

AMERICAN DIABETES ASSOCIATION (ADA)

ANDROMEDA STUDY RESULTS PRESENTED AT ADA'S ANNUAL MEETING

ORLANDO—The results of the ANDROMEDA Study were presented at the 64th Scientific Sessions of the American Diabetes Association. The study demonstrated that rosuvastatin at the lowest dose (10 mg) pro-

vides greater reduction in levels of non-high-density lipoprotein (non-HDL) cholesterol in patients with type 2 diabetes compared with atorvastatin (10 mg).

The study consisted of 509

adult patients who were randomized to receive rosuvastatin 10 mg or atorvastatin 10 mg for 8 weeks. Doses were then increased to 20 mg for an additional 8 weeks. The baseline non-HDL cholesterol levels in the rosuvastatin and atorvastatin groups were 4.30 ± 1.0 mmol/L and 4.33 ± 1.0 mmol/L. Baseline triglyceride (TG) levels in the rosuvastatin and atorvastatin groups were 2.04 ± 1.0 mmol/L and 2.12 ± 1.0 mmol/L, respectively.

Rosuvastatin at both doses, 10 mg and 20 mg, significantly reduced the non-HDL cholesterol and TG levels of patients compared with atorvastatin (Table). ■

TABLE

MEAN PERCENTAGE CHANGE FROM BASELINE

	WEEK 8		WEEK 16	
	ROSUVASTATIN 10 MG (N = 240)	ATORVASTATIN 10 MG (N = 240)	ROSUVASTATIN 20 MG (N = 227)	ATORVASTATIN 20 MG (N = 229)
NON-HDL-C	-45.4*	-35.5	-50.6 [†]	-41.5
LDL-C	-51.3*	-39.0	-57.4 [†]	-46.0
TG	-21.6 [‡]	-16.6	-22.7	-19.6

Non-HDL-C = non-high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; TG = triglycerides.

* $P < .001$ rosuvastatin vs atorvastatin 10 mg. [†] $P < .001$ rosuvastatin 20 mg vs atorvastatin 20 mg.

[‡] $P < .05$ rosuvastatin 10 mg vs atorvastatin 10 mg.

Source: Betteridge J, et al. Presented at: 64th Scientific Sessions of the American Diabetes Association; June 4-8, 2004; Orlando, Fla.

ALL PATIENTS WITH TYPE 2 DIABETES SHOULD BE CONSIDERED FOR A STATIN

ORLANDO—Statin therapy reduces the risk of a first major cardiovascular (CV) event in patients with type 2 diabetes and unremarkable cholesterol levels, said Helen Colhoun, MD, at the 64th Scientific Sessions of the American Diabetes Association (ADA). This finding strongly suggests that all patients with type 2 diabetes be treated with a statin, regardless of their cholesterol level.

She reported the findings from a study known as the Collaborative Atorvastatin Diabetes Study (CARDS), which is the first study of a lipid-modifying agent for the primary prevention of CV disease conducted solely in patients with type 2

diabetes. The study included 2838 patients with type 2 diabetes and low-density lipoprotein (LDL) cholesterol levels of ≤ 160 mg/dL who had no clinical history of coronary, cerebrovascular, or severe peripheral vascular disease. They were randomized to atorvastatin 10 mg/day or placebo. To be eligible, patients had to have one of the following CV risk factors in addition to diabetes: hypertension, retinopathy, micro- or macroalbuminuria, or currently smoking.

"Two thirds of the patients enrolled had LDL cholesterol levels below the current ADA guideline for pharmacologic intervention," said Dr. Colhoun, coprincipal

investigator of CARDS and professor of genetics and epidemiology, The Conway Institute, University College Dublin, Ireland. Twenty-five percent had an entry LDL cholesterol level of < 100 mg/dL, which is the current target of therapy in patients with type 2 diabetes.

LDL cholesterol was reduced by 40% in the group assigned to atorvastatin compared with the group randomized to placebo. By 48 months, about 80% of the atorvastatin group reached their LDL cholesterol level treatment target of < 100 mg/dL, compared with slightly more than 20% of the placebo group.

The trial was stopped 2 years before the planned termination

date because of a significant benefit on outcomes associated with atorvastatin, she said. After approximately 4 years, atorvastatin recipients had a 37% reduction in the risk of major CV events ($P = .001$), including a 36% reduction in the risk of acute coronary events and a 48% reduction in the risk of stroke. The treatment effect was apparent regardless of baseline LDL cholesterol levels, baseline high-density lipoprotein cholesterol levels, and baseline triglyceride levels.

The number of events avoided per 1000 patients treated for 4 years was 36.7, and the number needed to treat for 4 years to prevent one event was 27.

The incidence of muscle- and liver-related adverse events was similar in the placebo and atorvastatin groups. Elevations of alanine transaminase more than 3 times the upper limit of normal occurred in 14 placebo recipients and 17 atorvastatin recipients; elevations of aspartate transaminase occurred in 4 and 6 patients in the 2 groups,

respectively. No patient in either group had rhabdomyolysis.

Based on the results of CARDS, all patients with type 2 diabetes should be considered for statin therapy, regardless of their cholesterol level, said Dr Colhoun. "CARDS suggests that there is no justification for having a threshold level of LDL cholesterol as the sole arbiter of which patients with type 2 diabetes should receive statin treatment," she said. "The overall cardiovascular risk should be the principal determinant." ■

LIPIDS REMAIN UNCONTROLLED IN PATIENTS WITH DIABETES

ORLANDO—According to new data released at the 64th Scientific Sessions of the American Diabetes Association (ADA), a majority of patients with type 2 diabetes worldwide have not achieved their lipid goals.

A worldwide survey of physician practice patterns related to lipid levels in patients with type 2 diabetes was conducted by Lawrence Leiter, MD, professor of medicine and nutritional sciences, University of Toronto. Dr Leiter and colleagues surveyed 2043 diabetes specialists from 50 countries to compare attitudes and clinical practice patterns in the evaluation and treatment of dyslipidemia in type 2 diabetes patients.

Physicians in the survey tended to overlook recommendations from the ADA and other organizations that people with diabetes have their lipids managed as aggressively as patients with established heart disease, he found.

Although physicians recognized that dyslipidemia is an important risk factor for cardiovascular disease (CVD) in patients with type 2 diabetes, and nearly all (91%) patients with type 2 diabetes globally undergo CVD screening, only about half of the patients attain the goals set for them. Furthermore, the targets that diabetes specialists set for their patients are frequently not as low as their professional organizations recommend.

The ADA guidelines were selected by about one third of all physicians surveyed as the lead determinant in how they practice. In the United States, 51% of respondents said that they follow National Cholesterol Education Panel (NCEP) guidelines and 42% follow ADA guidelines.

Nearly half of physicians (46%) said that patient noncompliance is the main barrier to goal attainment.

In addition, many diabetes specialists do not recognize dia-

betes as a "coronary risk equivalent," as defined by the NCEP's Adult Treatment Panel III. Indeed, 45% of the physicians have a different low-density lipoprotein (LDL) cholesterol goal for persons with CVD versus those without CVD: 85% of physicians have an LDL cholesterol goal of 100 mg/dL for those with CVD versus 59% for patients with diabetes but without CVD.

"The results thus identify a gap between screening for dyslipidemia and aggressive treatment of lipids in type 2 patients, which means that type 2 diabetics aren't managed optimally to thwart the risk of cardiovascular disease and that type 2 diabetes is not widely considered a coronary risk equivalent," Dr Leiter said.

Other data from a major health maintenance organization (HMO) in Michigan showed that lipid testing, treatment, and LDL cholesterol goal attainment have improved but the percentage of patients at their LDL