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Safety and durability of treatment with Bictegravir/Emtricitabine/Tenofovir Alafenamide in a real-life cohort

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PURPOSE

Both randomized clinical trials and observational trial evaluated the efficacy and tolerability of bictegravir/emtricitabine/tenofovir (B/F/TAF) in people with HIV (1-2) . However detailed description of reasons for interruption are available only in few studies. The purpose of the study to investigate the durability of this regimen and the causes of discontinuation.

METHODS

Consecutive people with HIV infection (PWH) enrolled in SCOLTA project switching to or initiating their first antiretroviral treatment (ART) with B/F/TAF were included. PWH were followed up until treatment discontinuation and grade 3-4 adverse events (AE) were recorded. Hazard ratio (HR and 95% confidence interval, CI) for discontinuation were calculated using the Cox proportional hazard model. CNS events were defined as : Fatigue, Headache, Arthromyalgia, Sleep disturbances, Anxiety , Depression/Suicide.

CONCLUSIONS

B/F/TAF shows durability and tolerability in real-life use. The main reason for discontinuation is switching to a different regimen for reasons other than treatment failure or AE occurrence. The most frequent AEs were neuropsychiatric events. Younger age and naïve status were risk factors for switching therapy

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RESULTS

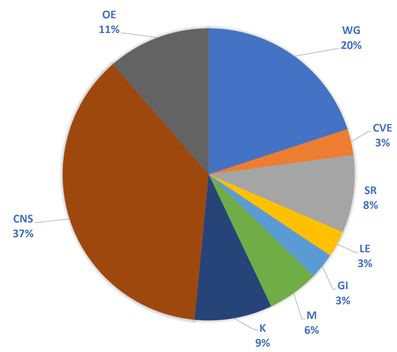
Of 1164 enrolled PWH, 961 had at least one follow-up visit and entered the analysis (See Table-1). Mean age was 48.2 y (±12.6), 75.4% were male, mean BMI was 25.3 Kg/m2 (±4.5), 27.0% were naïve (N) to antiretrovirals at T0. The median CD4+ count was 532 cells/mm3 (interquartile range (IQR) 320-785). After a median of 24 months of observation (IQR 13-36), 179 (18.6%) discontinued the treatment.
The main reason was the switch to a new treatment reported in 67 PWH (27 to long-acting ART, 27 to dual treatment, 13 unspecified).
Thirty-five people interrupted due to AE (see figure 1 for details) .
12 (1% of entire cohort) PWH switched for neuropsychiatric AE (See figure 2).
42 were lost to follow-up, 13 simplified treatment, 6 died (4 cancers, 1 sepsis and 1 unknown), 6 asked to change treatment, five had a treatment failure (3 ART-naïve, 2 ART-experienced), three switched for significant interactions, 2 for pregnancy
The median time at discontinuation was 17 months (IQR 8-27).
In a multivariate model, older age was protective (aHR 0.98, 95% CI 0.97-0.99 by 1 year) and being naïve represented a risk factor for discontinuation (aHR 1.54, 95% CI 1.08-2.19). CD4+ level >350 cells/mm3 decreased the likelihood of interruption (aHR 0.73, 95% CI 0.52-1.02, p=0.06). People starting the regimen in 2021-2022 were more likely to discontinue than those who started in 2019-2020 (aHR 1.65 95% CI 1.19- 2.29).

Table 1 Characteristics of 961 people with HIV (PWH) according to treatment status at last visit.

	Ongoing	Discontinued	All
Variables	N=782 (%)	N=179 (%)	N(%)
Males	593 (75.8)	132 (73.7)	725 (75.4)
Age, mean (SD)	48.9 (12.5)	45.3 (12.7)	48.2 (12-6)
Caucasian	679 (86.8)	157 (87.7)	836 (87)
CD4 counts ≥350 cells/mm^3	575 (73.5)	115 (64.2)	690 (71.8)
Diabetes	47(6)	11(6.2)	58 (6)
Hypertension	176(22.5)	26 (14.5)	202 (21)
Status at baseline			
TE with HIVRNA ≥40 copies/ml	110 (14.1)	12 (6.7)	122 (12.7)
TE with HIVRNA <40 copie/ml	484 (61.9)	96 (53.6)	580 (60.3)
Naïve	188 (24)	71 (39.7)	259 (26.9)

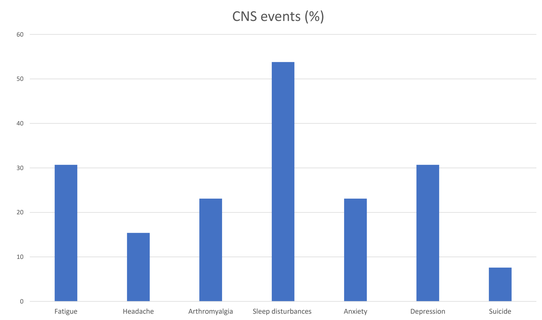
Legend to the table: TE : treatment experienced

Figure 1 ADVERSE EVENTS



Legend to the figure 1: WG= Weight Gain , CVE= Cardio Vascular Events , SR= Skin Reactions, LE= Liver Events; GI=GastroIntestinal Events; M= Metabolic Events ; K= Kidney Events; CNS= Central Nervous System Events; OE =Other Events

Figure 2 Central Nervous System Events



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