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

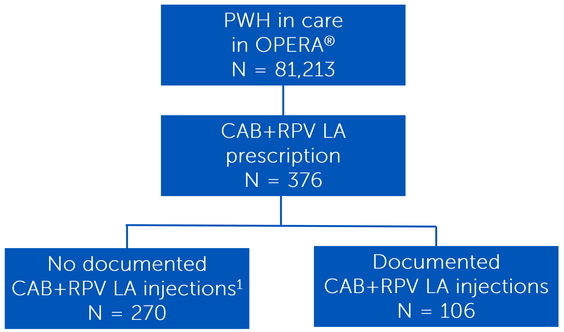
- OPERA® observational cohort
  - Prospectively captured, routine clinical data from electronic health records (EHR) in the US
  - Represents ~13% of PWH linked to care in the US[1]
- Inclusion criteria
  - 18 years of age or older
  - Active in care: Clinical encounter within the last 24 months
  - 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®



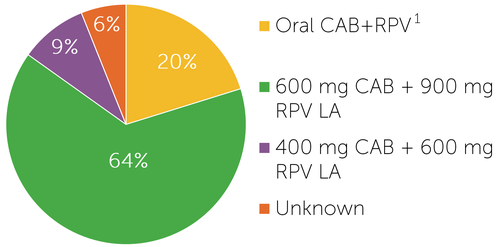
[1] At the end of observation, 72% had not yet received CAB+RPV injections as they were in the process of approval, were on oral lead-in, or had been denied.

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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