Clinical Outcomes Among Virologically Suppressed Women Receiving CAB+RPV LA in the OPERA Cohort

Poster #676

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Background

- CAB+RPV LA is the first complete LA ART regimen approved for HIV-1 treatment in the US
  - Injections once a month or every two months
  - Indicated for treatment-experienced individuals with VL < 50 copies/mL
- CAB+RPV LA may be a good option for women, who represent ~20% of people with HIV in the US and may experience unique challenges with HIV treatment
- LA ART may reduce psychosocial concerns around stigma, disclosure, and adherence associated with daily oral therapy

Objective

To assess clinical outcomes among virologically suppressed women receiving CAB+RPV LA in the OPERA cohort

Methods

Study population

- **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**
  - ART-experienced women with HIV aged ≥ 18 years
  - Received ≥ 1 CAB+RPV LA injection between 21JAN2021 and 31AUG2023
  - Virologically suppressed (VL < 50 copies/mL) at first injection
- **Censoring criteria**
  - Discontinuation of CAB+RPV LA regimen
  - Death
  - 12 months after last clinical contact
  - End of analysis period (29FEB2024)

Outcomes

- **Complete initiation**: First 2 sets of injections within 67 days
- **Persistence**: Months of follow-up; on regimen at study end
- **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

- **Virologic control**: Maintenance of VL < 50 copies/mL
- **CVF**: 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL followed by discontinuation within 4 months

Results

Table 1. Demographic and clinical characteristics at CAB+RPV LA initiation (N = 415)

	Women with ≥ 1 injection
Age, median years (IQR)	43 (34, 54)
Childbearing age (18 to 49 years), n (%)	268 (65%)
Transgender, n (%)	53 (13%)
Black race, n (%)[a]	264 (64%)
Hispanic ethnicity, n (%)[a]	81 (20%)
Married or domestic partner, n (%)[a]	72 (17%)
Injection drug use, n (%)	11 (3%)
Care in Southern US, n (%)	278 (67%)
Payer, n (%)[c]	
Medicare	66 (16%)
Medicaid	198 (48%)
Commercial Insurance	248 (60%)
Ryan White/ADAP	107 (26%)
Cash	6 (1%)
No Payer Data Available	≤ 5[b]
Years since HIV diagnosis, median (IQR)	9 (4, 18)
History of AIDS-defining illnesses, n (%)	97 (23%)
BMI, median kg/m² (IQR)	30 (26, 35)
VACS Index, median (IQR)[a]	18 (10, 26)
≥ 1 comorbidity, n (%)[d]	339 (82%)
Co-infections (ever), n (%)	
Hepatitis B	6 (1%)
Hepatitis C	26 (6%)
Syphilis	72 (17%)
CD4 cell count, median cells/µL (IQR)[a]	742 (542, 969)
Prior core agent class, n (%)[a]	
INSTI	289 (70%)
PI	22 (5%)
NNRTI	54 (13%)
≥ 2 core agents	36 (9%)
Other	≤ 5[b]

[a] N missing: race = 10, ethnicity = 14, marital status = 36, BMI = 30, VACS index = 38, CD4 cell count = 4, prior core agent class = 11
[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. Adherence of 2nd initiation injections among women who completed initiation (N = 381)

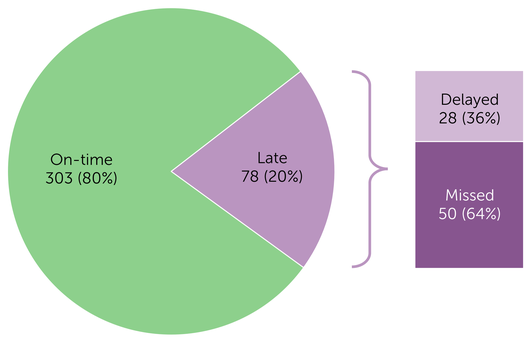


Table 2. Persistence and immunologic effectiveness among women who completed initiation (N = 381)

	Women with complete initiation
Months of follow-up, median (IQR)	12 (7, 19)
Receiving CAB+RPV LA at end of analysis period, n (%)[a]	297 (78%)
CD4 cell count available at baseline and during follow-up, n (%)	367 (96%)
Absolute change in CD4 cell count from baseline to last follow-up, median cells/µL (IQR)	40 (-91, 152)

[a] Including women who discontinued and reinitiated during the study period

Figure 2. Dosing schedules among women with complete initiation (N = 381)

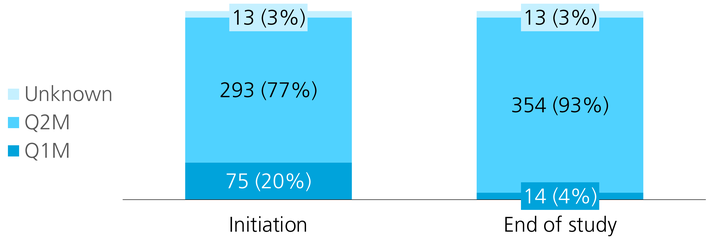
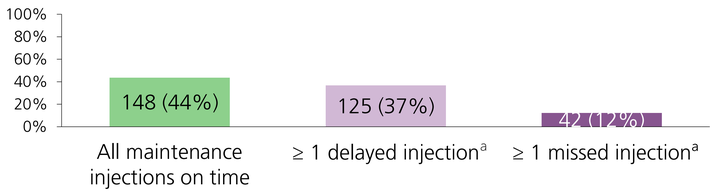
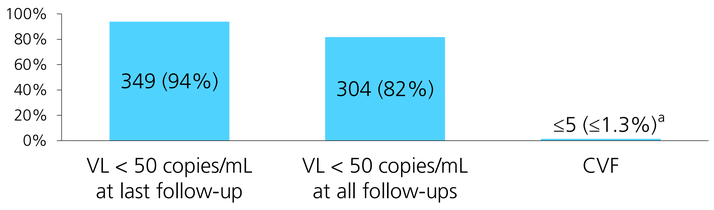


Figure 3. Adherence of maintenance injections among women with known dosing schedules and ≥ 1 maintenance injection (N = 340)



[a] Not mutually exclusive

Figure 4. Virologic effectiveness among women with complete initiation and ≥ 1 VL over follow-up (N = 372)



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

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; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitor; **PWH**, people with HIV; **Q1M**, monthly dosing schedule; **Q2M**, every 2 months dosing schedule; **US**, United States; **VACS**, Veterans Aging Cohort Study; **VL**, viral load

Discussion

- Of 532 women in OPERA initiating CAB+RPV LA during the study period, 415 (78%) had VL < 50 copies/mL at initiation
  - Most were of childbearing age, Black, had ≥ 1 comorbidity, had commercial insurance and/or Medicaid, and switched from an INSTI-containing regimen (**Table 1**)
- 381 women (92%) completed initiation (**Figure 1**) and were followed for a median of 12 months (**Table 2**)
- Most women were on Q2M schedules (**Figure 2**)
- While 56% of women did not receive all maintenance injections on time (**Figure 3**), ART coverage with oral bridging could not be assessed due to incomplete recording in EHR, and 78% of women were still receiving CAB+RPV LA at the end of the analysis period (**Table 2**)
- Median absolute change in CD4 cell counts over follow-up was 40 cells/µL (**Table 2**)
- Most women maintained virologic suppression (**Figure 4**)
  - ≤ 1.3% experienced CVF

    Duplicate VLs caused by an EHR migration were removed from the data, resulting in fewer CVFs than reported in the abstract
- **Strengths**
  - This was one of the first studies to examine CAB+RPV LA use and outcomes among women (exclusively) in a real-world setting in the US and included > 400 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**
  - This study was limited by a lack of data on reasons for discontinuation
  - As ≤ 5 women experienced CVF, there were too few cases to fit regression models to assess predictors of failure

Key Findings

- In this real-world study, CAB+RPV LA demonstrated high effectiveness among a diverse population of ART-experienced women with HIV
- Persistence of injections was high among this population and confirmed virologic failure was infrequent

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