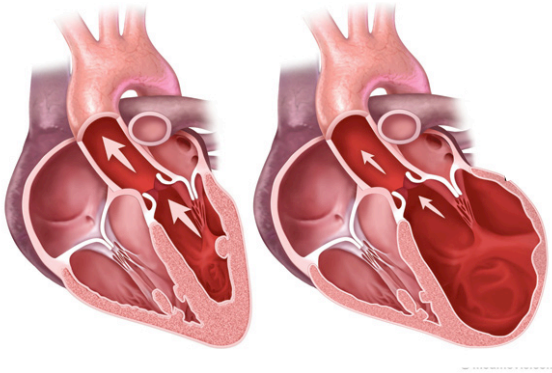
NEWSLETTER

Simvastatin: The FDA Alert

Clinical trials suggest that high doses may lead to risk of myopathy



In June 2011, the FDA completed a review of trial data involving simvastatin, and recommended against the 80mg dose due to a higher risk of myopathy (a serum creatine kinase level > 10 times the upper limit of normal with unexplained muscle weakness or pain), when compared to lower doses of simvastatin.

- In the SEARCH trial, the 80mg dose was associated with a 0.9% incidence of myopathy, vs 0.02% for the 20mg dose.
- The greatest incidence of myopathy was seen in the first year of use. Therefore, the 80mg dose should only be continued for patients who have been on simva-statin for 1 year or greater without any problems.
- Simvastatin is especially prone to drug-drug interactions, because it is extensively metabolized through the hepatic CYP3A4 enzyme system.
  - Therefore, myopathy was higher when simvastatin was used in association with: amiodarone, diltiazem, amlodipine, HIV protease inhibitors, ranolazine, cyclosporine, and the -azole class of meds. If on these meds, simvastatin dose should be decreased accordingly (10-20mg, depending on the drug), or an alternate statin should be used.
- Myopathy was 3x higher with simvastatin than other agents
  - If greater LDL reduction is required than can be achieved with 40mg of simvastatin, patients should be switched to either atorvastation (Lipitor) or rosuvastatin (Crestor).
- FDA labeling has been changed for simvastatin, Vytorin (ezetimibe + simvastatin) and Simcor (niacin + simvastatin).

Please obtain the advice of your local cardiovascular disease specialist for specific patient guidance.

Did you Know?

Your system of blood vessels -- arteries, veins and capillaries -- is over 60,000 miles long. That's long enough to go around the world more than twice!

The electrocardiograph (ECG) was invented in 1902 by Dutch physiologist Willem Einthoven. This test is still used to evaluate the heart's rate and rhythm.

Blood is about 78 percent water.

Blood takes about 20 seconds to circulate throughout the entire vascular system.

The structure of the heart was first described in 1706, by Raymond de Viessens, a French anatomy professor.

Plavix, Effient, and now... Brilinta

BRILINTA™
ticagrelor tablets

In July, the FDA approved Astra Zeneca's new drug, ticagrelor, which will be sold under the brand name Brilinta. In the PLATO trial (NEJM 9/10/09), ticagrelor was compared to clopidogrel. In patients admitted to the hospital with either NSTEMI or STEMI, at 12 months of study duration:

- There were less cardiovascular events if on ticagrelor, compared to clopidogrel.
- There was also a reduction in death, which was not seen in the TRITON-TIMI 38 trial, which compared prasugrel vs clopidogrel.
- The labeling will include a warning that aspirin doses higher than 100mg can reduce the effectiveness of ticagrelor.
- It is unclear where ticagrelor will fit in, relative to the already existing prasugrel and clopidogrel:
  - It is given as twice-daily dosing (the other two are once-daily)
  - It is thought to have a shorter half-life, thus possibly being a better choice for acute coronary syndrome patients being considered for bypass surgery, though this will have to be further validated.
  - A complaint of dyspnea was present in 13.8% of patients, though it was responsible for drug discontinuation in only 0.9% of patients.

Don't hesitate to contact your local cardiovascular disease specialist to help navigate through these complex antiplatelet medications.

AIM-HIGH: The end of Niacin?

AIM-HIGH
Cholesterol Management Program

In May 2011, the NHLBI halted the AIM-HIGH trial. The trial was designed to evaluate the effects of raising HDL in patients will well controlled LDL. The trial studied the efficacy of Niaspan (long-acting niacin) in addition to statin therapy, in patients with a history of cardiovascular disease, high triglycerides, and low HDL levels. The study was stopped 18 months early, because an interim analysis showed no additional benefit.

•In addition to lowering LDL, there has always been a question as to how to reduce "residual risk", referring to future cardiovascular risk. A popular target has been to raise HDL, the 'good' cholesterol. In conjunction with other trials, results of AIM-HIGH raise the question: what is the real value, if any, of raising HDL?

- It is important be cautious about generalizing these results to all patients on niacin. Patients in AIM-HIGH had a baseline LDL of 71 mg/dL, prior to beginning the study medicine.
  -Niacin may still be important in reducing LDL in patients in whom high-dose statin therapy has not achieved target LDL levels.
  -Niacin could also be important in patients in whom statin therapy is not tolerated.
- Final trial data from AIM-HIGH have yet to be presented. Study participants will be followed for another 12-18 months.

Your local cardiovascular disease specialist can help with optimal management of dyslipidemic patients.

Meet our Physicians: Dr Lababidi & Dr Kedia

Dr Zaki Lababidi

Dr. Zaki Lababidi, the founder of Gilbert Cardiology, has over 15 years of experience in cardiovascular medicine. He is board certified in cardiovascular disease and has specialized in interventional cardiology, a subspecialty of cardiology dedicated to the diagnosis, medical and catheter-based therapy of patients with acute and chronic forms of cardiovascular disease. Dr. Lababidi also specializes in treatment of patients with congestive heart failure, coronary artery disease, heart attack, abnormal heart rhythms, peripheral arterial disease (PAD), and varicose veins.

Dr. Lababidi completed his internal medicine residency in 1992 at Mercy Hospital and Medical Center in Chicago, IL. He did serve as chief resident from 1991 to 1992. He went on to participate in a cardiology fellowship at Marshall University in Huntington, WV. He completed this fellowship in 1995. Dr. Lababidi was in private practice in Chicago, IL for several years prior to returning to fellowship once again in 2004. He completed his Interventional Cardiology fellowship in 2005 at the Arizona Heart Institute in Phoenix, AZ. Dr. Lababidi founded Gilbert Cardiology in 2007 and has since opened a satellite office in Fountain Hills, AZ as well as Queen Creek, AZ.

Dr Gautam Kedia

Board-certified in echocardiography and nuclear cardiology, Dr. Gautam Kedia is a cardiologist specializing in noninvasive and preventative cardiology. Dr. Kedia also has a special interest in the management of patients with structural and valvular heart disease, as well as diseases of the aorta and peripheral arteries.

Dr. Kedia, who is an Arizona native, completed medical school at the University of Arizona in Tucson. He then fulfilled his Internal Medicine residency and Cardiology fellowship at Cedars-Sinai Medical Center in Los Angeles, California. Subsequently, he joined Dr Lababidi in Gilbert.

In his free time, Dr. Kedia enjoys watching sports and movies, playing soccer, and especially looks forward to the birth of his first child in late September.

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Services we offer

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