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Initiating long-acting cabotegravir and rilpivirine in a real-world setting: clinical characteristics and switch reasons from PLHIV and health care provider perspective in the German CARLOS cohort

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Summary/Conclusion

- The majority of people living with HIV (PLHIV) opting for long-acting therapy in this real-world setting previously experienced challenges related to daily oral therapy including fear of their status being disclosed, challenges with daily adherence and daily reminder of their HIV status.
- PLHIV most suitable for CAB+RPV LA injections from the perspective of the healthcare provider (HCP) included PLHIV who "are tired of taking pills every day", "feel stigmatized by their HIV", "experience stress or anxiety over daily adherence" and "have concerns about HIV status disclosure/others finding their daily pills".
- Although there were patient concerns regarding CAB + RPV LA injectable therapy (such as pain from the injection), these were outweighed by PLHIV desire to switch to CAB + RPV LA, with convenience and pill fatigue being the most often cited reasons for switching in this cohort.

Introduction

- Cabotegravir (CAB) + rilpivirine (RPV) is the first complete long-acting (LA) regimen recommended by treatment guidelines[1] for the maintenance of HIV-1 virologic suppression.
- Despite the success of daily oral antiretroviral therapy (ART), challenges still exist for some PLHIV associated with drug interactions, adherence, pill burden and stigma[2,3].
- Every 2 months CAB + RPV LA injections for HIV treatment offers a less frequent dosing alternative to daily oral ART and may address some challenges associated with daily oral ART, such as fear of inadvertent disclosure, anxiety related to staying adherent, and the daily reminder of HIV status.
- Efficacy and safety of switching to every 2 months CAB + RPV LA were demonstrated in ATLAS-2M (NCT03299049)[4].
- CARLOS provides first prospective real-world data for PLHIV switching to every 2-months CAB+RPV LA therapy in Germany.
- Here we describe the clinical characteristics and reasons for switching to LA therapy from a PLHIV and HCP perspective in a real-world setting.

Methods

- CARLOS is an ongoing non-interventional, 3-year, prospective, multi-center cohort study in Germany.

Outcome measures

- Clinical characteristics were identified from medical records.
- The perspectives of PLHIV and HCPs regarding CAB + RPV LA HIV treatment were assessed through surveys conducted at baseline

Results

Study population

- Between May and December 2021, 236 PLHIV initiated CAB + RPV LA across 19 sites in accordance with the SmPC. Baseline characteristics of the cohort are shown in Table 1.

Antiretroviral treatment (ART) prior to switch to CAB+RPV

- The median duration on ART before switch was 8.1 years.
- The most common regimens (in >10%) prior to switch were BIC/FTC/TAF (n=54/236; 22.9%), DTG/3TC (n=44; 18.6%) and RPV/FTC/TAF(*or* TDF) (n=24; 10.2%) (missing information for n=7; 3.0%).

Oral lead-in

- The majority (n=200/236; 84.7%) started with oral lead-in (OLI) therapy (once daily oral CAB + RPV) prior to the injectables. The median time of the OLI phase was 28 days (IQR: 27–30 days).
- For those choosing no OLI (n=36/236; 15.3%), "patient preference without medical need" was the main rationale given (n=31/36; 86.1%), followed by "difficulty swallowing" (n=2; 5.6%).

Table 1. Baseline Characteristics

242 PLHIV* were enrolled

236 PLHIV received treatment with CAB + RPV LA

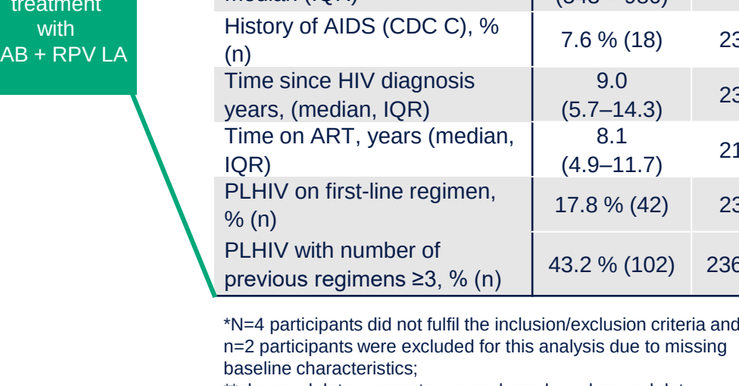
Parameter	Total	N**
Male (sex at birth), % (n)	95.3 % (225)	236
Median age, years, median, (IQR)	42.5 (36.0–49.5)	236
Age categories <50 years, % (n)	75.0 % (177)	
50-65 years, % (n)	24.6 % (58)	
> 65 years, % (n)	0.4 % (1)	
Body mass index (BMI), kg/m^2 (median, IQR)	24.5 (22.7–26.6)	181
BMI, ≥30 kg/m^2, % (n)	10.5 % (19)	
CD4 T-cell count, cells/µL, median (IQR)	714.5 (543 – 986)	228
History of AIDS (CDC C), % (n)	7.6 % (18)	236
Time since HIV diagnosis years, (median, IQR)	9.0 (5.7–14.3)	232
Time on ART, years (median, IQR)	8.1 (4.9–11.7)	210
PLHIV on first-line regimen, % (n)	17.8 % (42)	236
PLHIV with number of previous regimens ≥3, % (n)	43.2 % (102)	236***

*N=4 participants did not fulfil the inclusion/exclusion criteria and n=2 participants were excluded for this analysis due to missing baseline characteristics;
**observed data, percentages are based on observed data;
***number not available/documented for n= 42/236 (17.8%);
PLHIV, people living with HIV; CAB, cabotegravir; LA, long-acting; RPV, rilpivirine; IQR, interquartile range.

Challenges with daily HIV medication before deciding to switch to CAB + RPV LA therapy

- The most common challenges (in >20% of participants) with the daily HIV medication before deciding to switch to CAB + RPV LA therapy (multiple answers were possible) are shown in Figure 1.
- 32% of participants do not have any problems with their daily HIV medication.

Figure 1. Most common challenges with daily HIV medication



Experiences with oral ART prior to switch to CAB + RPV LA therapy

- Prior to switching, 28% of PLHIV (n=60/216) often/always "worried about forgetting daily ART" (Fig. 2a).
- 23% (n=50/216) of participants reported being often/always "worried about unintentional disclosure of their HIV status through oral therapy" (Fig. 2b).
- 30% (n=64/216) often/always felt "taking daily oral ART was an uncomfortable reminder of their HIV status" (Fig. 2c).

Figure 2a. PLHIV worried about forgetting ART

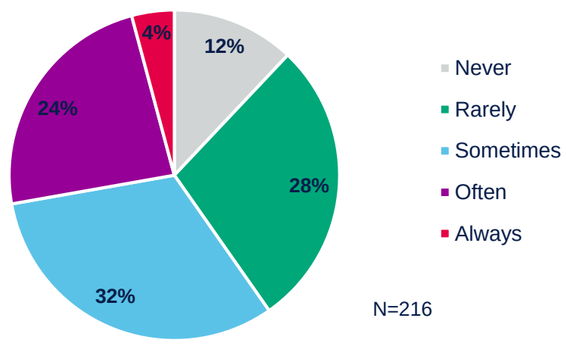


Figure 2b. PLHIV worried about disclosure of HIV status with oral ART

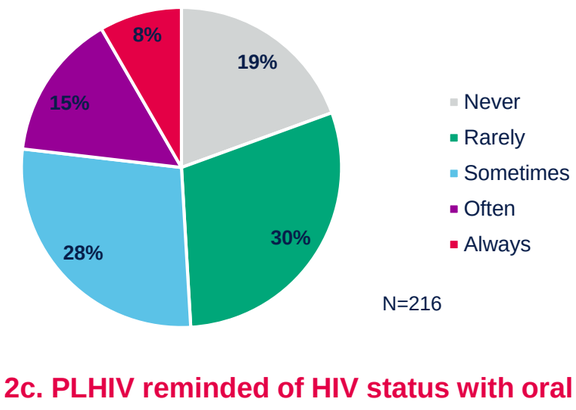
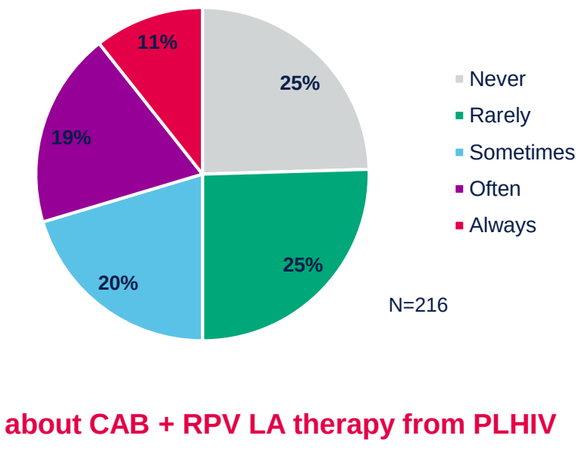


Figure 2c. PLHIV reminded of HIV status with oral ART



Concerns about CAB + RPV LA therapy from PLHIV

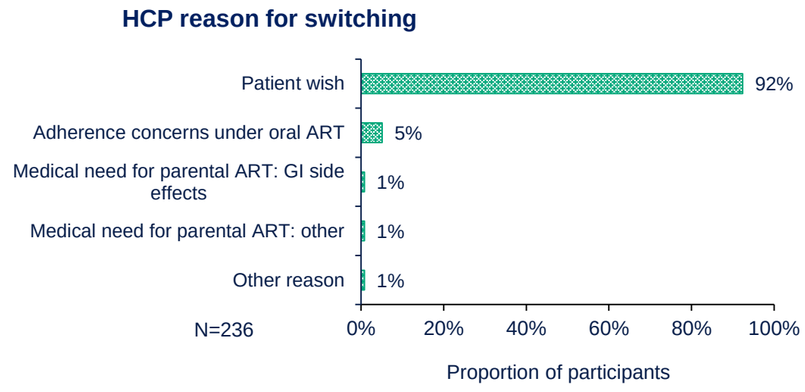
- Prior to receiving LA therapy, 94% of participants (n=221/236) responded to the survey on specific concerns about LA therapy (multiple answers were possible). For concerns (>20%) see Figure 3.

Figure 3. Most common patient-reported concerns about the CAB + RPV LA therapy

Reasons for switching to CAB + RPV LA therapy

- From the HCP perspective, the main reason (for 92% of PLHIV; n=218/236) for switching to CAB + RPV LA every 2 months injections was "patient wish" (Fig. 4).
- Among PLHIV, "convenience" (63%; n=140/223) and "pill fatigue" (52%; n=117/223) were the most often cited reasons for choosing CAB + RPV LA therapy (Fig. 4).

Figure 4. Reasons for switching from daily oral ART to CAB + RPV LA therapy from the HCP and PLHIV perspectives



General characteristics of PLHIV suitable for CAB + RPV LA therapy from the HCP perspective

- The most common patient characteristics suitable for LA therapy (for ≥80% of HCPs, i.e. for 16/20 prescribing physicians) are shown in Figure 5 (multiple answers were possible).

Figure 5. PLHIV suitable for CAB + RPV LA therapy from the HCP perspective

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