

Abstract

OBJECTIVE: To assess the effectiveness and safety of antiretrovirals (ARVs) used for treatment or prophylaxis in a breastfeeding population of HIV-1-infected women (Burkina-Faso, Kenya, South Africa). **METHODS:** HIV-1-infected pregnant women with <200 CD4 cells per cubic millimeter or with World Health Organization stage 4 disease (cohort A) and asymptomatic women with >500 CD4 cells per cubic millimeter (cohort B) were enrolled into 2 prospective cohorts. Women with 200-500 CD4 cells per cubic millimeter were enrolled in a parallel randomized trial. Women in cohort A initiated antiretroviral therapy. Women in cohort B received zidovudine from 34 to 36 weeks gestation until delivery, with single-dose nevirapine in labor (cohort B). All children received single-dose nevirapine. **RESULTS:** Of 248 women enrolled, 111 (cohort A) and 125 (cohort B) infants alive at 24 hours after birth were analyzed. Sixty-nine percent and 42% of women had undetectable viral load at delivery, respectively. Ten children in each cohort died. The 18-month cumulative incidences of HIV-1 infection were 7.5% (95% confidence interval: 3.8% to 14.5%) (cohort A) and 5.8% (2.8% to 11.8%) (cohort B). Sixty-one percent (cohort A) and 78% (cohort B) were breastfed for a median duration of 20 weeks. Four children in cohort A and only 1 in cohort B became HIV-1 infected after 6 weeks of age. **CONCLUSIONS:** Antiretroviral therapy initiated a median of 7 weeks before delivery in women with advanced HIV-1 disease was associated with a significant residual risk of HIV-1 transmission due to insufficient decrease in viral load by the time of delivery. Among women with >500 CD4 cells per cubic millimeter, the risk of breast-milk transmission was very low despite lack of postnatal prophylaxis.