Body Mass Index and Virologic Outcomes in Individuals on CAB+RPV LA in the OPERA Cohort

534

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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

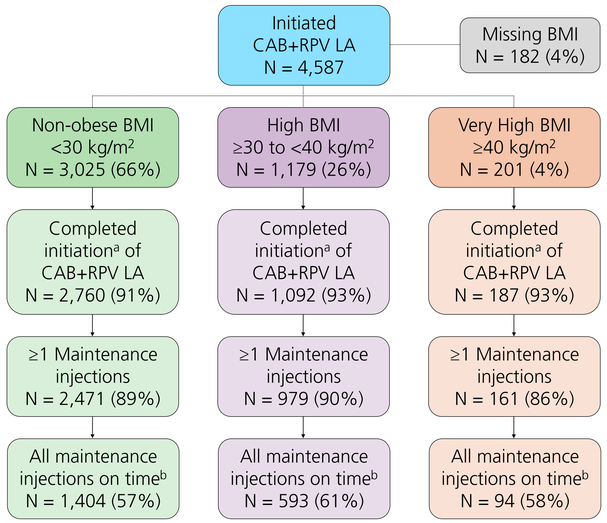
- Three study groups based on BMI at CAB+RPV LA initiation:
  - Non-obese BMI: <30 kg/m²
  - High BMI: ≥30 kg/m² to <40 kg/m²
  - Very high BMI: ≥40 kg/m²

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



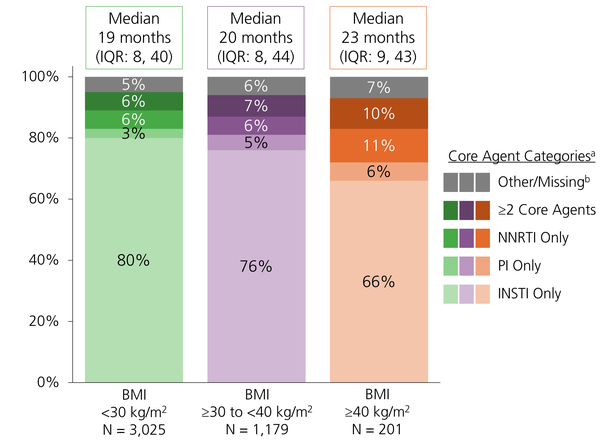
[a] Received initiation injections ≤67 days apart
[b] On-time maintenance injections are ≤37 days or ≤67 days after the last injection, for monthly or every two-month dosing schedules, respectively

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

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



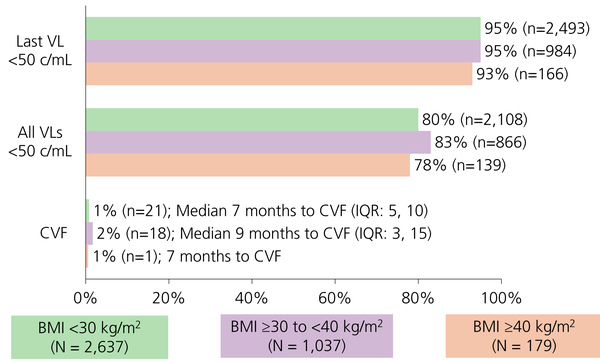
[a] Core agent categories are mutually exclusive
[b] 99% of individuals in this category were missing prior ART regimen information

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



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

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

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 (IT/data management), Lisa Lutzi & Nicole Shaw (data architecture), Judy Johnson (medical terminology classification), and Rachel Palmieri Weber (poster creation).

Support

This research was sponsored by ViiV Healthcare

The OPERA cohort is owned and operated by Epividian, Inc

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