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### Research Article

## Cellular HIV-1 DNA quantitation in patients during simplification therapy with protease inhibitor-sparing regimens

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### KEYWORDS

HIV-DNA • simplification therapy • HIV infection

### ABSTRACT

Simplified regimens containing protease-inhibitors (PI)-sparing combinations were used in patients with virological suppression after prolonged highly active antiretroviral therapy. This study evaluated the total HIV-1 DNA quantitation as a predictor of long-term success for PI-sparing simplified therapy. Sixty-two patients were enrolled in a prospective non-randomized cohort. All patients have been receiving a triple-therapy regimen, two nucleoside reverse transcriptase inhibitors (NRTIs) plus one PI, for at least 9 months and were characterized by undetectable plasma HIV-1 RNA levels (<50 cp/ml) for at least 6 months. Patients were changed to a simplified PI-sparing regimen to overcome PI-associated adverse effects. HIV-DNA levels in peripheral blood mononuclear cells (PBMCs) were evaluated at baseline and at the end of follow-up. Patients with proviral DNA levels below the median value (226 copies/10<sup>6</sup> PBMCs) had a significant higher CD4 cell count at nadir ( $P = 0.003$ ) and at enrolment ( $P = 0.001$ ) with respect to patients with HIV-DNA levels above the median value. At month 18, 53 out of 62 (85%) patients on simplified regimen showed virological success, 4 (6.4%) patients

experienced virological failure and 5 (8%) patients showed viral blip. At logistic regression analysis, HIV-DNA levels below 226 copies/10<sup>6</sup> PBMCs at baseline were associated independently to a reduced risk of virological failure or viral blip during simplified therapy (OR 0.002, 95% CI 0.001-0.46, *P* = 0.025). The substitution of PI with NRTI or non-NRTIs may represent an effective treatment option. Indeed, treatment failure or viral blip were experienced by 6% and 8% of the patients on simplified therapy, respectively. In addition, sustained suppression of the plasma viral load was significantly correlated with low levels of proviral DNA before treatment simplification. *J. Med. Virol.* 79:880-886, 2007. © 2007 Wiley-Liss, Inc.

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