

Effect of Mixed Fat Formula Feeding on Serum Cholesterol Level in Man

II. Further Study Utilizing a Twenty Per Cent Fat Formula

CHARLES B. DAVIS, JR. M.D.,* ROBERT EMERSON CLANCY, M.D.,† BARBARA E. COONEY, A.B.,‡
D. MARK HEGSTED, PH.D.§ AND JACK HUETT HALL, M.D.¶

STUDIES OF ANIMALS by Hegsted et al.¹ have demonstrated the ability of linoleic acid in combination with saturated fatty acids to alter levels of cholesterol in the serum. Extension of this observation into the area of clinical investigation of human subjects has also been reported,^{2,3} and the results have been so consistent that Keys and his associates⁴ have formulated an equation predicting the effect on levels of cholesterol in the serum of various proportions of linoleic acid and saturated fatty acids. These studies indicate that slightly more than 2 gm. of linoleic acid are needed to counter the effects of 1 gm. of saturated fatty acid. The results differ in studies of rats in which a mixture of equal amounts of saturated and unsaturated fatty acids produced the greatest lowering of serum cholesterol levels.

Clinical extension of these studies has been undertaken by our group in terms of formula type feedings as initiated by Ahrens et al.,² incorporating varying levels of saturated and unsaturated fatty acids in the form of coconut

and safflower oils. Formula feedings are particularly suitable for this type of investigation because the components can be measured accurately and all variables can be controlled.

The results obtained from the use of a formula diet containing equal amounts of coconut and safflower oils was included in our first report.³ The results obtained from ten patients, who were placed on similar formula diets consisting of a homogenous mixture of non-fat milk solids,¶ glucose, and safflower oil or a mixture of safflower and coconut oils, are reported herein. However, a formula containing 20 per cent fat rather than 40 per cent (used in the first portion of our study) was used, in order to determine whether or not the results of the previous study could be reproduced by simply reducing the total fat content by 50 per cent.

MATERIALS

The formula diet, originated by Ahrens et al., was used.² In the first part of our study, we utilized a caloric composition of 42 per cent fat, 43 per cent carbohydrate and 15 per cent protein. This formula was modified in the second portion of our study to contain 21 per cent fat, 64 per cent carbohydrate and 15 per cent protein. One gm. of NaCl and two multivitamins were given as daily supplements. Clinical data concerning the patients used in the study

From the Veterans Administration Hospital, West Roxbury, Massachusetts; and Department of Nutrition, Harvard School of Public Health, Boston, Massachusetts.

* Former Assistant Chief of Medicine, Veterans Administration Hospital, and Assistant in Medicine, Harvard Medical School, Boston, Massachusetts; † Research Associate in Medicine; ‡ Research Dietitian; § Associate Professor of Nutrition; ¶ Former Teaching Fellow in Medicine, Harvard Medical School, Boston, Massachusetts.

¶ Non-fat milk solids were supplied through the courtesy of the Carnation Company, Boston, Mass.

TABLE I
Clinical Data on Patients Used in the Study

Case No. (and Patient)	Age	Occupation	Height (inches)	Weight (pounds)			Clinical Diagnosis*
				Maximum Prestudy	Study	Poststudy	
1 (E. DuB.)	43	Salesman	72	185	177	174	MI
2 (J. H.)	50	Nurses aide	70	203	195	169 ^{1/2}	MI
3 (J. G.)	39	Truck driver	72	190	183	178	MI
4 (A. L.)	67	Salesman	63	183	164	161	MI
5 (J. G.)	50	Gardener	65	190	155	160	MI
6 (J. A.)	48	Truck mechanic	70	235	204	†	MI
7 (W. G.)	37	Machinist	64	220	166	152	MI
8 (W. A.)	54	Salesman	66	175	164	137	AP
9 (E. G.)	40	Social worker	68	195	192	156	AP
10 (E. C.)	46	Factory worker	65	162	143	143	MI

* All patients had coronary heart disease. MI = myocardial infarction; AP = angina pectoris.

† Patient lost to follow-up.

are provided in Table I. All patients had coronary heart disease; eight showed old or stable myocardial infarction by electrocardiogram, and the remaining two had angina pectoris. Constant body weight was maintained throughout the study by adjusting the amount of formula given. Six of the patients were obese.

METHODS

Patients were referred to the Nutritional Study Unit at the Veterans Administration Hospital by the Medical Service. Samples of blood were drawn from the patients to determine the presence of hypercholesteremia. Serum cholesterol was measured by the Sperry and Webb method,⁵ which makes possible definite determination of the cholesterol content by using only a single sample of blood. Subjects with diseases of the liver or kidneys or endocrine dysfunctions were omitted from this study.

Patients selected for study were placed at random into Groups A and B. Control determinations of serum cholesterol were obtained and analyzed in duplicate immediately prior to the initiation of the formula regimen. The subjects were studied during two periods of two weeks each. The members of Group A were given a formula containing 20 per cent

fat (safflower oil) during the initial two week period. Fats in non-fat milk solids were present in negligible amounts. During the second period, they were again given a 20 per cent fat formula, however, this time the fat consisted of an equal mixture of safflower and coconut oils. Subjects in Group B were fed in the reverse, receiving the safflower-coconut oil mixture in the first period and the formula with only safflower oil in the second period.

On the first day of the study, two blood samples were drawn, two hours apart, from the fasting patients. These were analyzed in duplicate for levels of cholesterol. At the end of the second week, prior to changing the formula, two similar samples were again drawn. At the end of the fourth week, another two samples were obtained. Following the study period, the obese patients were placed on weight reduction diets (Table I).

Serum cholesterol determinations were also performed on the first, seventh, fourteenth and twenty-eighth days. Samples obtained on the first, fourteenth and twenty-eighth days were drawn from the fasting patient at 8:00 A.M. and again at 10:00 A.M. Double samples were used in an effort to eliminate error due to hourly variations.

TABLE II
Mean Cholesterol Values

Group and Subject	Mean Serum Cholesterol (mg./100 ml.)		
	Control	Safflower	Mixture
Group A			
1	327	196	227
3	333	206	249
5	411	307	348
7	380	294	336
9	385	307	328
Mean	367	262	298
Group B			
2	320	249	240
4	330	251	261
6	249	204	220
8	403	370	362
10	396	282	246
Mean	340	271	266
Grand Mean	358	264	284

RESULTS

Changes in the levels of cholesterol in the serum of ten patients, who were placed on formula diets, are indicated in Table II. Mean values of the different phases of the study are also recorded in this table.

The formula containing 20 per cent safflower oil lowered the levels of cholesterol in the serum significantly, as did the formula consisting of 20 per cent coconut and safflower oils. Levels of lipids in the blood were lowered more effectively in man by the safflower oil formula than by the mixture.

During the second two week period, the 20 per cent safflower oil formula maintained lowered levels of cholesterol in the serum, whereas the levels increased slightly when the formula with the mixture was administered (Table II).

COMMENTS

Our previously reported investigation³ indicated that formulas containing 40 per cent fat, either safflower oil or safflower and coconut oils, were equally effective in lowering cholesterol levels in human serum. This

second investigation indicates that a comparable lowering effect is obtained with a formula containing 20 per cent fat consisting of only safflower oil.

The current literature evidences concern with the effect of dietary fat, both the quantity and quality, on human metabolism as applied to the etiology of disease of the coronary arteries. We have demonstrated that the effect of lowering the levels of cholesterol in the serum can be accomplished just as well with a formula containing only 20 per cent fat. With the data available from this and the first part of our study, no one level of total fat or unsaturated fat can be chosen as optimal. The results of three of the four formulas were almost identical. The only formula which did not show appreciable changes was that with the 20 per cent fat mixture. Some observers⁶ have stated that total fat, and others that total unsaturated fat, are the significant elements in the production and reduction of cholesterol in the blood. Our results show that wide variations in both produce similar results. Perhaps the optimal level is within the 20 to 40 per cent range of total fat and unsaturated fat. Further work with both higher and lower variations of total and unsaturated fats should be carried out.

The number of patients and the duration of study were not sufficient to enable evaluation of any effect on atherosclerotic processes.

SUMMARY

Formula type feedings, utilizing reduced quantities of safflower oil and safflower-coconut oil mixture, were administered to ten patients with hypercholesteremia. It was observed that similar reduction in levels of cholesterol in the serum can be obtained with this type of regimen as compared to that using a formula which contains twice the amount of fat in the same proportions. A slightly greater reduction of cholesterol in the serum was obtained when a formula containing 20 per cent safflower oil was used.

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