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BACKGROUND

- In Mozambique, national policy provides potent antiretroviral therapy (nevirapine plus two nucleosides) for HIV-infected pregnant women with CD4 cell counts < 350 cells/ μ L
- Women are encouraged to continue antiretroviral therapy postpartum
- Many HIV-infected women choose to breastfeed their infants



METHODS

Prospective observational study of HIV-1-infected pregnant women receiving prenatal care at Primateiro de Maio Hospital, Maputo, Mozambique from August 2004–June 2005, and their infants.

Inclusion Criteria

- HIV-1 infection
- CD4 < 350 cells/ μ L
- \geq 18 years old
- > 16 weeks gestation
- Antiretroviral-naïve (previous single-dose nevirapine allowed)
- ALT, AST < Grade 3
- Hemoglobin > 7.0 g/dL

Study Procedures

- HAART initiation three weeks after enrollment
- Follow-up 1–2 weeks after starting ART, then monthly visits until delivery
- Women counseled about infant feeding options
- Formula available for all subjects
- Maternal postpartum and infant visits occurred one week after delivery and monthly thereafter
- Infant HIV testing occurred at six months by HIV-1 RNA PCR using dried blood spots

Antiretroviral Medications

Mother (beginning at enrollment and continuing through six months postpartum)

- Nevirapine 200 mg QD x 14 days, then 200 mg BID¹
- Lamivudine 150 mg BID
- Zidovudine 300 mg BID² or Stavudine 30 mg BID

Infant (within 48 hours of birth)

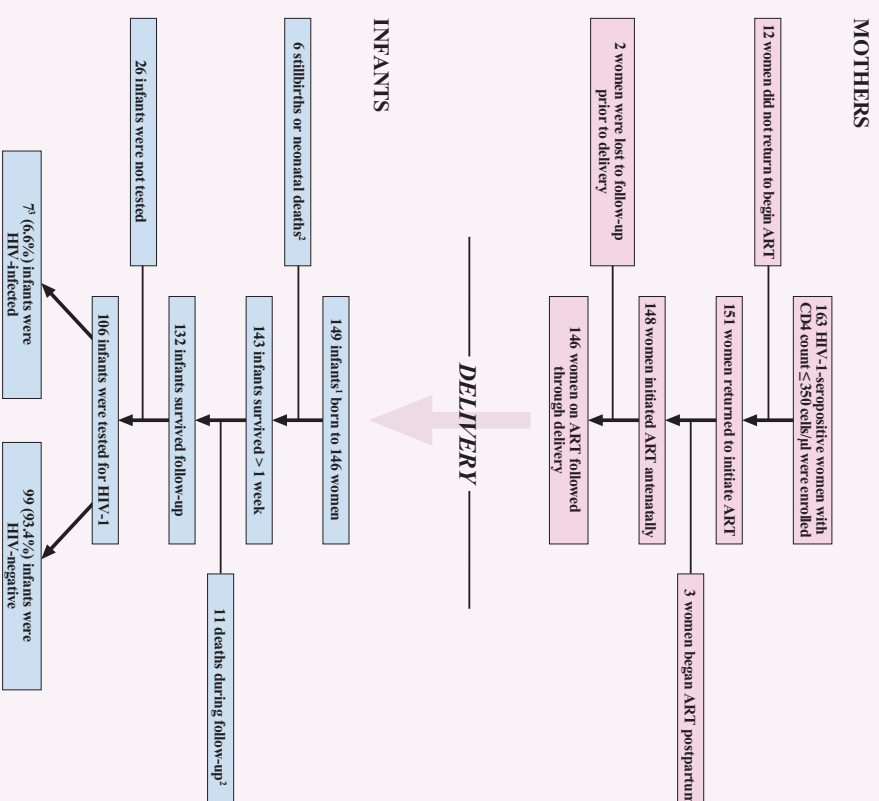
- Single-dose nevirapine
- Nelfinavir 1250 mg BID substituted for significant hepatic or skin toxicity
- Stavudine substituted for severe anemia

Statistical Methods

- Associations between infant HIV infection and maternal, obstetric and infant characteristics were examined using Pearson's chi-square or Fisher's exact test for categorical variables, and the Wilcoxon rank sum test with unequal variances for continuous variables.

RESULTS

Study Population



Characteristics associated with perinatal HIV transmission

Maternal characteristics ¹	HIV-infected (N=7)	HIV-negative (N=99)	P-value ²
Age	29 (22–32)	27 (24–30)	0.90
Weight	56 (44–60)	62 (56–69)	0.10
Married/Regular Partner	5 (71)	63 (64)	0.33
\geq Secondary education	4 (57)	51 (50)	0.47
CD4 category ¹			
\leq 250	4 (57)	57 (58)	0.98
250–350	3 (43)	42 (42)	
WHO disease stage			
I	1 (14)	44 (44)	0.17
II	0 (0)	11 (11)	
III	6 (86)	42 (42)	
IV	0 (0)	2 (2)	
Anemia at baseline			
Normal (\geq 8.5)	7 (100)	85 (86)	0.57
Moderate (7.0–8.4)	0 (0)	12 (12)	
Severe (< 7.0)	0 (0)	2 (2)	
HAART regimen			
ZDV/3TC/NVP	4 (57)	46 (46)	0.58
D4T/3TC/NVP	3 (43)	53 (54)	
Antenatal HAART duration (wks)	5.5 (4–21)	8 (6–13)	0.57
Postnatal HAART duration (mos)	7 (6–9)	7 (5.5–10)	0.79
Mode of delivery			
Vaginal	5 (71)	77 (78)	0.84
Cesarean	2 (29)	22 (22)	
Infant characteristics¹	HIV-infected (N=7)	HIV-negative (N=99)	P-value²
Gestational age	38 (38–40)	39 (38–40)	0.62
Birth weight	2850 (2650–3250)	3000 (2700–3300)	0.84
Feeding type			
Any breast feeding	2 (29)	47 (48)	0.60
Formula (no breast feeding)	4 (57)	44 (44)	
Unknown	1 (14)	8 (8)	
Age at HIV-1 testing (mos)	6 (4.5–7.5)	6.5 (4.5–9)	0.52

¹Median (IQR) or N (%)

²Wilcoxon test or chi-squared test

CONCLUSIONS

- The HIV MTCT rate appears to be unexpectedly high in this cohort of infants whose mothers took potent ART in late pregnancy and postpartum.
- Alternatively, maternal postpartum ART may not be the optimal PMTCT strategy in the context of breastfeeding because of limited penetration of ART into breast milk or other factors.
- These data could reflect *in utero* HIV transmission.

OBJECTIVE

- Describe perinatal HIV transmission in the context of nevirapine-based antiretroviral therapy during late pregnancy and postpartum.

