

# Gatifloxacin Can Disturb Glucose Homeostasis

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WASHINGTON — New data suggest that gatifloxacin (Tequin) may be associated with a much higher rate of glucose homeostasis abnormalities than has been observed for quinolone antibiotics in general, Richard Frothingham, M.D., reported at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Gatifloxacin is responsible for many more adverse drug event reports than are other quinolones, and should not be used in patients with diabetes, said Dr. Frothingham of Duke University, Durham, N.C., and a physician at the Durham VA Medical Center.

In preclinical and early clinical studies, there was some suggestion that gati-

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floxacin might cause some problems with glucose homeostasis, but in the pivotal studies, the drug was equal to other drugs with which it was compared, Dr. Frothingham said at the meeting, sponsored by the American Soci-

ety for Microbiology.

When gatifloxacin was approved in 1999, the Food and Drug Administration did not add any warnings about glucose metabolism.

Since that time, there have been reports of adverse effects, including severe hypoglycemia in patients with type 2 diabetes treated with oral medications. Hyperglycemia in diabetic patients, usually occurring 4-10 days after starting gatifloxacin, has also been reported.

These episodes are described in the warnings section of the drug's label. Physicians are urged to closely monitor glucose levels in diabetic patients taking the drug and to adjust the dosage based on underlying renal function.

But Dr. Frothingham said he thinks physicians aren't heeding the warnings, and also that problems with glucose homeostasis are underreported. In a Freedom of Information Act request, he queried the FDA's adverse event reports database to compare reports for gatifloxacin and several other marketed quinolones, including ciprofloxacin (Cipro), levofloxacin (Levaquin), and moxifloxacin (Avelox).

He evaluated adverse drug event reports filed for the four drugs from November 1997 until September 2003 and found that gatifloxacin had the largest number of reports related to glucose homeostasis abnormalities per number of prescriptions: 477 per 10 million prescriptions, compared with 39 for moxifloxacin, 11 for levofloxacin, and 4 for ciprofloxacin.

The FDA's database—because it is made up of data collected passively—cannot establish a direct link between a drug

and a side effect, Dr. Frothingham noted.

He said he believes "this is a compelling association" between gatifloxacin and glucose homeostasis problems. Dr. Frothingham called it "a rare side effect," but suggested that physicians never exceed the recommended dosage. He added that gatifloxacin should not be prescribed for diabetics at all. The dosage should be reduced to 200 mg daily in patients who are over age 65 or who have a creatinine clearance of less than 60 mL/min.

In a separate presentation at the meeting, Ben Lomaestro, Pharm.D., of Albany (N.Y.) Medical Center Hospital presented data on the use of gatifloxacin in his facility that suggested there was no difference in glucose levels when gatifloxacin was compared with piperacillin/tazobactam in elderly patients; however, the study had some important limitations, he said.

It was a small study, with 134 patients in the gatifloxacin arm and 82 in the piperacillin arm, and their glucose levels

were checked only in the morning.

Despite these limitations, the study demonstrated that glucose intolerance is relatively common in elderly hospitalized patients.

In another presentation, Paul Iannini, M.D., chairman of the department of medicine at Danbury (Conn.) Hospital, evaluated glucose intolerance during treatment with gemifloxacin, compared with other drugs in the class. He said that it was probably not a class-wide problem. ■

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