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Long-Term Durability and Virological Effectiveness of Long-Acting Cabotegravir plus Rilpivirine in Routine HIV Care: Updated Real-World Data from the Spanish RELATIVITY Cohort

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Background

Long-acting cabotegravir plus rilpivirine (CAB+RPV LA) is an established maintenance option for virologically suppressed people with HIV. Extended real-world data on treatment persistence, timing of virological failure (VF), resistance and outcomes after failure remain limited.

Objective

To evaluate long-term virological suppression, treatment persistence, discontinuation patterns, timing and resistance consequences of VF, injection adherence among VF cases, and outcomes after return to oral ART in the nationwide RELATIVITY cohort

Methods

Design and setting:

Nationwide, multicenter, ambispective RELATIVITY cohort (Spain). Data cutoff: March 1, 2026; 53 participating centers.

Population and eligibility:

Adults with HIV-1 RNA <50 copies/mL on oral ART and at CAB+RPV LA initiation, with ≥1 intramuscular dose before December 31, 2024.

Definition of virological failure:

Two consecutive HIV-1 RNA values ≥200 copies/mL, or one value ≥500 copies/mL prompting discontinuation. Suspected rebounds were centrally adjudicated.

Outcomes and statistical analysis:

Descriptive summaries and Kaplan–Meier estimates of VF and discontinuation. Injection adherence: PDC with a ±7-day dosing window. Missing data were not imputed.

Results

The cohort included 3,349 participants followed for a median 25.1 months (IQR, 19.3–30.8). HIV-1 RNA was <50 copies/mL in 3,197/3,309 (96.6%). Among 3,280 evaluable schedules, 99.3% had PDC ≥90%. Overall, 2,979/3,349 (89.0%) remained on CAB+RPV LA.

P-1042

Main results

Protocol-defined VF occurred in 28/3,349 participants (0.8%). Median time to VF-related discontinuation was 9.1 months (IQR, 7.1–13.3). Twenty of 28 events (71.4%) occurred by month 12, including 17 between >6 and 12 months; only 8 events occurred thereafter.

Permanent discontinuation occurred in 370/3,349 participants (11.0%). Recorded discontinuation-related events included other non-virological reasons in 248 (7.4%), injection-site reactions in 79 (2.4%), systemic adverse events in 54 (1.6%), and VF in 28 (0.8%); categories could overlap

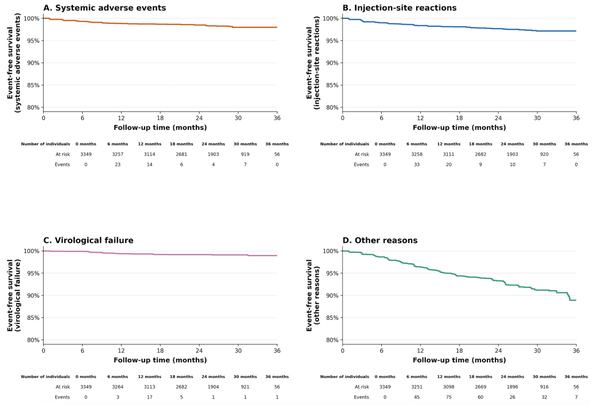


Figure 1. Event-free survival by recorded discontinuation-related event.

Table 1. Cohort profile and overall outcomes

Characteristic	Value
Participants	3,349
Participating centers	53
Follow-up, median (IQR), months	25.1 (19.3–30.8)
Pre-switch regimen including INSTI	2,592/3,349 (77.4%)
Previous VF documented	108/3,349 (3.2%)
Historical genotype available*	1,540/3,235 (47.6%)
HIV-1 RNA <50 copies/mL**	3,197/3,309 (96.6%)
PDC ≥90%	3,257/3,280 (99.3%)
Persisting on CAB+RPV LA	2,979/3,349 (89.0%)

*Among participants with evaluable genotype-availability data. **Closest evaluable viral-load assessment.
IQR, interquartile range; INSTI, integrase strand transfer inhibitor; PDC, proportion of days covered.

Resistance and injection adherence

Among those with hystorical genotype available (17/28,60.7%)mutations expected to compromise CAB+RPV were not identified. At failure, clinically relevant emergent INSTI RAMs were detected in 16/28 (57.1%), NNRTI RAMs in 14/28 (50.0%), and either class in 19/28 (67.9%); dual-class resistance occurred in 11/28 (39.3%). 9/28 (32.1%) did not develop RAMs after VF.
27/28 VF cases (96.4%) had PDC 100%, and none had PDC <90%.Overall, PDC<90% was 0.7%. Six participants had one delayed injection interval, but none had ≥2. Thus, most failures occurred despite apparently appropriate recorded injection timing; PDC does not measure injection technique or pharmacokinetic exposure.

Table 2. Characteristics and outcomes of the 28 virological failures

Characteristic	VF cases (n=28)
Male sex	21/28 (75.0%)
Age, median (IQR), years	42.0 (34.0–50.5)
BMI, median (IQR), kg/m²	28.4 (24.8–30.8)
BMI ≥30 kg/m²	9/28 (32.1%)
VF by month 12	20/28 (71.4%)
PDC 100%	27/28 (96.4%)
Emergent INSTI and/or NNRTI RAMs	19/28 (67.9%)
Dual-class emergent resistance	11/28 (39.3%)
Resuppressed after oral ART	24/28 (85.7%)

BMI, body mass index; IQR, interquartile range; PDC, proportion of days covered; RAM, resistance-associated mutation; VF, virological failure.



Figure 2. Timing of virological failure after CAB+RPV LA initiation.

20/28 VF events (71.4%) occurred by month 12

Outcomes after virological failure

All 28 participants with VF switched to oral ART: 17/28 (60.7%) received protease inhibitor-based regimens, mainly darunavir-based; 8/28 (28.6%) received B/F/TAF; and 3 received other regimens. At database lock, 24/28 (85.7%) had achieved virological resuppression. The remaining four failures occurred close to the analysis cut-off and had limited post-switch follow-up.

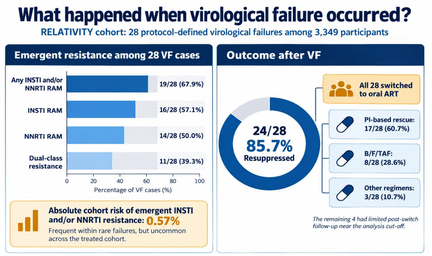


Figure 3. Resistance and outcomes after virological failure.

Conclusions

CAB+RPV LA maintained high virological suppression and treatment persistence beyond 2 years in routine clinical care.

VF was rare (0.8%,) and clustered predominantly within the first 12 months. When VF occurred, emergent INSTI and/or NNRTI resistance was frequent.

Performing resistance testing on VF and individualized rescue therapy remain important. Most individuals with VF subsequently resuppressed on oral ART.

The limited number of VF events and incomplete historical genotype availability preclude robust inference regarding determinants of failure.

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RELATIVITY