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One drug used to prevent HIV transmission during pregnancy shows evidence of developmental effects

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The antiretroviral (ARV) drug atazanavir—sometimes included in treatments to prevent mother-to-child HIV transmission during pregnancy—may have small but significant effects on infant development, reports a study in the journal *AIDS*.

One-year-olds whose mothers took atazanavir during pregnancy have slightly reduced scores for language and social-emotional development, compared to ARV regimens not containing atazanavir, according to the new research by Dr. Ellen C. Caniglia, ScD, of Harvard T.J. Chan School of Public Health and colleagues.

Small Developmental Effects after Exposure to Atazanavir—Not Other ARV Drugs

Members of the Pediatric HIV/AIDS Cohort Study (PHACS) group analyzed data on 917 infants who were born to HIV-positive mothers but did not acquire HIV infection. As recommended by current US and European guidelines, all mothers took ARV therapy during pregnancy to reduce the risk of transmitting HIV.

At around one year old, the infants were assessed on a standard test of infant development—the Bayley Scales of Infant and Toddler Development-Third Edition, or "Bayley III." Scores on the five Bayley III subscales were compared for 167 infants whose mothers took

atazanavir-containing ARV regimens versus 750 infants whose mothers received ARV, but not atazanavir.

The results showed lower language development scores were lower for infants whose mothers received atazanavir. That was so for infants whose mothers initiated atazanavir during the first trimester of pregnancy as well as during the second or third trimester.

Scores for social-emotional development were also lower for infants whose mothers took atazanavir. However, the difference was significant only for infants whose mothers initiated ARV during the second or third trimester—but not the first trimester. This may have reflected the fact that many women who started taking atazanavir during the first trimester switched to a different ARV regimen later in pregnancy.

Other Bayley III subscales—cognitive, motor (movement), and adaptive behavior—were similar for atazanavir-exposed versus unexposed infants. On all subscales, the average scores in this group of infants born to HIV-infected mothers were within the normal range.

Atazanavir is a type of drug called a protease inhibitor, which is included in some of the combination ARV regimens used for HIV treatment. The new study was prompted by previous research suggesting delayed language development in infants whose mothers took atazanavir during pregnancy.

The findings add to those concerns, suggesting small reductions in scores for language and social-emotional development among infants exposed to atazanavir. And yet, they emphasize that the "absolute differences" between groups are small.

Language score was about three points lower in the atazanavir group, compared to an average subscale score of 93; while social-emotional

score was five points lower, compared to an average of 100. These differences "may not have large clinical implications, but they add another risk to the constellation of existing biological and socio-environmental risk factors to which these children are often exposed," according to Dr. Caniglia and coauthors.

Further studies are needed to assess whether the differences persist beyond one year of age, Other key questions include the mechanism by which the apparent developmental effects of atazanavir occur; and whether they could be related to another drug, tenofovir, which is typically used together with atazanavir. The researchers conclude, "These results may be useful in treatment planning for women with HIV Infection."

More information: Ellen C. Caniglia et al. Atazanavir exposure in utero and neurodevelopment in infants, *AIDS* (2016). DOI: 10.1097/QAD.0000000000001052

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