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Neuropsichiatric, Clinical and Laboratory Changes in Patients Prospectively Switching from EVG/Cobi/FTC/TAF to BIC/FTC/TAF

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INTRODUCTION

In recent years, data from various cohorts have raised concerns about the safety of integrase strand transfer inhibitors (INSTI) in clinical practice, especially in relation to the appearance of specific adverse events such as neuropsychiatric (NP) symptoms. NP adverse events leading to discontinuation were more often reported in real-life data than in clinical trials. Weight gain on INSTI (mainly second generation compounds) is also a matter of concern. We report NP, clinical and laboratory changes in patients switching from EVG/Cobi/FTC/TAF to BIC/FTC/TAF in clinical practice.

OBJETIVES

The aim of the study was to identify changes in neuropsiquiatric outcomes (anxiety, depression and sleep quality), clinical and laboratory outcomes in patients switching from EVG/Cobi/FTC/TAF to BIC/F/TAF.

METHODS

All subjects switching from EVG/Cobi/FTC/TAF to BIC/F/TAF from June 2019 to September 2019, in a single center were prospectively followed. A validated sleep quality questionnaire [Pittsburgh Sleep Quality Index (PSQI)] as well as the Hospital Anxiety and Depression Scale (HADS) were administered after 4 weeks from treatment switch. Adverse events, side effects and discontinuation were recorded at week 4 and 24. Pre-treatment switch and week 24 body weight and laboratory data were compared.

RESULTS

		Total patients (n=96)
Baseline characteristics		
Age (years)		49.5 ± 12.3
Gender (male)		86.4% (83)
ART start	Before 2000	21.8% (21)
	Between 2000 y 2009	38.5% (37)
	Between 2010 y 2019	39.5% (38)
Time on previous ARV regimen (years)		1 (0,5-2)
AIDS history		40.2%
Nadir CD4 (cells/mm3)		368 (245-508)
Comorbidity	Anxiety	9.3% (9)
	Cardiovascular	3.1% (3)
	Diabetes	7.2% (7)
	Hypertension	14.5% (14)
	Obesity	1.04% (1)
	Depression	8.3% (8)
	Dyslipidemia	27.08% (26)
	Drugs	5.2% (5)
	Ex drugs users	4.1% (4)
	Hepatitis	19.7% (19)
	Insomnia	1.04% (1)
	Renal	2.08% (2)
	Mental health	5.2% (5)

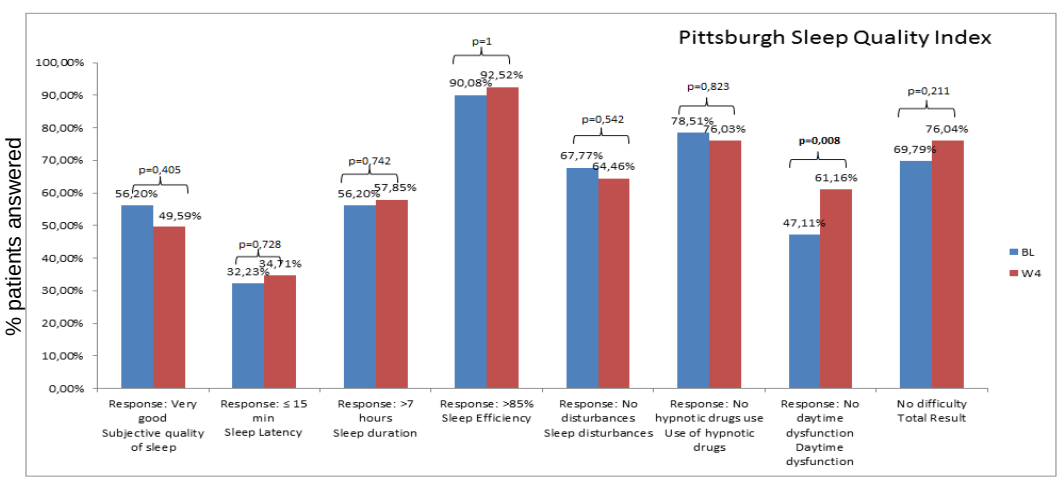
Side effects leading to discontinuation by Week 4*	
1	GI symptoms
2	Headache
3	Insomnia
4	Insomnia
5	GI symptoms

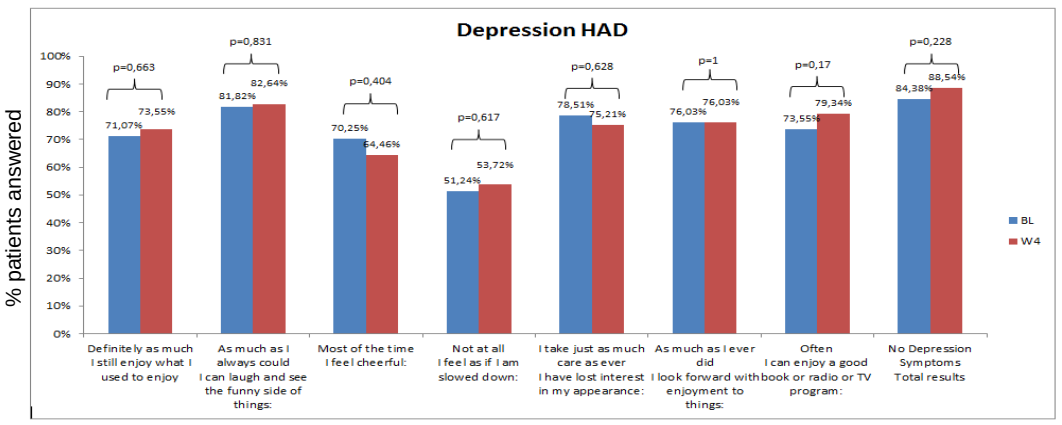
GI: Gastro-Intestinal symptoms. *Number of BIC/FTC/TAF discontinuations until W4.

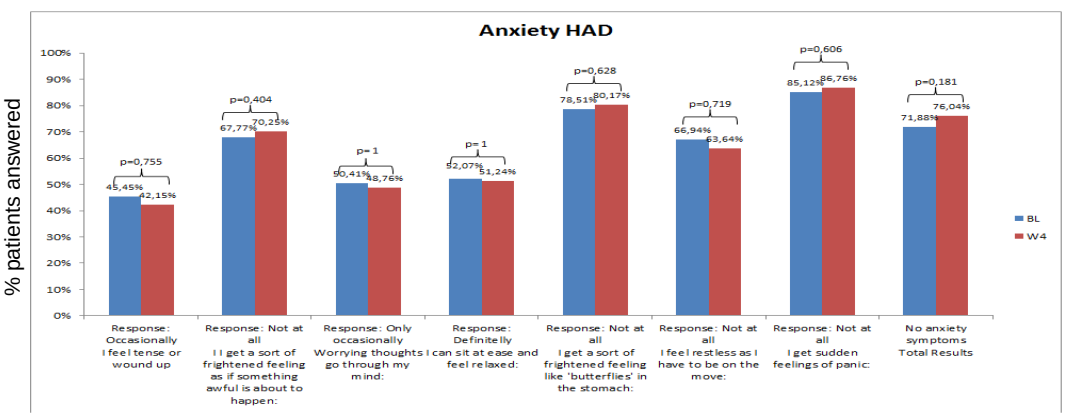
	Baseline	Week 4	P
Pittsburgh Sleep Quality Index (PSQI)*			
Subjective quality of sleep	0 (0-1)	0 (0-2)	0.2
Sleep latency	1 (0-2.25)	1 (0-3)	0.5
Sleep duration	0 (0-1)	0 (0-1)	0.6
Usual sleep efficiency	0 (0-0)	0 (0-0)	0.3
Sleep disturbances	1 (1-1)	1 (1-1)	0.1
Use of hypnotic medication	0 (0-0)	0 (0-0.5)	0.6
Daytime dysfunction	1 (0-1)	0 (0-1)	0.006
PSQI score	4 (3-7)	4 (2-7)	0.1

*Patients who discontinued BIC/FTC/TAF were scored as the worst score at week 4.

RESULTS II







Body weight and laboratory data			
	Baseline	Week 24	P
Laboratorio			
Body Weight (kg)*	71.8 (60.8-83.9)	72.25 (61.4-86.5)	0.02
Glucose (mmol/L)*	5.2 (4.9-5.8)	5.2 (4.8-5.7)	0.4
Hemoglobin (g/L)*	148.5 (142-158)	153 (144-161)	<0.001
Leukocytes (10^9 cel/L)*	6.15 (5.4-7.1)	6.4 (5.3-7.7)	0.1
Platelets (10^9 cel/L)**	230.8 ± 54.3	232 ± 53.3	0.7
CD8 (U/mmc)*	773 (598-1032)	793 (606-1000)	0.2
CD8 (%)**	37.4 ± 9.2	36.71 ± 9	0.8
CD4 (cells/mm)*	739 (592-924)	818 (631-1028)	0.007
CD4 (%)*	35 (28-41)	37 (28.25-42)	0.5
Alanine Aminotransferase (ALT) (ukat/L)*	0.34 (0.2-0.4)	0.35 (0.2-0.5)	0.8
Alkaline Phosphatase (ALP) (ukat/L)*	1.1 (0.9-1.3)	1.12 (0.9-1.4)	0.4
Gamma-Glutamyl Transferase (GGT) (ukat/L)*	0.39 (0.3-0.6)	0.35 (0.2-0.5)	0.001
Creatinine (umol/L)**	86.4 ± 14.1	89.5 ± 14.1	0.002
GFR(ml/1000/1.73 m2)*	90 (78-91)	85 (74-91)	0.008
Triglycerides (mmol/L)*	1.3 (1.06-1.8)	1.26 (0.9-1.6)	0.02
Total cholesterol (mmol/L)**	4.9 ± 0.9	4.5 ± 0.9	<0.001
HDL (mmol/L)*	1.31 (1.03-1.5)	1.2 (1.07-1.4)	0.4
LDL (mmol/L)**	2.9 ± 0.92	2.63 ± 0.8	0.003

Median, first and third quartile; Wilcoxon Test (*). Mean and standart deviation; Paired t-Test (**).

CONCLUSIONS

Except in a few patients, treatment switch from EVG/Cobi/FTC/TAF to BIC/FTC/TAF was not associated with poorer sleep outcomes. Anxiety and depression remained unchanged. BIC/FTC/TAF was associated to a small but statistically significant increase in body weight but presented a better lipid profile.