Clinical outcomes among women in the OPERA Cohort initiating CAB+RPV LA with viral loads ≥ 50 copies/mL

WEPEB036

Jessica Altamirano[1], Brooke Levis[2], Cindy Markarian[3], Quateka Cochran[4], Courtney Sherman[5], Mona-Gekanju Toeque[3], Laura Armas[6], Gayathri Sridhar[7], Vani Vannappagari[7], Kimberley Brown[7], Jennifer S. Fusco[2]

[1] CAN Community Health, Miami, FL, USA; [2] Epividian, Inc., Raleigh, NC, USA; [3] AIDS Healthcare Foundation, Los Angeles, CA, USA; [4] AIDS Healthcare Foundation, Fort Lauderdale, FL, USA; [5] CAN Community Health, Arlington, TX, USA; [6] Human Centered Consulting & Care, McKinney, TX, USA; [7] ViiV Healthcare, Durham, NC, USA

IAS 2025 13–17 July

OPERA® The Longitudinal Cohort

Background

LA ART

- Convenience with potential for improved adherence
- Reduced daily reminders of HIV, stigma, and fear of disclosure
- Minimized pill burden and gastrointestinal issues
- May be a good option for women, who represent > 50% of people with HIV worldwide (~20% of people with HIV in the US)

CAB+RPV LA

- The first and currently only complete LA ART regimen
  - Injections once a month or every 2 months
  - Indicated for ART-experienced individuals with VL < 50 copies/mL
- In US cohorts, 9-35% of CAB+RPV LA users initiated the regimen with viremia (VL ≥ 30[1] or ≥ 50[2-4] copies/mL)
  - Among women in the OPERA Cohort, 20% initiated with VL ≥ 50 copies/mL[5]

Objective

To assess clinical outcomes among women initiating CAB+RPV LA with VL > 50 copies/mL over the first 3 years of regimen availability

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 (~11% of women with HIV in the US)

Inclusion Criteria

- Cisgender and transgender women living with HIV
- Aged ≥ 18 years
- ART-experienced
- Received ≥ 1 CAB+RPV LA injection from 21JAN2021-31AUG2023
- VL ≥ 50 copies/mL at first injection

Censoring Criteria

- Regimen discontinuation
- Lost to follow-up (12 months after last clinical contact)
- Death
- End of analysis period (29FEB2024)

Outcomes

- **Complete initiation**: First 2 sets of injections within 67 days
- **Adherence of initiation/maintenance injections**:

	Days after last injection	
	2nd initiation or Q1M maintenance injections	Q2M maintenance injections
On-time	23-37	53-67
Late	38-67	68-127
Delayed	38-52	68-112
Missed	53-67	113-127
Discontinued	> 67	> 127

- **Persistence**: On regimen at time of analysis; cumulative months of exposure among those on regimen at time of analysis
- **Virologic suppression**: Achievement of VL < 50 copies/mL at any time during follow-up, during the 1st 6 months, and at last follow-up
- **CVF**: VL suppression < 50 copies/mL followed by 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL and discontinuation

Abbreviations

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

Results

Table 1. Demographic and clinical characteristics at CAB+RPV LA initiation (N = 105)

	Women with ≥ 1 injection
Age, median years (IQR)	43 (35, 52)
≥ 50 years old, n (%)	37 (35%)
Transgender, n (%)	8 (8%)
Black race, n (%)	83 (79%)
Hispanic ethnicity, n (%)[a]	9 (9%)
Married or domestic partner, n (%)[a]	15 (14%)
Injection drug use, n (%)	≤ 5[b]
Care in Southern US, n (%)	85 (81%)
Payer, n (%)[c]	
Medicare	28 (27%)
Medicaid	54 (51%)
Commercial Insurance	67 (64%)
Ryan White/ADAP	17 (16%)
Cash	≤ 5[b]
Years since HIV diagnosis, median (IQR)	13 (4, 22)
History of AIDS-defining illnesses, n (%)	40 (38%)
BMI ≥ 30 kg/m², n (%)[a]	46 (44%)
VACS Index, median (IQR)[a]	28 (17, 47)
≥ 1 comorbidity, n (%)[d]	90 (86%)
Co-infections (ever), n (%)	
Hepatitis B	≤ 5[b]
Hepatitis C	10 (10%)
Syphilis	21 (20%)
Viral load, median copies/mL (IQR)	1090 (89, 24700)
CD4 cell count, median cells/µL (IQR)[a]	438 (253, 686)
Prior core agent class, n (%)[a]	
INSTI	61 (58%)
PI	14 (13%)
NNRTI	12 (11%)
≥ 2 core agents	14 (13%)
Other or missing	≤ 5[b]
Duration of prior regimen, median months (IQR)	17 (8, 34)

[a] N missing: ethnicity = 1, marital status = 7, BMI = 4, VACS index = 4, CD4 cell count = 1
[b] HIPAA regulations require masking cells with 1 to 5 individuals
[c] Payer categories are not mutually exclusive
[d] At least one of the following comorbidities (ever): autoimmune disease, cardiovascular disease, invasive cancer, endocrine disorder, mental health disorder, liver disease, bone disorder, peripheral neuropathy, renal disease, hypertension, or substance use disorder

Figure 1. CAB+RPV LA dosing at initiation and at time of analysis among complete initiators (N = 95)

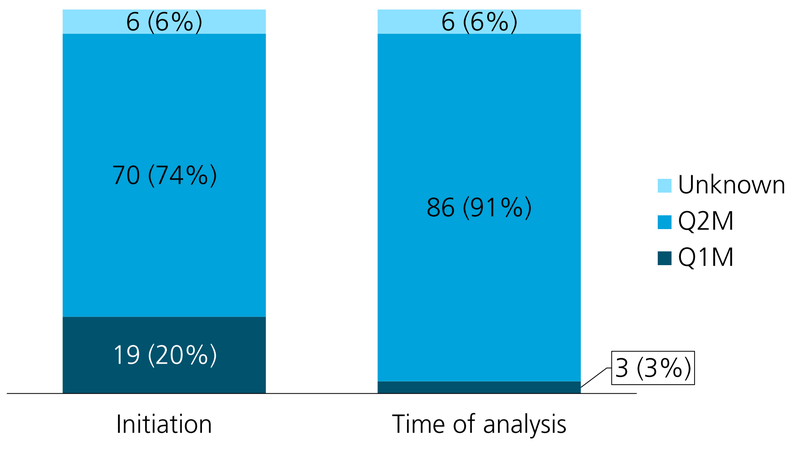


Figure 2. Persistence on all CAB+RPV LA exposures, among complete initiators (N = 95)

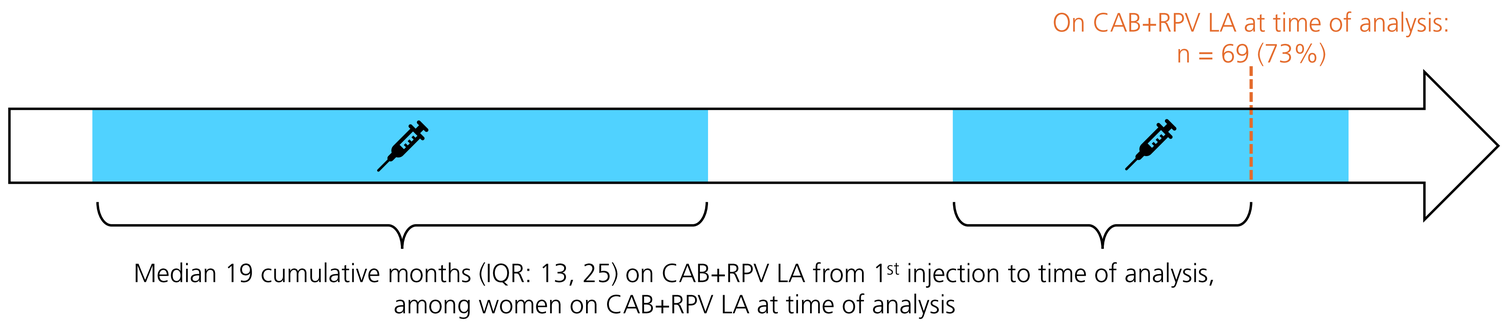
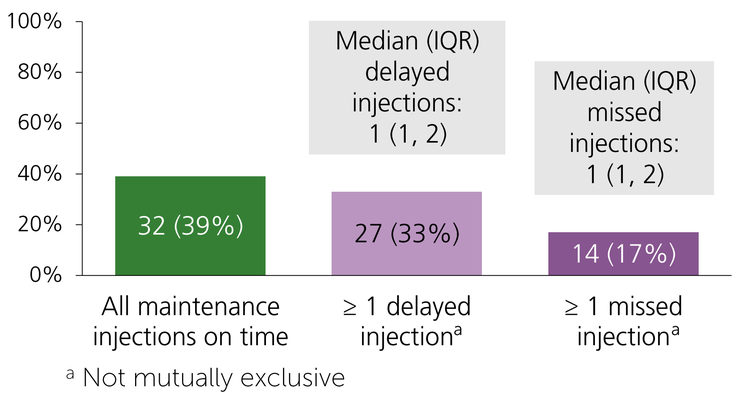


Figure 3. Adherence of maintenance injections among women with known dosing schedules and ≥ 1 maintenance injection (N = 82)



[a] Not mutually exclusive

Figure 4. Virologic suppression to VL < 50 copies/mL among women with ≥ 1 VL over follow-up (N = 91)

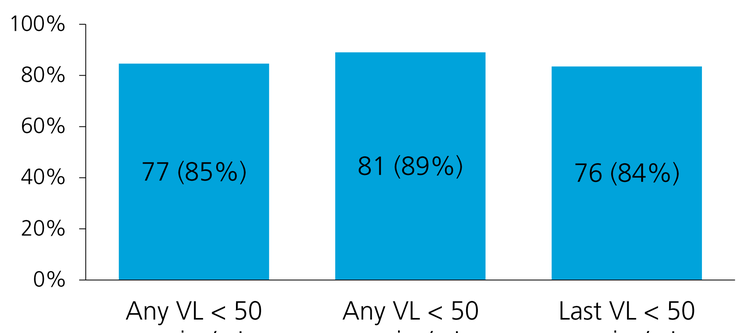
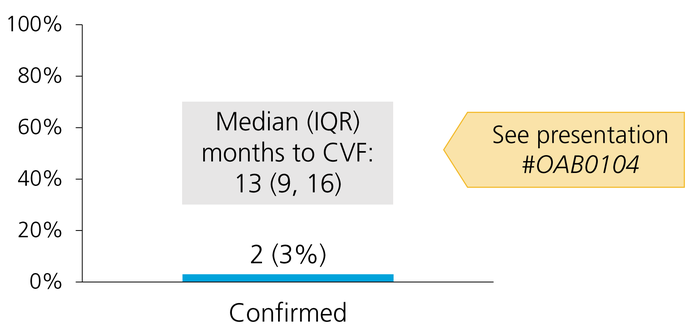


Figure 5. CVF among women with ≥ 1 VL available after suppression to VL < 50 copies/mL (N = 64)



Discussion

Summary of Findings

- Of 532 women in OPERA initiating CAB+RPV LA during the study period, 105 (20%) had VL ≥ 50 copies/mL at initiation
  - Median age was 43, 79% were Black, and 44% had a BMI ≥ 30 kg/m²
  - Most had longstanding HIV, ≥ 1 comorbidity, commercial insurance and/or Medicaid, and switched from an INSTI-containing regimen (**Table 1**)
  - Median VL was 1090 copies/mL (IQR: 89, 24700).
- Most women (90%) completed initiation (**Figure 1**)
  - Most were on Q2M schedules (**Figure 1**)
  - Almost three-quarters were on regimen at time of analysis, with a median follow-up of 19 months (**Figure 2**)
- 61% of women were late for ≥ 1 maintenance injection and/or discontinued (**Figure 3**)
  - Median of 1 delayed injection/woman with delay(s)
  - Median of 1 missed injection/woman with missed injection(s)
- Most women achieved virologic suppression (**Figure 4**)
  - 85% suppressed within 6 months
  - 11% never suppressed throughout follow-up
- Only 2 women (3%) experienced CVF, after a median of 13 months (**Figure 5**)

Strengths

- This was one of the first studies to examine CAB+RPV LA use and outcomes among women (exclusively) who initiated CAB+RPV LA with VL ≥ 50 copies/mL and included > 100 women
- This study was conducted using data from the OPERA cohort database, which includes > 155,000 PWH (~20% women) from clinics across the US, representing approximately 11% of women with HIV in the US

Limitations

- Possible misclassification of non-persistence due to:
  - Incomplete documentation of oral bridging in EHR
  - Loss to care (e.g., care interruption, transfer to a non-OPERA clinic)

Key Findings

- In this diverse cohort of 105 women in routine clinical care in the US who initiated CAB+RPV LA regimen with VL ≥50 copies/mL
  - Most suppressed to VL < 50 copies/mL within 6 months
  - Confirmed virologic failure was rare
- CAB+RPV LA may have a role for women with VL ≥ 50 copies/mL who may be struggling with adherence or tolerability of oral therapy

References

[1] Spinelli, et al. *JAMA*. 2025;333(16):1451-1453; [2] Sension, et al. *Infect Dis Ther*. 2023;12:2807-2817; [3] Elion, et al. Abstract 1592. IDWeek 2023; [4] Hickey, et al. *Clin Infect Dis*. 2025;80(4):864-870; [5] Altamirano, et al. P-559. IDWeek 2024

Acknowledgements

This research would not be possible without the generosity of people living with HIV and their OPERA caregivers. Additionally, we are grateful for the following individuals: Kristine Ferguson (SAS programming), Bryan Stagner & Lito Torres (QA), Bernie Stooks (data management), Lisa Lutzi & Nicole Shaw (data management/quality), and Judy Johnson (clinical data classification)

Support

This research was supported by ViiV Healthcare

Contact: Brooke Levis; brooke.levis@epividian.com