MedicalXpress

Anti-HIV drug tenofovir is safe to take during pregnancy

May 15 2012

Pre-birth exposure to the anti-HIV drug tenofovir does not adversely affect pregnancy outcomes and does not increase birth defects, growth abnormalities, or kidney problems in infants born to African women who are HIV positive, supporting the use of this drug during pregnancy, according to a study by a team of international researchers published in this week's *PLoS Medicine*.

The researchers led by Diana Gibb from the MRC Clinical Trials Unit in London, UK, analyzed data collected on pregnancy and infant outcomes among Ugandan and Zimbabwean HIV-positive women who took Antiretroviral therapy (ART - a combination of anti-HIV drugs) during pregnancy in the Development of AntiRetroviral Therapy in Africa (DART) trial. DART was a large randomised controlled trial that compared different approaches for monitoring anti-retroviral therapy in over 3000 adults. As part of the trial, researchers collected data on any pregnancies among women taking part, including drugs they received; babies were followed for up to 4 years.

Most of the women who became pregnant were taking a tenofovir-containing combination of anti-HIV drugs before and throughout their pregnancies and out of the 226 live births, the researchers recorded that there was no increase in the proportion of infants who died soon after birth (3%) or had birth defects (also 3%), comparing those exposed and not exposed to tenofovir-containing anti-retroviral therapy during pregnancy.

Of 182 surviving infants enrolled in a follow-up study, 14 subsequently died giving a 1-year mortality rate of 5%, similar to the 2% infant mortality normally seen in the region, and much lower than among babies born to severely HIV infected untreated mothers. Furthermore, the researchers found that none of the surviving infants who were tested for HIV were positive and no bone fractures or kidney problems occurred during follow-up and there was no effect on growth at 2 years.

The researchers say: "we observed no evidence that tenofovir versus non-tenofovir ART had any adverse effects on pregnancy outcomes or on congenital, renal, bone, or growth abnormalities up to age 4 y among children born to women with severe HIV immunodeficiency at ART initiation and exposed throughout the intrauterine period."

They continue: "Our findings suggest tenofovir-containing ART is a reasonable choice in pregnancy and that tenofovir pre-exposure prophylaxis is also reasonable for women who are at high risk of seroconverting during pregnancy."

The researchers add: "Detailed safety of tenofovir for pre-exposure prophylaxis will need confirmation from longer term follow-up of larger numbers of exposed children."

More information: Gibb DM, Kizito H, Russell EC, Chidziva E, Zalwango E, et al. (2012) Pregnancy and Infant Outcomes among HIV-Infected Women Taking Long-Term ART with and without Tenofovir in the DART Trial. *PLoS Med* 9(5): e1001217. doi:10.1371/journal.pmed.1001217