

PHARMINFO

LIPITOR SHOWN TO STOP PROGRESSION OF PLAQUE BUILD-UP IN ARTERIES

Patients taking Pfizer Inc's cholesterol-lowering medicine Lipitor (atorvastatin calcium) experienced a significant reduction in the progression of atherosclerosis compared with patients who received Prava (pravastatin), according to new data presented at the annual meeting of the American Heart Association in Orlando, Florida, in November 2003.

The Reversing Atherosclerosis with Aggressive Lipid Lowering (REVERSAL) study followed up 502 patients who were diagnosed with coronary heart disease and required cardiac catheterisation or angiograms. Patients in the 18-month study had at least one arterial vessel with 20% or more constriction due to plaque build-up. The study compared the effectiveness of Lipitor (80 mg/day) versus Prava (40 mg/day) in reducing plaque build-up. Lipitor-treated patients experienced a median 0.4% reduction in total plaque volume, defined as all of the plaque present within a segment of a single artery, while patients who received Prava showed a significant increase in total plaque volume (2.7% median).

'These results clearly show that aggressively lowering cholesterol levels with atorvastatin calcium stopped the progression of atherosclerosis,' said Dr Steve Nissen, Medical Director of the Cleveland Clinic Cardiovascular Coordinating Center and Principal Investigator of the REVERSAL study.

It is estimated that atherosclerosis accounts for more than 75% of all deaths from cardiovascular disease.

'The REVERSAL results reinforce the outstanding effectiveness of Lipitor in treating patients who have high cholesterol and signs of heart disease,' said Dr Joseph Feczko, Pfizer's executive vice-president of Global Research and Development and president of Worldwide Development. 'These results provide important new information that will help physicians in treating the millions of patients who suffer from this devastating disease.'

The average LDL cholesterol levels of patients at the beginning of the study was 3.9 mmol/l, while accepted guidelines call for levels of < 2.6 mmol/l. Prior to enrolment, study participants were not taking medication to treat their high cholesterol. Additionally, patients in the study had other heart disease risk factors which may have included a history of diabetes, hypertension or a previous heart attack. Ninety-seven per cent of patients taking Lipitor reached their recommended LDL cholesterol goal levels compared with 67% of pravastatin patients. The rates of elevated liver enzymes were low and similar in patients taking Lipitor 80 mg and pravastatin 40 mg. There were no reported cases of rare muscle problems associated with muscle breakdown.

Researchers used technology known as intravascular ultrasound, which is a three-dimensional method of imaging, to measure the total plaque volume in a cross-section of the artery wall over the length of the vessel. The total plaque volume of the patients was measured at the beginning and at the conclusion of the study.

Since the introduction of Lipitor 7 years ago, its safety and effectiveness have been supported through an extensive clinical trial programme, the Atorvastatin Landmark Program, with more than 400 ongoing and completed trials involving more than 80 000 patients. Lipitor is the leading cholesterol-lowering therapy in the world with more than 62 million patient years of experience.

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