How to Manage Statin-Associated Myopathy Risk

BY BRUCE JANCIN
Denver Bureau

SNOWMASS, COLO. — When starting patients on statin therapy, it's important to acquaint them with the characteristic ways in which statin-associated myopathy differs from everyday aches and pains, Dr. Robert A. Vogel said at a conference sponsored by the Society for Cardiac Angiography and Interventions.

Statins, he stressed, are a "tremendously safe class of drugs." The most feared complication—rhabdomyolysis—is rare. A great many patients inappropriately stop taking their medication because they overinterpret the significance of their aches and pains, said Dr. Vogel, professor of medicine and director of clinical vascular biology at the University of Maryland, Baltimore.

Statin-associated myopathy involves symmetric large-muscle pain, usually associated with tenderness upon squeezing. It is often accompanied by weakness. In fact, in older patients muscle weakness very often predominates over pain.

It's very helpful to provide a creatine kinase lab slip at the time you write a statin prescription.

DR. VOGEL

"I tell patients it feels like the flu. You're sore all over. You're weak. And I think it's very helpful to provide a [creatine kinase] lab slip at the time you write a prescription for a statin. I tell the patient that if you get symmetric big-muscle pain and weakness, go to the lab and get this test drawn and call me. Four hours later I can get your CK, and we'll know what we're dealing with," he explained.

The distinction between statin-associated myalgia and myositis is crucial. In myalgia, which is a benign condition, the serum CK level is within the normal range. Management involves reassurance, a change of statin, a lower dose, or 30 mg/day of over-the-counter coenzyme Q10, which Dr. Vogel has found works well in many of his patients, even though randomized trial results have been mixed.

In contrast, statin-associated myositis as defined by a CK level greater than 10 times the upper limit of normal dictates that statins be discontinued altogether.

However, statin-associated myositis with histologic muscle damage despite a normal CK result has been described (Ann. Intern. Med. 2002;137:581-5). This condition is thought to be rare and usually is linked with objective signs of muscle weakness.

Until Dr. Vogel began issuing CK lab slips when prescribing a statin, he found many of his patients who developed muscle soreness simply quit taking their medication and didn't inform him until they came in several months later for their scheduled liver function tests. By then it was impossible to determine whether they'd had myalgia or myositis because a statin-related elevated CK would have returned to normal.

Benign statin-associated myalgias are relatively common.

In the landmark 10,001-patient Treating to New Targets (TNT) trial, for example, myalgia occurred in 4.8% of patients randomized to atorvastatin (Lipitor) at 80 mg/day and 4.7% on 10 mg/day.

And therein lies an important lesson.

"By dosing up, which is often required to get patients to goal, we're not costing our patients more muscle pain. That's a key concept for consideration because you are not making your patients safer by keeping the dose of statins low," Dr. Vogel stressed.

In the Collaborative Atorvastatin Diabetes Study (CARDS), the incidence of myositis was 0.1% with atorvastatin at 10 mg/day and 0.7% with placebo.

The complication of statin therapy every physician justifiably fears is rhabdomyolysis. It is marked by muscle symptoms accompanied by a greatly elevated CK—"I've seen levels of 300,000 IU/L," Dr. Vogel said—along with elevated creatine and myoglobinemia. Rhabdomyolysis carries a 4% mortality.

But rhabdomyolysis is exceedingly rare. A Food and Drug Administration study of more than 250,000 statin users concluded that a physician with 2,000 patients on either of the two most widely prescribed statins—atorvastatin and simvastatin (Zocor)—for 20 years will encounter, on average, one case of rhabdomyolysis (JAMA 2004;292:2585-90). ■

CALLING ALL ADOLESCENTS AND ADULTS

A CALL TO ARMS AGAINST PERTUSSIS

Pertussis protection for adolescents and adults 11 through 64 years of age

Adacel™
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

Arming More People Against Pertussis

Safety Information

ADACEL vaccine is indicated for active booster immunization for the prevention of tetanus, diphtheria, and pertussis as a single dose in persons 11 through 64 years of age.

As with any vaccine, ADACEL vaccine may not protect 100% of vaccinated individuals. There are risks associated with all vaccines. The most common local adverse events include injection site pain, erythema, and injection site swelling. The most common systemic adverse events include headache, body ache, tiredness, and fever. ADACEL vaccine is contraindicated in persons with known systemic hypersensitivity to any component of the vaccine or a life-threatening reaction after previous administration of the vaccine or a vaccine containing the same substances. Because of uncertainty as to which component of the vaccine may be responsible, no further vaccination with the diphtheria, tetanus, or pertussis components found in ADACEL vaccine should be carried out. Because intramuscular injection can cause injection site hematoma, ADACEL vaccine should not be given to persons with any bleeding disorder, such as hemophilia or thrombocytopenia, or to persons on anticoagulant therapy unless the potential benefits clearly outweigh the risk of administration.

Before administering ADACEL vaccine, please see brief summary of full prescribing Information on next page.

sanofi pasteur. Discovery Drive. Swiftwater, Pennsylvania 18370. www.sanofipasteur.us
MKT11510 © 2006 Sanofi Pasteur Inc. 2/06 Printed in USA

sanofi pasteur
The vaccines business of sanofi-aventis Group