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Background

- CAB+RPV LA is the first and only complete LA ART regimen approved for HIV-1 treatment in the US
 - Approved by the FDA as monthly (2021) or every two months (2022) pairs of injections
 - Indicated for treatment-experienced individuals who are suppressed (VL <50 copies/mL) and on a stable regimen
- Previous analyses from the OPERA Cohort showed that 30% of individuals initiating CAB+RPV LA had a BMI ≥30 kg/m²

Objective

Describe demographic and clinical characteristics, adherence, persistence, maintenance of virologic suppression, and confirmed virologic failure among individuals initiating CAB+RPV LA, stratified by BMI at initiation

Methods

OPERA Cohort

- Prospectively captured, routine clinical data from US-based electronic health records, representing ~14% of people with HIV in the US

Inclusion Criteria

- ART-experienced adults, ≥18 years of age
- Initiated CAB+RPV LA from 21JAN2021 – 31DEC2024
- Virologically suppressed (VL <50 c/mL) at initiation

Censoring Criteria

- Discontinuation of CAB+RPV LA (>67 and >127 days after last injection for the monthly and every 2 months dosing schedules, respectively)
- Death
- Lost to follow-up (12 months after last clinical contact)
- End of analysis period (28FEB2025)

Stratification

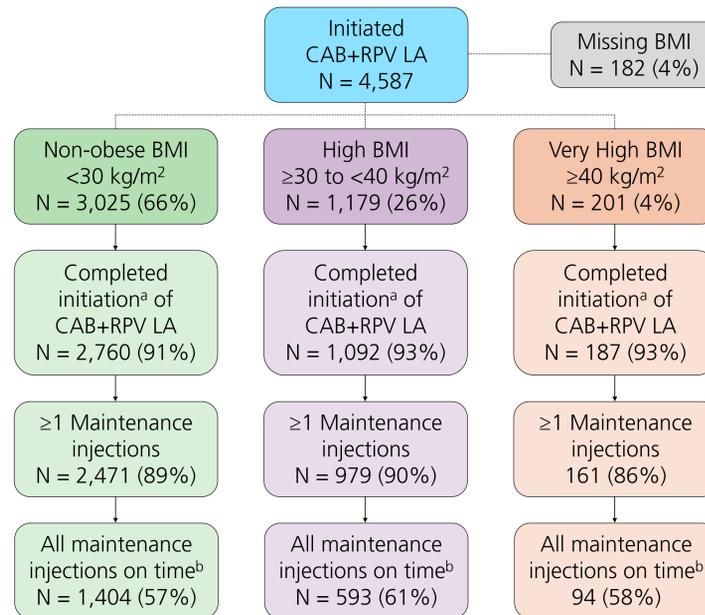
- Three study groups based on BMI at CAB+RPV LA initiation:
 - Non-obese BMI: <30 kg/m²
 - High BMI: ≥30 kg/m² to <40 kg/m²
 - Very high BMI: ≥40 kg/m²

Analysis & Outcomes

- Virologic outcomes were assessed among individuals who completed initiation and had ≥1 VL through 28FEB2025
- Virologic Suppression**
 - All follow-up VLs were <50 c/mL or
 - Last follow-up VL was <50 c/mL
- Confirmed Virologic Failure**
 - Two consecutive VLs ≥200 c/mL or
 - Discontinuation of CAB+RPV LA after a VL ≥200 c/mL

Results

Figure 1. CAB+RPV LA usage and adherence among individuals in the OPERA Cohort, by BMI at initiation



^a Received initiation injections ≤67 days apart
^b On-time maintenance injections are ≤37 days or ≤67 days after the last injection, for monthly or every two-month dosing schedules, respectively

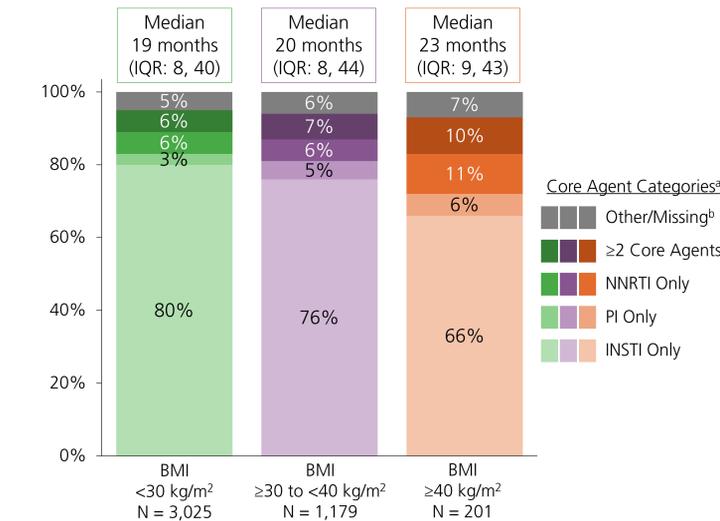
Table 1. Demographic, clinical, and HIV infection characteristics of CAB+RPV LA initiators, by BMI at initiation

	BMI <30 N = 3,025	BMI ≥30 to <40 N = 1,179	BMI ≥40 N = 201
Age, median years (IQR)	37 (31, 49)	41 (33, 51)	39 (33, 48)
Age ≥50 years, n (%)	726 (24)	319 (27)	42 (21)
Female sex, n (%)	292 (10)	252 (21)	93 (46)
Black race, n (%)	1,168 (39)	558 (47)	137 (68)
Hispanic ethnicity, n (%)	996 (33)	355 (30)	40 (20)
Any comorbidity ^a , n (%)	2,317 (77)	981 (83)	169 (84)
HBV co-infection, n (%)	78 (3)	25 (2)	≤5 ^b
HCV (ever), n (%)	195 (6)	67 (6)	≤5 ^b
Syphilis (ever), n (%)	1,532 (51)	512 (43)	71 (35)
Years since HIV diagnosis, median (IQR)	6 (2, 12)	6 (2, 14)	5 (2, 10)
Years since ART initiation, median (IQR)	3 (1, 7)	4 (1, 7)	3 (1, 6)
History of AIDS-defined events, n (%)	719 (24)	251 (21)	42 (21)
CD4 cell count (cells/μL), median (IQR)	685 (510, 882)	746 (563, 982)	812 (599, 1142)
VACS Mortality Index score, median (IQR)	6 (0, 16)	10 (0, 16)	10 (0, 22)

^a Categories included: Autoimmune disease, cardiovascular disease, invasive cancers, endocrine disorders, mental health disorders, liver disease, bone disorders, peripheral neuropathy, renal disease, hypertension, substance abuse
^b HIPAA regulations require the masking of cells with 1 to 5 individuals

Abbreviations: AIDS, acquired immunodeficiency syndrome; ART, antiretroviral therapy; BMI, body mass index; c/mL, copies per milliliter; cells/μL, cells per microliter; CAB+RPV LA, cabotegravir plus rilpivirine long-acting; CVF, confirmed virologic failure; HIV, immunodeficiency virus; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; kg/m², kilogram per square meter; n, number; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; US, United States; VACS, Veterans Aging Cohort Study; VL, viral load; vs., versus

Figure 2. Duration on and core agents in the ART regimen prior to CAB+RPV LA initiation, by BMI at initiation



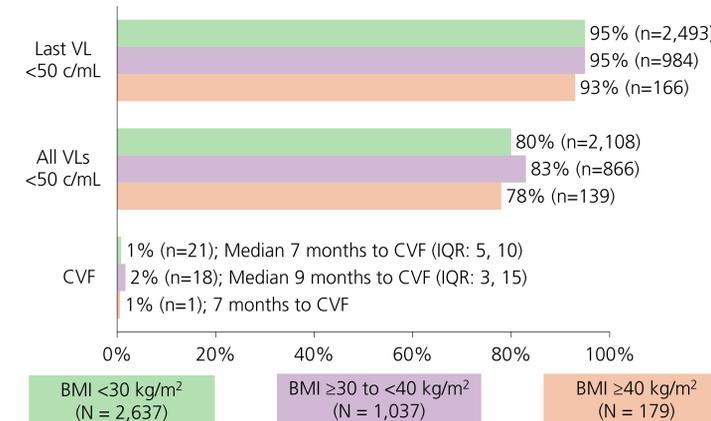
^a Core agent categories are mutually exclusive
^b 99% of individuals in this category were missing prior ART regimen information

Table 2. Persistence among CAB+RPV LA initiators, by BMI at initiation

	BMI <30 N = 3,025	BMI ≥30 to <40 N = 1,179	BMI ≥40 N = 201
Completed initiation, n (%)	2,760 (91)	1,092 (93)	187 (93)
Months of follow-up, median (IQR)	14 (7, 23)	14 (8, 22)	13 (7, 23)
On CAB+RPV LA at end of analysis period, regardless of discontinuation, n (%)	2,159 (78)	858 (79)	139 (74)
Months on CAB+RPV LA, median (IQR)	16 (9, 26)	16 (9, 26)	14 (8, 27)

^a Months until first censoring event

Figure 3. Virologic outcomes among complete initiators with ≥1 VL over follow-up, by BMI at initiation



Discussion

- Among 4,587 adults initiating CAB+RPV LA, 3,025 (66%) had non-obese BMI, 1,179 (26%) had high BMI, and 201 (4%) had very high BMI at initiation (Fig 1)
 - Nearly all individuals (91-93%) completed initiation and among those, most (86-90%) received ≥1 maintenance injection over follow-up
 - Over half of individuals received all maintenance injections on time; of those with ≥1 late maintenance injection, the median number of late injections was only 1 (IQR: 1,2) in each of the groups defined by BMI at initiation
- Characteristics of individuals at initiation varied across the groups (Table 1). Compared to individuals with non-obese or high BMI, respectively, those with very high BMI were:
 - More likely to be female (46% vs. 10% & 21%) and Black (68% vs. 39% and 47%)
 - Less likely to be Hispanic (20% vs. 33% and 30%)
- Non-obese and high BMI individuals were more likely to have switched from an INSTI-based regimen (80% and 76%, respectively) than very high BMI individuals (66%) (Fig 2)
 - All groups were on their prior regimen for a median of over a year (19, 20, and 23 months, respectively)
- Approximately three quarters of individuals were on CAB+RPV LA at the end of the analysis period (Table 2)
 - Most were on CAB+RPV LA for over a year (medians of 16, 16, and 14 months, respectively)
- Virologic outcomes were comparable across groups (Fig 3):
 - Nearly all (93-95%) were suppressed at last VL
 - Most (78-83%) were suppressed at all VLs
 - Very few individuals (1-2%) experienced CVF
- Limitation: ART coverage between injections with oral bridging could not be assessed due to incomplete recording in the electronic health records

Key Finding

Individuals on CAB+RPV LA in this large, real-world cohort consistently maintained virologic suppression regardless of their BMI at initiation of CAB+RPV LA and differences in other characteristics; confirmed virologic failure was rare

Acknowledgements

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