



# FACTORS ASSOCIATED WITH VIRAL LOAD CONTROL AND ITS IMPACT ON HIV VERTICAL TRANSMISSION RATES IN A HIV PREGNANT WOMEN COHORT FROM RIO DE JANEIRO DURING HAART ERA.

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## ABSTRACT

## OBJECTIVES

## RESULTS

## CONCLUSIONS

## METHODS

## REFERENCES

**BACKGROUND:** Effective use of anti retroviral (ARV) in pregnancy and appropriate management of delivery have significantly reduced MTCT rates to less than 2% in developed countries and in Brazil. HSE, a reference center for PMTCT, has a cohort of HIV pregnant women since 1996. This study's goal was to evaluate the impact of virologic control (VC) with ARV (HAART X Non-HAART) in PMTCT. **METHODS:** From 1996 to 2008, 824 HIV pregnant women were selected, who received ARV at least for 4 weeks during pregnancy and had measured baseline viral load (VL) and near to delivery. 634 used HAART and 190 used Non-HAART. 117 who had undetectable viral load (VL<400 copies/ml), at entry in the cohort were excluded of analysis. Statistical analysis was performed using SPSS, v 13.0. Means were compared using t-test, Mann-Whitney, ANOVA, or Kruskal-Wallis methods. Multivariate analysis was employed using binary logistic unconditional models. **RESULTS:** From the 824 pregnant women with median of gestational age was 21 weeks for initiating ARV. At baseline CD4 count median was 371 and near delivery was 462 cells/mm<sup>3</sup> and the median VL at baseline was 8599 (3,93 log) and near to delivery 400 (2,6 log) copies/ml. Subsequent analysis included 707 women who had baseline VL > 400copies/ml. Global effectiveness in VC was 57% (n=403). Vertical transmission (VT) rate was reduced significantly with VC (See Figure 1). VT rates were 0.25% (CI 95% 0.01-1.62) for <400 copies; 1.38% (CI 95% 0.17-9.6) for copies 400-1000; and 4% (CI 95% 1.96-7.71) for > 1000 copies..

Using logistic model, HAART was associated with a 4-fold increase in CV control when compared non HAART (OR=4,15, 95%CI, 2,9-5,95) and, time of ARV use>12weeks (OR= 2.75, 95%CI 1,96-3,85) and CD4 near delivery >400 (OR=1,55, 95%CI 1,08-2,2) were either associated to success VC. The newborn outcomes low birth weight < 2500g in HAART was 15.3%, non HAART 10.25% (p=0.40) and preterm birth < 37 weeks in HAART was 8.8% and non HAART was 5.12% (p=0.43). **CONCLUSIONS:** VC (VL< 400 cp/ml), especially with HAART use and CD4 cell count near to delivery, as time of use ART (>12 weeks) had an impact in reduction of MTCT. Efforts to start ARV early during the pregnancy and reach VC near of delivery should be the goal of PMTCT.

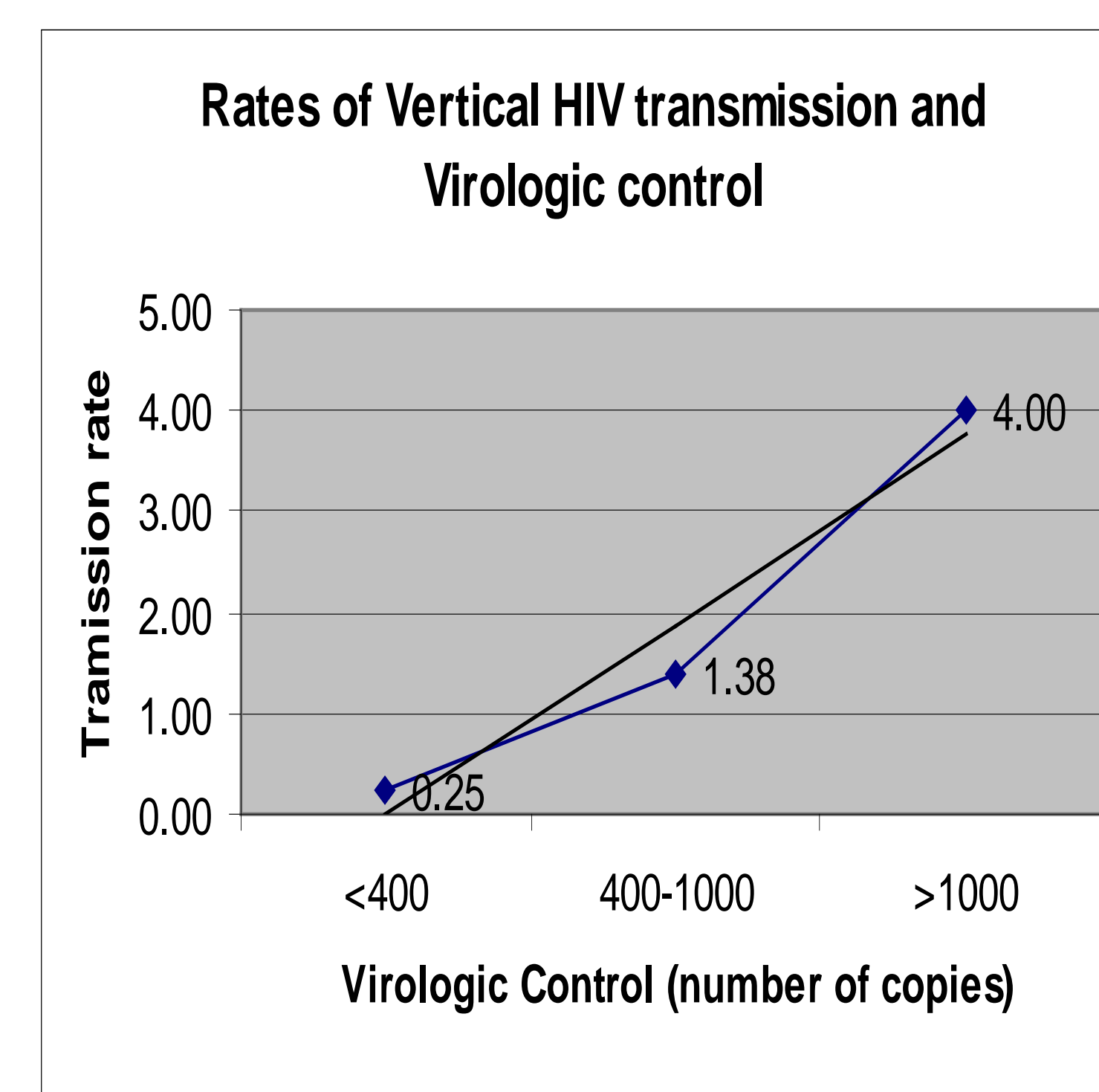
## BACKGROUND

•Effective use of antiretrovirals (ARVs) during pregnancy, labor and delivery, and by infants after birth, appropriate management of delivery and avoidance of breastfeeding, have significantly reduced HIV mother- to- child transmission (MTCT) rates to less than 1-2 % in countries where ARVs are widely available. HAART has been the standard of care in these countries, and has had a great impact in reducing the rate of HIV vertical transmission through viral load (VL) control.

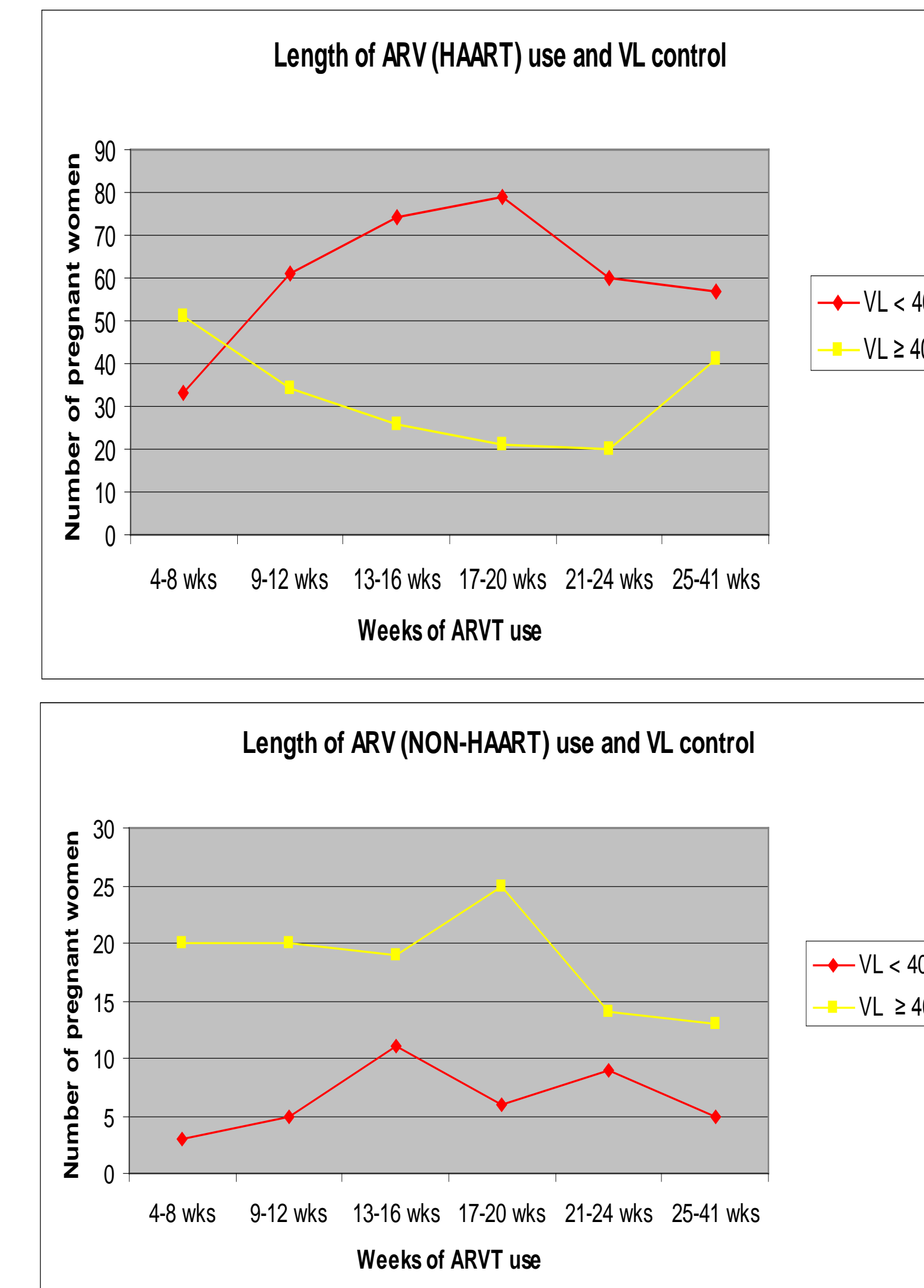
•The main objective of the current study is to evaluate factors associated with viral load control, i.e, the achievement of undetectable VL (<400 copies/mL) near delivery, in a cohort of HIV-infected pregnant women receiving HAART and non-HAART regimens at a center for PMTCT in Rio de Janeiro. The impact of VL control on HIV vertical transmission rates and the influence of ARV use on infant outcomes in this cohort were also analyzed.

From a cohort of 1218 HIV+ pregnant women followed 01/ 1996 – 12/ 2008, 824 women who had received at least 4 weeks of ARVs until delivery and their newborns were selected. Women lost to follow-up, with sequential pregnancies or a length of ARV use less than 4 weeks were excluded. Pregnant women started ARVs either before or during pregnancy: 190 non-HAART (zidovudine (AZT) monotherapy or two Nucleoside Reverse Transcriptase Inhibitors (NRTI) and 634 HAART (two NRTIs plus a Protease Inhibitor (PI) or nevirapine). Pregnant women who had a VL <400 copies/mL at entry in cohort were excluded from subsequent analysis. Final subset analysis included 707 women who fulfilled the inclusion criteria. Statistical analysis was performed using SPSS, v 13.0. Means were compared using t-test, Mann-Whitney, ANOVA, or Kruskal-Wallis methods. Multivariate analysis was employed using binary logistic unconditional models.

In the 824 pregnant women, the median gestational age for initiating ARV was 21 weeks. Median CD4 count at baseline was 371 and near to delivery 462 cells/mm<sup>3</sup>. Median VL at baseline was 8599 (3,93 log) and near to delivery 400 (2,6 log) copies/ml. Subsequent analysis included only 707 women who had baseline VL > 400copies/ml. Global effectiveness in VC was 57% (n=403), with HAART was 65% (n= 346) and non HAART was 26% (n=39). Vertical transmission (VT) rate was reduced significantly with VC (See Figure 1). VT rates were 0.25% (CI 95% 0.01-1.62) for <400 copies, 1.38% (CI 95% 0.17-9.6) for copies 400-1000 and 4% (CI 95% 1.96-7.71) for > 1000 copies.



**Figure 1. Rates of MTCT of HIV and Virologic control (Chi-square for trend: p< 0.01).**



**Figure 2. Length of ARV use comparing HAART and NON-HAART and Virologic control (<400; ≥ 400).**

Length of ARV use was also associated with undetectable VL near delivery. Figure 2 shows that this association is significant for women receiving HAART. Using a logistic model, HAART was associated with a 4-fold increase in CV control when compared with non HAART (OR=4,15, 95%CI, 2,9-5,95) and use of ARV >12weeks was associated to successful VC (OR= 2.75, 95%CI 1,96-3,85). CD4 near delivery >400cells/mm<sup>3</sup> (OR=1,55, 95%CI 1,08-2,20) was also statistically associated to successful VC. Newborn outcomes: LBW (< 2500g) was 15.3% with HAART, and 10.25% (p=0.40) with non HAART regimens and preterm birth (< 37 weeks) was 8.8% with HAART and 5.12% (p=0.43) with non HAART regimens.

•VC (VL< 400 cp/mL), especially with HAART use and a CD4 cell count>400 cells near delivery and use of ARV >12 weeks had an impact in reduction of MTCT. Efforts to start ARV early during pregnancy and reach VC near delivery should be the goal of PMTCT of HIV.

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