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Two is a company: results from a multicenter cohort of PLWHIV starting dolutegravir plus lamivudine as first-line regimen

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Introduction/Summary

- Results from clinical trials have shown the efficacy and safety of dolutegravir+lamivudine (DTG+3TC) as a 2DR, first-line regimen, for treatment naïve PLWHIV. However, long-term data from clinical practice are still scarce. Aim of our study was to confirm, in a real-life setting, the efficacy of this regimen.

Methods

- We collected data from a multicenter cohort of treatment-naïve PLWHIV starting a first-line regimen with DTG+3TC, evaluating the virological efficacy and the immunological recovery. We evaluated time to virological failure (VF, defined as 2 consecutive HIV-RNA >50 copies/ml or a single determination above 1000 copies/mL) as well as time to treatment discontinuation (TD, defined as the discontinuation of one or both analyzed drugs). Changes from baseline were evaluated via linear mixed models for repeated measures. Linear regression analyses were performed to explore variables associated to significant changes in laboratory parameters.

Results

- We analyzed data from 66 PLWHIV: 55 (83.3%) were males, with a median age of 38 years (IQR 30-49), a median HIV-RNA at diagnosis of 4.49 log10 copies/mL (3.84-4.89) and a median CD4+ cell count at diagnosis of 475 (338-636). One person was HCV-coinfected (1.5%). At time of diagnosis, on 41 individuals was performed a genotypic analysis: no major resistances to INI nor a single M184V resistance mutation were observed.
- Two individuals experienced VF during 113.8 PYFU. Estimated probability of not experiencing VF was 98% at week 48 and 96% at week 144. Both individuals were switched to a 3-drug regimen (1 to FTC/TAF/BIC and 1 to FTC/TAF/DRV/cobi), with subsequent virological suppression.

Results of 2

- As to treatment tolerability, we observed 4 TD during 113.8 PYFU. Reasons to TD were: virological failure in 2 cases, pregnancy in 1 case and individual choice in 1 case. Estimated probability of maintaining DTG/3TC was 98.4% at week 48 and 90.3% at week 144. In a multivariate analysis considering age, sex, HCV serostatus, baseline CD4+ cell count and peak HIV-RNA, we did not find any predictor of treatment discontinuation.
- As to immunological parameters, we observed a significant increase in CD4+ cell count at week 48 (median +242, p<0.001) and week 144 (+288, p<0.001). No predictors of CD4+ changes were found.

Variables	
Age (years), Median (IQR)	38.5 (25.2-53.5)
Female, n (%)	11 (16.7)
Risk factor for HIV infection, n (%):	
- Heterosexual	15 (22.7)
- MSM	39 (59.1)
- IDU	1 (1.5)
- Others	11 (16.7)
Anti-HCV antibodies positive, n (%)	1 (1.5)
CDC stage C, n (%)	0
CD4+ count (cell/µL), Median (IQR)	475 (338-636)
HIV-RNA (log10 copies/mL), Median (IQR)	4.49 (3.84-4.89)

Conclusion

- In our cohort DTG+3TC as a first line regimen showed overall great efficacy and tolerability, with a low number of TD in the first 144 weeks from treatment initiation.

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