-up studies of long duration may be required to reconcile these divergent findings.

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