

P-4 **LOW LEVEL VIREMIA AT THE BEGINNING AND IN COURSE OF LONG-ACTING TREATMENT WITH INJECTABLE CABOTEGRAVIR AND RILPIVIRINE**

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Background The aim of this study is to describe the frequency and management of low-level viremia (LLV, i.e. HIV RNA >50 but <200 copies/mL) at the beginning and in course of long-acting (LA) injectable cabotegravir (CAB) and rilpivirine (RPV).

Methods Observational multicentre cohort study. HIV RNA values were collected prospectively in people on LA CAB +RPV.

Results 417 PWH, (97 women, 23.3%), started CAB+RPV. Mean age was 48.5 (+/- 11.3) years and the median CD4 were 806 cells/mm³ (IQR 582–1040). Most participants were Caucasian (397, 95%), with 198 (47%) being men who have sex with men and 143 (34%) heterosexuals PWH. Most were in CDC stage A (253, 62%). All were treatment experienced, with median 10 (IQR 6.2–16.5) years of ART.

Before starting LA, 313 (75%) PWH were on an integrase inhibitor (INSTI), 202 (48%) on a non-nucleoside reverse transcriptase inhibitor (NNRTI), 108 (26%) were on both INSTI+NNRTI and 11 (3%) on a protease inhibitor regimen. At the time of initiating LA, 6 (1.5%) participants had LLV. All achieved undetectable HIV RNA <50 copies/mL at the following visit. Among the 231 PWH with at least one follow-up visit (median follow-up of 7 months, range 0–16), five episodes (2%) of LLV occurred, with HIV-RNA levels ranging from 52 to 140 copies/mL (table 1). In two participants, the subsequent HIV-RNA was <50 copies/mL without changing therapy, in one the treatment was continued but HIV-RNA from the next visit was still not available, and in two the treatment was stopped due to a concomitant adverse event. Two virological failures with HIV-RNA >200 copies/mL were also registered, and both discontinued LA treatment.

Conclusions LLV is a rare event, and its frequency did not change during LA therapy. All PWH with LLV who remained on CAB + RPV obtained an undetectable viremia.

Abstract P-4 Table 1 Description and timing of the episodes of low-level viremia and virological failure in SCOLTA cohort

#	Sex at birth, age (years)	Previous ART (years)	Previous regimen	HIV RNA T0	Week T1	HIV RNA T1	Week T2	HIV RNA T2	Week T3	HIV RNA T3	Management
1	M, 49	2.4	RPV/DTG	81	37	<50	Continue CAB+RPV
2	M, 54	4.2	FTC/TAF/RPV	172	23	<50	Discontinuation for AE
3	M, 46	1.4	FTC/TAF/BIC	61	33	<50	Continue CAB+RPV
4	M, 54	20.0	3TC/DTG	88	16	<50	Continue CAB+RPV
5	M, 26	3.0	RPV/DTG	56	27	<50	Continue CAB+RPV
6	F, 45	6.8	FTC/TAF/RPV	59	16	<50	Continue CAB+RPV
7	F, 55	8.3	FTC/TAF/RPV	<50	19	88	28	<50	.	.	Continue CAB+RPV
8	M, 35	8.6	3TC/DTG	<50	12	52	Continue CAB+RPV
9	M, 51	19.4	RPV/DTG	<50	27	140	Discontinuation for AE
10	M, 49	22.1	3TC/DTG	<50	25	67	Discontinuation for AE
11	M, 35	4.1	RPV/DTG	<50	16	70	40	<50	.	.	Continue CAB+RPV
12	F, 45	15.0	RPV/DTG	<50	12	<50	21	3614	22	3435	Discontinuation for VF
13	F, 55	25.8	FTC/TAF/RPV	<50	13	<50	38	<50	56	236	Discontinuation for VF*

AE: adverse event; CAB: cabotegravir; RPV: rilpivirine; VF virological failure.

*At the genotypic resistance test no resistance mutation for rilpivirine or cabotegravir was found on both HIV-RNA and HIV-DNA sequencing.