Management of Hyperlipidemia in Patients With Abdominal Aortic Aneurysm

TO THE EDITOR: Congratulations to Lederle and the In the Clinic team (1) on their well-written and informative issue on abdominal aortic aneurysm (AAA). Although it gives many evidence-based recommendations for screening, management, and follow-up of patients with AAA, the issue was missing recommendations on management of hyperlipidemia in these patients. Patients with AAA are at high risk for coronary artery disease, as shown by Hertzer (2), who followed patients after AAA resection. In that study, the incidence of coronary heart disease (CHD)—associated mortality was about 1.9% per year in patients with no history of CHD. Therefore, Adult Treatment Panel (ATP) III guidelines (3) consider AAA equivalent to CHD and recommend aggressive management of hyperlipidemia, with a target low-density lipoprotein cholesterol level less than 25.9 mmol/L (<100 mg/dL).

Ankur Sethi, MD
Rosalind Franklin University, Chicago Medical School
North Chicago, IL 60064

Potential Conflicts of Interest: None disclosed.

References
3. Grundy SM, Cleeman JI, Merz CN, Brewer HB Jr, Clark LT, Hunneninghake DB, et al; National Heart, Lung, and Blood Institute. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines (3) consider AAA equivalent to CHD and recommend aggressive management of hyperlipidemia, with a target low-density lipoprotein cholesterol level less than 25.9 mmol/L (<100 mg/dL).

Annals of Internal Medicine

COMMENTS AND RESPONSES

Potential Conflicts of Interest: None disclosed.

References

IN RESPONSE: I thank Dr. Sethi for pointing out this omission, because the recommendation merits discussion. Treatment of patients with occlusive vascular disease with statins is based on convincing data from randomized trials. No such data are available to support lipid lowering in patients with AAA without known occlusive disease. The ATP III classified AAA as a “clinical form of non-coronary atherosclerosis” (1). Few AAA investigators would agree with this, because a large body of evidence (2) increasingly suggests a distinct genetic and immune cause, most clearly differentiated from atherosclerosis by the negative association of AAA with diabetes.

The only evidence cited in support of the ATP III recommendation was the article by Hertzer (3), an observational study that included 105 patients without a history of CHD who had AAA repair between 1969 and 1973 and in whom 15 late coronary deaths occurred up to 11 years after repair. This study does not reflect modern diagnosis and management, and it is not surprising that some coronary deaths should occur in a group of mostly elderly male smokers. The same is true for other conditions, such as chronic obstructive pulmonary disease (COPD). The prevalence of a history of myocardial infarction in men with AAA in a large screening study (32%) (4) was similar to that of men with COPD in a national sample (27%) (5). The ATP III correctly makes no recommendation for lipid lowering in COPD and should not recommend it for AAA without convincing evidence from randomized trials.

Aside from the risk for overtreatment, the ATP III’s recommendation has the drawback of impeding further investigation. Preliminary observational data (6) suggest a possible benefit from statins in reducing AAA enlargement. However, in 2002, the manufacturer of simvastatin declined to provide placebo tablets for a randomized trial intended to test this effect, citing the ATP III recommendation as its reason.

Frank A. Lederle, MD
Veterans Affairs Medical Center
Minneapolis, MN 55417

Potential Conflicts of Interest: None disclosed.

References

Annals of Internal Medicine

Comments and Critiques on the EMBRACE Health Care Reform Plan

TO THE EDITOR: Although the objectives of providing universal coverage, reducing administrative costs, and building on the public financing of health care are laudable, the proposal by Lancaster and colleagues (1) for a 3-tiered health insurance system is fatally flawed.

Dividing the population’s health coverage into tiers—a major share of which is to be controlled by for-profit, private insurers—would perpetuate the wasteful fragmentation of our dysfunctional system. Such multipayer inefficiency would continue to deny us the vast administrative savings achievable only under a single-payer plan.

The proposal’s vague language differentiating the basic, publicly financed level of care (Tier 1, covering therapies regarded as “life-saving, life-sustaining, or preventive”) from the optional, privately financed Tier 2 coverage (covering “all therapies considered to help...”)

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with the quality of life”) would invite frequent quarrels over claims. Insurance companies would exploit such ambiguities to evade payment and shift costs to patients and the government.

Such an arrangement would also perpetuate disparities in access to care. Some patients would be unable to afford Tier 2 insurance. Others might end up buying skimpy coverage, leaving them vulnerable to financial hardship when illness strikes.

If Tier 1 covered all medically necessary care, including long-term and dental care, with no co-payments or deductibles, it would be similar in terms of patient benefits to those offered by a single-payer system. But Tier 1 offers no such thing. Nor, for that matter, does the overall proposal provide the strong cost control and health planning advantages of a single-payer system.

Why do Lancaster and colleagues feel obliged to offer their alternative? It boils down to the familiar “feasibility argument.” Lancaster and colleagues write, “A system that continues to allow private, for-profit insurance and some degree of free market forces would be more viable than a system that attempted to control or eliminate them” (1). This conclusion reflects the power of the private health insurance industry to dictate the acceptable boundaries of discourse.

Single-payer systems are not only viable (Medicare being an example) but also enjoy solid majority support among the public. And 1 year ago, *Annals* published a study (2) showing that 59% of physicians now support government action to establish national health insurance. We should implement single-payer health reform without delay.

Quentin D. Young, MD
Physicians for a National Health Program
Chicago, IL 60602

**Potential Conflicts of Interest:** None disclosed.

**References**


TO THE EDITOR: Regarding the proposal by Lancaster and colleagues (1), what tier would persons with chronic, debilitating, but not life-threatening, diseases fit into? Consider persons with rheumatoid arthritis or those with developmental disabilities who also have mental illness. Treatment for these persons clearly falls into the category of “quality of life” and maintenance of function.

It therefore seems that such persons would fall into Tier 2. If so, and if persons with such conditions cannot afford private insurance premiums, will they simply suffer “functional impairment,” pain, and disability? Will they qualify for Tier 1 only after their condition deteriorates to the point that it is life-threatening? This perpetuates rationing by income, rationing for the poor but not others. And it could actually increase overall expenses as noncovered chronic conditions deteriorate.

If the review board considered the economic effects that such functional impairment might have on society and concluded that such conditions should be covered because treating them would improve economic productivity, they could include them in Tier 1. But if persons so afflicted are not economically productive or if their economic productivity decreases, will they then fall into Tier 2? This would constitute allocation of resources on the basis of the relative worth of individuals.

Do we really want to make choices on the basis of differences of individual worth? Is that ethical? Will insurers in Tier 2 be allowed to adjust premiums to charge more for preexisting conditions or deny coverage to persons whose chronic diseases may be particularly expensive to treat? If so, Tier 2 coverage will again be rationed by income and wealth, because many persons either will be unable to afford high-risk-adjusted premiums or will be denied coverage and will not be able to afford the out-of-pocket costs of care.

Because of the disparities of income and wealth in the United States, this seems like a continuation of the current policy of rationing care on the basis of income and wealth. The proposal by Lancaster and colleagues, presented in such general terms, could perpetuate or even expand injustice in our health care. As such, it is not supportable.

Richard L. O’Brien, MD
Donald Frey, MD
Creighton University
Omaha, NE 68178

**Potential Conflicts of Interest:** None disclosed.

**Reference**

Potential Conflicts of Interest: None disclosed.

Reference

TO THE EDITOR: The proposal by Lancaster and colleagues (1) is a good start in returning care to U.S. health care. In addition, the following 5 elements should be addressed.

The ethical duties of physicians shall not be infringed (2).

No taxpayer monies or government funds shall subsidize private (Tier 2 or Tier 3) health care.

The U.S. government should initiate and maintain a national medical information bank accessible by physicians at the point of care as part of Tier 1 health care.

At least 90% of all money paid in medical liability expenses in the United States should go to injured parties.

Wasteful and corrupt profiteering that infringes on the rights of patients and physicians should be exposed and eliminated.

Gary R. Gibson, MD
Northeastern Ohio Universities Colleges of Medicine and Pharmacy Rootstown, OH 44272

Potential Conflicts of Interest: None disclosed.

References

IN RESPONSE: The Expanding Medical and Behavioral Resources with Access to Care for Everyone (EMBRACE) plan was developed as a blend of what is needed and what is feasible in health care reform, but because of space constraints, many details of the plan were omitted. For more details, readers can visit www.hphbr.org.

EMBRACE is not based on opposition to single-payer proposals; rather, it shares the goals of a single-payer system but seeks to achieve those goals in a form more likely to be tenable in the context of U.S. politics and values and that might even offer operational advantages. The inclusion of private, for-profit health insurance carriers in EMBRACE is not only pragmatic but also follows the example of most of the successful single-payer systems in Europe and Canada. In those systems, private insurance has developed “after the fact,” but efforts have been made to integrate it into the publicly financed system, often with great difficulty. By designing EMBRACE around a multitiered system from the start, this integration can occur more effectively. The idea that you can get more by paying more is part of the U.S. psyche and attitude toward health care. EMBRACE, in essence, embraces health care as both a right and a privilege and uses a multidisciplinary board of experts to draw the line between the two.

We agree with Dr. Young that much of the dysfunction of the existing health care system is related to the enormous profit and overhead associated with private insurance but take exception to the suggestion that Tier 1 would exclude “all medically necessary care, including long-term and dental care, with no co-payments or deductibles.” The opposite is evident: If the board decides that certain services are life-saving, life-extending, or preventive, those services would be available universally in EMBRACE through Tier 1. We also disagree that EMBRACE “would continue to deny us the vast administrative savings achievable only under a single-payer plan.” Use of the Web-based universal billing system would eliminate almost all administrative overhead for physician offices and hospitals.

In regard to Drs. O’Brien and Frey’s comments, all health care systems ration care; no country can afford to cover all services for everyone. In our current system, this rationing occurs irrationally, on the basis of income, employment, preexisting conditions, and age. In countries with single-payer systems, the rationing is more rational and often depends on evidence-based data. Because these systems always have a limit on funding, not every service can be covered. This effectively makes all systems multitiered. EMBRACE acknowledges this and incorporates the tiers in a cohesive system. In other words, our proposal accepts that rationing at some level is unavoidable, and thus approaches it methodically and rationally. The multidisciplinary board proposed in EMBRACE is specifically conceived to oversee this issue and to ensure that the availability of services conforms to the prevailing priorities and values of our society.

For the health care system as a whole, it is important for the board to be able to tailor Tier 2 plans to complement but not duplicate Tier 1 services. It is also important for the board to be able to change Tier 2 plans as more evidence-based data become available and services are moved from tier to tier. The board might create plans that are specific to certain populations (such as poor persons, elderly persons, or physical laborers) and even purchase or at least subsidize Tier 2 coverage for persons who are now on Medicaid (or coverage could be purchased by individual states). In addition, we believe that Tier 2 plans will be substantially cheaper than private plans in our current system; therefore, it would be easier for small businesses, government (federal, state, or local), and especially individuals to afford such coverage. With some public supplementation, we believe that near-universal Tier 2 coverage is possible.

In response to Dr. Johnson, the menu system with a limited number of plans creates a fully portable Tier 2 and allows the consumer to compare prices between insurance companies in a way that the current system (or a system that allows insurance companies to develop their own plans) does not. This will be particularly important in such a system as EMBRACE that moves away from employer-based insurance coverage.

Regarding the concerns raised by Dr. Gibson, EMBRACE would allow physicians to work independently in compliance with the guidelines on the World Medical Association International Code of Medical Ethics Web site. However, as noted previously, situations could occur in which the board would subsidize some plans in Tier 2. As for allowing the U.S. government to initiate and maintain a national medical information bank accessible by physicians at the point of care as part of Tier 1 health care, we fully agree. In fact, we envision this data bank encompassing all 3 tiers in the EMBRACE system.
We are at a critical juncture in the debate on health care reform, and we should not miss this opportunity by failing to make what is necessary for all acceptable to a majority.

Gilead I. Lancaster, MD
Ryan O’Connell, MD
Bridgeport Hospital and Yale University School of Medicine
New Haven, CT 06519

David L. Katz, MD, MPH
Yale Prevention Research Center
Derby, CT 06418

Potential Conflicts of Interest: None disclosed.

CLINICAL OBSERVATION

Fulminant Hepatic Failure After Use of the Herbal Weight-Loss Supplement Exilis

Background: After reports of hepatotoxicity, the U.S. Food and Drug Administration (FDA) issued a warning on the use of Hydroxycut (Iovate Health Sciences, Oakville, Ontario, Canada), and the manufacturer agreed to a voluntary recall (1–5). However, the compounds in Hydroxycut are still available in other supplements sold in the United States.

Objective: To report a case of fulminant hepatic failure associated with use of Exilis (Fusion Health Products, Houston, Texas), an herbal weight-loss supplement with ingredients similar to those in Hydroxycut.

Case Report: A 25-year-old man presented to a walk-in clinic with tea-colored urine and fatigue. He was given reassurance and sent home. He presented 1 week later to our center with ongoing symptoms in addition to nausea, vomiting, aches, and fever. His serum aspartate aminotransferase level was 1394 U/L, alanine aminotransferase level was 2362 U/L, and total bilirubin level was 179.6 μmol/L (10.5 mg/dL). He was previously healthy, with no history of liver disease. He occasionally drank beer on weekends and reported no recent travel or illicit drug use. He had been taking Exilis, which contains xenobiotics and minerals similar to those in Hydroxycut (Table). He bought Exilis online and began using it in late December 2008, less than 2 weeks before becoming ill. His acetaminophen connection test result was still less than 30 seconds. The patient was transferred to the University of Washington for evaluation for liver transplantation. His international normalized ratio continued to increase, and he became disoriented because of encephalopathy. He became unresponsive to external stimuli and was placed on assisted mechanical ventilation. He underwent cadaveric liver transplantation on the fifth hospital day. His postoperative course was complicated by rejection and hepatic artery dysfunction, but he now feels well and clear minded.

Discussion: Although a temporal association exists between the use of Exilis and our patient’s fulminant hepatic failure, we cannot prove this was the cause. The recent determination by the FDA that Hydroxycut poses “a serious health risk” for “severe liver injury” highlights 1 of the conundrums posed by the dietary supplement industry (6). Nowhere is this more obvious than in the case of Hydroxycut, which posed “a serious health risk” for “severe liver injury” highlighting the need against the use of all Hydroxycut-like compounds.

Conclusion: If a pharmaceutical compound was found to have substantial hepatotoxicity, the FDA would ban the compound, no matter the manufacturer or distributor. We suggest that similar injunction is needed against the use of all Hydroxycut-like compounds.

W. Michael McDonnell, MD
Renuka Bhattacharya, MD
Jeffrey B. Halldorson, MD

Potential Conflicts of Interest: None disclosed.

References
CORRECTION

Correction: Evidence for Improving Palliative Care at the End of Life

The article by Lorenz and colleagues (1) contains an error. The article says that “Nebulized and oral opioids were equivalent,” but it should instead say that nebulized opioids were not effective whereas oral opioids were.

Reference