2 Adult Diabetes Drugs Appear Safe in Children

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SAN DIEGO — Two oral glucose-lowering agents that are commonly used in adults with type 2 diabetes appeared safe and effective in children in two industry-funded studies presented at the annual scientific sessions of the American Diabetes Association.

Although the prevalence of type 2 diabetes among children is increasing, only one oral drug (metformin) is currently approved for pediatric use (ages 10-16 years).

Michael Gottschalk, M.D., head of endocrinology at the University of California, San Diego, presented data on a 26-week, randomized, single-blind study comparing the safety and efficacy of glimepiride (Amaryl) with metformin in 263 children aged 9-17 years with type 2 diabetes who were inadequately controlled (hemoglobin A_{1c} 7.1%-12.0%) on diet and exercise alone or failed oral monotherapy (HbA_{1c} greater than 7.5% for 3 or more months).

After a 2-week run-in period, 132 of the children were randomized to receive glimepiride at a starting dose of 1 mg/day, which was then titrated to 2 mg, 4 mg, and 8 mg at 4-week intervals to achieve a fasting glucose level of less than 126 mg/dL. The other 131 children received 500 mg metformin twice daily and were titrated up only once—to 1,000 mg twice daily—if their mean self-monitored blood glucose values exceeded 126 mg/dL at 12 weeks.

The two groups were similar at baseline, with a mean age of 13.8 years. About one-third were male, and nearly one-fourth were African American. About 40% were Hispanic. Body mass indexes were 31.57 kg/m^2 in the glimepiride group and 31.60 for metformin. Their mean HbA_{1c} values were 8.52% and 8.54%, respectively.

By 24 weeks, the proportion of patients achieving good control, defined as an HbA_{1c} below 7%, were also similar: 42% with glimepiride and 48% with metformin. Lipid parameters also did not differ between the two treatment groups, Dr. Gottschalk reported.

At 24 weeks, the glimepiride patients gained an average of 2.2 kg while the metformin group gained just 0.7 kg. That difference was significant.

Safety was analyzed for the initial cohort of 284 subjects (142 in each group). Rates of headache, diarrhea, and nausea were low, and occurred more frequently in the metformin group. The incidences of hypoglycemia (blood glucose less than 50 mg/dL) were reported in 4.9% of the glimepiride group compared with 4.2% of the metformin group, with one severe hypoglycemic event requiring assistance occurring in each group. These differences were not significant, Dr. Gottschalk said.

The data on rosiglitazone (Glaxo-

Glucose Meters: Watch Change In Measurement

LifeScan Inc. is notifying users that it is possible to accidentally change the measurement units on its OneTouch Ultra, InDuo, and OneTouch FastTake blood glucose meters, which can lead patients to misinterpret their results.

The company has found that users can inadvertently change the unit of measurement in the course of setting their meter's time and date. The two possible units on the affected meters are mg/dL and mmol/L.

The choice of measurement unit is generally determined by the country where the patient lives, and mg/dL is usually used in the United States.

About 40 adverse events worldwide related to incorrect measurement settings on these meters have been reported to LifeScan.

Most of the adverse events consisted of temporary periods of low or high blood glucose.

Patients using the affected meters are advised to contact the company to confirm that their meter is set to the proper unit of measurement. Users may contact LifeScan customer service by calling 800-515-0915.

For more information, see the Food and Drug Administration's firm safety alert at www.fda.gov/oc/po/firmrecalls/lifescan04_05.html.

—Kerri Wachter

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See following page for brief summary of prescribing information.

*Based on Formulary Compass™ managed care database available through MediMedia Information Technologies, March 2005. At least one PREVACID product is covered.

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SmithKline's Avandia) were presented in a poster by Guissou Dabiri, a clinical pharmacologist with the company in King of Prussia, Pa., and her associates.

A total of 208 children aged 8-17 years with type 2 diabetes entered a 4-week run-in period, and 200 were randomized to either rosiglitazone 2 mg twice daily or metformin 500 mg twice daily. Both were titrated up as necessary—twice daily rosiglitazone to 4 mg or metformin to 1,000 mg—to achieve a fasting plasma glucose value less than 126 mg/dL.

Fifty-five percent of the 97 who received rosiglitazone and half of the 98 patients randomized to receive metformin had been treated with diet only, while the rest had been on oral monotherapy. Both groups had diabetes a little over 1 year, and neither was in good control at baseline—the rosiglitazone group had a mean HbA_{1c} of 7.88% and the metformin group had a mean HbA_{1c} of 8.17. This difference—which had not been present at screening—was statistically significant, probably due to the higher proportion in the rosiglitazone group who had received prior therapy, Dr. Dabiri and her associates noted.

At week 24, reductions in HbA_{1c} from baseline were 0.25% among the rosiglitazone patients and 0.55% in the metformin group.

Compared with screening, the reductions were 0.5% in both groups. Median HbA_{1c} values at 24 weeks were 7% for rosiglitazone and 7.1% for metformin. The proportion achieving HbA_{1c} values of 7% or less were 51.5% of rosiglitazone and 48% for metformin, while 42.7% and 43.9%, respectively, achieved fasting plasma glucose levels of 126 mg/dL or below.

Adverse events occurred in a total of 61.6% of rosiglitazone patients and 59.4% of metformin subjects. As expected, the incidences of nausea, vomiting, and diarrhea were higher with metformin than with rosiglitazone (8.9%-12.9% vs. 1.0%-4.0%). Edema occurred in one rosiglitazone patient and in none of the metformin group. Incidences of hypoglycemia were similar (4.0% in the rosiglitazone group, 5.0% in the metformin group). The rosiglitazone group gained a mean of 3 kg at 24 weeks. No effects on serum lipid parameters were seen in either group, the investigators said.

In April, the FDA rejected GlaxoSmithKline's request for a pediatric indication for rosiglitazone, citing concern about statistical limitations with regard to efficacy and certain adverse effects of rosiglitazone therapy. However, GlaxoSmithKline continues to work with the FDA in pursuit of the pediatric indication, according to the company. ■