A Strategy to Arrest and Reverse Coronary Artery Disease: A 5-Year Longitudinal Study of a Single Physician's Practice

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Background. Animal experiments and epidemiological studies have suggested that coronary disease could be prevented, arrested, or even reversed by maintaining total serum cholesterol levels below 150 mg/dL (3.88 mmol/L). In 1985, we began to study how effective one physician could be in helping patients achieve this cholesterol level and what the associated effect of achieving and maintaining this cholesterol level has on coronary disease.

Methods. The study included 22 patients with angiographically documented, severe coronary artery disease that was not immediately life threatening. These patients took cholesterol-lowering drugs and followed a diet that derived no more than 10% of its calories from fat. Disease progression was measured by coronary angiography and quantified with the percent diameter stenosis and minimal lumen diameter methods. Serum cholesterol was measured biweekly for 5 years and monthly thereafter.

Results. Of the 22 participants, 5 dropped out within 2 years, and 17 maintained the diet, 11 of whom completed a mean of 5.5 years of follow-up. All 11 of these participants reduced their cholesterol level from a mean baseline of 246 mg/dL (6.36 mmol/L) to below 150

By the mid-1980s, experimental studies on animals and epidemiological studies had indicated that total serum cholesterol levels below 150 mg/dL (3.88 mmol/L)

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mg/dL (3.88 mmol/L). Lesion analysis by percent stenosis showed that of 25 lesions, 11 regressed and 14 remained stable. Mean arterial stenosis decreased from 53.4% to 46.2% (estimated decrease=7%; 95% confidence interval [CI], 3.3 to 10.7, P < .05). Analysis by minimal lumen diameter of 25 lesions found that 6 regressed, 14 remained stable, and 5 progressed. Mean lumen diameter increase=0.08 mm; 95% CI, -0.06 to 0.22, P=NS). Disease was clinically arrested in all 11 participants, and none had new infarctions. Among the 11 remaining patients after 10 years, six continued the diet and had no further coronary events, whereas the five dropouts who resumed their prestudy diet reported 10 coronary events.

Conclusions. A physician can influence patients in the decision to adopt a very low-fat diet that, combined with lipid-lowering drugs, can reduce cholesterol levels to below 150 mg/dL and uniformly result in the arrest or reversal of coronary artery disease.

Key words. Coronary disease; cholesterol; nutrition; atherosclerosis; preventive medicine. (J Fam Pract 1995; 41:560-568)

were associated with the absence of atherosclerotic heart disease and with possible arrest and even reversal of the effects of heart disease.^{1,2} It was also evident that very low-fat diets, with and without drugs, could reduce progression and achieve partial regression of coronary artery disease in humans.^{3–15}

These studies caused one of the authors (C.B.E) to rethink the treatment of heart disease, as well as his own lifestyle. Aware that medical, angiographic, and surgical interventions were treating only the symptoms of heart

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disease and believing that a fundamentally different aproach to treatment was necessary, he identified through referrals a number of heart patients willing to adopt a program of major dietary change and to be followed for everal years so that the effects of the regimen could be locumented.

This article describes the medical changes that ocarred in these participants after maintaining a very lowit diet over several years. It presents the results of an eploratory study on what a single physician can accomplish with his or her patients, without additional funding, expensive interventions, or a large medical infrastructure.

Methods

Participants

several patients who were not considered to have immediately life-threatening coronary artery disease or who had declined or were not considered candidates for intervenion by their cardiologists were referred to the principal investigator, a general surgeon, by colleagues in the Deartment of Cardiology, The Cleveland Clinic Foundaion. Some patients had heard of the study and asked to be involved. The only inclusion criteria were angiographially documented evidence of severe coronary heart disease, and the willingness to attempt the dietary changes described below and to be examined periodically so that mogress could be monitored. All participants were informed about the purpose and nature of the study and consented to the follow-up activities. The study was conlucted with the approval of The Cleveland Clinic Founlation's Institutional Review Board.

Therapeutic Interventions

Participants were asked to adhere to a diet that derived less than 10% of its calories from fat. They were to avoid oils, meat, fish, fowl, and dairy products, except for skim milk and nonfat yogurt. Grains, legumes, lentils, vegetables, and fruit comprised the major portion of the diet, which contained adequate amounts of vitamins, minerals, protein, and iron.^{16,17} A list of fat-free recipes taken from cookbooks and other resources that focus on weight loss, mutrition, and lifestyle changes to improve heart health^{18–26} was provided to each participant. Daily food diaries were kept and reviewed with the physician during biweekly visits. Participants were also encouraged to take a daily multivitamin and were asked, but not required, to moderate their consumption of alcohol and caffeine. There were no prescribed exercise requirements.

Each participant also received an individualized pre-

scription for a cholesterol-lowering drug. The most frequent regimen included cholestyramine, 4 g twice daily, and lovastatin, 40 mg to 60 mg daily. Time-release niacin was prescribed for a short while but was discontinued when many patients reported nausea, vomiting, and swollen ankles.

Participants also received several hours of instruction in relaxation and meditation techniques through the Cleveland Clinic's Department of Psychology. However, all participants discontinued these techniques after only a few weeks of sporadic use, so this part of the intervention was abandoned.

Measurements of Outcome Variables

The degree of coronary artery disease was determined from angiograms using both the percent stenosis and minimal lumen diameter (MLD) methods.^{5,12} These methods were applied independently by two senior angiography laboratory technicians with angiographic evaluation experience in national multicenter cardiac trials. The technicians were masked as to whether the angiograms were from the initial or follow-up catheterization. Data were obtained for the initial angiogram, which helped identify patients who would be appropriate to participate in the study, and for a minimum of one follow-up angiogram. Most follow-up angiograms were taken in 1992.

One technician evaluated all lesions from both the baseline and the follow-up angiograms on two separate occasions, the second time at least 6 months after the first to prevent recall bias. The second technician independently evaluated both the baseline and the follow-up angiograms. Thus, each lesion was measured three times. The mean of the three measurements for each lesion on each angiogram was used in the statistical analysis, and the standard deviation of each mean was used to check for consistency with published guidelines for lesion progression or regression. The percent stenosis and minimal lumen diameter were measured for each lesion identified on the angiogram as described above. Disease status was defined by the criteria of Hambrecht et al12 for each method. For the percent stenosis method, an increase in stenosis of 10% or more was considered to indicate disease progression; a decrease in stenosis of 10% or more was considered to indicate disease regression; and a change of less than 10% in either direction was considered to indicate no change in disease status. For the MLD method, a decrease of more than 0.18 mm was considered to indicate disease progression; an increase of more than 0.18 mm was considered to indicate disease regression; and a change of less than 0.18 mm in either direction was considered to indicate no change in disease status.

Baseline angiograms were reviewed before the follow-up angiograms were made so that the projection angles, cardiac segments, and lesions could be matched with those present at baseline. Previously dilated lesions (n=3) were not studied. Fasting serum lipid levels were analyzed biweekly during the first 5 years of the study and monthly thereafter. Weight and blood pressure were also recorded biweekly. Angina was graded on the Canadian Cardiovascular Society Scale.²⁷ During the second year of the study (1987), participants' food diaries were analyzed with the 3-Day Nutrient Intake computer program²⁸ to determine the fat content of the diet.

Promoting Adherence to the Diet

The strategy used to foster adherence to the diet had four components. First, the physician conducted a 1-hour interview with the participant and his or her spouse and reviewed the history, epidemiology, angiographic data, research findings, and therapeutic options of coronary heart disease. The purpose of the interview was to explain the rationale for the study, to impress upon participants the importance of the diet and of keeping a food diary, and to establish informed consent with each participant.

Second, the physician saw each participant every 2 weeks for 5 years and every month thereafter for an additional 5 years. At each visit, the participant's food diary was discussed, blood pressure and weight were recorded, and blood samples were drawn so that lipid profiles could be determined.

Third, during the first year of the study, the physician called each participant on the evening after his or her clinic visit (every 2 weeks) to report the results of the blood test and discuss any adjustments to the diet or medication.

Fourth, three or four times each year, participants met at the home of the physician or one of the participants to discuss the low-fat diet program, trade recipes, and socialize. The physician was personally committed to adhering to a low-fat diet, as well as to supporting patients in their efforts to adopt the diet.

The costs of the study were limited to blood tests and a follow-up angiogram, which were paid for by each participant (or the insurance carrier) as part of regular medical care. During the first 3 years of the study, the costs of the lipid profiles were borne by the Cleveland Clinic.

Statistical Analysis

Disease progression was analyzed with each method (percent stenosis and MLD) by averaging the three measurements taken on each lesion of each angiogram and comparing the averages of the initial and follow-up angiograms. Changes in lesion characteristics were examined using mixed-effects models, which take into account that most participants had multiple lesions and that some data were therefore correlated. Results are reported by average degree of arterial patency, by change in individual lesions, and by overall change in disease status for each patient.

Three reference points were chosen for analyzing cholesterol data: baseline (the value measured just before or just after beginning the study), onset of medication effect (3 weeks after participants began taking the cholesterol-lowering drugs, which were prescribed soon after entering the study), and follow-up (the date of the most recent angiogram). Cholesterol data for each visit between onset of medication effect and the follow-up angiogram were averaged to create a single cholesterol value for each participant for the entire study period.

Analyses were performed with the SAS software. Alpha was set at .05, and all tests were two-tailed.

Results

Participants

Between 1985 and 1988, 21 men and one woman who were referred to the principal investigator agreed to take part in the study. This number was determined by the physician as the most manageable, given his other professional obligations. Five participants left the study within the first 2 years and six maintained the diet but did not complete the data-collection portion of the study. The results of the remaining 11 participants are reported here. These participants had completed a mean follow-up period of 5.5 years as of 1992. All participants had severe, progressive triple-vessel coronary heart disease documented by angiography. In the 8 years before the present study began, these 11 participants, who were receiving state-of-the-art cardiac care at The Cleveland Clinic Foundation, collectively experienced 37 cardiovascular events, including 15 cases of increased angina, 6 cases of angiographically determined disease progression, 6 cases of coronary artery bypass surgery (2 others had had bypass surgery more than 8 years before the study), 4 myocardial infarctions, 3 strokes, 2 angioplasty procedures, and] abnormal (worsening) stress test.

All participants were nondiabetic, nonhypertensive, and nonsmokers. They ranged in age from 43 to 67 years (mean age, 56 years).

Angiographic Results

Baseline angiograms were obtained within 60 days of the sart of the study for 10 of the 11 participants analyzed here. The remaining participant's baseline angiogram was taken 1 year into the study. Every participant had a folow-up angiogram.

Among the 11 participants, the two angiographers identified 38 lesions associated with more than 20% stenosis. Of these lesions, three were excluded from analysis, wo of which had been treated before and one that was reated after entry into the study with percutaneous transminal coronary angioplasty (PTCA). Another four leions in native vessels immediately proximal to bypass rafts were excluded from analysis a priori because accelrated disease is known to occur in this circumstance, 29-32 nd their inclusion would confound the analysis by introlucing a new variable. As expected, these lesions proressed during our study. Of the remaining 31 lesions, 18 (58%) produced stenosis of greater than 50%. Of these 18 isions, six could not be accurately assessed at follow-up because of discrepancies in the angle of projection or isual overlap, which prevented the evaluation of changes. The final analysis, therefore, involved 25 lesions in 11 patients.

MEAN PERCENT STENOSIS. The mean percent stenosis ±standard deviation) on all 25 lesions decreased from 3.4% (±14.8%) to 46.2% (±16.8%) from baseline to blow-up. The mean percent reduction in stenosis estimated by the mixed-effects model, which adjusted for orrelations between lesions in the same participant, was 7% (95% CI, 3.3 to 10.7, P<.05). The average standard deviation of the three stenosis measurements was 4.4% at baseline and 4.9% at follow-up, which is consistent with the values reported by Hambrecht et al.¹²

According to this method of analysis, of the 25 lesions, 14 remained unchanged and 11 regressed. Thus, stenosis decreased in 8 of the 11 participants, indicating regression of the disease, and was unchanged in 3.

MINIMAL LUMEN DIAMETER. Mean minimal lumen dimeter (\pm standard deviation) of the 25 lesions was 1.3 mm (\pm 0.6) at baseline and 1.4 mm (\pm 0.6 mm) at followup. The mean increase in diameter as estimated by the mixed-effects model was 0.08 mm (95% CI, -0.06 to 0.22, P=NS). The average standard deviation of the three diameter measurements was 0.14 mm at baseline and 0.15 mm at follow-up, which again is consistent with the values reported by Hambrecht et al.¹²

Of the 25 lesions, 14 remained unchanged, 6 regressed, and 5 progressed. Of the lesions that progressed, 4 were arterial (see below) and 1 was venous. Among the 11 participants, stenosis generally decreased in 5, remained stable in 1, progressed in 4 (although the change



Figure. Angiographic images of the distal right coronary artery in a 54-year-old male patient at baseline in 1987 (left) and in 1992 after 5 years on a very low-fat diet (right). The lesion regressed by more than 30% (1.21 mm).

was not statistically significant), and both regressed and progressed in 1.

The four arterial lesions that progressed according to the MLD method occurred in four participants. In one participant, the lesion progressed 0.03 mm beyond the cutpoint, although another lesion showed marked regression. In another participant, the lesion also progressed only 0.03 mm beyond the cutpoint but was accompanied by the complete recanalization of the left circumflex artery. This recanalization was not defined as regression because this phenomenon can occur spontaneously.12 In a third participant, one lesion progressed 0.04 mm beyond the cutpoint, whereas another remained unchanged. Finally, in a fourth participant, the lesion progressed 0.07 mm beyond the cutpoint, making it the most advanced progression. Two other lesions in the same participant remained unchanged. The regression of coronary artery disease is illustrated in the Figure.

Lipid Results

The mean number of lipid analyses performed on each participant was 126 (range 74 to 156). The mean baseline (fasting) total cholesterol level for the 11 participants was 246 mg/dL (6.36 mmol/L). The mean total cholesterol level between the onset of the medication effect and the follow-up angiogram was 132.4 mg/dL (3.42 mmol/L). The range was 109.9 mg/dL (2.84 mmol/L) to 149.9 mg/dL (3.88 mmol/L). Thus, each participant had a mean total cholesterol level under the target level of 150 mg/dL (3.88 mmol/L). Individual and average lipid values are shown in Tables 1 and 2. For all patients, the mean follow-up high-density lipoprotein (HDL) value was 36.3 mg/dL (0.94 mmol/L), and the mean low-density lipoprotein (LDL) was 71.6 mg/dL (1.85 mmol/L).

Table 1. Mean Lipid Values and Angina Class in 11 Patients with Coronary Heart Disease at Baseline and After 5 Years on a Very Low-Fat Diet

	Patient Number										
Characteristic	1	2	3	4	5	6	7	8	9	10	11
Age at initiation of drug therapy, y	61	57	55	63	54	60	44	48	59	51	68
Sex	М	М	М	М	М	F	М	М	М	М	М
Cholesterol level, mg/dL											
Baseline	178	306	221	270	260	241	240	225	256	275	227
Study duration, mean	136.8	135.7	130.1	124.4	109.9	141.8	139.8	149.9	146.2	130.1	23/
High-density lipoproteins, mg/dL											
Baseline	33	30	30	_	28	and the		32	No Trans	55	
Study duration, mean	28	33	37	33	29	52	43	32	40	41	31
Low-density lipoproteins, mg/dL											
Baseline	124	219			197			126	A 2500	100	
Study duration, mean	91	72	72	58	65	75	77	63	90	76	48
Triglycerides, mg/dL											
Baseline	127	285	196	_	173	279	1 100100	334	arienter.	106	
Study duration, mean	108	167	127	206	97	78	117	362	91	72	188
Angina class*											
Baseline	0	III	II	II	III	П	I	Ш	0	II	Ш
End of study	0	Ι	0	I	I	I	0	II	0	I	I

*Angina was graded according to the functional classification system of the Canadian Cardiovascular Society,²⁷ which grades angina severity on a four-point scale, with Class being the least severe and Class IV being the most severe. We used a score of 0 if a patient had no angina. NOTE: Some entry data for some patients were missing at the beginning of the program.

Other Outcomes

Mean baseline and follow-up weight and blood pressure values are shown in Table 2. Angina, initially reported by nine participants, was eliminated in two and reduced in seven. In six patients the angina decreased by one grade, and in three patients it decreased by two grades, as determined by the Canadian Cardiovascular Society Scale.²⁷

Two participants required coronary interventions during the study period. A 67-year-old man with 70% stenosis of the left anterior descending artery at baseline suffered from angina. Although the lesion and the angina were stable, the patient desired to be free of angina, so he

Table 2. Mean Lipid Values and Clinical Measurements from the Beginning of the Medication Effect to the Follow-up Angiogram for 11 Patients with Coronary Heart Disease Treated with a Very Low-Fat Diet

小门 有限的 生生无少 用的词	Mean (SD)	Median	Range			
Cholesterol, mg/dL	132.4 (12.89)	135.7	109.9 to 149.9			
HDL, mg/dL	36.3 (7.34)	33.5	28.1 to 52.5			
LDL mg/dL	71.6 (12.69)	72.3	48.5 to 91.0			
Triglycerides, mg/dL	146.6 (84.11)	117.4	72.3 to 362.5			
VLDL mg/dL	24.4 (11.97)	20.0	12.8 to 52.9			
Weight, lb	163.7 (23.30)	165.6	122.3 to 194.1			
SBP, mm Hg	111.5 (8.60)	111.7	98.3 to 124.4			
DBP, mm Hg	67.4 (4.17)	66.1	61.2 to 76.1			

SD denotes standard deviation; HDL, high-density lipoprotein cholesterol; LDL, lowdensity lipoprotein cholesterol; VLDL, very-low-density lipoprotein cholesterol; SBP, systolic blood pressure; DBP, diastolic blood pressure. underwent PTCA 20 months into the study. The artery restenosed 12 months later, and he underwent a second angioplasty. An angiogram 22 months later showed no restenosis. This lesion was not included in the analysis.

A 64-year-old man began the study 2 weeks after an anterior myocardial infarction that occurred during an unsuccessful angioplasty. Severe left ventricular dysfunction was documented on an angiogram 7 months later. A thallium test confirmed anterior myocardial ischemia, and he underwent coronary artery bypass surgery. Four and one-half years into the study, four lesions remote from the bypass were examined angiographically. Two of the lesions were unchanged and two had regressed. The left ventricular ejection fraction was estimated to be less than 20%. The patient died of cardiac arrhythmia 10 months later, and no new occlusions or infarctions were found at autopsy.

Analysis of Dropouts and Those Not Completing the 5-Year Follow-up

Of the initial 22 participants, 11 left the study within the first 2 years: 3 moved from the area; 4 were employed in jobs that prevented them from making regular clinic visits, 2 of whom returned to their prestudy diet; 3 were unable to maintain a very low-fat diet; and 1 patient who had stable angina and adhered to the diet underwent

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wpass surgery at another institution to eliminate his anina, which this highly competitive patient contended abilited his ability to play tennis aggressively.

Ten of these 11 patients were contacted by the primary investigator in 1995, 9 years after the study began. Five participants still adhered to the diet: two kept their erum cholesterol below 150 mg/dL (3.88 mmol/L), one to below 175 mg/dL (4.53 mmol/L), one had not had a cholesterol measurement for 7 years, and one had indergone elective coronary bypass surgery. These patents reported no new cardiac events. One patient who ontinued the study diet has not been heard from since 1992.

All five dropouts who resumed their prestudy diet reported new cardiac events. These included four inrances of increased angina, two episodes of ventricular achycardia, one coronary arterial bypass operation, one mgioplasty, one case of congestive heart failure, and one teach from complications of arrhythmia.

Current Participant Status

follow-up angiogram and lipid measurements were taken in 1992. In the 3 years since, other than the one death from arrhythmia, no new coronary events have been reported among these 10 participants. The remaining six participants also continue to follow the diet and drugmonitoring program and remain free of clinical progression of disease as they complete their 9th year of study. No accidents, suicides, cancer deaths, or aggressive behavior³³ have been observed in any participants.

Discussion

We studied the effect of a very low-fat diet and cholesterolowering drugs on the progression of coronary heart disase. All 11 participants were able to maintain a mean otal serum cholesterol level of 132.4 mg/dL (3.42 mmol/L), which is the lowest level reported to date for atients such as ours. In addition, our data suggest that maintaining total cholesterol levels below 150 mg/dL 3.88 mmol/L) is associated with the arrest of coronary rtery disease and appears to promote selective disease rgression. This is the longest study of minimal fat nutrition used in combination with cholesterol-lowering drugs onducted to date, and our finding of a mean decrease of rterial stenosis of 7.0% is greater than any reported in previous research.³⁻¹⁵

Although the sample was small, self-selected, and not andomly assigned to treatment, careful angiographic malysis by the percent stenosis method documented artest in 100% and regression in 73% of patients. Analysis by the MLD method revealed that 20 of 24 arterial lesions (83%) remained stable or regressed, whereas 4 lesions barely progressed. No new infarctions or clinical evidence of progression has occurred in any participant as of 1995. In contrast, these 11 participants had experienced 37 cardiovascular events in the 8 years before beginning the study, and the 5 dropouts who resumed their prestudy diet experienced an additional 10 cardiac events.

Although Ornish and colleagues6 have also reported successful arrest and reversal of coronary artery disease with lifestyle changes and less than 10% fat nutrition, others have analyzed more modest low-fat diets used in combination with drugs and achieved only partial success.^{3-5,7-15} If the ultimate goal of treatment is total arrest of heart disease, it appears that the combination of less than 10% fat nutrition and cholesterol-lowering drugs is most likely to achieve the greatest reduction in serum lipids. A recent report indicates that the lowest incidence of coronary events and mortality is associated with cholesterol levels of 140 mg/dL (3.62 mmol/L) or below.33 Our participants lowered their total serum cholesterol by 46%, to a mean of 132.4 mg/dL (3.42 mmol/L), and their LDL to a mean of 71.6 mg/dL (1.85 mmol/L), values lower than previously reported, and, furthermore, participants experienced no new coronary events. The mean serum triglyceride level during the study period was 146.6%.

Gould³³ and others^{34–36} recently emphasized the importance of lowering cholesterol levels to restore endothelial-mediated coronary vasodilation. These data confirm that low cholesterol levels are essential to restoring endothelial integrity over large and small plaques to protect against rupture, thrombosis, and infarction. The results of our study in achieving and maintaining a total serum cholesterol level below 150 mg/dL (3.88 mmol/L) suggest that changes in the functional status of the arterial wall may be more important in decreasing coronary events than is reducing the degree of stenosis.

In a recent editorial, Roberts³⁸ further emphasized the importance of maintaining serum cholesterol level below 150 mg/dL (3.88 mmol/L) because a high cholesterol level is the single most important and perhaps the solitary risk factor in the genesis of coronary atherosclerosis. Of additional interest is the average HDL value of 36.3 mg/dL (0.94 mmol/L) of our participants. Although this value is below the accepted normal range (45 to 55 mg/dL [1.16 to 1.42 mmol/L]), it was sufficient to sustain these beneficial results. Because this report is the first on the effects of long-term diets containing less than 10% fat coupled with the use of cholesterol-lowering drugs, other studies are necessary to confirm these results.

Participants' Experience in Adopting the Diet

In general, participants were initially excited about a new form of therapy for which epidemiologic studies and research indicated great promise. Their early difficulty recognizing acceptable no-fat foods and dealing with the constant challenge of redesigning most traditional choices at every meal was offset by their initial weight loss, improved feeling of well-being, and decreasing angina. At the time when "no fat" labeling was first permitted, patients began buying foods labeled "0 fat per serving." By law, such foods may, and most often do, contain just less than 0.5 g of fat per serving. Because this amount of hidden fat is still too much, these foods should be omitted from very low-fat diets. A list of fat-free recipes taken from low-fat cookbooks and other resources on weight loss, cardiac health, and healthy lifestyle changes18-26 was given to each participant. In the early phases, the group support was especially helpful and solidified participants' resolve. For the initial several months, the constant challenge of shopping for appropriate foods and finding appropriate menus was a major focus.

Factors Contributing to Patients' Long-term Success

Of the original 22 patients, 73% (16) continue to follow the nutritional guidelines. Therefore, we believe that patients with coronary artery disease are willing and able to follow a diet so devoid of fat, and some may become independent of assistance and surveillance once they have achieved the goal for cholesterol level. Evidence from the Monel Chemical Senses Center, which studied three groups of volunteers who consumed different levels of dietary fat,³⁹ confirms our findings. In the Monel study, only the patients whose diet contained less than 15% of calories from fat lost their desire for fat after 90 days. Our patients received intense social support through the initial 90-day period, and they, too, lost their craving for fat. They can now travel away from home for weeks at a time while still adhering to the diet.

The participants' success in adhering to the dietary and pharmaceutical intervention can be also attributed to at least two other factors. First, the physician had also adopted the diet and was thus a consistent role model for the participants. He actively involved himself in their care through frequent personal contact over a period of years and through periodic semisocial meetings that centered around the treatment plan. His personal investment in the success of his participants was clear to them. He was a credible source of information and was supportive of their efforts, especially through the more difficult initial stages of the study. Second, evidence suggests that interventions will be most effective when (1) the threat of death or major disability is high, (2) the participant is convinced that the threat is real and eminent, (3) the proposed intervention will remove the threat (response efficacy), and (4) the participant is capable of adopting the intervention (personal efficacy).⁴⁰

The first two points, which are related to a high-risk and eminent threat of cardiac disease, were established by the time the participants entered the study. The third point, response efficacy, and the fourth, personal efficacy, were the purposes of the study. With time, participants became more comfortable with their diet and their symptoms improved, which provided evidence of both response and personal efficacy. As the incidence of angina lessened, for example, participants became aware that they were feeling better for the first time in years, and they attributed this improvement to the treatment and their ability to stay with the treatment. For these patients, health became its own reward.

Implications of Our Findings

Our findings support studies that together suggest the need to reassess existing therapies for coronary artery disease and atherosclerosis.41,33 The present treatments of beta blockers, calcium channel blockers, pacemakers, thrombolytic therapy, atherectomy, angioplasty, stenting, and bypass surgery carry significant morbidity, mortality, and expense, and are essentially temporary "holding ac tions." Although further research is needed on minimal fat intake and cholesterol-lowering drugs, it would seem prudent to offer these modalities as an adjunct therapy for cardiac patients who are not enrolled in such studies. Patients incur little additional expense, except for the cholesterol-lowering agents. No known morbidity or mortality is associated with the decreased fat intake, although the drugs may have side effects. We made no attempt to determine the contribution of the cholesterollowering medications to the total reduction of serum cholesterol levels. All the participants continue to take these medications as well as to follow the diet.

Is there a need for aggressive cholesterol-lowering therapy? Gould³³ notes that many cardiac patients are aware and desirous of such treatment but cannot find practitioners willing or able to provide it. It is difficult to know the number of patients in any individual practice who would qualify for such treatment. All patients with coronary artery disease are potential candidates and should be made aware of the opportunity for such therapy. Patients with progressive but not immediately lifethreatening coronary artery disease are often very motivated and make ideal candidates.

What components of this experience can be modified application in other clinical practices? Of the four therence strategies mentioned, the bimonthly evening hone call and group meetings could conceivably be acomplished by a physician assistant. Because the group meets only quarterly, many practitioners should, howver, be able to attend. It is vital that the physician conhet the initial interview with the patient and spouse to mlain the natural history of coronary artery disease, its midemiology, and the animal and human research data mfirming arrest and reversal, and to instill the idea that inimal fat nutrition is the hallmark of therapy. The binonthly clinic visits to determine weight and blood presme, to review the diet diary, and to measure total serum holesterol can be conducted by a nutritionist, nurse, or ealth care worker, with physician input in selective or hallenging cases. These visits are more frequent than ther treatment protocols, which are usually quarterly, ut confirm for the patient that dietary adherence is the edrock of success of this type of treatment and, also, its nost vulnerable aspect. An authoritative, caring, yet unompromising figure regarding dietary adherence is vital these visits. Creative appointment schedules that offer erv early, very late, evening, or Saturday appointments Il minimize absenteeism. The cost of total serum chosterol determinations can be reduced by employing a wroducible fingerstick method and extending visits to mce a month for those whose cholesterol goals have been ttained. Follow-up angiograms are probably unnecessary instable patients.

Conclusions

It the outset of this study in 1985, patients were told that his type of program might work because of its success in mimal studies,² but the more recent investigations that onfirm and illustrate its success in humans cannot be weremphasized.^{3–15} Although quality-of-life measurements were not a part of this study, all patients indicated cs fear of relapse and increased confidence. As they comlete a disease-free decade, these patients are empowered by the knowledge that they are in control of the disease that was destroying their lives.

When total serum cholesterol is maintained at less han 150 mg/dL (3.88 mmol/L) with less than 10% fat make and cholesterol-lowering drugs, this treatment apvars to treat not only the symptoms but the cause of teart disease and to prevent its clinical progression, as remonstrated in 100% of the 16 adherent patients in this mudy. The techniques needed to implement this treatment can be applied in most practices.

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