

Efficacy of Peripartum Nevirapine to Prevent Mother to Child HIV Transmission in Women Presenting Late for Antenatal Care in Thailand

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Background: Given the efficacy of ART in preventing mother-to-child transmission of HIV (MTCT), an increasing proportion of pediatric HIV infections are the result of situations where pregnant women receive minimal or no antenatal care. Interventions specifically targeting these women are being evaluated.

Methods: In the context of a large perinatal HIV prevention trial in Thailand, women who could not enroll because they presented too late during pregnancy were offered open-label antiretroviral prophylaxis and followed separately. In addition to zidovudine (ZDV) for the remaining part of pregnancy, women were offered a single dose nevirapine (NVP) during labor, and their infants 4 weeks ZDV and a single-dose NVP 48 to 72 hours after birth. Infants HIV status was assessed using the HIV DNA PCR Roche 1.5 test kit. Kaplan Meier transmission rates and 95% confidence intervals (CI) were estimated (Stata 8.0).

Results: Emergency antiretroviral prophylaxis was offered to 137 HIV+ women. Baseline characteristics of mothers were: median age 26 years; weight 59 kg, hemoglobin level 11.1 g/100 mL, CD4 count 411 cell/mm³, and gestational age at delivery 38.1 weeks; 41 delivered by caesarean sections; 138 children were born, including 2 sets of twins. The median birth weight was 2.8 kg (24% equal or below 2.5 kg); 98% of the children had at least one PCR test and the HIV status was confirmed in 115 infants (84%); 90 women (66%) did not receive any ZDV before labor and the other received < 15 days of ZDV; 82% received a ZDV loading dose; 95% of the newborn were prescribed 6 weeks of ZDV but 5% received ZDV for 1 week. Transmission rates were 15.7% (CI 9.7 to 25%) among the 103 cases where NVP was administered to the mother and the newborn, 23.2% (CI 11.1 to 45%) in 29 cases where only to the newborn received NVP. There were no transmissions in the 3 cases where only the mother received NVP, and in the 2 cases where neither the mother nor the infant received NVP.

Conclusions: Compared with the results of PHPT-2, where women received ZDV at 28 weeks or as soon as possible thereafter, the efficacy of peripartum NV P following no or < 2 weeks of ZDV prophylaxis was very poor. This emphasizes the need for ART prophylaxis during the whole third trimester of pregnancy and therefore medico-social interventions targeting these women.

Support

National Institutes of Health (R01 HD 36915), USA; Agence Nationale de Recherches sur le SIDA (ANRS 1208), France; Ministry of Public Health, Thailand; Department of Technical and Economic Cooperation, Thailand; Institut de Recherche pour le Développement, France ; Institut National d'Etudes Démographiques, France Fogarty international, USA; Glaxo-Smith-Kline, Boehringer-Ingelheim (drugs) and Roche Molecular Systems (kits for DNA PCR)



Introduction

The primary objective of the Perinatal HIV Prevention Trial 2 (PHPT-2), conducted in 37 sites in Thailand, was to assess the safety and efficacy of adding nevirapine to zidovudine for the prevention of mother-to-child transmission of HIV*. For this reason and based upon the results of HIVNET 012, women who had not received zidovudine prophylaxis for at least two weeks were not enrolled in this trial. Instead they were offered nevirapine single dose during labor and their infants 48-72 hours after birth to prevent perinatal transmission.

In this study, we looked at the efficacy of peripartum nevirapine to prevent perinatal transmission in this specific population.

*Lallemant M, Jourdain G, Le Coeur S, et al. Single-dose perinatal nevirapine plus standard zidovudine to prevent mother-to-child transmission of HIV-1 in Thailand. *N Engl J Med* 2004;351:217-28.

** Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999;354:795-802.



PHPT network

37 public hospitals in Thailand

- Physicians, Nurses, Counselors, Laboratory Technicians, Pharmacists
- ANC-OB-GYN, Pediatrics, Internal Medicine

A center for clinical research in Chiang Mai: protocol development, trainings, data management, monitoring, statistical analysis, and laboratory dedicated to HIV *studies* and antiretroviral pharmacokinetics assessments



Maternal Characteristics

Treatment actually received	NVP-NVP	Ø-NVP
N women	103	29
Median Age (years) [IQR]	26 [23 to 30]	23 [21 to 29]
Received some ZDV before labor (%)	41 (40%)	5 (17%)
Median VL at enrolment (\log_{10} cp/mL)	4.1	4.6
Median CD4 cell count (per mm ³)	433	375
CD4 \leq 200 cells (%)	6	1
Positive HB S-Ag (%)	5	3
Positive HCV antibodies (%)	6	3
SGPT grade 1 (31 to 62 U/L) (%)	3	2
grade 2 (63 to 125 U/L) (%)	2	2

Patient disposition

137 HIV-1 infected pregnant women were not enrolled in PHPT-2 because they received less than 2 weeks ZDV prophylaxis

N-N

103 cases
Mother and neonate received nevirapine (including 62 mothers who did not receive zidovudine before labor)

N-Ø

3 cases
Only mother received nevirapine (including 2 mothers who did not receive zidovudine before labor)

Ø-N

29 cases
Only neonate received nevirapine (including 24 mothers who did not receive zidovudine before labor)

Ø-Ø

2 cases
Neither mother nor neonate received nevirapine (none of the mothers received zidovudine before labor)

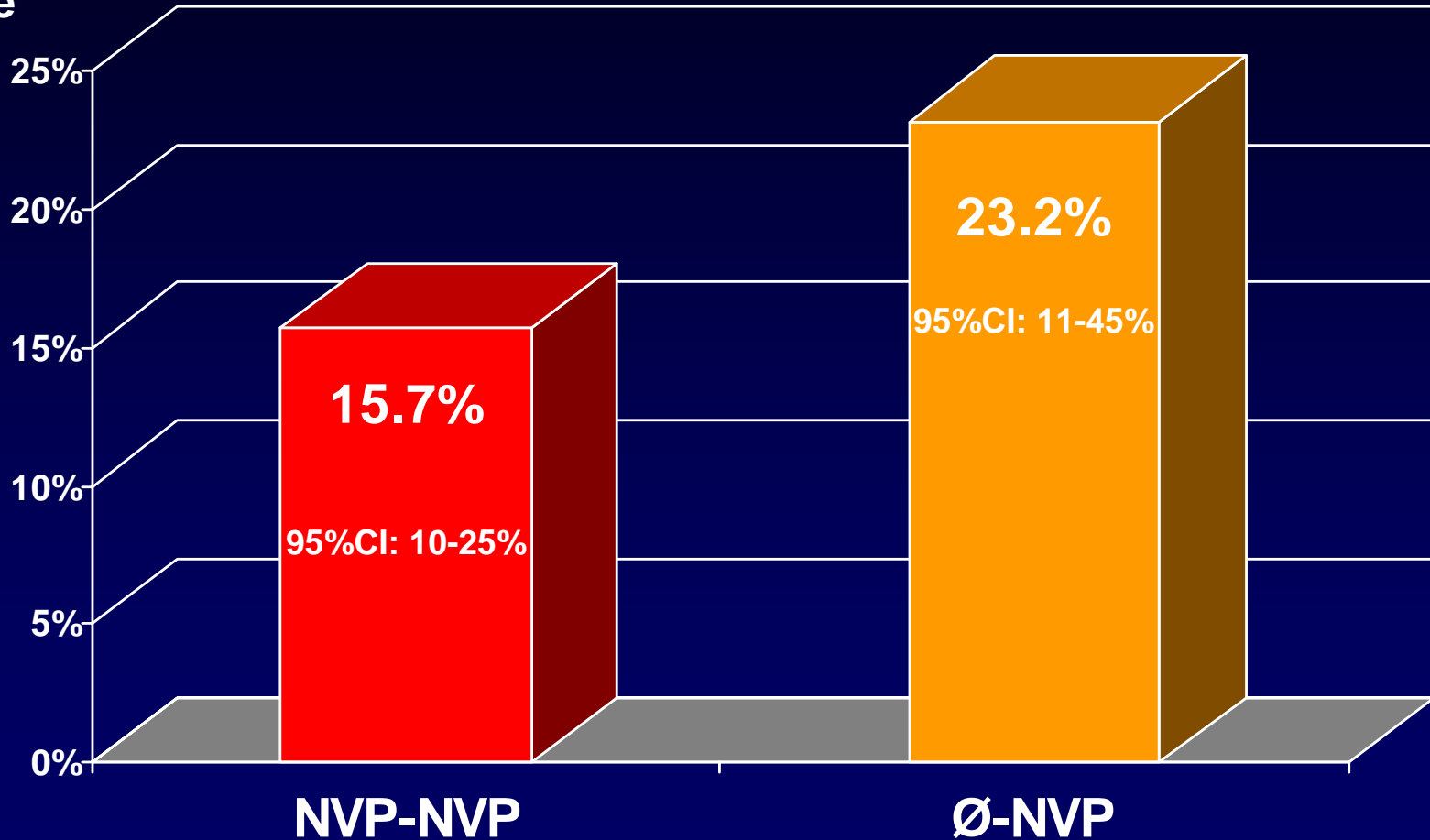


Delivery and Infant Characteristics

Randomization arm	NVP-NVP	Ø-NVP
Total deliveries	103	29
Median GA at delivery (weeks)	38	38
Delivery <= 37 weeks gestation (%)	27	5
Median labor duration (hours)	11.5	6.4
Median time between study drug intake and delivery (hours)	4.5	39.8
Caesarean-section (non-elective) (%)	26	4
Total live born infants	104	29
Median birth weight (Kg)	2.86	2.80
Birth weight <2.5 kilograms (%)	19	28
Median time between birth and study drug intake (hours)	48.2	10.5

Zidovudine less than 2 weeks + peripartum nevirapine for PMTCT

Transmission
Rate



Conclusion

In PHPT-2, in the two arms where women received ZDV at 28 weeks or as soon as possible thereafter and single dose nevirapine at onset of labor, the transmission rate was below 3%.

In this study where women had received no zidovudine prophylaxis or for less than 2 weeks because they presented at the antenatal care clinics late during pregnancy or during labor, the efficacy of nevirapine appeared to be limited. This population of women may have other characteristics associated with poor access to antenatal care and higher risk of transmission.



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