Perspectives of People With HIV 6 Months Following a Switch to Cabotegravir and Rilpivirine Long-Acting (CAB+RPV LA) in an Observational Real-World US Study (BEYOND)

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Key Takeaways

- **The proportion of people with HIV (PWH) who switched to CAB+RPV LA in a real-world setting reporting fear of HIV status disclosure, adherence anxiety, and feeling reminded of HIV decreased from baseline to Month 6 (M6)**
- **PWH strongly preferred CAB+RPV LA over oral therapy, reported increased treatment satisfaction, and felt more engaged with their HIV care**
- **Overall, patient-reported outcomes from real-world use of CAB+RPV LA treatment in a US-based population are consistent with clinical study and early real-world experience results**

Introduction

- CAB+RPV LA is the first complete long-acting regimen for virologically suppressed adult PWH[1] that is recommended by treatment guidelines[2,3] and demonstrated non-inferiority to daily oral ART in phase III/IIIb studies[4-7]
  - Administered monthly or every 2 months by a healthcare provider (HCP), CAB+RPV LA may alleviate challenges associated with daily oral ART
- Participants in a recent randomized phase IIIb study (SOLAR)[6] and in a prospective real-world evidence (RWE) study (CARLOS)[8] in Germany reported significant improvement in treatment satisfaction after switching to CAB+RPV LA
- RWE data have been published on 1155 people globally, including 785 people in the United States, who have received CAB+RPV LA, but RWE from the patient perspective is not widely available
- BEYOND is one of the first US-based RWE studies evaluating the use of CAB+RPV LA; here we present patient-reported outcomes of adult PWH at baseline (BL) and at the M6 interim analysis after initiating CAB+RPV LA

Methods

- The prospective BEYOND study is an ongoing 2-year observational study of PWH initiating CAB+RPV LA (monthly or every 2 months) across 27 US sites
- Eligible participants were adults ≥18 years of age initiating CAB+RPV LA treatment per HCP decision, without prior CAB+RPV LA experience
- Before the first injection at BL and at M6 follow-up, participants completed surveys about reasons for initiating CAB+RPV LA, challenges with daily oral ART, ART preference, and perceived benefits of more frequent clinic visits
- Participants completed the Internalized AIDS-Related Stigma Scale (IA-RSS; to evaluate feelings of stigma experienced during the duration of the study) and the status version of the HIV Treatment Satisfaction Questionnaire (HIVTSQ) at BL and M6
  - IA-RSS scores range from 0 to 6, with higher scores representing greater internalized feelings of stigma
  - HIVTSQ scores range from 0 to 66, with higher scores representing greater treatment satisfaction

Results

Participants

- A total of 308 participants were enrolled and competed BL surveys; median age was 45 years, 83% identified as male, and 48% and 39% identified as White or Caucasian and Black or African American, respectively (Table)
- The most common HCP-reported relevant social determinants of health were comorbidities (23% [70/308]), adherence issues (19% [58/308]), and mental health issues (15% [47/308])

Reasons for Initiating CAB+RPV LA

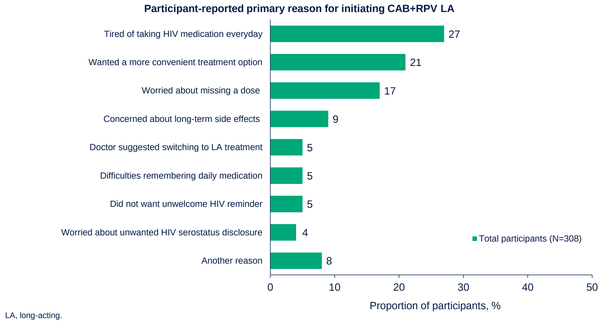
- The primary reasons why participants reported initiating CAB+RPV LA included: being tired of taking daily oral ART (27% [84/308]), wanting a more convenient treatment option (21% [63/308]), and being worried about missing a dose (17% [52/308]; Figure 1)

Table. Baseline Characteristics and Demographics of Participants Initiating CAB+RPV LA

Characteristic	Total participants (N=308)
Age, n (%)	
Median (range), years	45 (18, 80)
18 to <26	13 (4)
26 to <50	174 (57)
≥50	121 (39)
Gender identity, n (%)	
Male	256 (83)
Female	40 (13)
Transgender woman	5 (2)
Transgender man	1 (<1)
Non-binary	6 (2)
Race, n (%)[a]	
White or Caucasian	147 (48)
Black or African American	119 (39)
Native American, American Indian, or Alaska Native	19 (6)
Other race[b]	40 (13)
Prefer not to answer	14 (5)
Ethnicity, n (%)	
Hispanic/Latinx	68 (22)
Non-Hispanic/Latinx	220 (71)
Prefer not to answer	20 (7)
Time since initiation of first ART[c]	
Median (range), years	9.9 (0.1, 35.7)
HCP-reported relevant social determinants of health (last 5 years to present, >5%), n (%)[a]	
Comorbidities	70 (23)
Adherence issues	58 (19)
Mental health issues	47 (15)
Polypharmacy/multiple medications	44 (14)
Health insurance issues or changes	33 (11)
Substance use (eg, injection drug use, alcohol abuse)	30 (10)
Affordability of HIV medications	22 (7)
Job instability	19 (6)
Homelessness/unstable living conditions	19 (6)
Difficult work and/or family schedule	18 (6)

HCP, healthcare provider; LA, long-acting.
[a]Not mutually exclusive. [b]Asian (n=8), Native Hawaiian or other Pacific Islander (n=3), race(s) not listed (n=29). [c]n=302, missing data for 6 participants.

Figure 1. Participant-Reported Primary Reason for Initiating CAB+RPV LA

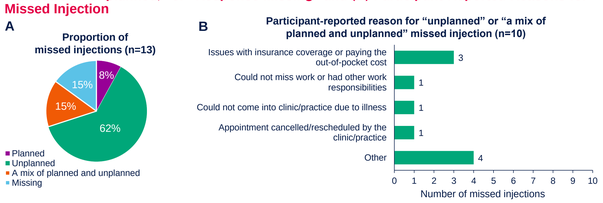


LA, long-acting.

Participant-Reported Adherence and Discontinuations

- At initiation of CAB+RPV LA, 52% (161/308) and 48% (147/308) of participants were scheduled to receive injections monthly and every 2 months, respectively
- At the time of data cut-off, 217 of 308 (70%) participants had reached M6 follow-up and completed surveys, and 8 (4%) completed surveys but had discontinued CAB+RPV LA
  - Reasons for discontinuation were injection pain (4/8), feeling that CAB+RPV LA did not control their HIV (1/8), and "another reason" (3/8)
- Only 13 (6%) of 217 participants reported missing an injection, with insurance issues or treatment cost as the primary reason for missing an injection (Figure 2)

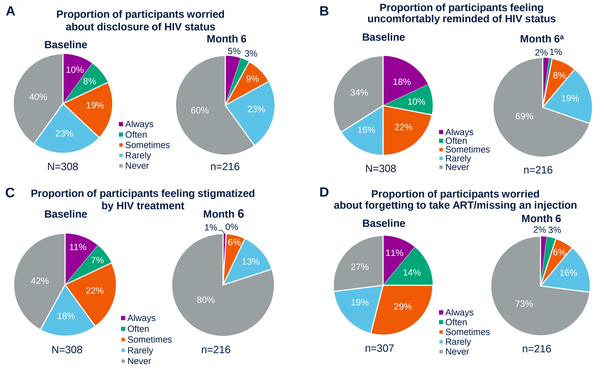
Figure 2. Proportion of Missed Injections That Were (A) "Planned," "Unplanned," "A Mix of Planned and Unplanned," or "Response Missing" and (B) Participant-Reported Reasons for Missed Injection



Experiences With ART Before and 6 Months After Initiating CAB+RPV LA

- The proportion of participants that reported often/always being worried about unintentional disclosure of their HIV status because of their treatment decreased from 18% (56/308) at BL to 7% (16/216) at M6 (Figure 3A)
- The proportion of participants that felt taking their HIV medication was an uncomfortable reminder of their HIV status decreased from 28% (86/308) at BL to 3% (7/216) at M6 (Figure 3B)
- A higher proportion of participants reported "never" to the question "In the past 6 months, how often did receiving treatment make you feel stigmatized?" at M6 (80% [172/216]) compared with BL (42% [130/308]; Figure 3C)
  - Participant-reported stigma, as measured by mean (SD) IA-RSS scores, remained stable over 6 months (BL, 2.6 [2.1]; M6, 2.3 [2.1])
- The proportion of participants concerned about forgetting to take ART was 25% (77/307) at BL. At M6, only 5% (10/216) were concerned about missing an injection (Figure 3D)
- Notably, the proportion of participants concerned with side effects or long-term effects of CAB+RPV LA injections, with treatment impact on viral load and/or CD4+/T cell count, and with scheduling to accommodate visits decreased from 42% (129/308), 32% (98/308), and 19% (57/308) at BL to 22% (46/206), 14% (28/206), and 11% (23/206) at M6, respectively (Figure 4)
- Treatment satisfaction, as measured by mean (SD) HIVTSQ scores, improved from BL to M6 (+6.0 [11.5]; n=207)

Figure 3. Proportion of Participants (A) Worried About Disclosure of Their HIV Status, (B) Feeling Reminded of Their HIV Status Because of Their Treatment, (C) Feeling Stigmatized by HIV Treatment, and (D) Worried About Forgetting to Take ART/Missing an Injection at BL and M6

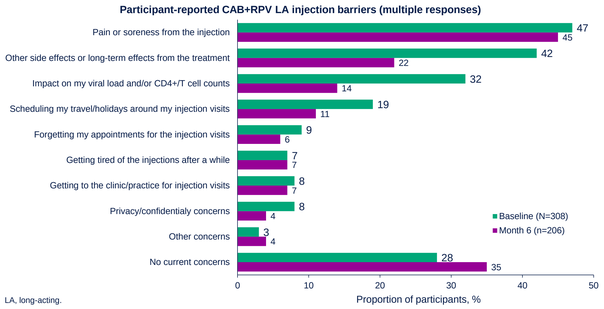


[a]After rounding to whole numbers, Month 6 proportions add to 99%. BL, baseline; M6, month 6.

Participant Preferences at M6

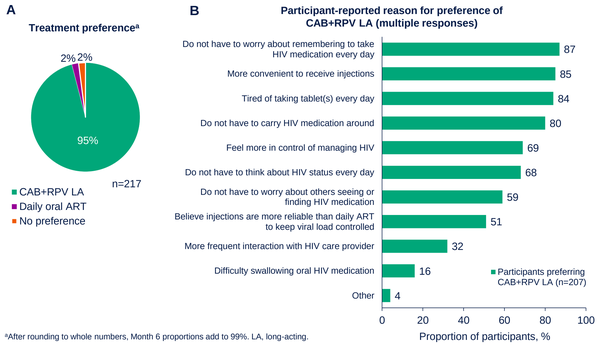
- Most participants preferred CAB+RPV LA (95% [207/217]); 2% (5/217) preferred daily oral ART and 2% (5/217) had no preference at M6 (Figure 5A)
- Top reasons for preferring CAB+RPV LA at M6 included "not having to worry about remembering to take HIV medication" (87% [181/207]), "convenience" (85% [176/207]), and being "tired of taking tablet(s) every day" (84% [173/207]; Figure 5B)
- Of the 5 participants that preferred daily oral ART at M6, 100% reported wanting to avoid injection pain and/or injection side effects

Figure 4. Participant-Reported Barriers to CAB+RPV LA Injections



LA, long-acting.

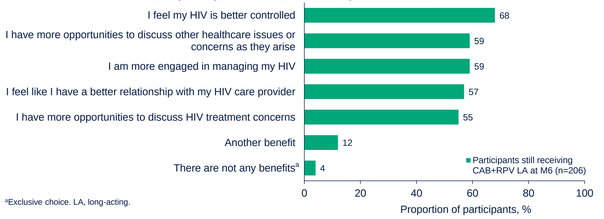
Figure 5. (A) Participant-Reported Treatment Preference and (B) Reasons for Preferring CAB+RPV LA at M6



[a]After rounding to whole numbers, Month 6 proportions add to 99%. LA, long-acting.

Figure 6. Benefits of More Frequent Clinic Visits

- At M6, most participants reported multiple benefits with more frequent clinic visits (Figure 6)



[a]Exclusive choice. LA, long-acting.

Conclusions

- In the BEYOND study, PWH living in the United States initiated CAB+RPV LA primarily because they were tired of taking daily oral ART
- The proportion of PWH receiving CAB+RPV LA reporting fear of HIV status disclosure, anxiety around adherence to treatment, feeling reminded about HIV, and feeling stigmatized by HIV treatment decreased from BL to M6
- At M6, most PWH preferred treatment with CAB+RPV LA, had improved treatment satisfaction, and reported fewer barriers to injections and multiple benefits with more frequent clinic visits

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