Real-World Effectiveness of Cabotegravir + Rilpivirine vs Standard of Care Oral Regimens in the US

Poster 623

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OPERA® The Longitudinal Cohort

Background

- Long-acting (LA) injectable antiretroviral therapy (ART) with cabotegravir + rilpivirine (CAB+RPV) was approved by the FDA in January 2021
- In trials, CAB+RPV LA was shown to be non-inferior to oral ART regimens in virologically suppressed (viral load [VL] <50 copies/mL) individuals[1]

Objective

To compare real-world effectiveness after a switch to CAB+RPV LA versus a new oral ART regimen

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 (PWH) in the US
- **Inclusion criteria**
  - ART-experienced PWH aged ≥18 years
  - Virologically suppressed (VL <50 copies/mL)
  - Switched to CAB+RPV LA or a new oral ART regimen between 21JAN2021 and 31DEC2022
- **Censoring criteria**
  - Discontinuation of ART regimen of interest
  - Death
  - 12 months after last clinical contact
  - End of analysis period (30JUN2023)

Statistical analyses

- Confirmed virologic failure (CVF; 2 VL ≥200 copies/mL or 1 VL ≥200 copies/mL + discontinuation) was assessed among those with ≥1 follow-up VL
- A logistic regression model was fit to assess risk of CVF by regimen, adjusted for age, sex, race, injection drug use (IDU), history of AIDS-defining events (ADE), CD4 count, comorbid conditions, and prior regimen class
- In those receiving CAB+RPV LA, a logistic regression model was fit to evaluate age, sex, race, US region, IDU, history of ADE, CD4 count (per 100 cells/μL), comorbid conditions, prior regimen class, and body mass index (BMI) as potential predictors of CVF

Results

Table 1. Baseline characteristics

	CAB+RPV LA N = 1,362	Oral ART N = 2,783
Age, median years (IQR)	39 (32, 52)	45 (34, 56)
Female sex, n (%)	237 (17)	514 (18)
Black race, n (%)[a]	557 (41)	1,198 (43)
Hispanic ethnicity, n (%)[a]	390 (29)	678 (24)
Care in Southern USA, n (%)	752 (55)	1,742 (63)
Viral load, median c/mL (IQR)	19 (19, 20)	19 (19, 19)
CD4 cell count, median cells/μL (IQR)[a]	686 (496, 902)	700 (524, 913)
Prior core agent class, n (%)		
INSTI-based	1,003 (74)	1,880 (68)
NNRTI-based	106 (8)	474 (17)
PI-based	42 (3)	203 (7)
More than one core agent	211 (16)	226 (8)
Months on prior ARV regimen, median (IQR)	20 (7, 38)	37 (20, 55)

c/mL, copies/milliliter; IQR, interquartile range; INSTI, integrase inhibitor; N, number; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor

[a] N missing = 133 (race), 132 (ethnicity), 35 (CD4 cell count)

Table 2. Virologic outcomes among those with follow-up VL

		CAB+RPV LA N = 1,293	Oral ART N = 2,523
Last VL	<200 c/mL, n (%)	1,281 (99)	2,431 (96)
	<50 c/mL, n (%)	1,229 (95)	2,298 (91)
CVF	n (%)	25 (2)	78 (3)
	Adjusted OR (95% CI)[a,b]	0.64 (0.40, 1.02)	Reference

c/mL, copies/milliliter; OR, odds ratio

[a] Excluding 148 individuals missing race or baseline CD4 cell count

[b] Adjusted for age (linear & quadratic terms), female sex, Black race, injection drug use, history of AIDS-defining events, CD4 cell count (linear & quadratic terms), presence of comorbidities, core class in prior regimen

Figure 1. Virologic suppression following confirmed virologic failure, among those with VL available post-CVF

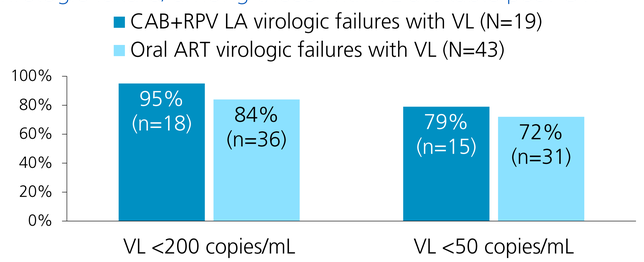


Figure 2. Regimens following confirmed virologic failure

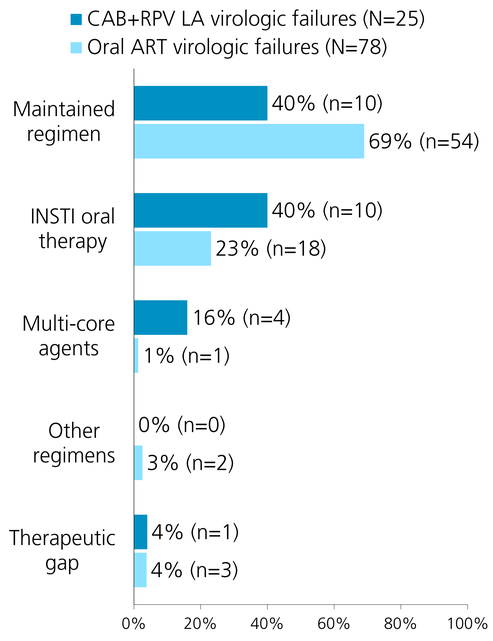
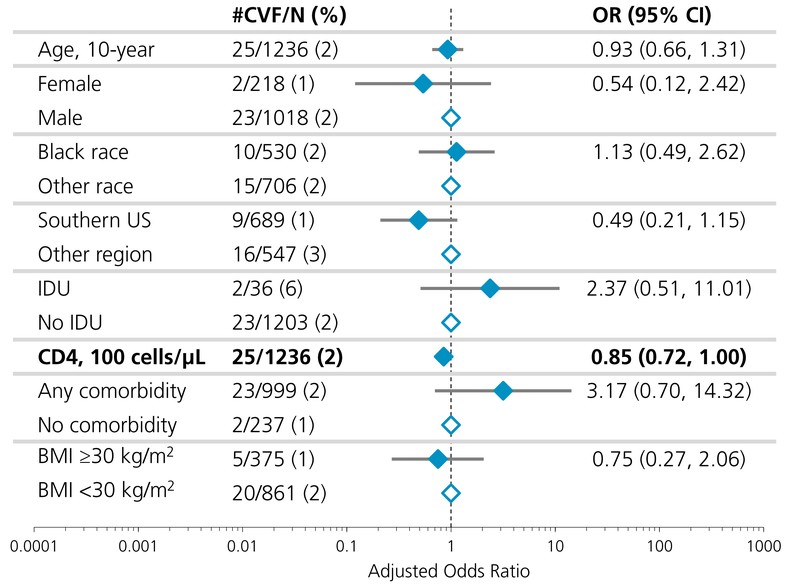


Figure 3. Predictors of confirmed virologic failure among people switching to CAB+RPV LA with ≥1 follow-up viral load (N=1,236)[a]



◊ reference

[a] Excluding 57 individuals without race or baseline CD4 cell count

Discussion

- Compared to oral ART users, CAB+RPV LA users were younger, had been on their prior regimen for a shorter period, were more likely to switch from an INSTI, but had similar median CD4 counts at initiation (**Table 1**)
- High levels of virologic suppression (VL <50 copies/mL) were observed at last VL with CAB+RPV LA (95%) and oral ART (91%; **Table 2**)
- Among individuals with follow-up VLs, CVF risk did not differ significantly for those on CAB+RPV LA vs. oral ART (OR [95% CI] = 0.64 [0.40, 1.02]; **Table 2**)
- Of CAB+RPV LA users with CVF, most (80%) either maintained CAB+RPV LA or switched to an INSTI oral therapy; those on oral therapy were more likely to maintain their current regimen after failure than those on CAB+RPV LA (**Fig 2**)
- After CVF, a higher proportion of individuals on CAB+RPV LA achieved VLs <200 and <50 copies/mL than those on oral ART (**Fig 1**)
- Among CAB+RPV LA users, only baseline CD4 marginally predicted CVF; every 100 CD4 cells/μL increase was associated with a 15% lower risk of CVF (**Fig 3**)

Key Findings

- This real-world data analysis of virologically suppressed PWH in the US demonstrated high levels of virologic control after switching to CAB+RPV LA regimen.
- The risk of confirmed virologic failure did not differ between individuals switching to CAB+RPV LA or oral ART regimens.

References

1. Wang et al. Safety and efficacy of long-acting injectable agents for HIV-1: systematic review and meta-analysis. JMIR Public Health Surveill. 2023;9:e46767.

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 & Stephen Connellee (data architecture), Lisa Lutzi & Nicole Shaw (data management/quality), and Judy Johnson (clinical data categorization).

Support

This research was sponsored by ViiV Healthcare.

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