Few differences in persistence and virologic outcomes across age groups among CAB+RPV LA users: Findings from the OPERA Cohort

P-371

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Background

- LA ART formulations may provide consistent therapeutic coverage with few drug interactions for older individuals living with HIV
- CAB+RPV LA is the first and currently only complete LA ART regimen approved for HIV-1 treatment in the United States
  - Approved by the FDA as monthly (2021) or every 2-month (2022) pairs of injections
  - Indicated for treatment-experienced individuals who are virologically suppressed (VL < 50 copies/mL)
- **Note**: This data has been updated since the abstract was submitted

Objective

To describe persistence and virologic outcomes in individuals across different age groups receiving CAB+RPV LA injections in routine clinical care

Methods

- **OPERA cohort**
  - Prospectively captured, routine clinical data from electronic health records in the US (101 clinics, 23 US states/territories), representing ~14% of PWH in the US
- **Inclusion criteria**
  - ART-experienced PWH aged ≥ 18 years (regardless of VL)
  - Received ≥ 1 CAB+RPV LA injection between 21JAN2021 and 31DEC2024
- **Censoring criteria**
  - Discontinuation of CAB+RPV LA regimen
  - Death
  - 12 months after last clinical contact
  - End of analysis period (28FEB2025)

Outcomes

- **Among individuals with ≥ 1 injection**
  - Demographic and clinical characteristics at first injection
  - Complete initiation: First 2 sets of injections within 67 days
- **Among complete initiators**
  - Persistence:
    - On regimen at time of analysis
    - Cumulative months on regimen
- **Among complete initiators with ≥ 1 VL during follow-up**
  - Virologic suppression: VL < 50 copies/mL at last measure
- **CVF**: 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL followed by discontinuation within 2 (Q1M) or 4 (Q2M) months
  - Those who initiated with VL ≥ 50 copies/mL had to suppress to < 50 copies/mL before meeting the CVF definition

Stratification

- Outcomes were assessed overall and stratified by age at first injection
- Virologic outcomes were additionally stratified by VL at first injection

Results

Table 1. Demographic and clinical characteristics at CAB+RPV LA initiation (N = 5,264)

	All (N = 5,264)	18-49 years (N = 3,955)	50-64 years (N = 1,083)	≥ 65 years (N = 226)
Age, median years (IQR)	38 (32, 50)	35 (30, 41)	56 (53, 59)	68 (66, 71)
Female, n (%)	841 (16%)	538 (14%)	247 (23%)	56 (25%)
Black race, n (%)[a]	2,300 (44%)	1,825 (46%)	395 (36%)	80 (35%)
Hispanic ethnicity, n (%)[a]	1,585 (30%)	1,290 (33%)	255 (24%)	40 (18%)
Injection drug use, n (%)	315 (6%)	209 (5%)	81 (7)	25 (11%)
Years since HIV diagnosis, median (IQR)	6 (2, 13)	5 (1, 10)	12 (4, 23)	18 (5, 28)
Hx of AIDS-defining illnesses, n (%)	1,271 (24%)	776 (20%)	395 (36%)	100 (44%)
BMI, median kg/m^2 (IQR)[a]	27 (24, 31)	27 (24, 31)	28 (25, 32)	27 (24, 30)
VACS Index, median (IQR)[a]	10 (0, 8)	0 (0, 10)	18 (12, 28)	39 (33, 49)
Co-infections (ever), n (%)				
Hepatitis B	132 (3%)	65 (2%)	56 (5%)	11 (5%)
Hepatitis C	326 (6%)	184 (5%)	110 (10%)	32 (14%)
Syphilis	2,500 (47%)	2,029 (51%)	412 (38%)	59 (26%)
HIV viral load, n (%)[a]				
< 50 copies/mL	4,587 (87%)	3,463 (88%)	934 (86%)	190 (84%)
≥ 50 copies/mL	582 (11%)	427 (11%)	124 (11%)	31 (14%)
CD4 cell count, median cells/μL (IQR)[a]	692 (507, 901)	703 (523, 910)	669 (470, 892)	602 (405, 794)
Prior core agent class, n (%)[a]				
INSTI	4,025 (76%)	3,165 (80%)	727 (67%)	133 (59%)
PI	225 (4%)	146 (4%)	69 (6%)	10 (4%)
NNRTI	312 (6%)	229 (6%)	70 (6%)	13 (6%)
≥ 2 core agents	374 (7%)	171 (4%)	148 (14%)	55 (24%)
Months on prior regimen, median (IQR)	19 (8, 41)	18 (8, 38)	24 (9, 49)	22 (7, 46)

[a] N missing: race = 225, ethnicity = 218, BMI = 228, VACS index = 572, VL = 95, CD4 cell count = 124, prior core agent class = 324

Table 2. Persistence among complete initiators alive and active in care at time of analysis (N = 4,748)

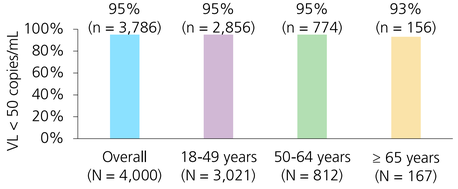
	Overall	Age at initiation			VL at initiation	
	(N = 4,748)	18-49 years (N = 3,567)	50-64 years (N = 979)	≥ 65 years (N = 202)	< 50 copies/mL (N = 4,153)	≥ 50 copies/mL (N = 516)
On CAB+RPV LA at time of analysis[a], N (%)	3,731 (79%)	2,825 (79%)	742 (76%)	164 (81%)	3,279 (79%)	388 (75%)
Cumulative months on CAB+RPV LA, median (IQR)	16 (8, 26)	15 (8, 25)	19 (11, 28)	18 (9, 30)	16 (9, 26)	15 (8, 26)

[a] Among those on CAB+RPV LA at study end, including CAB+RPV use among individuals who discontinued and restarted CAB+RPV use during the study period

Abbreviations

AIDS, Acquired immunodeficiency syndrome; **ART**, antiretroviral therapy; **BMI**, body mass index; **CAB+RPV**, cabotegravir + rilpivirine; **CVF**, confirmed virologic failure; **FDA**, Food and Drug Administration; **HIPAA**, Health Insurance Portability and Accountability Act; **HIV**, human immunodeficiency virus; **Hx**, history; **INSTI**, integrase inhibitor; **IQR**, interquartile range; **kg**; kilogram; **LA,** long-acting; **mL**; milliliter; **μL,** microliter; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitor; **PWH**, people with HIV; **Q1M**, monthly dosing; **Q2M**, every 2 months dosing; **US**, United States; **VACS**, Veterans Aging Cohort Study; **VL**, viral load

Figure 1. VL < 50 copies/mL at time of analysis among individuals who had **VL < 50 copies/mL at initiation**[a], completed initiation and had ≥ 1 follow-up VL (N = 4,000)



[a] Median months on CAB+RPV LA until first censoring: 14 (IQR: 7, 23)

Figure 2. CVF among individuals who had **VL < 50 copies/mL at initiation**, completed initiation and had ≥ 1 follow-up VL (N = 4,000)

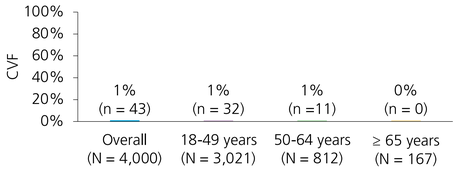
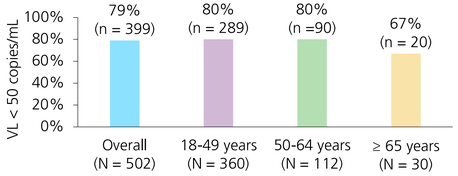
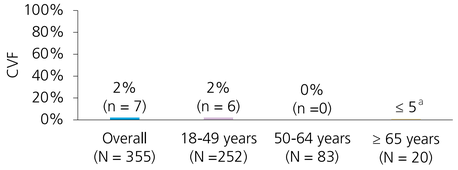


Figure 3. VL < 50 copies/mL at time of analysis among individuals who had **VL ≥ 50 copies/mL at initiation**, completed initiation, and had ≥ 1 follow-up VL (N = 502)



[a] Median months on CAB+RPV LA until first censoring: 12 (IQR: 7, 22)

Figure 4. CVF among individuals who had **VL ≥ 50 copies/mL at initiation**, completed initiation, and had ≥ 1 follow-up VL after suppressing to VL < 50 copies/mL (N = 355)



[a] HIPAA regulations require masking values of 1 to 5 individuals

Discussion

- Of 5,264 PWH initiating CAB+RPV LA in OPERA during the study period, 3955 (75%) were 18-49, 1083 (21%) were 50-64, and 226 (4%) were ≥ 65 years old (**Table 1**)
  - Compared to the youngest age group, individuals ≥ 50:
    - Were more likely to be female
    - Were less likely to be Black or Hispanic
    - Were more likely to have used injection drugs
    - Were less likely to have VL < 50 copies/mL at initiation
    - Had HIV for longer and had higher VACS scores at initiation
    - Were more likely to have had ≥ 2 core agents on their prior regimen
- The majority of complete initiators alive and in care at time of analysis (80%) remained on CAB+RPV LA (**Table 2**)
  - Those aged ≥ 50 had slightly longer cumulative months on CAB+RPV LA than those aged 18-49 (**Table 2**)
- Among individuals with VL < 50 copies/mL at initiation, similarly high proportions (93-95%) were suppressed at last VL measure across age groups (**Fig 1**)
  - CVF was rare (1%; **Fig 2**)
- Among individuals with VL ≥ 50 copies/mL at initiation, 67% of those aged ≥ 65 were suppressed at last measure, compared to 80% of those aged 18-49 and 50-64 (**Fig 3**)
  - Among those who suppressed, CVF was rare (2%; **Fig 4**)

Key Findings

In a diverse clinical population of > 5000 individuals initiating CAB+RPV LA over the first 4 years of its availability:

- Adults with HIV were able to stay on regimen and remain virologically suppressed across a wide range of ages
- Among those viremic at initiation, most were suppressed to < 50 copies/mL at last measure
- CVF was rare, regardless of VL at initiation

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