Real-World Utilization of Cabotegravir/Rilpivirine: An Observational Analysis of Adherence and Persistence using a Patient Support Program in Canada, Preliminary Results

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Key Takeaways

- **Optimal adherence to antiretroviral therapy (ART) is required to maintain viral suppression and prevent HIV transmission.**
- **Cabotegravir/rilpivirine long-acting (CAB+RPV LA) injectable is the only complete long-acting regimen for virologically suppressed persons living with HIV (PWH), reducing dosing to 6 or 12 days per year.**
- **98.7% of the 233 PWH receiving CAB+RPV LA in the CAB+RPV LA patient support program (PSP) were adherent (proportion of days covered ≥90%) over a 365-day follow-up period while 95.3% remained persistent through the 365-day analysis period.**
- **High adherence and persistence to CAB+RPV LA were observed among Canadian PWH receiving their injections through the CAB+RPV LA PSP.**

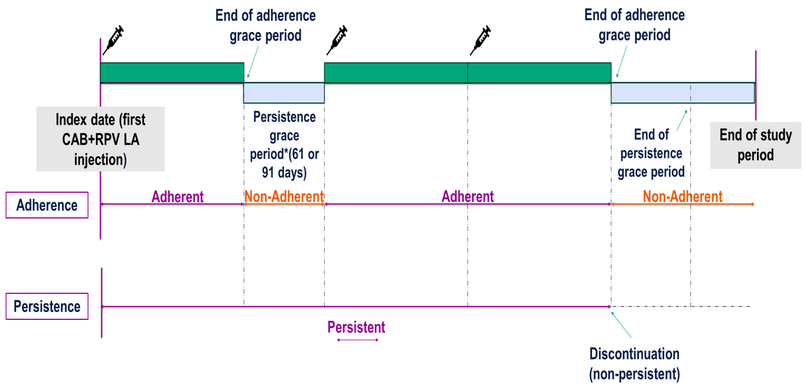
Introduction

- To maintain viral suppression and prevent HIV transmission, optimal adherence to antiretroviral therapy (ART) is required.[1,2,3]
- Persons living with HIV (PWH) continue to have suboptimal adherence to oral daily ARTs leading to treatment failure, increased risk of morbidity/mortality, decreased health-related quality of life, and substantial economic burden.[1,2,3]
- In a retrospective study of prescription data from 2010-2020, 44.7% of adult PWH in Canada had suboptimal adherence to oral ART.[3]
- Long-acting ART can benefit patients with adherence challenges due to side-effects and treatment burden (pill fatigue, pill aversion, or stigma).
- Cabotegravir/rilpivirine long-acting (CAB+RPV LA) injectable is the only complete long-acting regimen for virologically suppressed PWH, reducing dosing to 6 days (every 2 months dosing, Q2M) or 12 days (monthly dosing, Q1M) per year.
- This study evaluates real-world adherence and persistence to CAB+RPV LA among PWH who are enrolled in the Canadian CAB+RPV LA patient support program (PSP). The PSP navigates reimbursement pathways for patients with PSP nurses administering CAB+RPV LA. The program provide ongoing injection support and appointment reminders.

Methods

- A retrospective study of the CAB+RPV LA PSP data was conducted between 18/10/2022 and 30/05/2024 (interim analysis).

Figure 1. Adherence and Persistence Schematic



- For the Q1M and Q2M dosing for CAB+PPV LA, there is a +/- 7 days window between each injection (**adherence grace period**);
- The **persistence grace period** depends on the injection dosing after initiation injections: **Q1M persistence grace period is 61 days, Q2M is 91 days.**

- The CAB+RPV LA PSP contains demographic data, CAB+RPV LA therapy information (including optional oral lead-in and oral bridging), and discontinuation information for participants enrolled in the PSP.
- Participants in the CAB+RPV LA PSP (≥18 years of age) were followed from their first injection (index date) with the PSP to the interim data cut-off date (30/05/2024).
- Participants included those who enrolled in the CAB+RPV LA PSP and did not receive any CAB+RPV LA injection prior to enrolling in the PSP.
- Adherence is defined as proportion of days covered (PDC) ≥90%.

$$\textbf{\textit{Adherence}}\ (\%) = \frac{(\#of\ days\ covered\ by\ CAB/RPV\ LA\ +\ \#\ of\ days\ covered\ by\ oral\ bridge)}{total\ days\ in\ the\ period} \times 100$$

- PDC was calculated as the ratio of days covered by medication to the total days in the period.
- Persistence (duration of time from index date to discontinuation or end of analysis period) were evaluated for those with 365 days of follow-up from index date.

Results

- 629 eligible PWH were identified for this interim analysis (Table 1):
  - Age (mean ± SD): 46.5 ± 12.3 years; Male: 474 (75.4%);
  - Oral lead-in: 152 (24.2%);
  - ≥365 days of follow-up (**12-months cohort**): 233 (37%) PWH.

Table 1. Baseline Demographic Characteristics

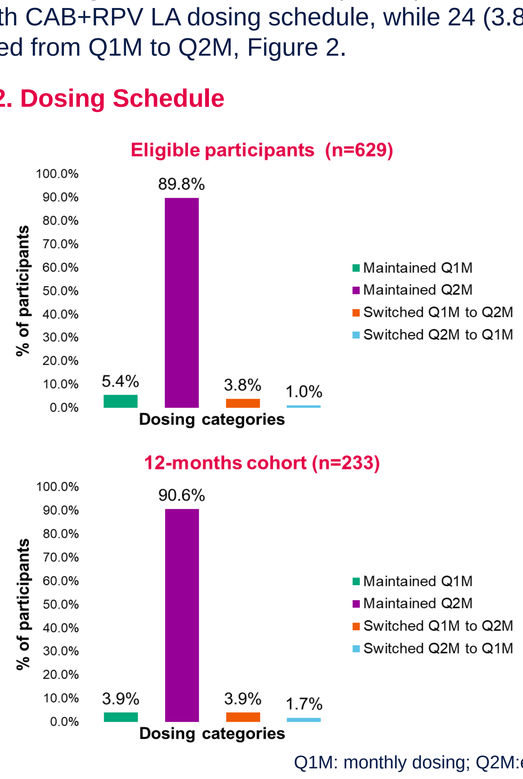
Baseline Characteristics	Eligible Participants (n=629)	12-months Cohort (n=233)
Age (years)		
Mean (SD)	46.5 (12.3)	46.3 (11.6)
≥50 years, n (%)	257 (40.9%)	92 (39.5%)
Min-Max	20-79	24-77
Male sex, n (%)	474 (75.4%)	183 (78.5%)
Province of patient		
Ontario, n (%)	348 (55.3%)	128 (54.9%)
Quebec, n (%)	257 (40.9%)	100 (42.9%)
Others, n (%)	24 (3.8%)	5 (2.2%)
Optional oral lead-in, n (%)	152 (24.2%)	73 (31.3%)
Time from index date to end of follow-up (days), median (IQR)	289 (163-423)	447 (414-499)

SD: standard deviation; IQR: interquartile range

CAB+RPV LA Dosing Schedule

- For the 629 eligible PWH, 565 PWH (89.8%) maintained a 2-month CAB+RPV LA dosing schedule, while 24 (3.8%) switched from Q1M to Q2M, Figure 2.

Figure 2. Dosing Schedule



Q1M: monthly dosing; Q2M:every 2 months

CAB+RPV LA Adherence (PDC)

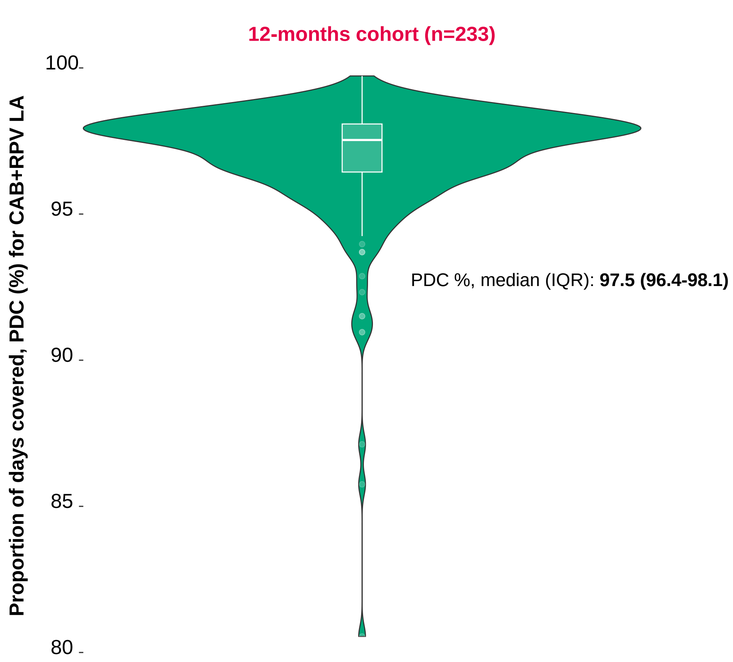
- The adherence analysis included participants who have 12-months of available follow-up time from index date (initiation injection) to the study period end date.
- 98.7% of the 233 PWH receiving CAB+RPV LA were adherent (PDC ≥90%) over a 365-day follow-up period (Table 2, Figure 3).
- The median (IQR) injections per participant through follow-up was 7 (7-7).
- Fewer than 5 persons received oral bridging.

Table 2. CAB+RPV LA Adherence (Proportion of Days Covered)

12-months Cohort (n=233)	
Adherence (PDC, %)	
Mean (SD)	97.0 (2.1)
Median (IQR)	97.5 (96.4-98.1)
Min-Max	80.6-99.7
≥80%, n (%)	233 (100.0%)
≥90%, n (%)	230 (98.7%)
90-94%, n (%)	18 (7.7%)
95-100%, n (%)	212 (91.0%)
Number of injections	
Mean (SD)	7.3 (1.1)
Median (IQR)	7 (7-7)
Min-Max	6-13

PDC: proportion of days covered; SD: standard deviation; IQR: interquartile range

Figure 3. Violin Plot Showing CAB+RPV LA Adherence



The violin plot visualizes the distribution and summary statistics of CAB+RPV LA adherence.

- 98.7% of the participants had PDC ≥90%.

CAB+RPV LA Persistence

- Of the 233 PWH with 365 days of follow-up, 95.3% of patients remained persistent through the 365-day analysis period, Table 3.
- 11 (4.7%) discontinued during the 365-day analysis period.

Table 3. Persistence to CAB+RPV LA

12-months Cohort (n=233)	
Persistent through 365 days, n (%)	222 (95.3%)
Discontinued during 365-day analysis period, n (%)	11 (4.7%)
0-30 days, n (%)	1 (0.4%)
62-91 days, n (%)	1 (0.4%)
92-122 days, n (%)	3 (1.3%)
123-152 days, n (%)	2 (0.9%)
153-182 days, n (%)	1 (0.4%)
183-213 days, n (%)	1 (0.4%)
305-334 days, n (%)	1 (0.4%)
335-365 days, n (%)	1 (0.4%)

Limitations

- The study results are limited to PWH who receive their injections from the CAB+RPV LA PSP.
- Pill counts of cabotegravir tablets, or any other oral ART dispensed to patients for oral bridges are not part of the PSP, and so the study assumes that patients are 100% compliant to the oral-bridge tablets based on the number of pills dispensed. This may bias adherence estimates upwards for patients with oral bridging however less than 5 persons received oral bridge in the 12-months cohort.

Conclusions

- High adherence and persistence to CAB+RPV LA were observed among Canadian PWH receiving their injections through the CAB+RPV LA PSP.
- Majority of participants were on CAB+RPV LA Q2M dosing.
- Long-acting injectables may improve adherence and persistence, potentially ensuring long-term treatment success with less frequent dosing.
- The adherence data from this study was based on actual CAB+RPV LA injection administered and not on prescription data.
- These results confirm prior studies from the US where CAB+RPV LA adherence and persistence have been reported to be high based on US administrative claims data.[4]

References:

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2. Cohen et al. *BMJ Open*. 2013;Volume 3, Issue 8.
3. Angel et al. *J Manag AIDS*. 2023;Volume 37, Issue 13: Page 2031-2040.
3. Garris et al. *Open Forum Infectious Diseases*. 2023;Volume 10, Issue Supplement 2: S32-S33.

Disclosures: Adenike Adelakun, Joann Ban, and Simbarashe Mhishi are employees of GlaxoSmithKline Inc. (GSK). Callahan LaForty, Ryan Ng, Bo Chen, Maria Esther Perez Trejo, and Lidija Latifovic are employed by IQVIA Solutions Canada Inc, which received consulting fees from the study sponsor to conduct this research.

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