Drug combo much better than AZT alone at preventing mother-to-infant HIV transmission

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Non-breastfed babies born to HIV-positive mothers who didn't receive antiretroviral therapy during pregnancy are routinely given zidovudine, commonly known as AZT, shortly after birth to prevent mother-to-child transmission of the virus that causes AIDS.

While effective, this strategy doesn't always protect the infant from acquiring the virus during the mother's labor and delivery. But a new UCLA-led study published June 21 in the New England Journal of Medicine finds that a two- or three-drug combination given to infants within 48 hours of birth can reduce the risk of such intrapartum HIV acquisition by about half, compared to AZT alone.

"Our research demonstrates that even in very high-risk situations where mothers are only identified as being HIV-positive when they give birth or shortly after birth, there is still an effective strategy that can be undertaken to prevent transmission of HIV to the baby," said Dr. Karin Nielsen-Saines, a professor of pediatric infectious diseases at the David Geffen School of Medicine at UCLA and the study's lead investigator. "While giving AZT alone to the infant can reduce intrapartum transmission to some degree, our data demonstrates that with the use of two- or three-drug regimens to the baby, you can cut transmission to half of what can be achieved with AZT alone."

The study is the first randomized controlled study of post-exposure HIV

prophylaxis for babies born in countries where the standard of care is to give the child AZT to prevent infection, said Nielsen-Saines, who is also a member of the UCLA AIDS Institute. Babies born to HIV-infected mothers who have not received antiretroviral therapy (ART) stand a 25 percent chance of becoming infected during the mother's pregnancy or at birth. Their chances increase to about 40 percent when they are breastfed, which is why HIV-positive women are advised not to breastfeed in many countries.

The study involved 1,684 formula-fed infants born to HIV-positive mothers in the United States, Brazil, Argentina and South Africa. Within 48 hours of birth, researchers assigned the newborns to one of three groups: 566 were placed in the AZT-alone group; 562 in AZT plus nevirapine group; and 556 in a group receiving AZT, nelfinavir and lamivudine.

Of the 1,684 infants, 140 were found to be infected with HIV — 97 were born with the infection (transmission occurred during pregnancy) and 43 were infected during the birth process.

Among the babies who became infected during the birth process, 24 in the AZT-alone group were found to be infected at 3 months of age, compared with 11 in the AZT/nevirapine group and 12 in the AZT/nelfinavir/lamivudine group. Using Kaplan–Meier statistics, this translated into a transmission of 4.8 percent in the AZT-alone group, 2.2 percent in the two-drug group and 2.4 percent in the three-drug group. (Kaplan–Meier estimates incorporate survival probabilities, time in follow-up and other factors.)

Therefore, giving two or three drugs to babies born to mothers who had received no HIV treatment significantly reduced HIV transmission, compared with AZT alone.

The researchers also found that the two-drug therapy was less toxic to the infants than the three-drug alternative.

Nielsen-Saines noted that the findings are applicable only to high-risk infants — those whose mothers didn't receive antiretroviral therapy during pregnancy. Babies born to HIV-positive women who are being effectively treated with antiretrovirals throughout pregnancy already have a less than 1 percent chance of acquiring HIV from their mothers.

"Our results support combination ART regimens instead of zidovudine alone for prophylaxis in the infants of mothers who have not received antenatal ART," the researchers write. "Ease of use, reduced toxicity, availability, and low cost suggest that zidovudine plus nevirapine is an attractive option for prophylaxis in infants at high risk for perinatal HIV-1 infection."

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