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Immune and virologic responses to Truvada or Combivir as a first-line therapy of HIV-infected, treatment-naïve patients

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Purpose of the study

Clinical, immunological and virologic parameters were assessed in HIV-infected antiretroviral (ARV) naïve patients who started therapy with either Truvada ® (TVD) or Combivir® (CBV) in combination with efavirenz (EFV) or a protease inhibitor (PI).

Methods

107 HIV-infected, ARV-naïve patients were prospectively enrolled and treated with TVD (300 mg TDF + 200 mg FTC QD) or CBV (300 mg AZT + 150 mg 3TC BID) in combination with EFV (600 mg QD) or a PI (LPV/r, ATV/r, fAPV/r and SQV/r). Twenty-seven patients received TVD-EFV, 33 received TVD-PI, 24 received CBV-EFV, and 23 received CBV-PI. Fifty-one of these patients have, so far, reached 12 months of therapy. Clinical, immunological and virologic parameters at baseline and after 12 months of therapy are presented.

Summary of results

Median CD4+ cell counts and HIV-RNA plasma viremia were comparable in the four groups at baseline. EFV-associated skin rash was observed in three of the TVD- and in one of the CBV-treated patients. Eight patients in the TVD groups (three TVD-EFV and five TVD-PI) and 12 patients in the CBV groups (seven CBV-EFV and five CBV-PI) dropped out of the study; in only two cases (one TVD: acute pancreatitis; one CBV: leucopenia) was the drop-out was due to SAE.

At month 12, HIV-RNA plasma viremia was < 50 cps/ml in all patients; median CD4 cell counts were higher, although not significantly, in EFV-treated patients: TDV-EFV = 462/mcl (IQR: 323–663.5); TDV-PI = 339/mcl (IQR: 298–365); CBV-EFV = 450/mcl (IQR: 388.75–525.75); CBV+PI = 390/mcl (IQR: 308–523). Median CD4 counts were significantly different, compared to baseline values, in TDV-EFV ($p = 0.01$); TDV-PI ($p = 0.03$); and CBV-EFV ($p = 0.02$) groups.

Interestingly, whereas CD8+/CD38+/CDRO+ T lymphocytes were significantly diminished (median delta T12-baseline) after 12 months of therapy in all groups of patients, a significant reduction of CD8+/CD25+ and of CD8+/DRII+ T lymphocytes ($p = 0.01$ and 0.02, respectively) was observed at month 12 only in the TVD-EFV group.

Conclusion

Although the four therapeutic regimens considered do not differ significantly in the ability to suppress HIV viremia, the TVD-EFV combination is associated with a significant down-modulation of immune activation. In the light of the increasing importance of immune activation in the pathogenesis of HIV infection, the ability of this combination to reduce this parameter seems potentially important.