HIV PIs Increase Risk of Preterm Delivery, but Not Serious Infant Health Problems

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The bad news: HIV-positive pregnant women who use protease inhibitors (PIs) are more likely to deliver preterm babies. The good news: This did not translate into increased serious complications or death rates among infants born to women using PIs, compared with those using other antiretroviral (ARV) regimens.

The results of this study, conducted in Batswana and reported in the August 15 issue of *The Journal of Infectious Diseases*, help clarify previous research related to PI use in pregnancy. According to Kathleen Powis, MD, of Massachusetts General Hospital and her fellow authors, some studies have reported an association between PI use and preterm delivery, whereas others failed to find a connection or weren't adequately designed to detect an increased risk in preterm deliveries.

The original results from the Mma Bana study—first reported at the 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention two years ago in Cape Town—were considered groundbreaking in sub-Saharan Africa. The trial, involving 730 HIV-positive pregnant women in Botswana allotted to receive one of three regimens, found an overall mother-to-child transmission rate of 1 percent—on a par with that seen in industrialized nations and the lowest perinatal transmission rate ever recorded in an African study.

In their most recent paper, the Mma Bana researchers note the potential importance of PI use and preterm deliveries. Most women who require ARV treatment in pregnancy live in resource-limited settings where access to neonatal care may be limited and where the effect of any increase in preterm deliveries on infant survival may be magnified.

Mma Bana—meaning "mother baby" in Setswana—enrolled one group of 560 women with CD4 counts of at least 200 to take either abacavir, zidovudine and lamivudine (coformulated as Trizivir in the United States), group A; or lopinavir/ritonavir (Kaletra) and lamivudine/zidovudine (Combivir), started between weeks 26 and 34 of their pregnancies, group B.

A second group of 170 pregnant HIV-positive women—those with fewer than 200 CD4 cells—were enrolled in a third group (group C) in which therapy containing nevirapine (Viramune) and

zidovudine/lamivudine (Combivir) was initiated by everyone between weeks 18 and 34 of pregnancy.

Only mother-infant pairs in Groups A and B, not Group C, were included in the preterm delivery analysis.

Preterm delivery rates were higher among the 267 women in Group B, compared with those in Group A: 21 versus 12 percent, respectively. This difference was statistically significant, meaning it was too great to have occurred by chance. When the researchers accounted for several variables that can contribute to preterm delivery, PI use stood out as the most significant risk factor, with a doubling of the risk of preterm delivery.

Very early preterm deliveries—babies born less than 32 weeks into pregnancy (normally, babies are born after 39 to 42 weeks of pregnancy)—were documented among 3.3 percent of women in Group B, compared with 1.8 percent of women in Group A. This difference, however, was not statistically significant. And because only three of the 12 mothers who gave birth to very early preterm infants completed at least 30 days of ARV treatment before delivery, Powis and her colleagues noted the difficulty of interpreting these findings.

No adverse outcomes were significantly associated with PI-based treatment. The frequency of severe or life-threatening respiratory illness, diarrheal disease, sepsis or hospitalizations did not differ between infants by maternal treatment selection. In fact, there were significantly more cases of meningitis among infants born to women in Group A compared with Group B.

During the first six months of life, death occurred among 2.6 percent of the infants born to women in the PI group, compared with 1.9 percent of the infants born to women in the triple nucleoside reverse transcriptase inhibitor group, with no statistically significant difference between the two groups.

In conclusion, Powis and her colleagues reiterated that “PI-based [ARV treatment] is a critical component of both [prevention of mother-to-child transmission, or PMTCT] and treatment programs in the developed and developing world, and offers proven benefits to maternal and infant health. However, skilled obstetrical and neonatal care may be required to manage preterm deliveries to maximize the benefits of PI-based [ARV treatment] use during pregnancy.”

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