Long-Acting Cabotegravir and Rilpivirine: Real World Outcomes at 3 Years. ANRS CO3 AquiVIH-NA Cohort

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BACKGROUND

- Long term safety and virologic outcomes, therapeutic drug monitoring and patient reported outcomes on health-related quality of life and treatment satisfaction of CAB-RPV LA in routine clinical care have rarely been described
- **Objective:** to retrospectively report real world outcomes at 3 years for people with HIV-1 (PWH) on CAB-RPV LA

METHODS

- HIV-1 adults from the ANRS CO3-AQUIVIH-NA observational cohort in South-Western France, who received their first CAB-RPV LA injection from January 1st 2022 were included.
- Virologic failure (VF) was defined as 1 HIV RNA > 1000 cp/mL or 2 consecutive HIV RNA > 50 cp/mL or no HIV RNA < 50 cp/mL at 6 months in PWH not virologically suppressed (VS) at baseline (HIV RNA > 50 cp/mL).
- Patients referring to the hospital pharmacy of one of the centers, for their drug delivery were proposed a questionnaire on their health-related quality of life (HR-QOL) under CAB-RPV LA and their treatment satisfaction.

RESULTS

464 PWH received at least one injection of CAB-RPV LA:

- At baseline:
  - 444 (96%) were VS, 9 had a VL between 50 and 200 cp/mL (Low level viremia: LLV) and 11 with a VL > 200 cp/mL,
  - Median age was 47 years (IQR 37-55),
  - 26% were female sex at birth, and 4 transgender women,
  - 73% were born in France and 16% in Sub-Saharan Africa,
  - Median BMI was 24.8 kg/m^2 (IQR 22.5-27.8) and 15% had BMI>30 kg/m^2,
  - Median time from HIV diagnosis was 12.6 (IQR 6.6-20.9) years.

Maintain of virologic control, safety and patient satisfaction at 3 years with CAB-RPV LA in real world

- At 36 months:
  - Median time of follow-up was 21.1 (IQR 12.2-29.6) months.
  - 20 patients experienced VF (4.3%) among which 17 had an available genotypic resistance test, 2 were LLV and 4 were not VS at baseline,
  - Median time to VF was 6.6 months (IQR 2.6-12.2).
  - Among 17 non LLV VF (3.7%), 4 (0.9%) had both NNRTI and INSTIs RAMs (#11, 12,13 and 17). They had low RPV (< 50 ng/mL) and CAB (< 1120 ng/mL) plasma concentrations at some time during the drug monitoring. Two had BMI>30 kg/m^2 (32 and 36). #17 had undetectable RPV and CAB plasma concentrations at the end of the lead-in phase.

Characteristics of PWH experiencing Virological Failure

#	ARV before CAB RPV	Clade	VL at baseline (cp/mL)	GSS	VL at VF (cp/mL)	Delay to VF (months)	GSS	ARV after VF	Delay to VL<50 cp/mL after VF (months)
1	TDF/FTC/EVG/c	B	19	2	401	11	2	TAF/FTC/BIC	11
2	DOR DTG	B	25	2	207	30	2	**CAB RPV**	0
3	DTG RPV	B	19	1,5[$]	66	2	ND	DOR DTG	3
4	TVD DRV/r	B	19	2	106	7	2	**CAB RPV**	2
5	TAF/FTC/RPV	B	0	2	975	17	2	**CAB RPV**	6
6	TAF/FTC/BIC	B	0	2	147	8	ND	TAF/FTC/BIC	0
7	TDF/3TC/DOR	02_AG	0	2	82	1	2	TDF/3TC/DOR	1
8	TAF/FTC/BIC	B	19	2	64	8	2	TAF/FTC/BIC	10
9	3TC/DTG	B	19	2	381	2	2	TDF/FTC DRV/r	NA[£]
10	3TC DRV/r RAL	B	24	2	87	1	2	**CAB RPV**	4
11	DTG RPV	B	0	2	321	10	**0**	TDF/FTC DRV/r	2
12	TAF/FTC/RPV	B	0	2	789	9	**0**	TDF/FTC DRV/r	8
13	ABC/3TC/DTG	02_AG	25	2	361	4	**0**	TDF/FTC DRV/r	NA*
14	TDF/3TC/DOR	22_01A1	69	2	169	18	2	**CAB RPV**	5
15	TAF/FTC/BIC	B	105	2	141	6	2	**CAB RPV**	25
16	No ARV	B	35,207	2	245	23	2	**CAB RPV**	0
17	No ARV	RF	63,800	2	75,200	3	**0**	TDF/FTC DRV/r	NA*

GSS: according to the v35 ANRS algorithm (HIV French Resistance), ND: not determined (no GRT available), NA: not applicable
[$] baseline PRM NNRTI: 98AG + 103N + 225PL, * lost to follow up, [£] VL > 200 cp/mL

Emerging RAMs at VF

# PID	VF NNRTI RAMs	VF INSTI RAMs
11	103N 138EA 179I 181YC	74I 138KE 140SG 148R
12	230L	74I 148R 230N
13	230L	74I 138K 148K
17	106I 138KQ 179I 181C 221Y	74IL 138K 148R 157Q

Underlined RAMs emerged after VF

- 85 PWH (18.3%) had discontinued treatment, 13 for VF (2.8%), 29 (6.2%) for adverse events (10 (2.1%) for injection site reactions)
- No significant changes in BMI nor LDL-C were observed.
- In the subgroup of 70 PWH responding to the questionnaire, the score of HR-QOL was improved in 75% of them with a high treatment satisfaction

CONCLUSIONS

In this large French cohort, 82% of PWH continued CAB-RPV LA injections at 3 years and virologic control was maintained in 96% of them. These results suggest that CAB + RPV LA injectable can be administered effectively during routine clinical care on a long period with no major impact on BMI and metabolic parameters and high HR-QOL score and treatment satisfaction.

PLAIN LANGUAGE SUMMARY

In a large group of people with HIV in France, most people (82%) kept using the long-acting injectable treatment (cabotegravir + rilpivirine) for at least 3 years. Among those who stayed on it, almost all (96%) kept their virus well controlled.
These findings show that this injectable treatment works well in regular, everyday healthcare settings over a long time. It didn't cause major changes in body weight or metabolism, and people generally reported good quality of life and were happy with the treatment.