High Real-World Adherence With Long-Acting Cabotegravir Plus Rilpivirine (CAB+RPV LA) Among People With HIV (PWH) in the United States (US)

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**Presenting on behalf of the authors.*

Key Takeaways

- **In real-world prospective and retrospective studies in the United States, adherence to long-acting cabotegravir + rilpivirine (CAB + RPV LA) was high among people with HIV with up to ~15 months of median follow-up, regardless of virologic suppression status at initiation of CAB + RPV LA**
- **Overall, the high adherence to CAB + RPV LA observed in real-world settings provides confidence in the use of CAB + RPV LA in clinical practice**

Introduction

- Adherence to antiretroviral therapy (ART) is critical for the long-term success of HIV treatment, but challenges with adherence to oral ART persist[1]
- Prior studies have shown that the proportion of people with HIV with optimal adherence to oral ART (proportion of days covered ≥90%) is as low as ~40%[2]
- Long-acting cabotegravir + rilpivirine (CAB + RPV LA) is the only complete LA regimen for treatment of HIV-1 in people who are virologically suppressed[3]
- With as few as 6 doses per year, CAB + RPV LA may alleviate challenges with daily oral ART, including stigma, daily reminder of HIV status, fear of inadvertently sharing status, pill fatigue, and missing pill doses
- An interim analysis of the phase 3 LATITUDE study showed high adherence to CAB + RPV LA (93% of injections administered on time) in people with HIV who were experiencing adherence challenges with oral ART[4]
- This analysis summarizes adherence outcomes among people with HIV using CAB + RPV LA in real-world studies in the United States

Methods

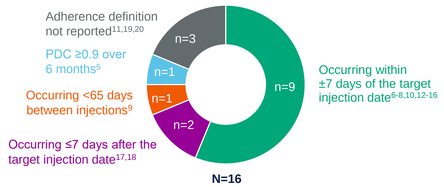
- A systematic literature review was conducted across PubMed, Embase®, Cochrane library, and 23 HIV-related conference proceedings between January 2020 and July 2024
- This analysis included only real-world studies conducted in the United States identified from the systematic literature review that reported adherence data among people with HIV aged ≥12 years using CAB + RPV LA; studies with <25 people with HIV were excluded
- Data were summarized descriptively and were not pooled, as adherence definitions and follow-up durations varied across studies
- Adherence outcomes were categorized by baseline virologic suppression status at the time of CAB + RPV LA initiation

Results

Included Studies

- 16 real-world studies reported data on adherence to CAB + RPV LA in the United States, with each study including 25 to 947 people with HIV[5-20]
- Adherence definitions varied across studies (Figure 1); the most common definition was proportion of injections and/or proportion of individuals with all injections occurring within ±7 days of the target injection date (on-time injections; n=9)
- 4 studies reported how the target injection date was set (based on initial injection vs previous injection), all of which used the previous injection date[6,8,10,16]

Figure 1. Adherence Definitions



PDC, proportion of days covered.

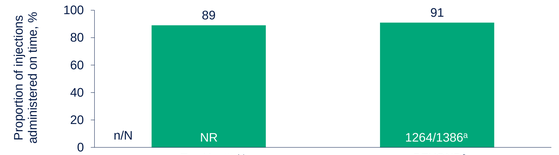
- Follow-up time, given as either a median value or a specified time point (eg, Month 12), ranged from 4 to 33 months (reported in 11/16 studies)[5,6,8,10,12,14-18,20]
- Median number of injections per person ranged from 3 to 11 (reported in 9/16 studies)[5,7,8,10,13-17]
- A majority of people received CAB + RPV LA every 2 months, either from initiation or with switch from monthly to every-2-month dosing by the time of analysis, in 10 of the 13 studies that reported dosing regimen[5,7,8,11-14,16,17,20]
- Use of oral ART to cover missed injections was inconsistently reported across studies (5/16)[5,6,8,11,16]
  - In the 5 studies reporting data, oral ART was used to cover missed injections in 2% to 17% of people with HIV using CAB + RPV LA (3 studies)[5,8,11] or used to cover 30% (13/44) to 46% (30/65) of late CAB + RPV LA injections (2 studies)[6,16]

Adherence Outcomes in Populations Virologically Suppressed at Baseline

- 6/16 studies specifically reported CAB + RPV LA adherence outcomes in people virologically suppressed at baseline (HIV-1 RNA <50 c/mL)[6,9,10,12,14,17]
- Of these 6 studies, 5 defined adherence as injections occurring within ±7 days of the target injection date or ≤7 days after the target injection date (on-time injections)[6,10,12,14,17]
  - In these 5 studies, 89% to 91% of injections were administered on time (n=2) and proportions of people receiving all injections on time were 71% to 88% (n=4), with 4 to 12 months of follow-up (Figure 2)
- The remaining study, a retrospective analysis using electronic health records, reported 56% of people (N=233) did not have a time gap of ≥65 days between CAB + RPV LA administrations; follow-up duration was not reported[9]

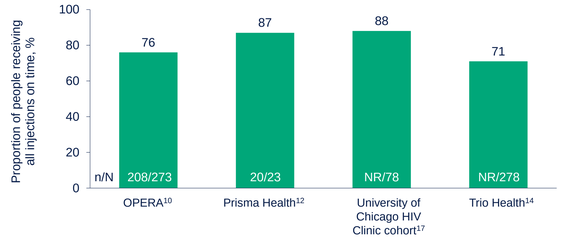
Figure 2. Adherence to CAB + RPV LA in People Virologically Suppressed at Baseline

Proportion of injections administered on time



	Trio Health[14]	BEYOND[6]
People with HIV, N	278	233[b]
Follow-up duration	10 mo (median)	12 mo (time point)
Adherence definition	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date

Proportion of people receiving all injections on time

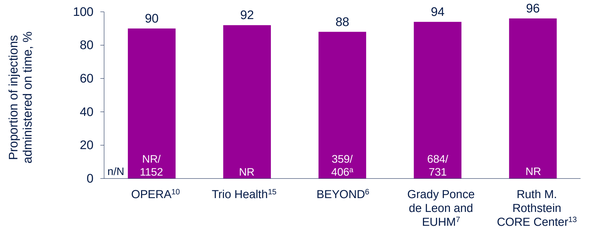


	OPERA[10]	Prisma Health[12]	University of Chicago HIV Clinic cohort[17]	Trio Health[14]
People with HIV, N	273	23	78	278
Follow-up duration	4.1 mo (median)	6 mo (time point)[c]	8 mo (median)	10 mo (median)
Adherence definition	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date	Occurring ≤7 days after the target injection date	Occurring within ±7 days of the target injection date

NR, not reported. [a]Value for n=1264 is data on file. [b]Included people with CAB + RPV LA treatment that was consistent with the label. [c]Reported as 24 weeks in the study.

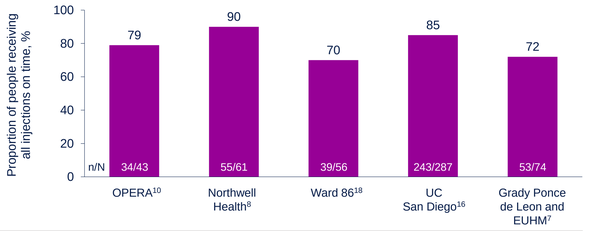
Figure 3. Adherence to CAB + RPV LA in People Not Virologically Suppressed at Baseline or With Mixed or Unknown Virologic Suppression Status Case

Proportion of injections administered on time



	OPERA[10]	Trio Health[15]	BEYOND[6]	Grady Ponce de Leon and EUHM[7]	Ruth M. Rothstein CORE Center[13]
People with HIV, N	321	32	75[b]	74	96
Baseline HIV-1 RNA <50 c/mL, n (%)	273 (85)	0	47 (63)	71 (96)	94 (98)
Baseline HIV-1 RNA ≥50 c/mL, n (%)	43 (13)	32 (100)	23 (31)	3 (4)	NR
Follow-up duration	4.2 mo (median)	5 mo (median)	12 mo (time point)	NR[c]	NR[d]
Adherence definition	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date

Proportion of people receiving all injections on time



	OPERA[10]	Northwell Health[8]	Ward 86[18]	UC San Diego[16]	Grady Ponce de Leon and EUHM[7]
People with HIV, N	43	73	59	287	74
Baseline HIV-1 RNA <50 c/mL, n (%)	0	NR[e]	0	252 (88)	71 (96)
Baseline HIV-1 RNA ≥50 c/mL, n (%)	43 (100)	NR	59 (100)	NR	3 (4)
Follow-up duration	4.7 mo (median)	9 mo (median)	12 mo (time point)[f]	15 mo (median)[g]	NR[c]
Adherence definition	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date	Occurring ≤7 days after the target injection date	Occurring within ±7 days of the target injection date	Occurring within ±7 days of the target injection date

NR, not reported. [a]Value for n=359 is data on file. [b]Included people with CAB + RPV LA treatment that was inconsistent with the label (not virologically suppressed [≥50 c/mL] at initiation, previous virologic failure, and/or documented prior resistance to CAB or RPV). Note: 5 people had unknown viral load at baseline. [c]Median (IQR) number of injections: 11 (7-14). [d]Median (range) number of injections: 4 (1-15). [e]All had baseline HIV-1 RNA <200 c/mL. [f]Reported as 48 weeks in the study. [g]Reported as 450 days in the study.

Adherence Outcomes in Populations Not Virologically Suppressed or With Mixed or Unknown Virologic Suppression Status

- 12/16 studies reported CAB + RPV LA adherence outcomes in people not virologically suppressed at baseline (4 studies)[6,10,15,18] or with mixed (combined results for people who were suppressed and unsuppressed at baseline) or unknown virologic suppression status (8 studies)[5,7,8,11,13,16,19,20]
- Of these 12 studies, 8 defined adherence as injections occurring within ±7 days of the target injection date or ≤7 days after the target injection date (on-time injections)[6-8,10,13,15,16,18]
  - In these 8 studies, 88% to 96% of injections were administered on time (n=5) and proportions of people receiving all injections on time were 70% to 90% (n=5), with 4 to ~15 months of follow-up (Figure 3)
- 1/12 studies, a retrospective study using administrative claims data, reported that a significantly higher proportion of people receiving CAB + RPV LA (72%; N=947) were highly adherent (proportion of days covered ≥0.9) over a 6-month follow-up period compared with the proportion highly adherent on oral ART (43%; N=950; $P<0.001$)[5]
- The remaining 3 studies found that 92% to 100% of injections were administered on time (n=3), and 76% to 100% of people received all injections on time (n=2), but did not report the adherence definitions used[11,19,20]

Discussion and Limitations

- Adherence definitions and reporting in real-world studies of CAB + RPV LA are highly variable
- Actual adherence may be higher than reported given the inconsistent reporting of oral ART to cover missed injections in the included studies
- These data highlight differences in describing adherence outcomes for oral ART vs CAB + RPV LA
- Definitions used in many real-world studies for CAB + RPV LA (eg, proportions of people with all injections on time, 100% adherence) may be more stringent than definitions commonly used for oral ART (eg, adherence defined as proportion of people with proportion of days covered ≥90%)
- By demonstrating high adherence to injections among people who were viremic before initiating CAB + RPV LA,[6,10,15,18] these data support that, given the opportunity to engage with LA ART as a therapy that fits with their lifestyle, people who likely had adherence challenges on prior oral ART were able to maintain high adherence to CAB + RPV LA, similar to interim data from LATITUDE[4]
- Overall, these results provide confidence in the use of CAB + RPV LA in clinical practice, and real-world studies with longer follow-up duration are warranted

Conclusions

- CAB + RPV LA adherence was high among people with HIV receiving CAB + RPV LA with up to ~15 months of median follow-up in real-world studies in the United States
- In these studies, adherence was high and similar regardless of virologic suppression status at CAB + RPV LA initiation

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