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Patients Treated with Lipitor Were Significantly Less Likely to Have a Cardiovascular Event Than Those Treated with Simvastatin, New Observational Study Shows

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One of the Largest Observational Studies of Cardiovascular Outcomes Published Today Online in Clinical Therapeutics Journal

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Results of an observational study of a large U.S. managed care claims database showed that new statin users without cardiovascular disease who took Lipitor® (atorvastatin calcium) Tablets had a significantly lower relative risk of experiencing any cardiovascular event, a heart attack, or revascularization (a type of heart surgery) compared to patients who took simvastatin.

Patients taking Lipitor had a significant 12 percent lower relative risk of experiencing a cardiovascular event. In a secondary analysis, patients taking Lipitor had a significant 15 percent lower relative risk of experiencing a heart attack, and a significant 12 percent lower relative risk of revascularization compared to patients taking simvastatin. These differences were evident in patients taking doses of Lipitor or simvastatin that would have been expected to deliver similar LDL reductions (Lipitor 10 mg or 20 mg or simvastatin 20 mg or 40 mg). There was no significant difference between the groups in stroke or mini-stroke.

As with all observational studies, the findings should be regarded as hypothesis generating.

“An important concern for clinicians, as well as for public health in general, is whether patients treated with different statins will experience different cardiovascular outcomes,” said Dr. JoAnne M. Foody, associate professor of medicine at Harvard Medical School and director of the Cardiovascular Wellness Center at Brigham and Women’s/Faulkner Hospitals, Boston. “This study suggests that there may be differences in cardiovascular outcomes between atorvastatin and simvastatin.

“Given the large number of patients receiving statin therapy, the availability of generic statins, and the clinical and economic burden of cardiovascular events, the results of this observational study could have significant public health implications.”

According to Dr. Michael Berelowitz, senior vice president of Pfizer’s global medical division, “There has been widespread encouragement by managed care companies and governments for physicians to prescribe generic statins based on what is believed to be comparable LDL-lowering doses, assuming that this will result in similar cardiovascular benefits. This analysis calls into question those assumptions and those policies and reaffirms that treatment decisions need to be made by physicians based on a patient’s risk for developing cardiovascular

disease."

About the study

This is one of the largest observational studies to date to examine cardiovascular outcomes in patients without cardiovascular disease treated with different statins in routine clinical practice.

The study was a retrospective analysis using anonymous patient-level health plan data from IMS Health, a healthcare information company. At the time of the analysis, the database, known as the PharMetrics Patient-Centric Database, included fully adjudicated medical and pharmacy claims for 52 million individual patients from 92 health plans across the U.S.

The analysis examined claims from 219,631 patients without cardiovascular disease who initiated statin therapy from January 2003 to September 2005 and who were enrolled in U.S. health plans (168,973 patients began therapy with Lipitor 10 mg or 20 mg daily and 50,658 patients began therapy with simvastatin 20 mg or 40 mg daily). Patients were followed for a median of one and a half years.

A cardiovascular event was defined as the time to first hospitalization due to a heart attack, chest pain or coronary artery disease, stroke, mini-stroke, vascular disease, or revascularization.

Since patients were not randomly assigned to each group, the two treatment groups were adjusted based on certain risk factors, such as age, gender, co-morbidities and prior healthcare cost. Various statistical methods were employed to address residual imbalances.

The results of this study complement the large body of evidence from multiple clinical trials demonstrating the cardiovascular benefits of Lipitor and support findings from previously published observational studies.

About Lipitor

Lipitor is the most prescribed cholesterol-lowering therapy in the world, with nearly 144 million patient-years of experience. It is supported by an extensive clinical trial program involving more than 400 ongoing and completed trials with more than 80,000 patients. There have been more than ten cardiovascular outcomes trials with more then 50,000 patients.

Important US Prescribing Information

Lipitor is a prescription medication. It is used in patients with multiple risk factors for heart disease such as family history, high blood pressure, age, low HDL ("good" cholesterol) or smoking to reduce the risk of a heart attack and stroke, certain kinds of heart surgery and chest pain.

Lipitor is also used in patients with type 2 diabetes and at least one other risk factor for heart disease such as high blood pressure, smoking or complications of diabetes, including eye disease and protein in urine, to reduce the risk of heart attack and stroke.

Lipitor is used in patients with existing coronary heart disease to reduce the risk of heart attack, stroke, certain kinds of heart surgery, hospitalization for heart failure, and chest pain.

When diet and exercise alone are not enough, Lipitor is used along with a low-fat diet and exercise to lower cholesterol.

Lipitor is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant.

Patients taking Lipitor should tell their doctors if they feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Patients should tell their doctors about all medications they take. This may help avoid serious drug interactions. Doctors should do blood tests to check liver function before and during treatment and may adjust the dose. The most common side effects are gas, constipation, stomach pain and heartburn. They tend to be mild and often go away.

For more information please go to www.lipitor.com.

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