One year of Bictegravir in Mexico City: Differences in the Neuropsychiatric Adverse Events vs. Efavirenz

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Background: In Mexico, Efavirenz (EFV) was considered as first-line regimen for several years. However, the Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) had a history neuropsychiatric effects such as depression, suicidal thoughts, insomnia, hypersomnia, impairment cognition, impairment in quality of life, these adverse events cause poor adherence and abandon EFV regimens. Since June 2019, bictegravir (BIC) in a single tablet regimen was introduced in Mexico as a first-line treatment. Therefore, the objective of the study was to compare the presence of depressive and cognitive symptoms, suicidality, sleep disturbances, quality of life between BIC and EFV regimens.

Methodology: Prospective cross-sectional study, non-probability sample, both groups BIC and EFV were matched according to age. Patients were recruited from June 2019 to May 2020 in Condesa Specialized Clinic in Mexico City. All the patients had 1 to 4 months from starting treatment. The evaluation test used were Medical Outcomes Study Short Form-36 (SF-36), Beck Depression Inventory (IDB-IA), Center for Epidemiologic Studies-Depression Suicidal Ideation subscale (CES-D IS), State Impulsivity Scale (SIS) and Pittsburgh Sleep Quality Index (PSQI).

Variable	BIC n= 800		EFV n= 800		*t*	
	Mean	±	Mean	±		p
PCS	78.53	25.18	77.6	26.94	5.05*	p<.01
MCS	65.7	20.42	64.09	22.14	10.61*	p<.01
SF-36	72.12	19.87	70.84	21.45	8.65*	p<.01
PF	89.54	18.58	88.13	19.97	9.87*	p<.01
PR	67.52	38.53	67.00	40.79	1.84	p>.05
MH	67.78	21.45	65.83	23.45	12.13*	p<.01
VT	63.62	23.57	62.34	24.83	7.42*	p<.01
BDI-I	5.77	5.73	6.09	5.05	2.18*	p<.03
CES-D SI	1.85	0.98	2.20	1.12	10.80*	p<.01
Impulsivity	7.1	6.41	7.78	7.50	15.28*	p<.01
SIS						
SQ	1.23	0.77	1.26	0.78	4.57*	p<.01
SL	1.28	0.94	1.30	0.94	5.15*	p<.01
SD	1.39	1.09	1.40	1.11	2.73*	p<.01
SE	0.97	0.61	0.99	0.64	0.51	p>.05
SDs	1.45	0.64	1.46	0.65	0.76	p>.05
SM	1.76	1.38	1.77	1.39	2.25*	p<.03
DD	1.21	0.91	1.23	0.90	1.12	p>.05
PSQI	7.5	3.73	7.67	3.80	1.91*	p<.03

Results: One thousand six hundred patients, 800 in BIC group and 800 in EFV group. The mean age 37 years. Non-statistical difference was found in sociodemographic and HIV-related variables. Statistically significant differences were found between BIC and EFV groups (t = 1.91 - 15.28, p < 0.03). The largest differences were seen in cognitive symptoms such as impulsivity, quality of life mental score and suicidal ideation (t > 10.61). No differences were found in physical role & sleep disorders.

*statistically significant differences. ± standard deviation. **BIC:** bictegravir**.**
EFV: efavirenz. **PCS:** Physical component of SF-36. **MCS**: Mental component of SF-36. **SF-36**: Medical Outcomes Study Short Form-36. **PS**: Physical Functioning. **PR:** Physical Role. **MH**: Mental Health. **VT**: Vitality. **BDI-I**: Beck Depression Inventory, HIV adapted. **CES-DIS**: Center for Epidemiologic Studies-Depression Suicidal Ideation subscale. **SIS**: State Impulsivity Scale. **SQ**: Perceived Sleep Quality. **SL**: Sleep Latency. **SD**: Sleep Duration. **SE**: Sleep Efficiency. **SDs**: Sleep Disturbances. **SM**: Sleep Medication **DD**: Daytime Disfunction. **PSQI**: Pittsburgh Sleep Quality Index

Conclusions: In this study we found BIC group have fewer neuropsychiatric events than EFV group. The principal differences were in cognitive symptoms, suicidality, functionality associated with central nervous system symptoms. We suggest having a long-term follow-up of the sleep quality variables, to observe patient's adaptation to treatment for a period over to 12 months. We recommended to evaluate the starting treatment effect like a symptom's manifestation.

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