Abstract

Impact of valacyclovir on genital and plasma HIV-1 RNA: a randomised controlled trial among women taking HAART (ANRS 1285b)

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Background: Epidemiological data suggest that HSV2 infection can increase HIV-1 genital shedding, but this causal relationship has never been proven in women taking HAART.

Methods: We conducted a proof-of-concept randomised placebo-controlled trial of valacyclovir suppressive treatment (1g-daily for 3-months) among HIV-1/HSV2 co-infected women taking HAART in Burkina Faso. We evaluated the impact on genital and plasma HIV-1 RNA. Participants were followed bi-weekly for 3 months prior to, and 3 months after randomization (=12 visits). Cervico-vaginal lavages were collected for HIV-1 RNA quantitation by real time PCR. Plasma HIV-1 RNA was assessed at every other visit by PCR. For each woman, the difference in median quantity of virus between the 2 phases was calculated, and this difference was compared between arms with the Wilcoxon ranksum test.

Results: 60 women were randomized to valacyclovir or placebo (mean CD4 count: 266 and 295/µl, respectively). Women attended 97.5% of visits and their mean drug compliance was 99%. Four women in valacyclovir arm (13%) and six in placebo arm (20%) had detectable plasma HIV-1 RNA at least once during the baseline phase. There was no overall reduction in the proportion of women with at least one episode of detectable genital HIV-1 RNA (36.7% vs 40.0%, p=0.79), nor in the median quantity of genital HIV-1 RNA detected (p=0.38). There was a borderline significant reduction in the quantity of genital HIV-1 RNA in the subgroup of women shedding HIV-1 at baseline (p=0.09). There was also some evidence of a reduction in plasma HIV-1 RNA among the women on valacyclovir (p=0.06).

Conclusions: Valacyclovir did not appear to have an impact on genital HIV-1 RNA beyond the levels afforded by HAART, but there was some evidence of a reduction in plasma HIV-1 RNA. This effect should be confirmed in larger trials.