

Poster presentation

## Impact of antiretroviral dosing and daily pill burden on viral rebound rates in naive patients receiving a tenofovir-based regimen

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from Ninth International Congress on Drug Therapy in HIV Infection  
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

*Journal of the International AIDS Society* 2008, **11**(Suppl 1):P3 doi:10.1186/1758-2652-11-S1-P3

This abstract is available from: <http://www.jiasociety.org/content/11/S1/P3>

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### Background

cART complexity is a major reason for non-adherence to medications and, therefore, may impact treatment outcome. The role of pill burden and dosing on virological failure in ARV-naive HIV-positive patients achieving virological suppression under a tenofovir-based regimen has not yet been assessed.

### Methods

A total of 480 ART-naive patients were selected from the GNOMO cohort. Incidence rate of viral rebound (VR = first of two consecutive VL > 50 cp/ml) was calculated as number of events over PYFU and expressed at univariate and multivariate analysis as incidence rate ratio (IRR). Number of both pills and doses per day were used to define three different types of regimens: twice-a-day regimens (BID regimens); once-a-day regimens with < 3 pills per day (low-pill QD [lp-QD]); and once-a-day regimens with > 3 pills (high-pill QD [hp-QD]). Adjusted rates of viral rebound were estimated by Poisson regression using date of first HIV-RNA < 50 c/ml as baseline. Follow-up was censored at the date of VR, death, or loss to follow-up.

### Summary of results

Male 74%; median pre-cART CD4 and HIV-RNA: 207/mm<sup>3</sup> (IQR 78–299) and 4.99 cp/ml (IQR 4.52–5.48), respectively. Regimens were: 45.8% BID, 17.1% hp-QD,

37.1% lp-QD. Incidence rate of VR was 10.5 × 100 PYFU (95% CI: 7.5–14.8) for BID, 7.4 × 100 PYFU (95% CI: 3.7–14.8) for hp-QD, and 5.8 (95% CI: 4.0–8.4) × 100 PYFU for lp-QD. At univariate analysis, taking as reference the BID group, QD dosing was associated with a significantly lower rate of VR (IRR 1.82; 95% CI 1.10–3.02). However, when comparing the three groups together, only lp-QD, but not hp-QD had a significantly lower risk of VR (IRR 0.50; 95% CI 0.29–0.88) with respect to BID.

After adjusting for age, gender, time to first HIV-RNA < 50 cp/ml, pre-cART CD4 and HIV-RNA, and daily pill burden, as appropriate, a trend towards a reduced rate of VR with respect to BID regimens was observed at the first multivariate model for QD regimens (IRR 0.62; 95% CI 0.37–1.06) and at the second model for lp-QD regimens (IRR 0.57; 95% CI 0.32–1.03). Of note, in both models pre-cART CD4 > 200/mm<sup>3</sup> was independently associated with reduced rate of VR (IRR 0.46; 95% CI 0.24–0.86) when compared with CD4 < 200/mm<sup>3</sup>.

### Conclusion

Once-a-day dosing of tenofovir-based regimens, especially when combined with low daily pill burden, favourably impacts on maintenance of virological response in cART-naive patients. Higher baseline CD4 cell count independently protects from loss of virological efficacy.