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First real world data of tenofovir alafenamide-based ART in adult HIV-1-infected patients enrolled in the French TARANIS cohort: results on the use of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF)

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Background

Tenofovir alafenamide (TAF), a novel prodrug of tenofovir (TFV) that is at least as potent as tenofovir disoproxil fumarate (TDF), results in 91% lower circulating levels of plasma TFV, has fewer off-target effects on renal and bone, was approved based on large controlled clinical trials in naïve and experienced subjects.

As no data are available for patients in routine clinical practice in France, the TARANIS study was developed to evaluate the effectiveness and safety of (F/TAF)-based regimens, starting with E/C/F/TAF, the first approved TAF-containing combination, in treatment-experienced (TE) and treatment-naive (TN) HIV-infected patients.

Methods

- TARANIS is an ongoing prospective, observational cohort study in France, which plans to enroll 600 HIV-1-infected patients taking E/C/F/TAF (n=300) or rilpivirine/emtricitabine/tenofovir alafenamide (R/F/TAF) (n=300).
- Of clinical outcome variables, only data assessed during the routine management of patients were captured in the eCRF.
- The study objectives are: HIV-1 RNA and CD4 cell count changes during 24 months and self-reported health-related quality of life (HRQOL) using the HIV Symptom Index (SI), SF-36, and HIV treatment satisfaction (TS) questionnaires.
- Here we present preliminary results in TN and TE patients at 3-month follow-up at time of data cut (data cut date: 15 May 2018).

Results

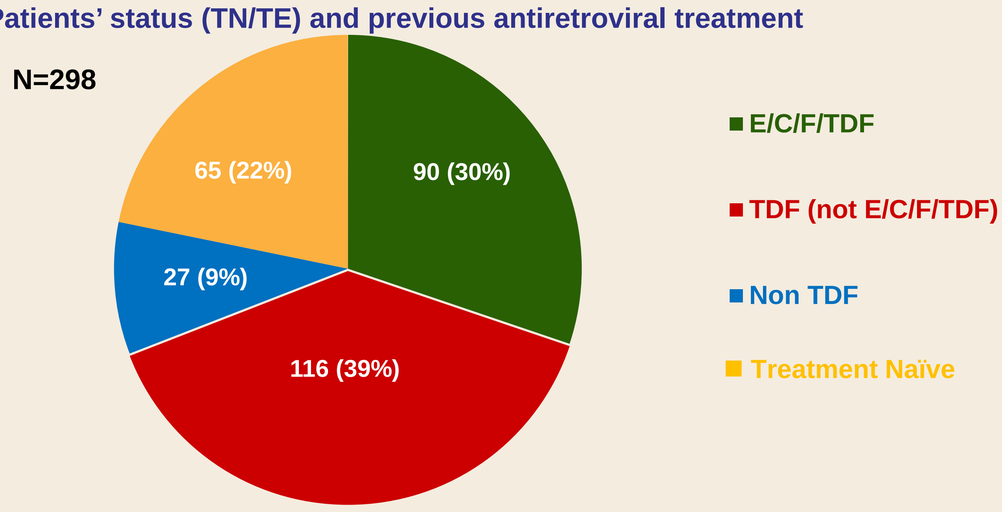
- The analysis population consists of 298 patients taking E/C/F/TAF.
- The majority of patients (78%) were treatment experienced: 30% with E/C/F/TDF, 39% with other F/TDF-containing regimens.
- Baseline characteristics for TN and TE patients are in Table1.

Table 1. Baseline characteristics

Study population	Treatment Naïve	Treatment Experienced
N (%)	65 (22)	233 (78)
Male gender, n (%)	59 (91)	178 (76)
Median age, years (IQR)*	37 (29-49)	49 (41-55)
Age <50 years, n (%)	49 (75)	124 (53)
CD4 count <200 cells/µl n (%)	12 (23)	11 (6)
Median log HIV RNA (IQR)	4.6 (4 - 5)	NA
HIV RNA> 100000 cp/ml, n (%)	17 (27)	NA
HIV-RNA level <50 cp/mL, n (%)	NA	198 (89)
Median serum creatinine, µmol/L (IQR) [range]	77 (68-88) [54-112]	84 (72-94) [43-136]
Median eGFR (MDRD), mL/min/1.73m^2 (IQR) [range]	102 (87-118) [66-160]	85 (75-98) [48-161]
eGFR (MDRD) <60 mL/min/1.73m^2, n (%)	0 (0)	12 (6)
Median CrCl (Cockcroft-Gault), mL/min (IQR) [range]	112 (95-131) [73-191]	95 (80-114) [49 -199]
CrCl (Cockcroft-Gault) <60 mL/min, n (%)	0 (0)	4 (2)
Reasons for switch to E/C/F/TAF, n (%) (multiple responses allowed)	NA	
• Simplification of ART		100 (43)
• Patients preference		27 (12)
• Side effects of current ART		82 (35)
• Other		74 (32)

*IQR, interquartile range; NA, Not Applicable; SD, standard deviation.

Figure 1: Patients' status (TN/TE) and previous antiretroviral treatment



Month 3 follow-up

- At month 3, HIV RNA was < 50cp/ml in 86% of TN and 95% of TE patients with Missing=Excluded analysis (Figure 2).
- Median changes in CrCl (Cockcroft-Gault/ mL/min) were -7 in TN and -2 in TE (Table 2).
- Mean HIV SI improvements were -5 in TN and -4 in TE (Figure 3).
- Mean improvement in SF-36 were respectively: mental: +1 and +1 in TN and TE; physical: +4 and +1 in TN and TE.
- For the TE population, the mean month 3 TS improvement was +19 (general satisfaction/clinical subscale +10; lifestyle/ease subscale +9) (Figure 3).

Figure 2. HIV-RNA level <50 cp/mL at baseline (BL) and month 3 (M3)

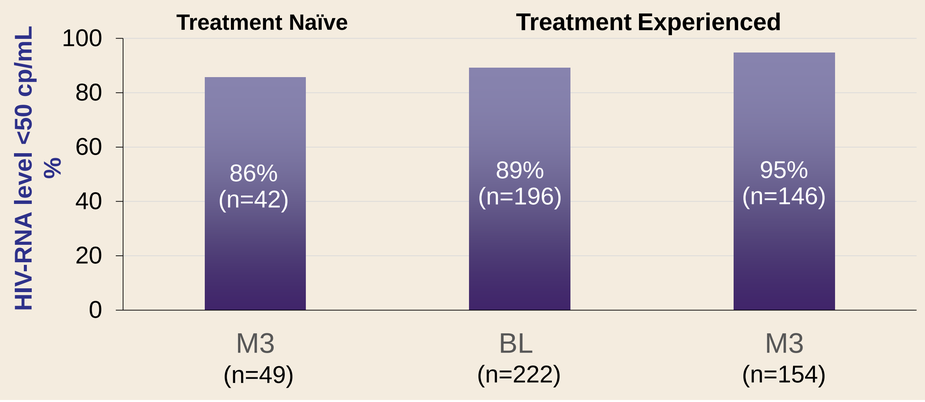
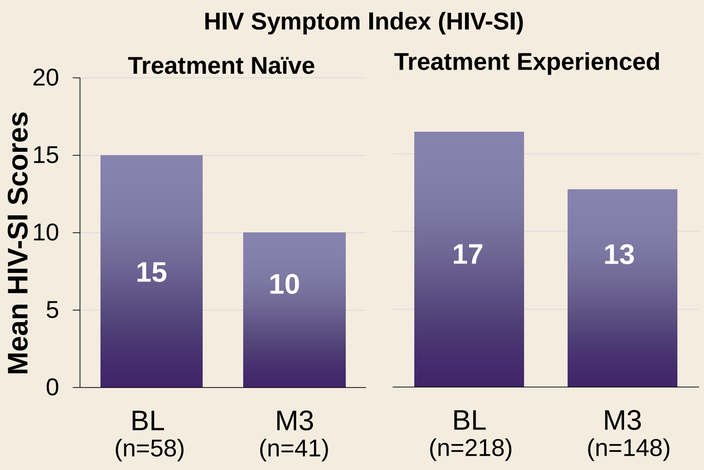


Table 2. Change in renal parameters from BL to M3

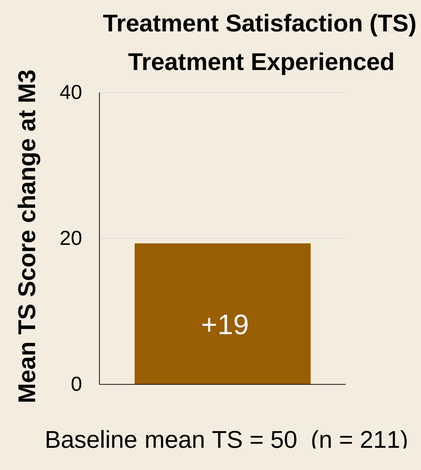
	Treatment Naïve	Treatment Experienced
Median change in serum creatinine, µmol/L (IQR) [n]	7 (1, 12) [45]	3 (-5, 9) [139]
Median change in eGFR (MDRD), mL/min/1.73m^2 (IQR) [n]	-9 (-18, -1) [45]	-3 (-11, 5) [139]
Median change in CrCl (Cockcroft-Gault), mL/min (IQR) [n]	-7 (-17, 0.0) [41]	-2 (-11, 5) [135]

IQR, interquartile range; Calculated Creatinine Clearance is calculated depending on gender based on serum creatinine, age and weight using the Cockcroft-Gault formula. Estimated Glomerular Filtration Rate (eGFR) is calculated depending on gender and race based on serum creatinine and age.

Figure 3. HIV Symptom Index (HIV-SI) and Treatment Satisfaction (TS) at BL and M3



HIV-SI: range 0-80, higher scores indicate more bothersome symptoms



TS status (BL): range 0-60 (higher scores indicate greater satisfaction); TS change (follow-up): range -30-30

Conclusions

In this cohort of 298 patients treated with E/C/F/TAF:

- 233 patients were pre-treated (88% of these with F/TDF-based regimens)
- E/C/F/TAF was efficacious and well tolerated in TN and TE patients
- There were small decreases of CrCl and eGFR in TN patients related to the known inhibitory effect of cobicistat on the tubular secretion of creatinine
- HIV Symptom Index improved in TN and TE patients
- Treatment Satisfaction improved in TE patients

Acknowledgments

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