Liver Toxicity From HIV Therapy More Common in Pregnant Women, But Not From Viramune

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Pregnancy increases the risk of liver problems for people using antiretroviral (ARV) therapy, according to a study published online August 7 in *AIDS*. Contrary to previous findings, however, Viramune (nevirapine)—even when started at high CD4 cell counts—was not associated with signs of liver inflammation in this population of women.

There have long been concerns that HIV therapy might have different effects in HIV-positive pregnant women, compared with HIV-positive women who are not pregnant. Most of these fears have not panned out, but there are exceptions. Damage to mitochondria—the energy centers of cells—caused by Zerit (stavudine) is more common and severe in HIV-positive pregnant women. Also, some studies showed that liver damage from Viramune appeared to happen more often in pregnant women who start treatment with higher CD4 cells than in nonpregnant women with higher CD4s.

To determine the risk of liver toxicity associated with ARV treatment during pregnancy—notably Viramune—David Ouyang, MD, at the Harvard School of Public Health in Boston and his colleagues evaluated medical records from three pivotal HIV studies: the Women and Infants Transmission Study, the International Maternal Pediatric Adolescent AIDS Clinical Trials protocol P1025 and the Women's Interagency Health Study (WIHS). Data on 2,050 HIV-positive women were included from the three studies, with 1,229 of them pregnant and 821 not pregnant. Ouyang's team looked at liver enzyme elevations (LEE), which can be a sign of liver damage.

Ouyang and his colleagues found that LEEs occurred in 14.2 percent of the pregnant women, compared with 9.1 percent in the nonpregnant women. This difference was statistically significant, meaning that the difference was too large to have occurred by chance. Severe LEEs occurred in 1.2 percent of pregnant women and 0.6 percent of nonpregnant women, but this difference was not statistically significant.

Taking Viramune, on the other hand, was not associated with LEEs regardless of pregnancy status. This is particularly striking given that more than three quarters of both pregnant and nonpregnant women started Viramune with CD4 counts greater than 250, which is not currently recommended because of the perceived increased risk of liver inflammation.

The authors acknowledge that, because their analysis was based on a review of medical records, they don’t have the same degree of confidence in the results that they would have if conducting an actual clinical trial comparing Viramune to other ARVs in both pregnant and nonpregnant women. However, they do state that this study is the first to directly compare pregnant and nonpregnant women, and that the results challenge the prevailing wisdom about liver damage from Viramune use during pregnancy.
