96 WEEKS EFFECTIVENESS AND TOLERABILITY OF DTG+ 3TC IN NAIVE PATIENTS: The EDEOLA study

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Background

DTG/3TC therapy is a preferred regimen for people living with HIV (PLHIV) in international guidelines, due to the efficacy observed in clinical trials. However, information in real-life cohorts is still scarce.

Materials and Methods

Multicenter retrospective and prospective cohort study of ART-naïve PLHIV starting DTG/3TC as first-line regimen before 31/March/2020. Confirmed virological failure (CVF): two consecutive plasma HIV-RNA≥50 c/mL. The study was funded by ViVi HealthCare.

Results

185 patients were included. Treatment was started without the results of the baseline drug resistance testing (bDRT) results in 71.4% of cases, which subsequently confirmed baseline resistance mutations in 22 patients (11.9%). Two of them needed to change ART due to the presence of M184V mutation.

One patient had CVF at week 96 (79 and 365 c/mL) and continues DTG/3TC (third determination with <50 c/mL); no resistance-associated mutations (RAM) emerged. Eleven patients (5.9%) discontinued treatment: three due poor adherence, with a single HIV- RNA≥50 c/mL and no emerging resistance; three due to CNS side effects (1.6%); two after receiving bDRT (M184V mutation); one due to an extrapulmonar tuberculosis (IRIS) and another two to be included in a clinical trial. Finally, 18 patients (9.7%) were lost to follow-up. There were no significant changes in the lipid profile. The mean weight gain in a subgroup of patients (N=70) was 2.6 ± 5.6 kg.

Conclusions

In a real-life multicenter cohort of ART-naïve PLHIV, treatment initiation with DTG/3TC, showed high effectiveness and tolerability, without treatment emergent resistance through 96 Weeks. Starting treatment without knowing results of the baseline drug resistance test did not have an impact on the effectiveness of the regimen.