Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project

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The Multicenter Lifestyle Demonstration Project was designed to determine if comprehensive lifestyle changes can be a direct alternative to revascularization for selected patients without increasing cardiac events. A total of 333 patients completed this demonstration project (194 in the experimental group and 139 in the control group). We found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable with what can be achieved with revascularization.
Am J Cardiol 1998;82:72T–76T

The idea that the progression of coronary artery disease is often reversible was once a radical concept but now has become mainstream, as these proceedings clearly demonstrate. A number of interventions have been shown to arrest or reverse the progression of coronary atherosclerosis, many of which have been detailed in this symposium. These include comprehensive changes in diet and lifestyle,[1–3] lipid-lowering drug therapy,[4–6] partial ileal bypass surgery,[7] and parenteral nutrition.[8]

Approximately 500,000 coronary artery bypass graft (CABG) operations and approximately 600,000 percutaneous transluminal coronary angioplasties (PTCAs) were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. The cost of treatment of coronary artery disease (CAD) in the United States was estimated to be $56.3 billion in 1994.[9] Thus, there is a potential for significant cost savings if safe and comparably effective, but less expensive, alternative interventions can be implemented.

The Multicenter Lifestyle Demonstration Project was designed to determine (1) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow a program of comprehensive lifestyle changes; (2) if this lifestyle program may be an equivalently safe and medically effective but more cost-effective alternative to revascularization in selected patients with severe but stable coronary artery disease; and (3) what the resulting cost savings might be. In other words, can patients avoid revascularization by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

Earlier studies demonstrated that the progression of even severe coronary artery disease often can begin to reverse in many patients by an intensive, multifactorial program of comprehensive lifestyle changes. These lifestyle changes include a very low-fat, low-cholesterol diet (approximately 10% fat, <10 mg/day dietary cholesterol, a whole-foods vegetarian diet high in complex carbohydrates and low in simple sugars), stress management techniques, moderate exercise, and psychosocial support. Endpoint measures included quantitative coronary arteriography to assess coronary artery stenosis and cardiac positron emission tomography to assess myocardial perfusion.[2,10]

In the past, insurance companies, managed care organizations, and Medicare have been reluctant to pay for lifestyle interventions, in part because these have been viewed as prevention—increasing costs in the short run for a possible savings years later. Also, since approximately 20–30% of patients change their insurance plans each year, even if cost savings result from lifestyle interventions, they may accrue to another insurance company.

However, a program of comprehensive lifestyle changes may be offered as a much less costly alternative treatment to revascularization for selected patients who are eligible for CABG or PTCA (under the supervision of the referring physician), thereby resulting in immediate and substantial cost savings.

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive CABG or PTCA may result in significant long-term cost savings. Despite the expense of bypass surgery and angioplasty, 30–50% of bypass grafts reocclude after only 5–7 years, and 30–50% of angioplastied arteries restenose after only 4–6 months.[11,12] When this occurs, then bypass surgery or angioplasty is often repeated, thereby incurring additional costs.

CABG is effective in decreasing angina and improving cardiac function. However, when compared with medical therapy and 16 years of follow-up, CABG improved survival only in a very small subgroup of patients: those with decreased left ventricular function and stenotic lesions of the left main coronary artery of >59%. Median survival was not prolonged in patients with left main coronary artery stenosis <60% and normal left ventricular function, even if a significant right coronary artery stenosis >70% was also present.[13–16]

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0002-9149/98/$19.00
PII 0002-9149(98)00744-9

PTCA was developed with the hope of providing a less invasive, lower-risk approach to the management of coronary artery disease and its symptoms. Although widely utilized, PTCA has never been compared with medical therapy in a randomized trial in stable patients with coronary artery disease; therefore, the mortality and morbidity benefits of PTCA are unknown.

The use of various types of stents (the insertion of a mesh brace into the lumen of the coronary artery during angioplasty) may slow the rate of restenosis, but there are no randomized controlled trial data supporting the efficacy of these approaches. The use of the left internal mammary artery in bypass surgery may reduce reocclusion, but vein grafts also must be used when patients have multivessel disease. Thus, in addition to the costs of the original bypass or angioplasty, there are costs of further procedures when restenosis and reocclusion occur.

The majority of adverse events related to coronary artery disease, myocardial infarction, sudden death, and unstable angina are due to the rupture of an atherosclerotic plaque of <40–50% stenosis. This often occurs in the setting of vessel spasm and results in thrombosis and occlusion of the vessel.[17] CABG and PTCA usually are not performed on lesions <50% stenosed and do not affect nonbypassed or nondilated lesions, whereas comprehensive lifestyle changes (or lipid-lowering drugs) may help stabilize all lesions, including mild lesions (<50% stenosis). Also, mild lesions that undergo catastrophic progression usually have a less well-developed network of collateral circulation to protect the myocardium than do more severe stenoses.

Bypass surgery and angioplasty have risks of morbidity and mortality associated with them, whereas there are no significant risks from eating a well-balanced low-fat, low-cholesterol diet, stopping smoking, or engaging in moderate walking, stress management techniques, and psychosocial support.

ASSESSING COSTS OF LIFESTYLE CHANGE

Thousands of dollars are saved immediately for every CABG candidate who can avoid the procedure by making intensive changes in diet and lifestyle. However, cost savings in avoided revascularization will occur only if patients who are trained in this lifestyle program adhere to it over time. If patients do not adhere, costs would increase rather than decrease because insurers would end up paying for both lifestyle training and subsequent revascularization. The missing link, therefore, are the data to demonstrate whether patients will adhere to this intensive lifestyle program. We wanted to determine whether patients who are motivated to make comprehensive lifestyle changes can maintain these changes in an ambulatory setting if given the proper support.

To address this question, we began the Multicenter Lifestyle Demonstration Project in 1993 at 8 sites. Also, we have trained practitioners at.0001 additional sites whose data are not included here. These sites are geographically, socioeconomically, racially, and culturally diverse. Approximately 40 insurance companies are now reimbursing at least part of the cost of this program at these sites for selected patients.

We trained teams of health professionals at each of these clinical sites, including cardiologists, registered dietitians, exercise physiologists, psychologists, chefs, stress management specialists, registered nurses, and administrative support personnel. These teams, in turn, worked with their patients to motivate them to make and maintain comprehensive lifestyle changes.

Patients were selected who had angiographically documented coronary artery disease severe enough to warrant revascularization and who were approved for insurance indemnity to undergo a procedural intervention.

In addition, patients were excluded for any of the following: (1) >50% stenosis in the left main coronary artery; (2) CABG within 6 weeks or angioplasty within 6 months; (3) chronic unresponsive congestive heart failure; (4) malignant uncontrolled arrhythmias; (5) myocardial infarction within 1 month; (6) homozygous hypercholesterolemia; (7) psychosis; (8) hypotensive response to exercise; (9) alcohol or drug abuse; and (10) life-threatening comorbidity.

Patients and staff met 3 times per week for 12 weeks plus once per week for the remaining 9 months. Most sessions were 4 hours long: 1 hour of exercise, 1 hour of stress management techniques, 1 hour of group support, and a 1-hour meal. The cost of the 1-year program averaged $7,000 per person. (Shorter and less-expensive versions of the program are now available for people with less severe coronary artery disease.)

All hospitals sent data directly to the independently funded data coordinating center at the Massachusetts General Hospital. Matched control-group patients were provided by Mutual of Omaha. Patients were matched for age, gender, left ventricular ejection fraction (<25%, 25–40%, or >40%), and cardiac score defined as the sum of the severity score for each of the 3 main coronary arteries rated as 0 (<50% stenosis), 0.5 (50–75% stenosis), or 1.0 (>75% stenosis). All control group patients were within 1 month of having undergone revascularization.

Although a randomized controlled trial intervention comparing comprehensive lifestyle changes with revascularization may seem ideal, it is not feasible in practice. The attitude of someone willing to make comprehensive lifestyle changes is often quite different from that of someone who wants to undergo revascularization. The decision to make comprehensive lifestyle changes requires commitment, discipline, and a willingness to assume personal responsibility for one's health. The decision to undergo revascularization is often made by patients who want the doctor to "fix" them—the other end of the personal responsibility spectrum. This is not a value judgment, only a reflection of different approaches, both of which may be valid. To be randomized, a patient has to be willing to undergo either treatment (revascularization or comprehensive lifestyle changes). Since the mindset is so different, it would be very difficult to find patients

who were willing to accept either choice determined by someone else; most patients want to choose one or the other for themselves.

Baseline demographics: A total of 333 patients completed this demonstration project. Of these, 194 were in the experimental group and 139 were in the control group.

At baseline, there were no significant differences between the experimental group and control group in age, gender, marital status, employment status, or history of hypertension, hypercholesterolemia, diabetes, smoking, or family history of heart disease. In the experimental group, the average age was 58 years, 79% were male, and 77% were married. Of particular note is that 63.5% of these patients were currently working yet were able to find time to adhere to the intervention of comprehensive lifestyle changes. Furthermore, 50% were hypertensive, 62% had hyperlipidemia, 19.6% had diabetes, 66% had smoked cigarettes, and 58% had a family history of heart disease. Finally, 54% of the experimental group patients and 32% of control group patients were taking lipid-lowering drugs.

Angiographic severity of coronary artery disease was comparable in both groups. However, 55% of experimental group patients had a prior myocardial infarction compared with only 28% in the control group; also, experimental group patients had a longer history of coronary artery disease than those in the experimental group. Taken together, these factors may bias toward higher morbidity for the experimental group than the control group during the demonstration project.

Adherence and changes in risk factors: These adherence data, changes in risk factors, and a more detailed description of the demonstration project will be described in greater detail in a forthcoming article. Not all patients completed adherence questionnaires; the validity of our adherence data depends on the assumption that the patients who did not provide follow-up data had the same adherence as those who did. If patients who had low adherence were more likely to avoid follow-up, then the adherence rates that we estimated would be overly optimistic.

RESULTS

In brief, patients exercised an average of 1.6 hours/week at baseline, increasing to 3.9, 3.5, 2.9, and 2.7 hours/week at 3 months, 1 year, 2 years, and 3 years, respectively. Patients practiced stress management techniques an average of 0.19 hours/week at baseline and 4.5, 2.6, and 2.0 hours/week at 1 year, 2 years, and 3 years, respectively.

Based on the results of 3-day diet diaries, the percentage of total calories as dietary fat was 6.5%, 6.8%, 7.4%, and 8.3% after 3 months, 1 year, 2 years, and 3 years. The cholesterol intakes for these 4 time periods were 14.1, 19.0, 22.7, and 25.7 mg/day.

Low-density lipoprotein (LDL) cholesterol levels decreased from a mean of 122.9 mg/dL at baseline to 106.1 mg/dL after 3 months ($p < 0.0001$), 104.2 mg/dL after 1 year ($p < 0.0001$), 107.5 mg/dL after 2 years ($p < 0.0001$), and 101.7 mg/dL after 3 years ($p < 0.0001$). Total cholesterol decreased from a mean of 202.0 mg/dL at baseline to 183.7 mg/dL after 3 months ($p < 0.0001$), 182.6 mg/dL after 1 year ($p < 0.0001$), 187.3 mg/dL after 2 years ($p < 0.0001$), and 183.4 mg/dL after 3 years ($p < 0.0001$). Thus, reductions in LDL and total cholesterol levels were maintained throughout the 3-year interval, although the lifestyle intervention was only 1 year long.

High-density lipoprotein (HDL) cholesterol levels initially decreased from 36.7 mg/dL to 32.8 mg/dL after 3 months ($p < 0.0001$) and to 36.1 mg/dL after 1 year ($p = 0.120$) but increased to 40.1 mg/dL after 2 years ($p < 0.005$) and increased to 42.2 mg/dL after 3 years ($p = 0.001$). Triglycerides initially increased nonsignificantly from 229.8 mg/dL to 235.7 after 3 months ($p = 0.494$), but stabilized after 1 year to 228.8 ($p = 0.946$) to 213.0 ($p = 0.607$) to 200.8 after 3 years ($p = 0.339$). These changes in HDL-cholesterol and triglyceride levels are particularly relevant in light of recent controversies in this area.[18]

Mean weight decreased from 187.3 lb at baseline to 178.0 lb after 3 months ($p < 0.0001$), to 177.0 lb after 1 year ($p < 0.0001$), to 176.6 after 2 years ($p < 0.0001$), to 179.9 lb after 3 years ($p = 0.007$). Long-term reductions in weight are unusual.[19] Percent body fat decreased from 25.7% at baseline to 22.9% after 3 months ($p < 0.0001$), to 21.3% after 1 year ($p < 0.0001$), to 22.4% after 2 years ($p < 0.0001$), to 23.4% after 3 years ($p = 0.134$).

Exercise capacity increased from 9.59 METS at baseline to 11.15 after 3 months ($p < 0.0001$), to 11.66 after 1 year ($p < 0.0001$), to 10.88 after 2 years ($p < 0.0001$), to 11.03 after 3 years ($p < 0.0001$).

CAN PATIENTS SAFELY AVOID REVASCULARIZATION?

We found that 150/194 of experimental-group patients were able to avoid revascularization and the frequency of adverse cardiac events was not increased. The number of cardiac events per patient-year of follow-up when comparing the experimental group with the control group was as follows: 0.012 versus 0.012 for myocardial infarction (p = not significant), 0.014 versus 0.006 for stroke (p = not significant), 0.006 versus 0.012 for noncardiac deaths (p = not significant), and 0.014 versus 0.012 for cardiac deaths (p = not significant).

As described above, a primary benefit of revascularization is reduction of angina. In the Multicenter Lifestyle Demonstration Project, we used a very conservative measure of angina: no angina at all in during the prior 30 days. For example, if a patient who had frequent angina at baseline—as many as 10 episodes per day—had even 1 episode in the prior 30 days, then the patient was still considered to have angina.

Of the experimental group patients who reported angina at baseline, 49% had no chest pain during the prior 30 days after 3 months, 65% had no chest pain during the prior 30 days after 1 year, 61% had no chest pain during the prior 30 days after 2 years, and 61% had no chest pain during the prior 30 days after 3

years. These reductions in angina are comparable with what can be achieved with revascularization but without the morbidity and costs.

As noted above, the average cost of the 1-year intensive lifestyle intervention was $7,000. The average cost for PTCA (with cardiac catheterization) was $31,000 and for CABG was $46,000. All of the experimental group patients were eligible for revascularization both by medical criteria and by reimbursement criteria from Mutual of Omaha. However, only 31 PTCAs were performed on the 194 experimental group patients (0.064 events per patient-year of follow-up) and 26 CABGs were performed on the 194 experimental group patients (0.053 events per patient-year of follow-up) after entry. Thus, the costs in the experimental group were: $(31 \times \$31{,}000) + (26 \times \$46{,}000) + (194 \times \$7{,}000) = \$3{,}515{,}000$, or an average cost of $18,119/patient.

All of the 139 control group patients were selected for having had a recent PTCA or CABG before entry: 66 underwent PTCA, and 73 underwent CABG. In addition, there were 23 PTCAs and 11 additional CABGs in the control group after entry. Thus, the costs in the control group were: $(66 \times \$31{,}000) + (23 \times \$31{,}000) + (73 \times \$46{,}000) + (11 \times \$46{,}000) = \$6{,}623{,}000$, or an average cost of $47,647/patient.

The average savings per patient, therefore, were: $\$47{,}647 - \$18{,}119 = \$29{,}529$. This number is a conservative estimate, since 8 experimental group patients who had a PTCA after enrolling had ≥1 additional PTCAs or CABGs during the study. Restenosis within 6 months following PTCA is a failure of the angioplasty rather than intensive lifestyle changes, yet we counted all procedures in this cost analysis, even PTCAs occurring within 6 months after a prior PTCA.

There is no way to know with certainty how many of the patients who were eligible for revascularization actually would have undergone revascularization in the absence of the lifestyle program. Whether or not a patient undergoes revascularization is a function of many factors, including disease severity, patterns of practice in the local community, individual preferences among cardiologists and cardiac surgeons, and method of reimbursement. Revascularization rates tend to be much higher when reimbursed on a fee-for-service basis than on a capitated basis. One of the sites in our demonstration project, for example, performed more angioplasties (17) than the other 7 hospital sites combined (14).

Given the large cost differential between the cost of revascularization and the cost of the year-long lifestyle intervention program, it would have been cost-effective to offer comprehensive lifestyle changes even if only 18% of patients who were eligible for revascularization actually would have had it in the absence of this program.

In practice, we believe that patients with coronary artery disease should be offered a range of therapeutic options, including comprehensive lifestyle changes, medications (including lipid-lowering drugs), angioplasty, and bypass surgery. The physician should explain the relative risks, benefits, costs, and side effects of each approach and then support whatever the patient decides.[20] At this time, however, most third-party payers will cover most of the costs of drug therapy and revascularization but not the costs of training patients in a program of comprehensive lifestyle changes. Approximately 40 insurance companies are covering this lifestyle program in the sites we have trained, but this is still a relatively small number.

Comprehensive lifestyle changes are not for everyone. We do not know how many patients with coronary artery disease in the United States would be interested in choosing to make comprehensive lifestyle changes rather than undergo revascularization. In practice, however, the primary limiting factor has been the lack of widespread insurance coverage rather than a shortage of motivated patients.

This is a particularly rewarding and emotionally fulfilling way to practice medicine, both for patients and the physicians and other healthcare professionals who work with them. Much more time is available to spend with patients addressing the underlying lifestyle factors that influence the progression of coronary artery disease, yet costs are substantially lower. Patients usually show rapid decreases in angina and often report other improvements within weeks; these rapid improvements in well-being sustain motivation and help to explain the high levels of adherence in these patients. The major reason that most stable patients undergo CABG or PTCA is to decrease the frequency of angina, and comparable results may be obtained by making comprehensive lifestyle changes alone. Instead of pressuring physicians to see more patients in less time, this is a different approach that is caring and compassionate as well as cost-effective and competent.

CONCLUSION

In summary, in the Multicenter Lifestyle Demonstration Project, we found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality.

Acknowledgment. Special appreciation to Marjorie McClain, Sam Lind, Zanse Smith and Bob Finkel for their invaluable assistance.

APPENDIX

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