Patient-Reported Burden of Daily Antiretroviral Therapy and the Lived Experience of Switching to Cabotegravir + Rilpivirine Long-Acting: Mixed-Methods Findings From the VOLITION Trial

P076

Cassidy A. Gutner,[1] Ian Jacob,[2] Julie Priest,[1] Rekha Trehan,[2] Anoushka Dugal,[3] Avishek Chatterjee,[3] Kehui Wang,[4] Miguel Pascual-Bernaldez,[5] Patricia de los Rios,[6] Monika Bui,[3] Kai Hove,[2] Cheryl McDonald,[7] Mezgebe Berhe,[8] Jean van Wyk,[2] Bryn Jones[2]

[1]ViiV Healthcare, Durham, NC, USA; [2]ViiV Healthcare, London, UK; [3]GSK, London, UK; [4]GSK, Collegeville, PA, USA; [5]ViiV Healthcare, Madrid, Spain; [6]ViiV Healthcare, Montreal, QC, Canada; [7]Tarrant County Infectious Diseases Associates, Fort Worth, TX, USA; [8]North Texas Infectious Diseases Consultants, Dallas, TX, USA

Please scan the QR code for additional resources

Key Takeaways

- **Lifestyle fit and freedom from daily pills were key motivations for participants with HIV who were naive to treatment choosing long-acting cabotegravir plus rilpivirine (CAB+RPV LA) in the VOLITION trial**
- **Switching to CAB+RPV LA was associated with less day-to-day treatment-related burden**
- **A greater proportion of participants reported feeling unworried about their HIV status over time**

Plain Language Summary

- Concerns about friends and family learning of one's HIV status, anxiety about taking medication on time, and daily reminders of HIV status can cause stress, making it harder to take medication as directed
- In the VOLITION clinical trial, participants who were newly diagnosed were first treated with oral antiretroviral therapy (ART), or pills, taken every day, to lower the amount of HIV that could be detected
- In this study, participants whose levels of HIV were lowered could choose to stay on daily oral ART or switch to an injection of long-acting cabotegravir plus rilpivirine every 2 months
- After switching, participants were less anxious about taking their HIV medication and less concerned about others accidentally discovering their HIV status

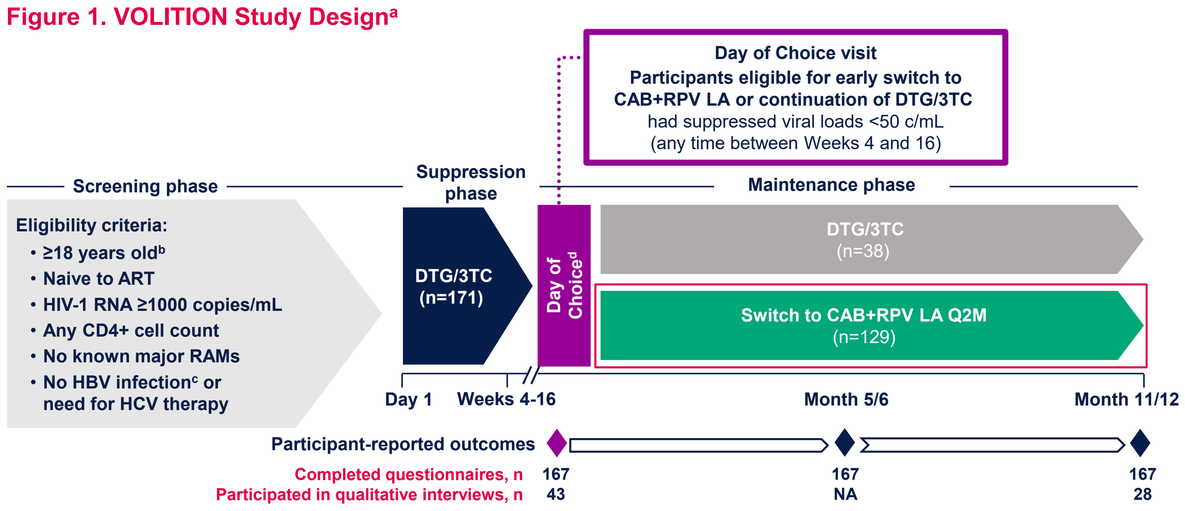
Introduction

- Daily oral antiretroviral therapy (ART) is highly effective but can impose psychosocial burdens, especially on people with HIV who are naive to treatment, including adherence-related anxiety, unwanted HIV status reminders, and pill fatigue[1]
- Traditional trials focus on virologic outcomes; yet, understanding the lived experience of treatment choice and patient-perceived burden from daily oral pills is essential to optimizing long-term adherence and well-being[2]
- The phase 3b VOLITION study (NCT05917509) evaluated participants naive to ART who received oral dolutegravir plus lamivudine (DTG/3TC) until their viral load was suppressed (median time to suppression was 4.1 weeks)[3]
- Once they had a suppressed viral load, participants reached a Day of Choice (DoC), where they could choose to switch to the long-acting injectable regimen, cabotegravir plus rilpivirine (CAB+RPV LA) every 2 months or remain on daily oral therapy[3]
  - 85% (129/151) chose to switch to CAB+RPV LA and 88% (113/129) still had a suppressed viral load at Month 11
- We report mixed-methods findings on the psychological drivers behind participants' choices and their longitudinal treatment experiences

Methods

- VOLITION was a multicenter, non-randomized, parallel-group, open-label effectiveness–implementation study conducted at 45 sites across Europe, North America, and South America[3] (Figure 1)
- This analysis included secondary endpoints assessing HIV-related stigma, feelings about diagnosis and treatment choice, and therapy-related mood, paired with qualitative interviews to explore barriers and facilitators to treatment and the lived experience of each treatment modality
  - Participants (n=167) completed questionnaires on the DoC and at Month 5/6 and Month 11/12 (Figure 1)
  - A subgroup of participants completed qualitative interviews at DoC (n=40 interviewed within a 2-week window) and Month 11/12 (n=28) to explore how treatment modality affected daily life and psychological burden
  - All interviews were transcribed and codebooks were developed as thematic frameworks to organize the content

Figure 1. VOLITION Study Design[a]

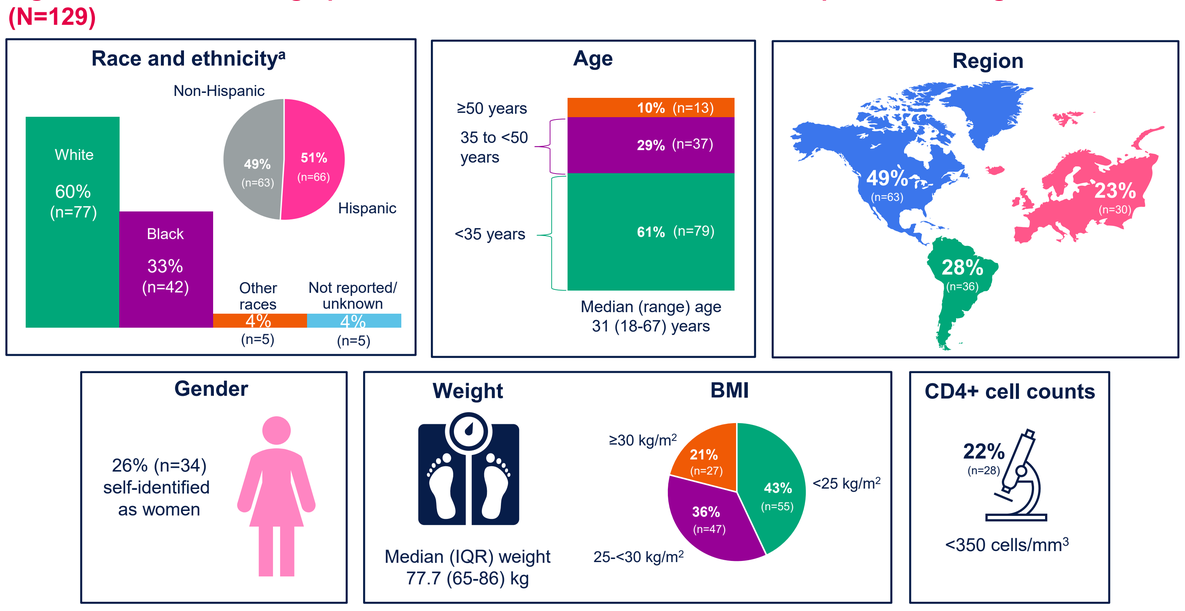


ALT, alanine transaminase; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; Q2M, every 2 months; RAM, resistance-associated mutation; ULN, upper limit of normal. [a]VOLITION was conducted at 45 sites across the United States (n=15), Spain (n=8), France (n=5), Italy (n=4), Argentina (n=4), Chile (n=4), Germany (n=3), and Canada (n=2). [b]Or older, if required by local regulations. [c]Participants positive for HBsAg were excluded. Participants negative for anti-HBs but positive for anti-HBc were excluded only if HBV DNA was detected. [d]Participants proceeded to DoC at the study visit following their first plasma HIV-1 RNA result <50 copies/mL (Week 4 at the earliest but no later than Week 16). Participants must have had a suppressed viral load <50 copies/mL to qualify for the optional switch to CAB+RPV LA. The exclusion criteria for switching included: treatment-emergent ALT ≥5 × ULN; ALT ≥3 × ULN and bilirubin ≥1.5 × ULN (with >35% direct bilirubin); and pregnancy.

Results

- Baseline characteristics are shown in Figure 2

Figure 2. Baseline Demographic and Clinical Characteristics for Participants Receiving CAB+RPV LA (N=129)



[a]Total percentage may add up to >100% due to rounding.

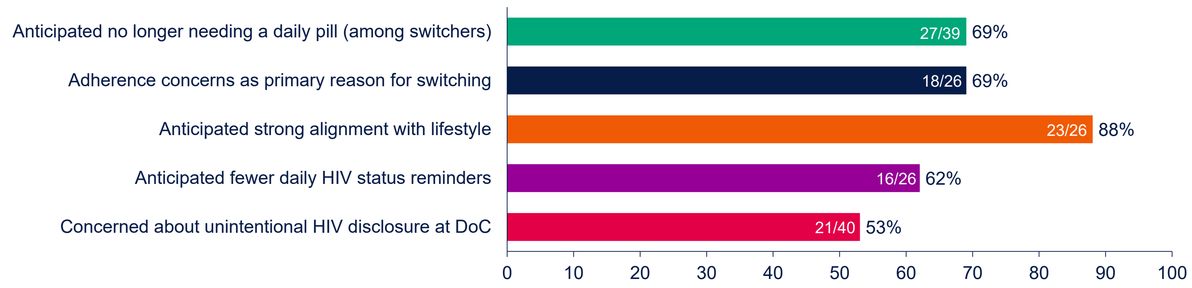
Acknowledgments: This study was funded by ViiV Healthcare. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by Fingerpaint Medical and funded by ViiV Healthcare.

References: **1.** de Los Rios et al. *AIDS Behav*. 2021;25:961-972. **2.** Kerrigan et al. *J Acquir Immune Defic Syndr*. 2026;101:183-190. **3.** Córdova et al. *Open Forum Infect Dis*. 2026;ofag383. **4.** Parcesepe et al. *AIDS Patient Care STDS*. 2023;37:146-154. **5.** Wykowski et al. *AIDS Behav*. 2019;23:2059-2071.

Switching to CAB+RPV LA Reduced Psychosocial Burden and Adherence-Related Anxiety

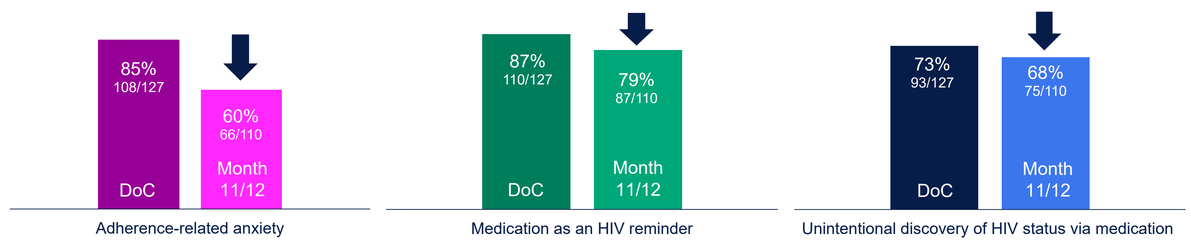
- Among interview participants who discussed CAB+RPV LA advantages (n=39), reasons for switching (n=26), and stigma (n=40; Figure 3):
  - Reduced pill burden and lifestyle fit were most commonly cited as anticipated benefits
  - Disclosure concerns were raised by roughly half of those discussing stigma

Figure 3. Participant-Reported Drivers of Switching: Qualitative Findings at Day of Choice



- Switching from daily oral ART to CAB+RPV LA was associated with reductions in psychosocial burden through Month 11/12 (Figure 4)
- At baseline, participants using CAB+RPV LA (n=127) reported high rates of adherence-related anxiety, HIV status reminders, and disclosure concerns
- Adherence-related anxiety, status-reminder concerns, and concern about others unintentionally discovering their HIV status through treatment declined from DoC to Month 11/12 among participants who completed surveys

Figure 4. Psychosocial Burden Declined From DoC Through Month 11/12 With CAB+RPV LA[a]

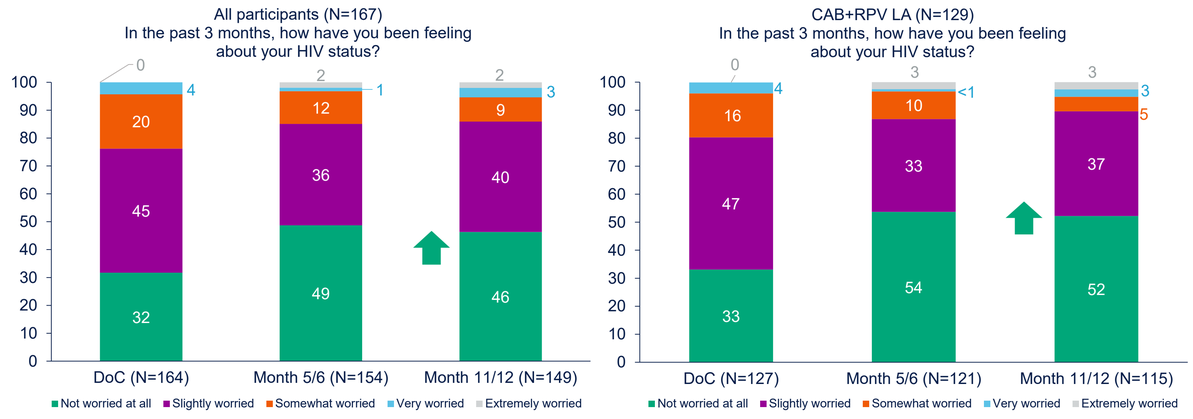


[a]Adherence-related anxiety, HIV status reminder, and unintentional discovery were assessed on a 5-point scale ranging from "never" to "always"; participants responding "rarely" or higher were counted as reporting the outcome.

Switching to Long-Acting Therapy Eased Long-Term Worry and Improved Feelings About HIV Status From DoC to Month 11/12

- On a 5-point scale, the proportion of participants who were "not worried at all" about HIV status increased from 32% to 46% (overall cohort) and from 33% (42/127) to 52% (60/115; CAB+RPV LA group) between DoC and Month 11/12 (Figure 5)

Figure 5. Quantitative Changes From DoC to Month 11/12 in Feelings About HIV Status[a]



[a]Missing participants were not included in the denominator.

Participant Voices: How Switching to CAB+RPV LA Alleviated the Daily Cognitive and Emotional Toll of Pill-Taking

- Qualitative interviews (n=39 individuals switching to CAB+RPV LA at DoC) identified the mechanisms underlying reductions in adherence anxiety and HIV status reminders

CAB+RPV LA reduced cognitive burden from pill-taking



"It was hard. Like I said, just going from not taking any kind of medication at all to having to take something every day, and then being reminded of what you're taking it for. That was…mentally and emotionally straining."

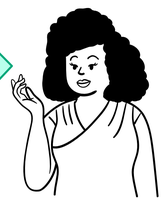
Reduced stigma and disclosure concerns

"…when I changed from the pills to the injections, at least it wasn't so conspicuous and it wasn't so obvious when I was taking the treatment…It makes me feel more comfortable, safer…less stressed



Fewer daily HIV status reminders

"When I was taking the daily pills, sometimes they reminded me that I had a virus that was going to be with me for the rest of my life. Now, with the injectable, no, I know I have the virus too, but it is not a constant reminder: hey, you have this, you have to take a medicine every day."



Strong alignment with lifestyle



"I mean it was, for me it was kind of a done deal…I just didn't want to have to worry about the daily pill and I felt like the injections fit my lifestyle better than taking the daily, taking an additional daily pill."

Conclusions

- Before switching, participants experienced substantial psychosocial challenges, including high rates of adherence-related anxiety, daily reminders of their HIV status, and fear of accidental disclosure, which are challenges known to impact long-term adherence and mental well-being of people with HIV-1[4,5]
- When given the choice, the vast majority of eligible participants switched to CAB+RPV LA, driven primarily by anticipated lifestyle fit and reduced pill burden; this switch was associated with reduced psychosocial burden through Month 11/12 while virologic suppression was maintained
- These findings are consistent with staff perspectives from the companion VOLITION analysis (see Poster P077), together supporting early-switch to CAB+RPV LA as an effective way to reduce treatment burden and stigma in people with HIV-1 recently starting treatment

Presenting author: Cassidy A. Gutner; cassidy.x.gutner@viivhealthcare.com