Real-World Utilization of Cabotegravir/Rilpivirine Long-Acting Injectable: An Observational Analysis of Adherence and Persistence Using a Patient Support Program in Canada

Joann K. Ban, MSc;[1] Adenike Adelakun Omomia, MSc;[1] Callahan Laforty, MSc;[2] Ryan Ng, PhD;[2] Adeteju Ogunbameru, MSc;[1] Peyman Nakhaei, PhD;[3] Simbarashe Mhishi, MSc;[1] Arushi Sharma, BA;[2] Bo Chen, PhD;[2] Maria Esther Perez Trejo, PhD;[2] Lidija Latifovic, MSc;[2] Jean-Francois Fortin, PhD[3] (presenting author).

[1] GlaxoSmithKline Inc., Mississauga, Canada • [2] IQVIA Solutions Inc., Kirkland and Mississauga, Canada • [3] ViiV Healthcare ULC, Montreal, Canada

Please scan the QR code for a copy of the poster and additional resources

Key Takeaways

- **High adherence (94.9%) and persistence (96.8%) to cabotegravir/rilpivirine long-acting injectable (CAB+RPV LA) were observed among Canadian persons living with HIV (PWH) enrolled in the CAB+RPV LA Patient Support Program (PSP) over 12 months.**
- **Our findings demonstrate high adherence and persistence with long-acting antiretroviral therapy (ART), which is crucial for the maintenance of viral suppression. Additional support from a PSP may also contribute to successful treatment.**
- **Adherence and persistence were higher for individuals initiating on every 2-months dosing compared to every 1-month dosing of CAB+RPV LA suggesting that the reduced dosing frequency of long-acting injectables helps to overcome some adherence barriers.**
- **Higher adherence and persistence were observed in privately insured PWH compared to PWH with public coverage only.**

Introduction

- Achieving and maintaining virologic suppression in PWH requires consistently high levels of adherence to ART.[1-3]
- However, lifelong daily oral ART can be challenging due to structural, behavioral, and social barriers. In Canada, a retrospective analysis of prescription data from 2010–2020 found that 44.7% of adult PWH had suboptimal adherence (<95%) to oral ART.[3]
- Poor adherence is associated with increased risk of treatment failure, morbidity, mortality, reduced quality of life, and greater healthcare costs.[1-3]
- Long-acting injectable ART offers an alternative to daily oral regimens, reducing pill burden, dosing frequency, and stigma, while supporting patient preference for treatment administration.[6]
- CAB+RPV LA injectable therapy, approved in Canada in March 2020, is a complete long-acting regimen for virologically suppressed PWH.[4,5] Administered either monthly (Q1M) or every two months (Q2M), CAB+RPV LA reduces dosing days from 365 to 12 or 6 per year, respectively.[4,5] Clinical trials have demonstrated its efficacy and safety.[7,8]

Objective

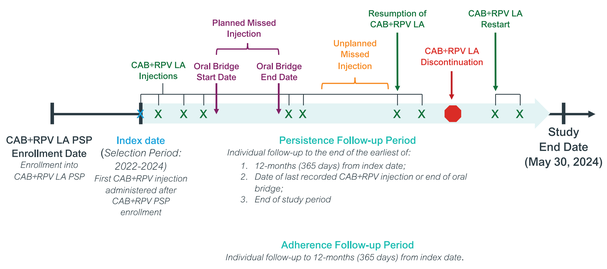
- This real-world study evaluated adherence and persistence to CAB+RPV LA among Canadian PWH enrolled in the CAB +RPV Supports Program, providing insights into treatment patterns outside of clinical trial settings.

Methods

Study Design:

- A retrospective cohort study was conducted using data from the CAB + RPV LA PSP (Figure 1).
- PWH, 18 years or older, initiating their first dose of CAB+RPV LA within the CAB+RPV LA PSP were identified between 18/10/2022 and 30/05/2024.
- PWH were followed from first injection (index date) up to 12 months with censoring at PSP opt-out or study end (Figure 2).

Figure 1. Study Design Overview



CAB+RPV LA Support Program:

- The PSP navigates reimbursement pathways for PWH with PSP nurses administering CAB+RPV LA and provides ongoing case management.
- The Case Report Management database of the CAB+RPV LA PSP contains demographic, CAB+RPV LA therapy (including optional oral lead-in and oral bridging), and discontinuation information for participants enrolled in the PSP.
- The data is recorded at the time of enrollment, at each CAB+RPV LA injection visit (injection dates are recorded at the time of injection), and at discontinuation.

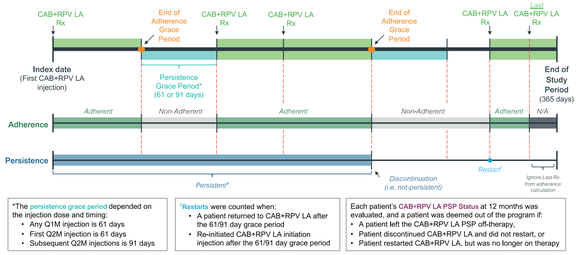
Outcomes:

- Baseline characteristics were assessed at time of CAB+RPV LA initiation.
- Adherence, defined as proportion of days covered (PDC), was calculated as the ratio of days covered by medication (CAB+RPV LA or oral bridge) to the total days in the period at 12 months follow-up.

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

- Persistence was measured as days to discontinuation from index date and assessed using Kaplan-Meier analysis with censoring at date of last recorded injection / oral bridge or end of 12-month follow-up.
- Fisher's exact and log-rank tests were used to estimate p-values for stratified analyses.

Figure 2. Adherence and Persistence Schematic



*The persistence grace period depended on the injection dose and timing:
- Any Q1M injection is 61 days
- First Q2M injection is 61 days
- Subsequent Q2M injections is 91 days

†Restarts were counted when:
- A patient returned to CAB+RPV LA after the 61/91 day grace period
- Re-initiated CAB+RPV LA initiation injection after the 61/91 day grace period

Each patient's CAB+RPV LA PSP Status at 12 months was evaluated, and a patient was deemed out of the program if:
- A patient left the CAB+RPV LA PSP off-therapy,
- Patient discontinued CAB+RPV LA and did not restart, or
- Patient restarted CAB+RPV LA, but was no longer on therapy

- The allowable grace period for persistence depended on the dosing schedule following initiation injections:
  - Q1M grace period was 61 days
  - Q2M grace period was 91 days
- From the dosing of CAB+RPV LA, there was a +/- 7 days window between each injection (adherence grace period)

Results

- Of the 628 PWH who initiated CAB+RPV LA in the PSP, 431 (68.6%) had 12 months of follow-up:
  - Mean age: 46.6 years [SD 12.3]
  - 76.1% male
  - 53.8% reside in Ontario
  - 59.6% have public insurance
  - 87.5% were on prior single-tablet ART
  - 33.2% were taking bictegravir/emtricitabine/tenofovir alafenamide
  - 91.6% on Q2M dosing

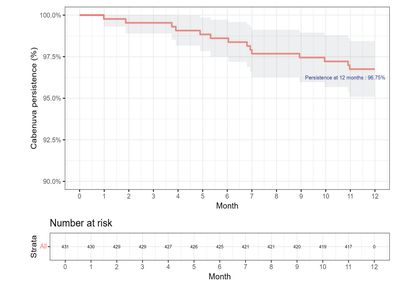
Table 1. Baseline Characteristics of PWH in CAB+RPV LA PSP.

Baseline characteristics	Eligible participants (N=628)	Minimum 12-month follow-up (N=431)
Age (years)		
Mean (SD)	46.4 (12.3)	46.4 (12.3)
≥ 50 years, n (%)	256 (40.8%)	179 (41.5%)
Min-Max	20-79	20-79
Male sex, n (%)	473 (75.3%)	328 (76.1%)
Ontario, n (%)	347 (55.3%)	232 (53.8%)
Quebec, n (%)	257 (40.9%)	185 (42.9%)
Other Provinces, n (%)	24 (3.8%)	14 (3.2%)
Public insurance, n (%)	394 (62.7%)	257 (59.6%)
Prior single-tablet ART, n (%)	551 (87.7%)	377 (87.5%)
Prior ART was bictegravir, emtricitabine, tenofovir alafenamide, n (%)	232 (36.9%)	143 (33.2%)
Initiated Q2M dose, n (%)	555 (88.4%)	395 (91.6%)

SD: standard deviation, ART: antiretroviral therapy, Q2M: every 2-months dosing

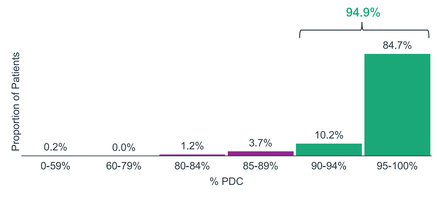
- At 12-months follow-up, 96.8% (417/431) were persistent (Figure 3) and 94.9% (409/431) had adherence rates ≥90% (PDC) (Figure 4).

Figure 3. Kaplan-Meier Curve of Persistence at 12 Months Follow-Up for Canadian PWH Enrolled in the CAB+ RPV LA PSP



Footnote: Number at risk =0 at month 12 as persistence was capped at 365 days, so all patients were either discontinued or censored by day 365, leaving no patients 'at risk'.

Figure 4. CAB+RPV LA Adherence (PDC) at 12 Months Follow-up



- Persistence was significantly higher for PWH who had private insurance than those who were covered by public insurance only (99.4% vs. 94.9%, p<0.01, Figure 5). Similarly, PWH with private insurance had significantly higher adherence than those with public insurance (PDC ≥90%: 99.4% vs. 91.8%, p<0.001) (Figure 6).

Figure 5. Kaplan-Meier Curve of Persistence Stratified by Insurance Type at 12 Months of Follow-Up for Canadian PWH Enrolled in the CAB+RPV LA PSP

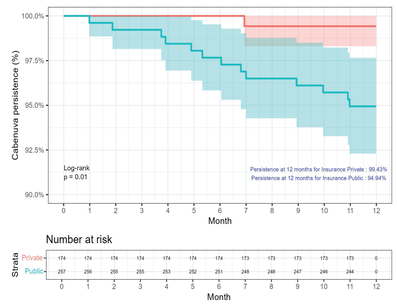
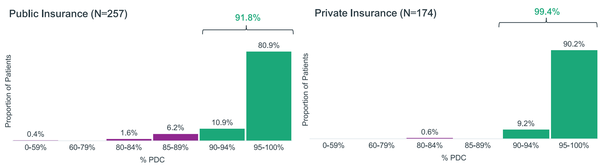
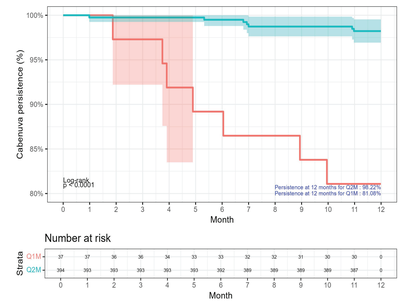


Figure 6. CAB+RPV LA Adherence (PDC) at 12 Months Follow-Up Stratified by Insurance Type



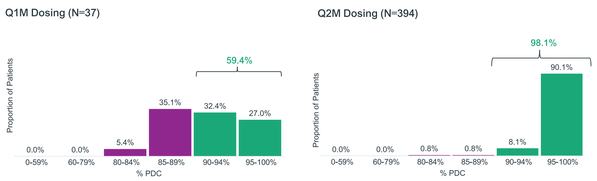
- PWH who initiated therapy on Q2M dosing had significantly higher persistence than those who initiated Q1M dosing (98.2% vs. 81.1%, p<0.0001, Figure 7). Adherence was also higher for PWH on Q2M dosing than PWH on Q1M dosing (PDC ≥90%: 98.2% vs. 59.5%, p<0.001, Figure 8). A high percentage (62.2%) of patients who initiated on Q1M dosing switched to Q2M at some point during follow-up.

Figure 7. Kaplan-Meier Curve of Persistence Stratified by Initiating Dose at 12 Months of Follow-Up for Canadian PWH Enrolled in the CAB+RPV LA PSP



Footnote: Number at risk =0 at month 12 as persistence was capped at 365 days, so all patients were either discontinued or censored by day 365, leaving no patients 'at risk.' There were 257 PWH with public insurance and 174 with private insurance.

Figure 8. CAB+RPV LA Adherence (PDC) at 12 Months Follow-Up Stratified by Initial Dose



- Most PWH initiated CAB+RPV LA on Q2M dosing. While the percentage of PWH with PDC ≥90% was lower among those who initiated on Q1M dosing, this difference should be interpreted with caution due to disparity in sample sizes.
- The Q1M group had a smaller sample size and included a high percentage of patients who later switched to Q2M dosing (62.2%). Among those who switched, 30.4% experienced a late Q2M injection following the transition.
- Importantly, across both groups, 99.7% of PWH achieved a PDC ≥80%, indicating overall high adherence to CAB+RPV LA therapy as compared to historical data with oral medication in PWH.[3]

Limitations

- Findings are limited to PWH enrolled in the CAB+RPV LA PSP. It remains uncertain whether similarly high rates of adherence and persistence would be observed in populations outside of the PSP. As such, it is difficult to disentangle the effects of the long-acting regimen itself from the structured support provided by the PSP.
- The PSP does not capture pill counts for oral cabotegravir or other ART used during oral bridging. Adherence during this period was assumed to be 100% based on pills dispensed, which may overestimate adherence. However, this likely had a minimal impact, as fewer than five individuals received an oral bridge at 12 months follow-up.

Discussion

- Real-world data from the CAB+RPV LA PSP aligns with prior studies (e.g., the ABOVE study[8]) demonstrating high adherence and persistence on long-acting ART.
- Adherence and persistence were higher with Q2M dosing and among those with private insurance, suggesting that longer dosing intervals and stable coverage may support treatment continuity potentially due to faster access and more stable provider relationships.
- These findings reflect outcomes among PSP-enrolled individuals; further research is needed to determine whether similar outcomes hold outside of structured support programs.

Conclusion

- Real-world data from the CAB+RPV LA PSP confirms high adherence and persistence among PWH, consistent with the ATLAS and FLAIR clinical trials.[7,8] These findings highlight the value of long-acting ART, especially for those struggling with daily oral regimens.

Acknowledgements: We gratefully acknowledge the contributions of PWH enrolled in the CAB+RPV LA PSP for their participation in this research.

Disclosures

Adeteju Ogunbameru, Adenike Adelakun Omomia, Joann Ban, and Simbarashe Mhishi are employees of GlaxoSmithKline Inc. (GSK) and may hold stocks with GSK. Peyman Nakhaei and Jean-Francois Fortin are employees of ViiV Healthcare ULC. Callahan LaForty, Ryan Ng, Arushi Sharma, 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.

References:

1. Glass et al. *Antiviral therapy*. 2008; Volume 13, Issue: p77-85
2. Cohen et al. *BMJ Open*. 2013; Volume 3, Issue 8
3. Angel et al. *J Manag AIDS*. 2023; Volume 37, Issue 13: p2031-2040
4. Cabotegravir/rilpivirine Product Monograph. ViiV Healthcare ULC. Last updated: June 15 2022
5. Overton et al. *Lancet*. 2021; Volume 396, Issue 10267: p1994-2005
6. Scarsi KK, Swindells S. *J Int Provid AIDS Care*. 2021; 2021;20:2325958221109011
7. Orkin et al. NEJM. 2020; Volume 382. Issue 12 : p1124-1135
8. Swindells et al. NEJM. 2020; Volume 382, Issue 12 : p 1112-1123
9. Garris et al. *Open Forum Infectious Diseases*. 2023; Volume 10, Issue Supplement 2: S32-S33

Presenting author: Jean-Francois Fortin; jean-francois.x.fortin@viivhealthcare.com

Disclaimer

This content was acquired following an unsolicited medical information enquiry by a healthcare professional. Always consult the product information for your country, before prescribing a ViiV medicine. ViiV does not recommend the use of our medicines outside the terms of their license. In some cases, the scientific Information requested and downloaded may relate to the use of our medicine(s) outside of their license.