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Low level viremia at the beginning and in course of long-acting treatment with injectable cabotegravir and rilpivirine

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Introduction/Summary

- Long-Acting (LA) injectable cabotegravir (CAB) and rilpivirine (RPV) have been approved for optimization in people with HIV (PWH). However, on the day of starting therapy or during the course of LA treatment, virological blips of HIV RNA below 200 copies/mL may occur (low level viremia, LLV). The aim of this study is to describe the frequency and management of LLV at the beginning and in course of LA CAB+RPV.

Study Design

- Observational multicentre prospective study in the SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretrovirals) cohort.
- The SCOLTA project is a multicenter observational study that involves 25 Italian Infectious Disease Centers, started in 2002 and following prospectively PWH who start to take new antiretroviral drugs, to identify toxicities in a real-life setting.
- For the present study, we considered only antiretroviral (ART) experienced people aged ≥18 years and who started LA CAB + RPV with HIV-RNA <50 copies/mL at the last virological test before the switch.
- Both those who directly started therapy with the long-draw formulation and those who carried out an oral lead in period were eligible for the study.

Methods

- Data were described using mean and standard deviation (SD) for normally distributed continuous variables, median, and interquartile range (IQR) for not normally distributed continuous variables and frequency (%) for categorical and ordinal variables.
- HIV RNA values were collected prospectively in people on LA CAB+RPV, with time intervals not decided a priori and based on clinical judgment at each center.

Results

- 417 PWH, of whom 97 (23.3%) women, started LA treatment in SCOLTA. Mean age at enrolment was 48.5 (±11.3) years and the median CD4 was 806 cells/mmc (IQR 582-1040). Most study 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%).

Results of 2

- All study participants 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 treatment, 6 (1.5%) participants had LLV. All achieved undetectable HIV RNA<50 copies/mL at the following visit.

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.

Among the 231 PWH with at least one follow-up visit (median follow-up of 7 months, ranging from 0 to 16 months), five episodes (2%) of LLV occurred, with HIV-RNA levels ranging from 52 to 140 copies/mL (Table 1). In two study 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.

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