Outcomes for Individuals Who Initiate CAB+RPV LA in OPERA with Viral Loads ≥50 vs. <50 copies/mL

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Background

- CAB+RPV LA is the first and only complete LA ART regimen approved for HIV-1 treatment in the US
  - Approved by the FDA as Q1M (2021) or Q2M (2022) pairs of injections
  - Indicated for treatment-experienced individuals who are virologically suppressed (VL <50 copies/mL)
- Real-world studies have reported off-label use among individuals viremic (VL ≥50 c/mL) at CAB+RPV LA initiation

Objective

Describe demographics, clinical characteristics, and virologic outcomes among individuals on CAB+RPV LA, stratified by viral load at initiation

Methods

OPERA Cohort

- Prospectively captured, routine clinical data from US-based EHRs, representing ~14% of people with HIV in the US

Inclusion Criteria

- ART-experienced adults, ≥18 years of age
- Initiated CAB+RPV LA from 21JAN2021 – 31DEC2024

Censoring Criteria

- Discontinuation of CAB+RPV LA
  - Q1M: >67 days after last injection
  - Q2M: >127 days after last injection
- Death
- Lost to follow-up (12 months after last clinical contact)
- End of analysis period (28FEB2025)

Stratification

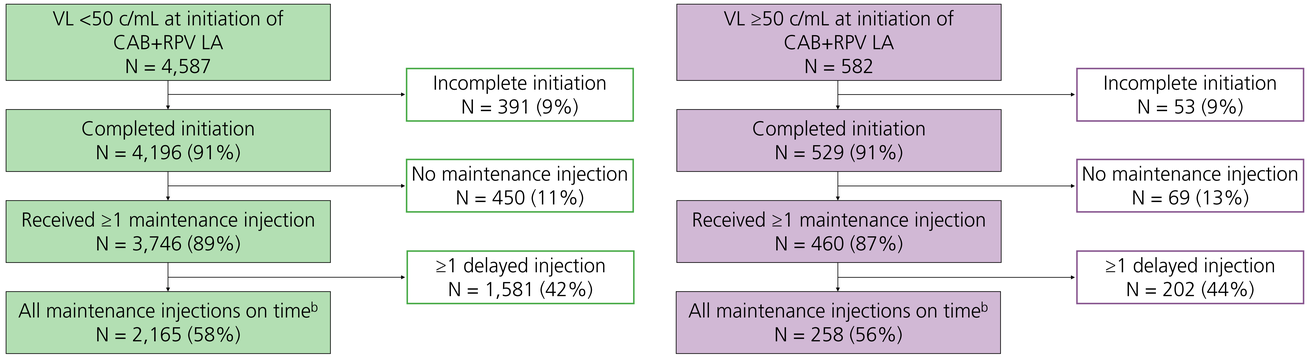
- Two study groups based on VL at initiation of CAB+RPV LA:
  - VL <50 c/mL
  - VL ≥50 c/mL

Analysis & Outcomes

- Virologic outcomes were assessed among individuals who completed initiation (i.e., received initiation injections ≤67 days apart) *and* had ≥1 VL through 28FEB2025
- **Among individuals with VL <50 copies/mL at initiation**
  - Virologic suppression was maintained if all VLs or the last follow-up VL was <50 c/mL
  - CVF was defined as 2 consecutive VLs ≥200 c/mL *or* discontinuation of CAB+RPV LA after a VL ≥200 c/mL
- **Among individuals with VL ≥50 copies/mL at initiation**
  - Virologic suppression was achieved if any or the last follow-up VL was <50 c/mL
  - CVF was assessed after virologic suppression to <50 c/mL
- Adherence to maintenance injection dosing was described among complete initiators with ≥1 maintenance injection

Results

Figure 1. CAB+RPV LA usage among individuals with VL <50 c/mL (green) and VL ≥50 c/mL (purple) at initiation[a]



[a] There were an additional 95 individuals who were missing VL at initiation, 79 (83%) of whom completed initiation. Of complete initiators, 69 (87%) received ≥1 maintenance injection, and of those individuals, 50 (72%) received all maintenance injections on time

[b] On-time maintenance injections were ≤37 days (Q1M) or ≤67 days (Q2M) after the previous injection

Table 1. Demographic characteristics at CAB+RPV LA initiation

	VL <50 c/mL N = 4,587	VL ≥50 c/mL N = 582
Age, median years (IQR)	38 (32, 50)	40 (32, 51)
Age ≥50 years, n (%)	1,124 (25)	155 (27)
Female sex, n (%)	668 (15)	153 (26)
Black race, n (%)	1,950 (43)	313 (54)
Hispanic ethnicity, n (%)	1,442 (31)	122 (21)
PWID, n (%)	265 (6)	47 (8)
Receiving care in US South, n (%)	2,494 (54)	338 (58)

Table 2. Clinical characteristics at CAB+RPV LA initiation

	VL <50 c/mL N = 4,587	VL ≥50 c/mL N = 582
Years since HIV diagnosis, median (IQR)	6 (2, 12)	8 (2, 16)
Years since ART initiation, median (IQR)	3 (1, 7)	4 (1, 8)
History of AIDS-defined events, n (%)	1,048 (23)	210 (36)
VL (c/mL), median (IQR)	19 (19, 20)	120 (60, 2,040)
VL ≥1,000 c/mL, n (%)	N/A	160 (27)
CD4 cell count (cells/μL), median (IQR)	707 (528, 913)	549 (342, 781)
BMI, median (IQR)	27 (24, 31)	27 (23, 31)
BMI ≥30 kg/m^2, n (%)	1,380 (30)	169 (29)
Any comorbidity[a], n (%)	3,600 (79)	473 (81)
Mental health disorders, n (%)	1,767 (39)	276 (47)
Substance misuse, n (%)	897 (20)	161 (28)
Endocrine disorders	2,417 (53)	300 (52)

[a] Categories included: Autoimmune disease, cardiovascular disease, invasive cancers, endocrine disorders, mental health disorders, liver disease, bone disorders, peripheral neuropathy, renal disease, hypertension, and substance misuse

Abbreviations: **ART**, antiretroviral therapy; **BMI**, body mass index; **c/mL**, copies per milliliter; **CAB+RPV LA**, cabotegravir plus rilpivirine long-acting; **CVF**, confirmed virologic failure; **EHR**, electronic health record; **HIV**, immunodeficiency virus; **IQR**, interquartile range; **LA**, long-acting; **n**, number; **N/A**, not applicable; **PWID**, people who inject drugs; **Q1M**, every 1 month; **Q2M**, every 2 months; **US**, United States; **VL**, viral load

Table 3. Adherence among complete initiators with ≥1 maintenance injection

	VL <50 c/mL N = 3,746	VL ≥50 c/mL N = 460
Any delayed injection, n (%)	1,581 (42)	202 (44)
Number of delayed injections, median (IQR)	1 (1, 2)	1 (1,2)
Any delay of 1 to 30 days, n (%)	1,288 (81)	161 (80)
Days after the target window[a], median (IQR)	3 (2, 9)	4 (2, 10)
Any delay of ≥31 days, n (%)	354 (22)	40 (20)
Days after the target window[a], median (IQR)	52 (45, 56)	52 (45, 55)

[a] Target window: ≤37 and ≤67 days after previous maintenance injection, for Q1M and Q2M dosing respectively

Table 4. Persistence among complete initiators

	VL <50 c/mL N = 4,196	VL ≥50 c/mL N = 529
Months on CAB+RPV LA until first censoring event, median (IQR)	14 (7, 23)	12 (7, 22)
Still on CAB+RPV LA at the end of the analysis period, regardless of discontinuation, n (%)	3,279 (78)	388 (73)
Months on CAB+RPV LA, median (IQR)	16 (9, 26)	15 (8, 26)

Table 5. Virologic effectiveness among complete initiators

	VL <50 c/mL N = 4,196	VL ≥50 c/mL N = 529
≥1 VL after initiation, n (%)	4,000 (95)	502 (95)
Last VL <50 c/mL, n (%)	3,786 (95)	399 (79)
Suppressed at all follow-up VLs, n (%)	3,233 (81)	N/A
Achieved suppression, n (%)	N/A	439 (87)
Experienced CVF, n (%)	43 (1)	7 (2)

Discussion

- Among 5,264 adults initiating CAB+RPV LA, 4,587 (87%) had a VL <50 c/mL, 582 (11%) had a VL ≥50 c/mL, and 95 (2%) were missing VL at initiation (**Figure 1**)
- Compared to individuals who were suppressed at CAB+RPV LA initiation, individuals who were viremic (**Tables 1 & 2**):
  - Were more likely to be female and to be Black
  - Were less likely to be Hispanic
  - Had greater time since HIV diagnosis and ART initiation
  - Were more likely to have history of an AIDS-defining event, mental health disorders, and substance misuse
- Among individuals with a VL at initiation who completed initiation and had ≥1 maintenance injection, a majority (56%-58%) received all maintenance injections on time (**Figure 1**)
- Among complete initiators who had ≥1 delayed maintenance injection (**Table 3**):
  - The median number of delayed injections was 1 (IQR: 1,2)
  - Most individuals experienced delays of <30 days, with median delays after the target window of 3 days (VL <50 c/mL) or 4 days (VL ≥50 c/mL)
  - The median days after the target window among individuals who experienced delays of ≥31 days was 52
- A majority remained on CAB+RPV LA at last follow-up (VL <50 c/mL: 78%, VL ≥50 c/mL: 73%) (**Table 4**):
  - Median time on CAB+RPV LA was 16 (IQR: 9, 26) and 15 (IQR: 8, 26) months among the VL <50 c/mL and ≥50 c/mL groups, respectively
- In the VL <50 c/mL group, 81% were suppressed at all follow-up VLs, 95% had a last VL <50 c/mL, and only 1% experienced CVF (**Table 5**)
- In the VL ≥50 c/mL group, 87% achieved suppression over follow-up, 79% had a last VL <50 c/mL, and only 2% experienced CVF (**Table 5**)

Key Findings

- Regardless of VL at initiation of CAB+RPV LA, virologic suppression was commonly achieved/maintained while CVF was rare
- Findings from this large, real-world cohort study reinforce CAB+RPV LA as a versatile and effective therapy for a diverse population, including people struggling with adherence or tolerability to oral regimens

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