

## The Safety of Lipid Therapy Michael Richman M.D.

The next topic that I am going to cover is The Safety of Lipid Therapy. The question I am always asked is “Are statins safe?” In the next series of posts, I will cover this topic and also discuss the safety of all the different classes of drugs used in lipid management. Many patients and physicians have questioned the safety of statins. These concerns have arisen from information from the news and print media, the internet, and from direct-to-consumer advertising. Unfortunately, much of the factual evidence is either overlooked or unknown and because of this often misinformation, many patients refuse to initiate statin therapy and others stop long term treatment out of fear for their safety. To address these concerns about the safety of lipid modulating drugs, The National Lipid Association appointed a Safety Assessment Task Force to evaluate statin safety and in a second report, the safety of nonstatin lipid altering drugs. The charge given to this task force was to conduct a “rigorous, scholarly, up-to-date, and unbiased assessment.” Four panels were assembled which focused on the muscle, liver, renal, and neurological effects of statins. To assure a rigorous comprehensive assessment of statin safety, the Task Force further commissioned reviews of special literature on adverse reactions and drug interactions. Reports of the work included an “up-to-the-minute systematic review of published cohort and clinical trial data on statin safety, the most recent data from the FDA’s AERS, an inspection of the data contained in the New Drug Applications, and the FDA’s Summary Basis of Approvals for marketed statins and associated adverse health events in a 22 million person managed health care data base. The results of the Task Force of Statin Safety was published in April 2006 in The American Journal of Cardiology and NonStatin Safety was published in the same journal in March 2007. In essence what I am saying is that to me this is the most comprehensive evidence-based unbiased assessment of all these drugs and the guidelines should be followed by all physicians and their patients.

Now a little background. Cardiovascular disease continues to be an epidemic and is responsible for more than half of all deaths in the United States. Each day more than 2600 Americans die from Cardiovascular disease. Approximately 80 million American are affected by CVD and more than 125 million lipid panels are performed annually. Despite the increase in cholesterol testing, the number of Americans affected with CVD continues to rise. Why is that? In subsequent posts I will cover the reason why I believe this is happening. Abnormal lipids (Dyslipidemia) is well established as one of the strongest independent predictors of CV morbidity and mortality. There have been large outcome trials that have consistently shown that lowering LDL cholesterol reduces morbidity and mortality associated with coronary heart disease. As the data continues to accumulate, the notion that “lower is better” has uniformly been supported. As a result of 5 large clinical trials, the National Cholesterol Education Panel (NCEP) Adult Treatment Panel (ATP) III has recognized this and new guidelines recommend further reducing the goal the LDL cholesterol to (<70mg/dl) in the most high risk patients. You can read the NCEP guidelines on Lipid Management as well as the newer NCEP guidelines on treatment of The Metabolic Syndrome on my website at [www.lipidcenter.com](http://www.lipidcenter.com). Despite

this new recommendation, the American Heart Association's 2007 statistical update shows that fewer than 20% of patients with CHD have achieved recommended goal levels of LDL cholesterol. In my next post, we will begin to look at the safety of each class of drugs starting with Statins.