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Background

- CAB+RPV LA is the first complete LA ART available for HIV-1 treatment in the US
 - 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)
- In individuals with BMI ≥ 30 kg/m², longer needles have been recommended to ensure proper administration of the full dose

Objective

To assess CAB+RPV LA use in a real-world setting over its first 3 years of availability

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**
 - ART-experienced PWH aged ≥ 18 years
 - Received ≥ 1 CAB+RPV LA injection between 21JAN2021 and 31DEC2023
 - 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

- Among individuals with ≥ 1 injection**
 - Complete initiation: First 2 sets of injections within 67 days
- Among complete initiators**
 - Persistence: Months on regimen; on regimen at time of analysis
 - Adherence of initiation/maintenance injections:

	Days after last injection	
	2 nd 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

- Among complete initiators with ≥ 1 VL during follow-up**
 - 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

Stratification

- Virologic outcomes were assessed overall and stratified by BMI at first injection (< 30 vs. ≥ 30 kg/m²)

Analyses

- Multivariable logistic regression was used to assess factors associated with CVF

Results

Table 1. Demographic and clinical characteristics at CAB+RPV LA initiation (N = 2,858)

	Individuals with ≥ 1 injection
Age, median years (IQR)	39 (31, 51)
Female, n (%)	448 (16%)
Black race, n (%) ^a	1,199 (42%)
Hispanic ethnicity, n (%) ^a	853 (30%)
Married or domestic partner, n (%) ^a	486 (17%)
Injection drug use, n (%)	86 (3%)
MSM, n (%)	1,619 (57%)
Care in Southern US, n (%)	1,577 (55%)
Payer, n (%) ^b	
Medicare	342 (12%)
Medicaid	945 (33%)
Commercial Insurance	1,954 (68%)
Ryan White/ADAP	900 (31%)
Cash	85 (3%)
Other Payer	
Years since HIV diagnosis, median (IQR)	6 (2, 13)
History of AIDS-defining illnesses, n (%)	680 (24%)
BMI, median kg/m ² (IQR) ^a	27 (24, 31)
VACS Index, median (IQR) ^a	10 (0, 18)
≥ 1 comorbidity, n (%) ^c	2,208 (77%)
Co-infections (ever), n (%)	
Hepatitis B	74 (3%)
Hepatitis C	193 (7%)
Syphilis	1,337 (47%)
CD4 cell count, median cells/μL (IQR) ^a	698 (519, 912)
Prior core agent class, n (%) ^a	
INSTI	2,227 (78%)
PI	109 (4%)
NNRTI	197 (7%)
≥ 2 core agents	207 (7%)
Other	≤ 5 ^b

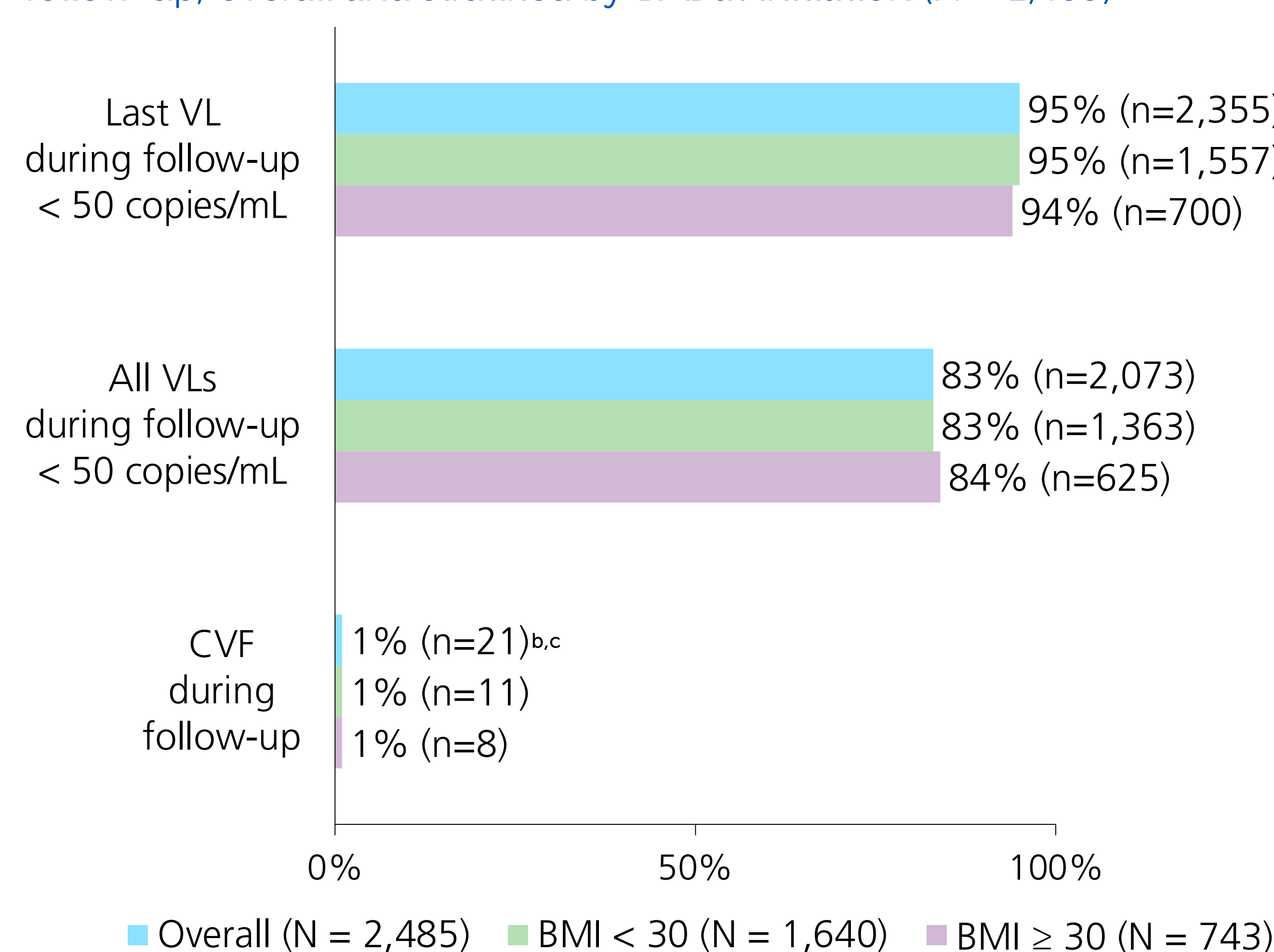
^a N missing: race = 120, ethnicity = 96, marital status = 185, payer = 10, BMI = 154, VACS index = 302, CD4 cell count = 27, prior core agent class = 116
^b HIPAA regulations require masking cells with 1 to 5 individuals
^c Payer categories are not mutually exclusive
^d At least one of the following 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

Table 2. Persistence and adherence among complete initiators (N = 2,618)

	Complete initiators
Months of follow-up, median (IQR)	11 (6, 18)
Receiving CAB+RPV LA at time of analysis, n (%) ^a	2,179 (83%)
Received 2 nd initiation injection on-time	2,188 (84%)
Individuals with ≥ 1 maintenance injection, n (%)	2,360
Received all maintenance injections on-time	1,475 (62%)
≥ 1 delayed maintenance injections, n (%)	711 (30%)
≥ 1 missed maintenance injections, n (%)	279 (12%)

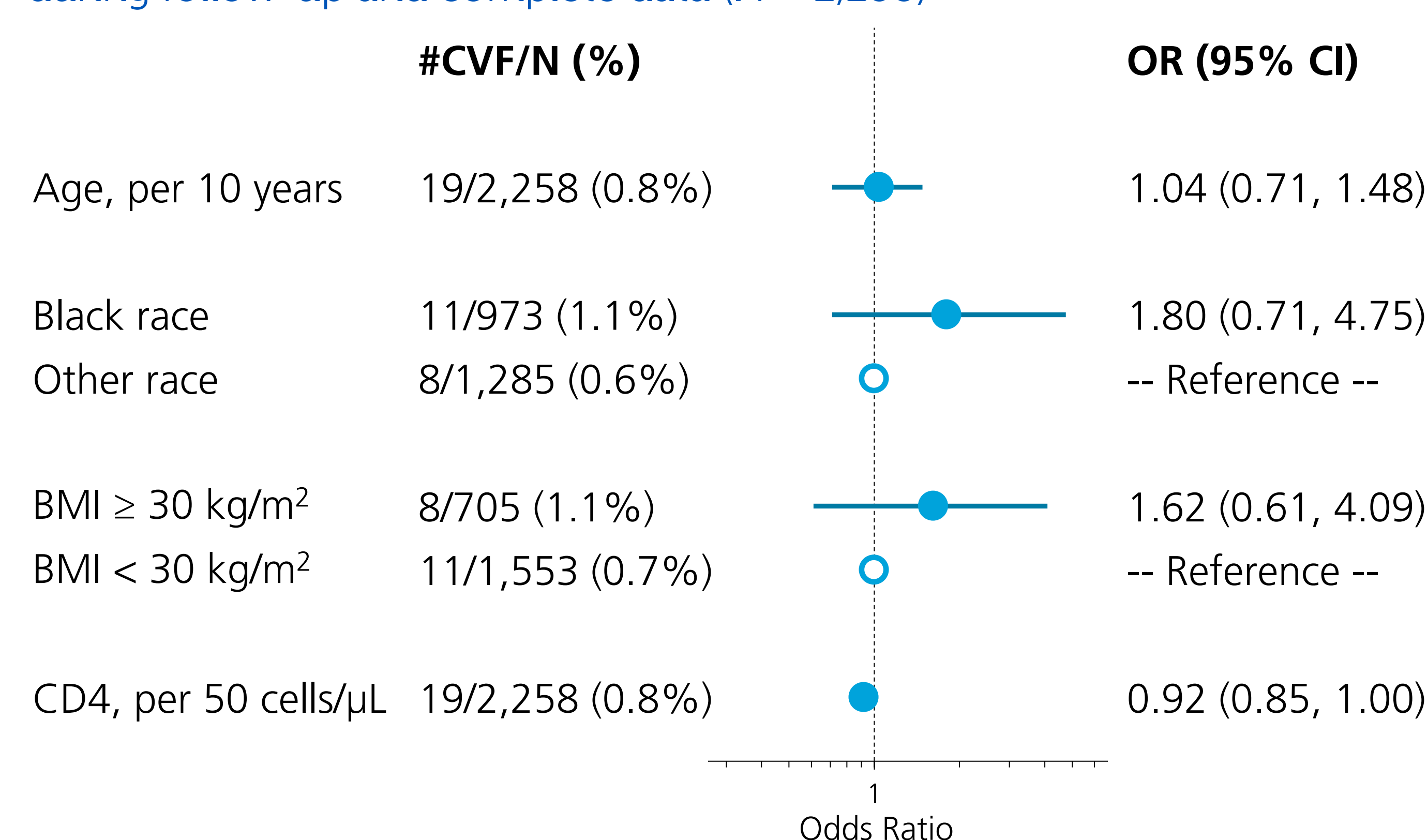
^a Including individuals who discontinued and reinitiated during the study period

Figure 1. Virologic outcomes among complete initiators with ≥ 1 VL during follow-up; overall and stratified by BMI at initiation (N = 2,485)^a



^a Among those with 6, 12, and 24-month VLs available, VL < 50 copies/mL was observed in 954/1,015 (94%), 511/538 (95%), and 85/89 (96%), respectively
^b After a median of 7 months (IQR: 3, 9)
^c 12 (57%) experienced CVF during the first 6 months of follow-up

Figure 2. Factors associated with CVF among complete initiators with ≥ 1 VL during follow-up and complete data (N = 2,258)^a



^a Sex, injection drug use, history of AIDS-defining illnesses, comorbidities, and core agent class of prior regimen were evaluated as potential predictors of CVF but not included in the multivariable model as one subgroup per variable had ≤ 5 CVFs

Abbreviations

ADAP, AIDS Drug Assistance Program; AIDS, Acquired immunodeficiency syndrome; ART, antiretroviral; 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; INSTI, integrase inhibitor; IQR, interquartile range; kg, kilogram; LA, long-acting; mL, milliliter; MSM, men who have sex with men; NNRTI, non-nucleoside reverse transcriptase inhibitor; OR, odds ratio; 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 3,304 PWH initiating CAB+RPV LA in OPERA during the study period, 2,858 (87%) had VL < 50 copies/mL at initiation
 - Median age was 39, median years since HIV diagnosis was 6, and median BMI was 27 kg/m² (Table 1)
 - A majority were male, received care in Southern US, had ≥ 1 comorbidity, had commercial insurance, and switched from an INSTI-containing regimen (Table 1)
- 2,618 individuals (92%) completed initiation and were followed for a median of 11 months (Table 2)
- Most individuals received their 2nd initiation injection on-time and over half received all maintenance injections on-time (Table 2)
- While 38% of individuals did not receive all maintenance injections on time (Table 2), ART coverage between injections with oral bridging could not be assessed due to incomplete recording in EHR, and most were still receiving CAB+RPV LA at time of analysis (Table 2)
- Most individuals maintained virologic suppression (Figure 1)
 - 21 (1%) experienced CVF after a median of 7 months
 - 12 (57%) during the first 6 months of CAB+RPV LA
 - Among those with 6, 12, and 24-month VLs available, VL < 50 copies/mL was observed in 954/1,015 (94%), 511/538 (95%), and 85/89 (96%), respectively
- Across BMI categories (< 30 kg/m² vs. ≥ 30 kg/m²), neither virologic suppression nor CVF differed (Figure 1)
- No variables were significantly associated with risk of CVF (Figure 2)
- This analysis has been updated since the abstract. A data issue was discovered after an EHR migration which populated duplicate VLs on different days. These have been resolved.

Key Findings

Over the first 3 years of CAB+RPV LA availability:

- Most individuals were able to remain on CAB+RPV LA and adhere to the dosing schedule
- Most individuals maintained virologic suppression (regardless of BMI at initiation), with 95% virologically suppressed at last visit
- CVF was infrequent

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 & Kristine Ferguson (QA), Bernie Stooks (data management), Lisa Luzzi & Nicole Shaw (data management/quality), and Judy Johnson (clinical data classification).

Support

This research was supported by ViiV Healthcare

