Mother-to-Child HIV Transmission Is Rare When Women Are on Treatment

Study results confirm that dolutegravir is a safe and effective treatment for pregnant women with HIV.

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Treatment with either dolutegravir or efavirenz was safe and effective for pregnant women with HIV and their infants, and mother-to-child transmission was uncommon during pregnancy and breast-feeding, according to research presented last week at the Conference on Retroviruses and Opportunistic Infections (CROI).

In a cohort of 250 women with HIV in Uganda and South Africa who exclusively breast-fed their infants for six months, one infant acquired HIV. The infants' mother, who was taking efavirenz, consistently had an undetectable viral load, aside from a blip at six months. This was the only one of 242 infants to acquire HIV in the year and a half following delivery.

This finding is part of the final read-out of the DolPHIN-2 trial, which was designed to see how effectively dolutegravir suppresses HIV compared to efavirenz in women who started treatment late in pregnancy. Viral suppression prevents mother-to-child transmission, so it's important for such women to reach an undetectable viral load as soon as possible.

Dolutegravir (sold alone as Tivicay and part of the Triumeq, Juluca and Dovato combination pills) is recommended by the World Health Organization (WHO) for pregnant women with HIV. Efavirenz (sold alone as Sustiva or Stocrin and part of the Atripla and Symfi combination pills) was the previous standard of care.

At last year's CROI, the DolPHIN-2 researchers reported that, at the time of delivery, more women taking dolutegravir plus two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) had an undetectable viral load compared with those taking efavirenz. Three of the infants born to women taking dolutegravir acquired HIV, presumably in utero, while the women's viral loads were still high.

At this year's meeting, Thokozile Malaba, MPH, an epidemiologist at the School of Public Health at the University of Cape Town, presented data up to 18 months after delivery. The postpartum period can be a hard time for women, for obvious reasons. It can affect their risk of acquiring HIV if they're not yet living with the virus or their ability to maintain an undetectable viral load if they

are. In 2019, Deborah Birx, then head of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) told Medscape Medical News that each year in Africa, 1 million people stop treatment with efavirenz because of side effects, such as fatigue and depression.

All participants in the trial were at least 18 years old with untreated HIV. The median age was 28, and the women entered the trial at a median of 31 weeks into their pregnancies—well into the third trimester. The women had previously given birth to an average of two children, but it was the first pregnancy for 12%. The women breast-fed exclusively for six months and then continued to breast-feed non-exclusively from six months to a year. Viral load at study entry was substantially above the threshold of 1,000 copies below which the risk of transmitting HIV to an infant drops significantly. The median CD4 count was 449.

The researchers found that women reached a viral load of less than 1,000 copies by one week and an undetectable viral load at a median of 4.14 weeks when they were on a dolutegravir-containing regimen. Meanwhile, women who were using efavirenz saw their viral load drop to below 1,000 copies by 3.71 weeks and reached an undetectable level by 12 weeks. That means that women on dolutegravir reached a viral load under 1,000 copies 83% faster and an undetectable viral load 93% faster than their counterparts on efavirenz.

Both regimens were effective at preventing viral load rebound and treatment failure, which women using dolutegravir experienced half as often as women on efavirenz—three versus eight women, respectively. Of those, six women (including one on dolutegravir) didn't suppress the virus by 24 weeks and five reached an undetectable viral load but saw their virus rebound.

Similarly, by 72 weeks, both drugs were relatively well tolerated. There were 57 total adverse events, of which 49 (18%) were severe. But just 3% of the adverse events were deemed to be drug-related (three in the dolutegravir arm and five in the efavirenz arm).

As for the infants, 136 of 242 infants (56%) experienced any adverse events, of which one in four were severe. These were primarily umbilical hernia and birth marks. None were deemed related to antiretrovirals. Eleven infants died, eight of them in the dolutegravir arm.

And then there's the single case of HIV acquisition among the infants. This infant was HIV negative at delivery, six weeks and 12 weeks, but wasn't brought to study visits at 24 and 48 weeks. The child tested positive for HIV at the end of the study at week 72.

The infant's mother did get her viral load tested consistently, however. She had a low but detectable viral load at delivery and 12 weeks postpartum (126 and 69 copies) and had an undetectable viral load at weeks 12, 48 and 72. But at week 24, she had a viral blip, to 126 copies. This is well below the 1,000-copy cutoff thought to the threshold for mother-to-child transmission.

Malaba said that the drug-resistance pattern and viral sequencing suggest that the infant's HIV was linked to the mother's, but deep phylogenetic analysis has not yet been completed . Still, the results "support WHO treatment recommendations for the use of dolutegravir in pregnancy," she said.

“Maternal dolutegravir-based [antiretroviral treatment] had superior virologic efficacy, with rapid viral suppression following initiation. And this virologic suppression was maintained throughout the breast-feeding period,” she said. “The infant HIV infection in the efavirenz arm highlights the potential for transmission during breast feeding in mothers despite evidence of virologic suppression.”

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