BY SIDNEY GOLDSTEIN, M.D.

HEART OF THE MATTER

Balancing Safety and Efficacy

In the last half-century, there have been major advances in the prevention of cardiovascular disease, and our success can be measured in the substantial decrease in mortality of myocardial infarction, stroke, and renal disease.

The decrease in the number of mortality events has occurred largely as a result of the introduction of drug therapy for hypertension. The original target of these efforts was directed at patients with severe hypertension, but over time, the target blood pressure has gradually been reduced.

In 1984, systolic hypertension was defined as blood pressure greater than 160 mm Hg. The most recent delineation by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), published in 2003, defines "normality" as a blood pressure of less than 120/80 mm Hg and pressures between 120/80 mm Hg and 140/90 mm Hg as "prehypertension."

The introduction of the concept of prehypertension has opened up a large segment of our population for consideration for drug therapy. Although the concept has come under significant challenge, there is general agreement that, within that population, there are patients with concomitant disease such as diabetes and hypercholesterolemia who are at increased risk and who could benefit from medical therapy and lifestyle modification.

At the same time, we have become increasingly aggressive in our treatment of hypercholesterolemia. Current guidelines advise drug therapy for primary prevention in patients with fewer than two risk factors for LDL greater than 160 mg/dL and 100 mg/dL for secondary prevention in patients with established cardiovascular disease. The reality, however, is that many physicians advise primary prevention drug therapy for patients with LDL concentrations well below 160 mg/dL. There has been a significant "therapy creep" in regard to the initiation of drug therapy for primary prevention without any supporting clinic data.

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The guidelines for therapy are based on randomized clinical trials in relatively high-risk patients carried out over relatively short time spans when considering the lifetime commitment to therapy that the prevention programs imply. The identification and treatment of prehypertension or hypercholesterolemia in a 20-year-old is a commitment to therapy for decades to come.

The impact of drugs on individuals exposed to lifetime therapy is unknown, and in fact, will probably never be ascertained. Attempts to extend mortality and morbidity observation beyond the temporal scope of clinical trials are still under consideration by the Food and Drug Administration.

The potential unforeseen risk of chronic therapy gained prominence with the rofecoxib (Vioxx) experience. The recent observation that therapy with ACE inhibitors for hypertension is associated with a significant increase in birth defects in children whose mothers were taking these drugs at the time of conception raises further concerns (N. Engl. J. Med. 2006;354:2443-51). Although the medical community has been aware of the potential hazard of this class of drugs in the second in third trimester of pregnancy, this information raises significant issues in young women of childbearing age. Other antihypertensive drugs appear to be safe, but with scant data to support a high degree of certainty.

The benefit of lifetime therapy for primary prevention in high-risk groups is supported by strong clinical research. However, as we lower our threshold for therapy, the benefit may be illusory and the potential for risk increased. The decision to treat our high-risk patients is relatively easy, but as we become increasingly aggressive about our therapeutic target and treat lower-risk patients, claims of the risk and benefits should be considered carefully. ■

DR. GOLDSTEIN, *medical editor of* CARDIOLOGY NEWS, *is professor of medicine at Wayne State University, Detroit, and division head, emeritus, of cardiovascular medicine at Henry Ford Hospital, Detroit.*

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Letters in response to articles in CARDIOLOGY NEWS and its supplements should include your name and address, affiliation, and conflicts of interest in regard to the topic discussed. Letters may be edited for space and clarity.

Mail: Letters, CARDIOLOGY NEWS, 5635 FIshers Lane, Suite 6000, Rockville, MD 20852
Fax: 240-221-4400
E-mail: cardnews@elsevier.com

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Editorial Offices 5635 Fishers Lane, Suite 6000, Rockville, MD 20852, 800-445-6975, cardiologynews@elsevier.com

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