

The Safety of Lipid Therapy  
The Statins Effect on the Liver  
By Michael Richman M.D.

Happy New Year!...We recently started a series in which we will be discussing the safety of all the different class of medications used in Lipid Management. As I stated in the last post, all the information is current and evidence based. It is provided by the National Lipid Association and was published in the American Journal of Cardiology.

I am asked on a daily basis if statins are safe? I always respond that they are and also are one of the most studied medications. All medicines have both a generic and a brand name but I am sure most people only know the brand names so I will list them for you. The statins include Lipitor, Zocor, Vytorin, Mevacor, Crestor, Pravachol, and Lescol.

When The National Lipid Association Statin Safety Task Force wrote their report, each panel of experts wrote about a different area of the body in which any of these medications had been shown to affect in some way. We will begin with the Liver. The word Liver and Hepatic can be interchanged so do not be confused with the nomenclature.

I am always asked by concerned patients if their statin will damage their liver? I will try to answer this question in a concise form. I would like to work backwards and give the final conclusion of the Report of the Expert Liver Panel and then detail how they came to this conclusion...."Outside of measuring liver biochemistries for the purpose of periodically updating a patient's medical history, we can find no scientific or medical basis for monitoring aminotransferase levels during long-term statin therapy as a measure to enhance patient safety. We acknowledge that the Panel's recommendations are at odds with current prescribing information for marketed statins: however, we are optimistic that the regulatory agencies and pharmaceutical industry will update their recommendations to be consistent with evidence-based data cited in this article." What does this mean? Well, it simply means that all the liver function tests, which are commonly known as AST and ALT levels, that one's physician routinely draws to check for liver problems are unnecessary with the exception of updating labs during an annual physical exam or if the physician having some concrete reason to do so. The evidence based data shows that routinely drawing these labs do not make statins any safer. The available data does not support doing so in the "asymptomatic" patient on a statin. Why do they say this? The reason the Panel says this is that believe it or not "Very rare case reports of liver failure have occurred in patients receiving statin therapy." Because the association between statin therapy and liver failure is so rare there is absolutely no way one can say with confidence that the liver failure was due to statin use. It is possible that this could be an "idiosyncratic reaction" to the statins....this means that a person could have an unexpected reaction or a type of allergy to the medicine and that is the reason for the liver failure. I like to think of it as the problem is with the way the patient's body responds to the drug rather than the class of drugs causing the problem. The Liver Panel could find

“no direct evidence of death due to liver failure caused by statin therapy.” This does not mean that statins will not elevate the liver enzymes because this is a known side effect. Generally a physician does nothing unless the level is >3 times the upper limit of normal but this does not mean that liver damage is occurring. This has been shown to happen <1% of the time across the dose range for marketed statins. I personally asked a friend of mine who is a liver doctor at the largest hospital in the Western US his opinion on liver problems and statins. He said that he rarely performs liver biopsies any more when patients are on statins and have elevated liver enzymes because he has yet to see a case on statin induced liver failure. There was always another explanation as to the cause of the liver failure. My own feeling is that too many physicians stop this medication unnecessarily and forget the benefits of statins in reducing Cardiovascular Morbidity and Mortality by at least 40% because they think a small rise in the liver function tests means that there is damage ongoing to the liver. Statins can be used safely in patients with chronic liver disease and well treated cirrhosis but the physician may need to follow the patient a little more closely than would occur in a normal healthy patient on a statin. I hope this explains the true story between statins and any possible interaction with the liver. In my next post we will talk about the effects of statin use of the kidney.