

Statins and the Soul of Medicine

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Reducing cholesterol levels saves lives. Statin drugs are effective ways of lowering cholesterol levels. Several large-scale randomized controlled trials have demonstrated that statin drugs can reduce cardiac events and premature death, and they may have additional anti-inflammatory benefits. I prescribe them for patients when indicated.

Clearly, though, it would be better if diet and lifestyle changes could accomplish the same goals, because all drugs are costly and have adverse effects, known and unknown. However, many physicians believe that only modest goals can be accomplished in this way, so they might as well give patients statins right away.

This view seems to be shared by the recent report of the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III). They urge more intensive treatment of elevated plasma cholesterol and other risk factors for coronary artery disease.¹ The diagnosis is right, but the prescription is incomplete.

I agree with the ATP III goals of reducing low-density lipoprotein (LDL) cholesterol to <100 mg/dl and have been advocating this for many years.^{2,3} However, the panel's "Therapeutic Lifestyle Changes (TLC)" diet and lifestyle recommendations do not go far enough to reduce LDL cholesterol sufficiently for most patients to avoid lipid-lowering drugs.

In tacit acknowledgment of the fact that the ATP III TLC diet has insufficient effect on plasma cholesterol levels, the panel encouraged physicians to simultaneously prescribe cholesterol-lowering drugs for those with LDL >130 mg/dl: "For most patients, an LDL-lowering drug will be required to achieve an LDL cholesterol <100 mg/dl; thus an LDL cholesterol-lowering drug can be started simultaneously with TLC to attain the goal of therapy."¹

We used to say, "try lowering it with diet first," but now the committee's chairman, Scott M. Grundy says, "if your LDL is >130 and you have coronary disease, you should be on drug therapy."⁴

Moderate changes such as a TLC diet or a step 2 diet reduce LDL cholesterol by only about 5% to 10% in most patients.^{5,6} In a recent study, the step 2 diet failed to lower LDL cholesterol significantly unless combined with exercise.⁷

In clinical practice, Jones and Smith go to their

doctors and are prescribed a step 2 or TLC diet. When they return on their next visit, their LDL cholesterol has not declined very much. Patients are then often told that they "failed diet," when, in actuality, they just didn't go far enough. Also, most patients with coronary heart disease who followed a step 1 or 2 diet had overall progression of atherosclerosis when measured by serial arteriography.⁵

Many patients, perhaps most, can achieve the therapeutic goal of LDL <100 mg/dl without lipid-lowering drugs if they make changes in diet and lifestyle that are more intensive than the NCEP panel recommends. These intensive changes in diet and lifestyle reduced LDL cholesterol by 40% (from an average LDL of 143.8 to 86.56 mg/dl) after 1 year in ambulatory patients who were not taking cholesterol-lowering drugs.⁸ In Asia, where a very low fat diet is the norm, the average LDL in the entire population of 4 billion people is <95 mg/dl.⁹

Given these data, it is unfortunate that the panel did not offer more intensive lifestyle changes as a therapeutic option, even for motivated patients. Why were patients not even given the option of making more intensive changes in diet and lifestyle that, for many, can be a safe and effective alternative to a lifetime of cholesterol-lowering drugs?

It has been estimated that the new guidelines could triple the sales of these medicines in the United States to nearly \$30 billion/year at a time when >48 million Americans cannot afford health insurance.⁴ World-wide sales of statin drugs are estimated to be \$300 billion/year.

All medications, including lipid-lowering drugs, have side effects, known and unknown. As tens of millions of people take these medications for decades, more long-term side effects may become apparent. (The recent example of cerivastatin being taken off the market is a reminder of this.) In contrast, it costs virtually nothing additional to eat a healthful diet, walk, meditate, and quit smoking, and the only side effects of these behaviors are beneficial ones.

The reason why intensive changes in diet and lifestyle have a much greater effect on LDL than a TLC diet is well understood, as Brown and Goldstein¹⁰ elucidated. The level of plasma LDL is regulated by the LDL receptor, a cell surface glycoprotein that removes LDL from plasma by receptor-mediated endocytosis.¹⁰ Most patients with atherosclerosis have plasma LDL cholesterol levels that are many times higher than necessary to saturate the LDL receptor system.¹¹ For them, a step 2 or TLC diet may still saturate and downregulate the LDL receptor system, thereby leading to further progression of atherosclerosis and little decrease in plasma cholesterol levels.

Further reductions in fat and cholesterol resulting

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from a low-fat vegetarian diet (providing approximately 10% of calories from fat, high in complex carbohydrates, low in simple carbohydrates, consisting primarily of fruits, vegetables, grains, legumes, soy products, egg whites, and nonfat dairy or soy) plus exercise, stress management, and group support have numerous additional benefits beyond lowering LDL cholesterol by 40%. These comprehensive lifestyle changes caused a 91% reduction in angina and significant improvements in myocardial perfusion and ventricular function after only 1 month.²

Also, there was some regression of coronary atherosclerosis after 1 year, and even more regression after 5 years as measured by quantitative coronary arteriography in ambulatory patients.^{8,12,13} Cardiac positron emission tomographic scans demonstrated that the progression of coronary heart disease stopped or reversed in 99% of experimental group patients.¹⁴ There was a dose-response correlation between adherence to the diet, lifestyle, and changes in percent diameter stenosis after 1 and 5 years.^{8,12} None of these experimental group patients took cholesterol-lowering drugs during the 5 years of intervention.

In contrast, patients in the control group following a step 2 diet (similar to the TLC diet) had some progression (worsening) in coronary atherosclerosis after 1 year, even more progression after 5 years, and 2.5 times more cardiac events than patients in the randomized experimental group. LDL cholesterol decreased by only 6%, a finding also noted in other studies. In the control group, 60% of these patients were taking lipid-lowering drugs during the intervention, and they had less progression than control-group patients who were not taking cholesterol-lowering drugs. In addition, patients in the experimental group lost 25 pounds during the first year. One half of that weight loss was maintained 5 years later, whereas patients in the control group gained weight.⁸ Some 300,000 Americans die each year from illnesses caused or worsened by obesity, a toll that may soon overtake tobacco as the chief cause of preventable deaths according to a recent report by the Surgeon General, Dr. David Satcher. "We're not talking about quick-fix diets," Dr. Satcher said. "We're talking about lifestyles."¹⁵ Of course, statin drugs do not affect weight.

Why didn't the recent NCEP report include more intensive changes in diet and lifestyle as a therapeutic option? Because they believe that most people will not follow them. "Nobody thinks those diets can be applied to the general population," says Peter J. Savage, acting director of epidemiology at the National Heart, Lung, and Blood Institute, which appointed the government panel.¹⁶

To assume this is often self-fulfilling. A physician says to a patient, "Oh, I know you're not going to be able to change your diet very much—and why even bother when I can just prescribe you a statin drug?" Then, the patient doesn't change his or her lifestyle or diet, and the doctor says, "See, I knew you couldn't do it."

By analogy, many patients find it very difficult to

follow advice to quit smoking. Nicotine is as addictive as cocaine.¹⁷ Most physicians, however, counsel their patients to quit smoking, even knowing how difficult it is to do so. Most wouldn't say, "Oh, I don't think you can quit, it's too hard, so just smoke more moderately. Just smoke two packs per day instead of three." To do so would be paternalistic, even patronizing.

Instead, most physicians advise their patients, "Yes, it *is* hard to quit smoking, but don't fool yourself. Smoking moderately instead of heavily will not improve your health very much. However, when you quit smoking, much of the damage is reversible."

I don't want to minimize the difficulty of making more intensive changes in diet and lifestyle than the NCEP recommends, but we need to tell our patients what is true, not just what we think is easy. My colleagues and I found that many people are willing to make intensive changes in diet and lifestyle when they are given support for doing so and understand the potential benefits. These include marked reductions in angina, weight loss, decreased blood pressure, and better control of diabetes. In a multicenter demonstration project of 333 patients at 8 sites, 77% of patients adhered to this program well enough to safely avoid bypass surgery or angioplasty for at least 3 years, saving almost \$30,000/patient.¹⁸ More recently, Highmark Blue Cross Blue Shield and Lifestyle Advantage also found that most patients were able to avoid revascularization by making comprehensive changes in diet and lifestyle, saving more than \$17,000/patient. Medicare is now conducting a demonstration project of 1,800 patients on this program at multiple sites.¹⁹

Whether people want to quit smoking or make other changes in diet and lifestyle is a personal decision, but they deserve to have accurate scientific information from their doctors that can help them make informed and intelligent choices. This includes the risks, benefits, costs, and side effects of *all* possible choices, including cholesterol-lowering drugs, revascularization, and comprehensive lifestyle changes. When they have the entire range of therapeutic options, then they can make a truly informed decision.

For example, a patient with hypercholesterolemia could be prescribed a TLC diet and other lifestyle changes. If that is enough to reduce LDL cholesterol to desired ranges without cholesterol-lowering drugs, then that may be all the patient needs to do. If not, instead of going directly to cholesterol-lowering drugs, the patient could be given a choice: either make more intensive changes in diet and lifestyle, or begin a lifetime of lipid-lowering drugs. Either choice is fine, as long as the patient is fully informed. The more a patient changes diet and lifestyle, the less medication he or she is likely to need. Unfortunately, the new NCEP guidelines do not provide this as an option.

It becomes very convenient for physicians to prescribe cholesterol-lowering drugs rather than to counsel patients about intensive changes in diet and lifestyle. As the pressures of managed care cause doctors to spend less and less time with more and more patients, there is barely enough time to go through the

Persistence with Statin Therapy

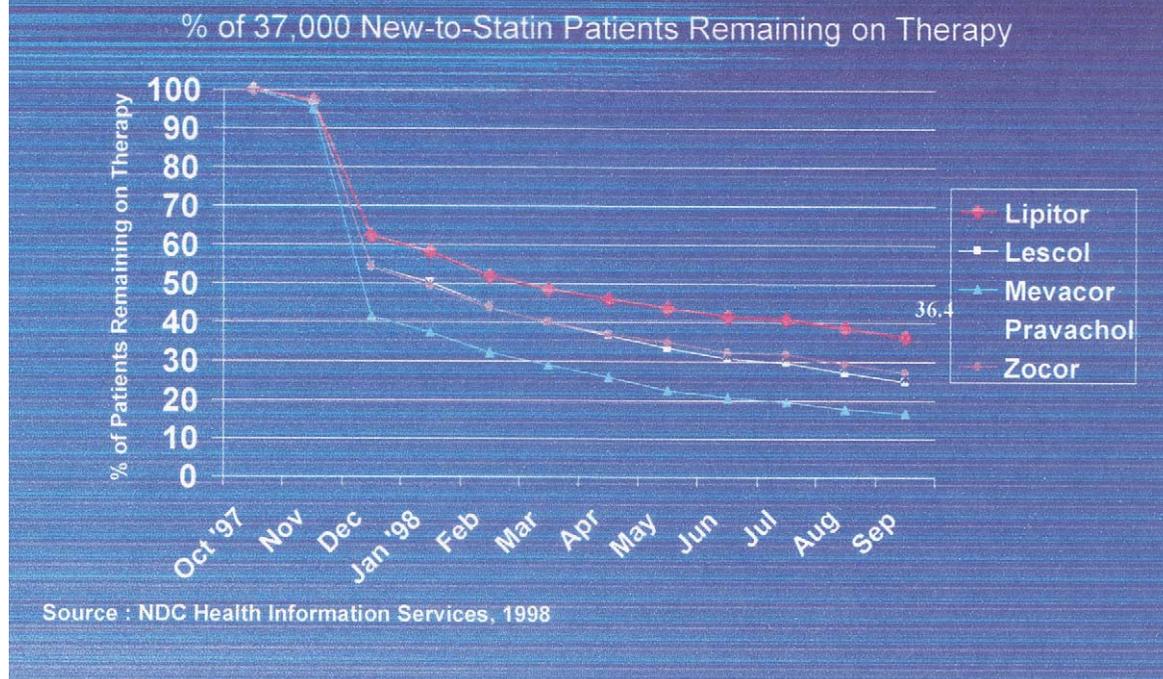


FIGURE 1. Chart showing the percentage of 37,000 patients remaining on statin therapy. (Reprinted with permission from Dr. James McKinney.)

problem list, do a cursory physical examination, write a prescription, and then go on to the next patient. This is profoundly unsatisfying for doctors and patients.

As a member of the White House Commission on Complementary and Alternative Medicine Policy, I have listened to >1,000 people testify. Although there is relatively little hard scientific evidence proving the value of most alternative medicine approaches, several studies have revealed that as much money is spent out of pocket for complementary or alternative medicine than for traditional physician services.²⁰

Why? One reason why many patients are seeking complementary and alternative medicine practitioners in record numbers is that these practitioners usually spend a lot of time with their patients, connect emotionally with them, and often advise them on various diet and lifestyle changes. They often address the underlying psychosocial, emotional, and spiritual dimensions of their patients, recognizing, for example, that many people smoke, eat unhealthful diets, and are sedentary because they are depressed and isolated. There is a basic human need for connection that is often unfulfilled in the modern doctor/patient encounter; as a result, many patients are “voting with their feet,” and many physicians are leaving the profession altogether.²¹

One reason for this is the feeling that physicians have been reduced to technicians rather than their time-honored role as healers. Most physicians have

neither the time nor the training to counsel patients in diet and lifestyle, and most third-party payers do not cover the cost of a registered dietitian for more than 1 or 2 visits—if even that. We need a new model of medicine that provides reimbursement for scientifically proved comprehensive lifestyle change programs as an alternative or as an adjunct to cholesterol-lowering drugs and revascularization.

The conventional medical thinking is that taking a statin drug is easy and most patients will comply, but making comprehensive lifestyle changes is virtually impossible for almost everyone. In fact, <50% of patients who are prescribed statin drugs are taking them as prescribed just 1 year later (Figure 1).²²

One might think that compliance to lipid-lowering drugs would always be much higher than to comprehensive diet and lifestyle changes, because taking pills is relatively easy and the side effects are minimal for most patients. However, cholesterol-lowering drugs do not make most patients feel better. They are taken today in hopes that there may be a long-term benefit by reducing the risk of a myocardial infarction or sudden cardiac death.

To many patients, concepts such as “risk factor modification” and “prevention” are considered boring and they do not initiate or sustain the levels of motivation needed to make intensive lifestyle changes. “Am I going to live longer, or is it just going to *seem* longer?”

Also, the prospect of a heart attack or death is so frightening for many patients that their denial often keeps them from thinking about it at all. Because of this, adherence becomes difficult for them to maintain. (Patients often will adhere very well for a few weeks after a heart attack until the denial returns.) Fear is a powerful motivator in the short run but not in the long run, for when it's too frightening to think about something, many people simply don't.

While fear of dying may not be a sustainable motivator, joy of living often is. In our experience, paradoxically, it may be easier for some patients to make comprehensive changes all at once than to make small, gradual changes, or even to take a cholesterol-lowering drug.

For example, when patients follow a step 2 or TLC diet, they often experience the challenges of making some changes in diet and lifestyle but not enough benefit to make it worthwhile because they don't feel much better and their LDL does not decrease very much. However, most patients who make more comprehensive lifestyle changes experience significant and sustained reductions in the frequency of angina, comparable to those achieved by revascularization.^{8,12} Also, coronary artery lesions tend to regress rather than progress, and myocardial perfusion often substantially increases.

These rapid improvements in angina, well-being, and quality of life sustain motivation and help to explain the high levels of adherence in these patients. Instead of viewing lifestyle changes solely in terms of risk factor reduction and the hope of some potential benefit in the distant future, patients begin to experience short-term benefits that reinforce the reason for making and maintaining these more intensive changes in diet and lifestyle.

The benefit of feeling better quickly is a powerful motivator and reframes therapeutic goals from only prevention or risk factor modification to improvement in the quality of life. When someone who is unable to work or walk without experiencing angina becomes essentially pain-free within weeks, then this is very motivating. Many patients have said, "Even if I knew I wouldn't live a day longer, I would still make these changes because I feel so much better."

Practicing medicine in this way is particularly rewarding and emotionally fulfilling both for patients and for the physicians and other health professionals who work with them. This approach is caring and compassionate as well as cost-effective and competent because it addresses the fundamental diet and lifestyle issues that are often underlying causes of chronic diseases such as coronary heart disease, type 2 diabetes, stroke, hypertension, obesity, and other illnesses rather than just literally or figuratively bypassing them with only surgery and/or medications.

Statins may have benefits beyond their ability to lower LDL cholesterol. However, many of these benefits also may be obtained by making comprehensive lifestyle changes.²³⁻²⁶

In summary, statin drugs have many therapeutic benefits and represent a breakthrough in treating and

helping to prevent coronary heart disease. However, the need for these drugs can be significantly reduced and, in some cases, eliminated by making more comprehensive changes in diet and lifestyle than the new NCEP ATP III guidelines recommend. This therapeutic option should be offered to all patients along with the support to make and maintain these comprehensive lifestyle changes. Patients who are not interested in making changes in diet and lifestyle to this degree should be prescribed statin drugs.

We can reclaim our time-honored roles of being physicians and healers by encouraging and supporting our patients as they wrestle with the difficult challenges inherent in major diet and lifestyle change rather than merely being technicians who are following algorithms that tell us which pills to dispense and at what dosage. We can incorporate both the art and science of medicine back into our practices, addressing the psychosocial, emotional, and spiritual dimensions of our patients that motivate their behaviors. I think that nothing less than the soul of our profession is at stake, and it is time for us to reclaim it.

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