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Efficacy and safety of TDF/FTC-containing first-line HAART in clinical practice – 2-year data from the German Outpatient Cohort

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Purpose of the study

First-line HAART with tenofovir DF (TDF) and FTC in pivotal trials has been associated with high efficacy and good tolerability. However, real-life clinical practice often differs from clinical trials due to co-morbidities, co-infections, and less intensive clinical monitoring. To evaluate efficacy and safety of first-line HAART in a day-to-day setting, this Gilead-sponsored non-interventional cohort was established.

Methods

Between July 2005 and August 2006, 533 HIV-1 infected antiretroviral-naïve patients from 50 German centres enrolled in this non-interventional cohort. All patients were followed every 3 months for 3 years to monitor efficacy (viral load [VL], CD4), tolerability, renal safety, regimen changes and resistance profile. All patients received TDF+FTC as a single tablet (Truvada, TVD) in combination with either an NNRTI or PI/r as their first antiretroviral regimen.

Summary of results

As of June 2008, 2 years of therapy have been documented for 330/533 (62%) patients. At treatment initiation, 81% were male; median age was 39 years; clinical AIDS diagnosis was documented in 22%; 47% started therapy with CD4 <200 cells/mm^3. TVD was combined with an NNRTI (43%) or a PI/r (57%).

After 24 months, in an As-Treated (AT) analysis, 85% patients achieved a VL <50 copies/ml (VL <500 copies/ml: 97%), median CD4 count increased from 217 at baseline to 450 cells/mm^3 (IQR: 325–608). Truvada showed a good safety profile; 76 adverse events (AEs) of any grade were reported in 66/533 patients (12%); six of these were judged serious. Fourteen (2.6%) patients discontinued TVD due to AEs. Renal abnormalities of any grade were reported in 10 patients (1.9%). Virological failure was documented in nine patients, of which eight were genotyped; M184V/I was detected in three, K65R in two patients.

Conclusion

During 2 years of follow-up, the overall safety of TVD was good; renal AEs of any grade were reported in 1.9% of patients. K65R was detected in two patients. First-line HAART with TVD plus an NNRTI or PI/r in clinical practice showed comparable efficacy to that observed in controlled clinical trials.