Real-World Effectiveness of Long-Acting Cabotegravir + Rilpivirine in Virologically Suppressed Treatment-Experienced Individuals: Two Years of Data from the OPERA® Cohort

Contact Information:
Jennifer Fusco
224-632-1863
jennifer.fusco@epividian.com

OPERA® The Longitudinal Cohort

Michael G Sension,[1] Ricky K Hsu,[2,3] Jennifer S Fusco,[4] Laurence Brunet,[4] Quateka Cochran,[5] Gayathri Sridhar,[6] Vani Vannappagari,[6] Jean Van Wyk,[7] Michael B Wohlfeiler,[8] Gregory P Fusco[4]

[1]CAN Community Health, Fort Lauderdale, FL, USA; [2]NYU Langone Health, New York, NY, USA; [3]AIDS Healthcare Foundation, New York, NY, USA; [4]Epividian, Raleigh, NC, USA; [5]AIDS Healthcare Foundation, Fort Lauderdale, FL, USA; [6]ViiV Healthcare, Durham, NC, USA; [7]ViiV Healthcare, London, England, UK; [8]AIDS Healthcare Foundation, Miami, FL, USA

Background

- Cabotegravir + rilpivirine (CAB+RPV) injections are the first complete long-acting (LA) antiretroviral therapy (ART) regimen
- Indication: ART-experienced people with HIV (PWH) who are virologically suppressed (viral load [VL] <50 copies/mL), with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
- FDA approval:
  - **Monthly** dosing schedule: January 2021
  - **Every 2 months** dosing schedule: February 2022
- It has been recommended that longer needles should be used for injections in individuals with a BMI ≥30 kg/m^2 to ensure proper administration of the full dose

Objective

- To assess the virologic effectiveness of CAB+RPV LA among ART-experienced individuals with VL <50 copies/mL at initiation in the first 2 years of use in the OPERA® Cohort
- To evaluate the virologic effectiveness of CAB+RPV LA, stratified by body mass index (BMI)

Methods

Study Population

- OPERA cohort
  - Prospectively captured, routine clinical data from electronic health records from 96 clinics in the US (22 states, 1 US territory)
  - >155K PWH as of March 2022, representing ~14% of people with diagnosed HIV infection in the US[1]
- Inclusion criteria
  - HIV-positive
  - ≥18 years old
  - Received their first CAB+RPV LA injection between 21JAN2021 to 28FEB2023 through routine clinical care
    - Monthly or every 2-month injection schedule
- Censoring events: regimen discontinuation, lost to follow-up, death, study end (25MAR2023)

Definitions

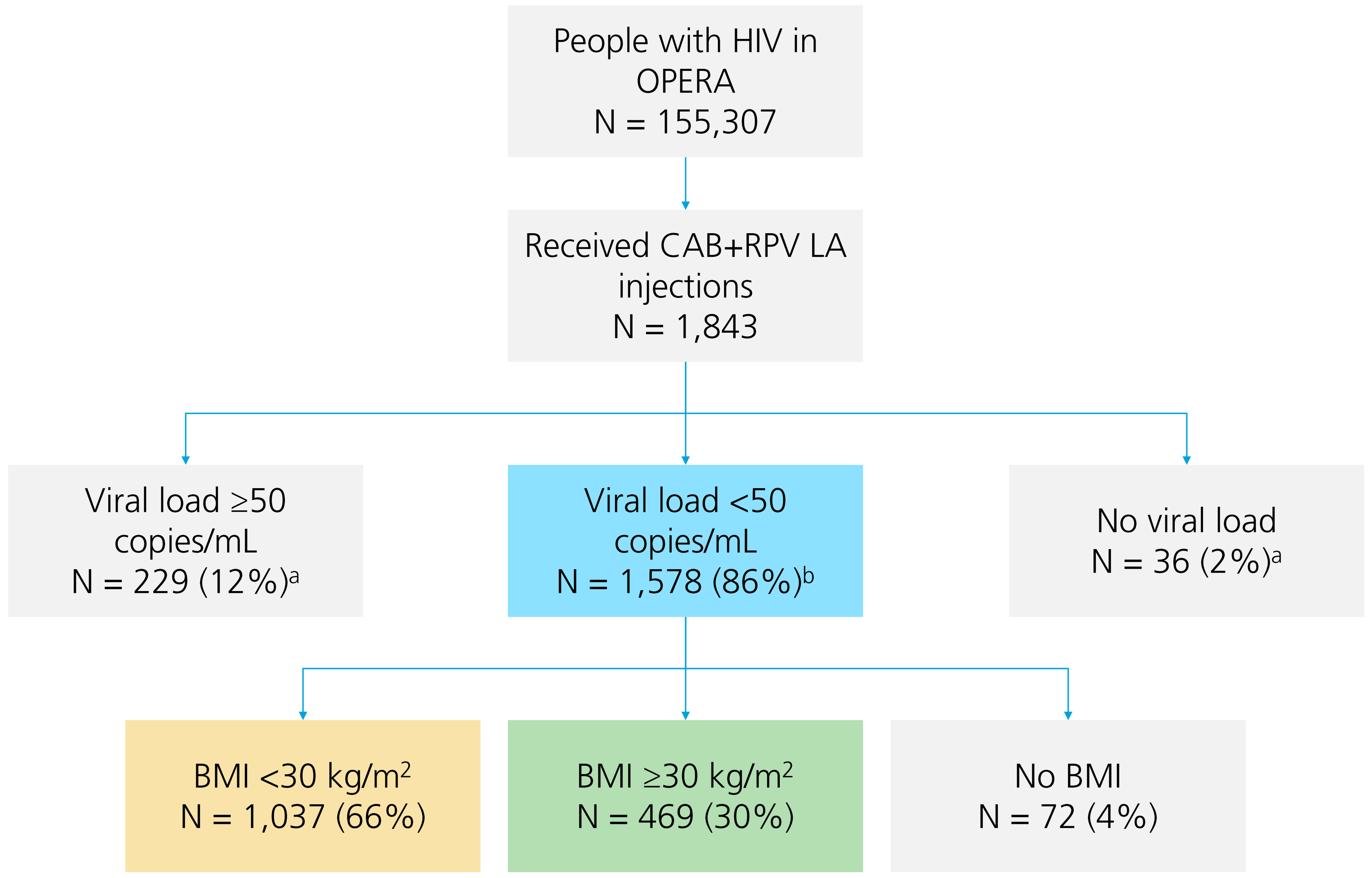
- Discontinuation
  - Monthly: ≥69 days without another injection
  - Every 2 months: ≥127 days without another injection
- Confirmed virologic failure (CVF)
  - 2 consecutive viral loads ≥200 copies/mL
  - 1 viral load ≥200 copies/mL followed by discontinuation

Stratification

- BMI at first injection: <30 vs. ≥30 kg/m^2
- P-values comparing BMI strata obtained with Wilcoxon rank sum test (continuous variable) or Pearson chi-square (categorical variables)

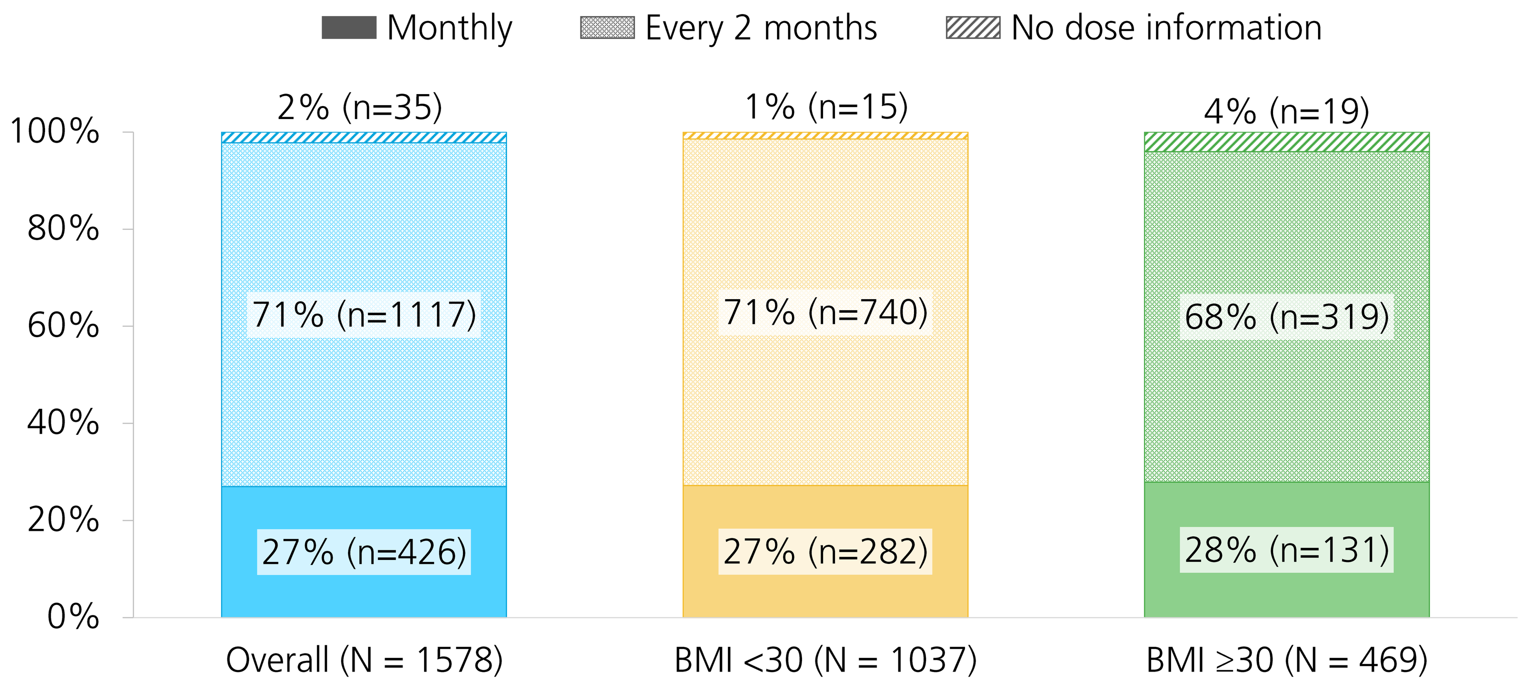
Results

Figure 1. Study population



BMI, body mass index; CAB+RPV LA, cabotegravir + rilpivirine long-acting; N, number
[a] See abstract #1028, 12OCT2023, 3:15 PM – 4:30 PM, Room 252AB
[b] Includes 72 individuals without a baseline BMI

Figure 2. CAB+RPV dosing schedule at CAB+RPV LA initiation



BMI, body mass index; CAB+RPV LA, cabotegravir + rilpivirine long-acting; N, number

Table 2. Follow-up among individuals with CAB+RPV dose information

	Overall[a] N = 1543	BMI <30 N = 1022	BMI ≥30 N = 450	p-value
Months of follow-up, median (IQR)	7.4 (3.9, 10.9)	7.3 (3.8, 10.9)	7.6 (4.3, 10.9)	0.26
On CAB+RPV LA on 25MAR2023, n (%)	1297 (84)	859 (84)	386 (86)	0.40
≥1 VL after first injections, n (%)	1323 (86)	873 (85)	393 (87)	0.33

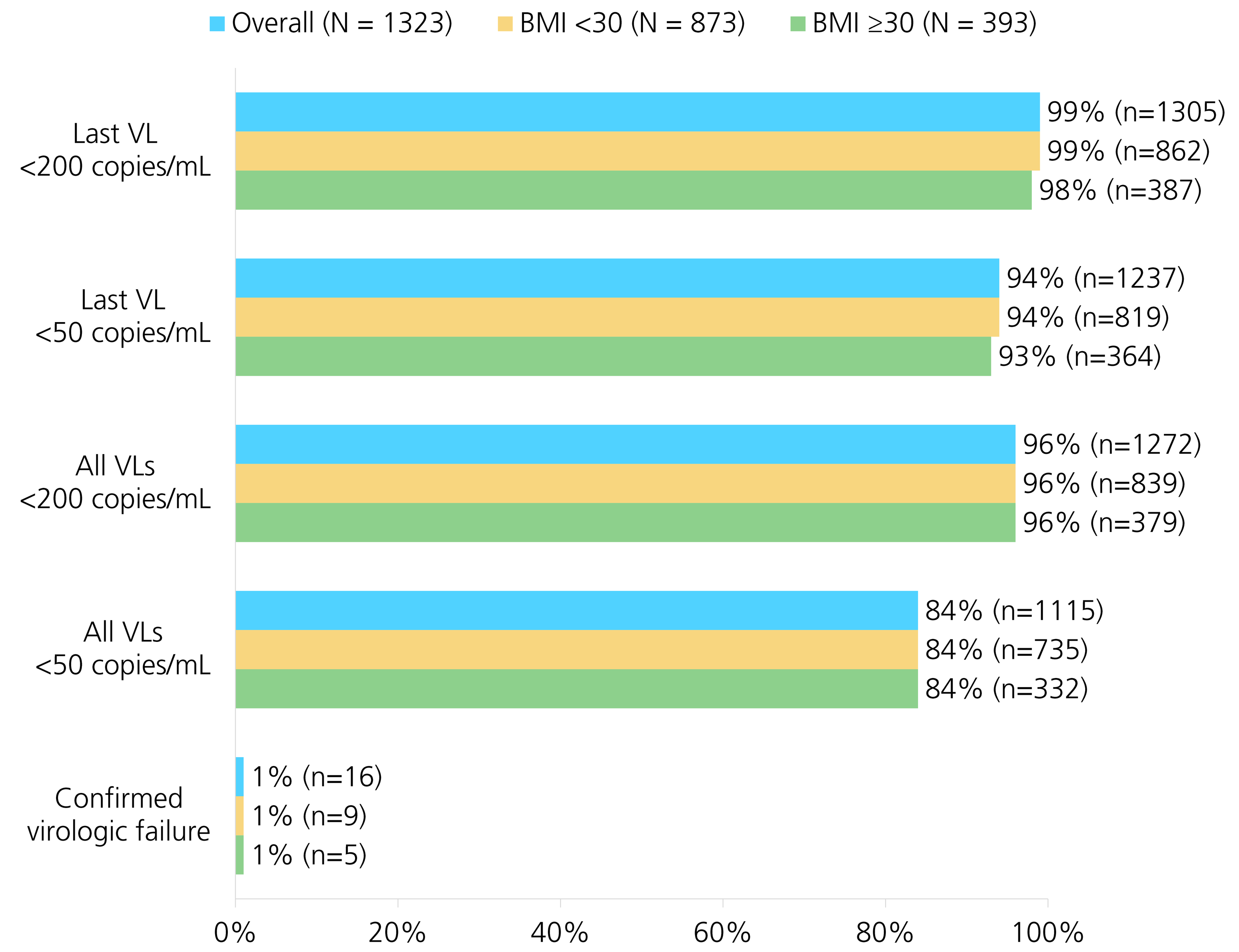
BMI, body mass index; CAB+RPV LA, cabotegravir + rilpivirine long-acting; IQR, interquartile range; N, number
[a] Includes 71 individuals without a baseline BMI who were excluded from the stratified analysis

Table 1. Demographic and clinical characteristics at first CAB+RPV injection, by BMI

	Overall[a] N = 1578	BMI <30 N = 1037	BMI ≥30 N = 469	p-value
Age, median years (IQR)	40 (32, 53)	39 (31, 52)	41 (33, 53)	0.06
Female sex, n (%)	267 (17)	111 (11)	137 (29)	<0.01
Race, n (%)				<0.01
Asian	29 (2)	25 (2)	≤5[b]	
Black	654 (41)	389 (38)	234 (50)	
White	758 (48)	523 (50)	200 (43)	
Other/Mixed	83 (5)	63 (6)	18 (4)	
Unknown	54 (3)	37 (4)	13 (3)	
Ethnicity, n (%)				0.02
Hispanic	451 (29)	317 (31)	115 (24)	
Not Hispanic	1087 (69)	695 (67)	341 (73)	
Unknown	40 (2)	25 (2)	13 (3)	
BMI, median kg/m^2 (IQR)	27 (24, 31)	25 (23, 28)	34 (32, 38)	<0.01
HIV risk factors, n (%)				<0.01
MSM only	864 (55)	631 (61)	199 (42)	
IDU + MSM	21 (1)	15 (1)	6 (1)	
IDU only	23 (1)	14 (1)	6 (1)	
Neither MSM nor IDU	673 (43)	377 (36)	258 (55)	
Years from HIV diagnosis, median (IQR)	7 (3, 14)	7 (3, 13)	7 (3, 14)	0.62
Viral load, median copies/mL (IQR)	19 (19,20)	19 (19,20)	19 (19,20)	0.15
CD4 cell count, median cells/μL (IQR)	689 (506, 908)	665 (488, 878)	744 (564, 1004)	<0.01

BMI, body mass index; CAB+RPV LA, cabotegravir + rilpivirine long-acting; IDU, injection drug use; IQR, interquartile range; MSM, men who have sex with men
[a] Includes 72 individuals without a baseline BMI who were excluded from the stratified analysis
[b] HIPAA privacy requirements preclude the reporting of 5 or fewer observations in any cell

Figure 3. Virologic outcomes among individuals with ≥1 follow-up VL



BMI, body mass index; N, number; VL, viral load
[a] Includes 72 individuals without a baseline BMI who were excluded from the stratified analysis
[b] HIPAA privacy requirements preclude the reporting of 5 or fewer observations in any cell

Discussion

- Large cohort of 1,843 individuals who received CAB+RPV LA injections through routine clinical care during the first 2 years since approval in the US, including 1,578 individuals with a VL <50 copies/mL at first injection.
- 14% of initiators had a viral load ≥50 copies/mL despite the fact that CAB+RPV LA has been approved for virologically suppressed individuals only (**Fig 1**); see oral presentation #1028 for details on unsupressed CAB+RPV LA use.
- Virologically suppressed CAB+RPV LA injection recipients were predominantly non-Hispanic men who have sex with men (**Table 1**)
- 30% had a BMI ≥30 kg/m^2 at first injection, where a longer needle is recommended; needle length used was not available in the EHR
- Injections every 2 months was the most prescribed dosing schedule, regardless of BMI (**Fig 2**)
- CAB+RPV LA was effective at controlling HIV (**Fig 3**)
  - 96% maintained VL <200 copies/mL throughout follow-up
  - 94% had a VL <50 copies/mL at end of follow-up
- Virologic effectiveness was consistent among individuals with a high BMI (**Fig 3**)
- Use of oral lead-in and bridging was not well documented in the EHR

Key Findings

- Large cohort of virologically suppressed individuals receiving CAB+RPV LA injections through routine clinical care in the US
- Virologic effectiveness was demonstrated: 96% maintained a VL <200 copies/mL throughout follow-up
- Individuals with a BMI ≥30 kg/m^2 had comparable virologic outcomes to those with a BMI <30 kg/m^2

References

1. Centers for Disease Control and Prevention. Diagnoses of HIV Infection in the United States and Dependent Areas, 2019. In: *HIV Surveillance Report*; 2021.

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: Lito Torres (SAS programming), Kelly Oh (QA), Bernie Stooks (Data Management), Lisa Lutzi (Database Architecture), and Judy Johnson (Medical Terminology Classification)

Support

This research was sponsored by ViiV Healthcare

Epividian