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wissen, ob es ein Gen gibt, daß den Namen „Ökonomie-Gen" verdient. Heute ist es noch nicht möglich, eine Prognose über die zukünftige Identifikation eines solchen Genes abzugeben. Auf alle Fälle haben zahlreiche Studien der letzten Jahre erlaubt zu zeigen, daß es tatsächlich eine genetische Basis der Fettsucht gibt. Diese Studien wurden an Familien von Fettleibigen, an Zwillingspaaren, die unterschiedlichen Ernährungen ausgesetzt wurden, und an adoptierten Kindern realisiert.

Zur Zeit werden Methoden der Molekularbiologie und der Molekulargenetik in verschiedenen Laboratorien angewandt. Das Problem wird dabei aus zwei verschiedenen Blickwinkeln angegangen. Der erste Ansatz basiert auf einer Studie von bekannten Genen, die eine Rolle im Lipidstoffwechsel spielen. Der zweite Ansatz besteht darin, Individuen auszuwählen, die wahrscheinlich Träger des oder der Gene(s) der Fettleibigkeit sind und zu versuchen, das oder die unbekannte(n) Gen(e) zu charakterisieren. Vergleichbare Studien werden bereits an Ratten und Mäusen, die eine genetisch bedingte Fettleibigkeit aufweisen, durchgeführt. Es wird jedoch zweifellos noch mehrere Jahre dauern, bis die entscheidenden Arbeiten realisiert sein werden und man wissen wird, ob die Hypothese eines „Ökonomie-Genes" gerechtfertigt war.

Danksagung

Für die Übersetzung ins Deutsche möchte ich mich bei Dr. *Susanne Klaus* bedanken.

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The Impact of Major Lifestyle Changes on Coronary Stenosis, CHD Risk Factors, and Psychological Status: Results from the San Francisco Lifestyle Heart Trial*

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Background Studies

The results presented here today from the San Francisco Lifestyle Heart Trial are based upon results from two previous trials using lifestyle changes with heart patients. The first investigation was a pilot study with a one-group, pre-post design of 10 patients who lived one month in a hotel in Houston, Texas. To assure daily adherence to the lifestyle changes, all patients' meals (vegetarian, low fat) were provided and stress management techniques (stretching, breathing, relaxation, visualization, and meditation) were conducted in the hotel. After one month, patients showed significant reductions in blood pressure, plasma cholesterol and triglyceride, and frequency of chest pain. Two of four patients with abnormal exercise thallium scans at baseline showed clear improvements in myocardial perfusion after one month (1).

These results were sufficiently encouraging to initiate a new study adding a usual-care control group and randomization into two groups. The experimental patients were fed a low-fat vegetarian diet and were taught the stress management techniques in a rural retreat for 24 days. Both medical and psychological measures were taken at baseline and 24 days later. While the experimental and control groups did not differ at baseline, after 24 days experimental patients had statistically significant improvements in blood pressure, serum cholesterol levels, frequency of angina, total work performed, total duration of exercise, global left ventricular ejection fraction response, and regional wall-motion response to exercise. Experimental patients also were significantly less depressed and anxious and reported less insomnia. The control group did not change significantly on these measures (2).

Current Clinical Trial

The third study (3), which I will present today, was designed with the aims of assessing whether:

1. lifestyle changes initiated in a retreat could be maintained on an ambulatory basis over a prolonged period
2. lifestyle changes could halt or reverse coronary artery stenoses assessed by quantitative coronary arteriography
3. lifestyle changes would have a favourable impact on a set of psychosocial factors that are believed to be related to CHD
3. adherence to the lifestyle changes were correlated with coronary atherosclerosis
4. adherence to the lifestyle changes were correlated with capacity
5. lipid levels were related to atherosclerosis

Design and Patients: To achieve these aims we used an individual randomized invitational design with one group receiving comprehensive lifestyle changes and the other group making only moderate lifestyle changes that were prescribed by their physicians. Patients were recruited into the study after they had undergone a catheterization for suspected coronary heart disease in two San Francisco hospitals. A nurse in each cardiac catheterization laboratory screened all patients for eligibility criteria and, if a patient was eligible, asked the cardiologist performing the angiogram to follow the quantitative coronary angiography protocol. All cardiologists agreed to follow the quantitative protocol. The patients under study consisted of male and female San Francisco Bay Area residents, ages 40 to 74 years. Patients were excluded who had a myocardial infarction during the preceding six weeks, had other life-threatening illnesses, were scheduled for coronary artery bypass grafting or angioplasty, had a history of receiv-

* The findings from this study originated from the collaboration of a distinguished research team including the principal investigator Dr. Dean Ornish, a co-principal investigator Dr. Shirley Brown, two cardiologists in charge of cardiac angiograms Dr. William Armstrong and Dr. Thomas Ports, a stress management instructor. Dr. Sandra. McLanahan, a clinical psychologist, Dr. Jim Billings, a cardiologist, Dr. Lance Gould, a physicist in charge of the quantitative angiography. Dr. Richard Kireeide, and a senior biostatistician, Dr. Richard Brand.

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ing streptokinase or t-PA, or were under treatment with lipid-lowering drugs. If patients had undergone prior percutaneous transluminal coronary angioplasty or coronary artery bypass surgery, they must have had at least one measurable lesion in a non-dilated or non-bypassed coronary artery. Of these 96 eligible patients during the recruitment period, 53 were invited to the experimental group, of whom 28 volunteered (53%), and 43 were invited to the control group, of whom 20 volunteered (47%).

Measures: In addition to quantitative coronary angiography before patients made lifestyle changes and after one year, each patient had PET scans, lipid profiles, Thallium exercise stress tests, and measures of blood pressure, weight, and angina frequency, duration, and severity. Also psychosocial measures were chosen based upon past research indicating that these may be associated with CHD. Global Type A behavior, particularly the hostility component, has been related both to CHD incidence and to severity of disease (4–9). Measures of mood states, including state and trait anger, anxiety, and depression, have also been related to CHD (10). Sense of coherence, as a measure of the extent to which individuals see their lives as comprehensible, manageable, and meaningful (11), is hypothesized to be related to constructive interpretation and coping with potentially stressful situations (12, 13).

Lifestyle Change Intervention

Overview: The lifestyle change program was implemented with 28 patients. Our strategy was to see what effects could be obtained with very substantial changes in diet, stress, exercise, and social support. The rationale was that if this combined program of substantial changes did not halt or reverse coronary atherosclerosis, we would more definitively know that the lifestyle change approach is not effective than we would have if we had made fewer or more modest changes. We did not want to be left wondering whether we had done enough.

Diet, exercise, stess management, and smoking cessation were selected as lifestyle components because we think they all could affect coronary blood flow. For example, mental stress can induce vasoconstriction, diet can affect blood viscosity, platelet stickiness, as well as cholesterol levels, and exercise can improve the efficiency of oxygen uptake as well as improve stamina. There is also good evidence that cigarette smoking reduces the oxygen, carrying capacity and increases catecholamine secretion thus further restricting coronary blood flow. Because of the difficulty in halting or reversing coronary heart disease, we felt that a multifaceted approach would be more effective than a single factor approach.

Diet: Experimental-group patients were asked to consume a low-fat vegetarian diet for one year. The diet included fruits, vegetables, grains, legumes, and soybean products without caloric restriction. No animal products were allowed except for egg whites and one-half cup per day of non-fat milk or yogurt. The diet was approximately 10% fat (14 grams/day, P/S ratio >1), 15% protein, and 75% carbohydrates – predominantly complex carbohydrates. Cholesterol intake was limited to 5 mg/day or less. Salt was restricted only for those with hypertension. Alcohol was restricted to 2 oz. per day or equivalent (though it was completely excluded for anyone with a history of alcoholism), and caffeine was eliminated.

Stress Management Techniques: Patients were asked to practice a minimum of one hour of stress management per day. The stress management practices integrated stretching, relaxing, breathing, meditation, and imagery (2, 3). Each technique was presented as having the common purpose of increasing a patient's sense of relaxation, concentration, and awareness of internal states. Patients were taught a series of 12 yoga poses designed to stretch, tone, and relax the body and to help develop internal awareness (14). Participants were advised to stretch slowly and gently while focusing attention on the areas being stretched to avoid injury or strain. Between poses they were directed to relax. Afterwards, participants were taught a progressive relaxation technique of sequentially tensing and relaxing specific muscle groups. Following the progressive relaxation, they were taught three breathing techniques. After this, they were asked to sit in a comfortable upright position and to focus their attention (meditate) by repeating a non-sectarian or sectarian sound, phrase, or prayer chosen by each patient (15–17). Afterwards, patients were directed to choose and maintain an image (picture, sound, idea, or feeling) of a healthy heart. Patients were asked to practice these stress management techniques for at least one hour each day. We provided a professionally produced audio cassette of these stress management techniques to help maintain adherence at home.

Smoking Cessation: Two experimental-group patients smoked cigarettes at baseline, and they agreed to quit smoking when entering the study. Analyses for plasma cotinine from unannounced blood drawings were conducted during the year.

Aerobic Exercise: Patients were asked to exercise for a minimum of three hours per week and to spend a minimum of 30 minutes per session exercising within their target heart rates. Patients were individually prescribed exercise levels according to a baseline treadmill heart rate, MET level, and perceived exertion to reach a target training heart rate of 50–80% of their age-adjusted maximum heart rate or to 50–80% of the heart rate in which 1 mm of S-T depression occurred during baseline treadmill testing (18, 19). Poorly conditioned patients who did not have S-T segment depression were trained to maintain heart rate levels beginning at 50% of their maximum heart rate, and as they became more conditioned to work up to 65–80% of this maximum (20). Better conditioned patients were trained to maintain heart rates at 65–80% of their stress test maximum (18). Patients were also trained to identify exertional levels using the Borg Rate of Perceived Exertion scale and to maintain a heart rate at least 10 beats per minute below the rate in which 1 mm of S-T segment depression began during exercise stress testing (18).

Procedure for Implementing Lifestyle Changes

To acquaint patients and their partners with the lifestyle program, the treatment intervention began with a week-long residential retreat at a local resort hotel. Patientsspouses or partners were required to attend. During the retreat, patients and partners were taught the lifestyle program, including daily lectures on the rationale for the intervention (with topics including the effects of smoking, stress, diet, and exercise on the heart), nutrition lectures and cooking/shopping classes. Also, patients received three hours per day of stress management training and one hour per day of aerobic exercise according to individualized prescriptions based on treadmill test performance, and one hour per day of group support meetings led by a clinical psychologist.

Following the retreat, patients attended group support meetings on Tuesday and Thursday evenings for one year. At each session, from 5:00–6:00 p.m. was an exercise class, from 6:00–7:00 p.m. was a stress management class, from 7:00–8:00 p.m. was dinner (catered on Tuesday and potluck on Thursday), and from 8:00–9:00 p.m. was a support group discussion.

During the retreat, a cook prepared all meals eaten by the participants. After the retreat, the cook provided up to 14 take-home lunches and dinners each week for participants who requested these. On average, approximately one-half of total calories consumed were provided by these packaged meals; participants prepared the remainder of their meals.

In addition to diet, exercise, smoking cessation, and stress management, the program provided social support to patients, which we think is important for treating heart disease. In both epidemiological and clinical studies social support has been linked to better health status. For example, in the Alameda Conty study (21) (6,928 men and women living near San Francisco) and in the North Karelia Study (22) (13,301 men and women in Eastern Finland), those who were socially isolated had a two- to three-fold increased risk of death from both heart disease and from all other causes over five to nine years when compared to those who felt most connected to others. In a recent clinical study of 119 men and 40 women angiography patients, the more people felt loved and supported, the less coronary atherosclerosis they had at angiography, independent of other risk factors (23).

Lifestyle Program Results

Baseline Comparisons: All possible subjects ($n = 48$) were included in the data analyses. Forty-one subjects were available for the one-year angiograms. There were no baseline differences in demographic characteristics, functional cardiac status, lesion severity, cardiac history, blood pressure, or lipids between experimental and control groups, with one exception. Control patients had significantly higher levels of apolipoprotein A1 than the experimental group, but the total cholesterol/HDL cholesterol and LDL/HDL cholesterol ratios did not differ significantly between the groups at baseline. There were no significant baseline differences between the experimental and control groups in the psychosocial measures.

One-year Adherence: There were no significant baseline differences in exercise levels, dietary fat and cholesterol intake, or practice of stress management techniques. After one year the results indicated that all but one of the experimental group patients were motivated to make comprehensive changes in lifestyle for at least one year on a free-living basis. Patients in the experimental group reduced fat intake from 71.3 to 14.0 gm/day, and reduced percent of calories derived from fat from 31.5 to 6.8%. Experimental patients reduced their cholesterol intake from 233.1 to 15.8 mg/day. Control patients did not significantly change their fat intake (from 56.1 to 53.6 mg/day), their percent of calories derived from fat (from 29.3 to 29.4%), nor did they significantly change their cholesterol intake (from 195.0 to 184.5 mg/day).

Experimental patients increased their exercise from 20.2 to 37.22 minutes per day, and they increased their stress management practice from 6.3 to 77.7 minutes per day. The control patients remained steady with exercise (from 18.3 to 20.6 minutes/day), but had little stress management practice (from 1.76 to 4.3 minutes/day).

Program Benefits

Psychological Factors: Sense of coherence increased somewhat in the experimental group and decreased in the control group; the difference was highly statistically significant ($p = .002$). There was very little change in state anger in either group from baseline to the one-year follow-up. However, trait anger decreased significantly in the experimental group, but did not decrease at all in the control group ($p = .035$). Experimental group patients reported a little more social support, whereas the control group patients reported a little less after one year; the differences are almost statistically significant for the overall score and the component of instrumental social support, but not for the component of social support adequacy. The experimental group showed a very significant improvement in overall general well-being, while the control group changed very little.

Although the experimental group mean Type A behavior score decreased by nearly a full standard deviation, the control group mean decreased by half a standard deviation, so that the group difference, with this sample size, did not quite reach statistical significance. The experimental group decreased the time urgency Type A component only slightly more than the control group, but not significantly. However, the experimental group significantly reduced their hostility component more than the control group, which changed little ($p = .04$).

Lipid Changes: After one year treatment patients lowered their total cholesterol from 229 to 178 compared with a slight drop of 248 topa 229 for the control group ($p = .05$). Similarly LDL cholesterol dropped from 150 to 102 mg/dl in the treatment group compared with 167 to 157 mg/dl in the control group ($p < .01$). HDL cholesterol did not change in either group (treatment 39 to 37 mg/dl, control 52 to 51 mg/dl). The LDL/HDL ratio improved more in the treatment group than the control group (treatment 4.07 to 3.09; control 3.59 to 3.33) ($p = .005$). Although nonsignificant, triglyceride rose in the treatment group from 223 to 257 mg/dl but changed little for control patients (from 215 to 212 mg/dl).

Angina: The treatment patients improved more in each measure of reported angina experiences. In the treatment group the angina frequency dropped from 4.38 to .38 times/week after one year, but increased in the control group from 2.35 to 6.24 times/week, a significant difference ($p =$

.05). Similarly, the duration of angina attacks became shorter for treatment patients (from 2.29 to 1.31 minutes), and increased for control patients (from 3.47 to 6.79 minutes) ($p = .13$). The rated severity of chest pain decreased for treatment patients, from 1.10 to 0.54 (scale of 0 to 6; 0 = no pain at all, 6 = extremely painful), but increased in the control group, from 0.76 to 1.28 ($p = .0005$).

Exercise: Baseline comparisons using treadmill exercise indicated that the two groups did not differ in functional capacity. After one year treatment patients improved exercise capacity, whereas controls decreased exercise capacity ($p = .002$). Degree of overall program adherence was correlated with increased exercise capacity ($r = .32$; $p = .05$). Diet adherence was related to exercise capacity ($r = .42$; $p = .01$) as was stress management adherence ($r = .37$; $p = .03$), but surprisingly exercise adherence was not related to exercise capacity ($r = .11$; $p = .5$). However, exercise adherence was strongly related to increased exercise capacity for those with low functional capacity at baseline ($r = .5$; $p = .04$), but not for those with high exercise capacity ($r = .09$; $p = .75$), suggesting that exercise helped more for those in poorer physical condition. The results suggest that patients can maintain major lifestyle changes and that adherence to comprehensive changes improves exercise capacity greater than exercise alone.

Angiographic Results: The statistical analyses included 195 detectable lesions which were analysed by a mixed model analysis of variance using a BMDP3V statistical program. The average percentage diameter stenosis decreased from 40.0% (S. D. 16.9) to 37.8% (16.5) in the experimental group yet progressed from 42.7% (15.5) to 46.1% (18.5) in the control group ($p = .001$). When only lesions greater than 50% stenosed were analyzed, the average percentage diameter stenosis regressed from 61.1% (8.8) to 55.8% (11.0) in the experimental group but progressed from 61.7% (9.5) to 64.4% (16.3) in the control group ($p = .03$). Averaging the changes in all lesions for each patient, eighty-two percent of patients in the experimental group showed average changes in the direction of regression of coronary atherosclerosis, whereas 53% of patients in the usual-care group had changes in the direction of progression of atherosclerosis.

Adherence and Lesion Changes: Another important finding that gives us confidence that the lifestyle changes were instrumental in halting or reversing the coronary stenosis is that lifestyle changes were strongly correlated with changes in stenosis. Using the mixed model analysis of variance, the overall adherence was positively correlated with lesion changes ($p = .003$). More detailed analyses indicated that dietary cholesterol was significantly correlated with lesion changes ($p = .004$), stress management was correlated with lesion changes ($p = .07$), and exercise was correlated with lesion changes ($p = .006$). Thus, each a spect of the program was correlated with lesion status. Unfortunately, we do not have a large enough sample size to conduct multivariate analyses to determine if the lifestyle components' effects on stenosis are independent of one another. However, they appear to work in concert with more change for each component resulting in more blood flow.

Conclusions

Patients can be motivated to make comprehensive lifestyle changes in a real-world environment. We were under no illusions that this is easy to do. Beginning the lifestyle changes with an intensive retreat, we used the patients' mutual support and continuous instruction to maintain adherence. But the patients' perceptions of their own and other patients'improvement in all areas was perhaps the most important factor for long-term adherence. Most patients' chest pains disappeared entirely. In addition, their appearance improved as they lost weight, their flexibility, breathing capacity, and exercise tolerance increased as they did the stress management and aerobic exercises, and their sense of well-being increased with the relaxation and meditation techniques. The questionaire and interview results indicated that the patients' psychological status improved as much as their cardiovascular status. Those in the lifestyle change group were observed to be less hostile, and they rated themselves as chronically less angry, less depressed and less anxious, and as being able to sleep better. Moreover, the patients' sense of coherence increased significantly over the control group. They perceived their lives as being more comprehensible, more manageable, and more meaningful. And not only did the patients experience these subjective benefits in themselves, but they also saw these benefits in other patients, which was encouraging for them.

The patients also had objective evidence of physical improvement including dramatic reductions in total cholesterol, LDL cholesterol, and apolipoprotein B after one year, without using lipid-lowering drugs. The treadmill results indicated that treatment patients increased their exercise tolerance.

The most exciting finding is that after one year patients in the lifestyle-change group demonstrated significant overall improvement of coronary artery blood flow, whereas patients in the ordinary-care group demonstrated overall progression of coronary stenosis. The strong correlation between adherence and coronary stenosis improvement suggests that each of the lifestyle components is related to improvement, and that together they have a bigger impact than does one factor alone. While the sample is small and one must be careful in making generalizations, the results indicate that in patients who are prone to developing coronary atherosclerosis a dramatic change in lifestyle can halt and even reverse the progression of disease.

However, a dramatic change in lifestyle does not appear to be required to begin to confer benefits on the heart. Our results strongly suggest that a threshold is not required before the progression is affected. Rather, in the men at least, a little change in diet and exercise appears to slow the disease down a little. While we cannot be definitive with only five women, they all did not require as much lifestyle changes to reverse their disease. All five women had evidence of reversal of disease despite only moderate lifestyle changes. These results raise the possibility that moderate changes in lifestyle may be sufficient in preventing atherosclerosis among those less prone to the disease.

Although more research has to be done to extend and replicate the results, the findings provide hope for treating heart disease. The therapy can work in conjunction with conventional forms of treatment, and there were no side effects of making lifestyle changes. unlike most therapies for heart disease which are very expensive, the lifestyle change approach, once learned and adhered to, can actually save the patient money. A vegetarian diet can easily be less expensive than a non-vegetarian diet, quitting smoking saves money, and there is very little cost required to walk or do the stress management techniques. What will be required, however, is a skilled and compassionate staff which is willing and able to intensively train and encourage patients and their partners.

We hope these findings will stimulate other researchers to further investigate the potentials of this kind of program for treating heart disease as well as other diseases. Clearly, the findings from our three trials need to be extended to other populations and we need to know whether other research teams can gain and maintain adherence to lifestyle changes.

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