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PATTERNS OF VIRAL LOAD AND DRUG RESISTANCE IN BREAST MILK AND BLOOD FROM WOMEN TREATED WITH SINGLEDOSE NEVIRAPINE TO REDUCE MOTHER-TO-CHILD TRANSMISSION OF HIV-1

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BACKGROUND: The use of single-dose nevirapine (NVP) to reduce mother-to-child transmission of HIV- 1 is increasing in the developing world. However, little is known regarding the effects of this regimen on viral loads in breast milk or on the temporal patterns of drug resistance that arise during the early postpartum period. These are important to determine because considerable HIV-1 transmission occurs during the first 6 weeks postpartum in breast-feeding populations. We have determined the effect of NVP on breast milk viral shedding and are examining the prevalence of NVP resistance during this early postpartum period.

METHODS: Thirty pregnant HIV-1 seropositive women in Nairobi, Kenya who planned to breastfeed were treated with the single-dose NVP regimen (HIVNET 012). Two to four breast milk samples were collected each week between delivery and 6 weeks postpartum. Breast milk HIV-1 RNA was quantified using the Gen-Probe HIV-1 viral load assay. HIV-1 DNA was extracted from blood samples collected at 1 month postpartum and was tested for NVP resistance using an allele-specific PCR assay that detects the K103N mutation.

RESULTS: Breast milk viral loads in 30 women treated with single-dose NVP were compared to breast milk viral loads from 30 women treated with the Thai-CDC short-course zidovudine regimen. A total of 404 breast milk samples from the NVP-treated women were tested, with a median of 14 samples per woman during the first 6 weeks postpartum. Between 3 and 21 days postpartum, treatment with NVP was associated with significantly greater suppression of breast milk $\log_{10}$ HIV-1 RNA: days 3 to 7 (1.98 vs 2.42, P=0.1); days 8 to 14 (1.78 vs 2.48, P=0.005); days 15 to 21 (1.90 vs 2.97, P=0.003).

In preliminary studies, utilizing an allele-specific PCR assay, we tested one-month postpartum blood samples from the NVP-treated women and determined that 40% of the women tested to date had detectable levels of the K103N mutation. Breast milk samples are currently being tested.

CONCLUSIONS: Compared to the Thai-CDC shortcourse zidovudine regimen, single-dose NVP results in sustained suppression of breast milk viral loads during the first 3 weeks postpartum. However, the benefits of this suppression may be counterbalanced with a high prevalence of resistance.

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