AMATA study :
Effectiveness of antiretroviral therapy in breastfeeding mothers to prevent post-natal vertical transmission : interim analysis

- Allaitement MAternel sous Trithérapie Antirétrovirale (“milk” in kinyarwanda)

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TRAC

LUX-DEVELOPMENT S.A.
Agence luxembourgeoise pour la Coopération au Développement

ESTHER
pour une Ensemble Solidarité Thérapeutique Hospitalière En Réseau

IAS 2007 SYDNEY AUSTRALIA

Background and Objectives

- Post-natal transmission through breastfeeding occurs in up to 15% of children born to HIV-1 infected mothers
- to compare breastfeeding under triple antiretroviral therapy (ART) with formula feeding (FF) for prevention of post-natal mother-to-child transmission
- Transmission rates
- Morbidity, mortality and child development under both feeding modes

Methods

- All HIV positive women at 4 antenatal sites are proposed to participate
- All receive NNRTI-based ART after 2nd trimester
- Choice is made before delivery between Exclusive BF under ART for 6 months or FF
- BF mothers continue ART until 1 month after end of BF

Methods: ARV treatment

- **Mothers eligible for ARV under national protocole (stage 4 and/or CD4 < 350/mm2): D4T + 3TC + NVP ; choice between FF and BF**

- **Mothers with stage 1, 2, 3 and CD4 > 350: AZT + 3TC + EFV from 26 weeks of gestation**
  - **stop at birth if FF**
  - **stop at 7 months if BF**
  - **Dual NRTI therapy for 7 days after HAART**

- **Baby: NVP single dose + AZT for 7 days**

Results (1)

- 573 women enroled
- 557 delivered (July 2007):
  - 316 FF (57%)
  - 238 BF + ART (43%)
- PCR in babies:
  - 484 (90%) at 6 weeks
  - 431 (87%) at 7 months: 255 FF, 176 BF
- Viral loads at delivery:

<40	40-1000	>1000
52%	38%	10%

Results (2):

Transmission:

- 7/431 children infected so far (1.6 %)
  - 6 at birth
  - 1/176 at M7 through BF (0.6%) (CI 0-3/100)
    - Viral loads in mother:
      - <40 at delivery
      - 3,6 log at weaning

Results (3)

- Morbidity

	Medical visits	Disease episodes	Hospital admissions
FF	39%	1.32	10%
BF	35%	1.23	6%
	P= 0.279	P=0.26	P=0.17

Results (4)

Mortality:

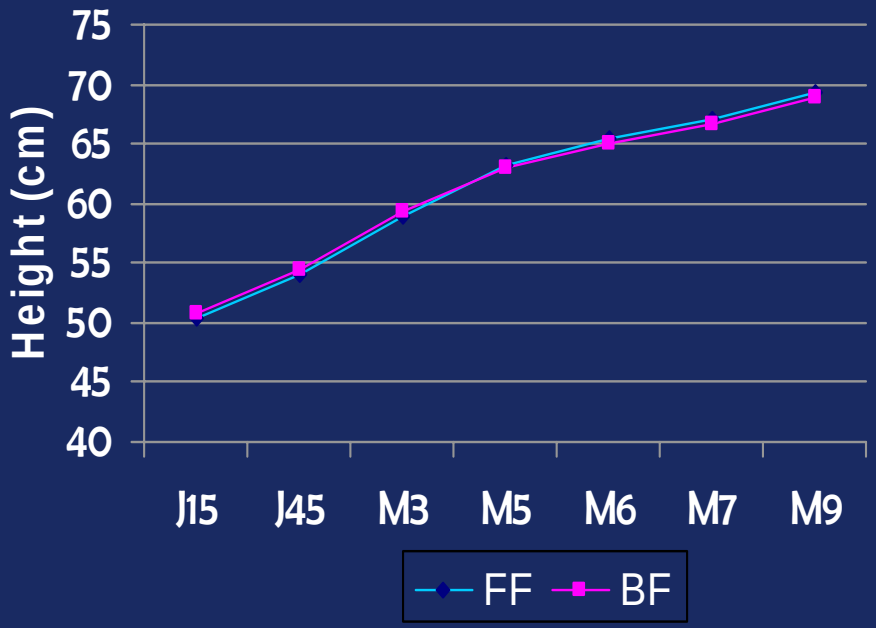
- **24 children died (4%)**
  - **BF: 6 children (3%)**
  - **FF: 18 children (6%)** **p=0,15**

Cognitive development

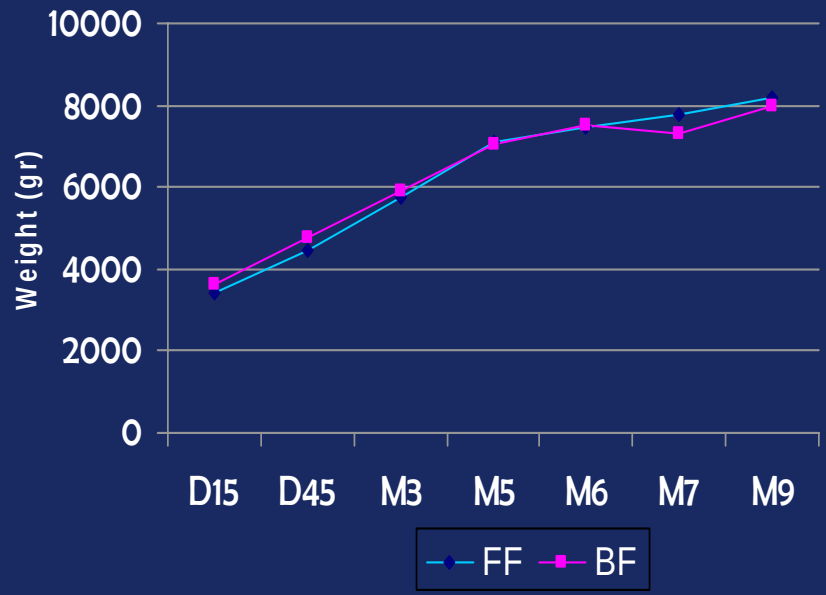
Mean age for	following w/eyes	holding head	sitting alone
FF	52 d	83 d	197 d
BF	56 d	85 d	200 d
p	0.37	0.22	0.52

Results (5)

Growth



Weight



No significant difference

Conclusion

- Low transmission rates can be achieved using ART pre- and postpartum
- BF under ART in children born to HIV-1 infected women is associated with a low transmission rate while keeping the benefits of BF
- No difference in morbidity, mortality and development in children under FF compared to BF under ART

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