High virologic suppression among individuals on cabotegravir + rilpivirine long-acting with viral loads ≥50 copies/mL regardless of body mass index in the OPERA Cohort

TUPEB091

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Background

- CAB+RPV LA is the first and only complete LA ART regimen approved (January 2021) for the treatment of HIV in the US
  - Injections monthly or every two months (Q2M)
  - Indicated for ART-experienced individuals with VL <50 copies/mL
- ~10% of individuals who initiated CAB+RPV LA in the OPERA Cohort had viremia (VL ≥50 c/mL)
- A substantial proportion of individuals initiating CAB+RPV LA have a BMI ≥30 kg/m^2
  - Longer needle lengths may be required for patients with higher BMI

Objective

To assess clinical outcomes in individuals in the OPERA Cohort who initiated CAB+RPV LA with viremia (VL ≥50 copies/mL) stratified by BMI at initiation

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 people with HIV in the US

Inclusion Criteria

- Treatment-experienced adults
- Switched to CAB+RPV LA between 21JAN2021 and 31DEC2024
- Initiated with HIV viremia (VL ≥50 copies/mL)

Stratification

- Non-obese BMI: <30 kg/m^2
- High BMI: ≥30 to <40 kg/m^2
- Very high BMI: ≥40 kg/m^2

Censoring Criteria

- Discontinuation of CAB+RPV LA (>67 and >127 days without injections for the monthly and every 2 months dosing, respectively)
- End of analysis period 28FEB2025
- Loss to follow-up (i.e., no clinic contact for 12 months)
- Death

Analysis & Outcomes

- Virologic outcomes were assessed among individuals who completed initiation *and* had ≥1 follow-up VL on or before 28FEB2025
- Outcome: Virologic Suppression
  - Achieved VL <50 c/mL
  - Last follow-up VL <50 c/mL
- Outcome: Confirmed Virologic Failure
  - Among those who suppressed to VL <50 c/mL
  - Two consecutive VLs ≥200 c/mL *or*
  - Discontinuation of CAB+RPV LA after a VL ≥200 c/mL

Abbreviations
AIDS, Acquired immunodeficiency syndrome; **ART**, antiretroviral therapy; **BMI**, body mass index; **CAB+RPV**, cabotegravir + rilpivirine; **CVF**, confirmed virologic failure; **FTR**, Fostemsavir; **HIV**, human immunodeficiency virus; **INSTI**, integrase strand transfer inhibitor; **IQR**, interquartile range; **LA,** long-acting; **LEN**, Lenacapavir; **(c/)mL**, (copies per) milliliter; **µL**, microliter; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitors; **US**, United States; **VL**, viral load.

Results

Table 1. Demographic and clinical characteristics of viremic individuals switching to CAB+RPV LA, by BMI (kg/m^2) at initiation

	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Age, median years (IQR)	39 (32, 51)	41 (34, 50)	39 (33, 50)
Age ≥50 years old, n (%)	105 (27)	34 (26)	10 (28)
Female sex, n (%)	78 (20)	46 (35)	21 (58)
Black race, n (%)	186 (48)	87 (65)	27 (75)
Hispanic ethnicity, n (%)	88 (23)	24 (18)	6 (17)
Care in Southern US, n (%)	210 (54)	83 (62)	29 (81)
History of AIDS-defined events, n (%)	148 (38)	46 (35)	10 (28)
BMI, median (IQR)	25 (22, 27)	33 (31, 36)	45 (42, 51)
CD4 <500 cells/µL, n (%)	177 (46)	57 (43)	15 (42)
Time since HIV diagnosis, median years (IQR)	8 (2, 16)	8 (3, 17)	10 (3, 17)
VL at CAB+RPV LA initiation, median c/mL (IQR)[a]	130 (60, 2550)	117 (62, 460)	180 (69, 1835)
VL ≥50 to <200, n (%)	227 (59)	90 (68)	18 (50)
VL ≥200 to <1000, n (%)	46 (12)	13 (10)	7 (19)
VL ≥1000 to <10,000, n (%)	31 (8)	12 (9)	≤5
VL ≥10,000 to <100,000, n (%)	61 (16)	13 (10)	≤5
VL ≥100,000, n (%)	22 (6)	≤5	≤5

Table 2. Persistence among viremic individuals with complete initiation of CAB+RPV LA, by BMI at initiation

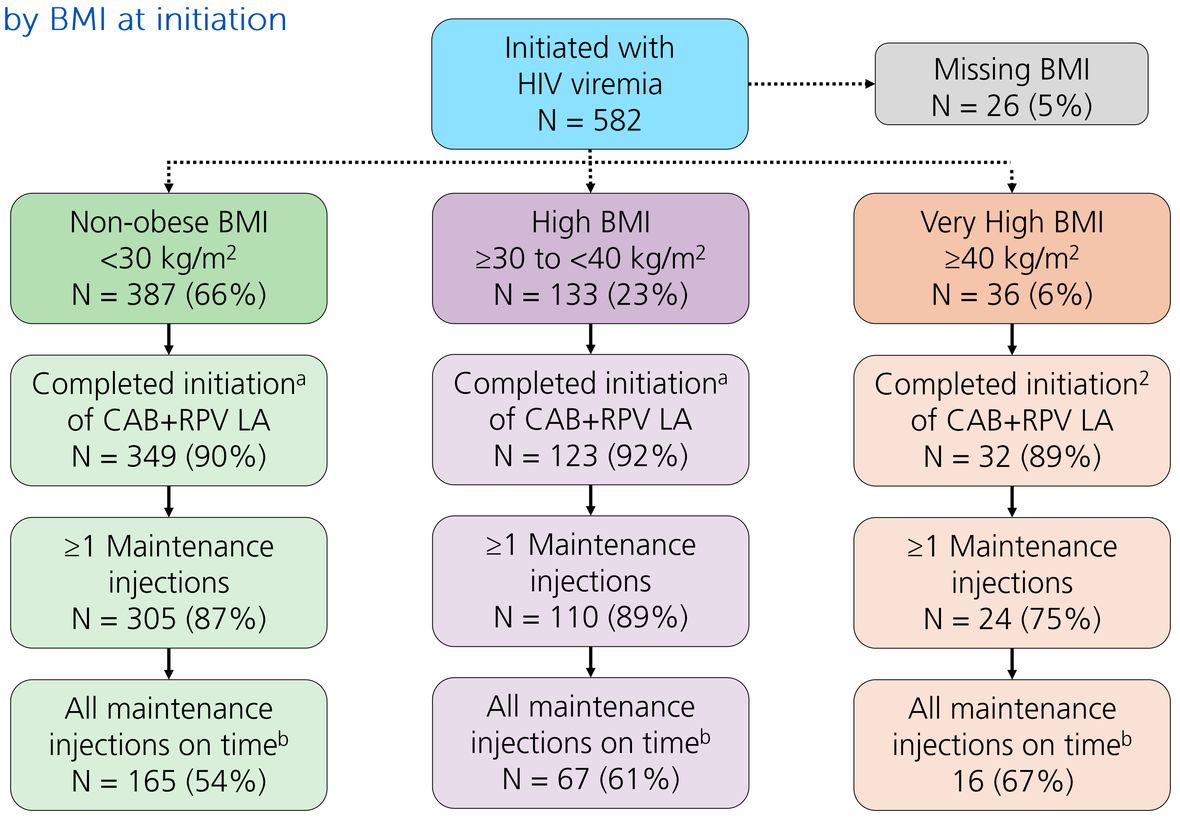
	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Completed initiation, n (%)	349 (90)	123 (92)	32 (89)
Alive and active in care[a] at study end, n (%)	339 (97)	122 (99)	30 (94)
Months on CAB+RPV LA, median (IQR)[b]	15 (8, 27)	15 (8, 27)	11 (7, 19)
On CAB+RPV LA on 28FEB2025, regardless of previous discontinuation(s), n (%)	259 (76)	87 (71)	22 (73)

[a] Last contact date on or within 24 months of study end
[b] Time until first censoring; addition of FTR or LEN did not stop CAB+RPV regimen (n=20)

Table 3. Dosing schedule at first & last injection, by BMI at initiation

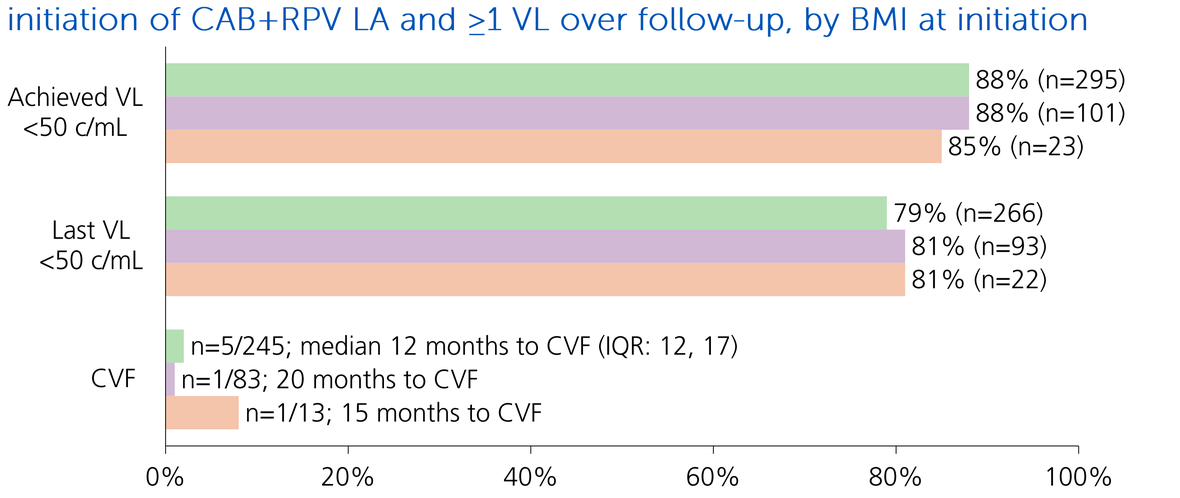
	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Completed initiation, n (%)	349 (90)	123 (92)	32 (89)
Q2M 600/900 mg at initiation, n (%)	298 (85)	106 (86)	26 (81)
Q2M 600/900 mg at last injection, n (%)	327 (94)	117 (95)	28 (87)

Figure 1. Adherence in individuals who initiated CAB+RPV LA with viremia, by BMI at initiation



[a] Received initiation injections ≤67 days apart
[b] On time was defined as within ±7 days of injection target

Figure 2. Virologic effectiveness among viremic individuals with complete initiation of CAB+RPV LA and ≥1 VL over follow-up, by BMI at initiation



BMI <30 kg/m^2 N = 336 | **BMI ≥30 to <40 kg/m^2** N = 115 | **BMI ≥40 kg/m^2** N = 27

Discussion

Summary of findings

- Among 582 individuals initiating CAB+RPV LA with viremia (≥50 c/mL), 387 (66%) had non-obese BMI, 133 (25%) had high BMI (≥30 to <40 kg/m^2) and 36 (6%) had very high BMI (≥40) at initiation (**Fig 1**)
  - Nearly all individuals (89-92%) completed initiation
  - Most (75-89%) received maintenance injections
  - Over half (54-67%) received all injection on-time, the very high BMI group had the best adherence
- Characteristics of individuals at initiation varied markedly across the groups (**Table 1**)
  - The very high BMI group was more likely to be female, Black, and receive care in the Southern US
  - The non-obese BMI group was more likely to be Hispanic and have a history of AIDS
- Approximately three-quarters of individuals were still on CAB+RPV LA at end of analysis period (76%, 71%, and 73%, respectively, among BMI groups; **Table 2**)
- Every two months dosing was more common at initiation and at last injections (**Table 3**)
  - The very high BMI group was most likely to use monthly dosing schedule
- All groups were similarly likely to achieve virologic suppression (88%, 88%, 85%) and remain suppressed at study end (79%, 81%, 81%; **Fig 2**)
  - CVF was rare across all BMI subgroups (**Fig 2**)

Strengths

- Real-world experience with CAB+RPV LA in individuals with viremia
  - Large population with variety of body sizes
  - All injections were observed in the clinic

Limitations

- Electronic health records data quality may vary quality practices and providers; measurement error is possible
- Oral bridging is not well documented; this may result in underestimation of CAB+RPV LA adherence
- The number of individuals in the BMI subgroups, especially the very high BMI subgroup, was small

Key Findings

- In this large, real-world analysis of 582 viremic individuals initiating CAB+RPV LA, the majority achieved virologic suppression to <50 copies/mL; CVF was rare across BMI categories
- These results support CAB+RPV LA as an effective treatment option for individuals who are viremic, including those with very high BMI, and may experience adherence or tolerability challenges with daily oral regimens

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