Victory Too Sweet?

FDA warns that protease inhibitors may cause diabetes

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In June, the Food and Drug Administration (FDA) issued a nationwide warning that protease inhibitors may cause elevated blood sugar (hyperglycemia) and even diabetes in people with HIV. Still, many questions remain about how the drugs are connected to the effect, and how severe a risk they pose.

The warning was issued after the agency received 83 reports of new or exacerbated diabetes mellitus or increased blood-sugar levels in patients taking protease inhibitors. Six cases were life-threatening and 21 required hospitalization. Many of the cases reversed when patients stopped taking the drugs -- but not all. The high blood sugar was often controlled with additional oral drugs or insulin injections.

All four of the currently approved protease inhibitors were implicated. “It looks like the number of cases [for each drug] was roughly parallel to prescription usage,” FDA medical officer Jeff Murray says. The FDA has estimated high blood sugar may occur in as few as 0.1 percent to 1 percent of people using protease in-hibitors -- rare enough that the problem was not recognized in clinical drug trials. Nonetheless, the FDA ordered manufacturers of all four drugs to change product labels to warn about the potential side effect.

Not all those who develop diabetes have pre-existing risk factors. Robin Dretler, MD, senior partner at Infectious Disease Specialists in Atlanta, has treated one case of diabetes in a man taking the combination of ritonavir, saquinavir and ddI. The patient, who had no family history of diabetes and was active and not overweight, showed symptoms within a couple of weeks of starting the drugs. Despite switching drugs, the diabetes did not resolve, and now the client has to self-inject insulin.

Although the FDA has associated the cases with protease inhibitors, Dretler says he actually suspected ddI, since it can cause pancreatitis, an inflammation of the insulin-making organ. So can the anti-HIV medications AZT, 3TC and d4T, as well as Bactrim and pentamidine, other drugs commonly used by people with HIV. The FDA does not have complete information on other drugs the 83 patients were taking. Still, 15 of the 83 cases reported being on other medications that could cause pancreatitis, and 14 were on medications that could cause high blood sugar.

Endocrine or hormonal disorders may be more common in people with HIV, which also complicates

the picture. “I see a lot of diabetes in my HIV patients in general,” Dretler says. “It’s not at all unusual, even in people who are not overweight.”

The FDA plans further studies to learn the mechanism by which protease inhibitors might cause high blood sugar. Meanwhile, the agency is not advocating patients stop protease inhibitor treatment. “I think these drugs have a great potential benefit. The death rate has been dropping. We didn’t want to scare anyone,” Murray says. Dretler adds, “Diabetes is certainly a concern, but it’s not going to make me stop using protease inhibitors.”

The FDA has urged patients to immediately alert their doctors to symptoms of hyperglycemia, such as more frequent urination; increased thirst; dry, itchy skin; fatigue; and unexplained weight loss.

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