Changes in Serum Lipids After 24 Weeks

	Pioglitazone Patients	Rosiglitazone Patients
Triglycerides (mg/dL)	–52	+13
HDL cholesterol (mg/dL)	+5	+2
LDL cholesterol (mg/dL)	+12	+21
LDL particle concentration (nmol/L)	–50	+110
LDL particle size (nm)	+0.46	+0.33

Source: Dr. Goldberg

Pioglitazone Beat Rosiglitazone In Lipid Level Improvement

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NEW ORLEANS — Treatment with pioglitazone led to better improvements in serum lipid measures compared with rosiglitazone in a study of 735 patients with type 2 diabetes and dyslipidemia.

"Whether these differences in lipid measures translate into differences for the future risk of cardiovascular disease has not yet been determined," but a comparison study of the two drugs using clinical end points is underway, Ronald B. Goldberg, M.D., said at the annual scientific sessions of the American Heart Association.

The study enrolled patients with type 2 diabetes who had fasting serum triglyceride levels of 150-599 mg/dL and fasting serum LDL-cholesterol levels lower than 131 mg/dL. The study was done at centers in the United States, Mexico, Puerto Rico, and Colombia, and was sponsored by Takeda Pharmaceuticals Co. and Eli Lilly & Co., which comarket pioglitazone (Actos) in the United States. Dr. Goldberg receives research support from and is on the speaker's bureau for Lilly and Takeda.

At the end of the study, several serum lipid values were substantially improved, compared with baseline, in patients taking pioglitazone.

After a 4-week washout period, patients were randomized to treatment with either 30 mg pioglitazone or 4 mg rosiglitazone (Avandia) daily for 12 weeks. At the end of this first treatment phase, patients receiving pioglitazone had their daily dosage boosted to 45 mg, and patients on rosiglitazone upped their daily dosage to 8 mg. The higher dosages were continued for another 12 weeks. The full 28-week study was completed by 299 patients in the pioglitazone group and 286 patients who took rosiglitazone.

By the end of the study, several serum lipid values had substantially improved in the patients taking pioglitazone, compared with the measures taken at baseline at the end of the washout period. These improvements were significantly better than the changes seen in the rosiglitazone group, said Dr. Goldberg, professor and chief of the division of diabetes and metabolism at the University of Miami.

The primary end point was the change in serum triglyceride levels. In the pioglitazone group, the average triglyceride level was 259 mg/dL at baseline, which then fell by an average of 52 mg/dL with treatment. Among patients treated with rosiglitazone, the average triglyceride level was 240 mg/dL at baseline, which then rose by 13 mg/dL with treatment.

The number and severity of treatment-related adverse events were similar in the two treatment groups, said Dr. Goldberg, but his report at the meeting did not include any details from the safety analysis.

It's not known why these two drugs—both thiazolidinediones with similar effects on glycemic control—would differ in their effects on serum lipids. Data from prior chart review or placebo-controlled studies had suggested that pioglitazone had substantially different lipid effects than did rosiglitazone. This is the first head-to-head comparison of the two drugs. ■