SOUTHWESTERN NEWS

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EXTENDED-RELEASE NIACIN PROVEN EFFECTIVE IN LOW DOSES FOR DIABETICS, UT SOUTHWESTERN RESEARCHERS REPORT

DALLAS – July 22, 2002 – Niacin, a medication once discouraged for the treatment of lipid abnormalities in patients with diabetes, has the potential ability, when given in low doses, to be well-tolerated and effective, according to UT Southwestern Medical Center at Dallas researchers, who led the multicenter trial.

The researchers report in today's issue of *Archives of Internal Medicine* that in the 148 study participants extended-release niacin (Niaspan) led to significantly improved lipid levels and minimal changes in glycemic control.

"Previous reports have shown that niacin in high doses raises blood glucose, but this trial shows that in doses of 1,000 milligrams per day and 1,500 mg/d, niacin therapy was well-tolerated and changes in glycemic control were minimal," said Dr. Scott Grundy, the study's lead author, director of the Center for Human Nutrition at UT Southwestern and holder of the Distinguished Chair in Human Nutrition. "Low doses of an extended form of niacin also had favorable effects on blood lipids and lipoproteins."

The researchers targeted niacin therapy for a condition in patients with diabetes called dyslipidemia, which is characterized by high levels of triglycerides and other lipid-related abnormalities along with depressed levels of the healthier high-density lipoprotein (HDL) cholesterol.

"Niacin therapy has been discouraged by clinicians because high doses can worsen glycemic control in patients with diabetes," said Dr. Gloria Vega, a professor of clinical nutrition and a study co-author. "In this study we evaluated the tolerance and effectiveness of niacin at low doses. This extended-release form is designed to circumvent the bothersome side effects of regular niacin, such as flushing of the skin."

(MORE)

During the trial, the study participants were divided into three groups. They received either 1,500 mg/d of extended-release niacin, 1,000 mg/d of extended-release niacin, or a placebo. About half of the study participants continued taking their prescribed statin drugs for cholesterol lowering during the trial, and 81 percent continued their medications for diabetes.

In the 1,500 mg/d group, HDL increased as much as 24 percent, triglycerides decreased as much as 36 percent, and the "bad" cholesterol, low-density lipoproteins (LDL), decreased by 7 percent. In the 1,000 mg/d group HDL increased by 19 percent.

Patients with diabetic dyslipipdemia are commonly treated with triglyceride-lowering drugs known as fibrates, but niacin is more effective for raising HDL, or the good cholesterol.

"Niacin clearly increases HDL cholesterol and reduces triglycerides in individuals with type 2 diabetes," Vega said.

Many of the 14 million Americans with non-insulin-dependent (type 2) diabetes are affected by dyslipidemia, which can increase the risk for cardiovascular disease. Last year, the National Institutes of Health's National Cholesterol Education Program deemed diabetes to be a very high-risk condition of cardiovascular disease.

"Most patients with diabetes will require lipid-lowering therapy," Grundy said. "The use of statins to lower LDL cholesterol is becoming routine therapy for the majority of patients; however, this study indicates that the addition of niacin to statin therapy will provide additional benefit for improvement of blood lipids and lipoproteins in patients with diabetes."

Also participating in the multicenter trial were investigators from Kos Pharmaceuticals; the Diagnostic Clinic of Houston; the International Diabetes Center in St. Louis Park, Minn.; the East-West Medical Research Institute in Honolulu; Harvard Medical School; Northwestern University Medical School; University of North Carolina at Chapel Hill School of Medicine; the Atlanta Diabetes Association; and the North Coast Institute of Diabetes and Endocrinology in Westlake, Ohio.

The study was supported by Kos Pharmaceuticals.