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Immune and metabolic profile in people living with HIV initiating emtricitabine/tenofovir alafenamide/bictegravir

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Introduction

- The impact of emtricitabine/tenofovir alafenamide/bictegravir (FTC/TAF/BIC) on weight gain, lipid profile and immunological status has been described in few cohorts until an observation period of 96 weeks (1,2).
- Our aim was to investigate the role of FTC/TAF/BIC regimen on metabolic and immune profile and on weight gain in naïve (N) and especially in experienced (E) people living with HIV (PWH).

Methods

Consecutive PWH enrolled in the Surveillance COhort Long-Term Toxicity of Antiretrovirals/antivirals (SCOLTA) project initiating an antiretroviral treatment (ART) with FTC/TAF/BIC were included.

- T0 and T1 and T2 were defined as results at baseline and 48- and 96-weeks follow-up respectively.
- PWH with HBV co-infection were excluded.
- PWH were classified according to **N** and **E** status. **E** PWH were divided into two groups according to previous ART including Cobicistat (C-E) or not (NC-E).

Table 1. Cohort's characteristics

Variables at enrolment	ART-experienced N=601 (73.9%)		ART-naïve N= 212 (26.1%)		P
	N or mean or median	% or SD or IQR	N or mean or median	% or SD or IQR	
Age, years	49.7	12.1	42.0	12.4	<0.0001
Male sex	445	74.0%	165	77.8%	0.27
Caucasian	527	87.7%	173	81.6%	0.03
Risk factor for HIV acquisition					
Sexual	373	62.1%	183	86.3%	
IDU	89	14.8%	9	4.2%	<0.0001
Other/ND	139	23.1%	20	9.4%	
BMI, Kg/m²(n=408)	25.9	4.7	23.8	3.6	<0.0001
Weight, Kg	75.5	14.8	70.8	13.3	<0.0001
HCV coinfection	110	18.3%	12	5.7%	<0.0001
HIVRNA>40 copies/micrL	108	18.0%	-	-	-
CD4+, cells/mm3	603	424-834	317	124.505	<0.0001
Total cholesterol, mg/dL	193	43	166	42	<0.0001
HDL-C, mg/dL	54	18	44	16	<0.0001
LDL-C, mg/dL	112	38	97	35	<0.0001
TGL, mg/dL	114	84-167	99	72-149	0.002
BG (in 765 non-diabetic pts), mg/dL	93	16	87	14	<0.0001
BG (in 48 diabetic pts), mg/dL	160	66	143	40	0.53
Diabetes	39	6.5%	9	4.2%	0.23
AST, IU/dL	22	18-27	24	19-31	0.003
ALT, IU/dL	22	16-31	23	17-33	0.12

Legend to table :SD, Standard Deviation; IQR, Inter Quartile Range; CI, Confidence Interval; IDU, Intravenous Drug Usera; BMI, Body Mass Index; HCV LDL-C, Low Density Lipoprotein-Cholesterol; HDL-C, High Density Lipoprotein; TGL, Triglycerides; BG, Blood Glucose; IU, International Unit; AST, aspartate aminotransferase; ALT, aspartate aminotransferase

Results/1

813 PWH were enrolled (601 E and 212 N to ART). C-E and NC-E were 267 and 334, respectively. PWH characteristics are depicted in Table 1.

Previous ART regiment were shown in Figure 1.

Figure 1 Previous ART regimen

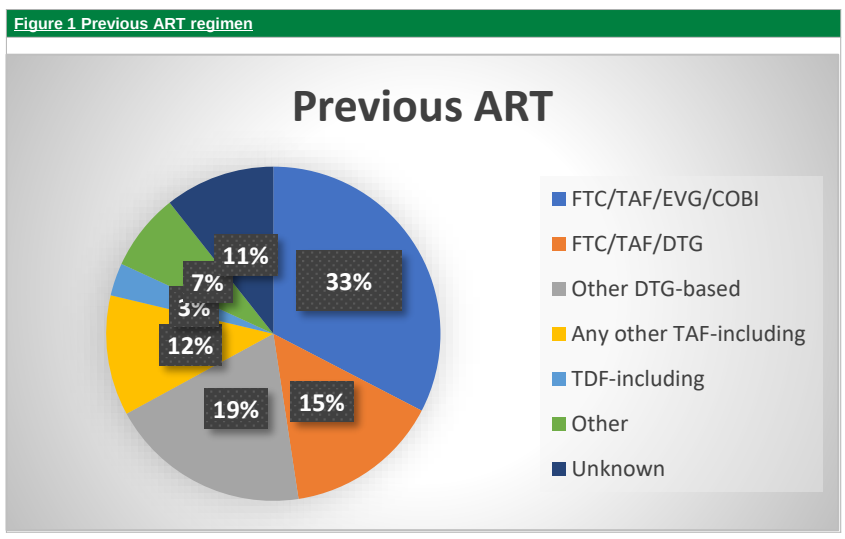


Figure 2 CD4/Cd8 ratio mean changes in C-E and NC-E

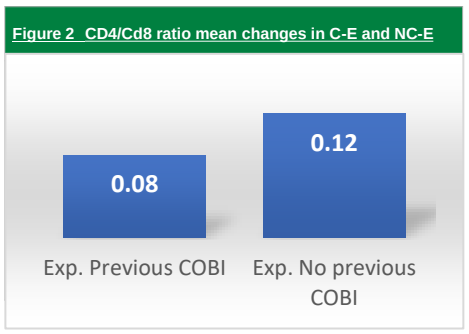
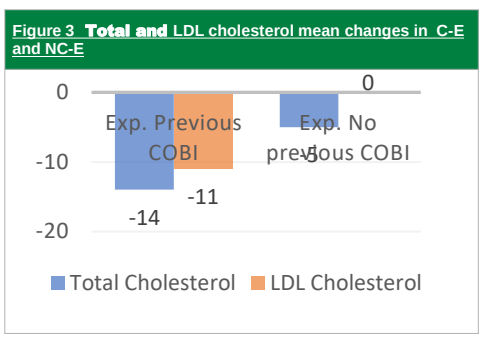


Figure 3 Total and LDL cholesterol mean changes in C-E and NC-E



Results/2

The following variables modified significantly at T2 both in C-E and NC-E:

- Weight (mean change 1.5 kg [95% CI 0-5 to 2.5] and 1.1 [0.1 to 2.1]),
- CD4 cell count (45 cell/micrL [13 to 78] and 46 [13 to 78]), CD4/CD8 ratio (0.08 [0.03 to 0.12] and 0.12 [0.07 to 0.16] see figure 2),
- Total Cholesterol (TC) (-14 mg/dl [-20 to -9] and -5 mg/dl [-11 to 0]), and
- Triglycerides (-19 mg/dl [-30 to -8] and -15 [-26 to -4]).

In C-E also LDL cholesterol (LDL-c) (-11 mg/dl [-16 to -6]) significantly changed at T2 (see figure 3) .

Results/3

- The following variables were significantly different between N and C-E and NC-E:
- TC (mean change 11 mg/dl [95% CI 3 to 19] vs -14 [-20 to -9] vs -5 [-11 to 0] p<0.0001),
- LDL-c (6 mg/dl [-1 to 14] vs -11 [-16 to-6] vs 0 [-5 to 5]; p=0.0002),
- ALT (-8 IU/L[-13 to -2] vs 3 [-1 to 7] vs 0 [-4 to 4]; p=0.008),
- CD4 cell count (292 cell /micrL [243 to340] vs 45 [13 to 78]vs 46 [13 to 78]; p<0.0001,
- CD4/CD8 ratio (0.43 [0.36 to 0.50] vs 0.08 [0.03 to 0.12] vs 0.12 [0.07 to 0.16]; p<0.0001).
- We found a significant higher weight increase at T1 in N vs C-E and NC-E (mean change 4 Kg [95% CI 2.6 to 5.4] vs 0.3 [-0.8 to 3.4] vs –0.2 [-1.2 to 0] p<0.0001), but not at T2 (3 Kg [95% CI 1.4 to 4.6] vs 1.5 [0.5 to 2.5] vs 1.1 [0.1 to 2.1] p=0.13) (see figure 4) . A significant between was seen comparing N and NC-E but not N and C-E.
- Interestingly, we observed a mild inverse correlation between weight at baseline and weight variation in CE but not in NC-E. (see figure 5)

Figure 4 Weight mean changes among N, C-E and NC-E

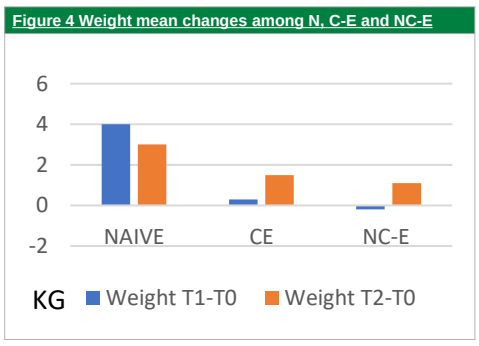
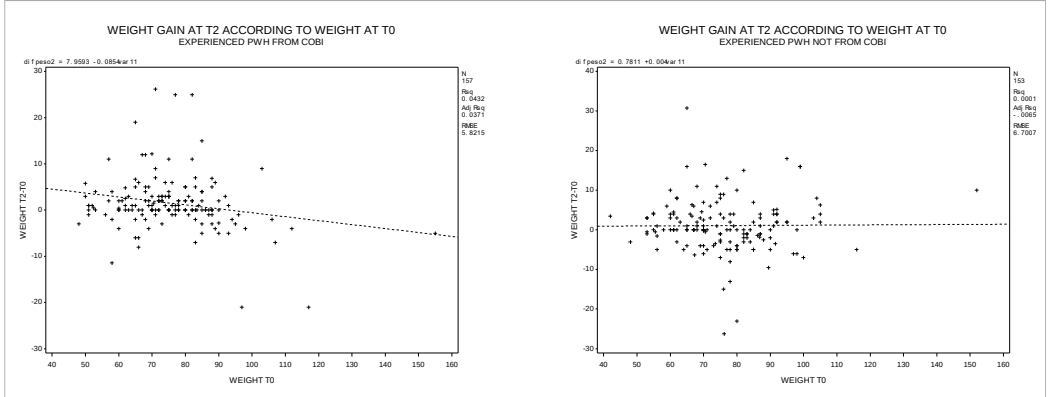


Figure 5. Weight variation according to weight at baseline in C-E and NC-E



Conclusions

- FTC/TAF/BIC initiation is associated with weight gain and amelioration of immune profile both in N and E PWH.
- A significant reduction in LDL-c was observed only in E with COBI in previous regimen.
- Weight changes are inversely associated with weight at baseline in PWH on a previous Cobicistat -including regimen

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