Characteristics of Women Initiating CAB+RPV LA in the OPERA Cohort

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

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Background

- CAB+RPV LA is the first complete LA ART regimen approved for HIV-1 treatment
  - Injections once a month or every two months
  - Indicated for treatment experienced individuals with VL < 50 copies/mL
- LA ART may reduce psychosocial concerns around adherence, stigma, and disclosure associated with daily oral therapy
- 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

Objective

To characterize women receiving CAB+RPV LA in the OPERA cohort and to describe their CAB+RPV LA dosing schedules

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
- Inclusion criteria
  - Women with HIV
  - Aged ≥ 18 years
  - Received ≥ 1 CAB+RPV LA injection between 21JAN2021 and 31AUG2023

Descriptive Analyses

- Demographic, clinical, and prior ART characteristics at the time of the first CAB+RPV LA injections
- CAB+RPV LA dosing schedule (every month vs. every two months), restricted to women with complete initiation (2 sets of injections ≤ 67 days apart)
- Overall and stratified by VL at first injection (< 50 vs. ≥ 50 copies/mL)

Abbreviations

ADAP, AIDS Drug Assistance Program; **AIDS**, Acquired immunodeficiency syndrome; **ART**, antiretroviral; **BMI**, body mass index; **CAB+RPV**, cabotegravir + rilpivirine; **HIPAA**, Health Insurance Portability and Accountability Act; **HIV**, human immunodeficiency virus; **INSTI**, integrase inhibitor; **IQR**, interquartile range; **LA,** long-acting; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitor; **PWH**, people with HIV; **US**, United States; **VACS**, Veterans Aging Cohort Study; **VL**, viral load

Results

Table 1. Demographic characteristics at initiation of CAB+RPV LA injections, stratified by baseline VL

	All N = 532	VL < 50[a] N = 415	VL ≥ 50[a] N = 105
Age, median years (IQR)	43 (34, 54)	43 (34, 54)	43 (35, 52)
Childbearing age (18 to 49 years), n (%)	341 (64)	265 (64)	68 (65)
Transgender, n (%)	61 (11)	53 (13)	8 (8)
Black race, n (%)[a]	356 (67)	264 (64)	83 (79)
Hispanic ethnicity, n (%)[a]	90 (17)	81 (20)	9 (9)
Married or domestic partner, n (%)[a]	90 (17)	72 (17)	15 (14)
Injection drug use, n (%)	16 (3)	11 (3)	≤ 5[b]
Care in Southern US, n (%)	373 (70)	278 (67)	85 (81)
Payer, n (%)[c]			
Medicare	95 (18)	66 (16)	28 (27)
Medicaid	256 (48)	198 (48)	54 (51)
Commercial Insurance	321 (60)	248 (60)	67 (64)
Ryan White/ADAP	125 (24)	107 (26)	17 (16)
Cash	7 (1)	6 (1)	≤ 5[b]
No Payer Data Available	≤ 5[b]	≤ 5[b]	0

[a] N missing: VL = 12, race = 10, ethnicity = 15, marital status = 44
[b] HIPAA regulations require the masking of cells with 1 to 5 individuals
[c] Payer categories are not mutually exclusive

Table 3. ART history at initiation of CAB+RPV LA injections, stratified by baseline VL

	All N = 532	VL < 50[a] N = 415	VL ≥ 50[a] N = 105
Number of core agents experienced			
Median (IQR)	2 (1, 2)	2 (1, 2)	2 (1, 3)
≥ 3, n (%)	127 (24)	90 (22)	35 (33)
Number of ARV classes experienced			
Median (IQR)	2 (2, 3)	2 (2, 3)	2 (2, 4)
≥ 3, n (%)	200 (38)	151 (36)	46 (44)
Prior core agent class, n (%)			
INSTI	355 (67)	289 (70)	61 (58)
PI	37 (7)	22 (5)	14 (13)
NNRTI	67 (13)	54 (13)	12 (11)
≥ 2 core agents	52 (10)	36 (9)	14 (13)
Other	≤ 5[b]	≤ 5[b]	≤ 5[b]
Duration of prior regimen, median months (IQR)	19 (8, 41)	20 (7, 42)	17 (8, 34)

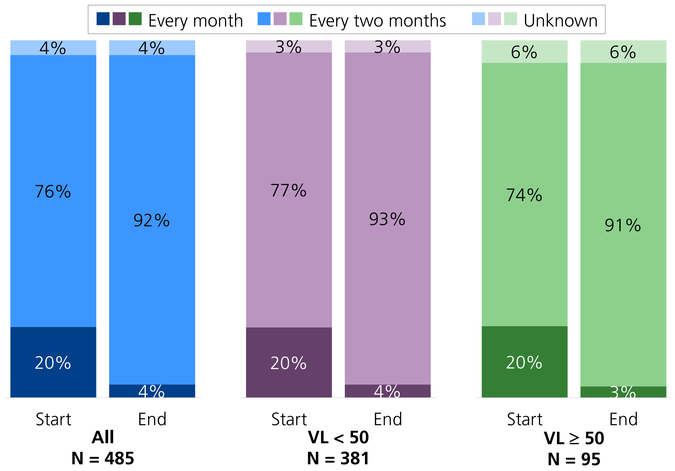
[a] N missing: VL = 12
[b] HIPAA regulations require the masking of cells with 1 to 5 individuals

Table 2. Clinical characteristics at initiation of CAB+RPV LA injections, stratified by baseline VL

	All N = 532	VL < 50[a] N = 415	VL ≥ 50[a] N = 105
Years since HIV diagnosis, median (IQR)	9 (4, 19)	9 (4, 18)	13 (4, 22)
History of AIDS-defining illnesses, n (%)	141 (27)	97 (23)	40 (38)
BMI, median kg/m² (IQR)	30 (26, 35)	30 (26, 35)	29 (23, 35)
VACS Index, median (IQR)[a]	22 (10, 28)	18 (10, 26)	28 (17, 47)
≥ 1 comorbidity, n (%)[b]	439 (82)	338 (81)	90 (86)
Co-infections (ever), n (%)			
Hepatitis B	13 (2)	6 (1)	≤ 5[c]
Hepatitis C	38 (7)	26 (6)	10 (10)
Syphilis	95 (18)	72 (17)	21 (20)
Viral load, median copies/mL (IQR)[a]	< 20 (< 20, 32)	< 20 (< 20, < 20)	1090 (89, 24700)
CD4 cell count, median cells/μL (IQR)[a]	683 (469, 936)	742 (542, 969)	438 (253, 686)

[a] N missing: VL= 12, VACS Index = 54, CD4 cell count = 16
[b] 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
[c] HIPAA regulations require the masking of cells with 1 to 5 individuals

Figure 1. CAB+RPV LA dosing at initiation and at study end among complete initiators, stratified by baseline VL



Discussion

- Out of 2759 CAB+RPV LA users in OPERA during the study period, 532 (19%) were women
  - Most were of childbearing age, Black, and had commercial insurance and/or Medicaid (**Table 1**)
  - They tended to have a high BMI, a high VACS index and most had ≥ 1 comorbidity (**Table 2**)
- Most switched from an INSTI-containing regimen, and had been on their prior regimen for a median of 19 months (**Table 3**)
- While 20% initiated CAB+RPV LA on a monthly schedule, most transitioned to every 2 months schedule during the study period, with only 4% on a monthly schedule by the end of the study (**Figure 1**)
- Of note, 20% of women had a VL ≥ 50 copies/mL at initiation
  - These women had more advanced HIV and were more treatment-experienced, with potentially fewer ARV options than their virologically suppressed counterparts

Key Findings

- **More than 500 women received CAB+RPV LA (19% of all CAB+RPV LA users)**
- **There was a notable diversity of gender, race, ethnicity, and social background among women receiving CAB+RPV LA**
- **One in five women started the regimen while having a detectable VL**

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Contact: brooke.levis@epividian.com