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Similar virological response rates for ART-naïve subjects starting KVX + LPV/r or TVD+ LPV/r. Data from the prospective observational STAR cohort

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Purpose of the study

Recently, an inferior virological response was observed in the ACTG 5202 trial for subjects with >10^5 copies/ml of HIV-RNA randomised to abacavir + lamivudine (KVX) as opposed to tenofovir + emtricitabine (TVD), each plus efavirenz or atazanavir/r. In contrast, the HEAT study using lopinavir/ritonavir (LPV/r) together with TVD or KVX reported similar outcomes for both nucleoside analogue fixed-drug combinations. We analysed data from the STAR cohort, a German prospective, multicentre, observational study, which includes HIV+ patients starting with a regime containing LPV/r, for differences in antiviral response between the nucleoside analogue regimens.

Methods

Virological and immunological treatment outcomes (time to <50 copies/mL, % with viral load (VL) <50 copies/ml, and time to >500 CD4 cells/μL) in the groups receiving KVX or TVD were evaluated using on-treatment (OT), intent-to-treat (ITT), Kaplan-Meier and Cox PH regression analyses.

Summary of results

A total of 801 ART-naive pts (704 men) were included. Median age was 40 years (range: 20–76). 113 received KVX and 563 TVD. Median baseline CD4 cell count was not significantly different between the groups (KVX 238 vs. TVD191/μL), whereas median viral load (VL) was significantly higher in the KVX than in the TVD group (5.3 vs. 5.1 $\log_{10}$ cop./ml, p = 0.01). Median follow-up time was 21 weeks in both groups. At 24 weeks, 63% in the KVX group and 67% in the TVD group had a VL <50 cop./mL (OT; ITT: 62% of KVX and 63% of TVD patients, p = ns). Median changes in CD4 cells were +192/μL in KVX and +170/μL in TVD treated pts; p = ns. When analysing pts with >10^5 or ≤10^5 cop./ml separately, there was no difference in response between KVX and TVD use in either group (57% vs. 54% and 67% vs. 80%, respectively, p = ns).

In the Kaplan-Meier analysis, the median time to a confirmed VL of <50 copies/mL was 25 weeks in the KVX and 24 weeks in the TVD group. Results of Cox PH analysis adjusting for baseline VL and CD4 confirmed that VL outcomes did not differ significantly if KVX or TVD was used.

Time to a confirmed CD4 count above 500/μL was 54 weeks in KVX and 83 weeks in TVD pts (p = ns).

Conclusion

This prospective non-interventional study so far fails to show a difference in antiviral response between subjects using KVX or TVD in conjunction with LPV/r adjusted for baseline VL and CD4 cells. The lack of a significant difference for KVX or TVD use confirms the results of the HEAT study in an observational setting.