Long-Term Outcomes of Cabotegravir Plus Rilpivirine Long-Acting Every 2 Months in a Real-World Setting: Effectiveness, Adherence, and Patient-Reported Outcomes From People With HIV-1 in the CARLOS Study 3 Years Post-Switch

P061

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Key Takeaways

- **In the real-world CARLOS study in Germany, suppressed switch from daily oral antiretroviral therapy to long-acting cabotegravir plus rilpivirine (CAB+RPV LA) generally maintained suppressed viral load 3 years post-switch, with no new protocol-defined virologic failures after Year 2**
- **CAB+RPV LA was well tolerated, with high rates of adherence through 3 years**
- **Treatment satisfaction showed a significant clinically meaningful improvement that was sustained through Year 3**
- **Most healthcare providers felt very or extremely positive about implementing CAB+RPV LA and cited manageable visit times**

Plain Language Summary

- CARLOS is a 3-year-long study in Germany that followed people with HIV during their regular clinic visits who switched from taking daily HIV tablets to injections of long-acting cabotegravir and rilpivirine (CAB+RPV LA), given 6 times a year
- CAB+RPV LA kept the virus under control in most people, and no one's virus levels raised above a certain limit (referred to as virologic failure) after 2 years of being on CAB+RPV LA. Most injections (94%) were given on time or early
- CAB+RPV LA was generally well tolerated and preferred by the majority of people (98%); people also felt more satisfied with their treatment after switch from daily tablets, and this improvement continued through 3 years

Introduction

- For adults and adolescents (aged ≥12 years) weighing ≥35 kg with HIV-1 and suppressed viral load on daily oral antiretroviral therapy (ART), transitioning to long-acting (LA) cabotegravir (CAB) plus rilpivirine (RPV) injections, a complete regimen endorsed by treatment guidelines, offers a less frequent dosing schedule that has been shown to improve quality of life while maintaining virologic control in clinical trials[1-7]
- Real-world studies are needed to further understand CAB+RPV LA across broader populations encountered in routine clinical practice
- CARLOS is a non-interventional, 3-year, multicenter real-world study in Germany enrolling people with HIV-1 who switched from suppressive daily oral ART to CAB+RPV LA every 2 months in routine care
  - Prior CARLOS data demonstrated that CAB+RPV LA maintained virologic suppression, was well tolerated, and was associated with improved treatment satisfaction through Year 2 after switch from daily oral ART[8,9]
- Here, we describe clinical and participant-reported outcomes at Month 36 (Year 3), the final analysis of the full 3-year observation period

Methods

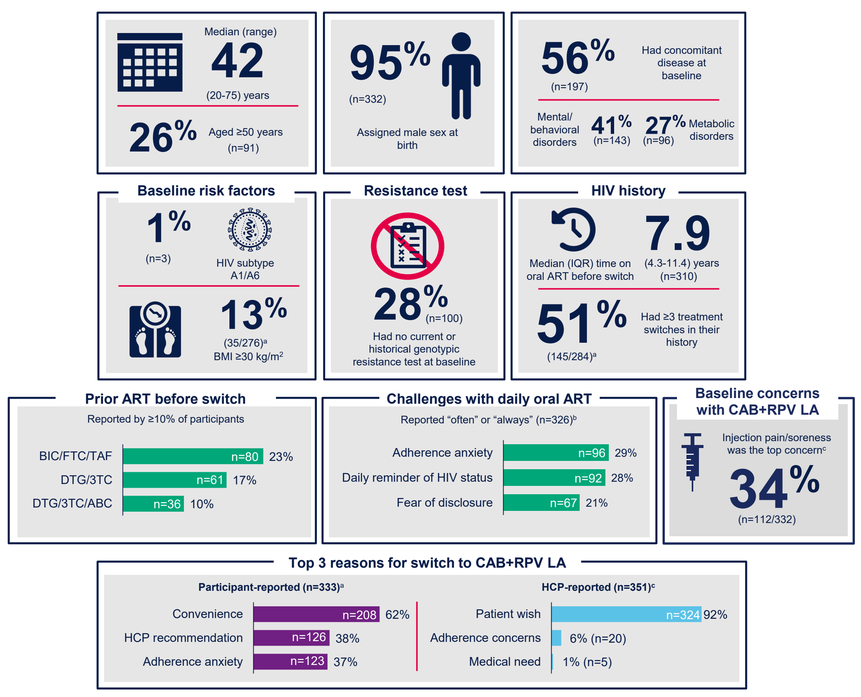
- Full study design details have been published previously[9]; briefly, effectiveness outcomes at Year 3 included virologic suppression (HIV-1 RNA <50 c/mL), virologic non-response (HIV-1 RNA ≥50 c/mL), and protocol-defined virologic failure (PDVF; 2 consecutive HIV-1 RNA ≥200 c/mL, or a single HIV-1 RNA ≥200 c/mL followed by discontinuation for any reason)
- Additional outcomes included adherence to the injection window, participant-reported outcomes (including reasons for switch, treatment satisfaction [HIV Treatment Satisfaction Questionnaire status version, HIVTSQs], and treatment preference), healthcare professional (HCP)–reported outcomes (including reasons for switch, perspectives on implementation and assessment of participant tolerability and/or acceptability of injections), and safety

Results

Demographics, Baseline Characteristics, and Reasons for Switch

- In total, 351 people with HIV-1 were included in the Year 3 analysis (Figure 1)
- HCPs cited patient wish (92% [324/351]) as the predominant reason for switching with adherence concerns being a relatively small contributor (6% [20/351]); in contrast, 37% (123/333) and 29% (96/333) of participants reported adherence anxiety and difficulty remembering to take HIV medicines daily, respectively, as a reason for switch

Figure 1. Demographics, Baseline Characteristics, and Top Reasons for Switch (N=351)

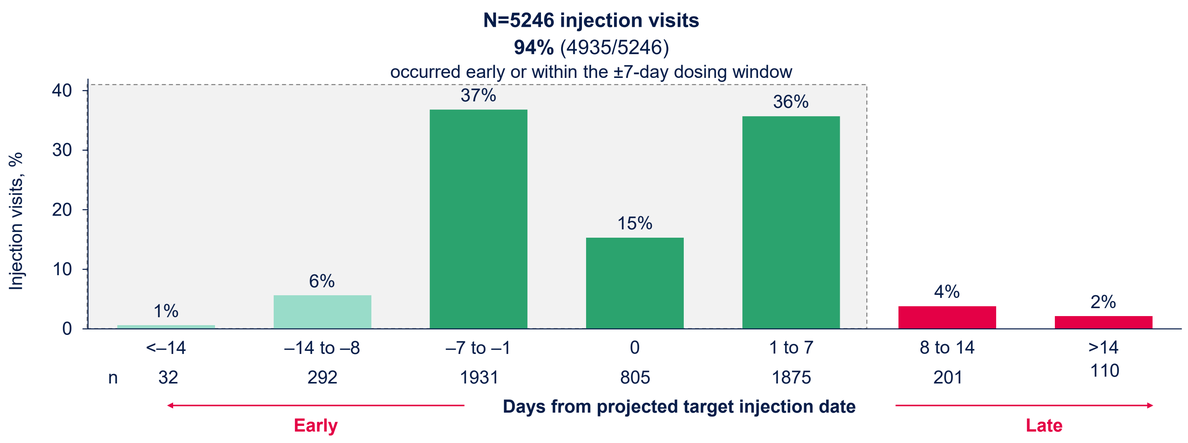


ABC, abacavir; BIC, bictegravir; BMI, body mass index; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; 3TC, lamivudine. [a]Denominator represents participants with available data or who responded to question. [b]Exploratory questionnaire at baseline. [c]Expectation questionnaire at baseline (multiple responses allowed). [d]Medical needs included difficulty swallowing (n=1), gastrointestinal side effects (n=2), and other (n=2).

Adherence

- Overall, 94% (4935/5246) of CAB+RPV LA injections were administered before or within the ±7-day injection window through Year 3; 6% (311/5246) occurred late overall (Figure 2)
  - Adherence remained high during Year 3 (94%, 1471/1570), consistent with that reported across Years 1 (95%, 1847/1943) and 2 (93%, 1617/1733)
- Oral bridging was rarely used (10% [36/351] of participants at any point during the study) and covered 8% (24/311) of delayed injections
  - The most used oral bridging regimens were CAB+RPV (38%, [9/24]), followed by BIC/FTC/TAF (21%, [5/24]) and DTG/3TC (17%, [4/24])

Figure 2. Adherence to ±7-Day Dosing Window (Injections 2-19)[a]



[a]Injection 1 was the initiation dose and is excluded from the dosing window adherence analysis.

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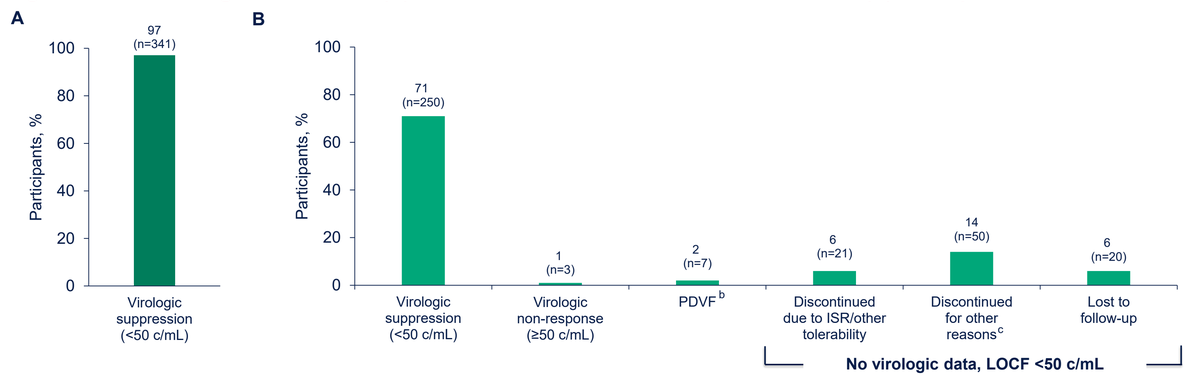
Effectiveness

- 97% (341/351) of participants had suppressed viral loads at Year 3 by a last-observation carried forward analysis (Figure 3A)
- At Year 3 in the ITT population, 71% (250/351) of participants had viral loads <50 c/mL (Figure 3B); the decline in virologic suppression from Year 1 (86%) was primarily driven by discontinuations for non-virologic reasons
- 26% (91/351) discontinued with a last observed viral load of <50 c/mL; due to tolerability, 6% (21/351); loss to follow-up, 6% (20/351); other reasons, 14% (50/351), mostly preference for oral ART (n=23) or appointment compliance concerns (n=8)
- Seven participants (2%) met PDVF through Year 2 (Year 1, n=5; Year 2, n=2)[9]
- No additional cases of PDVF occurred through Year 3

Figure 3. Year 3 Virologic Outcomes at (A) Last Observation Carried Forward[a] and for the (B) ITT Population

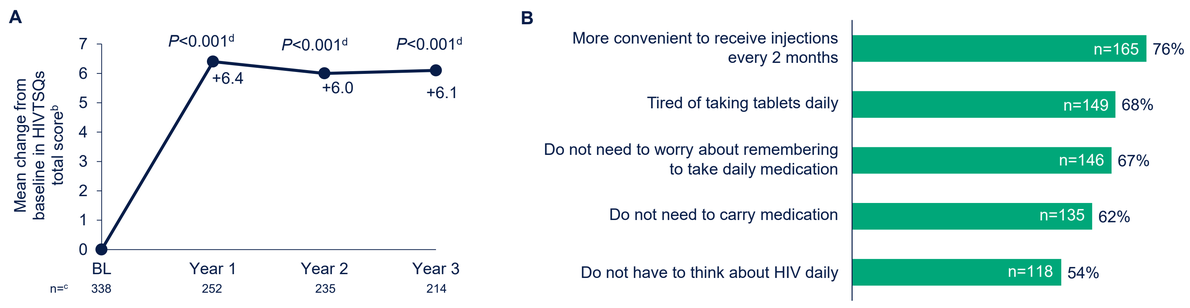


ITT, intention-to-treat; ISR, injection site reaction; LOCF, last observation carried forward. [a]Includes 91 participants who discontinued for non-virologic reasons or who did not have HIV-1 RNA in the Year 3 window but had suppressed viral loads at the last observation; 3 participants had HIV-1 RNA ≥50 c/mL and 7 had PDVF. [b]PDVF (2 consecutive HIV-1 RNA ≥200 c/mL, or a single HIV-1 RNA ≥200 c/mL followed by discontinuation for any reason); details of the 7 participants with PDVF have been reported previously.[9,10] [c]Reasons include preference for oral ART (n=23), non-virologic reasons (n=11), appointment compliance concerns (n=8), participant withdrew (n=3), virologic reasons (n=2), inconvenience of more frequent visits (n=2), and death (n=1).

Treatment Satisfaction, Preference, and Injection Experience

- Among participants completing both baseline and Year 3 HIVTSQs questionnaires (214/351), the statistically significant improvement in mean treatment satisfaction reported at Year 1 was maintained through Year 3 (P<0.001; Figure 4A)
  - This increase met the threshold for a minimum clinically important difference (greater than half of the baseline standard deviation [10.1]) at Year 1 and was maintained through Year 3
- At Year 3, 98% (218/222) of participants still on treatment who completed the questionnaire preferred CAB+RPV LA
  - 1% (2/222) each reported no preference or a preference for daily oral ART; of those who discontinued, 12/16 participants preferred daily oral ART
- Top preference drivers included convenience, pill fatigue relief, adherence ease, medication-free travel, and reduced HIV reminders (Figure 4B)
- Injection 19 acceptability was high at Year 3; 80% (160/201) and 70% (141/201) rated local reactions and pain, respectively, as "totally/very acceptable," and 88% (176/200) could return to daily activities immediately after injection visits "all" or "most of" the time
  - Participants tried a range of strategies to manage post-injection soreness, which evolved over time; by injection 19, the most common were over-the-counter pain relievers (37%, 75/203), light stretching and/or exercise (20%, 40/203), and avoiding sitting for long periods (14%, 29/203)
  - 24% (48/203) reported no soreness after injections

Figure 4. Participant-Reported Outcomes (A) Treatment Satisfaction and (B) Top 5 Reasons for CAB+RPV LA Preference Over 3 Years[a]



[a]Among participants preferring CAB+RPV LA at injection 19 (n=218); multiple responses allowed; top 5 reasons shown. [b]HIVTSQs: 12-item version; range per item 0 to 6, where 0 = "very dissatisfied" and 6 = "very satisfied." HIVTSQs total score was the sum of items 1 to 11 (range for total score 0-66); positive changes from baseline indicate improvement in treatment satisfaction. [c]Participants with documented baseline and specified follow-up (Years 1, 2, and 3). The mean HIVTSQs total score increased from 54.8 at baseline to 60.9 at Year 3. [d]Wilcoxon signed-rank test (change from baseline) at time point. Imputation was performed in n=3 participants at baseline, n=3 participants at Year 1, n=2 at Year 2, and n=2 at Year 3.

HCP Perspectives

- Of 45 HCP respondents, most were nurses (47%, 21/45) or physicians (42%, 19/45), and the remaining were office staff (11%, 5/45)
- Overall, 69% (31/45) reported feeling very or extremely positive about CAB+RPV LA implementation in their clinic; none reported feeling negative
- Most HCPs reported injection appointments typically took ≤40 minutes (84%, 38/45) and 78% (35/45) felt that individuals using CAB+RPV LA found the time spent in clinic very or extremely acceptable
  - The majority (91%, 41/45) reported people who used CAB+RPV LA could return to their daily activities most or all of the time
- While staff capacity for routine injection administration was a common concern, the proportion of HCPs not at all concerned about having enough staff to administer injections daily increased from 33% (14/43) at baseline to 44% (20/45) at Year 3, while the proportion of HCPs who were extremely concerned decreased from 21% (9/43) to 13% (6/45), respectively
- HCP investigators (n=21) considered CAB+RPV LA appropriate for people tired of daily pills, feeling stigmatized, or feeling concerned about disclosure (each 90% [19/21]); 71% (15/21) also considered it appropriate for people non-adherent to oral ART

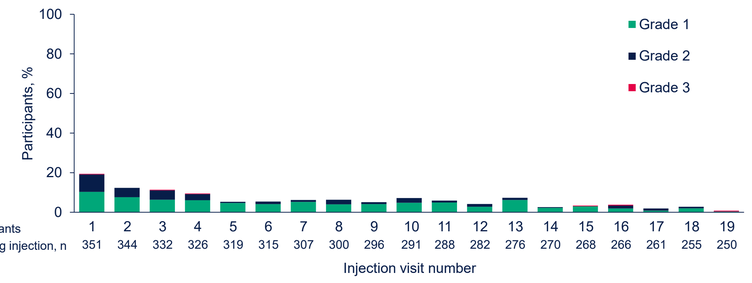
Safety

- The most common non-serious drug-related adverse events, excluding injection site reactions (ISRs) were pyrexia (n=13), nausea (n=5), pain/headache/pyrexia (n=4), headache (n=4), and pain in extremity (n=3; Table 1)
- Most ISR events were grade 1 or 2 (98%, 403/410; 7 grade 3; Figure 5), with pain being the most common ISR reported; median (IQR) ISR duration was 3 (2-6) days, and few participants (4%, 15/351) discontinued overall due to ISR-related reasons

Table 1. Drug-Related AEs and ISRs Through Year 3

Drug-related AEs (excluding ISRs)	CAB+RPV LA n=351
Drug-related AEs, n	60
Grade 1-2 events	57
Grade 3 events	3
Serious drug-related AEs, n	2[a]
Discontinuation due to drug-related AEs, n (%)	7 (2)[b]

Figure 5. Participants With ISRs by Injection Visit



AE, adverse event; I, injection. [a]Anxiety disorder (n=1); drug hypersensitivity (n=1). [b]Headache (grade 2, n=1), syncope (grade 2, n=1), anxiety disorder (grade 3, n=1), pyrexia (grade 2, n=2), joint swelling/arthralgia (grade 3, n=1), and drug hypersensitivity (grade 3, n=1).

Conclusions

- In this real-world study, CAB+RPV LA maintained high rates of virologic suppression (97%) 3 years post switch by last-observation carried forward, with no new instances of PDVF beyond Year 2, and discontinuations were primarily driven by non-virologic reasons
- CAB+RPV LA was well tolerated over 3 years; ISRs became less frequent over time, with few leading to discontinuation
- High levels of adherence to injection visits reported at Year 1 stayed consistent until Year 3, not showing evidence of injection fatigue over time
- Despite reporting high HIVTSQs baseline scores on oral ART, participant treatment satisfaction improved significantly and meaningfully through Year 3, maintaining high levels reported through Years 1 and 2[8-10]

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