THE National Diet-Heart Study which was supported by the National Heart Institute, has been completed, and the final report appears as a supplement to CIRCULATION. This was a large double-blind, 2-year study on the effects of diet on blood cholesterol levels in both free-living and closed populations. The relevance of such a study originated in our minds as a result of a study we conducted for 10 months with 55 volunteer couples using commercially prepared, fat-modified foods. These foods were low in saturated fat and relatively high in polyunsaturated oils. Individual diet instruction was not given. The average reduction in serum cholesterol was 14%.1

The general principles on which it was designed have already been presented.2 Its great importance lies in the demonstration that adequate techniques have now been developed for large experimental studies using volunteers. This is the first study of its kind in which so complex and important a factor as diet was controlled double-blind in a free-living population.

Centers were established in Baltimore, Minneapolis-St. Paul, Oakland, Chicago, and Boston, where studies of free-living participants were under the direction of Drs. B. M. Baker, A. Keys, L. W. Kinsell, J. Stamler, and F. J. Stare, respectively, and an institutional one in Faribault under Dr. I. D. Frantz. The central staff consisted of Drs. J. H. Bragdon, H. B. Brown, J. Cornfield, F. Ederer, J. G. Green, and E. E. Rice, with I. H. Page as overall chairman of the study.

Recruitment of free-living men through the Census Bureau and through life insurance companies proved a success. Of the 2,000 volunteers from 45 to 54 years of age who were screened in the first year of the study at the centers, about a third withdrew or were excluded because of the results of clinical and nutritional studies during the base-line period. As anticipated, the remaining participants proved not to be strictly representative of the U. S. population; for example, only 39% were smokers compared to 58% in the nation.

The participants were randomized into three main diet groups after the preliminary base-line period. The diets were designed so that one contained 30% of calories from fat, a relatively low cholesterol content, and amounts of polyunsaturated fatty acid which were high compared to saturated fatty acids. A second had 40% of calories from fat, the same reduced cholesterol content, and a somewhat higher polyunsaturated content; and
Lastly, a control diet comparable to the average American diet, but unfortunately as it turned out, because of practical reasons, a little lower in cholesterol content. In short, the diets expected to reduce blood cholesterol levels were high in polyunsaturates and low in saturates and cholesterol.

The diets were controlled through the use of special foods; except for lean meats, three varieties of each food product were prepared so that the diets could not be distinguished one from the other. The food manufacturers were extraordinarily successful in producing palatable food which met the requirements of the study. The foods were purchased and dispensed from food centers.

In the open study centers the average change in blood cholesterol with the two experimental diets was 25 and 28 mg/dl or −11 and −12%, while in the closed, institutional center at Faribault, it was 36 mg/dl or −17%. This seemed to reflect better adherence in closed population groups. Adherence in the open centers was measured in several ways, including tissue fatty acids. None proved as valid as the subjective estimates made by the nutritionists during periodic interviews. In all those assigned to the diets, about 20% were rated poor adherers.

The interesting observation was made that with the drop in serum cholesterol, there was a fall in diastolic blood pressure and body weight; there was also a reduction in smoking. This may be important in any large scale preventive program. It had been known that weight and cholesterol level are related. The largest drop in cholesterol occurred in men with the largest decrease in weight and with the highest initial cholesterol levels.

It was clearly shown that decrease in serum cholesterol occurred with the study diets which decreased the percentage of calories from saturated fatty acids and increased the polyunsaturated fatty acids. Although the same lowering in cholesterol occurred when only special instruction was given, the use of special foods made the nutritionist’s task much less onerous. Special foods were needed for the double-blind procedure. The groups of participants given unrestricted use of special foods the second year had as much reduction in blood cholesterol as those on a carefully planned food pattern. Because of the high cost of specially prepared lean meats, some participants were taught to buy and trim store meats in several sessions of instruction. This proved successful as the cholesterol response was as good as with the specially prepared, professionally trimmed meat.

To obtain a suitable control diet proved more difficult than had been supposed because of the double-blind restriction imposed on preparation of the foods. It was not feasible artificially to introduce the full complement of cholesterol into the control diet.

The above is only a sampling of the many things learned in this cooperative venture. After the most searching analysis of the results, the committee strongly recommended to the National Heart Institute that a major definitive study of the effect of diet on the primary prevention of myocardial infarction be planned and put into operation as soon as possible. It did not seem essential to recommend use of the double-blind method as had been done in the feasibility study. It is clear that such a paradigm is practical and more than worth the effort. This is why the feasibility study may be considered a milestone in mass environmental experimentation. Almost inevitably it will have an important effect on the food industry and the attitude of the public toward its eating habits.

While no one thinks diet alone is the key-stone to the control of coronary disease, enough evidence has already been published by investigators, such as Leren, Turpeinen, and Rinzler, to suggest that it may be helpful. The problem is too important to neglect any facet for which there is reasonable evidence. The time has surely come when the search for new ideas and the validation of old ones are the paramount issues in the control of heart attacks. From such studies will come the "practical" procedures applicable to any con-
control program for coronary disease. Committees can plan all they wish to coordinate health facilities, but not at the expense of vital controlled environmental experimentation, coronary care units, and support of creative research.

IRVINE H. PAGE AND HELEN B. BROWN

References

Ipsogenic, Iatrogenic, Icarogenic Heart Disease

... In keeping with the town-gown cleavage, it may be appropriate to define the hazards of "medical progress" as iatrogenic when they relate to the well-recognized and sometimes unavoidable complications of practice and as icarogenic disease in the investigative area, to commemorate Icarus, who flew high only to have his waxed wings wilt in the sun's rays and make him fall ignominiously, a condition with common parallel in research. ... Yet not all heart disease is the mysterious doing of nature or of the physician. A lot of his undoing is done by the patient himself. The innings have not all been played in the game of coronary heart disease, but it is already abundantly clear to all but those whose sight is fogged and who are hopelessly partisan that the way of life has scored cleanly and heavily in the line-up of pathogenetic factors. ... Smoking, diet, and sedentariness are all things the public can do something about were it so inclined. ... Without resorting to jeremiads, which may drive his patients away, he [the family physician] is in position to give constructive advice and supportive therapy to prevent ipsogenic heart disease. ...—RICHARD S. GUBNER: Ipsogenic Heart Disease. Med Tribune, July 20, 1967, p. 11.
Some Observations on the National Diet-Heart Study
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