MedicalXpress

Breastfeeding babies protected against HIV from their HIV+ mothers with 12 months of antiretroviral drug treatment

November 19 2015

A study from four countries in Africa, published in *The Lancet*, shows that providing babies with up to 12 months of liquid formula HIV drugs, while breastfeeding with their HIV-positive mothers, is highly effective at protecting them from infection, including in the 6-12 month period after birth which has not been analysed in previous research. The study is by Professor Philippe Van de Perre, INSERM, Montpellier, France, and colleagues.

Strategies to prevent postnatal mother-to-child transmission of HIV-1 in Africa, including directly protecting infants through prophylaxis with special child formulations of HIV drugs, have never been assessed past 6 months of breastfeeding, despite breastfeeding being recommended up to 12 months after birth. In this new study, the authors aimed to compare the efficacy and safety of infant prophylaxis with two drug regimens (lamivudine or lopinavir-ritonavir) to prevent postnatal HIV-1 transmission during up to 50 weeks of breastfeeding.

They did a randomised controlled trial in four sites in Burkina Faso, South Africa, Uganda, and Zambia in children born to HIV-infected mothers who were not yet eligible for antiretroviral therapy under the guidelines that existed when the trial took place (CD4 count >350 cells per μL—however, today, WHO advises that all people diagnosed with HIV immediately begin treatment, regardless of CD4 count).

In the study, HIV-negative breastfed infants aged 7 days were randomised to receive either lopinavir-ritonavir or lamivudine (paediatric liquid formulations, twice a day) up to 1 week after complete cessation of breastfeeding or at the final visit at week 50. Treatment allocation was hidden from participants and study physicians, and the primary outcome was infant HIV-1 infection between age 7 days and 50 weeks, in the modified intention-to-treat population (meaning all babies in the study who attended at least one follow-up visit).

Between November, 2009, and May, 2012, 1273 infants were enrolled and 1236 were analysed; 615 assigned to lopinavir-ritonavir and 621 assigned to lamivudine. A total of 17 HIV infections were diagnosed in the study period (eight in the lopinavir-ritonavir group and nine in the lamivudine group), resulting in cumulative rates of HIV-1 infection of 1·4% and 1·5%, respectively, and meaning that infection rates did not differ between the two drug regimens. Clinical and biological severe adverse events did not differ between groups.

The authors say: "Crucially, about half of the postnatal HIV-1 infections in both groups occurred after 6 months of breastfeeding, while HIV exposure was much reduced during this period because of mixed feeding (lowering milk intakes) and some women stopping breastfeeding before 50 weeks. This finding justifies the extension of infant pre-exposure prophylaxis (PrEP) until the end of HIV exposure and the need to inform mothers about the persistent risk of transmission throughout breastfeeding to prevent them stopping giving the treatment to their babies too soon."

Further analysis of the data suggested that most of the HIV infections in the babies in both groups occurred because of lack of adherence to the study drug, rather than a failure of the drug to protect the baby once ingested. The authors say: "Drug adherence therefore remains a key factor for success of infant PrEP. More research is needed for more

palatable oral paediatric formulations and long-acting injectable drugs." The data showed that when the drug was actually taken, rates of HIV infection fell to 0·2% for the lopinavir-ritonavir group and 0·8% in the lamivudine group, respectively, again without a statistically significant difference between the groups.

The authors conclude: "Infant PrEP proved an effective and safe alternative to prevent postnatal HIV-1 transmission for mothers who are not ready or prepared to embark on long-term ART.

In addition, adding infant PrEP in breastfed babies whose mothers are taking ART is a strategy that should be assessed...At the population level, in countries where universal maternal ART cannot be implemented as recommended by WHO, infant PrEP with either lopinavir-ritonavir, lamivudine,or nevirapine for the whole duration of breastfeeding is also advisable."

Writing in a linked Comment, Professor Hoosen Coovadia, Maternal Adolescent and Child Health, School of Public Health, University of the Witwatersrand, Durban, South Africa and Dr Dhayendre Moodley, Center for the AIDS Programme of Research in South Africa and Women's Health and HIV Research Unit, University of KwaZulu Natal, Durban, South Africa, say the data in this study show "that infant ART prophylaxis substantially decreases the breastfeeding risk of transmitting HIV, works at a scale greater than previously studied, and is effective and safe".

More information: *The Lancet*, www.thelancet.com/journals/lan … (15)00984-8/abstract

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