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INTENSIFICATION WITH EFAVIRENZ OR LOPINAVIR/RITONAVIR DOES NOT REDUCE RESIDUAL HIV-1 VIRAEMIA IN PATIENTS ON STANDARD ANTIRETROVIRAL THERAPY

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BACKGROUND: Currently recommended antiretroviral therapy suppresses plasma HIV-1 RNA to <50 copies/ml in most patients, but persistent, low-level viraemia can be detected with more sensitive assays. This residual viraemia may be produced by long-lived, chronically or latently infected cells, or by ongoing, complete cycles of virus replication. To differentiate between these sources, we conducted a trial of antiretroviral drug intensification in patients with HIV-1 RNA levels suppressed to <50 copies/ml plasma.

METHODS: Patients on combination antiretroviral therapy with non-nucleoside reverse transcriptase inhibitor (NNRTI)- or protease inhibitor (PI)-based regimens including two nucleoside reverse transcriptase inhibitors (NRTIs) and with stable HIV-1 RNA <50 copies/ml plasma for >1 year were screened for residual viraemia using a sensitive HIV-1 RNA assay (single copy assay [SCA]). Six patients with persistent viraemia (>1 copy HIV RNA/ml) were enrolled in a 30 day drug intensification study. Participants on PI-based regimens were intensified with efavirenz ($n=4$), and those on NNRTI-based regimens were intensified with lopinavir/ritonavir ($n=2$). Plasma for HIV-1 quantification was obtained weekly before, during and after the 30 day intensification period.

RESULTS: Enrolled patients (five male and one female) had HIV-1 infection for a mean of 9 years (range 4–16) and had received combination antiretroviral therapy for a mean of 4 years (range 1–10 years). The level of residual viraemia before intensification (mean=4.5 copies/ml plasma) was similar to that found in prior studies of patients on standard combination therapy. Drug intensification was well tolerated with no serious adverse events reported. Mean plasma HIV-1 RNA levels during intensification (5.3 copies/ml) and following intensification (5.2 copies/ml) were not significantly different from pre-intensification levels ($P=0.76$ and 0.79 , respectively). Similarly, no significant

decreases in HIV-1 RNA levels were observed during or after drug intensification in individual patient analyses. No significant changes in blood CD4+ T-cell counts were detected.

CONCLUSIONS: Antiretroviral intensification with lopinavir/ritonavir or efavirenz did not decrease the level of residual viraemia. This result is inconsistent with the idea that persistent viraemia results from ongoing, complete cycles of viral replication. New therapeutic approaches will be required to eliminate HIV-1 reservoirs.

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