Zetia Reduces LDL in People Living With HIV

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Zetia (ezetimibe) may be an effective option for HIV-positive patients who had moderately elevated low-density lipoprotein (LDL) levels—the "bad" form of cholesterol—and were on antiretroviral therapy (ARV), based on a small clinical trial reported in the October 15 issue of Clinical Infectious Diseases.

Studies of LDL-reducing therapies, such as statins (HMG-CoA reductase inhibitors), have demonstrated a strong relationship between LDL levels and the risk of cardiovascular disease (CVD). According to some research, for every 1 percent decrease in LDL while on lipid-lowering treatment, there is a 1 percent reduction in the risk of CVD.

Unlike statins, designed to block a liver enzyme that produces cholesterol, Zetia inhibits absorption of dietary cholesterol by the intestine (duodenum). In clinical trials involving HIV-negative volunteers, Zetia reduced "bad" LDL cholesterol by 20 percent when used without other lipid-lowering medications and by about 50 percent when used with a statin.

Until recently, little has been known about the safety and effectiveness of Zetia in HIV-positive patients on ARV therapy, notably protease inhibitors, who may be at an increased risk for cholesterol increases.

A 14-week study conducted by David Wohl, MD, and fellow researchers at the University of North Carolina at Chapel Hill and the University of California at San Francisco enrolled 48 HIV-positive patients—all of them were on ARV therapy and had moderately elevated "bad" LDL cholesterol levels. The average LDL cholesterol level was 128 mg/dL at the time of study entry (levels above 115 mg/dL are considered elevated).

In the first phase of the study, patients were randomized to Zetia (10 mg/day) or placebo for six weeks. This was followed by a two-week "washout period" in which no treatment was given. After the washout period, those originally randomized to Zetia took six weeks of placebo treatment, and those originally randomized to placebo took six weeks of Zetia treatment.

After six weeks of Zetia treatment, LDL cholesterol decreased by an average of 11 mg/dL, compared with an increase of 4 mg/dL in the placebo group—a 15 mg/dL difference between the two groups. And the average percentage of LDL cholesterol change attributable to Zetia, as compared with placebo treatment, was about 11 percent.

No significant changes in high-density lipoprotein (HLD) levels—the "good" form of cholesterol—or triglyceride levels were seen in either group. This finding contrasts with those of smaller studies

that reported beneficial changes in HDL and triglyceride levels in HIV-positive individuals using Zetia.

The study authors concluded that Zetia, used alone (monotherapy), led to significant declines in LDL cholesterol and was well tolerated. “A decrease in LDL cholesterol of 11 percent would be meaningful to many HIV-infected patients, with the assumption that ezetimibe-induced reductions in LDL cholesterol are equivalent to lifestyle or other lipid-lowering therapies in attenuating CVD risk,” they write. “Ezetimibe monotherapy should be considered to be a lipid-lowering option for HIV-infected patients requiring modest LDL-cholesterol reduction and may be particularly useful in patients who are unable to take or do not reach their treatment goals with statins.”

For patients unable to reduce their LDL cholesterol levels using either Zetia or a statin alone, an 18-patient study conducted in Spain reported in a 2006 issue of AIDS suggested that Zetia, combined with the statin Pravachol (20 mg/day), is an option. However, as was recently found in a large clinical trial involving HIV-negative volunteers, Zetia added to the statin Zocor (simvastatin) did not provide additional protection against arteriosclerosis—harmful artery-blocking plaques caused by high cholesterol levels.

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