Early Real-World Use of Long-Acting Cabotegravir + Rilpivirine in the US

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Background

- Cabotegravir + rilpivirine (CAB+RPV) intramuscular injection is the first long-acting (LA) antiretroviral therapy (ART) approved in the United States (US)
  - Approved by the FDA on 21Jan2021
- CAB+RPV LA is a complete regimen replacement for people living with HIV (PWH) who are on a stable ART regimen, with viral load < 50 copies/mL, and have no history of treatment failure or known/suspected resistance to CAB or RPV
- CAB+RPV LA has the benefit of less frequent dosing and directly observed therapy

Objective

Describe the early experience of a large clinical cohort of PWH receiving long acting cabotegravir + rilpivirine in the US

Methods

Study population

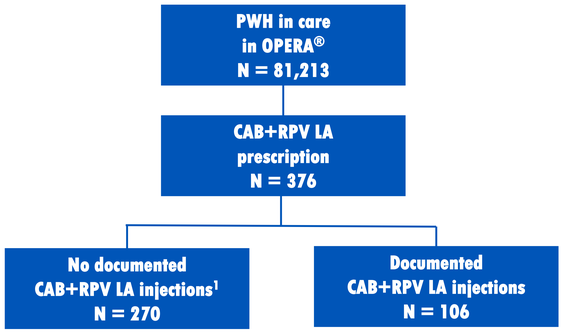
- OPERA® observational cohort
  - Prospectively captured, routine clinical data from electronic health records (EHR) in the US
  - Represents ~13% of PWH linked to care in the US[1]
- Inclusion criteria
  - 18 years of age or older
  - Active in care: Clinical encounter within the last 24 months
  - Initiating CAB+RPV LA for the first time between 21Jan2021 and 31Aug2021
- Follow-up through 03Oct2021

Analyses

- Descriptions of CAB+RPV uptake
- Demographic & clinical characteristics of CAB+RPV initiators stratified by viral load at prescription (copies/mL)
  - Undetectable (<50)
  - Suppressed (<200)
  - Viremic (≥200)

Results

Figure 1. CAB + RPV use in OPERA®



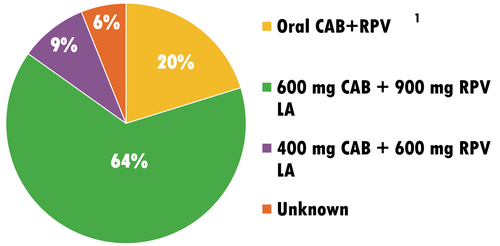
[1] At the end of observation, 72% had not yet received CAB+RPV injections as they were in the process of approval, were on oral lead-in, or had been denied.

Table 1. Time from prescription to first injection among CAB+RPV initiators (N=106)

CAB+RPV Initiators	Median (IQR), days
All	49 (22, 64)
Suppressed (<200 copies/mL) (n=91)	51 (30, 64)
Viremic (≥200 copies/mL) (n=12)	21 (3, 44)

CAB, cabotegravir; IQR, interquartile range; mL, milliliter; n, number; RPV, rilpivirine

Figure 2. Initial CAB + RPV formulation and dosing



[1] Oral lead-in was provided free through a non-retail pharmacy, which contributed to incomplete documentation in the electronic health records.

Table 2. Characteristics of PWH with ≥1 CAB+RPV LA injections, by viral load at prescription (N=106)[1]

Characteristic	Undetectable[2] (<50 copies/mL) N=87	Suppressed[2] (<200 copies/mL) N=91	Viremic (≥200 copies/mL) N=12
Age, median (IQR)	39 (32, 53)	39 (32, 53)	37 (28, 43)
Male sex, n (%)	76 (87)	80 (88)	6 (50)
Black, n (%)	26 (30)	27 (30)	9 (75)
Hispanic, n (%)	25 (29)	26 (29)	≤5[4]
MSM, n (%)	69 (79)	73 (80)	6 (50)
Geographic region, n (%)			
South	40 (46)	42 (46)	9 (75)
West	32 (37)	33 (36)	≤5[4]
Payer[3], n (%)			
Medicare	8 (9)	8 (9)	≤5[4]
Medicaid	38 (44)	40 (44)	≤5[4]
Commercial Insurance	45 (52)	47 (52)	8 (67)
Ryan White/ADAP	33 (38)	33 (36)	0 (0)
Unknown	≤5[4]	≤5[4]	0 (0)

ADAP, AIDS Drug Assistance Programs; IQR, interquartile range; mL, milliliter; MSM, men who have sex with men; n, number

[1] Three PLWH with ≥1 CAB+RPV LA injections did not have a baseline viral load
[2] Undetectable (<50 copies/mL) is a subset of Suppressed (<200 copies/mL)
[3] Payers are not mutually exclusive
[4] HIPAA privacy requirements preclude the reporting of 5 or fewer observations in any cell

Table 3. Persistence of CAB+RPV LA injections, by viral load at prescription (N=106)[1]

Characteristic	Undetectable[2] (<50 copies/mL) N=87	Suppressed[2] (<200 copies/mL) N=91	Viremic (≥200 copies/mL) N=12
VL at first prescription, median copies/mL (IQR)	19 (19, 19)	19 (19, 20)	26,700 (5,460, 107,205)
Months on CAB+RPV LA, median months (IQR)	3.2 (1.9, 4.2)	3.2 (2.2, 4.2)	3.7 (2.7, 4.6)
Still on CAB+RPV LA, n (%)	83 (95)	86 (94)	10 (83)
D/C[3], n (%)	≤5[4]	≤5[4]	≤5[4]
Time to d/c[3], median months (IQR)	2.8 (2.3, 3.5)	2.3 (2.3, 3.4)	3.9 (3.5, 4.3)

CAB, cabotegravir; D/C, discontinuation; IQR, interquartile range; LA, long-acting; mL, milliliter; n, number; RPV, rilpivirine; VL, viral load

[1] Three PLWH with ≥1 CAB+RPV LA injections did not have a baseline viral load
[2] Undetectable (<50 copies/mL) is a subset of Suppressed (<200 copies/mL)
[3] Discontinuation (D/C) defined as regimen switch or no new injection for >69 days
[4] HIPAA privacy requirements preclude the reporting of 5 or fewer observations in any cell

Discussion

- Of the 376 PWH with CAB+RPV prescriptions, only 28% had documented CAB+RPV LA injections.
- >25% of CAB+RPV initiators waited ≥2 months to receive injections.
- Oral lead-in was provided free through a non-retail pharmacy, which contributed to incomplete documentation in the EHRs.
- 11% of PWH who received ≥1 CAB+RPV LA injections were viremic at the time of prescription (viral load ≥200 copies/mL).
- Over half of viremic PWH had <28 days from prescription to injection, suggesting shorter or no oral lead-in.
- Median duration on CAB+RPV LA was 3 months for PWH who were undetectable or suppressed and nearly 4 months for PWH who were viremic at initiation.
- Discontinuations were infrequent in all groups.

Key Findings/Conclusions

- **All CAB+RPV initiators were ART-experienced and the vast majority (86%) were suppressed to <200 copies/mL at initiation.**
- **Though a substantial number of PWH received a prescription to initiate CAB+RPV, many remained in the process to initiate the regimen at the time of analysis.**

Reference

1. Centers for Disease Control and Prevention. Diagnoses of HIV Infection in the United States and Dependent Areas, 2019. In: *HIV Surveillance Report*; 2021.

Acknowledgements

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