Poster
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Use of long-acting Cabotegravir and Rilpivirine in a real-life setting: 12-month results of virological outcome, adherence, safety, durability, in the ANRS CO3 AquiVIH-NA Cohort-France.

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BACKGROUND

- The first complete long-acting antiretroviral therapy (ART) regimen, cabotegravir + rilpivirine long-acting (CAB + RPV LA) injectable, was approved in France in December 2021, for HIV-1 treatment in individuals on a stable antiretroviral regimen virologically suppressed (VS), with no virological failure (VF) history under NNRTIs or InSTIs, and no resistance to either cabotegravir or rilpivirine.
- We describe patient characteristics, safety and virologic effectiveness of CAB + RPV LA in routine clinical care in South-Western France.

METHODS

- The ANRS-CO3-AquiVIH-NA cohort is an open, prospective hospital-based cohort of HIV-1-infected adults (≥18 years old) in care in 15 hospitals in the Nouvelle Aquitaine region of south-western France.
- The cohort collects epidemiological, clinical, biological and therapeutic data from the medical records of PLWH and who have signed informed consent since 1987.
- We performed a retrospective analysis at month 12 and included all adults with HIV who received their first CAB + RPV LA injection from January 1st, 2022 to june 30 2024. VF was defined as one HIV RNA > 1000 cp/mL or 2 consecutive HIV RNA > 50 cp/mL; or no HIV RNA < 50 cp/mL at 6 months in patients not virologically suppressed at baseline.

RESULTS

Among **374** individuals who received at least one injection of CAB + RPV LA.

- **At baseline** (table 1) **:**
  - 179 (48%) received an oral lead-in,
  - Median age was 47 years (range 20-81),
  - 98 (26%) were female sex at birth, and 2 transgender women,
  - 275 (74%) were born in France and 55 (15%) in Sub-Saharan Africa,
  - 362 (97%) were virologically suppressed,
  - 5 had a VL between 50 and 200 cp/mL, and 7 > 200 cp/mL
  - The median number of previous lines of ART was 4.
  - Median BMI was 25.0 kg/m2 (IQR 22.7-27.8),
  - Median LDL-cholesterol was 3 mmol/L (IQR 2.5-3.7),
- **At month 12 :**
  - 12 patients experienced VF (3.5%) among which 3 were not VS at baseline and 6 had low level viremia (table 2),
  - 38 patients (10.2%) had discontinued the treatment with 43 causes including 13 (30.2%) for adverse events, of which 5 (11.6%) for injection site reactions (table 3), 10 (23.3) for physician's choice and 8 (18.6%) patient's choice and among VF patients only 7 (16.3%) stop CAB+RPV LA,
  - No changes in BMI or LDL-C were observed (table 4).

Table 1. Baseline characteristics of participants switching to CAB+RPV LA regimen, according to the uptake of a Lead-in phase before injection

Characteristics	No Lead-in N=195		Lead-in N=179		p*	Total N=374	
Age (in years),					0.13		
Median (IQR)	48.1	(37.9;56.4)	45.4	(36.1;55.0)		47.2	(36.9;55.5)
Gender, n (%)					.		
Male	141	(72.3)	133	(74.3)		274	(73.3)
Female	52	(26.7)	46	(25.7)		98	(26.2)
Transgender M to F	2	(1.0)	0	(0.0)		2	(0.5)
Region of birth, n (%)					0.76		
France	144	(73.8)	131	(73.2)		275	(73.5)
Sub-Saharan Africa	29	(14.9)	26	(14.5)		55	(14.7)
Other	22	(11.3)	22	(12.2)		44	(11.4)
Transmission group, n (%)					0.02		
Homo/bisexual	109	(55.9)	112	(62.6)		221	(59.1)
Heterosexuals	64	(32.8)	54	(30.2)		118	(31.6)
IV drug users	5	(2.6)	9	(5.0)		14	(3.7)
Other	17	(8.7)	4	(2.2)		21	(5.6)
Duration since first positive HIV test (in years),					0.08		
Median (IQR)	14.1	(7.1;21.9)	11.5	(6.2;19.4)		12.7	(6.6;21.2)
CD4 in classes ***, n (%)					0.3660		
≥500	138	(78.9)	138	(84.1)		276	(81.4)
200-500	33	(18.9)	24	(16.6)		57	(16.8)
<200	4	(2.3)	2	(1.2)		6	(1.8)
CD4 Nadir (cells/mm^3),					0.0422		
Median (IQR)	337.0	(185.0;524.0)	366.0	(237.0;551.0)		350.0	(213.0;541.0)
HIV viral load in classes, n (%)					0.2485		
≤50	189	(96.9)	173	(96.6)		362	(96.8)
51-200	1	(0.5)	4	(2.2)		5	(1.3)
>200	5	(2.6)	2	(1.1)		7	(1.9)
Nb of previous lines of ART,	195		179			374	
Median (IQR)	4.0	(2.0;8.0)	3.0	(2.0;7.0)		4.0	(2.0;7.0)
BMI (kg/m^2),					0.27		
Median (IQR)	24.6	(22.5;27.1)	25.6	(23.2;28.1)		25.0	(22.7;27.8)
BMI , n (%)					0.8049		
<30kg/m^2	144	(85.2)	137	(86.2)		281	(85.7)
≥30kg/m^2	25	(14.8)	22	(13.8)		47	(14.3)
Level of cholesterol LDL, n (%)					0.4929		
≤ 3.5mmol/L	108	(69.7)	95	(66.0)		203	(67.9)
>3.5mmol/L	47	(30.3)	49	(34.0)		96	(32.1)

Table 2. Comparison of cumulative viral load characteristics from initiation of treatment to month12

Characteristics	Total N=374	
At least 1 virological failure since baseline, n (%)		
No	334	(96.5)
Yes	12	(3.5)
Type of virological failure, n (%)		
Low level viremia (2 consecutive VL>50 cp/mL)	6	(50.0)
High level viremia (at least 1 VL >200cp/mL if 2 consecutive VL>50 cp/mL	3	(25.0)
For unsuppressed at baseline patient, No VL<50 between 3 and 12 months	3	(25.0)
Delay of first virological failure, Median (IQR) in month	4.9	(1.8;6.9)
At least 1 Blip (VL>50cp/mL after VL≤50cp/mL) since baseline, n (%)	346	
No	319	(92.2)
Yes	27	(7.8)

Table 3. Reasons of treatment discontinuation at month 12

Characteristics	Total N=374	
Treatment discontinuation at 12 months, n (%)	374	
No	336	(89.8)
Yes	38	(10.2)
Cause of discontinuation at 12 months (grouped), n (%)	43	
Drug resistance	3	(7.0)
ISR : injection site reaction	5	(11.6)
Other Adverse event	8	(18.6)
Patient's choice	8	(18.6)
Physician's choice	10	(23.3)
Pregnancy	2	(4.7)
Virological failure	7	(16.3)

Table 4. Comparison of Metabolic-related characteristics between baseline and 12 months among patients who did not discontinue treatment at month 12

Characteristics	At baseline N=336		At 12 months N=336		p*
BMI in kg/m^2,					0.5123
Median (IQR)	24.8	(22.5;27.7)	25.0	(22.8;27.9)	
LDL cholesterol in mmol/L,					0.0866
Median (IQR)	3.0	(2.5;3.7)	3.2	(2.6;3.9)	
Triglycerides in mmol/L,					0.5873
Median (IQR)	1.2	(0.8;1.7)	1.2	(0.8;1.7)	
Glycemia in mmol/L *,					0.6090
Median (IQR)	5.1	(4.7;5.6)	5.1	(4.7;5.5)	

CONCLUSIONS

- **In this large French cohort, 90% of patients continued CAB + RPV LA injections at month 12 and VF was observed in 3.5% of them.**
- **There were no differences between the characteristics of lead-in and no lead-in groups.**
- **We observed no modification of metabolic parameters at 12 months.**
- **Adverse events leading to treatment interruption were noticed in 3.5% of patients, 12 months after beginning CAB + RPV LA.**
- **These results suggest that CAB + RPB LA injectable can be administered effectively and safely during routine clinical care.**

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