Comparable Virologic Effectiveness With Long-acting Cabotegravir + Rilpivirine vs. Daily Bictegravir/Emtricitabine/Tenofovir Alafenamide in the US-based OPERA Cohort

WEPEB099

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OPERA® The Longitudinal Cohort

Background

CAB+RPV LA

- The first and currently only complete LA ART regimen in the US[1]
  - Injections 6 times per year
  - Indicated for ART-experienced individuals with VL <50 copies/mL
  - Nucleoside sparing

BIC/FTC/TAF

- The most common ART regimen in the US-based OPERA Cohort[2]
  - Single tablet taken orally every day
  - Indicated for ART-naïve or experienced individuals regardless of viral load at initiation
  - Covers chronic hepatitis B

Objective

To assess real world effectiveness after a switch to CAB+RPV LA Q2M injections versus a daily single-tablet oral regimen, BIC/FTC/TAF

Methods

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

- Adults with HIV
- Treatment-experienced
- Virologically suppressed (VL <50 c/mL)
- Switched to CAB+RPV LA Q2M or BIC/FTC/TAF for the first time between 01FEB2022 and 31MAR2025

Censoring Criteria

- Discontinuation of regimen of interest
- End of study analysis (30SEPT2025)
- Loss to follow-up (no clinic contact for 12 months)
- Death

Outcomes

- Maintenance of virologic suppression over follow up
  - Last VL <50 c/mL
  - All VLs <50 c/mL
- Confirmed virologic failure (CVF): 2 consecutive VL ≥200 copies/mL or 1 VL ≥200 copies/mL followed by discontinuation within 4 months
  - Following regimen
  - Ever re-suppressed to VL <50 c/mL

Statistical Analysis

- Association between regimen and CVF: multivariable logistic regression
  - Adjusted for age, sex, ethnicity, US geographic region, injection drug use, AIDS-defining events, hepatitis C ever, CD4 cell count, comorbid conditions ever, and core agent of prior regimen
- Multiple imputation by chained equations (MICE) for missing data on ethnicity (N = 298) and baseline CD4 cell count (N = 33)
  - Included age, sex, ethnicity, US geographic region, injection drug use, AIDS-defining events, hepatitis C ever, CD4 cell count, comorbid conditions ever, core agent of prior regimen, clinic, race, BMI, VACS score, and prior core agent class
  - Analyses were updated since the abstract submission to exclude individuals with past exposure to regimens of interest

Results

Table 1. Baseline characteristics among individuals switching to CAB+RPV LA Q2M vs. BIC/FTC/TAF

	CAB+RPV LA Q2M (N = 4,090)	BIC/FTC/TAF (N = 2,699)
Age, median years (IQR)	38 (32, 49)	47 (36, 58)
50-64, n (%)	807 (20)	961 (36)
≥65, n (%)	140 (3)	244 (9)
Female sex, n (%)	569 (14)	448 (17)
Black race, n (%)[a]	1,739 (42)	1,112 (41)
Hispanic ethnicity, n (%)[b]	1,372 (34)	725 (27)
Injection drug use, n (%)	231 (6)	289 (8)
Care in Southern US, n (%)	2,166 (53)	1,723 (64)
AIDS-defining events (ever), n (%)	177 (4)	79 (3)
Any comorbid conditions, n (%)	3,065 (75)	2,229 (83)
CD4, median cells/µL (IQR)[c]	714 (532, 918)	694 (506, 914)
Prior core agent class, n (%)		
INSTI	3,433 (84)	1,847 (68)
PI	153 (4)	310 (12)
NNRTI	242 (6)	382 (14)
2 or more core agents	261 (6)	159 (6)
Other	≤5	≤5
Months of prior regimen, median (IQR)	20 (9, 44)	41 (12, 70)

[a] Missing race: N = 322
[b] Missing ethnicity: N = 298
[c] Missing CD4 count: N = 33

Figure 1. Maintenance of virologic suppression among individuals with ≥1 follow-up VL

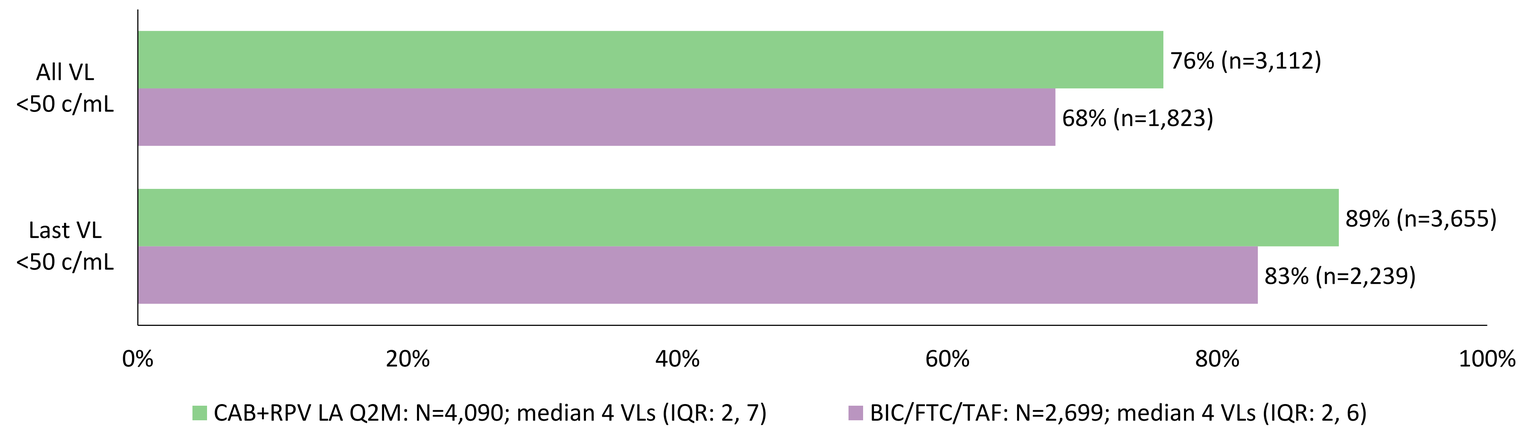


Figure 2. Confirmed virologic failure among individuals with ≥1 follow-up VL

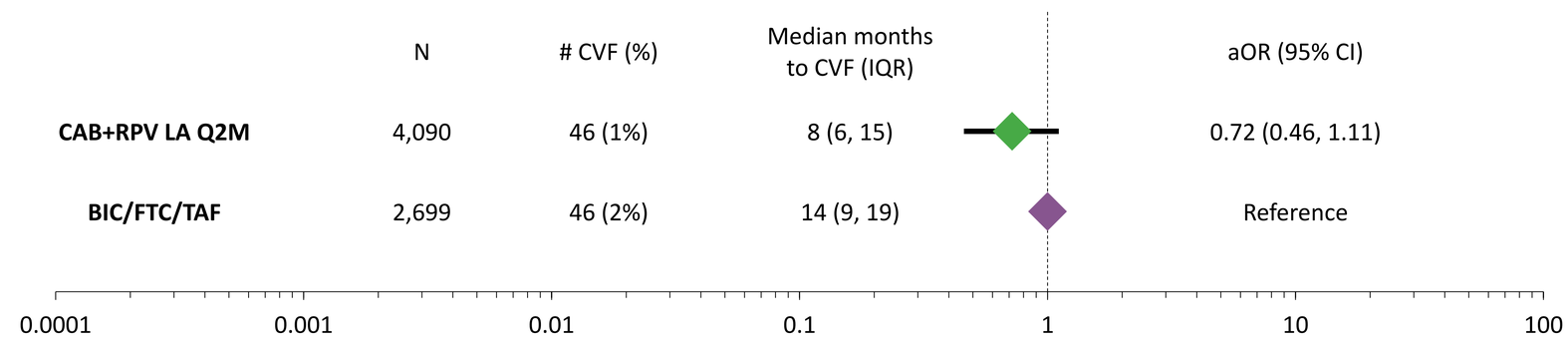
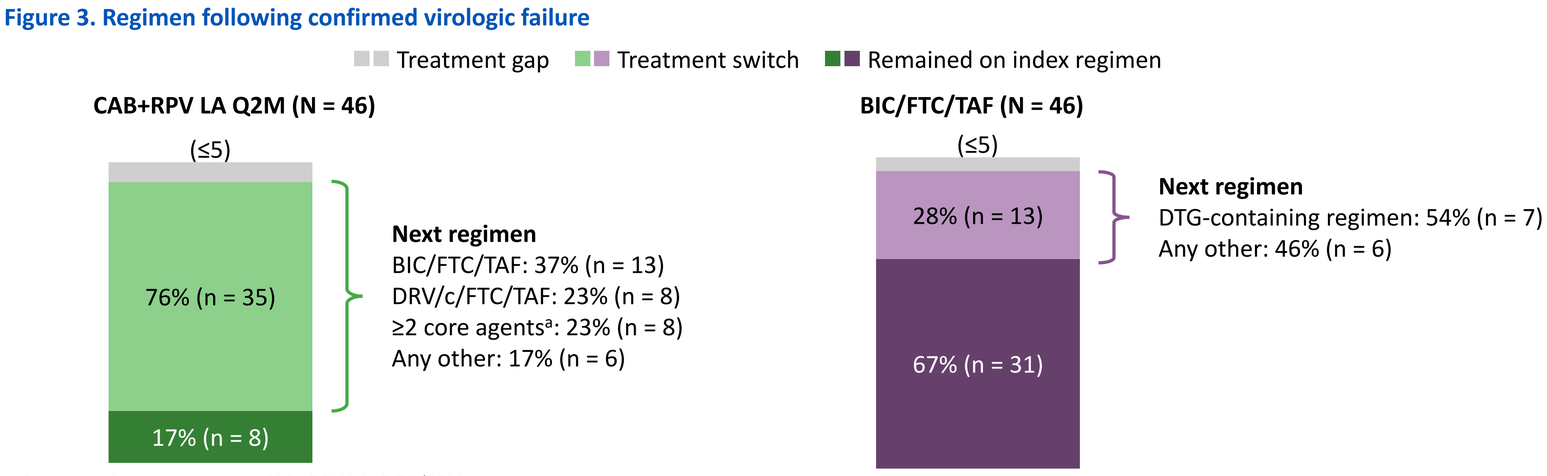


Table 2. Persistence

	CAB+RPV LA Q2M (N = 4,090)	BIC/FTC/TAF (N = 2,699)
Months on regimen until first censoring[a], median (IQR)	15 (8, 25)	22 (14, 31)
On regimen at study end (regardless of any discontinuations), n (%)	2,997 (73)	2,175 (81)
Cumulative months on regimen, median (IQR)	18 (11, 28)	23 (15, 33)

[a] Censoring at the first of regimen discontinuation, study end (30SEPT2025), loss to follow-up (no clinic contact for 12 months), or death

Figure 3. Regimen following confirmed virologic failure



[a] Excluding 2 drug regimens (CAB+RPV LA, DTG/RPV)

Table 3. Virologic re-suppression after CVF

	CAB+RPV LA Q2M (N = 46)	BIC/FTC/TAF (N = 46)
≥1 VL after CVF, n (%)	22 (48)	29 (63)
Re-suppressed to VL <50 c/mL, n (%)	15 (68)	20 (69)
Months to re-suppression, median (IQR)	2 (1, 3)	4 (3, 7)

Abbreviations

AIDS, Acquired immunodeficiency syndrome; **aOR**, adjusted odds ratio; **ART**, antiretroviral therapy; **BIC/FTC/TAF**, bictegravir/emtricitabine/tenofovir alafenamide; **BMI**, body mass index; **CAB+RPV**, cabotegravir + rilpivirine; **CVF**, confirmed virologic failure; **DRV/c/FTC/TAF**, darunavir/cobicistat /emtricitabine/tenofovir alafenamide; **DTF**, dolutegravir; **HIV**, human immunodeficiency virus; **INSTI**, integrase strand transfer inhibitor; **IQR**, interquartile range; **LA,** long-acting; **c/mL**, copies per milliliter; **µL**, microliter; **Q2M**, every 2 months dosing schedule; **US**, United States; **VACS**, Veterans Aging Cohort Study Index; **VL**, viral load.

Discussion

Findings

- Individuals who switched to CAB+RPV LA Q2M differed from those switching to BIC/FTC/TAF (**Table 1**)
  - CAB+RPV LA Q2M users were younger (23% vs. 45% ≥50 years old), Hispanic ethnicity (34% vs. 27%) and more likely to have been on an INSTI prior to the switch (84% vs. 68%)
  - BIC/FTC/TAF users were more likely to have comorbid conditions (83% vs. 75%) and be cared for in the Southern US (64% vs. 53%)
- Median time on CAB+RPV LA Q2M was 15 months vs. 22 months on BIC/FTC/TAF before censoring (**Table 2**)
- CAB+RPV LA Q2M users were more likely than BIC/FTC/TAF users to maintain virologic suppression at last VL (89% vs 83%) and all VLs (76% vs. 68%) (**Fig 1**)
- CVF risk was lower in the CAB+RPV LA Q2M group than BIC/FTC/TAF group (46 [1%] vs. 46 [2%]), but after adjusting for baseline characteristics, the difference was not statistically significant (adjusted odds ratio [95% CI] = 0.72 [0.46, 1.11]) (**Fig 2**)
- Of those who experienced CVF, most of the CAB+RPV LA Q2M group (76%), switched to a new regimen, while most of the BIC/FTC/TAF group (67%) did not (**Fig 3**)
- Of 22 (CAB+RPV LA Q2M) and 29 (BIC/FTC/TAF) individuals with VLs available post-CVF, 68% and 69%, respectively, resuppressed to <50 copies/mL before study end. (**Table 3**)

Strengths

- Real-world clinical experience of CAB+RPV LA and BIC/FTC/TAF
- With 6,794 individuals followed, this comparison is a robust evaluation of the regimens
- Diverse population from 24 US states & territories
- Power to control for many covariates

Limitations

- Electronic health records data may vary in quality across practices and providers; therefore, measurement error is possible
- Accuracy of exposures were not equal
  - CAB+RPV LA injections are directly observed in the clinic
  - BIC/FTC/TAF exposure is captured via prescriptions
- Selection bias may have been introduced when individuals lacking complete ART histories were excluded to avoid unobserved exposure time
- Oral bridging during CAB+RPV LA use is not well documented and may result in over-estimation of discontinuation

References

1. CABENUVA prescribing information; https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/212888Orig1s017lbl.pdf accessed: 19June2026
2. BIKTARVY prescribing information; https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/210251Orig1s026lbl.pdf accessed: 19June2026

Key Findings

- In this real-world analysis of nearly 6,800 virologically suppressed individuals, switching to CAB+RPV LA Q2M consistently maintained high levels of virologic suppression comparable to switching to daily BIC/FTC/TAF
- CVF risk and re-suppression after CVF did not differ between the groups
- These findings support that CAB+RPV LA Q2M is as effective as daily oral therapy in maintaining virologic suppression

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