Patient-Reported Outcomes Following Switch to Long-Acting Cabotegravir + Rilpivirine in Nordic Clinical Care: Results From the VALHALLA Study

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Key Takeaways

- **The VALHALLA study assessed participant-reported outcomes in people with HIV-1 in the Nordics who switched from daily oral antiretroviral therapy (ART) to long-acting cabotegravir plus rilpivirine (CAB+RPV LA) injections dosed 6 times a year**
- **After switching to CAB+RPV LA, fewer participants reported negative impacts on daily life and more participants felt positive about themselves and their HIV diagnosis**
- **Participants reported a positive change in treatment satisfaction versus prior oral ART, driven by greater convenience and lifestyle fit, and 95% preferred to remain on CAB+RPV LA, supporting the treatment as a switch option that addresses daily oral ART burden**

Plain Language Summary

- VALHALLA was a real-world study of people with HIV in the Nordics who switched from daily oral HIV treatment to injections of cabotegravir plus rilpivirine given 6 times a year
- While many people with HIV were satisfied with daily treatment, some participants reported challenges such as hiding their medication (38%) or being regularly reminded of their HIV status (30%)
- After switching to long-acting injections, fewer people reported treatment-related concerns and reminders of HIV, and more people reported positive feelings about themselves and their diagnosis
- People were also more satisfied with the injections than with daily pills, mainly because it fit their lifestyle, and most chose to continue treatment with the injections

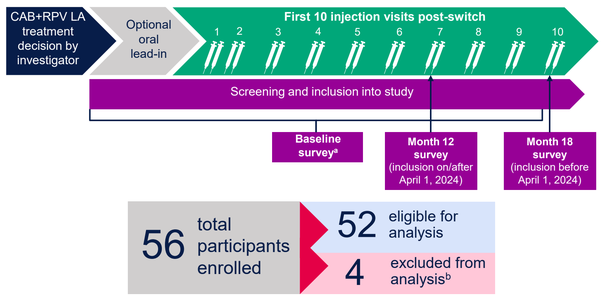
Introduction

- Daily oral antiretroviral therapy (ART) may be associated with treatment reminders, stigma, and psychosocial burden[1]
- Injectable long-acting intramuscular cabotegravir plus rilpivirine (CAB+RPV LA) is the first and only complete regimen for people with HIV who have a suppressed viral load that is recommended by treatment guidelines[2-7]
- CAB+RPV LA offers an alternative mode of administration with less frequent dosing than daily oral ART[2-4] with trial evidence demonstrating improvement in quality of life for people with HIV while continuing to suppress their viral load[8]
- Real-world data on patient-reported experiences following a switch to CAB+RPV LA remain valuable
- Here, we report patient-reported outcomes, including switch motivations and treatment satisfaction after switch to CAB+RPV LA in routine clinical care

Methods

- VALHALLA was a prospective/retrospective, non-interventional, single-arm, multicenter study conducted in Denmark, Sweden, and Finland (Figure 1)
- Adults with HIV-1 who had a suppressed viral load (HIV-1 RNA <50 c/mL) and had switched to CAB+RPV LA were included
  - Participants were enrolled at any time between decision to switch (prospective) and their injection 10 visit (retrospective)
- Participants completed surveys collected at baseline and follow-up at injection 7 (Month 12) or injection 10 (Month 18); these surveys included completion of the HIV Treatment Satisfaction Questionnaire status and change versions (HIVTSQs and HIVTSQc, respectively)
  - HIVTSQs was completed at baseline and follow-up; the score was the sum of 11 items (scored from 0 to 6) totaling between 0-66, with higher scores indicating greater treatment satisfaction
  - HIVTSQc was completed at follow-up only and assessed change in overall treatment satisfaction relative to prior oral ART (scored from −3 [greatest deterioration] to +3 [greatest improvement] per item)
  - The patient-reported outcome instruments used were the most appropriate available at study inception, having been developed with people with HIV-1 and their clinicians to capture psychosocial impact and engagement in care
- The primary outcome was participants' main reason for switching to CAB+RPV LA
  - Secondary outcomes included participant demographics; healthcare professional (HCP) perspectives on switch; virologic outcomes; and participant perspectives on prior oral ART, impact of ART on daily life, and treatment satisfaction
- For participant-reported and virologic outcomes, pooled injection 7 and 10 data are reported

Figure 1. VALHALLA Study Design



[a]Baseline survey was provided to participants upon inclusion into study, between a participant's decision to switch and injection 10. [b]Reasons for exclusion included inclusion/exclusion criteria (n=2), identification error (n=1), and withdrawal of consent (n=1).

Results

Participant Demographics

- Of 52 participants from 9 centers, 50 completed baseline survey and 39 completed follow-up surveys
- The study population was predominantly male with extensive prior ART experience (Table 1)

Table 1. Demographics and Baseline Characteristics

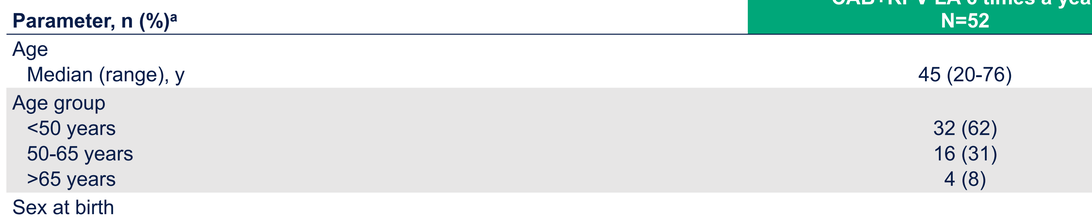
Parameter, n (%)[a]	CAB+RPV LA 6 times a year N=52
Age	
Median (range), y	45 (20-76)
Age group	
<50 years	32 (62)
50-65 years	16 (31)
>65 years	4 (8)
Sex at birth	
Male	39 (75)
BMI	
≥30 kg/m^2	8 (20)[b]
Baseline resistance test	
Current or historical genotypic resistance test available	34 (65)
HIV subtype (reported by ≥2 participants)	
B	19 (37)
C	4 (8)
A/A-recombinant (A, A2, CRF01_AE, CRF02_AG)[a]	9 (17)
Other/Unknown[c]	20 (38)
HIV history	
Time since year of first HIV-1 diagnosis, median (IQR), y	14 (5-18)
Time since first ART,[d] median (IQR), y	12 (5-16)
Number of prior ART regimens before CAB+RPV LA, median (IQR)	4 (2-6)
ART regimen before switch (reported by ≥10% of participants)	
BIC/FTC/TAF	11 (21)
DTG/3TC	11 (21)
DTG+FTC/TDF	7 (14)

BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; IQR, interquartile range; TAF, tenofovir alafenamide; 3TC, lamivudine; TDF, tenofovir disoproxil fumarate. [a]No A1/A6 subtype was reported (only reported for 34 participants). [b]Percentage out of participants with available data (missing data, n=12). [c]Includes 1 participant with subtype D. [d]Time was calculated from year of first ART start to year of LA treatment start (oral lead-in start, or if skipped, first injection).

Challenges With Daily Oral ART Reported at Baseline

- Daily oral ART was associated with both psychosocial and practical challenges, particularly around treatment visibility, reminders of HIV status, and maintaining a daily routine (Figure 2)

Figure 2. Participant-Reported Challenges[a] With Prior Daily Oral ART

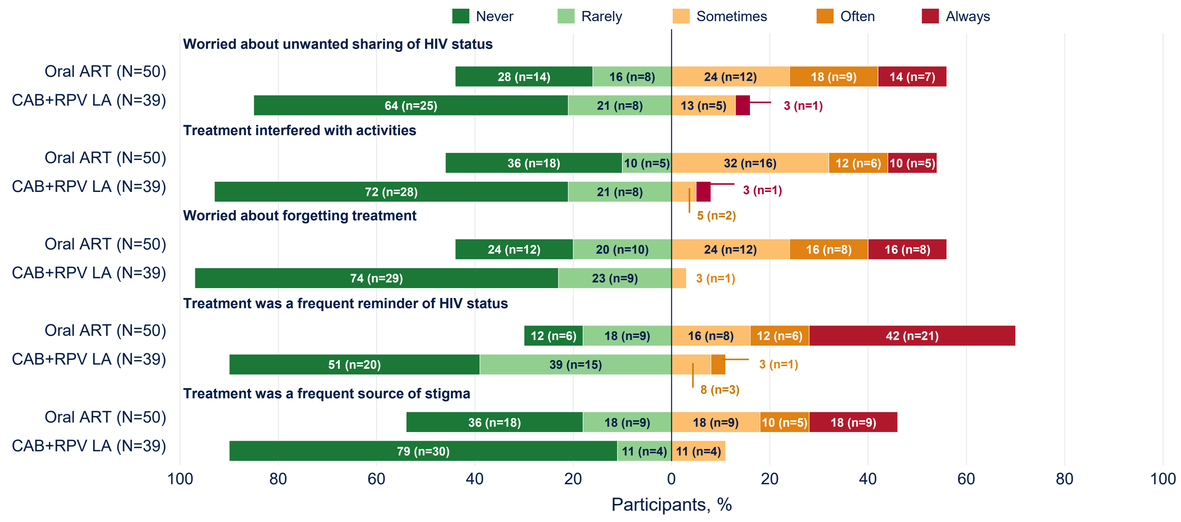


[a]Individual participants could select multiple options except for those who selected "no problems reported.

Daily Experience Before and After Switch to CAB+RPV LA

- Across every domain assessed, the proportion of participants who reported frequent negative impacts decreased greatly after switching from daily oral ART to CAB+RPV LA, with most participants stating "never" or "rarely" experiencing these burdens (Figure 3)
  - Participants receiving CAB+RPV LA were far less likely to see treatment as a source of stigma, to worry about unwanted disclosure of their HIV status, or to feel treatment interfered with their daily activities

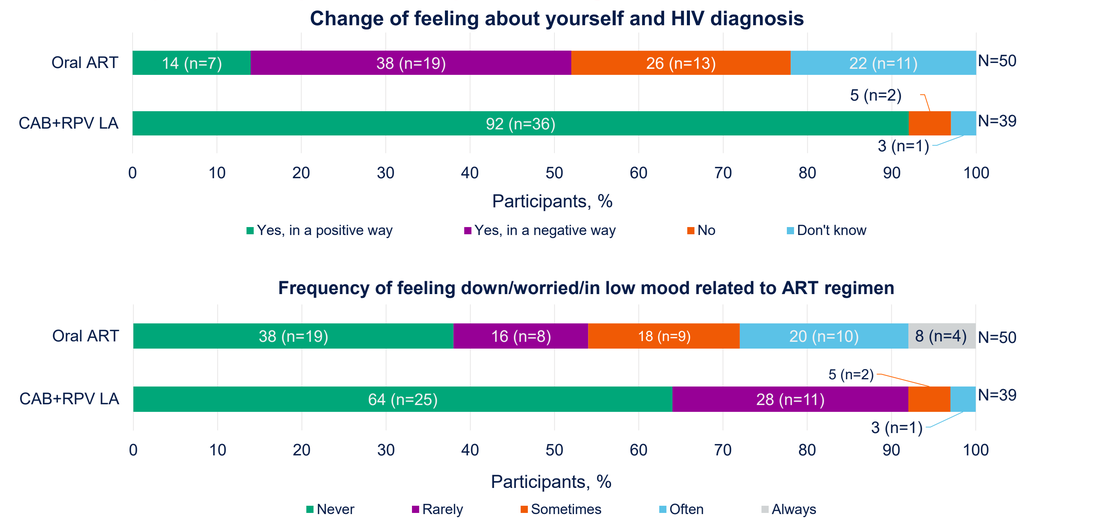
Figure 3. Impact of Daily Oral ART and CAB+RPV LA on Daily Life Before and After Switching to CAB+RPV LA



Treatment Impact on Self-Perception, HIV Diagnosis, and Mood

- On daily oral ART, few participants felt treatment had a positive impact on how they saw themselves and their HIV diagnosis; however, after switching to CAB+RPV LA, nearly all participants reported a positive change in self-perception as well as HIV diagnosis (Figure 4)
  - Frequently feeling down, worried, or low because of the treatment regimen was far less common after switching, and most (64%) participants reported never experiencing them

Figure 4. Treatment Impact on Participant Self-Perception, HIV Diagnosis, and Mood



Treatment Satisfaction and Preference

- Treatment satisfaction was high before and after switch; in paired assessment of HIVTSQs total score (n=12), mean (SD) score changed by +6.5 points from baseline (55.4 [11.4] points) to follow-up (61.9 [5.1] points) driven mainly by treatment "convenience" and "lifestyle fit" (Figure 5A)
- Because baseline satisfaction left limited room for increase on the HIVTSQs, the HIVTSQc was used to capture perceived change relative to prior oral ART. The mean (SD) HIVTSQc total score (n=39) change was +28.1 (5.9), indicating a strongly positive perceived change in treatment satisfaction that was primarily driven by high satisfaction with continuing current treatment
- At follow-up, 95% (37/39) of participants reported they preferred to remain on CAB+RPV LA, with none preferring to revert to oral ART; the remaining 2 participants were unsure or declined to answer
  - The majority primarily preferred CAB+RPV LA because it better suited their lifestyle (Figure 5B)

Figure 5. (A) Treatment Satisfaction per HIVTSQs (n=12) and (B) Primary Reasons for Treatment Preference (n=37)

[a]HIVTSQs total score computed based on items 1-11; range per item 0-6, where 0 = "very dissatisfied" and 6 = "very satisfied." Positive changes indicate improvement.

Virologic Outcomes on CAB+RPV LA

- At follow-up, 85% (44/52) of participants had suppressed viral load (HIV-1 RNA <50 c/mL); of the remaining 8 participants, 5 discontinued CAB+RPV LA and 3 were using CAB+RPV LA but did not have a reading during the window
  - Reasons for discontinuation included intolerability (n=1), virologic reasons (HIV-1 RNA ≥50 c/mL; n=2), and other reasons (n=2)
- Using the last observation carried forward (N=52), 96% (50/52) of participants had suppressed viral load and 2 discontinued due to virologic reasons
- Both participants discontinued for virologic reasons had previously received dolutegravir-based regimens
  - One of these participants had baseline resistance-associated and/or polymorphic mutations across multiple drug classes (nucleoside reverse transcriptase inhibitor: A62V; protease: M36I, H69K, T74P, L89M; and integrase: L74I)

Conclusions

- In this real-world study, daily oral ART was associated with psychosocial and lifestyle burdens, including treatment reminders, stigma, and concerns about inadvertent disclosure of HIV status
- After switching to CAB+RPV LA, participants reported improvements in treatment satisfaction and several aspects of daily life
- Most participants preferred CAB+RPV LA over their previous daily oral ART regimen
- These findings highlight the importance of incorporating participant-reported outcomes and treatment preferences into individualized HIV care

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References: 1. de Los Rios et al. *AIDS Behav*. 2021;25:961-972. **2.** Vocabria [summary of product characteristics]. ViiV Healthcare; 2025. **3.** Rekambys [summary of product characteristics]. ViiV Healthcare; 2025. **4.** Cabenuva [prescribing information]. ViiV Healthcare; 2025. **5.** European AIDS Clinical Society. https://eacs.sanfordguide.com. Accessed May 7, 2026. **6.** British HIV Association. https://bhiva.org/clinical-guideline/hiv-1-treatment-guidelines/. Accessed September 9, 2026. **7.** Department of Health and Human Services. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new. Accessed September 9, 2026. **8.** Vinay et al. *HIV Med*. 2025;26:1343-1355.

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