administrations, whereas it decreases during subsequent treatment phases. Although there is an initial increase in drug expenditure in the year when the long-acting regimen is introduced the investment seems to be almost fully amortized in the two years following the switch to therapy. Based on the observations, the long-term regimen thus appears to be an effective tool for curbing drug expenditure two and a half years after its introduction and improving adherence to HIV treatment.

P-11 CENTRAL NERVOUS SYSTEM AND NEUROPSYCHIATRIC ADVERSE EVENTS IN WOMEN LIVING WITH HIV TREATED WITH INSTI-BASED REGIMENS

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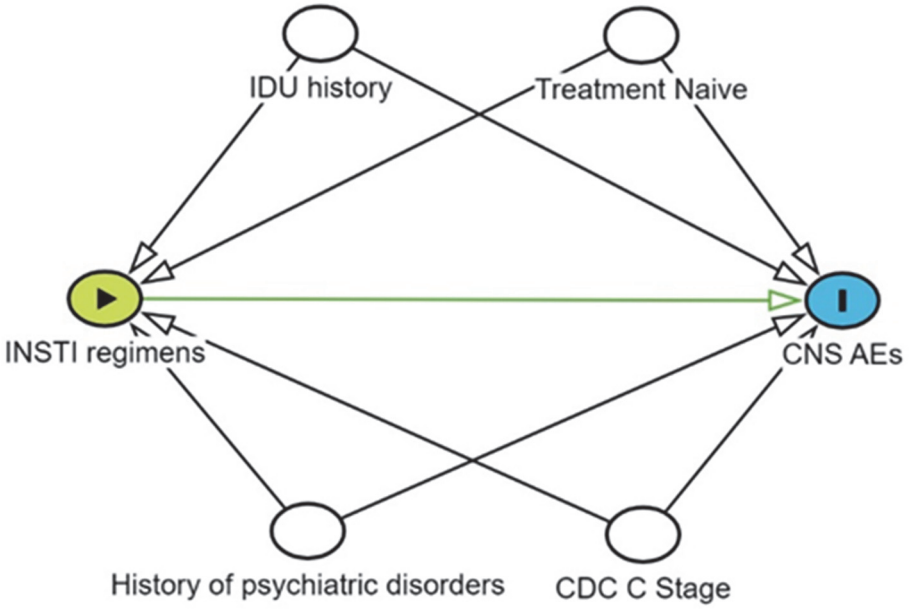
Background Some integrase inhibitors (INSTIs) have been associated with Central Nervous System (CNS) and Neuropsychiatric (NP) adverse events (AEs) in real-life studies. These complications can lead to decreased adherence, thereby interfering with treatment outcomes. However, data on INSTI CNS/NP AEs in Women Living with HIV (WLH) are scarce.

Methods Using data from the SCOLTA project, a multicenter observational study following PWH who start antiretrovirals to identify AEs in real-life, we performed a retrospective analysis (NEURO-INSTI) to assess incidence rates (IR) and 95% confidence intervals (95% CI) of CNS/NP AEs and myalgia. Qualitative variables were presented as absolute and relative numbers, while quantitative variables were described using the mean and standard deviation (SD) or median and interquartile range (IQR), depending on the distribution's normality. Group differences were assessed using the Chi-squared test or Fisher's exact test for qualitative variables and the t-test or Mann-Whitney U test for quantitative variables, as appropriate.

Abstract P-11 Table 1 Baseline characteristics of 738 women enrolled in the integrase inhibitor cohorts of the SCOLTA Project

	No AEs events		AEs events		All		p-value*
	N	%	N	%	N	%	
Total	700	94.8	38	5.2	738	100	
Age ≥ 50 years	269	38.4	15	39.5	284	38.5	0.90
Risk factor for HIV acquisition							0.01
IDU	116	16.6	13	34.2	129	17.5	
Sexual	495	70.7	23	60.5	518	70.2	
Other	89	12.7	2	5.3	91	12.3	
Caucasian ethnicity	575	82.1	33	86.8	608	82.4	0.46
HCV coinfection (38 missing)	142	20.3	16	42.1	158	21.4	0.003
CDC stage (1 missing)							0.03
A	345	49.3	12	31.6	357	48.4	
B	197	28.1	13	34.2	210	28.5	
C	157	22.4	13	34.2	170	23.0	
Treatment Naïve	103	14.7	4	10.5	107	14.5	0.48
Psychiatric comorbidity	60	9.9	5	13.2	74	10.0	0.51
Cohort							0.0003
Bictegravir	173	24.7	2	5.3	175	23.7	
Dolutegravir	303	43.3	17	44.7	320	43.4	
Elvitegravir	76	10.9	1	2.6	77	10.4	
Raltegravir	148	21.1	18	47.4	166	22.5	
Abacavir-including regimens	114	16.3	10	26.3	124	16.8	0.11

AEs: adverse events; IDU: intravenous drug users; CDC: Centre for Disease Control
* p-value was calculated using chi-squared test or exact Fisher test as appropriate.



Abstract P-11 Figure 1 Direct acyclic graph (DAG) of the underlying data structure and associations

Abstract P-11 Table 2 Number of any central nervous system adverse events, crude and adjusted incidence rates in women living with HIV starting a new integrase inhibitor-based treatment

	Number of people	PYFU	Any CNS AEs	Crude CNS AEs IR / 100 PYFU (95% CI)	Adjusted* CNS AEs IR / 100 PYFU (95% CI)
Treatment cohort					
Bictegravir	173	300.08	2	0.7 (1.7-2.7)	1.3 (0.3-5.9)
Dolutegravir	303	1065.71	13	1.2 (0.7-2.1)	2.2 (1.0-4.8)
Elvitegravir	76	170.18	0	n.e.	n.e.
Raltegravir	148	428.56	16	3.7 (2.3-6.1)	6.8 (2.9-16.0)
* adjusted for IDU history, ART status, CDC stage, psychiatric comorbidity					
PYFU: person years follow-up; CNS: central nervous system; AEs: adverse events; IR: incidence rate; CI: Confidence Interval; IDU: intravenous drug users; CDC: Centre for Disease Control					

Observation was truncated at the first occurrence of any CNS/NP AEs, even if not causing treatment discontinuation. IRs were calculated as number of first occurrences/1000 person years follow-up (PYFU). When crude IR were significantly different according to selected baseline variables, they were included in the multivariate generalized linear model, to calculate the adjusted IRs (aIRs). The significance level was set at <0.05. Statistical analysis was performed using the SAS/STAT statistical package (version 9.4; SAS Institute Inc., USA). The DAG was drafted using the R codes in www.dagitty.net (figure 1).

Results A total of 738 WLH were included in our study. The mean age was 46.4 years (SD ±11.2). Out of these, 107 (14.5%) were treatment naïve. Regarding INSTI-based-regimens, 175 (23.7%) were treated with bictegravir (BIC), 320 (43.4%) with dolutegravir (DTG), 77 (10.4%) with elvitegravir/cobicistat (EVG/c), and 166 (22.5%) with raltegravir (RAL) (table 1). In total, we documented 31 (4.2%) grade 3–4 CNS/NP AEs, 7 (0.9%) cases of myalgia and 1 (0.1%) case of peripheral neuropathy. WLW experiencing these AEs had more baseline risk factors (IDU, HCV coinfection, CDC stage C). Regarding the CNS/NP AEs, 14 (45.2%) led to treatment discontinuation. The overall incidence rate for AEs was 1.6 (1.1–1.2) per 100 person-years follow-up (PYFU). After adjusting for confounders (table 2), RAL-based regimens were associated with the highest incidence rate, followed by DTG and BIC.

Conclusions Our findings highlight the relatively low incidence of CNS/NP adverse events in women living with HIV treated with INSTIs. This suggests that while such events are a concern, they are not frequent in this population. These insights contribute to a better understanding of INSTIs tolerability and support their use in managing HIV in women, with an emphasis on careful selection and monitoring of treatment regimens.

P-12 SWITCHING FROM 3TC/DTG AND RPV/DTG TO TRIPLE DRUG AND DUAL PI-BASED THERAPIES FOR TOXICITY/INTOLERANCE: DATA FROM THE ICONA COHORT

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Background Two-drug regimens (2DR) [lamivudine (3TC)/dolutegravir(DTG) or rilpivirine(RPV/DTG)] are generally well tolerated but there is a proportion of people with HIV (PWH) who develops toxicity/intolerance to these regimens and are switched back to three-drug regimens (3DR) or dual PI-based therapies (2DR-PI/b). The frequency and factors associated with these switches have been poorly investigated.

Material and Methods We included all PWH enrolled in the Icona cohort who switched to 3TC/DTG or RPV/DTG with a plasma viral load (pVL) <50 copies/mL excluding people with a positive HBsAg. The primary aim was to estimate the cumulative incidence of switch from 3TC/DTG and RPV/DTG to 3DR or 2DR-PI/b due to toxicity and intolerance (including as