

ABSTRACT

BACKGROUND: Antiretroviral (ARV) prophylaxis effectively reduces mother-to-child transmission of human immunodeficiency virus type 1 (HIV). However, it is unclear whether stopping ARVs after breastfeeding cessation affects maternal HIV disease progression. We assessed 18-24-month postpartum disease progression risk among women in a randomized trial assessing efficacy and safety of prophylactic maternal ARVs. **METHODS:** From 2005 to 2008, HIV-infected pregnant women with CD4(+) counts of 200-500/mm³ were randomized to receive either triple ARV (zidovudine, lamivudine, and lopinavir/ritonavir during pregnancy and breastfeeding) or AZT/sdNVP (zidovudine until delivery with single-dose nevirapine without postpartum prophylaxis). Maternal disease progression was defined as the combined endpoint of death, World Health Organization clinical stage 4 disease, or CD4(+) counts of <200/mm³. **RESULTS:** Among 824 randomized women, 789 had at least 1 study visit after cessation of ARV prophylaxis. Following delivery, progression risk up to 24 months postpartum in the triple ARV arm was significantly lower than in the AZT/sdNVP arm (15.7% vs 28.3%; P = .001), but the risks of progression after cessation of ARV prophylaxis (rather than after delivery) were not different (15.0% vs 13.8% 18 months after ARV cessation). Among women with CD4(+) counts of 200-349/mm³ at enrollment, 24.0% (95% confidence interval [CI], 15.7-35.5) progressed with triple ARV, and 23.0% (95% CI, 17.8-29.5) progressed with AZT/sdNVP, whereas few women in either arm (<5%) with initial CD4(+) counts of ≥350/mm³ progressed. **CONCLUSIONS:** Interrupting prolonged triple ARV prophylaxis had no effect on HIV progression following cessation (compared with AZT/sdNVP). However, women on triple ARV prophylaxis had lower progression risk during the time on triple ARV. Given the high rate of progression among women with CD4(+) cells of <350/mm³, ARVs should not be discontinued in this group.